SCOTTISH HOSPITALS INQUIRY

Bundle 13 – Miscellaneous

Volume 8

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Infection Prevention Society

Competencies Framework for Infection Prevention & Control Practitioners

Competencies for infection prevention and control practitioners (IPCPs) were first introduced by the Infection Control Nurses Association (ICNA) in 2000 and subsequently revised by the Education and Professional Development Committee of the Infection Prevention Society (IPS). A competent practitioner can be defined as a person who has acquired a set of skills with the ability to apply and measure these skills against set standards (Winchcombe, 2000). Infection prevention and control (IPC) competences provide a framework to enable IPCP to develop and enhance their knowledge and skills to help increase patient safety and care quality (Burnett, 2011). They can also assist in the design of education programmes; staff appraisal and personal development plans and reviewing team structures and requirements.

Using the IPS Competencies Framework

Members of IPS can use the IPS Competencies Platform on the IPS website to build a portfolio of their competencies. This tool allows competencies to be documented, linked to evidence that demonstrates the relevant knowledge and skills acquired and signed-off by a mentor. The tool enables members to generate a progress report to summarise competencies achieved and areas that requiring further development. This report can be used to support appraisal, personal development, career progression and professional revalidation.

The IPS competencies reflect the broad range of competencies that a proficient IPCP would be expected to gain. They may not reflect all the higher-level competencies required of an IPCP who is managing the IPC service and not all domains, competencies or practice indicators will be relevant to all IPCP roles.

The competency framework comprises Core Competencies and four domains:

- Clinical Practice
- Quality Improvement & Research
- Education
- Leadership and Management

The following terms may be helpful to support assessment of competence:

1. **Working towards**
   Has acquired some experience of performing the skill, task or responsibility but still requires support or supervision

2. **Competent**
   Able to perform the skill, task or responsibility as an autonomous practitioner

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Core competencies (CC)

Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
CC1	***Deliver appropriate and effective information, advice and guidance on infection prevention & control***			
CC1.1	Apply the principles of microbiology, immunology and epidemiology to designing and implementing strategies to prevent and control infection.	Evidence underpinning IPC including: o Microbiology o laboratory methods and reporting o Immunology o antimicrobial agents, resistance and treatment of infection o epidemiology of HCAI o infection transmission and prevention o infection prevention in relevant invasive devices and procedures	Critical evaluation of guidelines, research and other sources of evidence and application of findings to clinical practice	
CC1.2	Communicate IPC information effectively in a verbal and/or written form at an appropriate level for the target audience.	Strategies for delivering information effectively	Communicate complex messages clearly and effectively Evaluate effectiveness of communication	
CC1.3	Identify IPC risks and develop appropriate strategies to manage, mitigate, minimise or contain them.	Principles of risk assessment, management, governance and assurance; systems for documenting, monitoring and reviewing risk	Evaluates current risk assessments, appropriately escalates them and communicates risks with appropriate persons. Design strategies to manage or mitigate IPC risks	
CC1.4	Recognise gaps in knowledge, skills and competence of self and others in relation to IPC and develops improvement strategies.	Evidence underpinning infection prevention and control practice	Critical evaluation of guidelines, research and other sources of evidence and application of findings to clinical practice	
CC1.5	Communicate confidently and competently to staff, including providers, stakeholder and partner organisations, and service users and the public about infection and IPC at a level to suit the audience.	Appropriate and timely IPC information	Uses a wide range of communication strategies to meet the needs of their audience i.e. leaflets, dashboards, reports	
CC1.6	Critically evaluate research and other forms of evidence to underpin IPC advice.	Interpretation of research findings, assessment of study quality and validity of study findings or recommendations	Apply research findings to clinical practice	
CC1.7	Develop, assist and encourage staff and team members to practice effectively and efficiently including engagement events with service users and the public where applicable and appropriate to do so.	Evidence underpinning infection prevention and control practice	Identify and build effective relationships	
CC1.8	Apply methodologies to develop, support and maintain effective root cause analysis processes or other similar processes.	Evidence underpinning infection prevention and control practice	Critical evaluation of guidelines, research and other sources of evidence and application of findings to clinical practice.	
CC1.9	Build and sustain effective working relationships, influencing others to recognize the importance of IPC practice in promoting, improving and maintaining patient safety.	Relationship management	Identify, build and maintain key relationships	
CC1.10	Develop a strategy for providing and sustaining an effective infection prevention & control service aligned to organisational objectives and vision.	Evidence underpinning infection prevention and control practice.	Critical evaluation of guidelines, research and other sources of evidence and application of findings to clinical practice	

Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
Domain: Clinical practice (CP)				
CP1	***Use surveillance data to inform infection prevention & control practice***			
CP1.1	Design, implement and/or utilise existing effective surveillance systems to inform practice based on epidemiological principles.	Methods of surveillance and their application	Utilise and analyse surveillance and other infection-related data,	
CP1.2	Apply the principles of epidemiology to the analysis and interpretation of data and use to inform appropriate interventions.	Understanding of the principles of statistics and limitations of data	Interpret surveillance reports	
CP1.3	Generate reports from surveillance and other sources of infection related information and feedback appropriately to key stakeholders.	o Understanding epidemiological metrics such as incidence and prevalence, significance of microbiological and diagnostic results and action/ implementation of results. o Reporting surveillance data. o National, regional and local surveillance systems for HCAI, legislation and National guidance	o Apply findings from surveillance to evaluate policies and programmes and identify action plans and priorities for infection prevention and control. o Prepare reports appropriate to the target audience. o Evaluate and review surveillance programmes against organisational IPC objectives	
CP2	***Advise on infection prevention & control in relation to the built environment and clinical equipment***			
CP2.1	Assess any IPC related risks and provide advice on their prevention and control in the design, construction, modification and maintenance of facilities.	o Evidence for infection risks associated with the built environment e.g. air handling, plumbing, water systems, and effective prevention and control strategies	Work with internal departments e.g. estates, facilities, capital planning and external contractors, other organisations	
CP2.2	Ensure key services supporting the IPC agenda e.g. cleaning and waste management are meeting the needs, requirements and specification of the service, assessing and identifying any risks or gaps in provision.	o The principles of decontamination, including relevant methods their application, effectiveness and limitations	Evaluate the IPC risks associated with equipment, medical devices and the environment, and identification of appropriate decontamination methods	
CP2.3	Assess the IPC risks associated with equipment and the environment and advise on appropriate actions to optimise decontamination processes promoting patient safety.	o Methods and processes for decontamination of the environment, medical devices (for example, endoscopes, surgical instruments) and equipment. o Local and national decontamination policies, guidelines and procedures for equipment, medical devices and the environment. o Evidence for the role of cleaning technologies in all decontamination processes. o Incorporate Health and Safety legislation and guidance in relation to the built environment (e.g. Health Technical Memoranda, Health Building Notes). o Consider national guidelines and legislation during the Tendering process for services. o Systems for waste management and laundry management, potential infection risks and control strategies and relevant National guidance	Incorporate infection prevention and control advice into tenders	

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Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
CP3	***Develop and implement evidence-based policies and guidelines for the prevention and control of infection.***			
CP3.1	Develop different forms of guidance based on the critical analysis of research evidence and interpretation of National guidelines	Evidence underpinning infection prevention and control practice	Critical evaluation of guidelines, research and other sources of evidence and application of findings to clinical practice i.e. SOP's, flow charts, policy and procedures.	
CP3.2	Work in partnership with key stakeholders to develop policies and guidelines that are evidence-based, relevant and understandable to health and social care staff	Legislation, national and local polices, guidelines and strategies relevant to infection prevention and control	Work in partnership with stakeholders to design, develop relevant and understandable polices/guidelines	
CP3.3	Monitor and evaluate the effectiveness of IPC policies and guidelines and identify areas for improvement	Principles of process and outcome audit	o Use audit to support quality improvement in relation to IPC. o Develop effective strategies to address deficiencies in practice	
CP3.4	Promote the application of evidence to infection prevention and control practice	Effective strategies for disseminating and implementing infection prevention and control polices and guidelines	Design and plan the effective implementation of polices and guidelines which follow local governance processes	
CP4	***Recognise, report and manage incidents and outbreaks.***			
CP4.1	Recognise and appropriately escalate significant incidents and outbreaks, and identify the evidence required to determine the nature, scale, and prevention strategies	Routes of transmission of micro-organisms, risk factors for transmission, common causes of outbreaks of HCAI, and sources of data on outbreaks e.g. national surveillance systems and factor in epidemiological links and risks	Identify and define outbreaks and incidents	
CP4.2	Work in partnership with others to agree and implement prevention and control measures, evaluate their effectiveness and adapt them if new information becomes available	Evidence for effectiveness of strategies to prevent outbreaks of HCAI	Interpret microbiological data and other information to inform effective prevention and control measures	
CP4.3	Communicate clear, accurate and timely information throughout the outbreak /incident to ensure risk is effectively managed	o Definitions of outbreaks/incidents of infection. o Data required to control outbreaks and analysis of data to understand factors responsible for transmission and identify efficacy of control measure	o Collect, analyse and interpret outbreak data. o Identify and communicate with relevant stakeholders. o Develop and communicate an outbreak management plan o Outbreak management plans should factor within a health economy approach i.e. acute & community o Identify the end of an outbreak o Report on lessons learned and recommendations for improvements to avoid reoccurrence o Present reports of outbreak to relevant stakeholders	
Domain: Education (ED)				
ED1	***Develop own knowledge and skills in infection prevention & control***			
ED1.1	Identify and evaluate own development needs, including strengths and limitations, to meet current and emerging work demands and organisational objectives.	Personal portfolio, documentation, organisational and professional revalidation requirements	Maintain a personal portfolio and identifying gaps in knowledge and skills or other development needs	
ED1.2	Develop clear plans, actions and outcomes to build and maintain expertise as part of ongoing professional development.	Formal and informal education and training opportunities	Take responsibility for addressing development needs and developing action plans	

Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
ED1.3	Maintain knowledge and skills in infection prevention and control practice utilising a breadth of resources across both academic and professional practice.	Sources of academic literature underpinning the science and practice of IPC i.e. academic journals and courses and participating in other educational and learning activities and opportunities.	Critical evaluation of published literature and research studies and application of findings to practice	
ED2	***Identify and respond to infection prevention & control learning needs in others***			
ED2.1	Influence others to recognise infection prevention and control as an essential learning need for all healthcare staff.	Resources available to support IPC training and education	Identify knowledge and training needs of workforce	
ED2.2	Use scoping exercises to identify emerging IPC risks and related learning needs.	Emerging IPC issues, innovations in practice, new technologies. Strategies for training and education	o Deliver training/education that meets the learning needs of the participants and organisation o Identify and negotiate opportunities for IPC training o Integrate IPC training with organization training and development programmes	
ED3	***Provide expert advice and education on infection prevention & control to staff and service users and providers***			
ED3.1	Design communication strategies, learning resources/information and educational events that are appropriate to the needs of the target audience.	National and local policies and guidelines that inform IPC practices	o Design evidence-based training/education on IPC appropriate for a range of audiences o Engagement in public awareness campaigns (local, national and international).	
ED3.2	Deliver flexible and creative education and training that supports effective learning.	o Strategies for delivering effective training and education o Sources of information on IPC for staff, patients, service users, service providers and the public	o Deliver IPC information to a range of audiences using a variety of presentation approaches and styles o Design effective evidence-based material to clearly communicate relevant information to staff, service users and providers. o Design and develop study days and conferences locally and nationally where applicable	
ED4	***Evaluate educational strategies for infection prevention & control***			
ED4.1	Work in partnership with others to ensure infection prevention is an integral part of staff learning and development.	Organizational objectives for staff training and development	Work collaboratively to develop effective training	
ED4.2	Provide support and expert advice to improve knowledge of infection prevention across the organisation.	Key stakeholders in determining Organisational strategy for staff training	Influence training and development strategies to address IPC training needs	
ED4.3	Evaluate the effectiveness of educational strategies and make recommendations to improve the knowledge, skills and competence of the workforce.	Evaluation strategies	Evaluate teaching and take account of feedback in revising teaching materials or strategy	
Domain: Quality improvement and Research (QR)				
QR1	***Use improvement methodologies to enhance and sustain infection prevention & control***			
QR1.1	Identify opportunities for improving the quality and safety of patient care	Methodologies used to drive improvement including route cause analysis, stakeholder analysis, process mapping, driver diagrams and improvement cycles such as PDSA	Work collaboratively to drive improvement applying appropriate improvement methodologies.	

Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
QR1.2	Apply improvement science methodologies to drive quality improvement through behavioural and system changes	Approaches to measurement to determine if change is effective.	Select appropriate measures of improvement	
QR1.3	Evaluate, review and refine improvement initiatives	o Knowledge and understanding of theories that inform improvement e.g. improvement science, human factors and ergonomics, behaviour change theory how these impacts on behavioural change o Methodologies to support effective root cause analysis	Apply the principles of root cause analysis to IPC incidents and/or outbreaks and work collaboratively to develop solutions	
QR2	***Minimise the risk of antimicrobial resistant (AMR) pathogen emergence and transmission***			
QR2.1	Promote and implement initiatives to prevent the transmission of antimicrobial resistant pathogens	The infection process, management of infection including the principles of antimicrobial prescribing	o Work collaboratively to implement and promote local AMR strategies and stewardship initiatives e.g. AMR stewardship groups. o Engagement of staffing groups on AMR campaigns.	
QR2.2	Utilise surveillance and prescribing data to identify report trends and inform IPC strategies	Mechanisms of resistance acquisition, strategies for preventing the emergence of resistance, epidemiology of resistant pathogens in the UK and world-wide	Use surveillance data to develop and inform improvement strategies	
QR2.3	Promote and implement strategies that encourage effective antimicrobial stewardship	Principles of antimicrobial stewardship. Surveillance of AMR and antimicrobial prescribing	Communication strategies	
QR3	***Use research to inform clinical practice***			
QR3.1	Critically assess and evaluate research and apply findings to inform evidence-based practice.	Research methods including quantitative and qualitative study design, assessing research quality and validity, influence of bias and confounding, measures of effect and basic statistics	Identify, critically review and synthesise research findings and apply them to clinical practice	
QR3.2	Design and participate in research independently and/or collaboratively.	Systematic literature searching to answer a clinical question	Apply the principles of research methodology to IPC interventions to provide evidence of efficacy	
QR3.3	Disseminate and apply findings of research to clinical practice.	o Developing research questions and selecting appropriate methods to answer them. o Principles of writing publications for peer review describing research, quality improvements and evidence review	Analyse data using appropriate methodologies	
Domain: Leadership and management (LM)				
LM1	***Lead and manage a range of strategies to prevent and control infection***			
LM1.1	Set realistic objectives (personal and teams) and work with staff, partner organisations, patients, carers and the public	Leadership and management styles and their application to practice	o Discuss personal scope of practice (professional ethical and legal) linked to organisational and governance structures. o Manage risk and maintain safety o Support and guide the performance of others.	

Competency	Practice Indicator	Knowledge	Skills	Working towards/ Competent
LM1.2	Assess and evaluate performance of self, individuals and/or teams and provide constructive feedback in a manner most likely to sustain and assist in the prevention and control of infection	o Legislation and guidance related to the management of employees. o Change management strategies. Human factors and implementation theory	o Participate in peer review and actively seek feedback on performance of self and others o Manage staff, including developing work plans and feedback on performance.	
LM2	***Develop and lead a high-quality infection prevention and control team and services.***			
LM2.1	Set realistic objectives, work and professional development plans with individual team members	Leadership styles and their application to practice	o Role model values of IPC team and organisation o Support and guide the performance of others within teams and organisations	
LM2.2	Develop, coach, assess and encourage team members to practice effectively and efficiently providing feedback when and where appropriate	o Performance reporting (IPC) as per organisational requirements. o Performance appraisals and staff management and wellbeing systems. o Legislation and guidance related to the management of employees including HR processes o	o Initiate and develop effective relationships within teams and across organisations. o Manage junior staff, including developing work plans, supervision and feedback on performance o	
LM2.3	Develop, supervise and participate in the development and implementation an annual IPC programme in partnership with key stakeholders and in line with organisational objectives and available resources.	o Principles of planning services, aligning to budget and resources o Governance arrangements, and the role of the IPC, in assuring patient safety	o Identify, measure and respond to outcomes and key performance indicators o Managing resources effectively	
LM2.4	Develop and sustain partnerships and networks to support the development of a high-quality IPC service	o Internal and external organisational contacts. o Local and National agencies and partners linked to IPC	o Develop communication engagement and network strategies for self and teams o Assess and evaluate effectiveness self and team	
LM2.5	Horizon scan to support building a strategic vision and identify and adopt innovation to improve service safety and quality	Epidemiology of emerging health threats to the local population.	o Recognize new and emerging threats in relation to infection prevention & control. o Identify opportunities for improvement and innovation. o Develop IPC practice in response to changing needs and priorities.	
LM3	**Design, plan and monitor care services to assure quality and safety in relation to infection prevention & control**			
LM3.1	Utilise data and other information to influence planning and inform service redesign	Evaluate and interpret surveillance and other infection-related data, including and understanding of the principles of statistics and limitations of data	Developing systems for measuring outcomes, processes and key performance indicators	
LM3.2	Develop performance management systems that monitor defined outcomes or indicators against defined standards linked to IPC	Systems for monitoring processes and outcomes	o Using and monitoring data to inform, drive and sustain quality improvement. o Liaising with key stakeholders (internal and external to organisation)	

Education Framework for the Infection Prevention and Control Practitioner (IPC) Workforce

The framework sets standards and identifies learning outcomes for the professional development and growth of the IPC practitioner workforce, promoting confidence and leadership skills to ensure practitioners can lead, challenge, and implement safe standards of IPC practice.

October 2023

Contents

1. Foreword

The SARS-CoV-2 pandemic highlighted the importance of Infection Prevention and Control (IPC). The contribution of our IPC practitioner workforce continues to be vital as the NHS moves forward in delivering the national commitments outlined in the NHS Long Term Plan, the UK 5-year action plan for antimicrobial resistance 2019-2024, The UK's 20-year vision for antimicrobial resistance and the NHS Operating Framework.

We must progress the learning from the pandemic, including the recommendations in the Healthcare Safety Investigation Branch's independent report: COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation, to develop a national IPC strategy which includes ambitions to enhance IPC capacity and capability across England.

This Education Framework for IPC Practitioners will form part of a national IPC workforce and education plan. The framework sets out clear outcomes for the development and growth of a skilled workforce, to promote the confidence and leadership skills necessary to ensure practitioners challenge, and effectively support the reliable implementation of safe standards of care for the patients we serve.

The framework supports the NHS Long Term Workforce Plan in upholding IPC as a valued career option. This framework provides a clear direction for career progression and aims to encourage the recruitment and retention of a skilled IPC workforce. This in turn contributes to the NHS Patient Safety Strategy, supporting and empowering IPC Practitioners with the ability, self-assurance and means to succeed.

I would like to thank all IPC practitioners across the NHS and social care in England for their expertise and commitment to safety. I encourage them and their organisations to use this framework to progress a capable and resilient IPC workforce.

Dame Ruth May,
Chief Nursing Officer, England.

2. Statements of Support

UKHSA are very pleased to have contributed to the Education Framework for the IPC practitioner workforce. This is a valuable resource to support the delivery of consistent IPC practice in healthcare.

Sarah Gigg, **Deputy Director Nursing, Midwifery and Allied Health Professionals**
UK Health Security Agency

The Infection Prevention Society (IPS) is pleased to support the Education Framework for Infection Prevention and Control (IPC) Practitioners developed by NHS England. As co-contributors to the Education Framework, we are encouraged that the importance of the contribution of the IPC workforce in the strategy to deliver of the NHS Long Term Plan and the Five-year Antimicrobial Resistance National Action Plan has been recognised.

Since its inception, one of the key activities of the IPS has been to deliver IPC-focused education and training for our health and care workforce, the Education Framework is relevant to IPC Practitioners working at all levels, and this is essential if we are to ensure the sustainability of our specialist and valued workforce.

The Education Framework for IPC Practitioners will support the professional development, improve capability and capacity of our IPC teams. In addition, we will continue to support and encourage the formation of a diverse, inclusive and resilient IPC workforce to improve the quality of IPC practice and improve health outcomes.

The Infection Prevention Society (IPS)

The Healthcare Infection Society (HIS) welcomes the production of this Education Framework for the Infection Prevention and Control Practitioner Workforce; a comprehensive plan designed to provide **ALL** healthcare workers with the knowledge and skills they need to prevent and control the spread of infections in healthcare settings.

The Framework provides clear outcomes for the development and growth of a skilled workforce as a basis for multidisciplinary IPC teams and promotes IPC as a career option for a wide range of individuals and gives a clear direction for career progression.

As a learning provider, the educational material and events produced by HIS fit well into this framework. HIS will further utilise this to inform the design and delivery of additional education and training programmes, in line with the Society's current strategic plan, aligning with the distinct levels of practice identified in the Framework.

Sarah Adibi, Chief Executive Officer, Healthcare Infection Society

I am pleased to support the development and introduction of the Education Framework for Infection Prevention and Control (IPC) Practitioners developed by NHS England.

The introduction of this Framework alongside the Infection prevention and control education framework published in March 2023, this now completes the practice and learning expectations of the entire health and care IPC workforce, it presents us with a unique opportunity to support a highly valued and respected group of individuals and teams in delivering high quality IPC practice and improving outcomes for individuals, patients and communities.

Professor Steve Hams, Chief Nursing Officer, North Bristol NHS Trust

As Chair of the Steering Group which has overseen the work to develop this framework, I am delighted to endorse this NHS England *Education Framework for IPC Practitioners*. The Steering Group have been involved in the co-design of the framework, and as a result it has received overwhelming support.

Many years spent working as a specialist IP practitioner have taught me the importance of effective education and career development for Infection Prevention and Control Practitioners, both in terms of specialist knowledge for practice, and the ability to lead and influence your team, organisations and networks.

I believe this education framework will assist Higher Education Institutions, employers, and IPC Practitioners to develop, support and utilise a range of educational opportunities which better meet the needs of our specialist workforce. The result will be an increasingly well-trained specialist workforce, who are better able to provide the expert advice and leadership needed to protect people from infections across the spectrum of health and social care. Ultimately, this will improve both patient/client safety and staff safety and support increased role satisfaction and staff retention of specialist IPC Practitioners.

Tracey Cooper, Chair of Education, Workforce & Leadership Steering Group.
Independent Nurse Consultant Infection Prevention, Lecturer in Health Sciences (Infection Prevention and Control) Bangor University, Past President IPS

The Independent Healthcare Providers Network (IHPN) welcomes the publication of the NHSE Education Framework for IPC Practitioners.

The framework enhances the development and growth of the Infection Prevention and Control (IPC) practitioner workforce within the NHS and the Independent Sector and will support a more resilient and skilled IPC workforce of the future.

The framework is a crucial step in the right direction in the promotion of consistency in IPC education and practice across health care systems. It will significantly strengthen IPC as a career of choice, as well as helping retain and develop those currently in an IPC role.

We will promote this important framework within our membership to improve practice, reduce infection, and maintain the safety of our patients, while attracting, retaining and developing our current and future workforce.

Dawn Hodgkins, Director of Regulation, on behalf of Independent Healthcare Partners Network.

3. Introduction and Background

NHS England have committed to deliver the actions outlined in the NHS Long Term Plan (2019) and the Five-year Antimicrobial Resistance (AMR) National Action Plan (2019).

NHS England commissioned Skills for Health (SfH) to review and develop an Infection Prevention & Control (IPC) Framework for those individuals who would be considered part of the **IPC Practitioner workforce**, to improve the quality of IPC practice and health outcomes, as well as promote IPC as a positive place to work and increase its reach to those who would consider a career in IPC.

The Framework provides clear outcomes for the development and growth of a skilled workforce, promoting confidence and leadership skills to ensure practitioners can lead, challenge, and implement safe standards of IPC practice for the patients we serve.

This Framework supports the NHS Long Term Workforce Plan in promoting IPC as a career option for a wide range of individuals, giving clear direction for career progression and supporting recruitment and retention of the IPC workforce. This in turn contributes to the NHS Patient Safety Strategy, supporting and empowering IPC Practitioners with the skills, confidence and mechanisms to improve safety and saving lives.

4. Purpose of Framework

The framework identifies outcomes for the development and growth of the IPC practitioner workforce, to help build confidence and leadership skills to lead, challenge and implement safe standards of IPC practice.

It is important to note this framework is not intended for the wider health and care workforce, a separate framework has been produced for them and can be located here: IPC Education Framework

Roles and responsibilities for IPC is outside the scope of this document: a national strategy for IPC Workforce and Education is currently being developed and will include a “blueprint” for an IPC service along with defined roles and responsibilities for IPC within an organisation.

The framework identifies **four distinct levels of practice** which create an incremental pathway for the IPC practitioner workforce, ranging from someone starting their IPC career through to someone working at advanced level IPC practice. There is also a section outlining the role of the non-IPC trained Director of Infection Prevention and Control (DIPC).

It is important to note however, the framework **is not suggesting** there are 4 roles/jobs within IPC practice; therefore, individuals may have many more ‘job-steps’ in their overall

IPC career and employers are not limited to the number/types of roles they wish to have in their services.

The framework **aims to support** managers, in growing and developing a skilled workforce as a basis for multidisciplinary teams within health and social care organisations.

The framework will assist with curriculum design and development to support the advancement of IPC practitioner capability and capacity. In turn, this will support the development of a skilled and competent IPC workforce and supporting organisations in maintaining a resilient and sustainable IPC service.

Learning providers and professional training bodies **are encouraged to consider** this document to inform the development of curricula for the courses and training they deliver and qualifications they award.

The framework enables the development of required outcomes for practice and supports professional growth and workforce transformation.

The framework **is not** intended to replace current relevant frameworks but supplement them.

5. Who will be interested in this framework?

Service commissioners

The framework sets out clear expectations about what the IPC practitioner workforce needs to do. The outcomes identified support the development and planning of the workforce to meet need and support a common understanding and expectation of this workforce.

Employers

The framework enables employers and managers to demonstrate that IPC practitioner staff they employ/manage meet the outcomes identified or have developmental plans in place along with the necessary supervision to ensure safety and meet the needs of the service and organisation(s).

This underpins and supports the need for continuing professional development of staff to ensure their practice is safe, effective, remains up-to-date and supports the process of quality assurance to ensure the safety and effectiveness of primary care roles. It can be used as part of appraisal processes.

Education and training providers

Educational institutions can use the framework to inform the design of their curricula and the delivery of education, training, and development programmes, including identifying learning outcomes. This will ensure that their learning and development provision contributes to the full range of knowledge to support the outcomes required to make individuals safe and effective members of the workforce.

The framework will inform those who design and deliver training and development opportunities to focus on the key outcomes that learners need to achieve and maintain. This in turn, will guide the content to be included and the use of appropriate learning and teaching strategies.

Use of this framework also supports organisational and system wide effectiveness and efficiencies by encouraging the delivery of education and training that is focused on developing identified outcomes and optimises opportunities for interprofessional learning; focused on outcomes-based curricula which equips individuals with the attributes required to meet the needs of the population. In so doing, it should help to increase consistency in knowledge and skills development, prevent unnecessary duplication in education and training delivery and strengthen skill mix and teamworking.

Current and future staff

The framework promotes IPC as a career option for a wide range of individuals as well as giving a clear sense of the ways in which to progress.

It provides clarity about characteristics and requirements to practice at each level and offers a structure of outcomes that enable practice at each level.

It can be used to conduct formal or informal appraisal, alongside a training needs analysis, comparing current skills and knowledge with required skills and knowledge.

This framework may assist staff in the development of a portfolio of evidence.

6. Structure of the framework

The framework is comprised of three components:

A. Levels of practice for IPC professionals (with a detailed practice descriptor)
B. Identified Domains
C. Outcomes for practice (for each level of practice and identified domain).

These three components are explained in more detail on the following pages.

This framework aims to support the sustainability and growth of the IPC workforce and facilitate the professional development of staff within IPC services. It also provides insight into what characteristics are required to work at each level of practice.

This framework **does not** mandate roles/ or specific jobs; nor does it suggest the amount of renumeration or terms and conditions that maybe associated with jobs/roles which must be dealt with locally by employers.

The framework does; however, identify **potential** roles that **may be** seen at each level of practice.

7. A. Levels of Practice for IPC Professionals

Description of Levels

Each Level of Practice is further detailed by the following Practice Descriptors.

8. A. Practice Descriptors

<table>
<tr><td colspan="2">Practice Descriptor: Introduction Level

This level describes people for whom IPC is not their main role. This role is taken on in addition to their main role. Staff may or may not be supported by a substantive IPC team or IPC practitioner.

People at this level
• Require knowledge of facts, principles, processes, and general concepts of IPC.
• Carry out a wide range of duties and will have some responsibility for the delivery of IPC care, but with further guidance, support, and supervision appropriately available when needed.</td></tr>
<tr><td>Indicative learning and development</td><td>Potential roles at this level</td></tr>
<tr><td>Appropriate units of learning that enable the capabilities identified to be achieved, for example:
• Development of relevant IPC clinical practice outcomes; (typically delivered by senior IPC professionals).
• Supporting the development and delivery of training events.
• Completing audits and supporting quality improvement work.</td><td>• Link practitioners.
• IPC Champions.
• Surveillance staff.
• Care home IPC leads.
• Administrative roles supporting IPC Teams.</td></tr>
</table>

Practice Descriptor: Foundation Level

Staff working at this level will be occupying a role where IPC practice forms the core and substantive part of their role.

All staff at this level

- Will be working towards an IPC qualification/agreed level of training to obtain a comprehensive and thorough knowledge of IPC and can use knowledge to solve problems, make judgements which require analysis and interpretation; however, they will have an awareness of the boundaries of their knowledge.
- Will have responsibility for the delivery of staff training and supporting the development needs of identified staff.
- May carry out a wide range of duties and will have some responsibility for the delivery of care, with guidance and supervision available when needed. They will contribute to service improvement and are responsible for their own self-development.
- Recognise and work within the boundaries of their practice, knowing when and to whom to refer patients/situations. They may delegate work or work with other members of the multidisciplinary team and take accountability for the delegated activity.

Indicative learning and development	**Potential roles at this level**
Appropriate units of learning that enable the outcomes identified to be achieved, e.g. • Further development of relevant IPC and AMS clinical practice knowledge & outcomes. • Principles of leadership and behavioural change. • Principles of data collection, audit, and research. • Facilitating learning events and principles of effective teaching	• Newly appointed IPC practitioner staff. • Surveillance Staff.

Practice Descriptor: Enhanced Level

Enhanced practice registered professionals will have typically completed some form of post graduate education (level 7) (e.g., post-graduate diploma) relevant to their area of practice and role.

Enhanced practice is a level of practice used to describe the practice of highly experienced, knowledgeable IPC professionals.

Staff in this role usually work as part of a multidisciplinary team and apply their enhanced skills, knowledge, and experience to contribute to episodes of care.

Enhanced IPC Practice professionals:

- Provide a high standard of complex, enhanced care for patients, using enhanced levels of clinical judgement, skills, and knowledge.
- Critically evaluate and analyse clinical problems using their expertise and clinical knowledge, seeking out and applying relevant evidence, enhanced clinical assessments, diagnostics, interventions, and equipment to make clinical decisions.
- Deliver complex care in the context of continual change, challenging environments, different models of care delivery, innovation and rapidly evolving technologies using critical analysis and their underpinning knowledge to manage complex interventions.
- Teach and advise others and/or support the multi-disciplinary team to do so.
- Participate in clinical audits, research projects, and implement changes as required, including the development, and updating of practice protocols/guidelines and procedures. They will work within national and local protocols where these exist.
- Continuously update their knowledge, enhance their clinical practice, and provide support, mentoring and supervision of others.
- Recognise and work within the boundaries of their practice, knowing when and to whom to refer patients/situations. They may delegate work or work with other members of the multidisciplinary team and take accountability for the delegated activity.

Indicative learning and development	**Potential roles at this level**

Appropriate units of learning that enable the outcomes identified to be achieved, for example: • Evidence of appropriate post-graduate learning in IPC relevant to scope of role; ensuring the outcomes for practice at this level are met. • Continuing Professional Development (CPD) that enables the delivery of care aligned to role and level of practice. • Practice Supervisor/Assessor status. • Leadership, influencing, and behaviour change relevant to role. • Quality Improvement.	• Specialist infection prevention control practitioner. • Clinical specialist – infection prevention. • Healthcare Scientist.

Practice Descriptor: Advanced Level

- Advanced Practice is a level of practice characterised by a high degree of autonomy and complex decision making, that encompasses the four pillars of clinical practice, leadership and management, education, and research.
- Advanced practice is a level of practice in which a practitioner has demonstrated their ability to work autonomously at a high-level (level 7/ Masters level IPC training).
- Advanced Practice embodies the ability to manage clinical IPC care in partnership with individuals, families and carers and the requirement to work in close partnership with all members of the multi-professional team.
- Advanced Practice is designed to transform and modernise pathways of care, enabling the safe and effective sharing of IPC skills across traditional professional boundaries.

Advanced Practitioners

- Demonstrate initiative and are creative in finding solutions to IPC problems.
- Have responsibility for IPC performance and service development.
- Operate in the context of continual change, challenging environments, different models of care delivery, innovation and rapidly evolving technologies using critical analysis and underpinning knowledge to manage complex interventions in relation to IPC.
- Act as a role model, educator, supervisor, coach, and mentor in relation to IPC, seeking to instil and develop the confidence of others.
- Where the IPC Practitioner has completed level 7 IPC training, they may also hold the Deputy/Associate or DIPC (for more information on the DIPC role see Appendix 1.

Indicative learning and development	Potential roles at this level

Appropriate units of learning that enable the outcomes identified to be achieved, e.g. • Advanced-level practice is underpinned by a full post-registration MSc programme that enables the development and demonstration of the capabilities articulated in the *multi-professional framework in advanced clinical practice for England* (Health Education England, 2017) across the four pillars of practice (clinical, leadership and management, education, and research), including in ways that meet area-specific (IPC) needs. • CPD that is relevant to the scope of role and workplace setting. • Advanced learning in relation to leadership, research, influencing and behaviour change. • The potential for practitioners to demonstrate equivalence of the above through the successful completion of the Centre for Advancing Practice's e-Portfolio (supported) route. • Potential progression to level 8 (doctoral level) learning/award as part of practitioners' ongoing development from their advanced practice role, where this fits with workforce development/deployment and service delivery needs.	• Advanced clinical practitioner (IPC). • Non-medical consultant practitioner. • Consultant in Infection specialities (Medical microbiology/ virology/ infectious diseases). • Consultant level practitioner. • Consultant clinical scientist. • Lead Nurse IPC. • Deputy / Associate DIPC (who is trained in IPC. • Infection Control Doctor • IPC trained DIPCs* (Non-IPC trained DIPCs do not fall into this category)

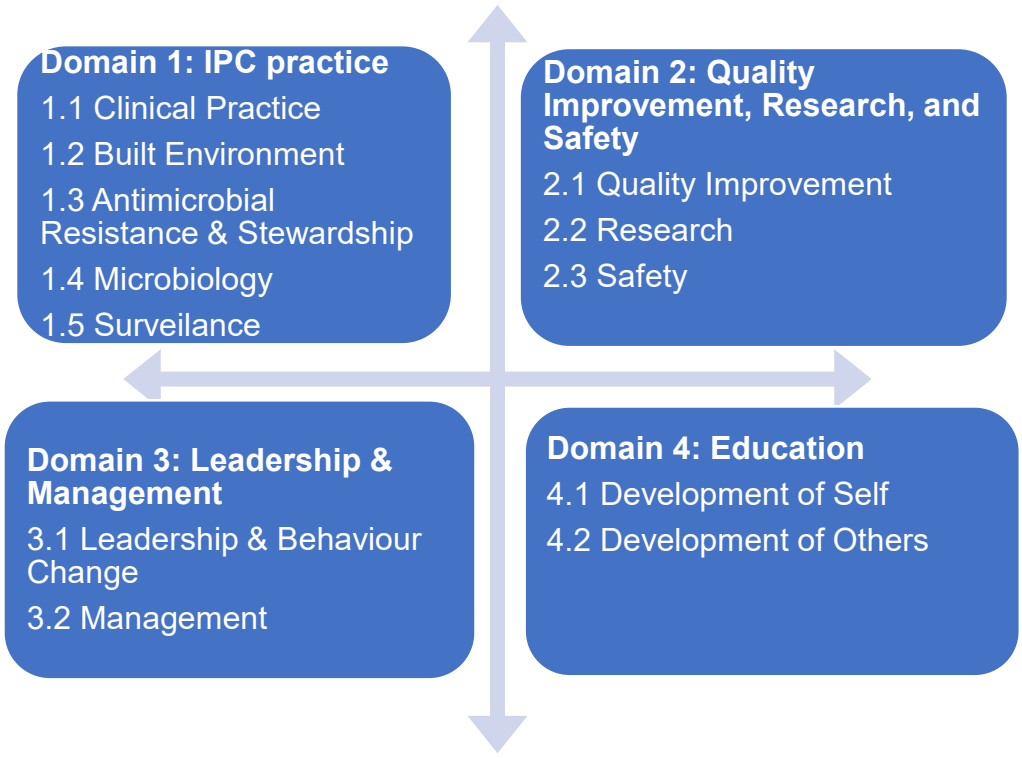
*Further information about the DIPC role can be found in Appendix 1

9. B. Framework Domains

The Framework identifies the following four domains:

- Domain 1. Clinical Practice.
- Domain 2. Quality Improvement, research, and safety.
- Domain 3. Leadership and Management.
- Domain 4. Education.

Within each Domain there are a number of sub-domains as shown below, which are numbered for ease of reference.



10. C. Outcomes for Practice

The framework articulates outcomes for practice necessary for safe and effective IPC care delivery.

They are written at a relatively ‘high-level’ and allow for the ability to contextualise them to suit the environment of care in which their service operates and the many roles they utilise. It is also for employers to agree a scope of practice and a job description with their employees.

The outcomes for practice **do not** indicate a prescribed pathway or process.

The outcomes for practice are incremental, building across the four practice descriptors (e.g., advanced level statements assumes that those people to whom they are applicable, possess those at preceding levels (to minimise unnecessary repetition).

Domain 1: IPC Practice				
1.1 Clinical Practice				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Act as a point of contact on IPC matters.	x	x	x	x
2. Advise on IPC measures related to cleaning, disinfection, and sterilisation processes.	x	x	x	x
3. Establish and maintain good communication with patients/clients/residents and relatives regarding their IPC care.	x	x	x	x
4. Communicate IPC action plans with healthcare staff maintaining appropriate records of work per agreed protocols.	x	x	x	x
5. Always apply Standard Infection Control Precautions, for all individuals (whether infection is known to be present or not), to ensure the safety of everyone.	x	x	x	x
6. Implement on IPC measures related to invasive devices and procedures.	x	x	x	x
7. Utilise current evidence-based guidance, policies, and protocols to inform IPC practice.	x	x	x	x
8. Apply Transmission Based Precautions when indicated by using clinical judgement and making risk assessed decisions based on: ▪ Suspected/known infectious agents and the severity of the illness caused. ▪ Transmission route of the infectious agent. ▪ Care setting and procedures undertaken.	x	x	x	x
9. Encourage individuals to give feedback on guidance, policies, systems, procedures, and practices and how improvements could be made.	x	x	x	x

10. Contribute to and participate in IPC monitoring, audit, and significant event reporting.	x	x	x	x
11. Form respectful relationships with individuals, teams and organisations representing diverse constituencies, seeking regular input to better understand equality, diversity & inclusion issues.	x	x	x	x
12. Plan, monitor and review guidance, policies/procedures designed to promote good IPC.			x	x
13. Recognise circumstances or settings which create barriers to effective delivery of IPC and take appropriate action to overcome these barriers.			x	x
14. Investigate outbreaks using appropriate methods and interpretation of outbreak findings, by working with others to: • Establish the case definition. • Identify the parameters of the investigation and the case-finding methodology. • Make hypotheses and identify the source and mode of transmission.			x	x
15. Undertake IPC assessments of clinical areas, providing feedback, identifying areas of good practice and areas for remedial activity.			x	x
16. Evaluate clinical areas; ensuring any improvement plans are being acted upon.			x	x
17. Develop IPC policies and guidelines, which are evidence-based, clinically relevant and accessible to those who will follow them.			x	x
18. Evaluate IPC assessments, noting trends/patterns at a team/department/organisational level; working with clinical leads and others to embed required changes.				x
19. Lead how IPC risks are managed in unpredictable and complex situations, including where a precedent has not been set.				x

20. Lead the ongoing development of IPC pathways, standards, policies, guidelines, procedures, service improvement and practice accreditation.				x
21. Adapt national guidance, policies, and standard operating procedures to local needs.				x
22. Put in place a joint review of IPC services through peer reviews, audits and evaluations of safety, quality, and health outcomes.				x
23. Establish professional IPC practice across pathways, services, organisations, and systems, working with individuals, families, carers, communities and others.				x
24. Collaborate with key stakeholders to ensure that measures are in place to effectively recognise and respond to an infectious disease threat.				x
25. Ensure IPC is an integral element in formal systems for collecting and reviewing feedback from patients/service users/carers and staff across services are in place; working with service teams to identify and put in place any actions as a result of their feedback.				x
Domain 1: IPC Practice				
1.2 Built Environment				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Support interventions which tackle climate change and broader sustainability issues, in the context of providing high standards of IPC practice.	x	x	x	x
2. Support estates department, hygiene services and others with IPC advice on cleaning standards and cleaning specifications for the working environment.		x	x	x
3. Engage and collaborate with stakeholders to promote IPC in the built environment.			x	x

4. Complete IPC risk assessments and advise on IPC key measures for the built environment, taking into consideration current building guidance and legislation.			x	x
5. Provide IPC advice on water safety, specialist ventilation, decontamination, personal protective equipment, and investigations.			x	x
6. Assess the potential IPC risks on design, construction and renovation that may impact on patient care and provide recommendations to minimise such risks.				x
7. Audit and monitor implementation of IPC recommendations related to the built environment, reporting, and advising on corrective actions.				x
8. Ensure key services supporting IPC (e.g., cleaning and waste management) are meeting the needs and requirements of the service.				x
Domain 1: IPC Practice				
1.3 Antimicrobial Resistance (AMR) & Antimicrobial Stewardship (AMS)				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Deliver education in relation to AMR and AMS.	x	x	x	x
2. Apply AMS principles and good practice, using evidence-based guidance and local policies.	x	x	x	x
3. Report patient safety incidents related to antimicrobial use (e.g., hospital admissions for potentially avoidable life-threatening infections, infections with C. difficile or adverse drug reactions such as anaphylaxis).	x	x	x	x
4. Identify, challenge, and take action to rectify and report inappropriate antibiotic prescribing	x	x	x	x

5. Support the implementation of IPC measures and transmission-based precautions when caring for people colonised or infected with resistant microorganisms.	x	x	x	x
6. Support incident reviews and remedial actions related to AMR and AMS.		x	x	x
7. Integrate audit into existing quality improvement programmes in relation to AMR/AMS.			x	x
8. Work collaboratively with key stakeholders in implementing national IPC guidance on Healthcare Associated Infections (HCAIs), AMR and AMS.			x	x
9. Support efforts to minimise AMR, including diagnostic and AMS initiatives, reporting multidrug-resistant microorganisms, according to local and national requirements.				x
10. Use multimodal strategies to implement IPC measures to reduce AMR and HCAIs Infections.				x
11. Enable an effective system for ongoing surveillance and rapid alert/detection of AMR at organisational level.				x
12. Evaluate antimicrobial prescribing and how this relates to local resistance patterns by working with AMS teams and laboratory staff to provide regular feedback to individual prescribers in all care settings.				x
13. Work with AMS and IPC committees to develop and update plans to reduce AMR in healthcare, based on local AMR determinants and data including the consumption of antimicrobial agents.				x

Domain 1: IPC Practice				
1.4 Microbiology				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Apply knowledge of the microorganisms that cause infection in humans in healthcare and community settings.	x	x	x	x
2. Support with diagnostic and antimicrobial stewardship programmes when required.	x	x	x	x
3. Recognise key characteristics of pathogenicity, transmission, virulence, and other risk factors associated with chain of infection.	x	x	x	x
4. Apply knowledge about clinical manifestation and presentation of infection, diagnostic, laboratory testing and screening methods to interpret reports and advise others in line with organisational protocols and guidance.			x	x
5. Advise in discussions on the microbiological specimens to be taken in specific infection cases and/or outbreaks.			x	x
6. Provide advice and support in applying standard and transmission-based precautions depending on the modes of transmission and virulence patterns identified through microbiological tests.			x	x
7. Communicate in a timely and effective manner about modes of transmission and risks of specific pathogens and necessary microbiological investigations.			x	x

Domain 1: IPC Practice				
1.5 Surveillance				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Contribute and participate in IPC monitoring, audit, and significant event reporting.	x	x	x	x
2. Use surveillance data to reduce the risk of Healthcare Associated Infections among patients, staff, and others.			x	x
3. Develop protocols for a surveillance programme with clearly defined objectives and goals that are relevant for the target areas, procedure, population, or event of interest.			x	x
4. Work with wider stakeholders to determine organisational priorities for surveillance, based on available evidence and resources.				x
5. Develop plans to collect data: choose surveillance protocols, create or adapt practical data collection forms and identify data collection systems.				x
Domain 2: Quality Improvement, Research, and Safety				
2.1 Quality Improvement				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Identify opportunities to improve the quality and performance of IPC practice to promote efficacy, safety and improve patient care outcomes.	x	x	x	x

2. Implement a range of identified improvement activities to enhance quality IPC practice – working in partnership with key stakeholders.	x	x	x	x
3. Monitor guidance, policies, systems, procedures, and practices to identify improvements for IPC practice.		x	x	x
4. Evaluate and adapt Quality Improvement (QI) methodologies using a variety of styles to sustain or drive improvements in IPC practice.			x	x
5. Lead collaboration across a wide system of professionals and agencies, fostering collaboration and co-production to ensure IPC practice is optimal.				x
6. Critically evaluate and assimilate relevant IPC data and information from a range of sources to ensure complex decisions regarding IPC practice, reflect the analysis of several different perspectives.				x
7. Lead strategic development, improvement, inquiry and innovation across specific workstreams that informs and responds to system objectives and supports commissioners and senior leaders with their decision-making in IPC practice and service delivery.				x
Domain 2: Quality Improvement, Research, and Safety				
2.2 Research				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Contribute to the development of new knowledge through supporting research in IPC.		x	x	x
2. Critically evaluate published literature, research studies and application to IPC practice.			x	x

3. Develop a combined approach to practice focused research, academic inquiry and innovation across the IPC service/pathway.			x	x
4. Develop a culture of sharing knowledge that values research, evaluation and academic inquiry & its importance to contemporary IPC practice.			x	x
Domain 2: Quality Improvement, Research, and Safety				
2.3 Safety				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation level**	**Enhanced Level**	**Advanced Level**
1. Work with those affected by IPC safety incidents to understand and answer IPC related questions, signposting to additional support as required.	x	x	x	x
2. Use information to identify, monitor and report trends, informing IPC priorities and areas of concern.	x	x	x	x
3. Learn from action and analyse information from IPC reporting systems.		x	x	x
4. Enable an approach to IPC safety that prioritises compassionate engagement with those affected by IPC incidents.			x	x
5. Embed IPC incident responses within a wider system of improvement.				x
6. Initiate activities and measure impact to guide future IPC risk reduction based on experience and awareness.				x
7. Collaborate, support and provide advice to occupational health and health and safety professionals to develop and adapt evidence-based guidance/ national recommendations to undertake risk assessment, inform practice, monitor				x

performance, evaluate practice and respond to situations and adverse incident/s.				
Domain 3: Leadership & Management				
3.1 Leadership & Behaviour Change				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Support and encourage colleagues in implementing changes relevant to best IPC practice.	x	x	x	x
2. Encourage colleagues to ask questions, make suggestions and seek clarification in relation to the IPC work they have been allocated.	x	x	x	x
3. Provide values-based leadership across the IPC care pathway, services and systems in complex and changing situations.	x	x	x	x
4. Review changes made – identifying any 'lessons learned' for future IPC work activities.		x	x	x
5. Critically evaluate the culture present within IPC teams and enable an optimal working environment through positive compassionate role modelling and leadership skills.			x	x
6. Lead change processes: ensuring collaborative working to improve the quality of IPC practice.			x	x
7. Lead with emotional intelligence, in line with NHS constitution values of compassionate leadership to enable individuals/ teams to flourish, grow and deliver high standards of IPC.			x	x

8. Enable others to positively contribute to IPC service improvements and better ways of working, recognising their own role in such endeavours.			x	x
9. Ensure support is made available for staff to be able to innovate IPC practice, balancing such innovation with service requirements and overall clinical safety and effectiveness.				x
10. Lead the development of IPC strategy and ensure collaborative working with others to advocate practice development and improve the quality of care and professionalism of others, upholding the profession in the face of adversity.				x
11. Critically evaluate an outcomes-based approach to IPC practice, developing and leading on strategies for dissemination with a wider audience.				x
12. Build and maintain sustainable partnerships across organisations and systems, drawing on standards and best practice evidence to guide decision-making.				x
Domain 3: Leadership & Management				
3.2 Management				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Allocate work to others by taking account of their skills, knowledge, competence, backgrounds and experience.			x	x
2. Provide opportunities for colleagues and peers to get to know each other's strengths and weaknesses and build mutual respect and trust.			x	x
3. Enable the wider IPC team to positively contribute to better ways of working.			x	x

4. Implement IPC interventions working with multidisciplinary teams, using multimodal strategies, and campaigning as required.			x	x
5. Recruit, interview and appoint team members, align workloads, prioritise, and motivate members of IPC team/s to ensure delivery of high-quality care through excellent teamwork.				x
6. Work collaboratively with key stakeholders in conducting facility/organisational wide IPC risk assessments, developing plans to manage risks as a strategy for compliance with IPC elements of national quality standards.				x
7. Demonstrate an ability to examine problems/situations and find solutions through creative application of knowledge, experience, data, and evidence.				x
8. Coordinate required preparedness and response to requests for advice, education, support, and planning including emerging infectious disease, emergencies, and threats at organisational, system and national level.				x
9. Manage assurance systems and processes to develop robust outcome indicators for clinical practice and other aspects (such as clinical governance).				x
Domain 4: Education				
4.1 Development of self				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Remain up to date with contemporary IPC practice.	x	x	x	x
2. Engage in a range of appropriate learning and development, continually reflecting on their IPC practice to maximise their capabilities.	x	x	x	x

3. Be open to feedback on IPC practice by colleagues to promote ongoing development.	x	x	x	x
4. Evaluate at appropriate intervals, the current and future requirements of their practice.	x	x	x	x
5. Identify any capability gaps in their IPC practice, agreeing personal development plans with line manager through activities such as induction and appraisal.	x	x	x	x
6. Review and update personal development plans in the light of performance, any development activities undertaken, and any wider changes as identified.	x	x	x	x
Domain 4: Education				
4.2 Development of others				
The IPC Practitioner will be able to:	**Introduction Level**	**Foundation Level**	**Enhanced Level**	**Advanced Level**
1. Deliver an identified range of IPC education and learning programmes; targeted to meet the needs of the individual learner(s) and the care environment in which they operate.	x	x	x	x
2. Support practice development by acting as a mentor and/or clinical supervisors as appropriate.		x	x	x
3. Contribute to the planning and evaluation of IPC learning activities.		x	x	x
4. Use a range of learning methods and resources to help the learners acquire/develop their IPC practice as identified.		x	x	x
5. Use information gained from learner evaluations to inform the development of future learning activities		x	x	x

6. Deliver rapid training refresher courses in the case of change of policies and/or in special situations, such as during the response to outbreaks and emergencies.		x	x	x
7. Recognise the importance of taking account of career and personal goals when supporting professional development of others.			x	x
8. Advocate for and contribute to a culture of learning to inspire future and existing staff.			x	x
9. Undertake Appraisals with IPC team members and support their Personal Development Plans as appropriate.			x	x
10. Identify collective learning and development needs of the IPC team(s).			x	x
11. Design and develop a suitable range of IPC learning activities/education and learning programmes which equip learners with relevant IPC capabilities needed to deliver safe and effective practice.			x	x
12. Evaluate the effectiveness of learning activities/programmes using appropriate IPC data sets as well as learner feedback.			x	x
13. Facilitate collaboration of the wider team and support peer review processes to identify individual and team learning and support them to address these.			x	x
14. Continually synthesise current practice and wider knowledge to inform IPC learning & development activities.			x	x
15. Build capacity and capability to support learning and collaborate with education service providers and education commissioners to ensure IPC workforce/learner needs are met.				x
16. Lead planning, implementation, and evaluation of educational interventions at a local, regional and national level for individuals, informed by training needs analysis and in response to IPC policy and strategy.				x

17. Enable the IPC team to build individual/team/organisational capacity and capability in IPC through work-based and interprofessional learning, and the application of learning to practice.				x
18. Build capacity and capability to support learning and collaborate with education service providers and education commissioners to ensure workforce/learner needs are met.				x

11. Appendix 1 – Directors of Infection Prevention & Control

Whilst this Education Framework focusses on defining levels of practice and not roles; there is one role where it is felt helpful to provide additional clarity – namely Directors of Infection Prevention & Control (DIPC).

DIPCs are accountable for the planning, delivery, and monitoring of IPC services within an organisation in accordance with the Health and Social Care Act (2008) Code of Practice on the prevention and control of infections and other relevant standards.

DIPCs are required to be in place in all registered NHS care providers under current legislation (Health and Social Care Act 2008) and compliance with these regulations is monitored by the Care Quality Commission (CQC).

The Director of Infection Prevention and Control:

- Has executive authority and responsibility for ensuring that strategies are developed and implemented to prevent avoidable healthcare associated infections (HCAIs) at all levels in the organisation and that the organisation meets its requirements; this will include leading on the development and implementation of an effective, organisational wide, IPC service.
- Has executive authority and responsibility for ensuring that strategies are developed and implemented to prevent avoidable healthcare associated infections (HCAIs) at all levels in the organisation and that the organisation meets its requirements; this will include leading on the development and implementation of an effective, organisational wide, IPC service.
- Are accountable to the Board and have a vital role in operational and board level decision making regarding IPC, for example closing/opening of facilities and/or provision of additional capacity.
- The DIPC is responsible for the development and implementation of operational and strategic plans for the IPC service, and for ensuring the development of a progressive and responsive service within a robust clinical governance framework.

It is acknowledged that the professional background of DIPCs is varied across the country and includes Medical, Nursing, Allied Health Professions and Clinical scientists and where IPC is not the principle role of the DIPC, it is really **important** that the DIPC is

supported by a blended workforce of foundation, enhanced and advanced level IPC practitioners, in order to discharge their duties under the current legislation. This will include the DIPC working collaboratively with colleagues, particularly if IPC is not their area of personal expertise, to ensure that their executive function and advocacy is fully informed by appropriate IPC expertise.

Outcomes for Practice for DIPCs	
Governance, Assurance and Quality Improvement	
1.	Responsible for the development and implementation of operational and strategic plans for the IPC service, and for ensuring the development of a progressive and responsive service within a robust clinical governance framework.
2.	Has executive authority and responsibility for ensuring that strategies are developed and implemented to prevent avoidable healthcare associated infections (HCAIs) at all levels in the organisation and that the organisation meets its requirements; this will include leading on the development and implementation of an effective, organisational wide, IPC service.
3.	Has either has a **board executive leadership role** (most likely the Chief Nursing Officer or Chief Medical Officer), reporting to the Chief Executive Officer (CEO), or a senior clinical role with direct access to the CEO and Board. They are responsible for providing assurance to the Board that systems and processes are in place and correct policies and procedures are adhered to across the organisation, to ensure safe and effective healthcare.
4.	Accountable to the Board and involved in operational and board level decision making regarding IPC e.g., closing/opening of facilities/provision of additional capacity.
5.	Is a member of the Board and relevant board sub committees such as Quality Assurance Committee.
6.	Ensures IPC is integral in formal systems for collecting and reviewing feedback from patients and service users, carers and staff across services, working with service teams to identify and put in place any action needed as a result of feedback.
7.	Reviews changes made – identifying any ‘lessons learned’ for future IPC work activities.

8. Facilitates continuous improvement in relation to IPC which will be demonstrated, in part, by the achievement of national targets, such as MRSA and Clostridium difficile reduction targets, as well as other quality standards.
Leadership and Management
9. Highly visible, authoritative individual, responsible for providing assurance to the Board that systems are in place and correct policies and procedures adhered to across the organisation to ensure safe and effective healthcare.
10. Models a strong, visible presence, open and trusting relationships with both internal and external partners to achieve IPC service objectives, based on a foundation of self-awareness and emotional intelligence.
11. Demonstrates strong executive authority with leadership visibility and presence.
12. Critically evaluate the culture within IPC teams and enable an optimal working environment through positive compassionate role modelling and leadership skills.
13. Provide values-based leadership across the IPC care pathway, services and systems in complex and changing situations.
14. Leads with emotional intelligence, in line with the NHS constitution values of compassionate leadership to enable individuals and team/s to flourish, grow and deliver high standards of IPC practice.
15. Demonstrate understanding and flexibility to support others during uncertainty, as IPC practice continues to evolve on the health agenda and with ever changing demands.
16. Develop a culture of sharing knowledge that values research, evaluation and academic inquiry & its importance to contemporary IPC practice.
17. Provides advice and guidance at all levels of an organisation with a focus on delivery of high quality, safe, effective and person-centred care, achieving the best outcomes for patients.
18. Leads on how IPC risks are managed in unpredictable and complex situations, including where a precedent has not been set.
19. Lead collaboration across a wide system of professionals and agencies, fostering collaboration and co-production to ensure IPC practice is optimal.
20. Lead strategic development, improvement, inquiry and innovation across specific workstreams that informs and responds to system objectives and supports commissioners and senior leaders with their decision-making in IPC practice.

21. Ensure support is available for staff to innovate IPC practice, balancing innovation with service requirements, overall clinical safety and effectiveness.
22. Build and maintain sustainable partnerships across national/international systems, drawing on standards and best practice to guide decision-making.
23. Collaborate with key stakeholders to ensure that measures are in place to effectively recognise and respond to an infectious disease threat.
24. Be open to feedback on IPC practice by colleagues to promote ongoing development.
25. Engage in a range of appropriate learning and development, continually reflecting on their IPC practice to maximise their capabilities.
Strategy and Policy
26. Implements a joint review of IPC services through peer reviews, audits and evaluations of safety, quality and health outcomes.
27. Work with AMS and IPC committees to develop and update plans to reduce AMR in healthcare, based on findings related to local AMR determinants and data including the consumption of antimicrobial agents.
28. Work collaboratively with key stakeholders in implementing national IPC guidance on HCAI, AMR and AMS.
29. Establish IPC practice across pathways, services, organisations and systems, working with individuals, families, carers, communities and others.
30. Ensure key services supporting IPC (e.g., cleaning, waste management) meet the needs and requirements of the service.
31. Engage and collaborate with stakeholders to advocate for IPC in the built environment.
32. Work with wider stakeholders to determine organisational priorities for surveillance, based on available evidence and resources.
33. Develop plans to collect data: choose surveillance protocols, create or adapt practical data collection forms and identify data collection systems.
Standards and Practice

34. Adapt national guidance, policies and standard operating procedures to local organisation's needs.
35. Support and encourage colleagues in implementing changes relevant to best IPC practice.
36. Apply knowledge of the microorganisms that cause infection in humans in healthcare and community settings.
37. Contribute and participate in IPC monitoring, audit, and significant event reporting.
38. Use surveillance data to reduce the risk of Healthcare Associated Infections among patients, staff and others.
39. Be an advocate for AMS best practice and deliver education in relation to AMR/AMS.
40. Apply AMS principles and good practice, using current evidence-based guidance and local policies.
41. Engage with others in implementing change in IPC practice.
42. Support efforts to minimise AMR, including diagnostic and AMS initiatives and reporting of multidrug-resistant microorganisms, according to local and national requirements.
43. Communicate in a timely and effective manner with stakeholders about modes of transmission, risks of specific pathogens and necessary microbiological investigations.
44. Encourage colleagues to ask questions, make suggestions and seek clarification in relation to the IPC work they have been allocated.
45. Enable others to positively contribute to IPC service improvements and better ways of working, recognising their own role in such endeavours.
46. Ensure support is made available for staff to be able to innovate IPC practice, balancing such innovation with service requirements and overall clinical safety and effectiveness.
47. Leads the ongoing development of IPC pathways, standards, policies, guidelines, procedures, service improvement and practice accreditation.

Knowledge, skills, and Behaviors required by DIPCs to support workforce development activities.

Knowledge	Skills	Behaviours
• Evidence of continued advanced study/action learning/CPD. • Demonstrable in-depth knowledge of healthcare systems, modern methodology, service redesign and project management. • Demonstrable sound theoretical knowledge to support the clinical aspects of commissioning. • Proven clinical knowledge skills in relation to infection prevention and control including: o SICPs and TBPs o Regulatory requirements for IPC o Key national IPC policies, guidance o HCAI surveillance and reporting requirements	• Proven advanced clinical skills in relation to infection prevention and control. • Advanced IT and analytical and interpretation skills. • Awareness of the political agenda. • Effective interpersonal and influencing skills. • Demonstrable negotiation skills. • Proven record of effective team leadership. • Able to deal with/respond appropriately to unpredictable emergency situations. • Demonstrated formal presentation skills. • Evidence of excellent relationship skills with partners resulting in demonstrable quality improvements. • Confidence and ability to communicate highly complex/ contentious information with a variety of audiences. • Ability to successfully engage with patients, public and clinicians relating to the field of Infection Prevention and Control and Antimicrobial Stewardship. • Experience of significant budgetary management.	• Self-confidence and personal drive. • Ability to deal with conflicting demands and pressures. • Ability to solve complex problems. • Results focused. • Resilience. • Commitment to equalities in employment and the promotion of diversity in the workplace. • Flexible, positive, outward looking. • Approachable, compassionate • Working collaboratively with colleagues, particularly if IPC is not their area of personal expertise to ensure that their executive function and advocacy is fully informed by appropriate IPC expertise.

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13. Appendix 3. Related frameworks & standards

National Infection Prevention and Control Manual for England (NIPCM)

The NIPCM provides an evidence-based approach to IPC practice across all health and social care in England. This policy manual should be adopted as mandatory guidance in NHS settings or settings where NHS services are delivered, and the principles should be applied in all care settings.
C1244_National-infection-prevention-and-control-manual-for-England_April-2022_v1.1.pdf

Infection Prevention Society Competencies Framework for IPC Practitioners

Competencies for infection prevention and control practitioners (IPCPs) were first introduced by the Infection Control Nurses Association (ICNA) in 2000 and subsequently revised by the Education and Professional Development Committee of the Infection Prevention Society (IPS). IPC competencies provide a framework to enable IPC Practitioners to develop and enhance their knowledge and skills to help increase patient safety and care quality. They can also assist in the design of education programmes; staff appraisal and personal development plans and reviewing team structures and requirements.
https://www.ips.uk.net/resources/view/IPS-R-QMVNQ2HHNX3P9L6

NICE Quality standard [QS61] Infection prevention and control

This quality standard covers IPC in adults, young people and children receiving healthcare in primary, community and secondary care settings. It includes preventing healthcare-associated infections that develop because of treatment or from being in a healthcare setting, describing high-quality care in priority areas for improvement: https://www.nice.org.uk/guidance/qs61

Multi-professional framework for advanced clinical practice in England

This multi-professional Advanced Clinical Practice (ACP) framework set out a new and bold vision in developing this critical workforce role in a consistent way to ensure safety, quality, and effectiveness. It has been developed for use across all settings including primary care, community care, acute, mental health and learning disabilities. This framework recognises that the health and care system rapidly evolve to deliver innovative models of care, health and care professionals have adapted, to meet the increasing demands of individuals, families and communities.

multi-professionalframeworkforadvancedclinicalpracticeinengland.pdf (hee.nhs.uk)

Health Education England: Enhanced Practice.

Enhanced practice makes a significant and essential contribution to health and care. The Long-Term Plan (2019) signalled the need to realise the full trained potential of the workforce and the need for meaningful career pathways to retain our valued staff in clinical roles.

See here for more information: Enhanced practice | Health Education England (hee.nhs.uk)

Health Education England: Consultant.

Enhanced practice makes a significant and essential contribution to health and care. The Long-Term Plan (2019) signalled the need to realise the full trained potential of the workforce and the need for meaningful career pathways to retain our valued staff in clinical roles.

More information can be found here: Consultant - Advanced Practice (hee.nhs.uk)

Core Skills Training Framework (CSTF)

Since its launch in 2013, the CSTF has become widely regarded as the benchmark for statutory/mandatory training in the health sector. The aim is to help ensure the quality and consistency of such training and to prevent unnecessary duplication of training. The CSTF comprises 11 subjects including Infection Prevention and Control.

Skills for Health and Health Education England are currently working in collaboration to ensure the sustainability of a robust CSTF with agreed requirements for learning outcomes, training standards and frequency of refresher training for NHS Trusts in England. The aim is to ensure CSTF alignment, which is assured and related data which transfers efficiently, safely and accurately between employer organisations. For more information see here: https://skillsforhealth.org.uk/info-hub/category/cstf-for-nhs-trusts-in-england/

Care Certificate Standards

The Care Certificate is a set of standards that define foundation knowledge, skills and behaviours expected of roles in the health and social care sectors. Designed with the non-regulated workforce in mind, the Care Certificate was launched in 2015 and developed jointly by Skills for Health and Skills for Care and is based on 15 standards, including:

- Standard 15. Infection prevention and control.

Individuals need to complete all 15 standards before they can be awarded their certificate. Each standard is underpinned by full learning outcomes and assessment criteria.

For further information about the Care Certificate see Skills for Health and Skills for Care.

National Occupational Standards (NOS)

National Occupational Standards (NOS) are statements of the standards of performance for individuals when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding.

NOS are developed for employers by employers through the relevant Sector Skills Council or Standards Setting Organisation.

The following NOS are offered as guidance to help further underpin IPC practice.

Reference	NOS for Infection Prevention & Control
IPC1.2012	Minimise the risk of spreading infection by cleaning, disinfecting and maintaining environments
IPC2.2012	Perform hand hygiene to prevent the spread of infection
IPC3.2012	Clean, disinfect and remove spillages of blood and other body fluids to minimise the risk of infection
IPC5.2012	Minimise the risk of exposure to blood and body fluids while providing care

IPC6.2012	Use personal protective equipment to prevent the spread of infection
IPC7.2012	Safely dispose of healthcare waste, including sharps, to prevent the spread of infection
IPC8.2012	Minimise the risk of spreading infection when transporting and storing health and care related waste
IPC10.2012	Minimise the risk of spreading infection when transporting clean and used linen
IPC11.2012	Minimise the risk of spreading infection when laundering used linen
IPC12.2012	Minimise the risk of spreading infection when storing and using clean linen
IPC13.2012	Provide guidance, resources and support to enable staff to minimise the risk of spreading infection

Additional suites of NOS (such as Leadership & Management) are also available from the Skills for Health Tools web site.

14. Appendix 4. How the framework was developed

Development of the framework was guided by a ‘short life working group’ (SLWG) representing key stakeholders including clinical practitioners, professional bodies, and IPC experts.

Oversight of the SLWG was provided via the Education, Workforce and Leadership (EWL) Steering Group.

Initial desk research was undertaken to identify key references, resources and significant themes or issues for consideration – further references and resources continued to be identified during the development of the framework. (See Appendix 2. Bibliography).

Initial iterations of the framework were developed based on the findings of the desk research and consultation with the SLWG.

Subsequently, in June 2023, wide consultation of the framework was undertaken through the networks/contacts of SLWG and other identified stakeholders.

Based on analysis of comments received, further amendments and refinements were undertaken.

15. Acknowledgements

This framework was commissioned by the Infection Prevention and Control (IPC) Team at NHS England and development was guided by a Short Life Working Group (SLWG) chaired by Professor Steve Hams and project management was provided by Andrew Lovegrove, Senior Consultant at Skills for Health.

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Steve Hams	Chief Nursing Officer, North Bristol NHS Trust
Matthew Cripps	NHS England, Behavioural Change Lead
Sue Millward	NHS England, Clinical Lead IPC Education
Dave Cunningham	NHS England Clinical Lead IPC Workforce & Leadership
Gill Damant	NHS England Regional AMS Lead
Esther Taborn	NHS England National IPC Improvement Lead
Kirsty Morgan	NHS England Regional IPC Lead
Sally Gosling	NHS England Workforce, Training and Education Dept.
Amanda Robson	NHS England Workforce, Training and Education Dept.
Andy Gardiner	Dept. Health & Social Care (DHSC)
Patricia Kydd	Higher Education Institution: Scotland (Dundee)
Dr Jaci Huws	Higher Education Institution: Wales (Bangor)
Prof Heather Loveday	Higher Education Institution: England (London)
Tracey Cooper	Independent Nurse Consultant- Lecturer in Health Sciences, Bangor University
Dr Manjula Meda	Healthcare Infection Society (HIS)
Karren Staniforth	Consultant Clinical Scientist, IPC Specialist, United Kingdom Health Security Agency (UKHSA)
Ben Stanfield-Davies	Independent Healthcare Sector (Education)
Amanda Miskell	IPC Mental Health/Learning Difficulties
Carrie Godfrey	IPC Shared Professional Decision-Making Council (SPDMC)
Erika Bowker	IPC SPDMC, Primary care
Kerry Holden	Infection Prevention Society (IPS) Education Special Interest Group
Lisa Butcher	IPS President
Neil Wigglesworth	IPC Director East Kent Hospitals NHS Foundation Trust
Chris Piercy	Integrated Care Systems (ICS) representative
Karl McGilligan	Head of Public Health & IPC, West Midlands Ambulance Service, National Ambulance Service IPC Group Vice Chair Ambulance service
Jude Robinson	IPS lead for Developing an Optimal IPC Service (DOIPS), Infection Control Manager

Further detail of how the framework was developed is presented in Appendix 4.

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

This publication can be made available in a number of alternative formats on request.

Healthcare Improvement Scotland | Evidence
Advice, guidance and intelligence

Infection prevention and control standards

For health and adult social care settings

May 2022

NHS SCOTLAND

A47310563

We are committed to advancing equality, promoting diversity and championing human rights. These standards are intended to enhance improvements in health and social care for everyone, regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic status or any other status. Suggested aspects to consider and recommended practice throughout these standards should be interpreted as being inclusive of everyone living in Scotland.

We carried out an equality impact assessment (EQIA) to help us consider if everyone accessing health and social care services will experience the intended benefits of these standards in a fair and equitable way. A copy of the EQIA is available on request.

Healthcare Improvement Scotland is committed to ensuring that our standards are up-to-date, fit for purpose and informed by high-quality evidence and best practice. We consistently assess the validity of our standards, working with partners across health and social care, the third sector and those with lived and living experience. We encourage you to contact the standards and indicators team at his.standardsandindicators@nhs.scot to notify us of any updates that the infection prevention and control standards project team may need to consider.

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www.healthcareimprovementscotland.org

Contents

Introduction

Infection prevention and control (IPC) is critical to keeping people safe when they are receiving health and social care. Effective IPC can help reduce the risk of infection and ensure the safety of people receiving care, staff and visitors. IPC is integral to quality health and social care delivery because anyone is at risk of developing an infection in these settings. Factors that are known to increase this risk include extremes of age (for example being older or very young), the complexity of interventions that are part of a person's care and prolonged or inappropriate use of antimicrobials.[1]

Good IPC practice can help to reduce the prevalence of infections (including healthcare-associated infections - HAIs[2]) that are associated with the delivery of care in hospitals, long-term care facilities (including care homes) and other care settings (such as ambulances, prisons, hospices and independent healthcare facilities).

HAIs can occur as a direct or indirect result of healthcare and treatment including the environment or setting where care is delivered.[3] Some HAIs are acquired through medical or surgical treatment (for example catheter-associated urinary tract infections) or from exposure to a pathogen within a health or social care environment (for example spread of an influenza virus within a hospital ward or care home). Common examples of HAIs include respiratory, urinary tract and gastric infections.

HAIs range from minor infections that require minimal intervention to more significant infections which cause illness and can have serious emotional and medical consequences for people. These consequences have financial implications for the health and social care system in Scotland.[1, 4]

All health and social care staff have an important role to play in preventing the spread of infection by recognising that IPC is everybody's responsibility. Though, not all HAIs are preventable because of factors including a person's pre-existing conditions or the complexity of the treatment they are receiving.

Infection prevention and control standards

IPC standards are a key component in the drive to reduce the risk of infections in health and social care in Scotland. Standards support:

- organisations to quality assure their IPC practice and approaches, and
- the IPC principles set out in the National Infection Prevention and Control Manual.[2]

A single set of standards has been developed for use across health and adult social care. This will support the *Once for Scotland* approach and further integration of health and social care.

Standards underpin Healthcare Improvement Scotland's programme of inspection of the safety and cleanliness in acute and community hospitals.

The Care Inspectorate inspects services using self evaluation frameworks (which include IPC practice) that are informed by standards and the National Infection Prevention and Control Manual.[2, 5-7]

These standards are informed by current evidence, best practice and stakeholder recommendations and supersede Healthcare Improvement Scotland's HAI standards published in 2015. More information about the standards development process can be found at Appendix 1.

Policy context

Since March 2020, services across health and social care have responded to the significant challenges of the COVID-19 pandemic. The pandemic has reinforced the importance of a strategic organisational approach to IPC to ensure that people receiving health and social care, their representatives, staff and visitors experience safe, effective and person-centred care, including in the environment where care is delivered.

The health and care built environment where health and care is delivered can play a significant role in reducing the transmission of infection. In June 2021, NHS Scotland Assure was launched by NHS National Services Scotland. This new national body aims to strengthen IPC in the built environment through oversight of the design, construction and maintenance of major infrastructure developments within the NHS. NHS Scotland Assure will play a pivotal policy and guidance role in relation to incidents and outbreaks across NHSScotland.

In addition, the Care Inspectorate has developed guidance that sets out design, planning and construction considerations for new or converted care homes for adults.These standards align with and support the work of NHS Scotland Assure and the Care Inspectorate.[8]

IPC standards have been developed to complement the National Infection Prevention and Control Manual and Infection Prevention and Control Manual for older people and adult care homes.[2] **Please note: one reference to the National Infection Prevention and Control Manual (which includes the Infection Prevention and Control Manual for older people and adult care homes) has been cited in these standards. Organisations should apply the context specific elements of the manual to their area of practice.**

In addition to local guidance and standard operating procedures, the standards should be read alongside other relevant legislation, policies and guidance. In particular:

- National Infection Prevention and Control Manual[2]
- HAI Compendium: Guidance and resources[9]
- Health and Social Care Standards: my support, my life[10]
- National Health and Wellbeing Outcomes Framework[11]
- Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board: final report[12]
- Recover, Restore, Renew. Chief Medical Officer for Scotland Annual Report[13]
- Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011[14]
- Social Care and Social Work Improvement Scotland (Requirements for Care Services) Regulations 2011[15]
- Vale of Leven Hospital Inquiry[16]
- UK 5-year action plan for antimicrobial resistance 2019 to 2024[17]
- Patient Rights (Scotland) Act 2011[18]
- Scotland's public health priorities, and
- other applicable Healthcare Improvement Scotland guidance, including Scottish Intercollegiate Guidelines Network (SIGN) guidelines and Scottish Antimicrobial Prescribing Group (SAPG) guidance and Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland guidance.

IPC standards are intended to complement, not duplicate, existing standards and guidelines. Reference to appropriate and relevant documentation has been made throughout the standards to signpost organisations and staff to further information. These references are not an exhaustive list. Organisations, services and staff should continue to refer to appropriate and applicable professional guidance, policy and best practice appropriate to the setting where care is being delivered.

Scope of the standards

These standards were commissioned by the Chief Nursing Officer Directorate on behalf of the Scottish Government and co-produced with national and local stakeholders. They are based on current evidence and best practice and are considered to be a requisite of safe, high-quality care in all settings. As such, it is the Scottish Government's expectation that they will be adhered to across all health and social care settings including NHSScotland settings, independent healthcare and adult social care including care homes. The Care Inspectorate and Healthcare Improvement Scotland will take these into account during all relevant scrutiny and regulatory activities.

For more information about Healthcare Improvement Scotland's scrutiny work, see reporting on quality and safety of healthcare in Scotland (healthcareimprovementscotland.org) and for information about how Healthcare Improvement Scotland regulates the Independent Healthcare sector see Regulation of independent healthcare (Healthcareimprovementscotland.org). For more information on regulatory framework in social care settings see the Care Inspectorate's quality framework for care homes for adults and quality frameworks.

All other health (including independent healthcare) and adult social care organisations and settings (including adult day care) are encouraged to adopt the standards as good practice.

Where a principle or criterion applies to a specific setting this has been highlighted throughout the document. The standards should be reviewed pragmatically by service providers. Individual criteria will be applied by service providers in different ways in recognition of the breadth of services and support delivered across health and social care in Scotland.

While NHSScotland and older people and adult care home organisations and settings are expected to meet the standards, the detailed implementation of this document is for local determination.

The standards cover the following areas:

- leadership and governance
- education and training
- communication
- assurance and monitoring systems
- optimising antimicrobial use*
- infection prevention and control policies, procedures and guidance
- clean and safe care equipment
- the built environment, and
- acquisition and provision of equipment.

* including, but not limited to antibiotics.

Using the standards for self evaluation, assurance and improvement

All our standards follow the same format. Each standard includes:

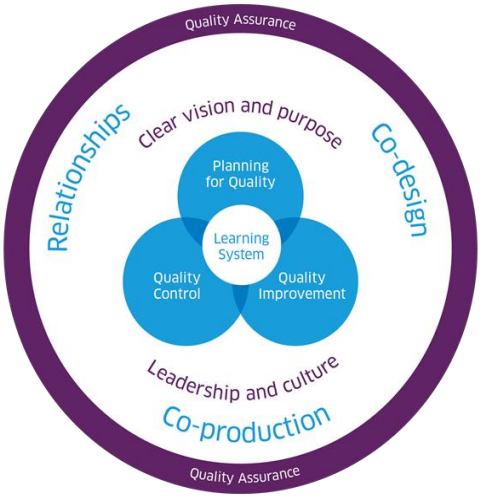
- a statement of the level of performance to be achieved
- a rationale providing reasons why the standard is considered important
- a list of criteria describing the required structures, processes and outcomes
- what to expect if you are a person experiencing care
- what is expected if you are a member of staff, and
- what the standards mean for organisations, including examples of evidence of achievement.

These standards have been published to inform organisational internal quality improvement, self evaluation and improvement. Organisations and services, for example NHS boards or older people and adult care home providers are responsible for implementing and monitoring compliance against these standards.

Healthcare Improvement Scotland and the Care Inspectorate may use these standards in a range of assurance and inspection activities. They may be used to assess registration applications, where appropriate, and review the quality of health and social care services.

Healthcare Improvement Scotland Quality Management System

The Healthcare Improvement Scotland Quality Management System (QMS) describes the key components and functions of a common framework that can be applied across different settings to support delivery of high-quality care.



Within a QMS, services take a holistic and evidence-informed approach to plan for quality including assessing what needs to change; apply quality improvement approaches to measure that changes have delivered improvement; and establish quality control mechanisms to ensure that changes are embedded and sustained in the system. A learning system is the way services use knowledge, evidence and evaluation to keep improving, measure how they are meeting their aims, and to learn and share with others.

Health and social care services are facing considerable financial and workforce challenges. These pressures could lead to a reduction in the quality of care being delivered. This in turn increases the need for a consistent approach to the management of quality, built on evidence and best practice. More information about this framework is available on the Healthcare Improvement Scotland website.

Terminology

Wherever possible, we have incorporated generic terminology, written in plain English, that can be applied across all health and social care settings:

- ‘healthcare organisations’ refers to all services delivered by NHS boards and independent healthcare providers
- ‘social care organisations’ specifically refers to providers of adult social care, and
- ‘staff’ refers to health and social care staff, students and volunteers.

Some sections of the standards document are technical, for example they outline specific aspects of care. Where technical terms have been included, for example *invasive device* or *antimicrobial stewardship*, these are defined in the glossary in Appendix 3. Hyperlinks to these definitions have been included throughout the document.

Summary of standards

Standard 1: **Leadership and governance**

The organisation demonstrates effective leadership and governance in IPC.

Standard 2: **Education and training**

Staff are supported to undertake IPC education and training, appropriate to their role, responsibilities and workplace setting, to enable them to minimise infection risks in care settings.

Standard 3: **Communication**

The organisation implements robust communication systems and processes to enable person-centred decision making, continuity of care and effective IPC throughout a person's care experience.

Standard 4: **Assurance and monitoring systems**

The organisation uses robust assurance and monitoring systems to ensure there is a co-ordinated and rapid response to reduce the risk of infections and to drive continuous quality improvement in IPC.

Standard 5: **Optimising antimicrobial use**

The organisation demonstrates reliable systems and processes for antimicrobial stewardship to support optimal antimicrobial use.

Standard 6: **Infection prevention and control policies, procedures and guidance**

The organisation uses evidence-based IPC policies, procedures and guidance.

Standard 7: **Clean and safe care equipment**

The organisation ensures that care equipment is cleaned, maintained and safe for use.

Standard 8: **The built environment**

The organisation ensures that infection risks associated with the health and care built environment are minimised.

Standard 9: **Acquisition and provision of equipment**

The organisation demonstrates the acquisition and provision of equipment that is safe for use in health and social care settings.

Standard 1: Leadership and governance

Standard statement
The organisation demonstrates effective leadership and governance in IPC.

Rationale

Leadership in IPC underpins an organisation's commitment, approach and mechanisms to reduce the risk of infection.[19]

Effective governance provides assurances that organisations have robust IPC measures in place. These measures include risk and adverse event management, escalation procedures and data monitoring and response.[12, 20] The organisation's governance arrangements adhere to, and support implementation of relevant statutory Duty of Candour regulations and responsibilities.[21]

A transparent IPC assurance and accountability framework, with clearly defined roles and responsibilities, is required to support strategic and operational decision making. It is important that staff are aware of their organisation's accountability and reporting structures, including which teams to contact for IPC leadership and expertise.

All staff working in health and social care have a responsibility to apply IPC measures. Effective IPC requires a strategic and co-ordinated approach and consistent action at all levels within an organisation. This is underpinned by high-quality role-specific education, training and support.

Assessment, monitoring and assurance of IPC is fundamental to reducing the risk of infection. Organisational commitment to a culture of quality improvement encourages teams to continuously assess their performance, identify areas for improvement and measure the results to achieve and maintain improvements.[22]

Criteria

1.1 Appropriate and responsive governance and accountability mechanisms are in place.

a **Healthcare organisations** have:

- an executive lead with accountability for IPC and responsibility for overseeing and providing assurances on IPC within their organisation
- an IPC manager with responsibility for leading local IPC teams and reporting IPC issues to the executive lead,[23] and
- local IPC and health protection teams (HPT) with the necessary expertise, leadership skills and resources to support their organisation.

b **Social care organisations** have:

- an appropriate management structure and/or system that sets out clear accountability and responsibility for IPC within the organisation
- an appropriately trained lead person to co-ordinate IPC within the organisation, and
- access to appropriate health and social care teams for IPC expertise, advice and support.

1.2 The organisation has an IPC assurance and accountability framework that specifies, as a minimum:

- defined roles and responsibilities
- quality monitoring and assurance arrangements
- reporting and escalation structures, and
- an IPC risk management strategy with clear lines of responsibility.

1.3 The organisation has clear systems in place to ensure that it takes a strategic and co-ordinated approach to IPC. This includes, as a minimum:

- compliance with IPC policies, procedures, guidance and standards[9] with appropriate follow-up action where there is non-compliance
- access to specialist IPC advice, guidance and support
- implementation of staff induction, role-specific education and training programmes
- ongoing and consistent data assurance and monitoring with improvement plans
- prompt identification of people who are colonised or are at risk of developing an infection
- accountability and responsibility arrangements for reporting adverse events, in line with the national adverse events framework and national reporting requirements,[24, 25] and
- adherence to Duty of Candour regulations and responsibilities.[21]

1.4 There are well-defined and locally agreed processes to enable:

- an effective multidisciplinary and multiagency approach to IPC
- cross-organisational support including access to specialist advice when indicated
- compliance with mandatory HAI reporting,[9] where required
- staff to implement, monitor and improve their compliance with IPC policies, procedures, guidance and standards[9]
- accurate and prompt communications and information exchange following consent (where applicable) from the individual and within, and between, services and settings, and
- communication and engagement with people that use services, staff, visitors and the public on matters related to IPC, including reducing specific risks.

1.5 The organisation demonstrates effective management of outbreaks, including:

- preparedness
- assessment of a person's care and safety
- reporting, and
- improvement plans.

1.6 The organisation communicates and engages with people/the public on matters related to IPC, including information on reducing specific infection-related risks.

1.7 The organisation communicates and uses information, data and learning from a variety of internal and external sources to support good practice and continuous quality improvement in IPC.

1.8 The organisation ensures that there is continuous engagement with staff, visitors and people that use services and their representatives to capture feedback and inform service improvements.

What does the standard mean for the person receiving care or visiting a health or social care setting?
People are confident that: • the organisation has effective leadership and governance, and is committed to continuously improving the quality of its IPC • staff work together to provide safe, effective and person-centred care • information about them and their care is shared with consent and in line with national guidance, as appropriate • the organisation communicates clearly and openly with them and their representatives, where appropriate • their feedback is used to improve services • the organisation has a system in place for learning, including where there has been an event that resulted in, or could have resulted in, harm.
What does the standard mean for staff?
Staff, in line with role, responsibilities and workplace setting: • are fully informed about their organisation's assurance and accountability framework • understand IPC policies, procedures, guidance and standards, and their role and responsibilities in IPC, including outbreak management • are supported to undertake learning and reflection from adverse events and outbreaks, and • have clear guidance on how to: o identify people at risk of infection o identify IPC-related risks, including those associated with the health and care built environment o report and escalate adverse events o adhere to organisational Duty of Candour regulations and responsibilities, and o share their feedback to inform service improvements.
What does the standard mean for organisations?
Organisations, in line with workplace setting: • demonstrate their commitment to IPC through effective leadership and governance • have a transparent and accessible IPC assurance and accountability framework • have clear systems in place to ensure that there is a co-ordinated and strategic approach to IPC • comply with Duty of Candour regulations and responsibilities • monitor data and use learning to support continuous quality improvement, and • take a multidisciplinary and multiagency approach to IPC.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- An organisational assurance and accountability framework describing lines of accountability, roles and responsibilities, and reporting and escalation structures.
- Implementation of an IPC risk management strategy with records demonstrating that risk registers are regularly reviewed and updated.
- Improvement plans, underpinned by quality improvement methodology, that demonstrate implementation of the IPC standards.
- Accessible documentation demonstrating evidence of staff and team performance, for example audit and improvement activity.
- Organisational responses to assurance visits with appropriate action taken, where required, which are accessible.
- Improvement work including improvement plans, data collection and review of data (for example feedback from people receiving care) and national benchmarking.
- Completion of Reporting of Incidents, Diseases and Dangerous Occurrences. Regulations (RIDDOR)[26] form, and notification to the Health and Safety Executive.
- Duty of Candour monitoring including evidence of organisational openness, honesty and supportiveness.
- Feedback from people receiving care and their representatives, and evidence of learning from complaints or feedback.

Practical examples: healthcare organisations

- Executive board reports or minutes.
- Infection control committee and internal clinical governance group reports Healthcare organisation use of risk assessment tools and risk registers.
- Quarterly reports on current and emerging issues being used for quality improvement.
- Outbreak management plans, including details of the incident management team, as instigated by the healthcare organisation.
- IPC key performance indicators.
- Healthcare Associated Infection Report Template (HAIRT).[2]

Practical examples: social care organisations

- Board reports or minutes.
- Minutes of staff meetings.
- Clinical and care governance group reports.
- Internal risk assessments.
- Quality assurance, risk and audit programme with improvement plans.
- Care Inspectorate notifications.[24]
- Communication and engagement with a person's representatives, for example a family member, in line with relevant governance arrangements and with consent.

Standard 2: Education and training

Standard statement

Staff are supported to undertake IPC education and training, appropriate to role, responsibilities and workplace setting, to enable them to minimise infection risks in care settings.

Rationale

All staff play a vital role in minimising the risk and spread of infection in health and social care settings. Accessible IPC education and training, as part of an organisation's training and development plan, enables staff to develop and maintain their knowledge, skills and competencies in line with national guidance.[2, 27-33] Access to role-specific resources is available to staff, as required. This supports staff to further develop in areas essential to their role, responsibilities and workplace setting.

Embedding positive working and learning environments across an organisation enables staff to continuously develop and improve their IPC knowledge, skills and confidence as part of their role. This includes evaluation of the effectiveness of the education and training programme and assessment of staff knowledge and competence, including how knowledge and skills are embedded into everyday practice.[34]

Empowering staff to act autonomously, confidently and skillfully within their professional and organisational codes, with opportunities to feed back on their experiences, underpins high-quality and person-centred health and social care.

Criteria

2.1 The organisation implements a comprehensive and accessible IPC education and training programme, in line with role, responsibilities and workplace setting, which includes:

- any local or national mandatory staff induction and training
- information on current IPC policies, procedures and guidance, including the National Infection Prevention and Control Manual[2]
- assessment of staff education and training requirements
- tailored education and training, for example infection-specific management and insertion and maintenance of invasive devices, where required
- allocation of dedicated time and resources for staff to access and undertake relevant IPC education and training, including refresher training
- learning and sharing of IPC best practice across settings and sectors
- application of quality improvement methodology for IPC, and
- evaluation of the provision, uptake and effectiveness of IPC training, including providing staff with opportunities to feedback on the education programme and training provided.

2.2 The organisation's training plan includes IPC education and training, in line with role, responsibility and workplace setting, to ensure that staff:

- are supported to maintain role-appropriate levels of skill, knowledge and competency in IPC
- have access to ongoing support, and
- have access to continuous professional development in IPC.

2.3 Staff, in line with role, responsibility and workplace setting have access to clear guidance and support:

- on their role and responsibilities in relation to IPC
- to identify and address their own ongoing continuous professional development, education and training needs
- on what to do when they experience barriers to implementing IPC measures
- on career frameworks and development opportunities in IPC, where relevant, and
- on infection-specific management, including outbreak management.

2.4 As part of educational monitoring across the organisation, organisations use local and national IPC-related data and information to:

- evaluate staff knowledge, skills, competency and confidence in IPC
- identify areas for improvement in relation to staff IPC practice, and
- improve staff IPC practice through further provision of education and training.

What does the standard mean for people receiving care or visiting a health or social care setting?

People are confident that:

- staff are appropriately educated, trained and competent in IPC, in line with their role, responsibilities and workplace setting
- staff have a clear understanding of their role and responsibilities in IPC, and
- the care and support they receive is informed by evidence and best practice.

What does the standard mean for staff?

Staff, in line with role, responsibilities and workplace setting:

- have knowledge and demonstrate skills, competence and confidence in IPC
- use their learning to ensure that they provide safe, effective and person-centred care, and
- can access and undertake relevant training to achieve, maintain and continuously improve their knowledge, skills and competencies including role-specific resources, where appropriate.

What does the standard mean for organisations?

Organisations, in line with workplace setting:

- demonstrate a continuous quality improvement approach and learning culture to ensure that the knowledge and competency of staff in IPC, in line with role, responsibilities and workplace setting, is developed and maintained, and

- ensure that staff are supported to access and undertake training and education appropriate to their role, responsibilities and workplace setting.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- Training and development plans and records, for example induction, e-learning, completion of competencies, safety briefs, conference or study-day attendance.[35, 36]
- Competency frameworks, appropriate to role and workplace setting.
- Where appropriate to role, responsibilities and workplace setting, staff access and participate in quality improvement methodology education and training, for example modules provided by NHS Education for Scotland.[37]
- Where appropriate to role and workplace setting, staff access national learning platforms and systems for health and social care staff, for example Turas Learn, LearnPro, Scottish Social Services Council (SSSC) Learning Zone.[36, 38-40]
- Availability of IPC-related information, which includes appropriate guidance, standards, manuals and audit tools and how they link to IPC practice.
- Where appropriate to role, demonstration of staff having access to regular supervision, appraisal and support to identify training needs.
- Dedicated learning time and support for staff included in the organisation's IPC education and training programme.
- IPC education and training that is easy to access and delivered in formats appropriate for staff learning styles and workplace setting.
- Use of adverse event reports to support training and education programmes.
- Evaluation of training needs and training programmes.
- Staff feedback being used to improve IPC education and training.

Practical examples: healthcare organisations

- Participation records in the organisation's IPC education and training programme, for example Scottish Ambulance Service Learning in Practice.

Practical examples: social care organisations

- Participation records for the NHS Education for Scotland Care Home Train the Trainer Programme.[41]
- Uptake of the Scottish Infection Prevention and Control Education Pathway.[30]
- Uptake of relevant SSSC learning resources.[38]

Standard 3: Communication

Standard statement

The organisation implements robust communication systems and processes to enable person-centred decision making, continuity of care and effective IPC throughout a person's care experience.

Rationale

Communication is fundamental to safe, effective and person-centred IPC. People receiving health and social care can be vulnerable to contracting infections and some present an infection risk to others, including staff and visitors. A person's care experience can involve multiple services and settings, which can increase infection risks. Continuity of care is underpinned by robust and reliable communication within, and between, health and social care organisations and providers.[16]

High-quality, accessible and timely IPC-related information underpins effective communication with the person receiving care, and their representatives where appropriate, and:

- enables informed choice
- supports person-centred decision making, and
- encourages people and their representatives to have meaningful discussions about their care, which can improve their care experience and personal outcomes.[42]

Criteria

3.1 All IPC-related communications with people, and their representatives where appropriate, are documented in the person's care record and used to inform their plan of care.

3.2 Staff are provided with clear, timely and responsive information and guidance on IPC to enable them to provide safe and effective care.

3.3 Staff, IPC teams and HPTs have effective and appropriate communication:

- when information and specialist advice for people receiving care is required
- when there is a known or suspected outbreak or incident, and
- throughout the outbreak management process.

3.4 Staff communicate and work collaboratively within, and between, health and social care settings. This is in line with relevant governance arrangements, including consent to share information, where applicable, to:

- support continuity of care, and
- minimise harm associated with infection, including when people are transferred between services.

3.5 People who are at risk of developing an infection, and their representatives where appropriate, are provided with high-quality and timely communication and information in a format that is right for them. This supports people to:

- understand the impact, consequences and risks of having an infection
- implement IPC precautions, where appropriate
- understand what actions they can take to minimise the risk of developing an infection
- understand what action the organisation is taking to minimise infection risks, and
- make informed decisions and ask questions about their care.

3.6 People that have become colonised or have developed an infection, and their representatives where appropriate, are:

- promptly notified of their infection
- provided with information in a language and format that is right for them
- signposted to support on IPC-related care and procedures
- informed about any impact their infection may have on their care
- given accessible and relevant information about minimising the infection risk to others, and
- provided with opportunities to ask questions about their care.

3.7 Where there is an IPC-related adverse event, the person, and their representatives where appropriate, are informed about this in line with organisational Duty of Candour[21] and professional codes of conduct.

3.8 There is continuous quality improvement of all IPC-related communication systems and processes. This includes:

- monitoring the effectiveness of communications, and
- evaluating and using feedback from staff, visitors and people receiving care and their representatives.

What does the standard mean for people receiving care or visiting a health or social care setting?
People: • receive information in a language and format that is right for them • are listened to and involved in decisions, and • are confident that the organisation or service that provides their care has processes in place to ensure that people have the right information at the right time.
What does the standard mean for staff?
Staff, in line with role, responsibilities and workplace setting: • ensure that people receive effective communication to help minimise infection risks • regularly communicate within, and between, relevant teams for expert information and advice

- effectively communicate with people receiving care, and their representatives where appropriate, regarding the mitigation of risks to the person and other people in the health and social care setting, and
- are competent in communicating risks within, and between, health and social care settings, to enable continuity of care, and to mitigate risks to other people in the health and social care setting.

What does the standard mean for organisations?

Organisations, in line with workplace setting, have IPC-related communication systems or processes in place:

- to enable safe, effective and person-centred communications throughout a person's care experience
- to ensure the availability of appropriate and easily accessible information in a range of languages and formats
- to ensure that communication of infection-related information and guidance is clear and timely, and
- that support collaborative working within, and between, health and social care settings.

Organisations evaluate and respond to feedback on IPC-related communications taking appropriate actions to learn and improve communication.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- Availability of information provided in alternative formats and languages.
- Timely communications and collaboration between health and social care settings detailing any infections, for example handovers, discharge summaries and admission letters.
- Mechanisms for communication regarding IPC issues within, and between, health and social care settings, for example electronic staff communication systems.
- Examples of person-centred communication with a person's representatives where a person has reduced capacity or is unable to make their own decisions.[43]
- Availability and use of information leaflets appropriate to individual need.[44]
- Duty of Candour monitoring.[21]
- Feedback from staff, visitors and people receiving care and their representatives, and evidence of learning from complaints or feedback.

Practical examples: healthcare organisations

- Enquiries and responses to and from the IPC team.
- Examples of completed care records/plans (anonymised) for communication between people receiving care and their representatives and healthcare staff about HAIs throughout a hospital episode. Examples include a person's methicillin-resistant *Staphylococcus aureus* (MRSA) status and cause of death.

Practical examples: social care organisations

- Enquiries and responses to, and from, the HPT.
- Minutes of relevant meetings.
- Care Inspectorate notifications.[24]
- Safety huddle and outbreak reporting tools.

- Setting-specific information, for example relative information leaflets and information provided through approved online platforms.
- Implementation of the Care Inspectorate's quality frameworks, for example 'A quality framework for adults'.[45]

Standard 4: Assurance and monitoring systems

Standard statement

The organisation uses robust assurance and monitoring systems to ensure there is a co-ordinated and rapid response to reduce the risk of infections and to drive continuous quality improvement in IPC.

Rationale

Robust assurance and monitoring systems support organisations to reduce infection risks and improve people's outcomes. The most effective systems enable organisations to:

- systematically collect, monitor, analyse and interpret data on an ongoing basis
- seek expertise that is proportionate to the complexity and seriousness of the incident, and
- act on the findings appropriately.

It is important that organisations understand the risk factors associated with the different groups of people they care for and support to ensure that the care and support is responsive to an individual's needs.

Monitoring results drives continuous quality improvement and reduces infection risks by enabling organisations to:

- inform, support and improve practice for clinical, care and support service staff
- analyse the effectiveness of responses
- monitor trends and identify areas for targeted improvement
- review the impact that responses and interventions have on reducing infections
- share learning across the organisation and with external partners, and
- report and communicate infection rates to people/the public.

Criteria

4.1 The organisation has robust assurance and monitoring systems and processes in place, with appropriate triggers:

- to carry out mandatory national and local surveillance of infections and alert organisms, in line with national guidance[2, 9]
- that enable access to multidisciplinary support from professionals and teams with specialist IPC knowledge and expertise, where required
- that enable prompt detection, response and ongoing monitoring of any variance from normal local infection limits, including incidents and outbreaks, in line with national guidance[2, 9]
- to respond to all infection-related incidents and outbreaks, in line with the National Infection Prevention and Control Manual,[2] and
- to help identify and plan areas for targeted learning and improvement.

4.2 The organisation reviews and evaluates assurance and monitoring activity to ensure that:

- information from assurance and monitoring systems is used to help reduce infection risks
- appropriate action is taken, where required, to further reduce infection risks, and
- learning can be shared across settings and sectors.

4.3 The organisation's assurance and monitoring system enables information and interpreted data to be communicated, in an accessible format, to:

- relevant health and social care teams, and
- people in receipt of care, and their representatives and visitors, as appropriate.

4.4 Staff that use assurance and monitoring systems:

- have their training needs assessed in line with career and development frameworks appropriate to their role, responsibilities and workplace setting, and
- undertake relevant and up-to-date training on the organisations system.

4.5 **Healthcare organisations** report performance against local and national measures:

- through internal reporting structures
- to external partners, for example ARHAI Scotland, and
- publicly at board meetings.

4.6 **Healthcare organisations** review and report assurance and monitoring system data, including new, emerging and re-emerging infection-related risks, in line with the National Infection Prevention and Control Manual.[2] This information is shared with external partners.

What does the standard mean for people receiving care or visiting a health or social care setting?
People: • can expect to be cared for in an environment where staff, teams and organisations work together to monitor, minimise and manage infection risks, and • can be confident that services are safe and effective.
What does the standard mean for staff?
Staff, in line with role, responsibilities and workplace setting: • understand how they support monitoring, reporting and responding to infection risks in line with the organisation's assurance and accountability framework as described in standard 1 – leadership and governance • participate in, and implement learning from, relevant education and training programmes as described in standard 2 – education and training • are empowered to report and escalate issues within the multiagency team • work collaboratively with multidisciplinary and multiagency teams to ensure that infection-related issues are understood and responded to as necessary to reduce infection-related risk

- know how to seek specialist support from relevant professionals and teams, where required, and
- use infection and IPC-related data and intelligence to drive improvements in care and support.

What does the standard mean for organisations?

Organisations, in line with workplace setting, can demonstrate that:

- assurance and monitoring systems are in place to support IPC practice and ensure that infection-related incidents are detected and responded to, and
- infection and IPC-related data are reviewed to ensure that assurance and monitoring activity is effective in reducing infection risks.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare organisations and social care organisations

- Local and national reporting and escalation of infection surveillance, incidents and outbreaks.
- Access and uptake of quality improvement training for staff, where appropriate, in relation to assurance and monitoring systems.
- Audit and improvement plans.
- Staff understanding of organisational monitoring, for example local standard operating procedures and guidance documents, with detail on how they would escalate.
- Responses to trigger alerts with improvement plans.
- Availability of communications on assurance and monitoring information in staff and public areas, for example audit result charts and graphs.

Practical examples: healthcare organisations

- Completed Healthcare Infection Incident Assessment Tool (HIIAT) assessments, where required.[2]
- Minutes of meetings from internal governance groups, for example problem assessment groups, incident management teams, ‘hot debriefs’ and infection control and clinical governance committees.
- Submission of data for national audit and surveillance programmes.
- Incident Management Team meeting minutes with improvement plans, where required.

Practical examples: social care organisations

- Reporting to public health departments on infection-related incidents and notifiable infections.
- Minutes of board meetings and internal governance groups, for example clinical and care governance.
- Care Inspectorate notifications.[24]

Standard 5: Optimising antimicrobial use

Standard statement

The organisation demonstrates reliable systems and processes for antimicrobial stewardship to support optimal antimicrobial use.

Rationale

Antimicrobial resistance is a significant threat to public health.[46] Overuse and misuse of antimicrobials (including antibiotics) drives the development of drug resistant pathogens that can adapt and find ways to survive the effects of antimicrobials.[47, 48] A key element of optimising antimicrobial use is that people receive the most appropriate antibiotic (type, dose, route and duration) promptly for their infection, according to local and national policy and guidance. An organisational approach to optimising antimicrobial use, in the form of a co-ordinated antimicrobial stewardship programme, ensures that antimicrobial use is safe, clinically effective and person-centred.

Criteria

5.1 All organisations can access appropriate antimicrobial expertise.

a **Healthcare organisations** have a core multiprofessional Antimicrobial Management Team, with defined roles and responsibilities, for the oversight and co-ordination of all aspects of antimicrobial use within the NHS board.

b **Social care organisations** access antimicrobial expertise through the local NHS board to ensure that there is optimal antimicrobial use for people receiving care.

5.2 All organisations support optimal antimicrobial use.

a **Healthcare organisations** implement and evaluate a planned programme of education for optimising antimicrobial use.[49] The programme is provided to all staff involved in the prescribing, supply and administering of antimicrobials.

b **Social care organisations** support optimal antimicrobial use through**:**

- promoting awareness to all staff involved in prescribing, supplying and administering antimicrobials, and
- enabling all staff involved in prescribing, supplying and administering antimicrobials to access relevant education and training.

5.3 **Healthcare organisations** support optimal use of antimicrobials by ensuring that:

- local antimicrobial policies are produced and updated at least every three years, or when indicated, in line with current national policy, guidance and best practice
- local antimicrobial policies and guidance are accessible to all health and social care staff, and
- staff who prescribe, supply and administer antimicrobials are alerted to any changes in antimicrobial practice policy and guidance.

5.4 **Healthcare organisations**, through the Antimicrobial Management Team, maintain an annual programme for antimicrobial stewardship.[50] This programme includes:

- monitoring data, including all adverse events relating to antimicrobial use
- providing feedback on prescribing practice to clinical teams
- targeted quality improvement interventions to address poor clinical practice in the use of antimicrobials,[50, 51] and
- reporting findings, including risk assessments, and improvement plans where appropriate, through internal governance structures.

5.5 To ensure that the **healthcare organisation** optimises its antimicrobial use through a quality improvement approach, the Antimicrobial Management Team:

- works with the multidisciplinary team to support and promote antimicrobial stewardship across health and social care
- participates in the implementation of an antimicrobial stewardship programme of education for optimising antimicrobial use
- reviews antimicrobial prescribing and resistance data in line with the annual programme for local surveillance of antimicrobial use[50, 52]
- feeds back the main findings of the review to clinical and management teams, and
- responds to data that indicate poor antimicrobial stewardship with targeted improvement interventions.[53]

What does the standard mean for people receiving care or visiting a health or social care setting?
People are confident that: • they will receive the most appropriate antibiotic (type, dose, route and duration) promptly for their infection, according to local and national policy and guidance • they will be involved in discussions regarding the reason for antimicrobial treatment, the intended duration and any potential adverse reactions • their care plan is updated with all information relating to their antimicrobial treatment, and • staff, in line with role, responsibilities and workplace setting, are appropriately trained and demonstrate knowledge of local and national antimicrobial prescribing policies, procedures and guidance.
What does the standard mean for staff?
Staff, in line with role, responsibilities and workplace setting: • are aware of the importance of their role in optimising antimicrobial use for the benefit of people receiving care and the wider public, and can demonstrate this in practice • are aware of the risks associated with poor prescribing and support colleagues where poor practice is identified • participate in education and training on appropriate antibiotic use as part of their continuing professional development, and • can demonstrate knowledge, skills and competences on rationales for antibiotic use.

Staff that prescribe antimicrobials:

- can demonstrate their competencies in relation to safe and effective antimicrobial prescribing for the treatment and prophylaxis of infection
- are enabled to access local antimicrobial policy and guidance, and
- engage in interventions to optimise antimicrobial prescribing.

What does the standard mean for organisations?

Organisations, in line with workplace setting:

- recognise the risks of antimicrobial resistance from poor antimicrobial use
- are assured that they have a programme in place for antimicrobial stewardship, including evaluation of the delivery of the annual work plan, and
- are assured that systems are in place to detect and respond to data on poor prescribing and administering practices.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- Availability of antimicrobial guidance, for example signposting to the Antimicrobial Companion[54] and Scottish Antimicrobial Prescribing Group guidance.
- Improvement plans to address areas for quality improvement and evidence of progress against improvement plans.
- Support for staff to access education and training on optimal antimicrobial use.
- Multidisciplinary working to support and promote antimicrobial stewardship.
- Processes in place to access advice from local experts on the use of antimicrobials.
- Audits on appropriate antimicrobial prescribing in line with current guidance and best practice with improvement plans.

Practical examples: healthcare organisations

- Local antimicrobial policies that are produced and updated at least every three years.
- Regular audit and surveillance, including improvement plans, of antimicrobial use in line with Scottish Antimicrobial Prescribing Group policy and guidance.
- Feedback from the Antimicrobial Management Team provided to all teams involved in the prescribing, supply and administering of antimicrobials.
- Antimicrobial stewardship reporting through internal governance structures.
- Availability of organism- and body-system-specific treatment decision making aids, for example urinary tract infection, respiratory tract infection and MRSA.
- Prescribing and resistance data have been used to inform continuous quality improvement.
- Information exchange with multidisciplinary teams, for example through email, electronic portals and regular reporting of antimicrobial data.
- Membership, terms of reference, minutes and annual programme/plan of the Antimicrobial Management Team.
- JRCALC (Joint Royal Colleges Ambulance Liaison Committee) app[55] for Scottish Ambulance Service staff.

Practical examples: social care organisations

- Education and training records.

- Availability of antimicrobial information and guidance, for example signposting to Scottish Antimicrobial Prescribing Group guidance.[48, 56]

Standard 6: Infection prevention and control policies, procedures and guidance

Standard statement

The organisation uses evidence-based IPC policies, procedures and guidance.

Rationale

Implementation of evidence-based and accessible IPC policies, procedures and guidance can help reduce the risk of infection and ensure the safety of people receiving care, staff and visitors. A consistent and evidence-based approach to IPC:

- enables staff to apply effective standard and transmission-based precautions
- can reduce unwarranted variation by reinforcing robust IPC practice, and
- helps to align IPC practice, monitoring, quality assurance and quality improvement.

Criteria

6.1 The organisation ensures that the National Infection Prevention and Control Manual[2] appropriate for the specific care setting is adopted, implemented and accessible to staff.

6.2 The organisation has, and implements, an annual IPC work programme in line with national requirements and the National Infection Prevention and Control Manual.[2, 57]

6.3 The organisation has systems and processes in place to ensure that:

- staff are alerted to any changes in IPC policy, procedures and guidance, including the National Infection Prevention and Control Manual,[2] that may impact practice
- risk assessments, with mitigating actions, are put in place and reviewed when staff are unable to adopt and implement the National Infection Prevention and Control Manual[2]
- audit data and information, including risks, are fed back to staff, leadership teams, the executive team and registered services, as appropriate
- when an audit programme is not undertaken within the agreed timescales the risks are discussed, agreed and recorded through internal governance structures
- an improvement plan with clearly defined responsibilities and evidence of review is developed in response to audit data
- data and themes emerging from audit(s) are used to inform staff education and training and drive improvement in IPC practice
- there is access to appropriate specialist clinical advice for IPC and the diagnosis, treatment and management of infections, and
- learning from instances where staff are unable to adopt and implement the National Infection Prevention Control Manual[2] is shared.

What does the standard mean for people receiving care or visiting a health or social care setting?

People are confident that:

- they receive care in a clean and well-maintained environment without unnecessary exposure to infection, and
- staff that provide their care have knowledge and can demonstrate competencies in IPC practices.

What does the standard mean for staff?

Staff, in line with role, responsibilities and workplace setting:

- are fully informed about where to access up-to-date and relevant IPC policies, procedures and guidance
- can access and implement relevant IPC policies, procedures and guidance, including the National Infection Prevention and Control Manual[2]
- are fully informed about their organisation's IPC work programme, including audit data and information
- can evidence their safe IPC practice
- know how to respond and escalate if they have insufficient resources or support to minimise infection risks, and
- can access specialist IPC advice and support to enable them to effectively implement guidance.

What does the standard mean for organisations?

Organisations, in line with workplace setting, ensure that:

- relevant policies, procedures and guidance are available and accessible for staff in line with role and responsibilities
- the current National Infection Prevention and Control Manual[2] is adopted, implemented and accessible for staff
- an annual IPC work programme is implemented, and
- effective systems are in place to monitor, report and respond to audit data and information.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- IPC education programme and training records.
- Environmental and equipment cleaning schedules.
- Membership, terms of reference and minutes of internal governance groups.
- National Infection Prevention and Control Manual[2] compliance audits and improvement plans.
- Audits with improvement plans.
- Completed improvement plans following an outbreak or adverse event.
- Risk assessments.
- Accessible up-to-date policy information displayed to staff.
- Lessons learned document themes are shared with appropriate improvement plan.

Practical examples: healthcare organisations

- Completed care plans for people with an alert organism.
- Completed rapid event investigations into HAIs, for example *Staphylococcus aureus* bacteraemia.

Practical examples: social care organisations

- Feedback from people receiving care and their representatives is used for service improvement.
- Care Inspectorate inspection reports.

Standard 7: Clean and safe care equipment

Standard statement
The organisation ensures that care equipment is cleaned, maintained and safe for use.

Rationale

Care equipment can be easily contaminated with infectious agents that can transfer during care delivery.[2] The effective cleaning or decontamination of care equipment is essential to minimise the risk of transmission of infectious agents between people.[2, 58, 59]

Organisations must demonstrate ongoing compliance with statutory legislation and implement national guidance to ensure that all care equipment is clean, maintained, free from damage and safe for use.[2, 9, 60, 61]

Please note: the decontamination of reusable invasive equipment, for example surgical instruments and endoscopes, is not within the scope of these standards.

Criteria

7.1 The organisation has, and implements, cleaning and decontamination policies and procedures in line with current:

- statutory legislation,[60] and
- national guidance.[2, 9, 61]

7.2 The organisation has effective cleaning and decontamination systems and processes in place to ensure that:

- all care equipment is clean, maintained and safe for users at the point of use to minimise the risk of cross-infection
- all care equipment is stored, installed, serviced, maintained, repaired, decommissioned and appropriately disposed of in line with the manufacturer's instructions, where relevant
- cleaning and decontamination of care equipment is carried out in line with the manufacturer's instructions and current national guidance, where relevant
- reporting and escalation of any cleanliness and maintenance issues are routinely undertaken, including evidence that issues have been addressed
- there is specialist input and guidance where cleaning or decontamination issues are identified, or existing activity does not meet requirements
- safety notices for care equipment are responded to
- there is accurate record keeping and documentation, where relevant, and
- feedback from people receiving care, staff and visitors is sought on the cleanliness and maintenance of care equipment and acted upon, where appropriate.

7.3 The organisation carries out regular audit to inform risk assessment, with mitigating actions, where any part of the cleaning or decontamination process cannot or has not been followed.

7.4 Where there is an adverse event associated with the cleaning or decontamination of care equipment, the organisation:

- investigates the reason for the adverse event and reports this using the HIIAT tool,[2] where relevant
- reviews processes during and following the adverse event or near miss in line with the national adverse events framework,[25] and
- reports through national reporting mechanisms,[24, 62] where required.

What does the standard mean for people receiving care or visiting a health or social care setting?
People are confident that any equipment used in their care is safe, clean and free from contamination at the point when it is being used.
What does the standard mean for staff?
Staff in line with role, responsibilities and workplace setting: • can articulate their individual role and responsibilities in the cleaning and decontamination of care equipment, including when there is an incident or outbreak • are aware of their organisation's cleaning and decontamination systems and processes relevant to their area of work • report and escalate issues and incidents, and • are committed to implementing learning from cleaning and decontamination-related incidents to support continuous quality improvement.
What does the standard mean for organisations?
Organisations, in line with workplace setting: • are compliant with the relevant regulations, cleaning and decontamination guidance and technical requirements and local policies and procedures • have effective systems and processes in place to assure the provision of clean, maintained and safe reusable care equipment • implement risk assessment mitigating actions, and • communicate and work collaboratively with agencies to share learning.
Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*
Practical examples: healthcare and social care organisations • Compliance with legislation and national guidance. • Records of the adverse event with improvement plans and evidence of learning. • Completed and signed cleaning schedules and records. • Minutes of local governance meetings. • Circulation of safety action notices to appropriate teams. • Maintenance records. • Risk assessments. • Education and training records. • Audits of care equipment with improvement plans. • Records/minutes showing how risk assessments for care equipment are regularly reviewed. • Audit reports of decontamination processes with improvement plans.

Practical examples: healthcare organisations

- Completion of HIIAT tool, where relevant.[2]
- Facilities monitoring tool feedback being used to inform service improvements.
- National reporting to Incident Reporting and Investigation Centre (IRIC).

Practical examples: social care organisations

- Care Inspectorate inspection reports and outcomes/findings.
- Care Inspectorate notifications, where appropriate.[24]
- Audits in line with the safe management of care equipment with improvement plans.

Standard 8: The built environment

Standard statement

The organisation ensures that infection risks associated with the health and care built environment are minimised.

Rationale

The health and care built environment (the environment) where health and care is delivered can play a significant role in the transmission of infection.[63] It is important that infection risks associated with these environments, for example water and ventilation systems, are minimised and managed through a co-ordinated and multidisciplinary approach. Organisational compliance with legislation, regulations and guidance, for example HAI-SCRIBE and Scottish Health Technical Memoranda (SHTM), underpins this approach.[2, 8-10, 61, 64, 65]

High standards of environmental cleanliness, IPC practice and ongoing maintenance of the environment can minimise the risk of the transmission of infection.[2] It is essential that the organisation provides a clean, well-maintained and safe environment.

Criteria

8.1 The organisation has, and fully implements, current policies and procedures to minimise the risk of infection across all areas of the environment in line with:

- statutory legislation and regulations, and
- national guidance and processes.[2, 8, 9, 61, 64, 65]

8.2 There are clear and agreed channels of communication and prompt information exchange across all relevant organisations, teams and settings to enable early assessment of potential and existing IPC risks associated with the environment.

8.3 The organisation ensures that IPC risks associated with construction, renovation, maintenance and repair of the environment are minimised by demonstrating that:

- building, refurbishment and maintenance work follow agreed processes and are planned, appropriately risk assessed, authorised, documented and carried out in ways that minimise infection risks and disruption to staff, people receiving care and visitors[61, 65]
- risks and issues are identified and communicated through appropriate mechanisms at the planning stage of building, refurbishment and maintenance work; a formal risk assessment with mitigation is put in place and acted on appropriately with key staff and teams involved at relevant stages
- there is regular monitoring and audit of maintenance and repair services to ensure that this is carried out in line with an agreed schedule[61]
- there is robust reporting, with follow-up action, including associated documented decision making and derogations,[61] where the environment cannot be accessed for maintenance or repair
- there is robust reporting, escalation, follow-up action, sign off and documentation of any IPC-related issues associated with the environment, and
- records and reports relating to maintenance, repair and refurbishment of the environment are accessible and regularly updated and reviewed.

8.4 The organisation ensures that the environment is safe and clean by demonstrating that:

- environmental cleanliness is in line with national guidance[61, 64]
- there is robust monitoring and audit of cleaning, including an escalation plan, where required
- there is robust decision making and reporting with appropriate follow-up action and escalation where the environment cannot be accessed for cleaning
- records and reports relating to the cleanliness of the environment are accessible and regularly updated and reviewed, and
- there is active engagement with people receiving care, staff and visitors to obtain feedback on the cleanliness of the environment. This includes development of an improvement plan, as appropriate.

8.5 Staff have access to information, specialist guidance and support to minimise infection risks associated with the environment. This ensures that staff are clear on their roles and responsibilities when:

- IPC risks and issues are identified in the environment
- additional cleaning activity is identified as necessary
- there is planned refurbishment or maintenance work in the environment
- there is emergency building or repair work to be undertaken
- known or suspected outbreaks and incidents relating to the environment are identified
- there is an alteration in the function or purpose of an area
- there is a change of use to an area, and
- the area cannot be accessed.

8.6 Learning from incidents, outbreaks and building and maintenance projects is shared throughout the organisation and across sectors to support continuous quality improvement in IPC.

What does the standard mean for people receiving care or visiting a health or social care setting?
People are confident that the environment is clean, maintained and safe.
What does the standard mean for staff?
Staff, in line with their role, responsibilities and workplace setting: • can articulate their individual role and responsibilities in providing a clean, maintained and safe environment • understand the risks associated with the environment and how to mitigate them • are aware of the level of cleaning required for the area that they are working in • are assured that there are effective systems in place to ensure a clean, maintained and safe environment, and • know who to escalate IPC risks and issues to in the event of a known or suspected environment incident or outbreak.

What does the standard mean for organisations?

Organisations, in line with workplace setting:

- are compliant with legislation, guidance and technical requirements associated with the environment
- have effective systems and processes in place to assure the provision of a clean, maintained and safe environment
- have transparent decision making and governance processes in place where derogations are required
- ensure staff are provided with the education and training, in line with role, responsibilities and workplace setting, to manage environment incidents and outbreaks and mitigate associated risks, and
- have quality assurance measures in place, including audits, to ensure compliance with systems and processes to mitigate risk associated with the environment.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- Compliance with legislation and national guidance, including the National Infection Prevention and Control Manual.[2]
- Evidence that learning has been shared within and across organisations.
- Assurance mechanisms and accreditation checks when working with external partners.
- Water safety policy.
- Water outlet monitoring records.
- Infection-related risk assessment, for example Legionella risk assessment.
- Inspection reports and improvement plans.
- IPC audits with improvement plans, for example audits in line with the Safe Management of the Care Environment.[61]
- Feedback from people receiving care and their representatives, and evidence of learning from complaints or feedback.

Practical examples: healthcare organisations

- National facilities monitoring tool.[61]
- Annual validation and verification of ventilation systems.
- IPC audits with improvement plans, for example Scottish Ambulance Service vehicle and station audits.
- Patient feedback, for example, Care Opinion reviews.
- Incident and outbreak data and reports.
- HAI-SCRIBE documentation.[61]
- IPC committee, water safety group, and ventilation and pressure systems management group minutes.
- Ventilation systems management records.
- Compliance with Scottish Capital Investment Manual including completion of NHS Scotland Design Assessment Process, where required.[65]
- Completion of key stage assurance reviews, where required, and improvement plans.
- National Infection Prevention and Control Manual compliance data.[2]

Practical examples: social care organisations

- Compliance with Building Better Care Homes for Adults.[8]
- Records of compliance with National Cleaning Services Specification[64] or equivalent.
- Completed cleaning schedules.
- Development/refurbishment plans.
- Quality assurance records with improvement plans.
- Maintenance logs and reports.
- Care Inspectorate reports and complaint findings.

Standard 9: Acquisition and provision of equipment

Standard statement

The organisation demonstrates the acquisition and provision of equipment that is safe for use in health and social care settings.

Rationale

In this context, equipment that is acquired and provided for use in health and social care settings relates to any equipment that is:

- procured
- donated
- loaned
- manufactured in house, and
- used within a trial or for research purposes.

Infection risks to people receiving care, staff and visitors can be minimised when there is an acquisition process in place to ensure that equipment is safe for its intended use and can be effectively cleaned or decontaminated in line with manufacturer's instructions.[59]

Please note: the scope of this standard does not apply to personal items/equipment that are brought into a health or social care setting for personal use.

Criteria

9.1 The organisation has, and implements, policies and procedures for acquiring equipment in line with current:

- statutory legislation and regulations,[66-68] and
- national guidance.[9, 58, 61, 69]

9.2 There is IPC consideration and multidisciplinary involvement in the acquisition process prior to procurement. This includes the acquisition of new equipment.

9.3 The organisation has systems and processes in place to ensure that:

- all acquired equipment is compatible with national guidance[2, 61]
- all acquired equipment that cannot be effectively cleaned or decontaminated is removed from use, and
- feedback is provided to relevant teams on equipment that cannot be effectively cleaned or decontaminated to support continuous quality improvement.

9.4 All adverse events associated with equipment are:

- reported through the organisations local adverse event system
- reported through national reporting mechanisms, where required,[24, 62] and
- managed in line with the organisation's adverse event policy and the national adverse events framework.[25]

What does the standard mean for people receiving care or visiting a health or social care setting?

People are confident that all equipment used by staff or used in health and care settings meets the required level of safety, quality and performance.

What does the standard mean for staff?

Staff, in line with role, responsibilities and workplace setting:

- demonstrate competency, where appropriate, in applying policies and procedures in relation to the acquisition and provision of equipment
- can describe their involvement in the acquisition process and how it impacts on IPC, where appropriate
- are confident in the safety, quality and performance of all equipment, and
- can describe the process for reporting non-compliant equipment.

What does the standard mean for organisations?

Organisations, in line with workplace setting, have systems and processes in place that demonstrate the effective and efficient acquisition and provision of equipment that is safe for use.

Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

Practical examples: healthcare and social care organisations

- Compliance with statutory legislation, regulations and guidance.
- Assessment of compatibility of all equipment, which impacts on IPC, with existing cleaning or decontamination processes.
- Adverse event reporting, where indicated.
- The implementation of a loan policy.
- The implementation of a procurement policy.

Practical examples: healthcare organisations

- Multidisciplinary involvement in decision making on the acquisition of equipment, where required.
- Procurement policy, procedures and records related to the acquisition of care equipment that impacts IPC.

Practical examples: social care organisations

- A procurement process that demonstrates consideration of IPC and cleaning or decontamination requirements.
- Care Inspectorate notifications, where appropriate.[24]

Appendix 1: Development of IPC standards

The IPC standards have been informed by current evidence and best practice recommendations and developed by group consensus.

Evidence base

A systematic review of the literature was carried out using an explicit search strategy devised by an information scientist in Healthcare Improvement Scotland. Additional searching was done though citation chaining and identified websites, grey literature and stakeholder knowledge. Searches included Scottish Government, Public Health Scotland, NICE, SIGN, NHS Evidence and Department of Health websites. This evidence was also used to inform all relevant impact assessments.

Development activities

A standards development group, chaired by Professor Hazel Borland, Executive Nurse Director, NHS Ayrshire & Arran was convened in April 2021 to consider the evidence and to help identify key themes for standards development.

Membership of the development group is set out in Appendix 2.

To ensure each standard is underpinned with the views and expectations of service staff from across health and social care, independent and third sector representatives and people/the public in relation to IPC, information has been gathered from a number of activities, including:

- a three-week scoping engagement period, and
- six development group meetings between April and August 2021.

Draft IPC standards were published on 12 October 2021. An 8-week consultation period was held to capture stakeholder feedback on the draft standards.

A summary of all feedback received during the consultation process, and details of any changes made to the final standards as a result, can be found on the Healthcare Improvement Scotland website.

Quality assurance

All development group members were responsible for advising on the professional aspects of the standards. Clinical members of the development group were also responsible for advising on clinical aspects of the work. The chair had lead responsibility for providing formal clinical assurance and sign off on the technical and professional validity and acceptability of any reports or recommendations from the group.

All development group members made a declaration of interest at the beginning of the project. They also reviewed and agreed to the development group's terms of reference. More details are available from the Healthcare Improvement Scotland website.

Healthcare Improvement Scotland also reviewed the standards document as a final quality assurance check. This ensures that:

- the standards are developed according to agreed Healthcare Improvement Scotland methodologies
- the standards document addresses the areas to be covered within the agreed scope, and

- any risk of bias in the standards development process as a whole is minimised.

For more information about Healthcare Improvement Scotland's role, direction and priorities, please visit: www.healthcareimprovementscotland.org/

Appendix 2: Membership of the IPC standards development group

Hazel Borland (*Chair*)	Executive Nurse Director/Deputy Chief Executive, NHS Ayrshire & Arran (until April 2022)
Lara Allan	Policy Manager, Chief Nursing Officer's Directorate, Scottish Government
Linda Bagrade	Consultation Microbiologist and Infection Control Doctor, NHS Greater Glasgow and Clyde
Michael Cassells	Principal Architect, Health Facilities Scotland
Alison Cockburn	Lead Antimicrobial Pharmacist, NHS Lothian
Linda Dalrymple	Lead Infection Prevention and Control Nurse, NHS Tayside
Karen Davidson	Podiatrist, NHS Dumfries and Galloway
Lynda Davidson	Health Protection Nurse, NHS Highland
Jackie Dennis	Senior Improvement Advisor, Care Inspectorate
Sandra Devine	Acting Infection Control Manager, NHS Greater Glasgow and Clyde
Jane Douglas	Chief Nurse, Care Inspectorate (until September 2021) Transforming Workforce Lead Nursing, Scottish Care (from October 2021)
Kay Duncan	Senior Charge Nurse, NHS Grampian
Hazel Dunsmuir	Care Home Manager, Abbotsford Care Home
Sofie French	Principal Educator, NHS Education for Scotland
Rhona Gardiner	Head of Service, Cross Reach
Susan Grant	Principal Architect, Health Facilities Scotland
George Grindlay	Public representative
Lindsay Guthrie	Associate Nurse Director Infection Prevention and Control, NHS Lothian
Lynda Hamilton	Specialist Advisor – Infection Prevention and Control, ARHAI Scotland
Sulisti Holmes	Head of Decontamination and IRIC, Health Facilities Scotland
Jonathan Horwood	Infection Control Manager, NHS Forth Valley
Laura Imrie	Lead Consultant, ARHAI Scotland
Jacqueline Jowett	Inspector, Healthcare Improvement Scotland
Ann Kerr	Lead Surveillance Nurse, NHS Greater Glasgow and Clyde
Grace MacDonald	Learning and Development Advisor, Scottish Social Services Council
Vince McCluskey	Lead Infection Prevention and Control Advisor, Scottish Ambulance Service
Donna McConnell	Infection Prevention and Control Nurse Lead, NHS Greater Glasgow and Clyde
Justine McCuaig	Health Protection Nurse, NHS Dumfries and Galloway
Pauline McIntyre	Deputy Director of Care, Erskine
Marie McKerry	Chief Nurse, Care Inspectorate
Alex McMahon	Executive Director of Nursing, Midwifery and Allied Healthcare Professionals, NHS Lothian (until December 2021)
David McNeill	Principal Engineer, NHS National Services Scotland

Fiona Mitchell	Nurse Manager, NHS Grampian
Fiona Mitchelhill	Lead Nurse, Aberdeen City Health and Social Care Partnership
Alison Moore	Senior Health and Safety Advisor, NHS Highland
Jacqui Neil	Lead Nurse, Scottish Care (until August 2021)
Sabine Nolte	Principal Educator, NHS Education for Scotland
Elaine Ross	Professional Nurse Advisor, HAI ARM Policy Unit, Scottish Government
Lesley-Ann Shand	Facility Support Manager, NHS Greater Glasgow and Clyde
Ian Smith	Head of Quality of Care, Healthcare Improvement Scotland
Jacqueline Sneddon	Project Lead, Scottish Antimicrobial Prescribing Group (until October 2021)
Diane Stark	Infection Prevention and Control Nurse Lead/Chair Infection Prevention Society Scotland, NHS Highland
Ian Storrar	Head of Engineering, NHS National Services Scotland
Lynsey Sutherland	Associate Nurse Director, Lanarkshire Health and Social Care Partnership

We would like to thank Helen Buchanan, former Executive Nurse Director, NHS Fife and chair of the IPC standards scoping group, for all of her input and support.

We would also like to thank the following colleagues for their support in finalising the standards:

Karen Jackson	Senior Engineer, Health Facilities Scotland
Frances Kerr	Project Lead, Scottish Antimicrobial Prescribing Group
Abigail Mullings	Clinical Lead, National Community ARHAI Programme, ARHAI Scotland

The standards development group was supported by the following members of Healthcare Improvement Scotland's Standards and Indicators Team:

Rebecca McGuire	Project Officer
Donna O'Rourke	Programme Manager
Christine Stuart	Administrative Officer
Fiona Wardell	Team Lead

Appendix 3: Glossary

adult social care organisations and settings	all organisations and settings that provide any form of personal and practical support for adults who need extra support including care homes, care at home, housing support services (for example sheltered housing services) and support services (for example adult day care).
adverse event	an event that resulted in, or could have resulted in, harm to people or groups of people. An event that could have resulted in harm is often referred to as a near miss.
alert organism(s)	an organism that is identified as being potentially significant for IPC practices. A full list of alert organisms is set out in the National Infection Prevention and Control Manual.[2]
antimicrobial	a term used to describe substances that kill micro-organisms or prevent them from growing. Antibiotics and disinfectants are examples of antimicrobials.
antimicrobial resistance	when pathogens adapt and find ways to survive the effects of an antimicrobial (including antibiotics) they become 'antimicrobial resistant'. The antimicrobial is no longer effective at treating infections.
antimicrobial stewardship	a co-ordinated programme that promotes the appropriate use of antimicrobials (including antibiotics). An organisational antimicrobial stewardship programme can help health and social care staff improve a person's outcomes and minimise harms. Improving the appropriate use antibiotic prescribing can decrease the spread of infections caused by micro-organisms that have become resistant to certain antibiotics.
assurance and monitoring systems	systems that enable organisations to monitor the outcomes of current practice and provide timely feedback to clinicians and care professionals to ensure practice improvement and better outcomes for people receiving care.
care equipment	within these standards the term care equipment refers to single individual use equipment (this can be reused by the same person, for example nebuliser equipment) and reusable non-invasive equipment (this can be reused on more than one person following cleaning or decontamination between each use, for example a commode or bath hoist. This is also referred to as 'communal equipment').
colonised/colonisation	the presence of micro-organisms on a person's body surface (such as the skin, mouth, intestines or airway) that do not cause disease in the person or signs of infection.
health and care built environment	this term covers all aspects of IPC associated with the construction and adaptation of health and care buildings,

	as well as the design and provision of care in these settings.
decontamination	the appropriate cleaning, disinfecting and sterilising of reusable medical devices, care equipment and the environment. Decontamination is essential to lower the number of cross-infections between people and also to prevent HAIs. Processes need to be in place within health and care settings to ensure the environment and equipment, for example a person's room or commode, is decontaminated properly.
derogation	the process of defining and applying a solution that is not fully in line with current guidance but the service can demonstrate the outcome would be of the same or a better standard than if the guidance been fully adhered to.
health protection team (HPT)	a team of healthcare professionals whose role it is to protect the health of the local population and limit the risk of them becoming exposed to infection and environmental dangers. Every NHS board has a HPT.
healthcare associated infection (HAI)	infections associated with the delivery of care in hospitals, long-terms care facilities, care homes and other care settings such as prison facilities. The term HAI covers a wide range of infections that are caused by pathogens such as bacteria, fungi or viruses.
Healthcare Infection Incident Assessment Tool (HIIAT)	used by the IPC team or HPT to assess every healthcare infection incident, that is all outbreaks and incidents including decontamination incidents or near misses in any healthcare setting (the NHS, independent contractors providing NHS Services and private providers of healthcare).
Healthcare Associated Infection System for Controlling Risk in the Built Environment (HAI-SCRIBE)	an online risk management tool that supports organisations to identify infection risks, and collaborate with others to manage or mitigate risks.
Infection Prevention and Control (IPC) team	a multidisciplinary team responsible for preventing, investigating and managing an infection incident or outbreak.
infectious agent(s)	a micro-organism which has the ability to cause disease.
invasive device(s)	a device which penetrates the body, either through a body cavity or through the surface of the body, for example a urinary catheter.
NHS board	NHSScotland consists of 14 regional NHS boards that are responsible for the protection and the improvement of their population's health and for the delivery of frontline healthcare services.
pathogen(s)	an organism that causes disease, for example bacteria, viruses and fungi.
representative(s)	any person an individual experiencing care choses to be involved in their care and support. This includes, but is not limited to, next of kin, a power of attorney,[70, 71] carers, family or an independent advocate.
reusable invasive equipment	equipment that is used once and then decontaminated eg surgical instruments and endoscopes.

social care	within these standards the term social care does not apply to children and young people's services. It refers to all forms of personal and practical care for adults who need extra support. It describes services and other types of help, including care homes and the support provided by unpaid carers. Social care services can be provided by local authorities, health and social care partnerships (HSCP), independent bodies and the voluntary sector to support people to live their lives as fully and as independently as possible.

The majority of the descriptions in this glossary have been taken directly from the National Infection Prevention and Control Manual.[2]

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Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0141 225 6999

www.healthcareimprovementscotland.org

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Outcome competences for practitioners in infection prevention and control

Infection Prevention Society and Competency Steering Group

Emma Burnett, Lead Coordinator, Infection Prevention Society Education and Professional Development Committee, University of Dundee, Scotland. Email: e.burnett@dundee.ac.uk*

**Corresponding author*

1. Foreword

As Chair of the steering group overseeing this work it is my great pleasure on behalf of the four United Kingdom Chief Nursing Officers to commend this document to you. The work, which was funded by the Department of Health, led by the Infection Prevention Society, developed in conjunction with government leads for infection prevention and control, and supported by Skills for Health is a milestone in the evolution of infection prevention and control practice in the UK. This is a real example of what can be achieved through effective collaboration, cooperation and consultation between the professions, stakeholders and practitioners in the field.

Although infection prevention and control has been an established part of the NHS landscape for many years, for a number of those years it has been seen as the domain of a small group of designated specialists and has mainly focused on acute care. More recently, the determination of all four UK governments to address public concerns about healthcare associated infection and to drive improvements in patient safety throughout the health and social care system has placed infection prevention and control at the very top of the health and social care agenda and radically changed the expectations and requirements of practitioners working in this important area of practice.

Today's infection prevention and control practitioners can come from a range of professional and occupational backgrounds and require a much broader range of competences than ever before. They know that a robust knowledge of infection prevention and control is not enough, they need to be looking ahead to future threats; developing the evidence base and working across the whole health and care system. They also need high-level leadership and team working skills if they are to effect strategic change at a national organisation level, and the interpersonal skills to use improvement science-based methods to sustain behavioural change in everyone involved in the care of patients and clients.

We, in turn have to ensure that our expectations of practitioners in infection prevention and control are clear and consistent and that appropriate education, training and development is in place to ensure that the right people with the right capabilities are available today and in the future as we take infection prevention and control forward. This competency framework provides a solid foundation on which to do that and I look forward to seeing it used to meet expectations.

Ros Moore, BSc (Hons) Nursing, MA, RGN, RNT
Chief Nursing Officer, the Scottish Government

2. Introduction

With our rapidly changing healthcare systems, a more flexible response is required from infection prevention and control (IPC) practitioners to be able to address the challenges that healthcare associated infection presents. We are continually being pulled in many different directions in order to improve the quality of healthcare delivery and to respond to the patient safety agenda and the zero tolerance culture to healthcare associated infection. Infection prevention and control practitioners continue to play a key role in improving the safety and quality of care delivered to patients by providing clinical colleagues with robust expertise, advice, support and guidance enabling them to prevent and control healthcare associated infections.

Competences were first developed and published by the Infection Control Nurses Association (ICNA) in 2000, followed by the second edition in 2004. These competences provided an overarching framework to enable IPC practitioners to develop and enhance their knowledge and skills to increase the safety and quality of patient care. Taking into account the changes in healthcare delivery throughout the United Kingdom (UK), the current political and economic drivers around healthcare associated infection and the evolving nature and diversity of infection prevention and control teams, we are now delighted to present the new competences framework developed by the Infection Prevention Society (IPS) the successor organisation to the ICNA. This framework has also been aligned with NHS Knowledge and Skills Framework and Skills for Health, National Occupational Standards.

The Infection Prevention Society recognises that IPC practitioners will already possess a higher level of knowledge, understanding and skills in accordance with their role and responsibilities. The purpose of this framework is not to define specific roles, but to assist practitioners to continually increase their existing knowledge, understanding and skills in order to reach our ultimate goal of safe, improved quality of care for our patients through reduction in the burden of disease and avoidable illness caused by healthcare associated infections.

The IPS Education and Professional Development Committee are privileged to have worked in partnership to produce this competency framework with:

- Scottish Government Health Department
- Department of Health, England
- Department of Health, Social Services and Public Safety Northern Ireland
- Welsh Assembly Government

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- Lindsay Mitchell, Prime R & D Ltd
- Skills for Health
- Council of Deans

Emma Burnett, MSc, PGCert, BN, SPQ, RGN Lead Co-ordinator Education and Professional Development Committee, Infection Prevention Society

3. Why do we need competences for infection prevention and control practitioners?

The focus on reducing healthcare associated infections continues throughout the UK and the introduction of patient safety improvement programmes has highlighted the role of healthcare associated infections as incidents that have an adverse effect on public safety and quality of care. The prevention, management and control of these infections is therefore a priority area for each of the four UK governments. It requires action by all organisations involved with health and social care.

Infection prevention and control practitioners have a key role to play in scanning the environment for new and emerging threats to safety, as well as improving the safety and quality of care delivered to individuals and populations. They provide colleagues across all health and social care settings with robust clinical expertise, advice, support and guidance so that they can work in partnership to prevent, manage and control healthcare associated infections

Infection prevention and control practitioners increasingly come from a wide range of professional or occupational backgrounds and often bring very different knowledge, skills and experience to the role. These competences have been produced by expert practitioners and academics in the field and endorsed by the UK health departments, to provide a consistent set of standards and expectations for the role across the UK.

The majority of practitioners working in NHS organisations (excluding medical personnel) will be working within the NHS Knowledge and Skills Framework (KSF) (Department of Health, 2004) and Career Framework for Health (Skills for Health, 2010). The role of IPC practitioner has therefore been positioned at senior practitioner level in the Career Framework for Health. There is an expectation that post-holders work at advanced-level practice (or are working towards that level), and are in possession of the qualifications and specialist knowledge commensurate with a senior practitioner. However, to retain flexibility and accommodate differences in the UK healthcare systems and between local service providers (for example, different patient/client case mix, staff skills mix and organisational structures) decisions about job titles, qualifications, pay bands and rewards should be made by the organisation that is employing the practitioner. It is also the employer's responsibility to ensure that practitioners working at an advanced level in infection prevention and control:

- have access to the qualifications at an appropriate level, ie at level 7 of the Framework for Higher Education Qualifications (FHEQ) (QAA, 2008) in England, Wales and Northern Ireland and level 11 of the Scottish Credit and Qualifications Framework (SCQF) (SCQF, 2009)
- are provided with appropriate certificated training
- have designated authority to carry out the competences safely and independently.

4. Who are these competences for?

These competences are designed for use by a number of people, including:

- organisations who are looking for an expert to drive forward their safety and quality agenda and prevent and manage healthcare associated infections
- managers of health and social-care services, so they can understand the expert advice that should be available to them and that they can draw on
- educational commissioners and providers, so that they can ensure that education and training provision meets service needs and promotes quality and safety
- practitioners working in IPC, so that they can better understand their role in all its aspects
- practitioners who contribute to IPC and who have an interest in developing their knowledge, understanding and skills in this area in the future.

Infection prevention and control practitioners are experienced and educated members of the multidisciplinary health and social-care team who work both on their own and in partnership with others. They have an extensive knowledge base that includes an understanding of microbiology, epidemiology and immunology, coupled with organisational strategy and operational practice. They use a range of skills, including:

- influencing and negotiating
- communicating
- complex decision making
- influencing strategic decision making
- information and knowledge management
- engagement and facilitation
- leadership and risk management.

These advanced practitioners ensure safe, high-quality services for the public, and support improvement so that the safety and quality of care is continually enhanced.

Infection prevention and control is a constantly changing field with emerging threats from new and resistant micro-organisms, new challenges arising, and new ways of managing healthcare associated infections being developed all the time. Practitioners working at an advanced level need to keep abreast of these threats and emerging methodologies, so that they can be proactive in dealing with the challenges faced by their organisations.

5. Who employs infection prevention and control practitioners?

A wide range of organisations in the public, private sector and voluntary sectors are interested in employing people working in IPC. These practitioners can be found in:

- acute and community healthcare settings
- the ambulance service
- mental health and learning disability services
- adult and paediatric services
- social-care services
- public health departments
- university departments
- the prison service
- policy and service development roles at national level in and outside the NHS.

6. Who works in infection prevention and control?

Traditionally, infection prevention and control practitioners have come from a nursing background. However, as the prevention, management and control of infection have developed, so has the pool of people who have developed their knowledge and skills in the area. Given the breadth of knowledge, understanding and skills that individuals need to be able to work in this area, practitioners will generally come from a clinical or healthcare-science background, and include nurses, podiatrists, paramedics and biomedical scientists. Examples of the career pathways of, and options for, practitioners in infection prevention and control are described in section 14, which also has some

real-life case studies of individuals who have developed their careers in this field.

7. How do these competences link to other frameworks?

These competences provide further, detailed content related to infection prevention and control to support the use of the generic Knowledge and Skills Framework (KSF) within the NHS. These competences can be used by organisations to develop the detailed content of KSF post outlines for practitioners working at an advanced level in infection prevention and control, and through this they can guide and support their ongoing learning and development while in post. Indicative links to the NHS KSF, which have been approved by the KSF Group of the NHS Staff Council, are shown attached to each of the competences.

The competences have been structured against the four domains within the Advanced Practitioner toolkit (Scottish Government, 2008) for Modernising Nursing Careers – the career and development framework for nursing. As with the KSF, the competences show the detailed specification of advanced practice in infection prevention and control.

The NHS Leadership Qualities Framework (LQF) is also of relevance to this work (DH, 2002). The LQF sets the standard for leadership in the NHS by describing the qualities expected of existing and aspiring leaders both now and in the future. The LQF will help individuals develop their leadership skills and understanding of leadership. This will therefore support the achievement of this competency framework for advanced practice in infection prevention and control.

Additionally, this framework resonates with the Department of Health's 'Advanced Level Nursing: A Position Statement' (DH, 2010) in that practitioners working at an advanced level will use complex reasoning, critical thinking, reflection and analysis to inform their assessment, clinical judgement and decisions.

Skills for Health, the Sector Skills Council for the health sector, has linked these competences to National Occupational Standards (NOS). These links are shown attached to each of the competences. Four of the competences have been adapted from Skills for Health National Occupational Standards, and full intellectual copyright for the original material rests with Skills for Health. We would like to express our gratitude to Skills for Health for giving permission to use this particular version of these national occupational standards in this work.

8. What competences are included?

There are 17 competences included in this resource set out against the four advanced practice domains as shown in Box 1.

9. How can the competences be used?

The competences are designed to be an information resource for a range of possible uses as shown in the diagram below.

The competences are designed to be a multi-purpose tool that will support and inform strategic planning, workforce development and

Box 1: Domains and competences

Clinical practice

1 Improve quality and safety by developing and implementing robust, high-quality policies and guidelines that prevent and control infection
2 Collate, analyse and communicate data relating to preventing and controlling infection for surveillance purposes
3 Manage incidents and outbreaks
4 Improve quality and safety through the application of improvement methodologies
5 Advise on the design, construction and modification of facilities to prevent and control infection in the built environment
6 Evaluate, monitor and review the effectiveness of decontamination processes for equipment and environment

Education

7 Develop own knowledge, skills and practice
8 Lead the development of the knowledge, skills and practice of the infection prevention and control team
9 Develop and implement learning and development opportunities and solutions to improve infection prevention and control
10 Work with others to develop, implement, evaluate and embed infection prevention and control within workforce development strategies

Research

11 Access, appraise and apply robust evidence of all types from a range of research and other sources, to the domains of the role
12 Lead high quality infection prevention and control services
13 Share best practice through the dissemination of evidence and knowledge

Leadership and management

14 Improve quality and safety through networking, influence, proactivity and challenge
15 Improve quality and safety through the design, planning, monitoring and development of services
16 Lead high quality infection prevention and control services
17 Lead and manage the work of the infection prevention and control team to achieve objectives

management at strategic and unit level. They will also provide guidance for educational commissioning and will structure the content of education and training programmes, whether these are developed internally by employing organisations or are university accredited. The competences will also enhance local accountability and support the role and development of current and aspiring infection prevention and control practitioners.

Some examples of how the competences might be used are set out below.

Service and strategic level

- Service reviews
- Workforce/role design and profiling
- Education commissioning, planning and provision

Unit and managerial level

- Recruitment and selection
- Staff appraisal
- Education, training and development planning and delivery
- Career development and advice
- Design of professional and vocational qualifications

Individual and team level

- Career progression
- Self assessment and personal development planning
- Coaching
- Clinical supervision
- Professional revalidation/registration

The competences:

1. Provide clarity for organisations as to what they can expect IPC practitioners to do, that is, the competences will identify the unique contribution that IPC practitioners make to the work of the organisation and hence the value that they bring to it
2. Provide benchmarks for organisations to use in the recruitment, selection, development, appraisal and performance management of IPC practitioners
3. Contribute to the development of specifications for IPC services by identifying the outcomes that IPC practitioners can be expected to deliver
4. Contribute to the education and training of individuals who are aiming to become IPC practitioners – both for organisations that are looking to commission education and training for practitioners to work at this level and for organisations providing that education and training
5. Contribute to the Continuing Professional Development (CPD) of individuals when they are in post in order to maintain and improve their competence
6. Contribute to the development of workforce specifications by identifying the role and contributions of IPC practitioners
7. Can be used as the basis of a skills and career framework for those whose interest lies in infection prevention and control (including IPC practitioners), for example in demonstrating how people develop to a consultant-level post
8. Support the mapping of the role of IPC practitioners with different regulatory requirements.

How can I continue to develop in infection prevention and control?

You can use these competences to inform your development. It does not matter what your starting point is – you might already be close to achieving all of these competences or might be a long way off and have a lot of development to undertake. The thought processes you need to go through and the actions you need to take will be similar, the difference will be in the amount of development that is needed. These competences describe what it is that an individual is expected and able to do when they are fully functioning at an advanced level.

To continue to develop yourself, you need to follow the process set down in competence 7 of this document and undertake an honest assessment of your current level of knowledge and skills and your ability to apply them in practice. It is recommended that you seek the help of others (for example, your colleagues, peers and your manager) as they are likely to have a different view of your current level of competence as well as an understanding of the exact meaning of the competences. This is particularly important when you are new to the area as some of the explanations might look simpler than they in fact are.

Once you have a realistic assessment of your own current level of knowledge, skills and competence against the advanced level competences, ie you have identified your learning needs, you will then need to plan how you can best develop yourself to the level required. This might be through self-study, undertaking learning programmes and/or academic qualifications, or seeking learning opportunities in the workplace, such as mentoring and job shadowing. As your learning and development progresses, you will need to revisit the competences and continue to assess yourself to identify your progress in achieving all of the competences. An example of how to do this against one of the competences is shown in section 15.

10. How can the competences be applied in workforce development and management?

As shown above, these competences can be used to recruit and select new staff by building job requirements and person specifications

Figure 1. Using the competences

around the four domains of advanced practice (with local stakeholders agreeing the essential and desirable elements). However, as part of the selection process, all new IPC practitioners should be able to provide evidence of the generic infection prevention and control competences expected in their previous role, as well as their willingness to work towards the full range of specialist advanced competences described in this document. On recruitment, a self and peer review of current levels of competence against the framework will be required, and a Personal Development Plan (PDP) with agreed timescales must be developed to fill identified learning needs. The PDP can then be used as a framework for coaching and for agreeing education, training and development.

For staff already in post the PDP can be used in the same way. However, it is important to note that as practitioners operate in an organisational context and work as part of a wider team and culture, the competences are not themselves a performance management tool. But they do have a clear part to play in that process. As the competences are intended to specify what it is that an individual should achieve, they do not include service outcomes or performance measures. Even though these practitioners should have a clear impact on the rates of healthcare associated infections and adverse effects, it is not possible to draw a firm, direct relationship between the two. The overall effectiveness of a practitioner will be affected by the support and priority that an organisation gives to their work. As well as using these competences to contribute to job descriptions, organisations might wish to add measurement indicators of safe, clean, high-quality care into an individual's personal objectives and include them in appraisal systems.

11. How are the competences structured?

The competences have been structured to focus on the outcomes of performance – that is, what is expected of an individual when they are fully functioning at an advanced level in IPC, and influencing key strategic decisions related to public safety and care quality.

Not all jobs for people working at an advanced level of IPC will incorporate all the competences that have been set out in this document. Similarly, not all individuals working in IPC will be able to demonstrate achievement of all the competences that have been specified. Individuals will need to develop their knowledge, skills and practice over time in order to show that they can function at this advanced level of practice. They also need to have the opportunity to do so within their employing organisation.

The competences have been structured as illustrated in Box 2.

There are some generic knowledge, understanding and skills that apply to all the competences. These are shown in Box 3.

The knowledge, understanding and skills that are more specific to each of the competences and to infection prevention and control are shown with the relevant competence to which they apply.

Box 2: Competency structure

1 **Domains of practice** – the four domains that describe the major components of advanced-level practice, that is:
   a clinical practice
   b education
   c research
   d leadership and management
2 **Competence statements** – these are the broad role expectations of practitioners working at an advanced level of practice in IPC. They describe the 'what has to be done'.
3 **Performance indicators** – aligned to each of the competence statements, the performance indicators describe what competent performance in advanced-level practice in IPC looks like. The indicators describe the level and scope of competent practice – that is, the indicator against which competence would be judged.
4 **Knowledge, understanding and skills** – these descriptions identify the knowledge, understanding and skills that a practitioner would need to develop in order to achieve the competences to the level of performance required in the indicators. These statements do not have a one-to-one relationship with the performance indicators, because to achieve one indicator it is often necessary to use a range of different knowledge and apply different skills.

Box 3: Generic knowledge, understanding and skills

a Influencing and advice strategies, including risk assessment to balance broader organisational needs with infection prevention and control requirements
b Action planning and follow up
c Change-management skills
d Partnership and team-working skills
e Communication skills
f Negotiating skills
g Leadership skills
h Report preparation (including annual reports) for the organisation and external agencies
i Developing and delivering training and education.

12. The competences' statements and performance indicators structured against the four domains

Box 4: Domain 1: Clinical practice

1 Improve quality and safety by developing and implementing robust, high-quality policies and guidelines that prevent and control infection

Performance indicators

1 Provide guidance for those working in all areas of health and social-care practice through critically analysing and interpreting national quality and safety resources and initiatives and presenting the information in a way that is suitable for the people concerned
2 Evaluate the effectiveness of existing policies and guidelines and identify areas for improvement
3 Promote evidence-based improvements in policies and guidelines through demonstrating their value in terms of safety and quality in the context concerned
4 Work in partnership with individuals, the population and colleagues to develop clear and robust policies and guidelines that prevent and control infection
5 Work in partnership with others to plan the effective implementation of policies and guidelines to prevent and control infection
6 Provide expert advisory support for the implementation of policies and guidelines to prevent and control infection
7 Monitor the implementation of infection prevention and control policies and guidelines, taking any corrective actions as and when necessary
8 Identify the need for improvements in infection prevention and control policies and guidelines in the light of implementation and the changing knowledge base and evidence
9 Provide expert infection prevention and control input to the development of broader policies and guidelines.

Knowledge, understanding and skills

a Applied microbiology in relation to the chain of infection and the infection process, alert micro-organisms and conditions, body defence mechanisms
b The significance of microbiological results, interpreting the diagnostic laboratory results, practices designed to break the chain of infection, including standard and transmission-based precautions including the placement of populations and individuals in care settings
c Hand hygiene (including social hand hygiene, antiseptic hand hygiene, surgical scrub)
d Safe management of invasive devices and prevention of device-related infections
e Asepsis
f Antimicrobial stewardship – prudent prescribing of antimicrobials and the surveillance of antimicrobial-resistant organisms
g Aligning infection prevention and control with the quality and safety agenda (using outcomes, risk assessment matrix, programmes and systems) and making use of health information exchange systems
h Legislation, national guidance and outcomes/indicators related to preventing and controlling infection in health and social-care environments and facilities (including ventilation, water sources, waste management, hygiene, isolation facilities, laundry management, food hygiene)
i Legislation, national guidance and outcomes/indicators related to preventing and controlling infection for individuals and populations in health and social-care environments and facilities (for example, communicable disease control; immunisation; prevention and management of injuries (including sharps); post-exposure prophylaxis; specific controls in specialist areas such as burns, critical care, renal and transplant, maternity, neonatal, children, operating rooms, mental health, dentistry and ambulance services)
j The evidence base on which infection prevention and control policies should be based
k Knowledge of national and organisational strategies, objectives, structure and accountability and how to present information in a manner that fits within the strategic context
l Policy development skills.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

Core 4 Service improvement Level 4
HWB3 Protection of health and wellbeing Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

GEN67: *Establish quality policy and quality assurance systems for the delivery of a service or function* – see https://tools.skillsforhealth.org.uk/competence/show?code=GEN 67

Clinical practice

2 Collate, analyse and communicate data relating to preventing and controlling infection for surveillance purposes

Performance indicators

1 Obtain and link data using appropriate methods and systems for the surveillance of infection
2 Structure and analyse the data correctly to identify patterns, trends and anomalies that may be significant in relation to preventing and controlling infection
3 Critically assess the strengths and limitations of the data using methods of analysis that are appropriate to the nature and form of the data and the purpose for which the results are to be used
4 Identify areas that might require further investigation or analysis in relation to potential risks
5 Analyse potential risks and reach conclusions appropriate to the risks
6 Critically assess the conclusions reached, identifying the strengths and limitations of the analysis undertaken
7 Act upon the risks identified, communicating them effectively to the appropriate people
8 Enable health and social-care staff to understand the data and make the necessary changes to achieve improved outcomes
9 Take the appropriate action when surveillance methods and data can be improved

Knowledge, understanding and skills

a Applied microbiology in relation to the chain of infection and the infection process, alert micro-organisms and conditions, body defence mechanisms
b The significance of microbiological results, interpreting the diagnostic laboratory results and practices designed to break the chain of infection, including standard and transmission-based precautions including the placement of populations and individuals in care settings
c Definitions, methods and types of surveillance, data handling, data analysis, interpreting outcomes, assessing limitations of data
d Epidemiology, descriptive and applied (that is, the application and evaluation of epidemiologic discoveries and methods in public health and health and social-care settings, including applications of aetiological research, priority setting and evaluation of programmes, policies and services)
e Principles of epidemiology, incidence, prevalence
f Principles of statistics and variation
g Feedback and reporting mechanisms.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

HWB3 Protection of health and wellbeing Level 4
IK2 Information collection and analysis Level 3

Links to national occupational standards

This competence used NOS HP2 *Collate, analyse and interpret surveillance data to assess risks to population health, wellbeing and safety* as its starting point for the development of the IPC competences. There are a number of similarities between the two sets of performance indicators/criteria but full intellectual copyright for the original material rests with Skills for Health. See https://tools.skillsforhealth.org.uk/competence/show?code=HP2

Clinical practice

3 Manage incidents and outbreaks

Performance indicators

1 Assess the information available on the incident/outbreak and seek any necessary further evidence to establish its nature and scale
2 Establish the appropriate response using local incident/outbreak/emergency planning guides
3 Inform and involve relevant colleagues and partner organisations in a timely manner consistent with incident or emergency plans
4 Facilitate the development of an outbreak/incident management team, ensuring that the appropriate organisations and functions are represented
5 Communicate clear, accurate and timely information with colleagues, partner organisations and others throughout the incident in a manner that effectively manages risk and supports effective team working
6 Establish agreement on the control measures to be taken to minimise exposure to hazards and to reduce risks and prevent secondary or further spread or exposures

(*Continued*)

3 Manage incidents and outbreaks — Continued

7 Review the availability of resources to implement the control measures throughout the duration of the incident/outbreak
8 Ensure accurate records of the investigation and management of the incident/outbreak are maintained throughout the process
9 Lead review of the investigation and management of the incident/outbreak and modify measures as a result
10 Produce a final report of the incident/outbreak and communicate it to all concerned
11 Evaluate the incident/outbreak and make recommendations for future improvement

Knowledge, understanding and skills

a Alert micro-organisms, baseline
b Defining and recognising outbreaks
c Investigation of outbreaks, data collection
d The significance of microbiological results; interpreting the diagnostic laboratory results; practices designed to break the chain of infection, including standard and transmission-based precautions including the placement of populations and individuals in care settings
e Control measures
f Epidemiology, descriptive and applied (that is, the application and evaluation of epidemiologic discoveries and methods in public health and health and social-care settings, including applications of aetiological research, priority setting and evaluation of programmes, policies and services)
g Principles of epidemiology, incidence, prevalence
h Principles of statistics and variation
i Feedback and reporting mechanism
j Epidemics, pandemics, endemic
k Public health dimension; public health epidemiology
l Methods of performing post-outbreak evaluation; report evaluation feedback; serious untoward incident tools
m Emergency systems and procedures for managing incidents and outbreaks
n The roles and responsibilities of national, regional and local agencies and departments in managing incidents and outbreaks
o Knowledge of sources of advice and expertise that can be drawn upon to contribute to investigating and managing the hazard
p Legal frameworks (that is, legal powers and duties, responsibilities and accountability) and organisational and professional policies and protocols when there is an outbreak or incident.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:
HWB3 Protection of health and wellbeing Level 4

Links to national occupational standards

This competence used NOS HP15 *Coordinate a team investigating and managing an incident or outbreak* as its starting point for the development of the IPC competences. There are a number of similarities between the two sets of performance indicators/criteria but full intellectual copyright for the original material rests with Skills for Health. See https://tools.skillsforhealth.org.uk/competence/show?code=HP15

Clinical practice

4 Improve quality and safety through the application of improvement methodologies

Performance indicators

1 Identify the need for change in practices and environments
2 Work in partnership with others to develop practice innovations and service re-design solutions to improve safety and quality
3 Lead the organisation's infection prevention and control programme to improve safety and the overall quality and experience of care through linking it with the work of internal and external partners and influencing direction
4 Ensure that audit, surveillance, epidemiology and risk register data are collated, communicated, used and interpreted effectively
5 Access existing and create new databases to manage and use data and information related to improving quality and safety
6 Guide practice in infection prevention and control through the critical analysis and effective communication of national quality and safety resources and initiatives
7 Work in partnership with individuals, populations, staff and others to develop improvement programmes that are in line with the culture and context of the area
8 Lead the implementation of improvement programmes, working in partnership with all involved

(*Continued*)

4 Improve quality and safety through the application of improvement methodologies — Continued

9 Evaluate the effectiveness of improvement programmes in partnership with individuals, populations, staff and others, identifying the improvements that need to be made in practice
10 Prepare and present infection prevention and control reports and recommendations to individuals, populations, staff, members of the organisation and others
11 Confirm that agreed actions have been taken to improve safety and the quality of health and social-care practice
12 Take the necessary action to escalate concerns when there is a failure to act which compromises safety and quality.

Knowledge, understanding and skills

a Clinical governance, quality assurance, clinical effectiveness, quality improvement framework and service improvement frameworks
b Risk identification, assessment and management including: risk register analysis, action planning, feedback and re-evaluation
c Serious untoward incident and root cause analysis
d Review of audit findings, action planning, feedback and re-evaluation
e Available quality and safety resources and initiatives
f Outcome measures including measures that are reported by individuals receiving health and social-care services
g Corrective and preventive actions
h Development, implementation and evaluation of evidence-based achievable metrics and outcome measures that can be audited
i Improvement and change methodologies.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

Core 4 Service improvement Level 4
HWB3 Protection of health and wellbeing Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

M&L B6: *Provide leadership in your area of responsibility* – see http://www.ukstandards.org.uk/Admin/DB/0033/B5%202009.pdf
M&L B5: *Provide leadership for your team* – see https://tools.skillsforhealth.org.uk/competence/show?code=M%26L+B5

Clinical practice

5 Advise on the design, construction and modification of facilities to prevent and control infection in the built environment

Performance indicators

1 Work with others on plans for the design, construction and modification of facilities to improve safety and quality through infection prevention and control
2 Advise on the infection prevention and control risk assessment criteria prior to a new build and in advance of any demolition or modification of a building consistent with current building guidance and legislation
3 Liaise with key health and social-care staff and others prior to and at every subsequent stage of the build, demolition or modification to ensure that infection prevention and control advice is effectively incorporated into the works
4 Work in partnership with key health and social-care staff to reduce the risk of infection to individuals, populations, staff and others during construction, demolition or modification activities
5 On the completion of the works, review with individuals, populations, staff and others the effectiveness of the development for preventing and controlling infection.

Knowledge, understanding and skills

a Applied microbiology in relation to the chain of infection and the infection process, alert micro-organisms and conditions, body defence mechanisms
b The significance of microbiological results, interpreting the diagnostic laboratory results; practices designed to break the chain of infection – for example, standard and transmission-based precautions including the placement of individuals and populations within care settings
c Antimicrobial stewardship – prudent prescribing of antimicrobials and the surveillance of antimicrobial resistant organisms

(*Continued*)

5 Advise on the design, construction and modification of facilities to prevent and control infection in the built environment — Continued

d Legislation, national guidance and outcomes/indicators relating to the design, construction and modification of the built environment in general and health and social-care facilities in particular (for example, ventilation, water sources, waste management, hygiene)
e Organisational strategy for new builds, refurbishments, planned programme maintenance
f Interpretation of architects', estates' and facilities' plans for new builds, refurbishment and modification

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

EF2 Environments and buildings Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

HSC 3117 *Conduct a health and safety risk assessment of a workplace* – see https://tools.skillsforhealth.org.uk/competence/show?code=HSC3117

Clinical practice

6 Evaluate, monitor and review the effectiveness of decontamination processes for equipment and environment

Performance indicators

1 Provide evidence-based infection prevention and control input in the development of decontamination policies and procedures
2 Audit decontamination methods to determine their effectiveness
3 Report the outcomes of the audit, drawing specific attention to the risks to safety and quality that have been identified
4 Advise on the actions that are required to improve quality and safety when decontamination processes are ineffective and the timescale in which they need to be implemented
5 Confirm that the required actions have been effectively undertaken to control infection and promote safety and quality
6 Take the necessary action to escalate concerns when there is a failure to act which compromises safety and quality.

Knowledge, understanding and skills

a Applied in relation to the chain of infection and the infection process, alert micro-organisms and conditions, body defence mechanisms
b The significance of microbiological results; interpreting the diagnostic laboratory results; practices designed to break the chain of infection – for example, standard and transmission-based precautions including the placement of individuals and populations in care settings
c Antimicrobial stewardship – prudent prescribing of antimicrobials and the surveillance of antimicrobial-resistant organisms
d Levels of decontamination – lifecycle and cycle parameters, use of various tests, water quality tests (for example, TVC levels)
e Methods and processes of decontamination (for example, physical and chemical disinfection, sterilisation)
f Methods and processes of decontamination for: medical devices (for example, endoscopes, surgical instruments), equipment and environments
g Risk assessment of processes, environments and systems used for decontamination
h Evaluation of application of decontamination processes in clinical practice
i National guidance on decontamination processes for equipment and reusable medical devices (for example, Health Technical Memorandum (HTM), Scottish HTM) and the evidence base on which they are built
j Legislation, national guidance and outcomes/indicators on decontamination processes for the built environment and the evidence base on which they are built
k Regional and local policies which differ from national guidance and the rationale for this.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

EF1 Systems, buildings and equipment Level 4
EF2 Environments and buildings Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

DEC6: *Monitor procedures and operate tracking systems and procedures* – see https://tools.skillsforhealth.org.uk/competence/show?code=DEC6

Box 4: Domain 2: Education

7 Develop own knowledge, skills and practice

Performance indicators

1 Evaluate own development and application of knowledge and skills to meet current and emerging work demands and organisational objectives
2 Identify own development needs and set own personal development objectives, including professional development
3 Develop a personal development portfolio, recognising strengths and limitations, with clear learning needs, plans, actions and outcomes
4 Develop own knowledge, skills and practice through active engagement in a range of learning and development opportunities
5 Continually maintain an up-to-date knowledge of infection prevention and control through a range of different activities (including reading peer-reviewed journals, accessing other sources of published information, and peer review sessions)
6 Seize opportunities to learn new knowledge and skills and apply them in the development of practice

Knowledge, understanding and skills

a Self awareness of competence and level required
b Critical analysis, evaluation and appraisal skills
c Critical analysis and evaluation of published literature and peer-reviewed research studies
d Writing for publication and reviewing journal articles
e Knowledge management and knowledge sharing
f Dissemination of best practice, internal to the organisation, at conferences and in journals.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:
Core 2 Personal and people development Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:
GEN13: *Synthesise new knowledge into the development of your own practice* – see https://tools.skillsforhealth.org.uk/competence/show?code=GEN13

Education

8 Lead the development of the knowledge, skills and practice of the infection prevention and control team

Performance indicators

1 Encourage others to make accurate and credible assessments of their knowledge and skills, challenging complacency and actions that are not in the interests of safety and quality
2 Identify and address gaps in knowledge, skills and competence of staff working within the infection prevention and control team
3 Develop an environment that values learning and development and promotes a learning culture in the workplace
4 Develop and inspire all members of the team to use their abilities to practise effectively and efficiently to deliver the infection prevention and control programme
5 Work in partnership with members of the infection prevention and control team to include professional development as part of their personal development planning
6 Alert relevant others to resource issues that affect learning, development and performance

Knowledge, understanding and skills

a Staff appraisal, feedback, action plan and re-evaluation skills
b The meaning of the term 'learning culture' and how it can be facilitated
c Facilitating work-based learning, practice development and research activities
d Staff development skills (including mentoring and coaching)
e Effective methods of levels of delegation and support
f Leadership models and styles and their application to practice.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:
Core 2 Personal and people development Level 4

(*Continued*)

8 Lead the development of the knowledge, skills and practice of the infection prevention and control team — Continued

Links to national occupational standards

The following national occupational standards relate to this competence:

HSC43: *Take responsibility for the continuing professional development of self and others* – see https://tools.skillsforhealth.org.uk/competence/show?code=HSC43

CMF1: *Provide clinical leadership and take responsibility for the continuing professional development of self and others* – see https://tools.skillsforhealth.org.uk/competence/show?code=CM+F1

Education

9 Develop and implement learning and development opportunities and solutions to improve infection prevention and control

Performance indicators

1 Identify the learning and development needs of individuals and teams through the use of epidemiological, surveillance and audit data
2 Evaluate with the relevant people the current approaches to learning and development related to infection prevention and control and identify areas for improvement
3 Work in partnership with individuals, populations and other relevant people to identify learning and development opportunities and solutions that offer best value for money and are targeted to address key issues
4 Develop a range of evidence-based learning and development activities that are tailored to the needs of specific groups of health and social-care staff and offer best value for money
5 Lead the implementation of learning and development activities to ensure that they are fit for purpose and improve infection prevention and control
6 Ensure the necessary modifications are made to learning and development activities to improve their effectiveness
7 Advise others on how to effectively include infection prevention and control in their own learning and development programmes and activities
8 Provide consultancy services on infection prevention and control to individuals and teams inside and outside the organisation

Knowledge, understanding and skills

a Models and theories of learning (for example, learning styles)
b Learning processes, methods and opportunities including innovative approaches to learning
c How to identify learning needs
d Types and methods of assessment
e Integration of learning and development with organisational strategy and objectives for infection prevention and control.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

G1 Learning and development Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

AC3: *Contribute to the development of the knowledge and practice of others* – see https://tools.skillsforhealth.org.uk/competence/show?code=AC3

LLUKL1: *Develop a strategy and plan for learning and development* – see https://tools.skillsforhealth.org.uk/competence/show?code=LLUK+L1

LLUKL2: *Identify the learning and development needs of the organisation* - see https://tools.skillsforhealth.org.uk/competence/show?code=LLUK+L2

LLUKL3: *Identify individual learning aims and programmes* – see https://tools.skillsforhealth.org.uk/competence/show?code=LLUK+L3

LLUKL7: *Prepare and develop resources to support learning* – see https://tools.skillsforhealth.org.uk/competence/show?code=LLUK+L7

Education

10 Work with others to develop, implement, evaluate and embed infection prevention and control within workforce development strategies

Performance indicators

1 Work with others to build infection prevention and control into workforce development strategies
2 Provide expert advice and support in implementing a strategy for developing the workforce to improve infection prevention and control
3 Influence and persuade others to see infection prevention and control as an integral part of the learning and development culture in health and social care and essential to safety and quality
4 Evaluate the effectiveness of workforce development strategies in improving infection prevention and control
5 Make recommendations to improve the knowledge and skills of the workforce to prevent and control infection

Knowledge, understanding and skills

a Risk management and quality improvement programmes
b Learning culture
c Integration of learning and development with organisational strategy and objectives for infection prevention and control
d Identifying and negotiating training programmes
e Clinical education and clinical teaching
f Preparation of practitioners for different roles in the infection prevention and control team and for preventing and controlling infection more generally
g Evaluation of the effectiveness of workforce development strategies including specific education and training programmes.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

G1 Learning and development Level 4
G7 Capacity and capability Level 3

Links to national occupational standards

The following national occupational standards relate to this competence:

LLUK L1: *Develop a strategy and plan for learning and development* – see https://tools.skillsforhealth.org.uk/competence/show?code=LLUK+L1

Box 4: Domain 3: Research

11 Access, appraise and apply robust evidence of all types, and from a range of research and other sources, to the domains of the role

Performance indicators

1 Appraise the validity, sufficiency and relevance of research methodologies and other information sources applicable to infection prevention and control
2 Critically appraise the literature to establish its validity and application to practice
3 Synthesise and analyse the arguments of others, identifying strengths and weaknesses
4 Apply the findings of the appraisal to practice
5 Evaluate the outcomes and findings of research and other literature to determine their impact on, and potential for, improving infection prevention and control

Knowledge, understanding and skills

a Organisational strategies and objectives
b The research process
c Research approaches and design
d Qualitative and quantitative research skills
e Literature searching
f Literature reviewing
g Peer review
h Secondary sources

(*Continued*)

11 Access, appraise and apply robust evidence of all types, and from a range of research and other sources, to the domains of the role — Continued

i Critical analytical skills
j Application of research evidence to practice.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

IK2 Information collection and analysis Level 3

Links to national occupational standards

This competence uses NOS PHS22 *Appraise, plan and manage research related to improving health and wellbeing* as its starting point and adapted it for advanced-level practice in infection prevention and control. The competence set out above is very similar to NOS PHS22 and full intellectual copyright for the original material rests with Skills for Health. See https://tools.skillsforhealth.org.uk/competence/show?code=PHS22

Research

12 Build the evidence and knowledge base to improve and develop infection prevention and control strategies and practices through participation in, or completing research and other related activities, including audit

Performance indicators

1 Determine priorities for research and development within infection prevention and control, working in partnership with individuals, populations and colleagues (at national and local level and within services and academia)
2 Identify, select and summarise research and other related activities from a variety of sources that are applicable to infection prevention and control
3 Work with others to develop clear proposals that are consistent with identified priorities
4 Present clear, succinct, valid, reliable and cost-effective proposals to appropriate people and organisations
5 Collect, collate, analyse and synthesise qualitative and quantitative data and information using appropriate methods
6 Ensure projects are delivered and reported to time, addressing the questions or issues posed
7 Reach agreements with key people and stakeholders about the need for applying research outcomes and findings to infection prevention and control practice and how best to do this
8 Monitor and review implementation against anticipated outcomes and findings and make necessary adjustments in agreement with others

Knowledge, understanding and skills

a Skills of interpreting research and related literature
b Skills for evaluating research and other related literature in relation to:
  – research questions
  – research design
  – study analysis
  – limitations of the study
  – clinical implications of the study
  – implications for practice
c Strategies for implementing findings in practice
d Role of the funder.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

IK2 Information collection and analysis Level 3
G5 Services and project management Level 3

Links to national occupational standards

This competence uses NOS PHS23 *Interpret research findings and implement them in practice* as its starting point and adapted it for advanced-level practice in infection prevention and control. The competence set out above is similar in content to NOS PHS23 and full intellectual copyright for the original material rests with Skills for Health. See https://tools.skillsforhealth.org.uk/competence/show?code=PHS23

Research

13 Share best practice through the dissemination of evidence and knowledge

Performance indicators

1 Communicate findings and outcomes in various ways, to relevant people and stakeholders in a manner that is appropriate to their needs
2 Defend the intellectual basis of the evidence underpinning findings and outcomes
3 Reach agreements with key people and stakeholders in applying the findings and outcomes to infection prevention and control practice
4 In collaboration with others, apply evidence and knowledge in developing policy and driving forward improvement

Knowledge, understanding and skills

a Skills of interpreting research and project outcomes
b Skills of communicating research and project outcomes
- implications for practice
- report writing
- writing for publication
- oral presentation skills

c Strategies for implementing research findings in practice.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:
G2 Development and innovation Level 3

Links to national occupational standards

This competence uses NOS PHS23 *Interpret research findings and implement them in practice* as its starting point and adapted it for advanced-level practice in infection prevention and control. The competence set out above is similar in content to NOS PHS23 and full intellectual copyright for the original material rests with Skills for Health. See https://tools.skillsforhealth.org.uk/competence/show?code=PHS23

Box 4: Domain 4: Leadership and management

14 Improve quality and safety through networking, influence, proactivity and challenge

Performance indicators

1 Scan worldwide developments for emerging threats to safety and quality, emerging measures to address threats, and opportunities for action
2 Measure the future risks and threats; infection and prevention control measures
3 Proactively develop and sustain new partnerships and networks to influence and improve safety and quality working across professional, organisational and system boundaries
4 Develop and sustain a strategic vision and related plans, and gather evidence of improved quality, safety and infection prevention and control, using a range of different skills and drawing on own and others' expert knowledge
5 Seize appropriate and timely opportunities to stress safety and quality across different pathways, health and social-care settings and institutions
6 Continuously assess and monitor the risks to safety and quality and challenge others' actions and decisions when they put individuals, populations and others at risk
7 Advise key people of the effect that their decisions will have on safety and quality and the risks of not taking actions related to infection prevention and control
8 Recommend courses of action to key people that will improve safety and quality and bring other related benefits
9 Develop quality and safety improvement practices through understanding the implications of epidemiological, micro-biological, demographic, social, political and professional trends and developments and applying them to the context and environment following horizon scanning
10 Effectively communicate key messages to wider audiences to influence the wider safety and quality agenda
11 Take the necessary action to escalate concerns when safety and quality are compromised and there is a failure to act

(*Continued*)

14 Improve quality and safety through networking, influence, proactivity and challenge — Continued

Knowledge, understanding and skills

a The national and local strategic context, and sources of information about relevant factors and trends

b How to present information in a manner that fits within the strategic context

c Organisational strategy, objectives, structure and accountability

d Local, regional and national networks.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

Core 1 Communication Level 4
HWB3 Protection of health and wellbeing Level 4
G2 Development and innovation Level 3

Links to national occupational standards

The following national occupational standards relate to this competence:

GEN32: *Search information, evidence and knowledge resources and communicate the results* – see https://tools.skillsforhealth.org.uk/competence/show?code=GEN32

Leadership and management

15 Improve quality and safety through the design, planning, monitoring and development of services

Performance indicators

1 Promote a vision of improved quality and safety and better infection prevention and control within health and social-care and related services to meet the needs of the population(s) that they are designed to serve

2 Actively engage with individuals and populations about their needs and priorities in relation to infection prevention and control

3 Enable different health and social-care providers and professionals within health economies to understand the need for, and commit to, common goals and objectives

4 Work with others to develop the standards of infection prevention and control that health and social-care services should meet so that they increase public confidence and deliver high-quality outcomes

5 Determine the needs of individuals and populations, and the outcomes they require from health and social-care services, from an analysis of hard and soft public health data

6 Draft specifications for services which contain clear and specific outcomes and indicators, sufficient levers to change practice, and identify the consequences of achieving or not achieving these

7 Secure the agreement of providers to the delivery of the specified services within available resources

8 Confirm that health and social-care providers have the necessary systems, policies, procedures and governance structures in place to provide high-quality and safe services and that they comply with national environmental standards

9 Analyse data on performance from service providers to determine if standards, indicators and outcomes are being met in service provision

10 Actively monitor and review the delivery of services against specification, outcomes and indicators (for example, through making unannounced visits) and take timely action when issues arise, including escalating to others if required

Knowledge, understanding and skills

a Effective engagement methods with individuals and populations about their needs and priorities in relation to infection prevention and control

b Engagement strategies with health and social-care providers and professionals to build common goals and interests

c Development of standards, indicators, outcome measures and so on

d Skills in analysing public health data (hard and soft) to identify the needs and interests of individuals and populations

e Service specifications – contents, driving quality and safety, specifying standards for monitoring and assurance, performance management requirements (services will include those relating to health and social-care services themselves and related services, for example, facilities management – cleaning, food, waste disposal, linen)

f Clinical governance, quality assurance, clinical effectiveness, quality improvement framework and service improvement frameworks

g Improvement and change methodologies.

(*Continued*)

15 Improve quality and safety through the design, planning, monitoring and development of services — Continued

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

Core 4 Service improvement Level 4

HWB3 Protection of health and wellbeing Level 4
G3 Procurement and commissioning Level 3
G5 Services and project management Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

ENTO HSP1: *Develop and review the organisation's health and safety strategy* – see https://tools.skillsforhealth.org.uk/competence/show?code=ENTO+HSP1

ENTO HSP13: *Influence and keep pace with improvements in health and safety practice* – see https://tools.skillsforhealth.org.uk/competence/show?code=ENTO+HSP13

Leadership and management

16 Lead high quality infection prevention and control services

Performance indicators

1 Communicate a vision of infection prevention and control that is related to major organisational objectives and captures the interests of key people
2 Develop a strategy for an effective infection prevention and control service
3 Negotiate and agree deliverables, outcomes and resource allocations for the infection prevention and control service and specific projects
4 Develop and facilitate the implementation of the infection prevention and control annual programme in partnership with key people
5 Review outcomes, plans, methods, processes and systems related to infection prevention and control and modify them to improve effectiveness
6 Prepare and present relevant and focused infection prevention and control reports and other forms of communication to key people

Knowledge, understanding and skills

a Organisational management strategy
b Individual and organisational management strategy
c Principles and methods of planning, resourcing, monitoring and controlling
d Leadership theories and styles (for example, situational leadership, transformational leadership, servant leaders, distributed leadership) and their application to practice
e Organisational and directorate communication strategy.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

Core 4 Service improvement Level 4
HWB3 Protection of health and wellbeing Level 4
G3 Procurement and commissioning Level 3
G5 Services and project management Level 4

Links to national occupational standards

The following national occupational standards relate to this competence:

M&L B6: *Provide leadership in your area of responsibility* – see https://tools.skillsforhealth.org.uk/competence/show?code=M%26L+B6

Leadership and management

17 Lead and manage the work of the infection prevention and control team to achieve objectives

Performance indicators

1 Agree and communicate clear team and individual objectives and work plans
2 Ensure objectives and work plans are realistic and achievable, making adjustments where necessary
3 Develop, coach and encourage all members of the team to use their abilities to practise effectively and efficiently to deliver the infection prevention and control programme
4 Ensure that team members have access to sufficient resources to deliver the programme
5 Assess the performance of the team and individuals at appropriate times, using valid and reliable information
6 Provide feedback to teams and individuals in a situation and in a manner most likely to maintain and improve their performance, including providing recognition of achievements
7 Where necessary, help team members to address poor performance
8 Encourage and support good relationships between the team and other teams and departments within the organisation

Knowledge, understanding and skills

a Leadership theories and styles (for example, situational leadership, transformational leadership, servant leaders, distributed leadership) and their application to practice
b Staff support mechanisms
c Resource management to deliver organisational strategy and objectives
d Time management
e Budget management
f Legislation, national guidance and outcomes/indicators related to the employment, management and development of employees.

Links to the NHS Knowledge and Skills Framework

This competence relates to the following dimensions and levels within the NHS KSF:

G5 Services and project management Level 4
G6 People management Level 3

Links to national occupational standards

The following national occupational standards relate to this competence:

M&L B5: *Provide leadership for your team* – see https://tools.skillsforhealth.org.uk/competence/show?code=M%26L+B5

13. Examples of career paths for IPC practitioners

There is no set career path for IPC practitioners, nor is there a 'typical career path' any more. Today's IPC practitioners increasingly come from diverse occupational or professional backgrounds, environments and disciplines, and enter at different points on the career ladder.

Like Rashid in the case study below, people often start their career in clinical practice or healthcare science, develop a passion or interest in IPC, and then pursue continuing education courses to develop specific expertise that qualifies them for the role.

Nor is there a single end point. Let's see how this worked for Jo:

Case study 1

Rashid

Rashid started his nursing career in general nursing. He took up his first post in acute elderly medicine, which allowed him to consolidate his basic nursing skills. He then moved to an acute general surgery setting and also completed his Masters in Healthcare Ethics. Experience in a number of specialties allowed him to progress through the nursing ranks, culminating in a lead-nurse role on a plastics, burns and maxillofacial ward. An interest in infection prevention led him to take up a post with the infection prevention team and to complete a management of infection prevention and control programme. He continues to work in this field as a matron for infection prevention, and he often draws on his previous nursing experience to support him in this role.

Case study 2

Jo

Jo trained in general nursing then specialised in intensive care and medicine. Her interest in infection control led to a seconded project in developing surveillance and a full-time infection prevention and control post. This provided her with opportunities to develop her expertise over 10 years. She then took up senior posts in both acute and community care, completing an MSc in professional development, and fulfilling regional and national roles in the Infection Prevention Society. As Consultant Nurse in a large university teaching hospital, she had input into university programmes as a lecturer. A role as Deputy Director of Infection Prevention and Control followed. Development opportunities arose at regional level and on the Department of Health's MRSA programme. Jo is still the Director of Infection Prevention and Control in a large acute trust, and has a continuing passion for professional development, supporting improved patient safety and use of competency frameworks.

Case study 3

Pat

Following general nursing and specialising in intensive care nursing, Pat was offered a part-time Infection Control Nurse (ICN) position while managing an acute unit in an independent healthcare company. The full-time ICN position provided opportunities to develop enhanced knowledge and skills, including quality improvement at national and local level, development of strategy, and policy skills.

But Pat's story does not stop there…

Case study 3A

Pat (continued)

A continuing interest in population health led Pat to an NHS public health protection post with wider public health activities and national working (for example, with government). This led to a number of national roles – a government advisory position leading a national IPC programme, and a consultant role in a health protection organisation, and in a non-NHS national organisation regulating all adult, child and independent healthcare services.

The role of IPC practitioner can take you in exciting new directions when you least expect it:

Case study 4

Rani

After training as a healthcare scientist, Rani was inspired to move outside the lab by the local infection control consultant, and seized the opportunity of a career progression into the specialty. A spell at a district general hospital and a large teaching hospital culminated in her involvement in pioneering improvement work. This took her to the national and international arena, working latterly for the World Health Organization in Geneva and its regional and country offices, ministries of health and professional medical, nursing and academic institutions, as well as with clinical staff in healthcare settings in South East Asia, the Americas and Africa.

IPC practitioners can also decide to pursue a clinical academic career like Megan:

Case study 5

Megan

After working as a general nurse in various specialities (orthopaedics, medicine, urology, surgery, A & E and care of the elderly), Megan then joined the infection prevention and control team, having responsibilities within both the acute and community setting. Twelve years later, Megan was appointed to an associate lecturer's role in the university. This allowed her to split her work between her clinical roles and the university (teaching in the undergraduate and postgraduate nursing and midwifery curriculum) and Megan also completed her Masters at that time. Following 18 months as an associate lecturer she took up the post of a full-time lecturer and gained her teaching qualification. After engaging in a number of research projects, her role then extended to that of a lecturer and researcher and she is now undertaking her PhD.

These real-life case studies suggest that IPC practitioners do need to plan ahead, but they also need be flexible. Most of all, they need to be open to new interests and opportunities.

14. Example of assessing oneself against the competences and planning learning

Zara has been working as an IPC practitioner for four years, with four others at the same band/grade. She is interested in developing herself so that she is able to apply for a higher banded/graded post in IPC. She is interested in this primarily because recently she has been working closely with her line manager and has had an insight into the leadership and management aspect of infection prevention and control and feels she has the qualities to be able to effectively deal with the challenges that this role presents.

Zara's current post is multifaceted, but her main responsibilities are responding to specific laboratory diagnosed infections; contributing to outbreak management; undertaking audit and surveillance; and the development and implementation of infection prevention and control education to multidisciplinary healthcare workers. Since Zara has been considering progressing her career, she has become increasingly conscious that whilst she has the fundamental knowledge, skills and competence to do some of the work undertaken by an advanced level practitioner, such as using some improvement methodologies – competence 4 – and using surveillance data – competence 2), there are broader aspects of the role that would be very challenging for her at the moment without further development.

One of the competences that Zara has identified as currently challenging is competence 5 related to advising on the design, construction and modification of facilities, because this aspect of the role has been predominantly dealt with by her line manager. Zara assessed herself against competence 5 and also asked for feedback from her line manager, Sam. Their initial assessments are shown in Box 5.

Conclusions on Zara's learning needs in relation to this competence

Zara and Sam agreed that Zara's main learning needs in relation to this competence are initially in the knowledge, understanding and skills area, ie

- Legislation, national guidance and outcomes/indicators relating to the design, construction and modification of the built environment in general and health and social-care facilities in particular (for example, ventilation, water sources, waste management, and hygiene)
- Organisational strategy for new builds, refurbishments, planned programme maintenance
- Interpretation of architects', estates' and facilities' plans for new builds, refurbishment and modification
- And the application of these to practice.

To meet these learning needs, Zara and Sam identified the following learning activities for Zara to undertake (see Box 6).

When Zara had undertaken the planned learning activities, she would provide appropriate evidence to her manager to demonstrate her developing competence. There would then be a need for her and her manager to review progress, address further learning needs, and for her to re-assess herself against the competences.

Box 5

5 Advise on the design, construction and modification of facilities to prevent and control infection in the built environment	**Zara's self-assessment**	**Sam's feedback**
Performance indicators		
1 Work with others on plans for the design, construction and modification of facilities to improve safety and quality through infection prevention and control	(1) I am used to working with people in healthcare teams and think I do this well, but have no experience of working with architects, surveyors etc. Similarly I definitely have learning needs in relation to knowledge of building regulations and the application of IPC principles to design and construction.	One of your skills, Zara, is working effectively with others and I have seen you do this with many different people including senior managers without a healthcare background. I agree your main learning needs to be developed around building guidance, regulations and legislation and who the key members of the team are. This will also allow you to see how the infection prevention and control strategy aligns with this type of work.
2 Advise on the infection prevention and control risk assessment criteria prior to a new build and in advance of any demolition or modification of a building consistent with current building guidance and legislation	(2) Are the IPC risk assessment criteria the same for construction as I realise that I'm not sure and would need to confirm this? I also don't know about building guidance and legislation!	The IPC risk assessment criteria that you need to look further into is around the assessment of proposed sites for the development of a healthcare facility; the design and planning stages; the construction and refurbishment stages and ongoing maintenance issues
3 Liaise with key health and social-care staff and others prior to and at every subsequent stage of the build, demolition or modification to ensure that infection prevention and control advice is effectively incorporated into the works	(3) Think I might be okay on this one as long as I can understand building plans, legislation etc!	
4 Work in partnership with key health and social-care staff to reduce the risk of infection to individuals, populations, staff and others during construction, demolition or modification activities	(4) Again this seems to build on my fundamental learning needs identified above.	
5 On the completion of the works, review with individuals, populations, staff and others the effectiveness of the development for preventing and controlling infection.	(5) Ditto	
Knowledge, understanding and skills		
a Applied microbiology in relation to the chain of infection and the infection process, alert micro-organisms and conditions, body defence mechanisms	(a) – (c) this is one of my strengths in relation to this competence I think	Agree with this assessment Zara. The major learning needs are in relation to the aspects identified in (d) – (f). I note your concerns about (f) – I had the same worries when I started my development in this area – but with the right support I am sure you have the ability to develop your knowledge and skills in this area.

Box 5 — Continued

b The significance of microbiological results, interpreting the diagnostic laboratory results; practices designed to break the chain of infection – for example, standard and transmission-based precautions including the placement of individuals and populations within care settings

c Antimicrobial stewardship – prudent prescribing of antimicrobials and the surveillance of antimicrobial resistant organisms

d Legislation, national guidance and outcomes/indicators relating to the design, construction and modification of the built environment in general and health and social-care facilities in particular (for example, ventilation, water sources, waste management, hygiene)

e Organisational strategy for new builds, refurbishments, planned programme maintenance

f Interpretation of architects', estates' and facilities' plans for new builds, refurbishment and modification

(d) – (f) and here are my weaknesses, I really don't know where to start on these except for the basic knowledge I have already related to the above such as in relation to hygiene and waste management. But there are the broader aspects and the link of this into building design etc. (f) is a definite learning need which I am worried about as I don't have much confidence in interpreting plans etc.

Box 6

Learning needs	Learning and development activities	Actions and timescale
1 Legislation, national guidance and outcomes/indicators relating to the design, construction and modification of the built environment in general and health and social-care facilities in particular (for example, ventilation, water sources, waste management, hygiene)	These three learning needs are inter-linked. It is not a particularly easy area on which to find learning programmes in the local area as it is so specialised and only attracts fairly small numbers. The following possible activities have been identified: • An accredited online e-learning module • Book(s) and journal articles • Locate resources available from the Infection Prevention Society website and communicate with members on their online discussion forum • Locate resources available from the Infection Prevention Society website and communicate with members on their online discussion forum • Tutorial help from the architectural postgraduate student on placement in the organisation helping them meet their development opportunities as well?	1 Zara to find out about available e-learning packages asap as this seems to be the ideal possible starting point. 2 Sam to find references to the books used in own development for Zara to access from the library 3 Zara to look on the Infection Prevention Society website and discussion forum and contact relevant members or committees for their help and possible support. 4 Zara to do a literature search and look for relevant books in the library 5 Sam to make contact with the line manager of the student to explore possibility – end of next month's planned strategy meeting best time probably as can raise informally. 6 Aim is for Zara to have completed development in relation to these learning needs within 6 months
2 Organisational strategy for new builds, refurbishments, planned programme maintenance 3 Interpretation of architects', estates' and facilities' plans for new builds, refurbishment and modification 4 And the application of these to practice	• Opportunities for shadowing colleagues in relation to the planned refurbishment for the local podiatry clinic and the new build day surgery unit? • Talk to colleagues outwith own clinical setting to gain further insight into specific issues and challenges that others have faced and addressed	Structured shadowing in this area to follow development activities above. Sam also to consider whether possible for Zara to attend one or more planning meetings for the refurbishment of the podiatry clinic and planning stages of the new build for the day surgery unit.

15. Websites for additional information

- Association for Professionals in Infection Control and Epidemiology: http://www.apic.org
- Code of Practice for the Assurance of Academic Quality and Standards in Higher Education: http://www.qaa.ac.uk/academicinfrastructure/codeofpractice/default.asp
- Community and Hospital Infection Control Association – Canada: http://www.chica.org/
- Department of Health, Social Services and Public Safety: http://www.dhsspsni.gov.uk/
- Department of Health, England: http://www.dh.gov.uk/en/index.htm
- European Centre for Disease Prevention and Control: http://www.ecdc.europa.eu/en/Pages/home.aspx
- Health Protection Agency: http://www.hpa.org.uk/
- Health Protection Scotland: http://www.hps.scot.nhs.uk/
- Infection Prevention Society: http://www.ips.uk.net/
- Institute for Healthcare Improvement (IHI): http://www.ihi.org/IHI/
- International Federation of Infection Control: http://www.theific.org/
- National Patient Safety Agency: http://www.npsa.nhs.uk/
- National Patient Safety Foundation: http://www.npsf.org/
- NHS Institute for Innovation and Improvement: http://www.institute.nhs.uk/
- Patient Safety First Campaign: http://www.patientsafetyfirst.nhs.uk/
- Royal College of Nursing: http://www.rcn.org.uk/
- Scottish Credit and Qualifications Framework: http://www.scqf.org.uk/
- Skills for Health: http://www.skillsforhealth.org.uk/
- The NHS Knowledge and Skills Framework (NHS KSF): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4090843
- The Scottish Government: http://www.scotland.gov.uk/Topics/Health
- Webber Training: http://webbertraining.com/teleclassesc1.php
- Welsh Assembly Government: http://wales.gov.uk/topics/health/?lang=en
- World Health Organization: http://www.who.int/en/

16. Glossary

Aetiology
Study of causes or origins.

Alert organisms
A set of pathogens that are considered to be indicators of real or potential infections.

Antimicrobial stewardship
Multifaceted approach to preventing the emergence of antimicrobial resistance including the prudent prescribing of antimicrobial agents, surveillance of antimicrobial-resistant organisms, audit, monitoring and education.

Career framework for health
The purpose of career frameworks is both to help individuals plan their development routes and organisations develop a flexible workforce to meet current and future needs. The NHS Career Framework consists of nine different levels from level 1 initial entry-level jobs to more senior staff at level 9. Skills for Health show pathways through the NHS Career Framework through the use of competences.

Clinical audit
A quality-improvement process that seeks to improve patient care outcomes through systematic review of care against explicit criteria and the implementation of change.

Commissioning
The process of meeting needs at a strategic level for whole groups of service users and/or whole populations, and of developing policy directions, service models and the market, to meet those needs in the most appropriate and cost-effective way.

Competences
There are different forms of competences such as: those that focus on the underlying characteristics or attributes of an individual; the learning outcomes that individuals need to achieve at the end of a programme of education and training; or the outcomes that individuals need to achieve in a particular field of activity such as work. These competences use the latter concept describing the outcomes that individuals need to achieve at work, specifically the work associated with an advanced level of practice in infection prevention and control.

Competent
Broadly, this can be seen as the ability to perform to a standard through applying knowledge, skills and attributes.

Critical analysis skills
The ability to make expert judgements to inform infection prevention and control processes.

Decontamination
A combination of processes, including cleaning, disinfection and/or sterilisation used to achieve decontamination of the environment and equipment, and to make reusable surgical instruments safe for further use. The term also applies to hand hygiene.

Emerging infections
Those organisms that have been newly identified as a potential threat, usually to humans, but can be related to birds, animals, plants or the environment.

Epidemiology
The study of the distribution and determinants of disease and their impact upon a population.

Horizon scanning
Looking ahead to systematically examine potential threats, challenges, opportunities and likely future developments, through critical thinking and planning.

Leadership quality framework
This framework profiles the characteristics of leadership and the effective behaviours and qualities that can enable successful leadership to take place.

Learning culture
A set of attitudes, values and practices to support the process of continuous learning in an organisation.

National occupational standards
National Occupational Standards (NOS) describe performance as outcomes of a person's work. They focus on what the person needs to be able to do, as well as what they must know and understand to work effectively.

NHS Knowledge and Skills Framework
The NHS Knowledge and Skills Framework (the NHS KSF) defines and describes the knowledge and skills that NHS staff need to apply in

their work in order to deliver quality services. It provides a single, consistent, comprehensive and explicit framework on which to base review and development for all staff. The NHS KSF and its associated development review process lie at the heart of the career and pay progression strand of Agenda for Change and it applies across all of the NHS in the UK for all staff groups who come under the Agenda for Change Agreement

Qualitative research
Qualitative research is the study of things in their natural settings in order to make sense of phenomena in terms of the meanings people bring to them.

Quantitative research
Quantitative research uses scientific method and generates numerical data in order to test hypotheses and establish causal relationships between two or more variables, using statistical methods to test the strength and significance of the relationships.

Surveillance
The ongoing, systematic collection and analysis of data about a disease or organism that can lead to action being taken to control or prevent the disease.

17. Competency Steering Group

Ros Moore	Chief Nursing Officer, Scotland (Chair)
Emma Burnett	Lead Co-ordinator Infection Prevention Society Education and Professional Development Committee
Daniel Crosariol	Department of Health
Catherine Deakin	Council of Deans
Carol Fraser	Scottish Government Health Department
Carole Fry	Department of Health
Tracey Gauci	Welsh Assembly Government
Rozila Horton	Infection Prevention Society Education and Professional Development Committee Deputy Co-ordinator
Richard Leigh	Department of Health
Lindsay Mitchell	Prime R&D Ltd
Anne Mills	Department of Health, Social Services and Public Safety Northern Ireland
Jacqui Reilly	Health Protection Scotland
Yvonne Robertson	Department of Health
Alison Strode	Skills for Health
Margaret Tannahill	Infection Prevention Society Education and Professional Development Committee Member

Administrative

Lynne Duncan	Secretariat, PA to the IPS Board

Funding
The competency development was funded by the Department of Health.

Acknowledgements
Prof. Janice Stevens CBE Department of Health

Infection Prevention Society

Tracey Cooper	President of the Infection Prevention Society

The Board and Members of the Infection Prevention Society

Education and Professional Development Committee

Jean Lawrence	Committee Secretary
Maria Bennallick	Committee Member
Angela Richards	Committee Member
Sarah Murdoch	Committee Member

All the individuals and organisations that have provided feedback and advice on the development of the competences at variousstages.

References

Department of Health (2002) NHS Leadership Qualities Framework. Available at: see http://www.nhsleadershipqualities.nhs.uk/ (accessed 12 January 2011).

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Department of Health (2010) Advanced level nursing: a position statement. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121739 (accessed 12 January 2011).

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Scottish Government (2008) *Supporting the development of advanced nursing practice*. Scottish Government: Edinburgh. Available at: http://www.aanpe.org/LinkClick.aspx?fileticket=giFsLijsCRw%3D&tabid=1051&mid=2508&language=en-US (accessed 12 January 2011).

Skills for Health (2010) Key elements of the career framework. Available at: http://www.skillsforhealth.org.uk/workforce-design-development/workforce-design-and-planning/tools-and-methodologies/~/media/Resource-Library/PDF/Career_framework_key_elements.ashx (accessed 12 January 2011).

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)
Sent: 05 August 2019 14:21
To: STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND)
Subject: Fwd: In confidence:FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Sensitivity: Confidential

Sent from my iPhone

Begin forwarded message:

From: "Guthrie, Lindsay" [redacted]
Date: 5 August 2019 at 13:14:18 BST
To: "'RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)'" [redacted]
Subject: In confidence:FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Annette
This email chain relates to a difference of opinion about the 'involvement' of IPCT in the project and hand over as part of settlement.

I had advised that IPCT had not completed the stage 4 SCRIBE at the time of settlement, or indeed at March 2019 – Fiona summarised that discussion and our position at the time. This is subsequent email trail.

Regards
Lindsay

From: Guthrie, Lindsay
Sent: 18 March 2019 09:47
To: Little, Kerryann; Inverarity, Donald
Cc: Cameron, Fiona; Sutherland, Sarah; Pennykid, Jennifer
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Sensitivity: Confidential

Yes that will be ok for me
Lindsay

From: Little, Kerryann
Sent: 18 March 2019 09:34
To: Inverarity, Donald
Cc: Guthrie, Lindsay; Cameron, Fiona; Sutherland, Sarah; Pennykid, Jennifer
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High
Sensitivity: Confidential

Thanks Donald

I have discussed with Alex. Alex has suggested Wednesday 20th March at 1130.

I have copied this email to Lindsay, Fiona and Sarah so they can also confirm if they can attend.

Thanks
Kal

Kerryann Little
PA to Professor Alex McMahon
Executive Director, Nursing, Midwifery and AHPs
Executive Lead for REAS and Prison Healthcare
NHS Lothian|2 - 4 Waterloo Place|Edinburgh|EH1 3EG|[redacted]

From: McMahon, Alex
Sent: 18 March 2019 09:28
To: Little, Kerryann
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Sensitivity: Confidential

Could we do later on Wed? Say the afternoon?

Professor Alex McMahon
Executive Director, Nursing, Midwifery and Allied Healthcare Professionals
Executive Lead, REAS and Prison Healthcare
NHS Lothian
[redacted]

From: Little, Kerryann
Sent: 18 March 2019 09:26
To: McMahon, Alex
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Sensitivity: Confidential

Hi Alex

See below from Donald – Do you want me to organise this for another dates/time. Finding 2 hours in your diary soon is going to prove tricky!

Thanks
Kal

Kerryann Little
PA to Professor Alex McMahon
Executive Director, Nursing, Midwifery and AHPs
Executive Lead for REAS and Prison Healthcare
NHS Lothian|2 - 4 Waterloo Place|Edinburgh|EH1 3EG|[redacted]

From: Inverarity, Donald
Sent: 15 March 2019 16:03
To: Little, Kerryann
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Sensitivity: Confidential

Hi Kal,
Probably at 9am but there is an Incident Management Team Meeting being chaired by Public Health at 11am about an issue at a community dental practice that I need to participate in and 2 hours may not be long enough for the walk round of the whole building. We would also need the input of Sarah Sutherland and Lindsay Guthrie (or deputy) from the Infection Control Nurses.
Thanks
Donald

From: Little, Kerryann
Sent: 15 March 2019 15:50
To: Inverarity, Donald
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Sensitivity: Confidential

Hi Donald

Following on from below, would you be able to do a walk round with Alex on Wednesday 20th March @ 0900am?

Thanks
Kal

Kerryann Little
PA to Professor Alex McMahon
Executive Director, Nursing, Midwifery and AHPs
Executive Lead for REAS and Prison Healthcare
NHS Lothian|2 - 4 Waterloo Place|Edinburgh|EH1 3EG|[redacted]

From: McMahon, Alex
Sent: 15 March 2019 15:48
To: Little, Kerryann
Subject: Re: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Sensitivity: Confidential

Could we look at next Wed morning if I don't do the budget sign off?

Sent from my BlackBerry 10 smartphone on the EE network.

From: Little, Kerryann
Sent: Friday, 15 March 2019 3:41 PM
To: McMahon, Alex
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Hi Alex

How quickly do you need this?

Thanks

Kal

Kerryann Little
PA to Professor Alex McMahon
Executive Director, Nursing, Midwifery and AHPs
Executive Lead for REAS and Prison Healthcare
NHS Lothian|2 - 4 Waterloo Place|Edinburgh|EH1 3EG|[redacted]

From: McMahon, Alex
Sent: 15 March 2019 15:40
To: Inverarity, Donald
Cc: Little, Kerryann
Subject: Re: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP KAL TO ORGANISE
Sensitivity: Confidential

Thank you. It's all a bit of an education for me but I agree a wak around with the 'interested ' parties would help being us all to hopefully an agreed place. Will get set up.

KAL can we pick up on Monday please.

Sent from my BlackBerry 10 smartphone on the EE network.

From: Inverarity, Donald
Sent: Friday, 15 March 2019 3:34 PM
To: McMahon, Alex
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Dear Alex,
Thanks for letting me see this.
The pdf attachment relates primarily to the decisions around the design of the building and its ventilation. Janette Rae (Richards) was heavily involved in that planning and design process as outlined by Brian. She did often contact me for my advice when she had questions about the design or ventilation when she required another opinion and I think we all agree there was active involvement by the Infection Control team in the design and planning process.
With regards to point 2 about water quality for clarity my comment that there was no further communication had been there was no further communication after receiving the e-mail from Ronnie (which was the one I had sent you). Perhaps I could have been clearer in that email that the person best placed to answer the question, "whether the presence of Psedomonas species is an indicator of future risk of Pseudomonas Aeuriginosa" is the Authorising Engineer for Water and not me as infection control doctor/medical microbiologist as it is a question about water and environmental microbiology and that strictly is not part of my training as a medical microbiologist. I had suggested contacting Alan Hambridge to answer that particular question as I believed he was still the NHS Lothian Authorising Engineer for Water. Alan replied to Ronnie promptly on 21st Feb to advise that he was no longer contracted by NHS Lothian to provide such advice. At that point I was no longer included in any e-mail communication regarding how this had been resolved. (Having met John Bryson at the DCN IMT on Wednesday I believe he and Westfield Caledonian were then involved.) So that is the context of the comment that there was "no further communication." It is reassuring from Brian's e-mail that corrective work seems to have currently dealt with the Legionella water contamination issues but I still don't know where in the building they occurred. I was told they were not in an augmented care area but I had been hoping for more specific information about the location(s) to be able to assess the clinical risk once the building is occupied.

Regarding point 3 about windows in the isolation rooms not being able to open. I'm very pleased if that's no longer the case but the room Ewan, Lindsay and myself were shown had a window that opened when we were there in December 2018 and it wasn't in a lobby but the actual patient room.

Regarding theatre ventilation validation Point 4. I'm glad there is an independent validation of these results although when the new theatres were commissioned at SJH in 2017 we were issued with a clear validation report that assured us all was well and functional (attached as an example of the sort of document we were hoping to receive). This is in line with SHTM 03-01 where it states the IPCT can legitimately request the validation report when a theatre is commissioned. I've pasted the relevant section from SHTM 03-01 below:

Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:

- the user department;
- infection control (where required);
- estates and facilities.

I've spoken with Sarah Sutherland this afternoon and both of us would welcome the opportunity to assist with a walk round as news that the commissioning was complete and the building was now accepted by NHS Lothian had been a surprise to us both.

Best wishes
Donald

From: McMahon, Alex
Sent: 15 March 2019 12:33
To: Inverarity, Donald
Subject: Fw: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High
Sensitivity: Confidential

Donald, just sending all for ease of communicating. Do you want to read and then we can agree how best to square the circle on getting is all agreed on our position.

Alex

Sent from my BlackBerry 10 smartphone on the EE network.

From: Goldsmith, Susan [redacted]
Sent: Thursday, 14 March 2019 2:40 PM
To: McMahon, Alex; Gillies, Tracey
Cc: Crombie, Jim
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Alex/Tracey

Response from Brian, clearly some frustration (sorry!), but happy to follow up as required. As will Brian be

Susan

From: Currie, Brian [redacted]
Sent: 14 March 2019 13:30
To: Goldsmith, Susan [redacted]
Cc: Crombie, Jim [redacted]
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Importance: High
Sensitivity: Confidential

Susan

Thanks for passing on further correspondence from Alex and Donald Inverarity.

I respond to various points contained in numerous recent emails as follows:

1 Infection Control involvement in the project

I reiterate my email of 12/03/19 at 8.06 and 12/03/19 at 10.09 with further clarification in yellow:

On further reading of the chain of emails from Lindsay Guthrie to Alex can we just advise that Sarah Jane Sutherland, Lead HAI Scribe Advisor, and IPCN Emma Collett last visited the project on Monday 28th January, 2019 at 9.15am.

The purpose of this visit was to reassure Sarah Jane that Janette (recently retired HAI Scribe advisor) was fully involved in the room review process and in anticipation of an imminent completion or handover of the facility. Janette was provided with the timetable for our first and second round of reviews and she chose which ones she wanted to attend. To ensure a consistent approach was taken to the reviews a checklist of what to look at was developed, which was discussed with Janette. The project team have been consistently checking that previous observations made by them have been addressed and to identify any further observations that have occurred since the 2nd room reviews though to completion.

A further meeting on 27th February with one of the project's Commissioning Managers also took place to review previous documentation signed off by Janette Richards.
However, it is accepted that given the uncertainty of the actual completion date, to almost the day before it occurred, ICPT were not involved in the actual day of completion. It is worth emphasising that patients will not occupy the facility until 9th July, 2019. It is our intention to carry out a pre handover check when all construction activity by IHSL/MPX completes in June.

We can confirm that the Board's Infection Control have been involved from the early stages in the project including competitive dialogue, evaluation of some parts of the submission; actively contributing with the clinical teams to the clinical area design development and approval process reviewing relevant specifications for items such as sanitary ware, flooring, vent coverings etc.

We have been fortunate in that there has always been a nominated IPCN for Reprovision and they have been an integral part of the process participating in key meetings and, if they could not be present at meetings, taking the opportunity to

comment on meeting outputs where required and following up on issues in consultation with project and other clinical staff.

Throughout each of the stages of the project they have provided expert advice on elements such as isolation room design and functionality, room ventilation design, and HAI Scribe.

They have also joined project team personnel in reviewing the rooms for adherence to design brief, quality of finish and functionality, (including ease of cleaning and compliance with SHTM ~~and HEI guidance~~) and advised us on aspects of the building that they felt HEI inspectorate may consider during any future inspections.

2 Water Quality

Before updating you on the current water quality status on site we are at a loss to understand Donald's comment that "there was no further communication". The email attached to Donald's email is clearly a response (text in red) from our Hard FM Commissioning Manager. Indeed, we have still to receive a response to our request from Donald on whether the presence of Psedomonas species is an indicator of future risk of Pseudomonas Aeuriginosa

Current update is that all test results from latest full batch of sampling have come back clear for Legionella. Pseudomonas positives were found in 2 of 14 samples with elevated TVC counts, this from a total sample of 115. Further disinfection has taken place and the 14 elevated TVC locations will be re-sampled with results due by 20/03/19, until such times as these come back clear MPX are continuing with their responsibilities for water safety management. Further sampling will be carried out by Bouygues in the next 2 weeks once the current batch are all confirmed as clear and in addition there will be a further round of sampling at a time to be agreed prior to full operation. In the intervening period between the last two sampling exercises, Bouygues will implement a robust water management system involving flushing of little used outlets as per the positive obligation in the settlement agreement. It will be for the NHSL water safety management group to decide if this is enough reassurance as it complies with SHTM 04-01.

3 Ventilation to Isolation Rooms

All windows to isolation rooms and their lobbies are fixed pane windows (they do not open) except lobby 1-B1-033 which has been reported as a defect. I suspect Donald viewed room 1-B1-068 where works to correct an earlier identified defect were incomplete, this has now been resolved.

4 Theatre Ventilation Validation

Theatre ventilation commissioning, include cascade and UCV validation took place between October 2018 and February 2019 and all certificates and reports have been examined and verified by Arcadis as Independent Tester. These are available on the project data storage system 'Zutec'. These have however been rendered void by the agreed post completion works to enhance fire safety across the site and will be fully re tested and validated which will be witnessed by NHSL and the Independent Tester once these works are complete. In the meantime the information on the system can be reviewed by ICD and IPC at any time to ensure they meet their requirements. MPX will carry out air sampling on completion of their builders clean

and prior to NHSL equipping the area. It is assumed IPC will wish to repeat this prior to theatres becoming fully operational.

5 Sub optimal Air Exchange Rates in clinical areas

During the review of the environmental matrix it was identified that air exchange rates within the single and 4 bedded rooms did not meet the recommendations of SHTM 03-01. Risk assessments were carried out and discussed with infection control staff (sample attached). A workable solution has been implemented which includes mixed mode ventilation where natural ventilation provides the difference between 4 and 6 ac/hr.

6 Consequences of water damage event

The project's Clinical Director and a Commissioning Manager toured the Facility on 5th July, 2019 with Janette Richards, Dr Pota Kalima and MPX and the remedial and reinstatement process proposed by IHSL/MPX was accepted in addressing the departments that were affected by the water damage. Donald's recommendation, in his email of 25/07/2018 to the project's Clinical Director that a building survey using a moisture meter to assess dryness of walls should be undertaken at the appropriate time will be undertaken. We assume the outcome of such a survey would suffice in providing the reassurance being sought by Fiona. To the best of our knowledge, and we believe also the Independent Tester's, all materials and systems damaged by water have been replaced.

We hope this clarifies the communications with Infection Control to date but needless to say we would welcome a walk round by Donald and members of the IPCT at any time as suggested by Alex.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Goldsmith, Susan
Sent: 13 March 2019 17:10
To: Currie, Brian
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP

Importance: High
Sensitivity: Confidential

Brian as discussed!

Thanks Susan

From: McMahon, Alex [redacted]
Sent: 13 March 2019 16:19
To: Crombie, Jim [redacted]; Goldsmith, Susan [redacted] Gillies, Tracey [redacted]
Cc: Inverarity, Donald [redacted]
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Importance: High
Sensitivity: Confidential

All

I caught up with Donald after the DCN IMT. He said he would send me this email and I have his permission to forward on. For transparency I have copied Donald in.

The content gives me some cause for concern. Jim and Tracey can we take the opportunity to discuss this with Donald tomorrow afternoon. I know Jim you and I are meeting others at 4 but I think if we can take 5 mins just for a quick discussion that would be helpful.

In the meantime happy to take thoughts but one action we I am going to instruct is that Donald and members of the IPCT do a walk around of the whole building with the appropriate personnel.

Donald asks for sight of reports as set out below, Jim/Susan can we make these available as well.

Alex

From: Inverarity, Donald
Sent: 13 March 2019 15:37
To: McMahon, Alex
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Sensitivity: Confidential

Dear Alex,
Following our discussion after the DCN IMT today, I'd like to raise a further issue that relates to water quality and ventilation in the new hospital site.
Please see the (confidential) e-mail dialogue attached which was sent to me by the commissioning team in the week before the building was handed over to NHS Lothian. It was highlighted that there were concerns about Pseudomonas aeruginosa and more concerningly Legionella in the water. Despite replying expressing concern particularly over the finding of Legionella, there was no further communication with me about the issue. I don't know where in the building this was found and I don't know what corrective action is/has been taken. Consequently it is not possible to risk assess whether there is a clinical risk to immunocompromised patients when they occupy the building without knowing if there are water issues in the clinical areas where such patients will be managed. Even if they have been addressed and corrected by the time patients are admitted later in the year, they would still count as higher risk areas that would deserve more scrutiny to ensure the level of Legionella remains low and would present a persisting clinical risk if in a clinical area.
I also mentioned to you the paediatric isolation rooms which are designed as positive pressure ultraclean rooms with HEPA filtered air and yet the windows open to the outside unfiltered

Edinburgh air defeating the purpose of the room. I don't know if any corrective action has taken place regarding this design flaw which was identified by Lindsay, Ewan Olsen and myself when we were invited to review the design of the room and its ventilation pre handover.
Although given assurances that pre hand over there would be validation performed on all theatre ventilation, as ICD I've never seen any of these validation reports and neither have any of my consultant microbiologist colleagues albeit we were given a tour of the ventilation system and theatres as they were being built.
All the best
Donald

From: Cameron, Fiona
Sent: 12 March 2019 12:25
To: Currie, Brian
Cc: McMahon, Alex; Guthrie, Lindsay; Inverarity, Donald
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP

Brian

Alex sent on your email I am unsure what HEI guidance you are referring to. Healthcare Environment Inspectorate do not have standards for buildings. I can confirm any reviews, recommendations IPC made would be in alignment with the SHTM guidance by HFS for building works. I agree we did have involvement and a dedicate person i.e. our HAI SCRIBE lead involved. However as per communications with Alex IPC were not involved in handover as per SCRIBE guidance recommendations

I cannot reliably say if all our recommendations were accepted. I am aware as a result of the cancelled FOI there was discussion re air exchanges rates perhaps being suboptimal in clinical areas and we don't know what the outcome of that report was. The HAI SCRIBE documents or minutes of your project meetings should be able to confirm.

Another example IPCT can only assume the building engineer who accepted the building on behalf of NHS Lothian saw evidence of theatre validation See p114-124 of SHTM 03-01. IPC to the best of my knowledge have not seen a validation report (section 8.64-8.65 of SHTM 03-01). The validation/commissioning report should be a clearly understood document that outlines that the theatre is working optimally, not just engineering data, which allows us to have confidence in the efficiency of theatre ventilation and would go some way to provide the board with a level of assurance.

In addition not have we seen what evidence was provided to give NHS Lothian assurance that the consequences of the flood were fully addressed. Did the contractors provide assurance that all water damaged construction materials were replaced and there is no unnecessary residual damp material, particularly not in clinical areas. As previously advised by our ICD Dr Inverarity, damp building materials that are left in place to dry out over time are predisposed to growing moulds and fungus and that could take some time to show. The clinical risk that can result in depends on where the damp material is situated e.g. theatre or isolation room designed to protect patients from infection. Did the contractor provide a comprehensive assessment for residual damp in clinical areas or was this checked by an external authority to the contractor as I think was recommended by Dr Inverarity at the time.

Alex I have copied Lindsay and Donald as they may also wish to comment as Lead Nurse and Lead ICD

Fiona

Ms Fiona Cameron
Head of Service

NHS Lothian Infection Prevention & Control Services
[redacted]

For more information visit the IPCT IPCT Intranet Homepage

From: McMahon, Alex
Sent: 12 March 2019 08:08
To: Cameron, Fiona
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Importance: High

Professor Alex McMahon
Executive Director, Nursing, Midwifery and Allied Healthcare Professionals
Executive Lead, REAS and Prison Healthcare
NHS Lothian
[redacted]

From: Currie, Brian
Sent: 12 March 2019 08:06
To: Goldsmith, Susan; McMahon, Alex
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Importance: High

Susan / Alex

FYI - see below.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 16:45
To: Currie, Brian
Cc: Crombie, Jim; Graham, Iain
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP

Thanks Brian – this is very helpful and much appreciated.
Regards
Judith

From: Currie, Brian [redacted]
Sent: 11 March 2019 16:43
To: MACKAY, Judith (NHS LOTHIAN)
Cc: CROMBIE, James (NHS LOTHIAN); iain.graham [redacted]
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH-RHCYP
Importance: High

Judith

Hopefully the following will be useful:

Infection Control

We can confirm that the Board's Infection Control have been involved from the early stages in the project including competitive dialogue, evaluation of some parts of the submission; actively contributing with the clinical teams to the clinical area design development and approval process reviewing relevant specifications for items such as sanitary ware, flooring, vent coverings etc.

We have been fortunate in that there has always been a nominated IPCN for Reprovision and they have been an integral part of the process participating in key meetings and, if they could not be present at meetings, taking the opportunity to comment on meeting outputs where required and following up on issues in consultation with project and other clinical staff.

Throughout each of the stages of the project they have provided expert advice on elements such as isolation room design and functionality, room ventilation design, and HAI Scribe.

They have also joined project team personnel in reviewing the rooms for adherence to design brief, quality of finish and functionality, (including ease of cleaning and compliance with SHTM and HEI guidance).

Let me know if you need more on HAI Scribe and contractual obligations.

Ventilation

Through witnessing of commissioning activities we can verify that the correct grade of filters are installed in the various air handling units and the ductwork is designed in accordance with relevant guidance. Regular inspections are carried out and alarm monitoring also occurs via the building management system and warns of deteriorating filter conditions.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 14:53
To: Currie, Brian
Subject: RE: Infection control- RHCYP

Thanks Brian.

From: Currie, Brian [redacted]
Sent: 11 March 2019 10:14
To: MACKAY, Judith (NHS LOTHIAN)
Cc: iain.graham[redacted]; fiona.cameron[redacted]
Subject: RE: Infection control- RHCYP
Importance: High

Judith

We will summarise what involvement Infection Control have had in the project to date, how HAI Scribe works and contractual obligations in terms of infection control standards.

The specific ventilation issues raised at Glasgow will also be responded to in relation to this project as I said earlier.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 09:27
To: Currie, Brian
Cc: Graham, Iain; Cameron, Fiona
Subject: RE: Infection control- RHCYP

Hi again Brian,
Most of this details the standard daily infection control measures we would expect to operate once the building is open. Presumably we can say the building has been built to industry standards (and that's a start) but I would expect the QEUH could have done the same?

If (and I do mean; if) our own infection control team was not involved specifically, then :

- is there something explicit in the contract that gives us assurance that the building was designed to satisfy all latest infection control standards?
- Retrospectively, do we know it doesn't have the same design weaknesses (in ventilation duct design and safety alarms) that is the issue with QEUH?

On that first point , there's been reference to the HAI Scribe but I don't know what (or who??!) the scribe is. Not looking for the contract – just a means by which we can describe in layperson's terms how we derive assurance that the design takes account of infection control requirements.

Thanks!

Judith

Judith Mackay
Director of Communications, Engagement and Public Affairs | NHS Lothian
[redacted]

From: Currie, Brian [redacted]
Sent: 11 March 2019 08:09
To: MACKAY, Judith (NHS LOTHIAN); iain.graham[redacted]
Cc: CROMBIE, James (NHS LOTHIAN)
Subject: RE: Infection control- RHCYP
Importance: High

Judith

Please see a draft MS Word version and final letter recently sent to Miles Briggs which should deal with the majority of questions on Infection Control.

In terms of the specific ventilation issues we will get back to you asap.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 07:39
To: Currie, Brian; Graham, Iain
Cc: Crombie, Jim
Subject: Infection control- RHCYP

Morning all,

I anticipate questions from media today about the formal involvement of Infection Control expertise in the design of RHCYP / DCN in the wake of criticisms about the apparent lack of documented evidence of their involvement in the design / commissioning / handover of QEUH.

Please see this piece from yesterday's Sunday Herald.

https://www.heraldscotland.com/news/17489840.50m-repair-bill-for-glasgows-troubled-queen-elizabeth-university-hospital/

Can we state categorically that Infection Prevention and Control Team were fully and formally (in a governance sense) involved in the commissioning or handover process of RHCYP/DCN?

We are also likely to be asked explicitly if we know / have assurance that the design does not suffer from the same ventilation duct / safety alarm weaknesses as QEUH.

Since these were 2 of the issues that led to some delay late last year am I correct in thinking we were are satisfied RHCYP does not share same design issues on those counts?

Thanks for your help with this,

Regards

Judith

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From: Calder, Marion on behalf of Curley, George
Sent: 25 February 2019 16:13
To: Inverarity, Donald; Curley, George
Cc: Douglas, Brian
Subject: RE: Glasgow report on water incident at QEUH
Attachments: Healthcare Governance Committee Briefing on Water Quality and Pest Control.docx

Hi Donald

Please see attached , this is not for further circulation at this time.
Kind regards
MArion
From: Inverarity, Donald
Sent: 25 February 2019 15:46
To: Curley, George
Cc: Douglas, Brian
Subject: RE: Glasgow report on water incident at QEUH

Hi George,
I forwarded the QEUH report link earlier today to Lindsay and Fiona so I can confirm they have it. I've not yet received your report for Clinical Governance from Marion but I'm happy to read through it once received.
All the best
Donald

From: Curley, George
Sent: 25 February 2019 15:40
To: Inverarity, Donald
Cc: Douglas, Brian
Subject: Re: Glasgow report on water incident at QEUH

Hi Donald, yes I have and again many of our proposals in the paper I sent you are based on the Glasgow experience. I was a little hesitant in the paper to sight Glasgow directly but I guess you can assume it is strongly inferred. However good that Brian can review this report more fully rather than the potted summary I could share.

I do think it is important that this is discussed at the water quality group on the 4 th March and would be helpful in advance if Lindsay or Fiona are aware of the contents of this report. Possibly because it was conducted by HPS they are already aware.

It would also be helpful if Lindsay could attend, Brian do you wish to invite them along. I know we have good ICN representation but possibly needs more senior input.

Much appreciated George.

Sent from my iPad

On 25 Feb 2019, at 15:11, Inverarity, Donald [redacted] wrote:
Hi George/Brian,

I was alerted that Glasgow had released this on Friday.

https://www.gov.scot/binaries/content/documents/govscot/publications/factsheet/2019/02/qe-university-hospital-royal-hospital-children-water-incident/documents/queen-elizabeth-university-hospital-royal-hospital-for-chidren-water-contamination-incident-hps-report/queen-elizabeth-university-hospital-royal-hospital-for-chidren-water-contamination-incident-hps-report/govscot%3Adocument

I'm not sure if you've seen it via another route?
All the best
Donald

NHS LOTHIAN
Healthcare Governance Committee

12th March 2019

Jim Crombie

BRIEFING ON WATER QUALITY & PEST CONTROL ASSURANCE MEASURES

1 Purpose of the Report

1.1 This update is necessary to provide reassurance on the safety of our inpatient sites in light of recent Estates related matters within another Health Board. These issues have been linked to two patient deaths and also a number of blood stream related infections.

2 Recommendations

The Committee are asked to note the contents of this paper

2.1 Endorse this report as providing moderate assurance, evidence based on our governance, policy and procedures related to the management and to control of critical ventilation systems and Scottish Health Technical memorandum 03-01.

2.2 Endorse this report as providing moderate assurance on the operational management and control of our water quality systems. Evidence based on adherence to and congruence to our Policy and Procedures, and following guidance within Scottish Health Technical Memorandum (Water Quality) 04-01 and updated guidance from Health Protection Scotland.

2.3 Endorse this report as providing moderate assurance for the design, implementation and validation of new projects, reprovisions within Lothian and that these follow guidance contained within the Scottish Technical Health Guidance and involve necessary stakeholders direct support, Estates, Infection Control, Fire Liaison, Micro Biology, Professional Clinical Expertise, Capital Planning and Strategic Planning.

2.4 Endorse the proposal to move to new testing regimes as outlined within the HPS Guidance update pre-Christmas. Albeit we are yet unaware of total financial exposure of moving to a methodology of testing for legionella and pseudomonas in augmented patient groups. This position is supported by Facilities and infection Control Leads.

2.5 Endorse the proposal to request that NHS Lothian Laboratory Services investigate and fully cost out moving to an accredited water testing facility. Three months time scale.

2.6 Take responsibility for potential loss of activity in high pressure services, augmented patient groups. This as a result of introducing a testing regime that monitors samples for pseudomonas.

2.7 The group endorse that the Infection Control Lead and the Facilities Director monitor the implementation of this interim guidance over two cycles, (Water Safety Group) and a sustainable plan for this be developed for the longer term and full adoption of the guidance of the UK guidance HTM 04-01.

3 Discussion of Key Issues/Pest Related, Water Quality, Quality Project Delivery and Links to Hospital Acquired Infections

3.1 Two patients who died within another Scottish Health Board at the turn of the year showed they had contracted infections caused by inhaling the Cryptococcus Fungus, which can be found in pigeon droppings.

3.2 This Board has put forward a hypothesis that pigeons were able to access a ventilation plant room containing machinery within the hospital through a small hole in the wall, leading to harmful fungus/bacteria from their droppings entering the ventilation systems and being inadvertently distributed throughout clinical and non-clinical areas, and an area used by immune comprised patients. As yet the transmission route remains theoretical and not proven.

3.3 Birds such as pigeons can carry a variety of diseases such as Ornithosis, Listeria and E-coli that can be transmitted to humans not only from the droppings but also the birds themselves. Nesting can also be harmful encouraging mites, ticks, fleas, beetles, larvae and flies.

3.4 NHS Lothian may be less susceptible to causing such infections as it deploys a number of control measures including a professional pest control company (Excel Environmental) to manage and control bird and other pest infestations (captured in 3.7). The services provided include both planned inspections and ad-hoc visits. Currently they are inspecting our acute sites and thus far, have not escalated to Estates teams any adverse activity.

3.5 PFI(6)/HUBCO(5) type properties follow a similar model however the service is provided by a number of different companies, but do follow our protocols.

3.6 Estates have collaborated with Infection Control leads and can confirm in the past 26 months there have been no reports of incidents similar to that experienced elsewhere in the Scottish setting. This is not to say that we have had no Cryptococcus but not linked to a source of pest contamination within our inpatient environments.

3.7 NHS Lothian does have relevant experience in managing such an event. There were two incidents (Aug 2016 & Feb 2017) at the RIE PFI campus involving pigeon infestations which resulted in the temporary closure of three patient activity areas to facilitate remedial estates type actions and the performance of domestic services terminal cleans. There is no evidence to suggest that these incidents were a source of the infection. A problem solving group was established early on in the process, it had representation from Clinicians Infection Control, Estates and Microbiology. An action plan of mitigation measures was implemented and most of these measures now continue as good housekeeping, and the basis for our assessment of moderate assurance.

- All plant rooms to be secure and have adequate (authorised) access controls in place at all times.
- Plant rooms (particularly ventilation), ducts and attic spaces checked for any “bird or vermin” activity/evidence.
- Netting and anti-bird roosting/resting systems checked – effective and in place.
- Building/roof checks for openings/gulley’s/hones/air intake/ventilation grilles/chimneys/broken open windows/other – protection in place or required.
- Winter tanks – confirm tank covers fitted and secure plus vent/overflow screens fitted.
- Pest control professional/experts – further analysis of previous inspections/observations of “bird” activity – where there have been concerns requests immediate re-inspection.
- Additional bird prevention/proofing/control measures and recommendations re above report(s).
- Droppings if found – cleaned up appropriately.
- All critical ventilation systems to be inspected and maintained in line with SHTM 03-01: Ventilation in healthcare premises – as per existing schedules and method statements. (The RIE currently operates to SHTM 2025, which is being assessed for appropriateness)
- Standard Operating Procedures for the management of plant rooms are in place and being followed.
- IPCT, H&S & Facilities teams to establish regular review meetings to review the above actions and share examples of best practice.

- The above controls are in line with instructions for the Specialist Ventilation for Healthcare Society (SVHSoc) and Scottish Government. These arrangements are on a Pan Lothian requirement.

3.8 Our reviews and audits undertaken and the analysis of these help evidence and demonstrate reasonable control and the measures are appropriate.

3.9 Scottish Government, Mr Paul Gray has written to all Boards seeing assurance on certain aspects of maintenance, validation commissioning of water systems and more recently, on plant rooms checks and critical ventilation systems. Copies of these are attached within the Appendices along with our replies.

Water Quality

3.10 Further patients receiving treatment at this Health Board Hospital also presented with a number of blood stream infections. These infections appear to have links to known water borne contaminants, namely Cupriavidus pauculus, Pseudomonas, Aeruginosa positive and Stenotrophomonas maltophilia. These specific organisms were identified following review of high total viable counts (TVC) which is a general indicator of the potential presence of harmful organisms.

3.11 These high TVC values were observed at the commissioning stage and later on in the full operational phase 2015-2016. This facility is now subject to a very in-depth review to establish the cause and effect of these organisms within the water system. It will be some time before the outcome of this report is known. Recommendations will be of a National nature and will also contain local arrangements. However, the issue of how the system became contaminated is assumed to be regressional contamination and/or contamination at installation/commission in both hypotheses these rule out patient contract route.

3.12 Facilities have led on compiling this report to NHSL Executives to provide assurance on such a likelihood occurring within its estate. If comparing estates and functions, there is a risk (high) purely on comparison with those of this similar sized Board. However when considering Lothian's control measures and management arrangements, this would reduce to medium. Attached is briefing that outlines aspects of our policy and procedures that provide evidence to the "medium risk assessment" and moderate assurance on overall conformance.

3.13 In addition, this facility was built to SHTM 04-01 dated circa 2009. The SHTM 04-01 was reviewed and updated in 2015. In our own recent re-provision Facilities conform to this newer version which has been substantially updated.

3.14 Furthermore, NHS Lothian Water Quality Group is reviewing conformance to the most recent guidance for water quality and the UK guidance (HTM 04.01 published circa 2017). This is substantially more onerous than the current SHTM 04.01. Moving to this guidance will only improve our level of quality assurance on our water systems and will enhance safety to our most vulnerable patients.. This review is also considering the most recent guidance issued from Health Protection Scotland on sampling and testing for pseudomonas Aeruginosa in vulnerable client groups.

New Guidance

3.15 A number of serious healthcare associated outbreaks of Pseudomonas aeruginosa in augmented care units have been reported in the UK in recent years. The most notable, Belfast, where there were 4 deaths including neonates as a consequence of these infections. Further evidence can be provided on request as to specific incidents. There is evidence to show that these outbreaks are associated with contaminated water systems and components (e.g. flow straighteners, taps, sinks, drains, flexible hoses).

3.16 Health Protection Scotland (HPS) have issued interim guidance on the requirements for water testing in augmented care areas (i.e. Transplant units, Neonatal units, Haematology oncology units, critical and intensive care, renal units, respiratory units, Cystic fibrosis units). Compliance with the interim guidance is not mandatory, but is recognised as best practice.

3.17 The interim guidance advises that routine sampling should be undertaken every 6 months as a minimum to establish baseline levels and provide ongoing assurance of water quality and safety to the organisation. This paper recommends moving to these arrangements.

3.18 The interim guidance is consistent with guidance in Health Technical Memorandum 04-01 (HTM 04-01) and the approach taken in other UK countries and is consistent with our own preferred guidance route.

3.19 Scottish guidance for neonatal units (NNUs) (levels 1,2 &3), adult and paediatric intensive care units (ICUs) (2018) is due for review in 2019. It is anticipated that the revised guidance will reflect the requirements of HTM 04-01 in full.

3.20 HPS recognise that routine water sampling for *P. aeruginosa* in augmented care areas may require an assessment of the costs and impact across Scotland.

Next Steps:

3.21 The interim guidance and update to HTM04-01 will impact on a significant number of clinical areas in all NHS Lothian acute hospital sites. Specifically:

- WGH – Wards CAU,1, 3,4, 6, 8 & 8u, 11, 20, 54, 58, satellite renal dialysis unit and (Ward 33 HDU beds – pending move to RIE campus)
- RIE – Labour ward, Neonatal unit; wards 111, 112, 114, 115, 116, 117,118; 204, 205, 206, 206,215, Transplant; renal dialysis unit
- SJH – Labour ward, Neonatal unit, ITU, satellite renal dialysis unit, Burns unit; ward 21, 25, oncology day unit
- RHSC – ITU, HDU, Ward 1; Ward 2; Ward 6
- Once the new DCN and Children's hospital opens on the RIE campus, this list will need to be revised to reflect new clinical service configuration.
- NHS Lothian laboratories do not hold accreditation for water testing. This service, where required, is provided through an external accredited laboratory and is costly and we have to compete for priority. It is also a Monday –Friday service and may not help when we have a positive result.

3.22 Depending on the results from baseline sampling, and where specific criteria are met, the frequency of sampling would increase to weekly sampling for a period of at least 4 weeks and there for a period at quarterly intervals.

3.23 NHS Lothian Facilities is to begin these new sampling arrangements the week beginning 11.02.2019. The cost to implement the regular testing is not yet known but is being supported by the Facilities Directorate. It is expected to be in the region of £30K.

New Builds/Re-provisions

3.24 It is clear that these arrangements must apply to all areas of our organisation. Design, Commission, Validation and smooth transfer into the operation phase must be managed, monitored just as vigorously as other aspects.

3.25 NHSL has worked extremely hard to ensure it has governance and appropriate control measures to ensure strict adherence to industry best practice and Health Technical guidelines is followed.

3.26 NHSL Water Quality Group does have Capital Planning representatives. Capital Planning when at all stage of the procurement also have a dedicated resource from Estates and Facilities and injection control.

3.27 All derogations to technical guidance are discussed, debated and if approved signed off by senior officials of our organisations. Prior to these arrangements each and individual derogation is agreed at Project Programme Boards as part of our comprehensive governance of such issues.

4 Key Risks

4.1 As a result of testing for specific organisms the likelihood of positive sampling is high. This could lead to impacts on patient activity reduction specifically in areas where services are under pressure to meet time to treatment guidance.

4.2 The framework for Management and Control is not followed leading to exposure of potential failure of a system leading to risk of hospital acquired infections.

4.3 Reporting mechanisms from staff out with Estates breakdown leading to reduced awareness and monitoring of local and or isolated areas.

4.4 Engineering staff do not recognise potential risk from systems and their related transmission routes. It is key we put in place rigorous training and control frameworks that remove such a risk.

4.5 Because of the national concerns, expert advice input is removed or significantly reduced.

4.6 The current hypothesis on transmission routes is proven to be wrong, and new routes not under our control are determined.

4.7 Relevant Stakeholders, Estates, Infection Control and Microbiology do not engage or provide insufficient resource to ensure all aspects of our organisation controls are followed. Our governance is the main control for this risk.

4.8 Design, validation and commission criteria policy and procedures are not followed. The enforcement of Estates, Infection Control leads within projects and use of independent testers will substantially reduce this.

4.9 Outbreaks and recurring water issues experienced in other parts of NHS Scotland have proven complex to manage, and have been associated with increased public concern and negative media interest.

4.10 NHS Lothian has had recurring issues with water quality in the Neonatal unit and Lothian Birth Centre. As part of water testing, ‘positive’ results showing the presence of microorganisms could not be used to provide assurance of water safety as they did not provide information about specific organisms (e.g. P. aeruginosa) in line with guidance. As part of the risk assessment and management of this issue, the birthing pools were taken out of use until this could be provided. This created significant disruption for staff and patients, and had a detrimental impact on patient experience (increased demand an analgesia including epidurals).

5 Risk Register

5.1 Legionella, pseudomonas and pest infestations are all captured within the Facilities Directorate risk register and reviewed regularly.

6 Impact on Inequality, Including Health Inequalities

6.1 Not applicable

7 Duty to Inform, Engage and Consult People who use our Services

7.1 This is a whole organisation arrangement and as such relevant stakeholders have been influential in the construct of the report. This specifically includes Infection Control, Estates, Facilities, Health Protection Scotland and Health Facilities Scotland.

7.2 This will help inform Clinical Teams who will need to assess individual service requirements and access arrangements.

8 Resource Implications

8.1 These issues described in the paper have been challenging to resource. In most circumstances there has not been any investment from the financial plan to support

8.2 We have self resourced some 7 Band 6 Assurance Posts (£250k).

8.3 Independent water quality risk assessments and water sampling (£100K)

8.4 In addition NHSL will have additional costs associated with moving to the interim guidance. Cost for six monthly Pseudomonas testing: this is being costed and will be of the order of around £30K.

8.5 Cost for removing and discarding contaminated water system elements and replacing with new. This would be costed at time of incident. NHSL has sought evidence on costs UK wide but this has not proved successful.

8.6 There will be a need to review our systems and identify high risk components and cost these for removal.

- Water straighteners
- Taps
- Flexible hoses

In high risk areas these should be removed.

George Curley
Director of Operations - Facilities
8th February 2019
[redacted]

Appendix 1: Health Protection Scotland Email re Water Quality

Appendix 2: Letter from Mr Paul Gray, Chief Executive at Scottish Government re Ventilation

Appendix 3: NHS Lothian reply to Health Protection Scotland re Water Quality

Appendix 4: NHS Lothian reply to Paul Gray re Ventilation

Appendix 5: Health Protection Scotland Interim Guidance

Appendix 1

Sent: 17 December 2018 12:44
To: [redacted]
Subject: Water Management in New Builds and Refurbishments. Information Requests

Dear [redacted],

In light of an ongoing water incident within a healthcare facility within NHS Scotland the HAI policy Unit at the Scottish Government have requested that HPS/HFS carry out a review of all other new builds and significant refurbishments across NHS Scotland.

In the first instance we would seek a response to the following questions by 3rd January 2019.

1 Please provide details of all areas across your NHS Board that have had significant refurbishment that has required installation of new water systems since January 2013 until present.

2 Please provide details of all new builds across your NHS Board area since January 2013 until present (including those in progress not yet handed over to your board).

3 Were any results of microbiological water testing undertaken in both hot and cold systems during commissioning, handover and thereafter in those areas identified in questions 1 and 2 positive for micro-organisms (including fungi) or TVCs greater than 10? If yes, please provide details of location/s.

4 Has there been any water treatment/dosing/sanitisation carried out in any area identified in Q1 or Q2 across your NHS Board since January 2013 to present?

ARHAI Team
NHS National Services Scotland
Health Protection Scotland
4th Floor Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

Appendix 2

Director-General Health & Social Care and
Chief Executive NHSScotland
Paul Gray

Scottish Government
Riaghaltas na h-Alba
gov.scot

[redacted]

NHS Chief Executives

Copy to Directors of Estates

25 January 2019

Dear Colleague

Queen Elizabeth University Hospital – follow up actions

This letter sets out actions following the meeting of the Strategic Facilities Group on Wednesday 23 January. There are a number of controls that I would like you to confirm are in place and working effectively:

- All plant rooms must be secure and have adequate access controls in place at all times;
- All plant rooms maintained clean and free of vermin;
- Standard Operating Procedures for the management of plant rooms are in place and being followed;
- All critical ventilation systems inspected and maintained in line with 'Scottish Health Technical Memorandum 03-01: Ventilation for healthcare premises'.

I have asked Health Facilities Scotland to co-ordinate the responses and would ask that you reply to [redacted] copied to [redacted] by Friday 1 February.

In addition to these control measures, the Strategic Facilities Group has undertaken to share best practice on relevant Standard Operating Procedures and anti-pest management. The Ventilation Group, which reports direct to the Scottish Engineering and Technology Advisory Group (SETAG), is also considering urgently whether SHTM 03-01 needs to be revised and updated in view of recent developments. I will ensure that you are kept in touch with any changes to that.

Yours sincerely

[redacted]

Paul Gray

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.gov.scot

Appendix 3

NHS Lothian has been asked by Scottish Government to provide assurance on the quality and capability of our water services within our facilities. These assurances on the back of recent events at the recently opened new facilities in Queen Elizabeth in Glasgow, Queen Margaret in Kirkcaldy and the new acute hospital in Dumfries and Galloway. These new facilities on opening have seen significant contamination in the water systems and have led to concerns of patient safety from water borne contaminants such as;

- Legionella
- Pseudomonas
- High TVC counts suggesting more rare contaminants

Following review of these issues we are led to believe that failings have been discovered in the following; design, construction, and operational phases of the implementations of the new builds. The period we have been asked to provide assurance on is ten years.
NHS Lothian can assure its Executives that it has a robust framework of governance and control mechanisms implemented by Capital and Estates limits the risk of the issues occurring within Lothian.
Any new build is closely scrutinised at the design stage by water quality experts within our own Board. These experts consist of our lead for water quality (Director of Facilities), Infection Control, Lead Microbiologist, Authorising Engineer, Authorised Person, Decontamination Committee chaired by our Executive for Public Health. In addition to the above we resource the projects with externally appointed technical advisors, appoint an Estate Projects Officer and a Project Director. These latter individuals ensure design, installation and the operational validations on capability are in line with best industry practice and more importantly adhere to SHTM 0401Water Systems and Quality and our own water quality policy that adheres to the SHTM. Where high TVC counts have been found, remedy measures with our operational protocol were undertaken and systems continue to be functionally suitable and safe.
Please provide details of all areas across your NHS Board that have had significant refurbishment that has required installation of new water systems since January 2013 until present.
Please provide details of all new builds across your NHS Board area since January 2013 until present (including those in progress not yet handed over to your board).

- Day Case Surgery , SJH
- Royal Victoria Building , WGH
- Mid Lothian Community Hospital (PFI)
- Wards120, 220, 116-118 RIE (PFI)
- Royal Edinburgh Phase 1 (Hub)
- East Lothian Community Hospital Out Patient Block (Hub)
- NHSL Partnership Centres (Allermuir, Blackburn & Pennywell All Care Centre) (Hub) Ratho Health Centre (Leased Property)
- Builds still to be handed over
- RHSC/DCN (NPD)
- REH Phase 2 (Hub)
- East Lothian Community Hospital Phase 3 in patient Facility (Hub)

Were any results of microbiological water testing undertaken in both hot and cold systems during commissioning, handover and thereafter in those areas identified in questions 1 and 2

positive for micro-organisms (including fungi) or TVCs greater than 10? If yes, please provide details of location/s.

Validation tests and sterilisation of systems has been conducted and signed off for these facilities. In addition ongoing testing for various contaminants is undertaken monthly and levels of TVCs are within agreed limits.

Two locations REH Phase 1 and Royal Victoria Building tested positive for TVC s greater than 10. Both installations were rectified through disinfection and ongoing testing and monitoring regimes implemented.

I can confirm that where there has been reoccurrence of low TVC counts we have undertaken further testing to reassure there is no risks to patients or staff.

These results are all available for external validation should that be necessary.

NHS Lothian however has experienced difficulties with HUB and PFI providers and has had to be very robust in holding such providers to account. This is something that could be improved through improvements to the Standard form of Contracts for Hub and NPD.

Appendix 4

Lothian NHS Board

FACILITIES DIRECTORATE

NHS Lothian

Mr Paul Gray
Director General Health & Social Care &
Chief Executive NHSScotland

Enquiries to: Mr George Curley

[redacted]

Date: 31st January 2019

Cc:gordon.james[redacted]
ailsa.atkinson[redacted]

Dear Paul

Queen Elizabeth University Hospital – follow up actions – NHS Lothian Response

With reference to your letter dated 25th January 2019, following extensive discussions with internal and external stakeholders across the whole of the NHS Lothian estate I can confirm the following;

- All plant rooms are secured and have adequate authorised access controls in place at all times.
- All plant rooms are maintained, clean and free of vermin.
- Standing Operating Procedures for the management of plant rooms are in place and being followed.
- Planned preventative maintenance (PPM) is carried out on critical ventilation systems. However the current method statements and frequencies do not meet the guidelines specified within SHTM 03-01, therefore our PPM schedules are being updated, and this will be completed within the next 4 weeks. We are being supported by our Authorising Engineer (AE) for ventilation.

I trust the above provides the necessary assurance required.

Yours sincerely

[redacted]

George Curley
Director of Operations Facilities

Cc: Mr Brian Douglas, Head of Operations HardFM.

Appendix 5

Second Draft

Interim guidance on managing the risk of fungal contamination from bird droppings in air handling plant areas.

Background

The production of this guidance is prompted by recent experience of infection, and presence of fungus, in areas occupied by immuno compromised patients. Investigations are ongoing and further guidance may be issued as evidence emerges. This guidance should be read in conjunction with Scottish Health Technical Memorandum (SHTM) 03-01 Ventilation for healthcare premises, Scottish Health Facilities Note 30 Part a – Manual and part b – HAI-SCRIBE.

Fungi are ubiquitous in the external environment and, whilst generally harmless to healthy people, susceptible patients can be infected by various fungi, not just those associated with bird droppings. For that reason ventilation systems serving areas housing patients susceptible to fungal infection are designed to minimise the risk of transmission of fungus into the occupied space by means of appropriate filtration and pressure differentials between relatively clean and less clean environments.

Ventilation systems serving general patient and non patient areas are designed primarily to dilute contaminants in the occupied space and maintain comfort conditions. Although the filters used will reduce contamination from external sources, they are not designed to eliminate fungus. More detailed information is given in SHTM 03-01. The guidance contained herein is intended to reduce the challenge ventilation systems face from fungi and to reduce the risks, particularly recognising that patients in general hospital environments may have reduced immunity for a number of reasons, whilst not requiring specialised environments. It is not intended to make areas served by non-specialised ventilation systems safe for patients who should be accommodated in specialised protective environments.

Fungi can enter general healthcare environments via doors, people's clothing, apertures in building fabric, supplies etc. Although the filtration in non specialised ventilation systems is not intended to eliminate spores, keeping plant areas free of vermin and bird droppings is good practice and helps prevent spores entering the occupied space.

Specialised advice on the management of ventilation systems, including the protection of plant from contamination from bird droppings should be sought as needed from the Board's appointed Authorising Engineer (Ventilation).

Plant rooms

To minimise the risk of contamination of ventilation systems with fungus, plant rooms should be maintained clean and free of vermin. Where bird droppings are found, the area should be cleaned, taking care not to produce dust or aerosol, and an investigation commenced into the source of the contamination.

External ventilation plant

External plant areas are more difficult to protect and measures should reflect the risks involved. NHS Boards should have a record of all external ventilation plant, which should identify the areas and patient groups served. The inspection and maintenance of external ventilation plant should be in accordance with the requirements of SHTM 03-01 and should include steps to reduce the risks from fungal contamination from bird droppings.

Where external plant serves areas where patients are considered to be susceptible to fungal infection, or housing immuno compromised patients, measures to minimise the risk of contamination by fungus from bird droppings should be considered, including bird netting, anti roost devices, partial enclosure combined with bird netting, enclosing the plant in a fabricated housing and/or regular inspection and cleaning as appropriate to the risk.

Solutions will need to take account of local conditions such as layout, weather exposure, roof

loading and maintainability. Integrity of any solution needs to be taken into account as a poorly designed or maintained solution might increase roosting risk.

Bird dropping contamination at air intakes

Bird droppings, in areas where they might be able to produce airborne fungus, which might be drawn into the system, should be cleaned taking care not to produce dust or aerosol. Where droppings are not likely to be disturbed and not close to air intakes, they are unlikely to shed spores in greater quantities that that present in outside air.

If regular inspection identifies places where contamination repeatedly builds up and needs to be cleaned, then appropriate steps should be take to deter birds from using that place, such as by placement of anti roosting spikes or netting. Prevention of bird dropping contamination is preferred to cleaning.

The measures adopted should be determined by risk assessment involving appropriate clinical, microbiology, IPC and estates disciplines, and should take account of patient susceptibility, filtration, location of plant, practicability of protective measures and other issues identified by those undertaking the assessment.

Removal of bird droppings

The fungi associated with bird droppings presents a risk to those engaged in its removal and any associated work should only be carried out following an appropriate risk assessment and following a procedure developed to control the risks. Microorganisms such as fungi may be substances hazardous to health as in the Control of Substances Hazardous to Health Regulations 2002 http://www.hse.gov.uk/coshh/.

Whether specialist contractors or in house staff are used to remove bird droppings, they should be appropriately trained and use appropriate methods and equipment, including personal protective equipment, as identified in the risk assessment and procedure above. Clothing, equipment and tools should be appropriately decontaminated or disposed of at the end of work in accordance with the risk assessment and procedure.

Health and safety assessments, records and other documentation should be updated in accordance with decisions made, risk assessments and work procedures.

Bird droppings should be removed using techniques designed to minimise the risk of releasing airborne fungi. As the risk of releasing airborne fungi increases when droppings are dry and can produce dust when disturbed, wet removal techniques are likely to be best. Pressure washing should be avoided as this will aerosolise and spread the droppings. When droppings are being removed, the associated ventilation systems should be off and isolated where practicable. Chemical inactivation of fungus during the removal process should be used, although this should not be relied on as a substitute for other protective measures.

Bird management

This guidance does not set out to address bird management in general, which is a complex multifactorial issue, although it should be noted that management of the bird population in the vicinity of buildings can affect the accumulation of droppings and the risk of contamination from fungi should be part of a bird management strategy.

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WORKING PARTY REPORT

Microbiological commissioning and monitoring of operating theatre suites

A report of a working party of the Hospital Infection Society

P. N. Hoffman*, J. Williams†, A. Stacey‡, A. M. Bennett§, G. L. Ridgway¶, C. Dobson†, I. Fraser** and H. Humphreys††

**Central Public Health Laboratory, London, UK; †Welsh Health Estates, Cardiff, UK; ‡Reading Public Health Laboratory, Reading, UK; §Centre for Applied Microbiology and Research, Salisbury, UK; ¶University College London Hospitals, London, UK; **NHS Estates, Leeds, UK and ††Royal College of Surgeons in Ireland, Beaumant Hospital, Dublin, Ireland*

Author for correspondence: P. N. Hoffman, Laboratory of Hospital Infection, Central Public Health Laboratory, 61 Colindale Avenue, London NW9 5HT, UK.
E-mail: phoffman@phls.org.uk

0195–6701/02/090001 + 28 $35.00/0

1. Background

Owing to the need to provide clear and practicable guidelines for infection control practitioners and others in operating theatres, the Hospital Infection Society (HIS) established a working party (WP) on infection control and operating theatres in 1999 to examine many of these issues. The remit of this group was:

(1) to review the scientific and other evidence for current infection control practices in theatre and following this, to make recommendations on which practices are essential, which are preferred and which are optional or are of little perceived benefit.
(2) to produce rational, feasible and applicable guidelines for the environmental monitoring (including bacteriological air sampling) of operating theatre facilities, and specifically to address when monitoring is indicated, how it should be carried out and what action should follow if abnormal.
(3) to consider optimal theatre facilities including when ultraclean or conventional theatre ventilation is required in the light of recent changes in surgical practice such as the increasing use of minimally invasive surgery. Work on this area is ongoing, and the conclusions reached will be available on the HIS website (www.his.org.uk) in the next 12 months or so.

The WP included microbiologists/infection control doctors, an infection control nurse, an operating theatre nurse, general surgeon, orthopaedic surgeon, aerobiologist, engineer and representatives of NHS Estates. The WP reviewed the literature in the relevant areas so that, as far as possible, the guidelines would be evidence-based. The WP also consulted with healthcare professionals and others as appropriate, and achieved consensus following discussion amongst the members on areas where scientific evidence was not available.

Draft documents were widely circulated to professional groups and organizations seeking comment and suggestions, and posted on the HIS website in early 2001. During the second half of 2001, the documents were revised in the light of this feedback, circulated to WP members and what follows is the result of this wide consultation exercise.

The members of the WP were: Gordon Bannister, Allan Bennett, Terie Chesworth, Chris Dobson, Ian Fraser, Marjory Greig, Peter Hoffman, Hilary Humphreys (Chair), Liz Jones, Geoff Ridgway, Ed Smyth, Andrew Stacey (Honorary Secretary), Eric Taylor, John Williams and Kate Woodhead; The members of the Commissioning and Monitoring subgroup were Alan Bennett, Chris Dobson, Ian Fraser, Peter Hoffman (Lead), Geoff Ridgway, Andrew Stacey and John Williams.

2. Introduction

Surgical operations and interventional procedures are performed in areas with various levels of microbiological control of the ventilation. The following areas are recognized:

(1) Conventionally ventilated operating suites
(2) Ultraclean-ventilated (UCV) operating theatres
(3) Unventilated theatres
(4) Treatment rooms

There is no technical difference between an unventilated theatre and a treatment room. This section refers only to conventionally ventilated and ultraclean-ventilated theatres. Discussion as to which procedures should be performed in which facilities will form a separate WP report.

Limited advice exists on conventionally ventilated and UCV theatres in the UK Health Technical Memorandum (HTM) 2025.[1] The HTM gives limits on the microbiological (bacterial and fungal) content of air in empty and working theatres, but states in a margin note ‘precise guidance is

inappropriate and will depend on local circumstances'. Whilst this remains true, it is apparent that many would welcome some advice on infection control aspects of these matters. This report seeks only to interpret HTM 2025 in a manner appropriate to infection control practitioners; we are not rewriting the standards within it.

HTM 2025 (volume A—Management Policy) gives the following role (paragraph 2.29) 'Infection Control Officer—or consultant microbiologist, if not the same person, nominated by the management to advise on monitoring infection control policy and microbiological performance of the system. Major policy decisions should be made through an infection control committee.'

It also states (paragraph 2.14) 'Increased health risks to patients will occur if the more specialised ventilation systems installed to supply high quality air to operating departments do not achieve and maintain the required standards. The link between postoperative infection and theatre air quality has been well established. Plants serving conventionally ventilated operating departments, for instance, will be required to ensure the separation of areas within the suite by maintaining a specific direction of airflow between rooms, even when doors are opened. They will also maintain the selected operating department environmental conditions regardless of changes in the outside air conditions or activities within the space. In addition ultraclean operating ventilation systems which are designed to provide an effectively particle-free zone around the patient while the operation is in progress, have been shown to reduce significantly postoperative infection in patients undergoing deep wound surgery. Their use for similar forms of surgery may well be indicated.'

One role of the infection control officer (ICO) in theatre commissioning and monitoring is to ensure the quality of the ventilation with respect to infection control issues. The ICO or infection control team (ICT) should be familiar with the outline structure, function and interrelationship of those engineering aspects that have an impact on infection control. A list of common problems in this respect and possible actions forms Annex A to this report.

3. Overall principles

The function of operating theatre ventilation is to prevent airborne microbial contaminants from entering surgical wounds. Under normal circumstances, the main source of airborne microbial contaminants is microscopic skin fragments given off by staff in theatre. A proportion of these skin fragments will be contaminated with microcolonies of bacteria resident, or perhaps transiently present, on that individual's skin. Whilst individuals will have different dispersion levels, overall dispersion is increased with movement and numbers of individuals present.[2]

Other sources of airborne micro-organisms are usually less significant. These include improperly filtered outdoor air, contaminated fabrics worn by theatre staff and backtracking of contaminated air from outside the theatre. The patient is not usually a significant source of airborne contamination; their movement is usually minimal. However, there exists the potential that power tools can create an aerosol from the tissues and any micro-organisms within them.

Airborne micro-organisms can enter surgical wounds by one of two routes: they can either fall directly into wounds or they can land on exposed instruments, and possibly surgeons' hands, and can later be transferred into the wound. The significance of this latter route will vary with the area of exposed instruments and the duration of their exposure, but is thought usually to exceed the contribution of direct wound contamination.[3]

4. Commissioning

Commissioning must occur before an operating theatre is first used and after any substantial modifications that may affect airflow patterns in pre-existing theatres (as part of a re-commissioning process). It is important that the ICT is involved at all stages from pre-design through to opening and that adequate time for commissioning is built in to the schedule, including an allowance of time for microbiological assessments. This may need particular consideration for facilities built under private finance initiatives. Contractual conditions should allow commissioning before handover of the theatre or have delayed acceptance after handover such that faults can be rectified.

4.1 Summary for conventionally ventilated theatres

Conventionally ventilated operating theatres must be commissioned before being used, after being built or

modified substantially. Commissioning is a task for both the Estates Department and the ICT, and co-operation and co-ordination between them is important. Below is a summary of matters that should be addressed when commissioning conventionally ventilated theatres (and by whom) and the section covering it in this report:

- The theatre interior should be checked for obvious defects (ICT), Section 4.1.1.
- The air distribution within the theatre and between rooms in the theatre suite should be checked by smoke tracing (ICT), Section 4.1.2.
- The air handling unit supplying the theatre should be properly constructed, the theatre should be properly constructed, finished and functioning (Estates Department and reported to ICO), Sections 4.1.2, 4.1.4 and Annexes D and E.
- Where 'setback' (reduction of ventilation rates when theatre is not in use) is in place, there should be indications in theatre of its function and safeguards against setback operating whilst the theatre is in use (Estates and ICT), Section 4.1.2.1.
- The air change rates in theatre and preparation room should be satisfactory (either Estates Department, or ICT with data supplied by Estates Department), Section 4.1.3.
- Airborne microbial contamination in an empty theatre should be satisfactory (ICT), Section 4.1.5.

4.1.1 Theatre interior

Inspection of the theatre interior before it is handed over from the building contractors to the hospital is the last convenient occasion to rectify faults. The following observations should be made:

- pressure-release dampers should move freely and be partially or fully open when doors are closed and move to shut when doors are opened;
- doors must close properly;
- the flooring should have no cracks or gaps in it and its coving joins to the wall;
- painted surfaces and finishes should be smooth, complete and without cracks;
- that there are minimal fixtures, shelves etc.;
- the windows should be sealed;
- the ceiling should be solid.

4.1.2 Ventilation engineering

The risk from airborne micro-organisms is minimized in the ventilation of conventionally ventilated theatres in three ways:

(1) by filtration of supplied air;
(2) by dilution of contaminated air in the theatre; and
(3) by preventing entry of contaminated air from areas outside the theatre.

The ICO/T should carry out airflow visualization (smoke testing) to ensure turbulent airflow in the theatre, particularly around the position of the operating table (a puff of smoke should disperse within seconds of creation). It should also be established that supplied air does not 'short-circuit', i.e., take a direct route out of the theatre such that it cannot entrain contamination generated in the theatre. Sources of such 'airflow indicators' are in Annex B. Large volume smoke generators are useful for tracing larger airflow patterns (also in Annex B). Fire alarms systems in the theatres should be disabled during testing.

Airflow visualization should also be used to establish that air flows in the desired direction between rooms in the suite (with all doors closed):

- from the theatre into
  - the anaesthetic room,
  - the disposal room,
  - the corridor;
- from the anaesthetic room and scrub area into the corridor;
- air should either flow from the preparation room into the theatre if it is used for lay-up or they should be at equal pressure if used as a sterile pack store (i.e., no direction of flow between them). Air should flow into the corridor from a preparation room used either for lay-up or as a sterile pack store.

Diagrams showing examples of suggested operating suite layouts (for example, with and without disposal corridors) and directions of airflow are in volume B of HTM 2025 (1994),[1] Design Considerations, Figures 6.1a and b. Figure 1 in this paper shows one of the suggested layouts.

The ICO should request a signed document from a senior member of the Estates Department that the ventilation to the theatre suite, including the air-handling unit, has been inspected and that the theatre is satisfactorily constructed, finished and is functioning to specifications. A sample letter forms Annex D to this report. Guidance on completion of this letter forms Annex E.

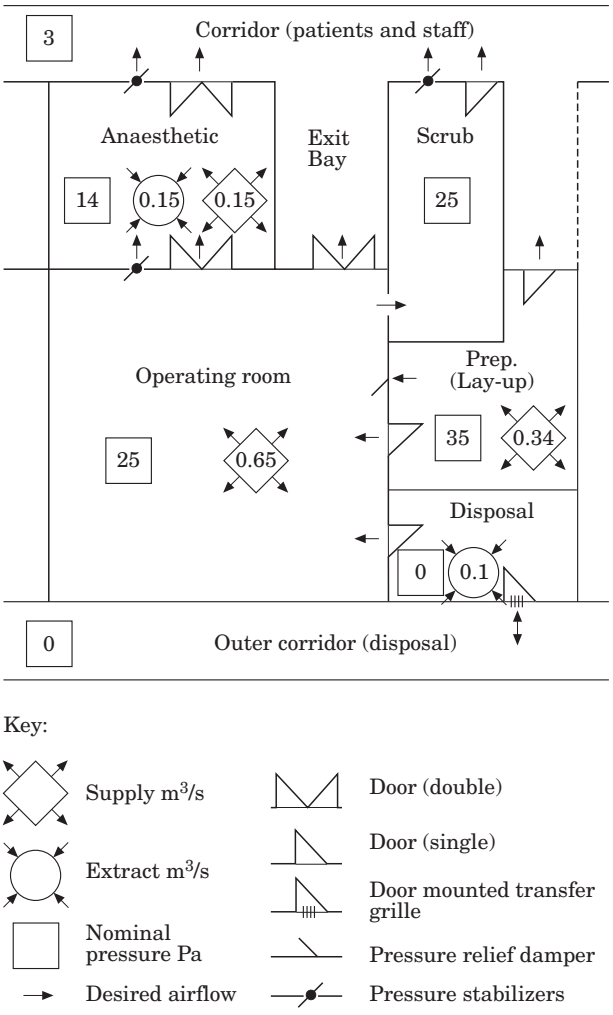


Figure 1 One of the eight 'suggested air movement schemes' from HTM 2025, volume B, Design considerations (Figures 6.1a and b, plan 5b).

4.1.2.1 Setback status

As an economy measure, ventilation rates can be 'set back' when the theatre is not in use. Ventilation should not be turned off completely, but volumes can be reduced provided that pressure relativities are maintained between the different areas of the operating suite to prevent backflow of contamination into clean areas. If a setback system is in place, there must be a clear visual indication in the theatre of whether the ventilation is on setback or normal flow rates. If pressure relativities are maintained during setback, all air in the theatre will have passed through the filters in the air-handling unit and there will be little microbial dispersion in an unused theatre; therefore we consider that the theatre will be usable 15 min after full ventilation has been restored. Control of setback is normally on a timed basis and there should be an override linked to the operating light or a movement detector so that set-back does not occur when lists over-run. There must be a setback override to allow for unforeseen use of the theatre to occur.

4.1.3 Air change rates

Details of ventilation rates to the theatre should be obtained from the Estates Officer and used to calculate air change rates (see Annex D). An air change is defined as occurring when a volume of air equivalent to the volume of the room has been supplied to or removed from that room (whichever airflow is greater). The rate of air change is usually given in terms of air changes per hour (ACH) and is derived from the volume of a room and the ventilation rate. Design and commissioning engineers do not however express ventilation parameters in terms of air change rates; they will express ventilation rates in terms of volume of air supplied or extracted per unit time, usually as cubic metres of air per second.

Worked example:

Room volume: An operating theatre measures 7 m long by 6 m wide by 3 m high: a total volume of 126 m^3.

Ventilation rate: If it has four ventilation supply grilles with observed flow rates of 0.18, 0.19, 0.18 and 0.17 m^3/s, it will have a total air supply (the sum of the individual grille flow rates) of 0.72 m^3/s (engineering air supply data is usually given as volume per second—either in cubic metres or litres; 1 m^3 is 1000 L) equivalent to 2592 m^3/h.

Air change rate: The air change rate is calculated by dividing the air supply rate by the room volume: $2592 \div 126 = 20.6$ ACH.

The Joint working party on ventilation in operating suites (1972)[4] ('The Lidwell Report') advised that clean areas (operating theatre and preparation room) should have ventilation equivalent to 20 ACH. If theatres are built to the size specifications in HBN 26[5] and have ventilation rates specified in HTM 2025,[1] there should be between 19.5 and 23 ACH in the theatre (i.e., ventilation rates in operating theatres should equate to around 20 ACH or above).

The air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH; a greater air change rate than in theatres

(the main route of airborne contamination entering surgical wounds is probably via instruments[3]). If preparation rooms are used only as sterile pack stores, the ventilation rate should be around 11 ACH.

If either the operating theatre or preparation room have been built to dimensions different from those in HBN 26,[5] ventilation rates given in HTM 2025 should be adjusted to achieve the required rate of air changes. Effective air changes will only occur if airflow is turbulent and there is no short-circuiting. These should have been established by smoke testing (see 4.1.2).

4.1.4 Pressure differentials and airflow

The direction of airflow between rooms in a theatre suite is used to ensure that there is no backflow of air from either 'dirty' rooms in the suite or from contaminated areas in the hospital. Air flowing between rooms can be measured in terms of the pressure differential between those areas. The pressure differential results from the volume of air flowing between those areas per unit of time and the size of the gap though which it flows. It is usually measured in units of pascals or sometimes in terms of inches or millimetres of water. Pressure differentials between rooms in the theatre suite are given in HTM 2025, volume B (Design considerations). The desired pressure differentials are small and not easily measured (usually either by an electronic micromanometer or inclined fluid manometer). The desired pressure differentials between the different rooms will vary from around 9 to 30 Pa (1 Pa is equivalent to the pressure exerted by 0.004 or 0.1 mm of water, i.e., a very small amount of pressure).

We advise that the ICO request a signed document from a senior member of the Estates Department that the pressure differentials have been assessed by the commissioning engineer and are satisfactory (see Annex D). However as the value of the differentials are as much a reflection of the size of the gaps that the air flows through, as well as the volume of air flowing through those gaps and the robustness of flow is related more to the volume flowing through a gap than the pressure across that gap, we do not consider the actual values of pressure differential to be vital in terms of infection control. The ICO/T should have carried out airflow visualization with smoke tubes to observe robust directional flow at the same time as determination of turbulent airflow in theatre (see 4.1.2).

4.1.5 Microbiological sampling

HTM 2025,[1] volume C (validation and verification) states (paragraph 5.33). 'The level of airborne bacteria introduced by the supply air can be checked by closing all doors and leaving the operating room empty with the ventilation system running for one hour, after which a bacterial sampler mounted on the operating table should be activated remotely. Aerobic cultures on non-selective medium should not exceed 35 bacterial and/or fungal particles per cubic metre of ventilating air'.

When to sample The most appropriate time for microbiological commissioning of an operating theatre should be shortly before it comes into use. The theatre should have had an 'in-depth' clean and be thoroughly clean and dust-free. The air handling unit should have been operating at normal flow rates (i.e., not on setback ventilation) continuously for at least 24 h before sampling. Given the usual timeframe for sampling, it is usually only the production of satisfactory microbiological sampling that is required to enable a new or refurbished theatre to come into use. It is therefore vital that:

(a) the checks on the engineering aspects listed above should have already occurred and be satisfactory before microbiological sampling is done;
(b) false-positive microbiological results (primarily from airborne contamination dispersed by the person doing the test) do not cast doubt on the adequacy of the ventilation.

The protocol given in the HTM is skeletal and one purpose of these guidelines is to record the practical experience of those who have been involved in this field.

How to sample In a clean, well-ventilated operating theatre, the main source of airborne contamination will probably be contaminated skin particles dispersed from people, even when wearing theatre clothing. It is vital that any microbial air sampler is only operated once all people are out of both the operating room and any area that feeds air into the operating room (such as the preparation room). Also, before the sampler operates, sufficient time must be allowed for the ventilation to dilute and disperse the contamination generated during the setting-up of the sampler. It is not good enough to switch the sampler on and then stand away from it. This will be one of the considerations affecting the choice of a suitable sampler. Some samplers can be operated remotely via a cable from outside the theatre, by an infra-red remote control

or by a time-delay mechanism on the sampler. HTM 2025 advises that the theatre be empty for 1 h before sampling. This can make commissioning a suite with more than one operating theatre time-consuming. Each change of air will, given perfect mixing, produce a 63% reduction in pre-existing air and its entrained contamination. If there are, for example, 20 air changes per hour in a operating theatre (one air change every 3 min), in 1 h airborne contamination levels will be reduced to 0.0000002% of their former levels by dilution alone (there will be additional losses due to particles settling-out over this time). It does not seem unrealistic to leave the operating theatre unoccupied for 15 min before sampling, in which time airborne contamination should have been reduced to less than 1% (actually 0.67%) of its former levels, if the ventilation is working adequately. If the ventilation is defective, either in the rate of airflow or its distribution (such as short-circuiting out of the theatre without diluting pre-existing air), it may be more evident if left for 15 min rather than 1 h (the contamination dispersed by the person setting the sampler up will not have been diluted out or have had a chance to settle-out). A gap of 15 min between set-up and sampling will also allow time for generation of a duplicate sample, useful for confirming unexpected results.

Clothes worn when doing microbiological testing in theatre are unimportant. Local dress codes should be observed but normal theatre wear does little to reduce dispersion; besides which remote operation of the sampler and the time gap between leaving the theatre and taking the sample make such dispersion unimportant.

How much to sample The volume of air to be sampled is not specified in the HTM. It is left to the individual directing the sampling and will be determined by the microbial numbers being sought and the sampling equipment. We suggest that sampling volumes around 1 m^3 (1000 L) are optimal. Using volumes above this generates no substantial problems until either the colonies on the incubated plate get too crowded to enumerate accurately or the agar starts to dry out due to the volume of air passed over it. Using volumes lower than this may result in interpretational difficulties and tends to make the data more qualitative as the volume decreases. It also gives undue weight to plate contaminants. We cannot be prescriptive on this matter, but advise sampling volumes greater than 0.25 m^3 (250 L) and optimally around 1 m^3 (1000 L). Whatever air volume is chosen, the sampler used should be capable of sampling it without causing excessive drying of the recipient agar surface.

It is important to ensure that the sampler is clean before use. It should also be run briefly in the theatre before the agar is loaded to blow any contamination out of the sampler. We recommend taking at least two samples per theatre, as this lessens the possibility of technical errors interfering with successful commissioning of a theatre. A short summary of the attributes of the common samplers available is given in Annex C.

4.1.5.1 Sampling media

HTM 2025,[1] volume C (validation and verification) states (paragraph 5.34): 'The results should be examined to establish the broad category of organisms present. A high preponderance of fungal organisms may be an indication of inadequate filtration for the particular installation.'

The choice of growth medium and recovery conditions can be varied according to the nature of the exploration and perceived problems. Nutrient agar incubated for two days at 37°C is an acceptable method for general work. If there is a more specific investigation, appropriate media and culture conditions can be used. The larger the plate used, the greater volume of air it can sample before drying-out of the agar interferes with bacterial recovery (e.g., large volume slit samplers, which can sample several cubic metres of air, use 15 cm plates). The plates should be poured such that the surface is flat (no lumps, no slope).

If the quality of the agar plates is at all suspect, pre-incubation (under conditions that match the incubation of the samples to be taken) will allow those plates with contaminants to be discarded.

4.2 UCV theatres

UCV theatres must be commissioned before being used, after being built or modified substantially. Commissioning is a task for both the Estates Department and the ICT, and co-operation and co-ordination between them is important. The following is a list of matters relevant to infection control that should be addressed (and by whom) and the section of this report in which they are covered:

- The theatre interior should be checked for obvious defects (ICT), Sections 4.1.1 and 4.2.1.
- The airflow between a preparation room used for instrument lay-up and the theatre is satisfactory

(ICT), Section 4.1.2, and the preparation room has an adequate air change rate (either Estates, or ICT with data supplied by Estates), Section 4.1.3.
- The air-handling unit supplying the theatre is properly constructed, the theatre is properly constructed, finished and functioning (Estates and reported to ICO) Annexes D and E where applicable, Section 4.2.2.
- The air velocities in the ultraclean zone are satisfactory (Estates and reported to ICO), Section 4.2.3.1 and Annexes F and G, the terminal high-efficiency particulate air (HEPA) filter is effective and the ultraclean airflow can resist particle penetration from outside (Estates and reported to ICO), Section 4.2.3.2 and Annexes F and G.
- The ultraclean zone resists ingress of air from outside, shown by smoke tests (ICT), Section 4.2.3.1.
- Airborne microbial contamination in the ultraclean zone is satisfactory (ICT), Section 4.2.4. This test is not necessary if the tests of the HEPA filter and the ultraclean airflow above have been done but, if agreed locally, can still be done with a sample taken in the centre of the ultraclean zone.

4.2.1 Theatre interior

See section 4.1.1 for general theatre interior requirements. In addition, the operating lights should ideally be of a type that offers minimal interruption to the airflow pattern, but in reality such a choice may well be a compromise between illumination efficacy and airflow considerations.

4.2.2 Ventilation engineering

Control of postoperative infection caused by airborne micro-organisms is achieved in UCV theatres by exclusion of contamination from the wound. Filtered air descends in a uni-directional flow over the patient, creating a 'clean zone', rapidly removing contamination generated within that zone and preventing entry of contaminated air. The large volumes of air required to maintain this zone make it necessary to recirculate air from within the theatre. Filtration of this recirculated air is essential to prevent contaminated particles also being recirculated. The filters used are HEPA filters (see Annex H). The existence of this clean zone largely negates the need for control over air movement between rooms in the theatre suite. However, there is still a need for the preparation room to be at positive pressure relative to other areas, and to have a high airchange rate if used for laying-up instruments.

4.2.3 Air change rates and velocity

UCV theatres need to be tested to ensure:

(1) that the velocity of air within the clean zone is sufficient to result in a robust, unidirectional flow capable of resisting ingress of contaminated air from outside the zone (Section 4.2.3.1);
(2) that filters are intact and properly seated so as to remove microbial contamination from both incoming and recirculated air (Section 4.2.3.2).

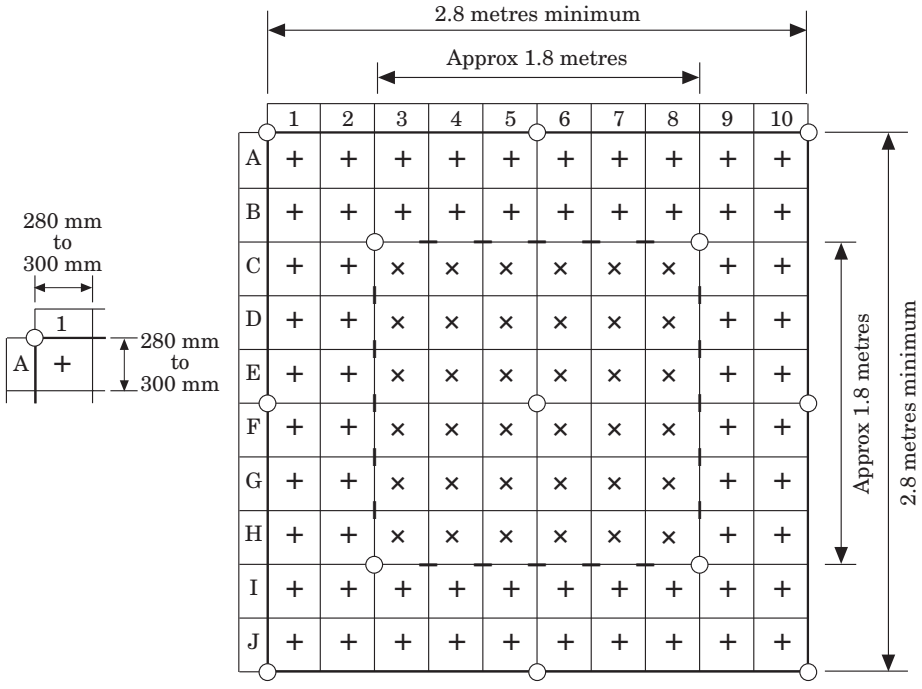
4.2.3.1 Air velocity and flow characteristics

A grid is marked out in the clean zone (at least 2.8 metres square) such that the area is delineated into 100 squares (10 by 10), each about 280 to 300 mm^2 (see Figure 2). In each of these squares, air velocity measurements are taken at 2 m above floor level. The air velocity should average 0.38 m/s if there are partial walls around the clean zone ending at a height of around 2 m above floor level (the usual case), or 0.3 m/s if there are full walls to 1 m or less above floor level. In the central 36 (6 by 6) squares, the velocity is also measured 1 m above floor level and should be at least 0.2 m/s. These data should be generated by the commissioning engineer and passed to the local Estates Department.

Airflow visualization of the resistance of the unidirectional flow to ingress from outside provides useful reassurance of the robustness of the system. Smoke should be aimed at the unidirectional flow from outside the area with various objects that may interfere with the airflow, principally the operating theatre light, in a variety of realistic positions and lack of ingress observed.

4.2.3.2 Contamination removal

To assess that the tested filters are intact and properly seated so as to remove microbial contamination from both incoming and recirculated air is tested by either microbiological air sampling or exclusion of tracer particles generated outside the clean zone. Volume C of HTM 2025 (1994) (Validation and



Key:

+ Measure air velocity 2 m above floor level

× Measure air velocity 2 m above floor level and also measure air velocity 1 m above floor level (min 0.2 m/s)

○ Bacteriological sampling position

Figure 2 Ultraclean-ventilated theatre test grid. (from HTM 2025, volume C, validation and verification, chapter 5, Figure 1).

verification), paragraph 5.36a states 'air leaving the final diffuser or final filters should contain not more than 0.5 CFU/m^3 of air. If the air filters have been tested after installation by a particle penetration test, this test is not necessary.' We consider particle testing to be a better test of filter integrity than bacteriological sampling: it poses a greater challenge to the filter assembly (there will be a far greater number of tracer than microbiological particles) and is less prone to technical errors (sampling for very low numbers of airborne bacteria is a skilled exercise). In addition to this test, there is a test to assess the capacity of the airflow in the clean zone to resist penetration from outside. Details of this test can be found in the same volume, paragraphs 5.28–5.31. In essence, after the filter installation has been shown to prevent passage of particles (i.e., the filters are not holed or mis-seated), DOP (dispersed oil particles) or other appropriate particles are generated outside the clean zone and their ability to enter into the clean zone assessed. This test would be done by expert consultants acting for the Estates Department or the commissioning engineers and the ICO should be informed of the result.

As the uni-directional flow in the clean zone will resist contamination from outside, there is no necessity to have the air movement control schemes (i.e., air moves from the cleanest to progressively less clean areas) that should exist in conventionally ventilated theatres. However there is still the problem of instruments being contaminated with airborne micro-organisms transferring that contamination into the wound.[3] Thus if instruments are laid up in a preparation room, that room should have air, filtered to the same specification as for the operating theatre, supplied such that it is at a positive pressure to surrounding areas. The air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH.

It is important to prevent contamination of instruments exposed in the theatre, whether they have been laid up in a preparation room or in the theatre itself. Ideally, exposed instruments should be kept within the clean airflow, just as the wound is. However, the minimum size of the clean zone is 2.8 m × 2.8 m. It is, in practice, usually impossible to site all laid-up instruments within this area. Other than the diluting effect of ventilation on airborne contamination outside the clean zone, control of such contamination on exposed instruments can only be by limiting the duration of their exposure. This will require good co-operation between the team in only laying-up those instruments that can be accommodated within the clean zone yet providing all instruments as soon as they are required. If the clean area could be sufficiently large to accommodate laid-up instruments, there would be a higher quality assurance of contamination prevention. This matter should be considered at the design stage.

4.2.4 *Microbiological sampling*

When commissioning an ultraclean theatre by microbiological sampling, HTM 2025 (1994) volume C chapter 5, Figure 1 shows 13 sampling points reproduced in Figure 2 of this document:

(1) one at each corner of the unidirectional airflow zone perimeter,
(2) halfway along each side of the perimeter,
(3) one at each corner of the inner zone,
(4) one in the centre.

Volume C of HTM 2025 (1994) (Validation and verification), paragraph 5.36a states 'air leaving the final diffuser or final filters should contain not more than 0.5 CFU/m^3 of air. If the air filters have been tested after installation by a particle penetration test, this test is not necessary.' However, it is not uncommon, if the theatre has already been tested by particle generation, for single or duplicate microbiological samples to be taken at the centre of the clean zone. The air should contain less than 0.5 CFU/m^3, or one colony for every 2 m^3 sampled (HTM 2025, volume C paragraph 5.36a). Accurate sampling for such low levels of bacterial contamination involves stringent technical requirements and operator skill. There is no need for the person operating the sampler to be outside the theatre when the sample is taken, as the unidirectional airflow should exclude ingress of contamination from outside that zone, but the sampler should still be operated remotely from outside the unidirectional flow canopy (someone bending over the sampler to switch it on and off would greatly compromise air quality). The sampler must be absolutely clean and should be run for a while in the clean air to remove any contamination from it before the plate is inserted. The ventilation should have been operating at full supply rate for at least 5 min before sampling occurs.

So that airflow patterns are not unduly disturbed by the act of sampling, the pump for the sampler should be either outside or close to the edge of the clean zone and its discharge, if directional, should be directed out of the clean zone. The larger the volume of air sampled, the greater the assurance of an accurate result; to detect 0.5 CFU/m^3, the volume sampled must be at least 2 m^3, preferably more, so high volume samplers are essential. Using 15 cm wide Petri dishes, the agar will dry out to levels that discourage bacterial growth after more than about 10 m^3 has been passed over its surface. As low numbers of plate contaminants can significantly affect results of commissioning UCV theatres, poured agar should be pre-incubated before use (under conditions that match the incubation of the samples to be taken) to exclude plate contaminants. Incubation, as with conventionally ventilated theatres, should normally be at 37°C for two days.

5. Monitoring

5.1 Conventionally ventilated theatres

5.1.1 *Routine monitoring*

Provided that engineering parameters are satisfactory and regularly monitored, microbiological air sampling in conventionally ventilated theatres need not be done on a routine basis, unless by local agreement. Microbiological air sampling of empty, conventionally ventilated theatres should be done either as part of an investigation into theatre-acquired infection with a possible airborne element or after any changes that may affect airflow supply rates or distribution patterns. This would include alterations to the fabric of the theatre or changes to the ductwork distribution that may affect airflow to

or within a theatre suite, but would not include routine filter changes. Such sampling should be identical to that on initial commissioning of the theatres.

5.1.2 Sampling in a working theatre

Microbiological sampling during normal working can be done as part of the microbiological commissioning process. HTM 2025,[1] volume C (Validation and verification) states (paragraph 5.35): 'A check of airborne bacteria should be carried out as soon as possible after handover. Unless there are unusually high numbers of personnel or extensive activity in the room, the number of airborne bacteria and/or fungal CFUs averaged over a five minute period, should not exceed 180 per cubic metre. This work should be carried out by the nominated infection control officer or consultant microbiologist if not the same person.' This standard has subjective elements to it: the existence of excessive numbers of personnel in the room and an assessment of their activity levels. The need to average the sample over a 5 min period means, in effect, taking a continuous sample over that time or a sequential series of continuous samples.

The positioning of the sampler in relation to the incoming flow of clean air or the dispersing sources (theatre staff) will also have an effect on the microbial numbers recovered. Sampling in a working theatre is very much a secondary check on engineering parameters. If, for example, airborne counts in excess of 180 CFU/m^3 were to be found, remedies other than engineering-based are not readily applicable (these would be to reduce the number of staff in theatre, their activity levels or their individual dispersion levels). The only practicable course of action is reassessment of the ventilation parameters. This would comprise rechecking the commissioning engineer's airflow data with the local Estates Department; re-assessing air distribution patterns to ensure effective dilution and possibly re-balancing or redirecting ventilation output to achieve more effective contamination dilution.

Sampling in a working theatre is as much a check on how that theatre is being used as on the engineering parameters. We do not consider that it should be done as a routine exercise. Such sampling should be employed selectively where use of a theatre may have an effect on surgical wound infection.

5.1.3 The air handling unit

Annex 1 of HTM 2025, volume D (Operational Management) requires that the humidifier and cooling coil in air handling units be disinfected at least six-monthly. It also states 'if any suspicion arises as to the possible contamination of the system then the microbiologist should be requested to take swab tests from all drain trays and cooler battery/cooling coil tubes and fins'. We consider it inappropriate to carry out such microbiological investigations on cooling coils as they do not contribute significantly to the microbial quality of air delivered by the system. We also consider it inappropriate to carry out such investigations on humidifiers since they should generate humidity via steam, in which case they pose a negligible risk. Humidifiers that aerosolize recirculated water (spinning disk humidifiers) pose too high a hazard to require routine microbiological assessment: they should not be used.

Annex 1 of volume C (Validation and verification) makes similar recommendations for ventilation plant about to come into service. Again we consider that physical cleaning, rather than disinfection with microbiological monitoring, is more appropriate.

If there is a build-up of biofilm on a cooling coil, the five parts per million chlorine recommended for disinfection is unlikely to make any contribution to its removal, even on a temporary basis. Use of a steam cleaner, given as an alternative to chlorine, may be more appropriate but any effective method of physical removal of biofilm is acceptable.

5.2 UCV theatres

5.2.1 Routine monitoring

The pattern of airflow in a UCV theatre should be stable given reasonably constant air velocities. HTM 2025 volume D (Operational Management, para 5.8 and 5.9) recommends that air velocity assessment and bacteriological air sampling in a working theatre are done annually. As has already been noted, sampling in a working UCV theatre is a difficult exercise and we consider that, given no change in the ventilation, equipment or use of the theatre, such sampling is unlikely to give fresh data and is thus difficult to justify.

We recommend that UCV theatres are re-commissioned annually and on HEPA-filter

replacement or disturbance. We recommend that, in empty UCV theatres, such testing is best accomplished by using inert particles rather than by bacteriological testing. Sampling in a working UCV theatre, as with conventional ventilated theatres, need not be done routinely but can form part of specific investigations.

5.2.2 Sampling in a working UCV theatre

Microbiological sampling during normal working can be done as part of the microbiological commissioning process. HTM 2025,[1] volume C (Validation and verification) states (paragraph 5.36 b and c):

(b) air sampled close to the wound site during operations, that is within 300 mm of the wound should on average, contain less than 10 CFUs/m^3 of air using conventional cotton clothes. Levels less than 1 CFU/m^3 can be expected when using occlusive clothing or body exhaust systems;

(c) air sampled at the perimeter of the clean zone during surgery should contain not more than 20 CFUs/m^3 using conventional clothing and levels less than 10 CFUs/m^3 when using occlusive clothing or body exhaust systems.

However, as with sampling in working conventionally ventilated theatres (5.1.2), such a course of action is more an indirect assessment of operating theatre procedures, personnel and practices than of engineering parameters. Given adequate airflow and engineering controls, it is factors such as individual dispersal, behaviour and clothing that will affect the airborne bacterial count. It is unrealistic to expect that if it is satisfactory on one occasion, it will consistently be satisfactory (and vice versa). Such sampling provides only a 'snapshot' of the effects of other parameters that could be better observed and addressed as matters of theatre practice. As such, these matters are best observed directly and dealt with as matters of theatre procedure and discipline; there should be no need repeatedly to prove their need by the results of bacterial sampling. In addition, sampling air within 300 mm of the wound during ultraclean surgery, is a highly exacting exercise where minor technical errors may lead to false-positive or -negative results. We therefore do not recommend air sampling in ultraclean ventilated operating theatres during surgery as a commissioning exercise. If performed by technically skilled operators, it has a role in specifically directed investigations but this is not interchangeable with routine, undirected sampling.

References

1. NHS Estates. Health Technical Memorandum 2025: Ventilation in Healthcare Premises. 1994; HMSO: London.
2. Noble WC. Dispersal of skin organisms. *Br J Dermatol* 1975; **93**: 477–485.
3. Whyte W, Hodgson R, Tinkler J. The importance of airborne bacterial contamination of wounds. *J Hosp Infect* 1982: **3**: 123–135.
4. Joint working party on ventilation in operating suites (chair Lidwell OM). Ventilation in operating suites. London. MRC and DHSS. 1972.
5. NHS Estates. Health Building Note 26. Operating departments. (1991) ISBN 0113213859.

Additional references/documents: references and documents used in the model letters and certification for conventionally and UCV theatres (annexes D–H)

BS 3928:1969 Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors), BSI, London.

DD ENV 12097:1997 Ventilation for buildings. Ductwork. Requirements for ductwork components to facilitate maintenance of ductwork systems, BSI, London.

BS EN 779:1993 Particulate air filters for general ventilation. Requirements, testing, marking, BSI, London.

BS EN 1822-1:1998 High-efficiency air filters (HEPA and ULPA). Classification, performance testing, marking, BSI, London.

BS EN 1822-2:1998 High-efficiency air filters (HEPA and ULPA). Aerosol production, measuring equipment, particle counting statistics, BSI, London.

BS EN 1822-3:1998 High-efficiency air filters (HEPA and ULPA). Testing flat sheet filter media, BSI, London.

Annex A: Problems and actions

A risk assessment should be carried out involving an assessment of the abnormal bacteriological results, the likely cause and the ease of rectifying this, the type of theatre and the procedures carried out there, and the consequences of theatre closure.

Table I. *Problems and actions*

Problem	Action
Conventionally ventilated theatre fails bacteriological sampling (empty theatre)	Check that sampling technique is satisfactory, then repeat sampling. If it still fails, discuss possibilities with people experienced in theatre testing. Explore possible engineering causes of failure (see Table II). Infection control team to discuss implications and options.
UCV theatre fails bacteriological testing (empty theatre)	Check that sampling technique is satisfactory (check with someone experienced in such sampling), then repeat sampling. If still fails, test particle penetration of filters outside clean zone to inside zone; test air velocity within clean zone.
Conventionally ventilated theatre fails bacteriological sampling (working theatre)	Test theatre empty, check airflow rates and distribution. If satisfactory, assess staff numbers inside theatre, activity levels and test again.
UCV theatre fails bacteriological testing (working theatre)	Test theatre empty as above; check that sampling technique is satisfactory. Repeat sampling. If still fails, discuss possibilities with people experienced in theatre testing.
Clusters of infection known or suspected (having excluded more obvious causes such as changes in operative procedures)	If an airborne component is suspected or needs to be excluded, do a full check on the ventilation: filters in air-handling unit, ventilation rates, airflows in theatre (and prep room), airflows between rooms, bacteriological air sampling in empty theatre, ascertain if anything has changed since before the cluster occurred.
Theatre staff 'uncomfortable'	This is primarily a problem for the Estates Department, but if staff are uncomfortable because of draughts (i) ensure that ventilation rates are not altered and (ii) if airflows are redirected by adjusting fins on outlets, smoke test to ensure air is still sufficiently turbulent at the table to disperse contamination.

Table II. *Possible engineering causes of microbiological test failures of theatres*

Problem	Possible engineering defects
Microbiological tests fail: possible engineering causes	Insufficient air volume Check no water-pooling in air-handling unit or ductwork (condensation or faulty drainage) Incorrect airflow direction between rooms in theatre suite Airflow pattern in working area poor Filters incorrectly fitted or damaged (gaps in filters or around filter housing) Filters very dirty Wrong filters fitted Temperature gradient too large across doorways from clean to dirty areas causing reverse flow Debris in ductwork and air-handling unit Incorrect interlocking of supply and extract fans, i.e., extract stops before supply

Annex B: Airflow indicators

Smoke tubes ('air current tubes' or 'airflow indicators') are available from:
Draeger Ltd,
Kitty Brewster Industrial Estate,
Blyth,
Newcastle upon Tyne, NE24 4RG,
UK.
Tel.: +44(0)1670-352891
Fax: +44(0)1670-356 266

Sabre Gas Detection
Protecor Technologies Group
Matterson House,
Ash Road,
Aldershot GU12 4DE,
UK.
Tel.: +44(0)1252-342352,
Fax: +44(0)1252-321921

MSA Britain Ltd.
East Shawhead,
Coatbridge ML5 4TD,
Scotland,
UK.
Tel.: +44(0)1236-424966
Fax: +44(0)1236-440881

Large volume smoke generators from:

Concept Engineering Ltd.
7 Woodlands Business Park,
Woodlands Park Avenue,
Maidenhead,
Berks, SL6 3UA,
UK.
Tel.: +44(0)1628-825555,
Fax: +44(0)1628-826261,
Website: www.concept-smoke.co.uk

Annex C: Air samplers for use in operating theatres

Until the 1980s the only microbial air samplers commercially available for measuring the microbial concentration of the air in operating theatres were the slit sampler and the sieve impactor. All the microbial aerosol levels recommended in guidance and in the papers of Whyte, Lidwell and others are based on experiments carried out with the large volume (700 L/min) slit samplers. New types of microbial air samplers have appeared since then. However, sampling air in operating theatres does not form a substantial section of this market, so many are not suitable.

The following points need to be considered in selection:

(1) Can it sample a suitable volume of air (greater than $2\,m^3$ may be needed in UCV theatres) within a reasonable length of time (e.g., 10 min) or before dehydration effects may occur?
(2) Can it be operated remotely (e.g., infra-red control or via extension lead)?
(3) Is it easy to use and clean?
(4) If unusual plates, strips or filters are used, how much do they cost? (Some can cost up to £5 per unit).
(5) Is it required to get close to the wound in a working ultraclean theatre?
(6) Has it been demonstrated to be reasonably effective in the published literature?

Table III *Characteristics of most available microbial air samplers*

Sampler	Flow rate (L/min)*	Collection method	Plate/strip/filter
Andersen sampler	28.3	Sieve impaction	Standard plate
Biotest RCS	40	Centrifugal impaction	Pre-filled strips
Biotest RCS Plus[1]	50	Centrifugal impaction	Pre-filled strips
Biotest HiFlow[1]	100	Centrifugal impaction	Pre-filled strips
Casella (high volume)[2]	700	Slit impaction	150 mm plate
Casella (low volume)[2]	30	Slit impaction	Standard plate
Mattson Garvin	28.3	Slit impaction	150 mm plate
Merck MAS[3]	100	Sieve impaction	Standard plate
Microbio 1	100	Sieve impaction	55 mm contact plates
Microbio 2	100	Sieve impaction	55 mm contact plates
Millipore	140	Sieve impaction	Pre-filled cassette
Negretti	100	Sieve impaction	55 mm contact plates
New Brunswick	28.3	Slit impaction	150 mm plate
Sampl'air	86–200	Sieve impaction	Standard plate
Sartorius MD8	42–133	Filtration	Gelatine filters
SAS 90	90	Sieve impaction	55 mm contact plates
SAS[2]	180	Sieve impaction	55 mm contact plates

* $1\,m^3$ is 1000 L
1 Infrared remote operation possible
2 Remote operation via cable possible
3 Delay of up to 60 min possible

Annex D: Model letter for operating theatre engineering compliance

This is a model letter requesting certification that an operating theatre has been assessed and complies with its design brief, HTM2025, the Component Database and other HTMs or standards relevant to infection control.

Letter should be on management's headed paper.

Microbiologists should check that the recipient of the letter is the person who is the Designated Person (an individual who has overall responsibility for the operating theatre systems within the premises and who has a duty under the Health and Safety at Work Act 1974, to prepare and issue a general policy statement on health and safety at work, including the organization of and arrangements for, carrying out that policy.)

To [(1)]

Certification of compliance for operating theatres.

Please confirm that the following have been tested and certified as to be correct to the design brief and the relevant standards and guidance by signing and returning to me the attached certificate (Certificate of Compliance)

Location [(2)]

Signed (Microbiologist)

(1) Insert name of person who has designated authority for the operating theatres with respect to Estates matters.
(2) Insert location and operating theatre identification.

CERTIFICATE OF COMPLIANCE

Location: . . . . . .

Details of the installation

(1) Does the system comply with the design brief? Yes ☐ No ☐

Details of departures (if any) from design brief:

(2) Does the system comply with HTMs 2025, 55, 56, 60, 61, 63 & Model Engineering Specification CO4 (Mechanical ventilation and air conditioning)? Yes ☐ No ☐

Details of departures (if any) from HTMs

(3) Has the system been formally commissioned and independently witnessed? Yes ☐ No ☐

Name of independent body:-

.....

Date of commissioning:-.....

Details of departures (if any) from HTM 2025

(4) Ventilation system hygiene. Level of cleanliness of ductwork. Does the ventilation plant and ductwork internal cleanliness comply with DHSS Standard Engineering Specification document CO4: DW/TM2 in the Guide to Good Practice Internal Cleanliness of New Ductwork Installations issued by the Heating & Ventilation Contractors Association? Yes ☐ No ☐

To what level?:
Basic Yes ☐ No ☐
Intermediate Yes ☐ No ☐
Advanced Yes ☐ No ☐
Details of departures (if any) from guidance:

(5) Level of filtration fitted to the air handling unit:

Primary filter –

Secondary filter –

Details of departures (if any) from guidance

(6) Air-change rate and room pressurization for the following:
(All areas not shaded should be filled-in)

Theatre suite zone	Room or area	Nominal pressure (Pa)	Air supply rate (m^3/s)	Room volume (m^3)	Air change rate (ACH)	Is an extract system in place & working?
'Sterile'	Operating room or area (and scrub bay)					
	Preparation room (lay-up)					
	Preparation room (sterile pack store)					
Clean	Scrub room					
	Anaesthetic room					
Transitional	Recovery room					
	Clean corridor					
	General access corridor					
	Changing rooms					
	Plaster room					
'Dirty'	Disposal corridor					
	Disposal room					

See the guidance notes on this table in Annex E.

Airflow direction between areas and rooms (check both with relevant door closed and door open), as in HTM 2025, Volume b (design considerations), table 6.6:

From lay-up to operating room	Yes/no
No flow between sterile pack store and operating room	Yes/no
From operating room to disposal room	Yes/no
From operating room to corridors (clean and/or disposal)	Yes/no
From operating room to anaesthetic room	Yes/no
From anaesthetic room to corridor	Yes/no
From lay-up or sterile pack store to corridor	Yes/no
From scrub area/room to corridor	Yes/no
No flow between disposal corridor and disposal room	Yes/no
From clean corridor to disposal room	Yes/no

(7) Confirmation of turbulent air distribution within operating theatre and other clean rooms, either by measurement of average air speed or by observation of turbulent smoke

Operating theatre table	average . . . . . m/s} working height
OR turbulent smoke	Yes/no
Preparation lay-up	average . . . . . m/s} working height
OR turbulent smoke	Yes/no

(8) Confirmation that drainage systems on the air-handling unit comply with HTM 2040 The control of legionella in healthcare premises code of practice. Yes ☐ No ☐

Details of departures (if any) from guidance:

(9) Outstanding defects:

(10) Comments related to possible microbiological problems:

Name (BLOCK LETTERS): ..... Position: .....
Date: .....

Signature: .....

For and on behalf of: .....

Completed certificates returned to:

Name:

Address:

Queries regarding completion to:

Name: Contact details:

Annex E: Guidance for completion of the model letter for operating theatre engineering compliance certificate

Submission of certificate:

Separate certification needs to be made for each operating theatre.
Certificates need to be completed for each operating theatre whether owned or leased by the Trust.

GUIDANCE NOTES FOR INDIVIDUAL QUESTIONS

Question Number

1 Does the system comply with the design brief? Details of departures (if any) from design brief.

Does the final project comply with design brief details and appropriate health building standards? Assessment should be based upon following:

Appropriate space standards (from HBN 26)
Layout of operating theatre which may compromise airflow control (e.g., dirty utility opening on to outdoors)
Engineering standards and installation (examples: position of fresh air inlet, situation of air-handling plant, layout of plant & position of air inlet diffusers or grilles into the operating room
Compliance with BSI DD ENV 12097 'Ventilation for buildings: Ductwork requirements for ductwork components to facilitate maintenance of ductwork systems'

2 Does the system comply with HTMs 2025 (ventilation), 55 (windows), 56 (partitions), 60 (ceilings), 61 (flooring), 63 (fitted storage systems) & Model Engineering
Specification CO4 (Mechanical ventilation and air conditioning)? Details of departures (if any) from HTMs.

Does the installation comply with the above standards and guidance for the following:

Minimum air volumes
Air pressures between areas and rooms
Air filtration
Ductwork cleanliness

(further details required under question 6)

HTM 55 Windows
Where windows are installed in operating theatre suites then the installation and materials used shall comply with HTM55. Areas which could affect microbiological standards are:

Weathertightness
Thermal performance (are windows correctly designed or specified to prevent airflow pattern distortion and condensation forming)
Amenable to cleaning, disinfection and maintenance

HTM 56 Partitions
Where partitions are installed in operating theatre suites then the installation and materials used shall comply with HTM56. Areas which could affect microbiological standards are:

Stability to prevent cracking and movement
Biological attack resistance
Mechanical damage resistance
Hygrothermal performance
Hygienic finishes
Thermal performance (may affect airflow patterns)
Amenable to cleaning, disinfection and maintenance

HTM 60 Ceilings
Ceiling installations in operating theatre suites shall comply with HTM60.

Areas which could affect microbiological standards must be scrubbable and have a completely sealed finish.
Lighting fitting shall be sealed fittings to IP56 (ingress protection number under Guidance note 1 of BS 7671 & BSEN 60947-1: 1999), or Chartered Institute of Building Services Engineers LG2

HTM 61 Flooring
Flooring in operating theatre suites shall comply with HTM61. Areas which could affect microbiological standards are:

Stability to prevent cracking and movement from weight or use
Hygienic finishes
Manufacturer's information supplied on suitable cleaning, disinfection and maintenance procedures
Impervious, smooth and jointless

HTM 63 Storage systems
Storage systems in operating theatre suites shall comply with HTM63. Areas which could affect microbiological standards are:

The performance and strength are such that the units will resist surface cracking, absorbence etc. (Manufacturer's data should be supplied)
Surface finishes
Hygienic finishes
Moveable units can be easily disinfected (wheels etc)

3 Has the system been formally commissioned and independently witnessed?

The independent body carrying out the witnessing shall be accredited by UKAS.
Is the theatre performing to the design intent in respect of:

Air dilution and turbulence
All inlet air passes through the filters.
Air pressures
Air change rate
Plant layout and installation
Operating theatre suite configuration

4 Ventilation system hygiene. Level of cleanliness of ductwork

Detail level of cleanliness of ductwork and air-handling plant carried out under the contract. Model Engineering Specification CO4 (Mechanical ventilation and air conditioning) requires compliance with good practice guide DW/TW2 (internal cleanliness of new ductwork installations). There are three levels with six control means for cleanliness in the code of practice. DHSS standard specification for ventilation systems CO4 calls for intermediate level of cleanliness unless otherwise specified to a higher standard. Cleanliness should be to a minimum of 'intermediate' standard.

Level	Factory seal	Protection in transit	Protection during site storage	Clean on-site	Cap-off on site	Special clean once installed
Basic	No	No	No	No	Risers only	No
Intermediate	No	No	Yes	Yes	Yes	No
Advanced	Yes	Yes	Yes	Yes	Yes	No

Note: Site storage shall be permanently clean, dry and dust-free.

5 Level of filtration fitted to the air-conditioning system

The level of air filtration to be installed is in HTM 2025. Filters should comply with BS EN 779 and should be installed in air-handling units in accordance with figure 4.1 of HTM 2025, volume B; in essence the secondary filter should be the last piece of equipment installed in the air-handling unit and must be situated after the fan.

Primary filter suitable G3 (possibly G2)

Secondary filter suitable F8 (depends on inlet air pollution level; F7 in lower particulate pollution areas and in much pre-existing ventilation plant)

6 TABLE: Air change rate and relative pressures between rooms

Detail air change rates in the operating and preparation rooms. The air change rate depends upon the control scheme for the operating theatre suite as detailed in HTM2025, volume B (Design considerations) paragraph 6.19 and 6.20: systems 1a to 5b.

Target air change rates can be calculated from ventilation volume rates given in HTM 2025 and room dimensions given in HBN 26: The numbers (1a, 1b etc.) refer to suggested layouts given in HTM 2025, Design considerations (volume B), Figures 6.1a and b.

The air change rate for operating theatres should, as a minimum, be around 20 air changes per hour (ACH). If room dimensions are as in HBN 26 and airflow rates are as in the various suggested layouts in HTM 2025, volume B, Figures 6.1a and b (this shows eight suggested layouts:
1a & b, 2a & b, 3, 4 and 5a & b), air change rates should be as below:

Conventionally ventilated operating room plan:

1a, 2a & 5a 22.5 ACH
1b, 2b & 5b 19.5 ACH
3 24 ACH
4 23 ACH
(These do not apply to ultraclean ventilated operating theatres)

Preparation room plan:

1a, 2a, 4 & 5a 11 ACH (Preparation room suitable for sterile pack storage)
1b, 2b & 5b 37 ACH (Preparation room suitable for instrument lay-up)
(These also apply to preparation rooms for UCV operating theatres)

If room dimensions differ from those in HBN 26, ventilation rates should have been adjusted to compensate such that the above air change rates are still achieved.

Extract rate related to the pressure requirements see table 6.1 HTM 2025, volume B.

Notes on question 6 table.
These values relate to the Figures 6.1 in HTM 2025 Design for suggested air movement control systems in conventionally ventilated operating suites (shaded boxes do not need to be filled in).

Only the air change rates and pressures in preparation rooms and anaesthetic rooms are applicable to ultraclean ventilated operating theatres, but see the notes at the start of Annex F.

Theatre suite zone	Room or area	Nominal pressure* (Pa)	Air supply rate (m^3/s)	Room volume (m^3)	Air change rate (ACH)	Extract system in place and working
'Sterile'	Operating room (and scrub bay)	25	0.65–0.75		$\geq$20 See note 6	No
	Preparation room (lay-up)	35	0.33		$\geq$37 See note 6	No
	Preparation room (sterile pack store)	25 ± 5	0.1		$\geq$11 See note 6	No
Clean	Scrub room	14–25 See note 1				No
	Anaesthetic room	14 See note 2	0.15 supply 0.15 extract		See note 2	Yes
Transitional	Recovery room	3 See note 3	See note 3		15	Yes
	Clean corridor	3 See note 4				Yes
	General access corridor	3 See note 4				Yes
	Changing rooms	3 See note 4				Yes
	Plaster room	3 See note 4				Yes
'Dirty'	Disposal corridor	0 See note 5				Yes
	Disposal room	0 to -5 See note 5	0 to -0.41 Extract			Yes

*A 'nominal' pressure is the pressure relative to ambient (i.e., outside the theatre suites). A pressure differential or relative pressure is the difference in nominal pressures; for example, if an operating theatre is at a nominal pressure of 25 Pa and the adjacent anaesthetic room is at 14 Pa, the pressure between these areas is 11 Pa.

Notes

(1) Scrubroom: Normally the scrub and handwash facility are part of the operating room often a bay. If a separate room is required then a door between the scrub room and operating room is an inconvenience to scrubbed staff and should be replaced by a permanent opening larger than a doorway. In this case the room pressure should be 25 Pa (If a door is in place, the nominal pressure should be 14 Pa).
(2) Anaesthetic room: This ventilation is primarily for the dilution of anaesthetic gases, not infection control. It should have a balanced inlet and extract (i.e., equal volumes supplied and extracted) with the air entering from the operating room sufficient to pressurise the room to 14 Pa, being lost to the corridor.

(3) Recovery room: The precise pressure differential of 3 Pa is very difficult to achieve or measure and in general it should have a pressure of 0 or be slightly positive. If the recovery room is positioned as indicated in HBN26 or HTM 2025 then the room should have a negative pressure with respect to sterile and clean areas and positive with respect to dirty areas. The extract rate of 15 ACH is for the removal of anaesthetic gases with the inlet air volume being balanced to the extract rate. The supply and extract rate will depend upon the size of the recovery: e.g., for a suite of four theatres, the recovery extract and inlet will be 1 m^3/s.
(4) Clean corridor, general access corridor, changing rooms and plaster room: A slightly pressurized or zero value is acceptable as long as the area is positive with respect to dirty areas and negative with sterile or clean areas.
(5) Disposal room and disposal corridor: dirty areas should be negative with respect to clean, transitional and sterile areas. From a practical point of view dirty areas should have a negative air pressure of 25–30 Pa with respect to the operating theatre.
(6) This is the variable that is important in terms of dilution of airborne contamination. If room volume varies from standard, air supply volume should be adjusted to achieve an adequate air change rate.

Air movement control transfer devices and open door shall comply with Table 6.6b and 6.6c of HTM 2025 Design considerations.

7 Confirmation of turbulent air distribution within operating theatre and other clean rooms

This test is to confirm that there is an airflow in the region of the operating table to ensure that dilution of pollutants takes place.

8 Confirmation that drainage systems on the air-handling unit comply with HTM 2040. The control of legionellae in healthcare premises code of practice

This is a visual check compliance with HTM2040 paragraph 7.0, in particular the existence of an air break soon after the outlet from the air-handling unit drain point. This will prevent contamination of the ventilation system by the drainage system.

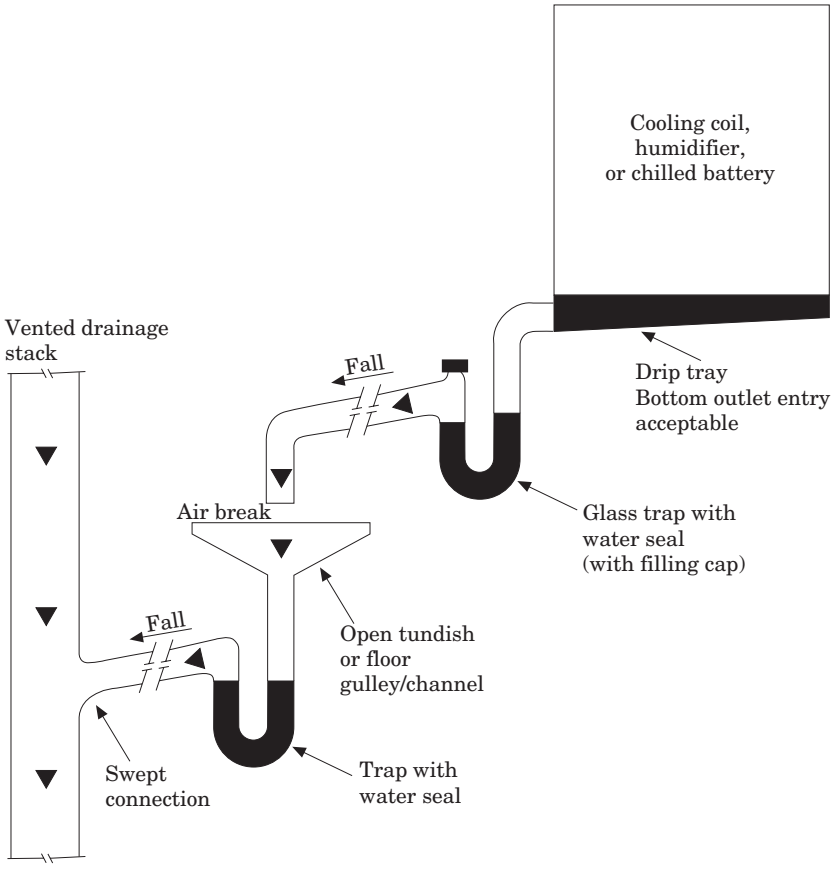


Figure 3 Typical air-conditioning plant drain.

9 Outstanding defects

The outstanding defects listed should be those that relate to hygiene, air change rate and airflow pattern.

10 Comments related to possible microbiological problems

The comments should be concerns relating to possible microbiological contamination.

Annex F: Supplementary certificate for UCV theatres

This should be completed in addition to the basic certificate (Annex D)

General note: Whilst it states in HTM 2025, volume B (Design considerations) paragraph 6.77 'There is no strict requirement when using a UCV system to have an air movement control system, except in the preparation room', surrounding areas should be controlled such that they do not interfere with the integrity of the UCV enclosure. In general, if those areas surrounding UCV operating theatres are ventilated as for similar areas surrounding conventionally-ventilated theatres, this will not compromise the integrity of airflow in the UCV enclosure.

(1) HEPA grade and efficacy of filter assembly

Grade of HEPA filter fitted:

Results of in situ particle testing:

(a) Terminal filter installation test (HTM 2025, volume C, para 5.26)

(b) Lack of entrainment from outside clean zone (HTM 2025, volume C, para 5.28–31)

(2) Monitoring system to show clean and dirty state of HEPA filter: Specify system

Clean/dirty pressure differentials

(3) Type of system fitted:
Vertical flow
Horizontal or cross flow

(4) Test procedure for verification of system parameters:

Brief description of tests and results:

(5) Vertical discharge ultraclean system.
(a) Discharge within the clean zone velocity at 2 m above floor finish (average velocity 0.38 m/s with fixed walls terminating 2 m above floor or 0.3 m/s with fixed walls terminating 1 m above floor):

Test results:

(b) Discharge within the clean zone velocity at 1 m above floor finish (average velocity 0.2 m/s)
Test results:

(6) Comments related to possible microbiological problems:

Name (BLOCK LETTERS) . . . . . Position . . . . . .

Date . . . . . .

Signature . . . . . .

For and on behalf of: . . . . . .

Specify

Annex G: Guidance for completion of supplementary certificate for UCV theatres

To be completed on commissioning and on annual re-commissioning

1 HEPA grade and efficacy of filter assembly.

The HEPA filter should comply with BSEN1822 and be site tested to BSEN1822 parts 4 and 5.

The penetration resistance of the UCV clean zone is set out in HTM 2025 Validation and verification, paragraphs 5.30 and 5.31.

The grade of HEPA filter depends on the specification of the manufacturer of equipment.

2 Monitoring system to show clean and dirty state of HEPA filter.

Describe monitoring method and indicate pressure readings on filters when clean and when dirty.

3 Type of system fitted.

Indicate manufacturer and type of system. Horizontal or cross-flow systems are not recommended by HTM2025.

4 Test procedure for verification of system parameters.

Test method should follow HTM2025, volume C (Validation and verification), paragraph 5.0: The following test applies to a typical UVC system. Any unit which does not comply with this standard design should have its method of verification agreed and documented. Data should include discharge area, diffuser height (from 2.45 to 2.9 m from finished floor level subject to local conditions and operating lamp selection) and whether full or partial walls are fitted.

Air velocity test. Grid size: 2800 mm × 2800 mm. Test measurements taken at 2.00 m above finished floor level

	1	2	3	4	5	6	7	8	9	10
A										
B										
C										
D										
E										
F										
G										
H										
I										
J										

Average velocity over area = m/s

Note: average velocity must not be less than 0.38 m/s for fixed partial walls finishing 2 m above finished floor level
average velocity must not be less than 0.3 m/s for full walls finishing 1 m above finished floor level.

Comments:

Air velocity test. Grid size: 1800 mm × 1800 mm. Test measurements taken at 1.0 m above finished floor level

	1	2	3	4	5	6
A						
B						
C						
D						
E						
F						

All grid velocities must not be less than 0.2 m/s

5 Vertical discharge ultraclean unit.

Test results inline with HTM2025.
The test results should comply with HTM2025 validation and verification Chapter 5 (Performance tests) and the results tabulated as detailed in tables above.

6 Comments related to possible microbiological problems

Comments regarding any problems that could compromise microbiological standards.

Annex H: Air filters

Sub-HEPA filters are classified by BS EN 779: 1993. Under this standard they are graded by either percentage retention ('arrestance') of a test dust of assorted particle sizes (grades G 1–4) or by the passage ('efficiency') of a finer test dust, again of assorted particle sizes.

Arrestance (%)	
G1	(A) < 65
G2	65 > (A) < 80
G3	80 > (A) < 90
G4	(A) > 90

Efficiency (%)	
F5	40 < (E) < 60
F6	60 < (E) < 80
F7	80 < (E) < 90
F8	90 < (E) < 95
F9	(E) > 95

As the test dusts used are of assorted sizes, it is not possible to make accurate predictions about retention of particles of any particular size.

HEPA filters are classified by BS EN 1822-1: 1998. HEPA filters are tested against particles of a definite size range relevant to microbiological applications (mean particle diameter 0.4 μm). The efficiencies (H) of HEPA grades 10 to 14 are:

Initial efficiency (%)	
H 10	85
H 11	95
H 12	99.5
H 13	99.95
H 14	99.995

There also exist 'ultra-low penetration air' filters ('ULPA')
Grades U15 to U17. These are not relevant to operating theatre ventilation.

Filter Applications

G2/3 Filter for air-handling systems not requiring any great degree of cleanliness.
Primary filter for operating theatre air-handling plant.
G4 Where low to moderate cleanliness is required.

F5 Final filter where decor protection is not required.
F6 Final filter but better decor protection than 5.
F7 Final filter used when decor protection is required.
F8 High degree of protection no dust staining.
F9 High quality filtration but where HEPA filters are not justified. (If manufacturer agrees, rigid F9 filters can be tested to BS3928 and therefore classified as a HEPA filter.)
H13 Fitted in ultraclean ventilation terminals, but the grade used will depend upon manufacturer's specifications.

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MEETING REPORT

The future of the UK infection control doctor: report of a one-day Association of Medical Microbiologists organized workshop

B. Cookson[a,*], E.L. Teare[b], R. Slack[c]

[a]*Specialist and Reference Microbiology Division, Health Protection Agency, 61 Colindale Avenue, London NW9 5HT, UK*
[b]*Mid-Essex Hospitals NHS Trust, New Writtle Street, Chelmsford, UK*
[c]*Health Protection Agency East Midlands (North), Nottingham Office, Standard Court, Nottingham, UK*

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Background

Several years ago the UK's Association of Medical Microbiologists (AMM) proposed a job description for an infection control doctor (ICD). Since that time there have been many changes in healthcare delivery, and it is now recognized that infection control needs to be integrated into clinical and corporate governance processes. The AMM therefore convened a workshop and produced recommendations for the way forward. The workshop was at the London headquarters of the National Audit office.

At the beginning of the workshop, four lectures were delivered, illustrating different perspectives of the topic. Attendees were then divided into three groups to debate three different areas chosen before the meeting. The outcome of debate and recommendations were discussed in an afternoon plenary session. All members of the AMM PIC (Prevention of Infection Committees, the organizing group) either attended the workshop or made contributions in writing. There were no attendees officially representing the Welsh, Northern Ireland and Scottish AMM members or infection control professional groups.

Section 1: roles and responsibilities of the ICD in the acute sector

Key recommendations were as follows

1. The job description and competencies of the ICD need to be reviewed and re-written. Infection control is an integral part of a hospital consultant medical microbiologist's (CMM) role and there are insufficient CMMs to have full-time ICDs other than in major centres. In the longer term, there may be 'infection control professionals' drawn from a variety of professional disciplines. The membership examination of the UK's Royal College of Pathology (MRCPath) should remain a requirement for the ICD as described in the new MRCPath syllabus. If the ICDs are medical staff with other backgrounds, e.g. in infectious diseases, cross-cover needs to be addressed. The Diploma in Hospital Infection Control (DipHIC) is a desirable qualification for the ICD.

*Corresponding author. Tel.: +44-2082004400 x4249; fax: +44-2082007449.
E-mail address: barry.cookson@hpa.org.uk

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2. CMMs need time and funding to attend educational events and courses for their further professional development.
3. The group reviewed all the listed activities in the current AMM ICD job description (JD) and felt that the infection control team (ICT) should be involved jointly in these, and that the ICD did not necessarily have to take the lead. However, the group felt that incident and outbreak management, particularly with unusual organisms and antimicrobial prescribing control, were areas where the ICD would lead, as the CMM/ICD competencies were particularly relevant.
4. One could not be prescriptive about the amount of time the CMM spends in the ICD role. There was a consensus that this had to be appropriate for agreed objectives, e.g. controls assurance targets and Department of Health performance indicators. The current AMM job description recommends one-third of a full-time ICD for a typical district general hospital. The parameters on which this is based, e.g. the number of beds and specialties included, should be stated. Although many ICD activities could not be timetabled, some could be, e.g. policy writing. The amount of time needed could be decided using a similar scheme to that for calculating CMM numbers, which has been prepared by the Royal College of Pathologists.
5. The ICD is advisory and not executive, and should be managerially accountable to the Chief Executive (CE) and professionally accountable to the Medical Director.
6. The Infection Control Committee Chair should be a trust board member.
7. There needs to be a review of the need for and requirements of an infection control budget. Funding of multi-disciplinary infection control training needs to be addressed. There were problems in funding or even finding the time for link nurses to attend educational activities. We need recommendations for the funding of outbreak and important incident investigations and control in line with the Clinical Negligence Scheme for Trusts (CNST) level two recommendations. There should be information technology (IT) support from the trust to the ICT.

Section 2: accountabilities within and of the ICT

Key recommendations were as follows:

1. The key functions of the ICT should be identified.
2. ICTs are accountable to the CE for delivery of agreed targets. Accountabilities within the ICT should relate to the targets in this agreed infection control programme.
3. The CE is accountable for agreed standards reviewed through external peer review. This is reviewed by external bodies such as the Commission for Health Audit and Inspection (CHAI) and perhaps the Inspector of Microbiology in the future. It was noted that the CHAI-led Review Coordination Group (CHAI, CNST, Health and Safety Executive, Cabinet Office etc.) were considering harmonising current infection control and risk assessments performed in reviews.

The group did not favour targets such as specific reductions in healthcare-associated infections. Instead it recommended the identification of specific deliverables from activities related to education, surveillance, audit and risk assessment.

Section 3: inter-relationships between acute and community infection control professionals

Key recommendations were as follows:

1. There should be access to appropriate infection control advice in primary care at all times.
2. An infection control service in a primary care trust (PCT) or community-based trust could be provided by a doctor and/or a nurse, but the group felt that the lead could be the infection control nurse.
3. The lead infection control person could be called the 'primary care infection control practitioner'.
   The lead may be the clinical governance officer in a lead PCT, provided she or he had sufficient authority and experience to be responsible. Some PCTs have inherited certain functions, e.g. renal services, that need specialized input. Many PCTs are too small to be self-sufficient, so there may need to be a lead PCT.
4. Consideration should be given to the role of strategic health authorities, given their performance management function.
   All PCTs need to be represented at each infection control committee meeting, taking ratified policies back to their respective PCTs for local endorsement and implementation. Health protection officers, environmental health officers and veterinary practitioners will be involved in Health Protection Agency

(HPA) consultant in communicable disease control-chaired (CCDC) large-scale district committees, that will manage community outbreaks and incidents.

5. There should be national policies and guidance for community infection control.

   The UK National Institute for Clinical Excellence guidelines on the prevention and control of infection in primary and community care settings were currently out for consultation. There is also a newly published book on infection control in the community (Infection Control in the Community, edited by Jean Lawrence and Dee May, Churchill Livingstone, 2003).

6. There should be defined and accredited training for infection control in the community.

General discussion

Summary points of the afternoon sessions were as follows.

There was concern that there is insufficient infection control expertise in the proposed HPA establishment. It is essential for there to be greater 'ownership' of infection control by clinical teams within the context of corporate and clinical governance, and for this to be supported by the CE.

Standards documents with clear statements will help ensure that infection control is taken with the seriousness it deserves. The analogy was made that, in the UK, fire-safety exercises have a legally enforced system to ensure that they take place annually, whereas we only 'fire fight' for infection control.

IT and management are critical to the success of ICTs. The infection control committee should report to the risk assessment or clinical governance committees.

Overall recommendations and follow-up

- The infection control committee should sit within an appropriate acute trust committee structure, to improve integration with corporate and clinical governance.
- Specific deliverables for infection control should be identified, e.g. education, surveillance, audit and risk assessment.
- The value of a link infection control person in directorates could be explored.
- The roles, responsibilities and lines of accountability for infection control staff in the acute and community sectors should be agreed.
- The core competence required for the different infection control specialists should be agreed.
- The AMM and Infection Control Nurses Association should revise the job descriptions for the ICD and infection control nurses, respectively.
- There must be adequate resources and time for education and training in infection control in the acute and community sectors.
- There should be harmonization of infection control standards initiatives.

Acknowledgements

We would like to thank Dr Judith Richards, Dr Hilary Pickles and all the attendees for their participation as well as Ms Karen Taylor and Ms Judith Sedgwick of the National Audit Office for kindly providing the venue and refreshments for the workshop meeting.

NSS Health Facilities Scotland

Lessons Learned & Recommendations Report on Cowlairs CDU Incident Nov 2018

September 2019

A47310563

Executive summary

The NHS Greater Glasgow & Clyde (GG&C) Central Decontamination Unit (CDU) at Cowlairs in Glasgow was the subject of an unannounced audit by their Notified Body on 13th November 2018. As a result of the audit findings, principally related to inadequate cleanroom environmental controls, the Notified Body instructed the CDU management to halt production.

Over the eleven days of downtime there were principally two streams of work, one being the continuation of a sterile service making use of contingency support from other decontamination units and the other being remedial actions required to return the Cowlairs CDU to an operational state.

Suspension of the sterile service provision from the Cowlairs CDU had a profound effect on patient operations. There were also significant financial, staff and reputational impacts. This became a national event due to the support required from other decontamination facilities across multiple healthboards.

The Strategic Facilities Group (SFG) requested that a lessons learned report be prepared via a short term working group.

The working group identified the root causes of the production shutdown from the lack of environmental control in the cleanroom used in production. There were concerns over cleanroom design, maintenance, microbial monitoring, document control, staff training and corrective action effectiveness. The overall cause was assigned to not dealing with audit non conformities in a timely manner. These failings were across the quality management system.

Based on feedback collected from contingency providers it was concluded that the tracking systems did not work well between different decontamination units. There was mixed feedback on staffing and communication while the contingency was in use.

From review of the incident details available a series of recommendations are made based on both prevention measures and those applicable should there be a future shutdown of production.

It is noted that in the short term should a large scale output central decontamination unit have an unplanned prolonged shutdown the contingency support required would be national in nature and not local.

The recommendations should be considered by each healthboard and an update on progression monitored through the expert steering group, Reusable Medical Device-Decontamination Operational Group (RMD-DOG) starting at their December 2019 meeting.

Content

1. Introduction

The NHS Greater Glasgow & Clyde (GG&C) Central Decontamination Unit (CDU) at Cowlairs in Glasgow was the subject of an unannounced audit by their Notified Body on 13th November 2018. As a result of the audit findings the CDU's production was ceased on 15th November until 26th November. Contingency support was sought from other healthboards and the private sector during this time. This removal of sterile service provision from Cowlairs had a profound effect on patient operations, with around one thousand operations being cancelled over November/December with NHS GG&C. There were also financial, staff and reputational impacts. Subsequently the Strategic Facilities Group (SFG) requested that a lessons learned report be prepared within 2019. This would be used with the intention of preventing a reoccurrence of this incident. To develop the report a short term working group was convened (its terms of reference including membership is in appendix 1) and meetings were held on 16th May and 19th June 2019.

2. Background

2.1 The NHS Greater Glasgow & Clyde (GG&C) Central Decontamination Unit (CDU) at Cowlairs in Glasgow was the subject of a routine surveillance audit in July 2018 by their contracted Notified Body (number 0088), Lloyd's Register Quality Assurance (LRQA). A number of non conformities were raised at the surveillance audit. LRQA then issued a three year EC certificate from 4th August 2018 as shown in appendix 2.

2.2 Three months later, the CDU at Cowlairs in Glasgow was the subject of an unannounced one day audit (on 13th November 2018) by their contracted Notified Body Lloyds Register Quality Assurance (LRQA) three persons assessment team. Numerous major non conformities were identified during the unannounced audit. On 15th November LRQA issued a suspension notice to Cowlairs CDU (dated 13th November) LRQA reference LRQ 4002546 number on their Annex V – Production Quality Assurance Certificate number LRQ 4002546/B and instructed that production should cease immediately. The suspension letter of 13th November indicated the relevant European Competent Authorities would be informed of their decision. The associated report LRQA reference LRQ 4002546/ 1988562 stated MDD, 93/43/EEC and ISO 13485:2016 certificates were suspended.

2.3 The audit report highlighted the principal issues related to inadequate cleanroom environmental controls. These included:

- The process of record control was not effective;
- The process of corrective action was not effective;
- The process of training and competence was not effective;
- The process of validation of processes for production was not effective.

These matters relate to failures across the quality management system. LRQA lifted their suspension on the afternoon of 22nd November.

2.4 GG&C Infection Control required additional checks to be made before start-up of production could commence. Agreement was reached on the afternoon of 25th November that the cleanroom environmental monitoring results were satisfactory and production started midday on the 26th.

2.5 Over the two week down time of production at Cowlairs (due to the cleanroom being out of service) it has been reported that in excess of 1000 operations were cancelled. The impact of this rare event was widespread making it a national event. Aspects of fragility around the cleanroom were highlighted.

2.6 Over the period of downtime there were principally two streams of work, one being the continuation of a sterile service making use of other decontamination units and the remedial actions required to return the Cowlairs decontamination unit to an operational state.

HFS support in returning the CDU to an operational state

2.7 Support by way of advice and information was provided to NHS GG&C Senior management, Tom Steele (the principal contact, Director of Estates and Facilities) and Jane Grant, Chief Executive.

2.8 Advice and information was provided to Head of Maintenance, David Shaw as remedial works/corrective actions were progressed.

2.9 Advice and support in liaising with their notified body LRQA and assisting with management of the LRQA follow up audit conducted on 20th November was provided.

2.10 Advice and support was provided to the CDU management with regard to NHS GG&C Teresa Inkster/John Hood (Infection Control), requests/requirements to enable the start-up of production on 26th November.

2.11 Multiple daily meetings were held principally at the Cowlairs CDU.

HFS initial set of national recommendations November 2018

2.12 An initial set of national recommendations (Table 1) were prepared on 25th November for early discussion with the Strategic Facilities Group (SFG) at their December 2018 meeting.

Reference	Subject	Recommendation
1	Fragility	Communicate the fragility identified in this event. Capture the things that have worked during the event and the things that have not worked and communicate these to the Service.
2	Contingency	Contingency for CDUs in Scotland should be reviewed again particularly looking at high volume & long opening hours units & at the age & condition of CDU buildings.
3	Critical Maintenance priority	Maintenance & testing of decontamination equipment & building fabric needs to be allowed to take place & not put off due to production pressure. Support should be given from senior management at the HB to allow essential maintenance.
4	Scrutiny monitoring	Auditing of CDUs by NHSScotland experts from outwith each CDU should be considered to identify non conformities/ concerns.
5	Specification for national guidance	Consider the introduction of a national specification for microbial limits in the cleanroom. Ensure there are separate limits for bacteria and fungi (yeasts/moulds).
6	Responsibility	Review each board's approach to recovery back to production in the event that a certificate suspension takes place defining who has final say on start up.

7	Responsibility	All HBs / CDUs should ensure that the roles identified in SHTM 01-01 are filled by appropriately trained staff who are familiar with the facility. The Infection Control Doctor/ Microbiologist (Decontamination) role should be a particular focus.
8	Responsibility	Discussions should take place between NSS, SG & HBs to ensure that suitably qualified and experienced Quality Managers are in post.
9	Responsibility	Consideration should be given to the creation of a Regional CDU Quality Control Manager at the 3 Regions in Scotland. Postholders should be responsible for detailed contingency planning & arranging for shutdowns for essential maintenance, equipment replacement.
10	Education/training	Review the cleanroom training of all staff interacting with the cleanroom including those involved in investigations.
11	Notified Bodies and MHRA	NSS should have discussions with both LRQA & MHRA about the decision to close Cowlairs & their slow response in assisting with recovery.
12	Notified Bodies and MHRA	NSS should review the position of LRQA as a Notified Body (NB) in Scotland & the requirement for CDUs to be accredited under the quality management system standard EN ISO 13485.

Table 1

Future Design and upgrade work involving the cleanroom

2.13 Design out the presence of liquids above the cleanroom ceiling. This includes drain pipes and wet fire systems. If not possible, protection measures from liquids for the ceiling should be in place along with monitoring measures. The cleanroom floor must be laid and be of the required quality to prevent the introduction of cracks over time. Given that all production passes through the cleanroom which tends to be a single room consider solutions that may enable duplex cleanrooms.

Root cause of the lack of cleanroom environmental control

Design and construction of the cleanroom

2.14 A single cleanroom through which all production flows was and is in use. Consequently all on-site production ceases at times of significant maintenance (including any recovery period) of the cleanroom. There is no on-site backup that allows production to continue.

2.15 There are other design issues around protection of the cleanroom fabric that contributed to this incident. These include the floor quality required to ensure no cracks develop, the ceiling quality and protection measures for the cleanroom ceiling. Pipework carrying liquids (e.g. drain water) was installed directly above (and through) the cleanroom ceiling when the facility was built. This built in fragility as the cleanroom ceiling and (hence the room) is compromised by exposure to liquids which

break up the fabric or result in formation of unacceptable levels of biocontamination on the inside of the cleanroom ceiling. Damage to the cleanroom floor and the cleanroom ceiling did occur and was observed during the audit.

Maintenance of the cleanroom environment - Production downtime required.

2.16 Access for planned critical maintenance of the cleanroom fabric, such as cracks in the floor and water damage to the ceiling, which required a significant production downtime was limited due to production pressures.

Action to be taken based on environmental monitoring results

2.17 The microbial air samples (active and passive) limits were based on a total count of bacteria and fungi. Had separate action limits been set for bacteria and for fungi the requirement for corrective action in the cleanroom may have been confirmed earlier through review of the test results. It is also noted there were gaps in sampling exercises.

Other aspects impacting on environmental control

2.18 The other aspects highlighted in the audit report such as document control, staff training and corrective action effectiveness are standard matters covered by the in-house quality management system. These were not effectively managed in the months prior to the unannounced audit.

Interim work undertaken to bring the cleanroom environment back in control.

2.19 Repairs to the cleanroom fabric were undertaken. The cleanroom floor cracks were sealed. The cleanroom ceiling was repaired on the clean side and work was done in the ceiling void above to reduce the likelihood of future water leaks onto the ceiling. In addition routine visual inspection of the cleanroom ceiling void and plant room floor was introduced onto the preventative maintenance register. After the repair work was completed the cleanroom internal fabric was subjected to high level cleaning and then exposed to a chemical disinfection process. On completion of this a microbial monitoring exercise commenced (with the cleanroom in the at-rest condition) and was carried out on three days Mon 19th, Wed 21st and Fri 23rd November. The results were carefully scrutinized and agreement was reached with Infection Control that the microbial levels found were satisfactory and that based on this production commenced in a staged manner. Initial cleanroom recommendations were supplied to NHS GG&C by HFS on 27th November 2018.

3. Feedback from contingency providers

Activities keeping the service operational during the shutdown event

Feedback from the boards who provided contingency

Table 2 outlines the positive feedback from some boards who provided a contingency service during the incident.

Table 3 outlines the negative feedback from some boards who provided a contingency service during the incident.

Board feedback - site	Things that worked well
A	Staffing "The supervisor that was sent was very good".
B	Staffing "Our supervisor controlled packaging and consumable goods and ensured adequate stocks were maintained."
B	Production "We managed two work streams within the Department which worked well and avoided any confusion".
B	Logistics "Drivers and goods arrived as agreed"
C	Staffing "All staff worked well in difficult circumstances. Staff cooperation at the provider sites was excellent. Cooperation from other facilities support services e.g. domestics was excellent."
C	"Partnership – union participation from the start was critical."

Table 2 – positive feedback from contingency providers (anonymised)

Board feedback - site	Things that did not work well
A	Tracking system "found the tracking a nightmare especially matching up the trays to tray lists was difficult because of the coding and missing items locating trays that were priority as labels or user departments were difficult to see ".
A	Staffing "Some of the staff didn't work as efficiently as mines which causes unrest when [redacted] staff were working on Glasgow work." "The length and the number of breaks their staff had in comparison to ours were awful especially under the circumstances." "Some of the staff did not accept that they would have to work as my staff do abiding by the cleanroom rules and procedures of [redacted]."
A	Capacity "Our department is not big enough to hold the number of staff so may have been better coming out of hours."
B	Communication "Same question being asked by a number of people – one point of contact would have been beneficial".
B	Tracking system "IT tracking system compatibility – manual recording of sets was very time consuming".
B	Instruments "Repair/ replacement of items for repair, missing etc."
C	Staff safety "Safety of [redacted] unit providing contingency potentially became compromised – too much work, equipment, staff and deliveries were too frequent."
C	Communication "Communication and listening could have been better."
C	Tracking system "Incompatible IT systems a problem"
C	Staffing "Productivity of visiting (Cowlairs) staff was a major issue. Including travel time in shift there was a huge impact on productivity – a 7.5 hour shift lost 3 hours due to travel and breaks that visiting (Cowlairs) staff expected in full. Staff working too many hours with occasional accidental breached in employment law, we need to learn from this."

Table 3 – negative feedback from contingency providers (anonymised)

4. Conclusions

Cause of the shutdown

4.1 The main cause was not dealing with non conformances including the minor ones in a timely manner.

4.2 It is concluded a number of factors were responsible for the shutdown of production. Design issues around the cleanroom, including the site location being close to sources of vibration and the quality of finishes and protection measures employed for the cleanroom fabric impacted adversely on the long term condition of cleanroom leading to its closure and cessation of production. Interpretation of the cleanroom environmental monitoring trend results (microbial) with respect the in-house limits was unclear which contributed to a delay in corrective action prior to the shutdown. Documentation control, staff training and corrective action effectiveness were also not as required in the run up to the incident.

Cause of the time to recovery of production

4.2 It is concluded that there were two elements involved in returning the decontamination unit to production. The first element related to the time taken for remedial works in the cleanroom and convincing the notified body that the cleanroom environment was back in control. The time taken for this activity was exacerbated by the slow response of the notified body at a time of great need of their services. The second element of the time delay related to the further cleanroom testing required to demonstrate to Infection Control that the environment was fit for use. It is concluded that CDU design guidance and operational procedures require to be improved taking account of these findings.

Cause of the lack of available contingency at the time of need

4.3 The national fragility related to both the scale of processed RMDs required and the extended time over which alternative arrangements for processing were required. One large scale output decontamination unit required unplanned immediate assistance from other decontamination units that had little or no spare capacity individually to help. Therefore assistance for processing RMDs was required from multiple decontamination units from around Scotland and beyond. As a consequence this became a huge logistics exercise with no notice period.

Contingency providers

4.4 From the feedback from contingency providers over the incident it is concluded that the tracking systems did not work well. Given that RMDs were being sent to and being returned from multiple sites the absence of a GS1 coding over tracking systems had a profoundly negative impact on the processing of RMDs and the service to Users. There was mixed feedback on staffing and communication.

Short term impact of large scale CDUs being closed

4.5 In the short term, should one of the large scale production CDUs be closed for more than a few days due to an unplanned event, there would likely be a national impact on cancellation of patient operations due to lack of processed product. Patient care

would be impacted by the closure of small scale CDUs, though the impact would be local.

5. Recommendations - Steps to improve performance

Prevention measures

Notified body audit non conformities

5.1 Assurance should be given to the government that the service takes immediate corrective actions to deal with the non-conformities raised and highlight risks for potential future non conformities.

5.2 Minimise the number of notified body non-conformities raised through the increase of internal audit or peer review audits.

5.3 The establishment of a NHSScotland specific quality management system standard and National Procurement Framework should be explored.

5.4 Feedback from audit activities non conformities should be included on Boards' clinical governance. The actions dealing with non conformities should be timely, monitored and reported to senior management as a part of escalation process.

5.5 Audit non conformities should be shared with other Boards through the agenda for the National expert steering group RMD-DOG, the Quality Group and other stakeholders.

Notice of suspension of production quality certification

5.6 A system with clear lines of communication (including backup contacts) is established to ensure that where a notified body recommends the suspension of a CDU's production quality certificate, the following organization are contacted prior to a decision by the notified body to suspend the certificate: HFS - who will liaise with MHRA. Note: HFS have had discussions with MHRA. It was agreed, for future serious incidents including suspension, both parties should be informed and discuss immediately.

Building design – Central Decontamination Unit (CDUs)

5.7 Seek a mandate letter from government directing Board design teams and their contractors to follow the planning note for Central Decontamination Units SHPN 13 Part1 and be compliant with guidance GUID 5014 – Requirements for compliant CDUs. Revise SHPN 13 Part1 taking account of new recommendations.

5.8 New build/refurbishment of cleanrooms - Design out the presence of liquids above the cleanroom ceiling. This includes drain pipes and wet fire systems. If not possible, protection measures from liquids for the cleanroom ceiling should be in place along with monitoring measures.

5.9 When considering the location (including an offsite build) for a new CDU consider risks from the surrounding environment that may adversely affect the building structure/fabric.

Maintenance

5.10 Critical maintenance in the cleanroom - Maintenance & testing of decontamination equipment & building fabric needs to be allowed to take place & not put off due to production pressure. Support should be given from senior management at the healthboard to allow essential maintenance. There should be adequate provision of estates staff to enable this maintenance to be completed in a timely manner. There should also be a procedure to describe what to do in the event of unplanned maintenance work arising from example water passing through the ceiling or the floor being flooded. There should be a national programme of major maintenance and equipment replacement.

5.11 If maintenance activities are undertaken while production is live there should be clear evidence that the cleanroom continues to meets its required performance over this period.

Cleanroom microbial limits

5.12 Consider the introduction of a national specification for microbial limits in the cleanroom to complement the existing non-viable contamination specification ISO class 8. Ensure there are separate limits for bacteria and fungi (yeasts/moulds).

Training

5.13 Review the cleanroom training of all staff interacting with the cleanroom including those involved in investigations including Infection Control Doctors, Microbiologists (Decontamination) and Estates staff etc.

5.14 Regular refresher training on staff dealing with auditors should be in place.

5.15 Establish training in the use of SHPN 13 Part 1 for Boards developing outline business cases and as a commissioning tool for Users.

5.16 There should be provision of Quality Management System (QMS) training particularly for the manager, quality manager and supervisors.

5.17 Cleanroom expertise comprising of microbiology/engineering and controlled environments required and employed in internal audits.

Contingency and Capacity

5.18 A sufficiently sized workforce should be developed to aid contingency provision.

5.19 Robust business continuity and national contingency plans, that have been tested, should be developed.

5.20 Existing contingency plans should be reviewed with respect to this report.

5.21 Arrangements should be made to enable Staff to be familiar with the equipment, facility etc of other CDUs providing contingency.

5.22 A review of CDU capacity should be undertaken with a view to increasing capacity.

5.23 Where the board requiring contingency has supplied staff to work at the contingency site, the supervisors' authority must be clear for all concerned at the contingency provider site.

5.24 An electronic tracking system which is compatible across all NHSScotland boards should be in place.

Measures to be taken in the event of a production shut down

5.25 Immediately notify HFS and HPS and senior management and the comms officer.

5.26 Within the site recovery plan have a detailed start-up/recommissioning plan for the cleanroom in the event of a significant shutdown period. This would define those responsible for approving the start-up of production.

5.27 Implement the tracking system agreed between user and providers of a contingency service.

5.28 A communications plan should be in place for CDU staff, theatre staff, government and press.

5.29 Clear guidance on staffing should be employed ensuring staff representative involvement.

5.30 Follow procedure with regard to extra instrumentation and dealing with missing or damaged instruments.

5.31 Follow procedure on transport and storage as relevant to the situation.

6. Action Plan

The recommendations should be considered by each healthboard and an update on progression monitored through the expert steering group RMD-DOG starting at the December 2019 meeting. Updates on progression will be forwarded to SFG.

Appendix 1: Short Life Working Group ToR

Short Life Working Group Critical Incident Review -Cowlairs November 2018

Terms of Reference

Purpose

The purpose of the short life working group is to learn from the incident at Cowlairs Central Decontamination Unit which occurred over November 2018. This is intended to prevent repetition of similar incidents in the future and minimise impact on the service.

Remit

To gain an understanding of the nature of the incident that took place in Cowlairs Central Decontamination Unit on November 2018, when the notified body issued a suspension certificate.

To learn lessons from the incident and to share learning with the Boards via the Strategic Facilities Group (SFG). The Reusable Medical Device – Decontamination Operational Group (RMD-DOG) will manage the roll out of these lessons.

Membership

The list of group members is as follows.

Title	Health Board/Organization/Group
Eddie McLaughlan (Chair)	Health Facilities Scotland
Sulisti Holmes	Health Facilities Scotland
Andrew Tweedie	Health Facilities Scotland
Paul Howard	Health Facilities Scotland
Tom Steele and Lynsay Gracie	NHS Greater Glasgow and Clyde
George Curley	NHS Lothian
Paul Allen/Juliette Watson/Gavin Payne	NHS Grampian
Phyllis Watt	Inverclyde _ NHS GGC
Barbara Casey	Golden Jubilee National Hospital
Anne Cosh	NHS Highland
Laura Burnside	NHS Ayrshire & Arran
Annette Rankin/Heather Wallace	Health Protection Scotland

Timeline

The group will meet on two occasions set for 16th May and 19th June 2019. The final output will be to SFG in September 2019.

Output

An action plan will be prepared (after the June group meeting) and submitted to SFG by September 2019 for their consideration.

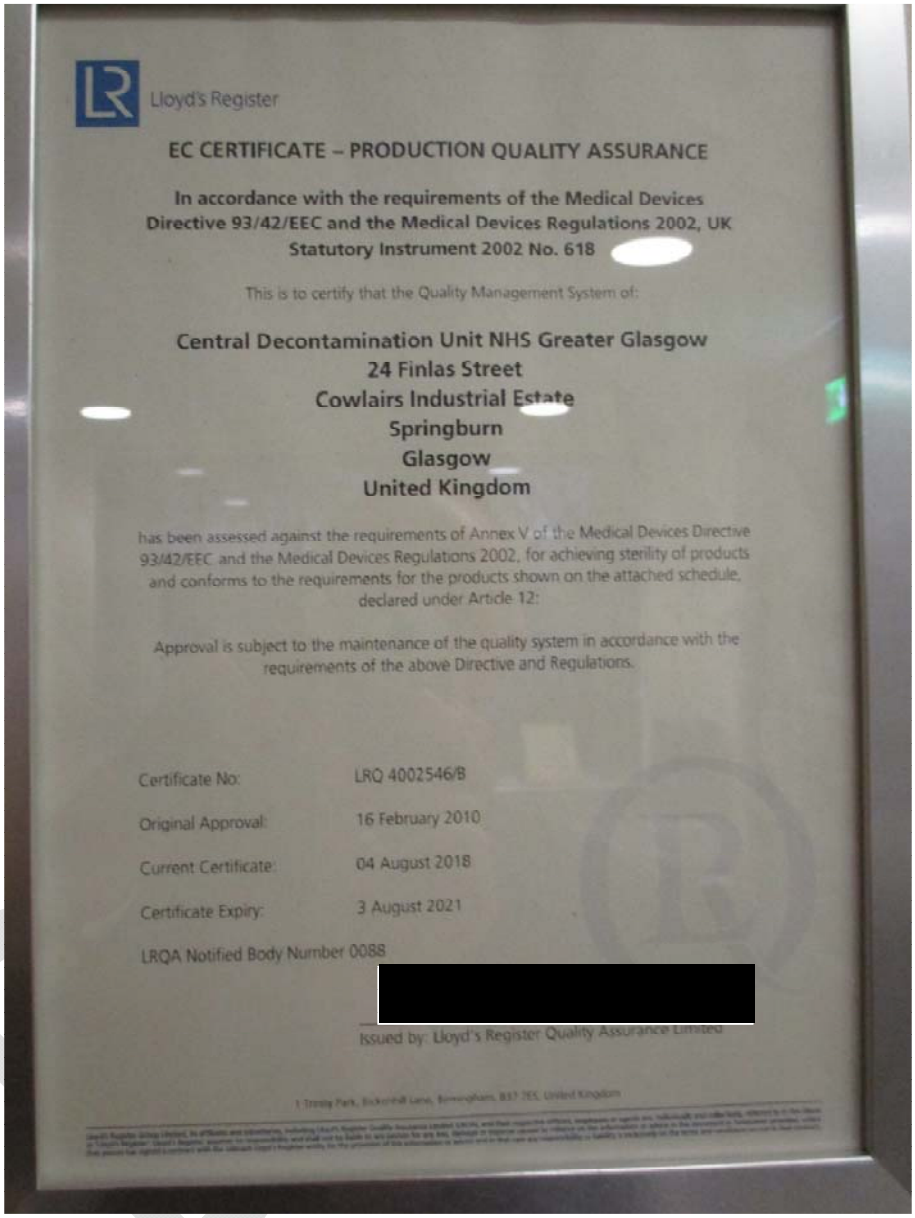
Secretariat and Support

Secretarial support is provided by HFS providing detailed action notes. The group meets as required at National Services Scotland's office or other nominated locations. Teleconference facility will be provided.

Chair of the Group

The Chair of the group is Eddie McLaughlin.

Appendix 2 – Cowlairs EC Certificate – Production Quality Assurance



Lloyd's Register

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Central Decontamination Unit NHS Greater Glasgow
24 Finlas Street
Cowlairs Industrial Estate
Springburn
Glasgow
United Kingdom

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, for achieving sterility of products and conforms to the requirements for the products shown on the attached schedule, declared under Article 12:

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Certificate No: LRQ 4002546/B

Original Approval: 16 February 2010

Current Certificate: 04 August 2018

Certificate Expiry: 3 August 2021

LRQA Notified Body Number 0088

[redacted]

Issued by: Lloyd's Register Quality Assurance Limited

References

Requirements for compliant Central Decontamination Units – GUID 5014, HFS 2019.

Scottish Health Planning Note 13 Part 1: 2010 Decontamination Facilities: Central Decontamination Unit, 2010, HFS.

EN ISO 14698-1: 2003 Cleanrooms and associated controlled environments. Biocontamination control. General principles and methods. CEN.

prEN 17141: September 2018 Cleanrooms and associated controlled environments -- Biocontamination control. CEN.

EN 13485: 2016 Medical Devices. Quality management systems. Requirements for regulatory purposes. CEN.

Doc control

D0.01 – 14/06/19 – initial release

D0.02 – prepared 21/6/19 - post meeting of 19/6/19, the ToRs were amended and information was supplied from boards (FV and A&A) that provided contingency.

D0.03 – 4/7/19 – Information supplied from Inverclyde on their contingency

Sulisti comments on D0.02 on 25/6/19.

D0.04 – 5/8/19 – revised based on Sulisti's comments on D0.03 on 2/8/19 on recommendations – removed sections on 'Scrutiny' and 'Specialist expertise in cleanrooms'.

D0.05 - 5/8/19 – removed complaint item with respect to LRQA.

D0.06 – 10/9/19 – amended based on the analysis of the August 2019 feedback from the short life working group.

D0.01 Discussed with working group at meeting of 19th June-

D0.05 Raised at RMD-DOG meeting of 4th September 2019

The Infection Prevention and Control Doctor in Scotland - Report on current position

Version	Date	Release	Author	Reviewed	Approved
1.0	07-09-2020	Draft	AM		
2.0	29-11-20	Draft	AM		
3.0	21-12-20	Draft	AM		
4.0	10-03-21	Draft	AM		
5.0	29-3-21	Final	AM		

1. Introduction

There is a recognised lack of clarity surrounding the role of the Infection Prevention and Control Doctor (IPCD). Following the Vale of Leven inquiry the roles and responsibilities of the Infection Prevention and Control Manager (IPCM) were detailed but this piece of work was never completed for the IPCD. Additionally, since then the role has changed, becoming more involved and with a greater emphasis on the impact of the built environment on healthcare associated infection.

The Scottish Microbiology and Virology Network (SMVN) IPCD subgroup has discussed this subject with the aim of providing clarity at local and national level around the role to ensure the broad range of skills and knowledge are utilised effectively for the health and safety of patients and staff working in healthcare premises.

A draft of a roles and responsibilities document has existed since 2015 (Philips et al) and this paper builds on this. Additionally a number of helpful documents have been published in this area by WHO and ECDC and this paper takes account of these. It aims to set out some of the functions of the IPCD as directed by what is currently in place in Scotland and highlights some key current issues. A small list of recommendations for additional work are detailed at the end. This report does not carry out a systematic evidence based review of the role of the IPCD.

Infection Prevention and Control Doctors (IPCD) have a broad range of knowledge and skills and are subject matter experts to varying degrees depending on experience, in microbiology, laboratory work, epidemiology, antimicrobial usage and Infection Prevention and Control including environmental issues such as water, air, decontamination. It is a unique cross speciality role. In addition, they will be gathering and interpreting often complex data and give advice on the correct response to these data including advice on risk assessment

Although the IPCD term is used some aspects of the role may be filled by clinical scientists.

It is recognised that Infection Prevention and Control (IPC) is a core function in the job of all clinical microbiologists and other infection specialists. IPC considerations should feature in any clinical interaction. However effective input to and co-ordination of the activities of the IPC team requires specialist expertise from the nominated IPCD. Additional advice may be given to the Infection Prevention and Control Team (IPCT) by any clinical microbiologist however the nominated IPCD would usually lead on longer term activities described in more detail below.

Finally, COVID19 has exacerbated problems with access to expert IPC advice on specialist issues such as dental infection control including respiratory PPE, control of aerosols, AGP fallow period, practice (& dental hospital) ventilation risk assessment and Legionella control.

2. The Infection Prevention and Control Doctor in Scotland

2.1 Models of Infection Prevention and Control Doctor provision

It is recognised that across Scotland the different sizes and geographies of health boards may lend themselves to different models of provision of the IPCD role. Some boards may wish to have a single individual with adequate time dedicated in their job plan for the majority of the functions detailed below. Others may wish to have a number of individuals with a smaller amount of time dividing this either by specialist area (such as water, ventilation, decontamination or by alert condition) or geographic area. Some larger health boards with a number of individuals contributing time to the IPCD role may designate a lead or co-ordinating IPCD. Additionally some aspects of cover may be provided for smaller boards through service level agreements.

Selection of individuals for management positions should be by competitive recruitment. As the role of the IPCD has developed there is recognition that it is becoming in some boards too large for a single individual. Multiple individuals contributing to the IPCD role can allow cross cover for leave and provide reassurance for the board. However, if there are other Medical staff undertaking some of the IPC duties there must be clear roles, responsibilities and lines of accountability written and communicated, including for periods of leave.

There has been recent debate about the benefit or otherwise of increasing specialisation within the role. It is widely recognised that some areas of the infection control doctor's role benefit from additional experience and time dedicated to these areas and as with other areas of microbiology such as paediatrics or transplant microbiology these may lend themselves to being covered by a person or persons with specialist interest. Increasing specialisation however may come with risks and it is important that these are actively explored. Adequate attention to succession planning is vital to prevent an organisation becoming too dependent on a single person. Additionally some areas of microbiology might be less popular and the tendency might be for other microbiologists to delegate these. It is key to remember that infection control really is everyone's business and should be part of every clinical interaction rather than some aspects of an interaction being ascribed to the infection control team.

2.2 Recruitment

Recruitment into this role has sometimes been a challenge and in some settings the most recently appointed consultant clinical microbiologist is given the role as part of their job plan. This situation is both undesirable and critical to avoid. Lack of formal recognition of the role, lack of a formally recognised training programme and often lack of sufficient time along with increasing media scrutiny and a fear of litigation may make the role of IPCD less desirable. As more experienced consultants move out of the IPCT key skills are lost.

However Infection Prevention and Control training across Europe is becoming increasingly formalised and good quality training is available. It is conceivable that with better recognition of the role of the IPCD and a more defined training then recruitment issues may be resolved.

2.3 Roles and Responsibilities

The main functions of the IPCD may be summarised under the headings below. These have been generated through consensus between the current practicing IPCDs in Scotland.

- Clinical Leadership for Infection Prevention and Control

  The IPCD is the clinical link for the IPCT, who in partnership with IPCM and Lead Infection Control Nurses, and the surveillance team will develop and implement a comprehensive and effective Infection Prevention and Control Service and prioritise resources to meet the organizational objectives relating to Infection Prevention and Control. There is a role in ensuring the Team functions effectively and the IPCD works with the IPCM in job descriptions, shortlisting and appointing other key team members.

  The IPCD will promote an organisational culture of Infection Prevention and Control as a priority patient and staff safety measure. The key feature should be on prevention and developing a culture where this is paramount.

- Expert knowledge

  The IPCD will act as an expert clinical resource in the delivery of the IPC service being a member of, and working in partnership with, all members of both the Health Protection Team (HPT), Occupational health and others as required. Such matters may include surveillance and control of hospital and community infection, sterilisation and decontamination methods, types of ventilation, operating theatres, isolation facilities, kitchens, laundries, housekeeping, waste disposal, pest control, and Infection Prevention and Control aspects of clinical procedures.

The IPCD will lead (or give direction) on the investigation and management of outbreaks, clusters and incidents of hospital infection in close collaboration as required with other infection experts such as virologists, Infection Prevention and Control Nurses and infectious diseases physicians. They will liaise as required with Health Protection Team in outbreaks in community settings as well as the medical microbiology service in the direction and interpretation of typing information in close collaboration with relevant reference laboratories. They will direct additional sampling including environmental sampling such as may be warranted by the nature of the outbreak. The IPCD in partnership with the senior IPCT, management and communications teams will formulate the outbreak communications strategy as well as ensuring that duty of candour considerations are adequately addressed in partnership with the relevant clinicians.

The IPCD in partnership with the senior IPCT will develop and guide implementation of lessons learned from outbreaks to inform quality assurance measures.

The IPCD will contribute expert knowledge to facilitate the day to day functioning of the IPCT through interpretation of diagnostic and reference lab data in terms of surveillance and the knowledge of microbial habitats, pathogenesis of infection and virulence factors.

- Governance

The IPCD contributes to effective structures for risk management such as error reporting and dissemination of lessons learned, challenges inappropriate practices and policies which impinge on effective IPCT. They will contribute to ensuring that hospital acquired infection (HAI) prevention policies are integrated with other risk management policies.

This aspect is also discussed under item 2.6.

- Assurance

The IPCD will contribute to the design, functioning and interpretation of an effective HAI surveillance and audit programme and will input into to the development of annual reports, including the Infection Prevention and Control Annual report. They will be involved in setting of local quality standards in respect to HAI and audit.

- Development and research

The IPCD will contribute to policy development and update; implementation of standards; support the promotion of prudent antimicrobial prescribing; surveillance programmes. The IPCD will also guide and contribute to relevant research.

The IPCD will contribute advice on barriers to compliance and work to promote and evaluate compliance.

They will advise on developments in IPC and contribute to the development of business cases to allow necessary development.

- HAI Education

The IPCD will contribute to the development and implementation of the annual Infection Prevention and Control programme of education and will be involved in assessment of the training needs of the organisation, integration with current training programmes and ensuring that training programmes are up to date and accurate. The IPCD will also contribute to the monitoring of the effectiveness of the training programmes provided.

Additionally the IPCD will be involved in providing specialist IPCD training to joint infectious diseases/microbiology trainees if there are any within the department. More senior IPCDs may also have a mentoring role for other IPCDs who have more recently taken up positions.

- Effective Communication and team working skills

Professional and management objectives shall be met through close working relationships with medical microbiology, other relevant clinical services such as infectious diseases, the health protection team, the antimicrobial management team and senior management of the organisation. In aspects of the built environment the IPCD will also liaise closely with estates, facilities and the relevant authorising engineers.

Meetings that require input include IPCT meeting, healthcare governance meetings, meetings of the health protection unit, antimicrobial management team as well as meetings involving specialist estates and facilities sectors such as water, and decontamination. This list is not exhaustive.

The IPCD will work with the microbiology management team to ensure that those individuals providing out of hours Infection Prevention and Control cover have the knowledge and skills to carry out the first response to an incident or outbreak.

2.4 Time requirements

An effective IPCD has a thorough understanding of the hospitals they cover, the staff and their processes. A physical presence is required for effective IPC. This along with prompt reaction to issues requires an appropriate allocation of time.

The European Centre for Disease Control (ECDC) has a recommended formula of number of beds per whole time equivalent Infection Prevention and Control nurse of 1 per 250 beds. No such formula exists in Scotland currently for IPCDs. The TRICE study in 2010 indicated that ratios for IC/HH doctors per bed or admission were recommended in 54% of respondent countries (18/33), although not always monitored in their application. For example France has a requirement for 1 whole time equivalent Infection Prevention and Control practitioner per 800 beds and Germany uses a formula based on number of beds and additional weighting is added for specialties which require more IPC involvement such as transplant units with immunosuppressed patient. Numbers of sessions across Scotland vary from between 1 session per 111- 425 acute beds (data still to be verified). However it is widely accepted that the role is not the same as it was at the time of writing of the Watt and Vale of Leven inquiry reports. To develop a proactive service and with the expanding recognition of the importance of the built environment adequate time for this function is vital. For boards with large or complex geography sessions must include travel time to remote areas. It is appreciated that large sessional requirements might be difficult to achieve in smaller Boards or Island Boards in which case the situation should be risk assessed and controls in place to ensure protection of patients and staff from infection.

A suggestion is that boards should have a minimum number of sessions to cover the minimum requirements, this would then be supplemented depending on the number of beds and weighted for the acuity of the specialities covered as well as the geography involved.

The requirement for CPD must be recognised in time allocations, as for complex and developing areas such as this built environment this is likely to be significant.

Expected involvement since the onset of the Covid-19 pandemic has been dramatically different with expansion in some boards into care homes etc. This needs to be taken into consideration as well as coverage of specialist areas such as dental schools.

2.5 Training

The majority of IPCDs have a background in clinical microbiology, however this does not exclude other training backgrounds with equivalent qualifications and experience such as Public Health and Infectious Diseases from taking on the IPCD role.

For microbiologists it is considered that the FRCPath is an essential qualification. Other relevant post graduate qualifications may include FFPH or FRCP in public health or infectious diseases. Whatever the background, the amount of Infection Prevention and Control in the current postgraduate curriculum is limited and the

experience that pre-certificate of completion of training (CCT) trainees obtain is variable. Microbiology post graduate training has now been combined with infectious diseases reducing the time spent in each speciality. This further reduces the time available specifically for Infection Prevention and Control, making post CCT in post training even more vital. Some countries have opted to develop a separate speciality of the IPCD with a distinct post graduate curriculum.

In Scotland traditionally experience has been gained in post, supplemented by a variety of courses which are listed in Appendix A. These would be tailored to the needs of the specific position and organisation.

It is vital that an appropriate proportion of continuous professional development (CPD) time is spent on IPCT related activities and leadership and team working skills should be included within this. Annual appraisal specifically covers the Infection Prevention and Control aspect of a job description and this should include inquiry about challenges and problems encountered in the role, including team effectiveness. Critical incidents where Incident Management Teams present dilemmas and challenges should provide candid and confidential material for discussion with a view to continuous improvement.

It is considered good practise that a newly appointed IPCD should have access to an experienced mentor.

Some countries use a system of a junior and senior IPCD and this might be a system which could be considered and which would take account of a period of in role training.

For clinical scientists the qualifications above would be suitable.

2.6 Governance structures

IPCDs provide a key safety function for the board, as such they need to be sitting on board level clinical governance groups to allow issues to be flagged at the highest level wherever there is concern that the standard routes of communication are insufficient. Many boards have the IPCD as a permanent member of Healthcare Governance Committees, and a direct line of access to the Board Chief Executive Officer and the HAI executive lead, to discuss issues of IPC concern. This should be regarded as vital.

The feeling that the current system is a title without executive power has possibly fed into current recruitment issues.

Currently IPCDs are most frequently consultant microbiologists and this would be the route of line management. In terms of professional accountability for IPC matters this would be to the HAI executive lead for the organisation.

2.7 Built environment and decontamination

The increased focus on the role of the built environment on HAI with the QEUH inquiry report and the Covid-19 pandemic means that the IPCD role in this area deserves particular mention. The demands for infection control expertise in the built environment have increased dramatically in less than a decade.

The IPCD is in a unique position to give advice at the interface between estates, facilities and clinical teams. For building projects the IPCD is critical to guide in interpretation of national guidance for the local situation and the needs of the clinical population in question. They can offer insight into first principles of Infection Prevention and Control in areas where guidance is not available.

As supported by the recommendations of the QEUH inquiry report the IPCD will be involved in the full cycle of the SCRIBE process for new builds or major refurbishment projects. This involvement will be sustained throughout the life of the project. However for this to function effectively a culture where this involvement is welcomed needs to be fostered with the understanding from the full design team that improvements in the design of a building from an Infection Prevention and Control point of view have wide ranging implications for patient care. The IPCD should not however be considered to have a compliance function in relation to

behaviours of contractors or design teams as this is out with the scope of the role and would be more appropriately be carried out by a 'clerk of works' etc.

For large building projects the time required to give well considered IPCD input is significant and this function for large building projects should not be considered as an add on the usual function of the IPCD. Dedicated time from an appropriately experienced individual should be allocated with backfill of the usual duties of this individual or outsourcing to an IPCD with appropriate built environment expertise and knowledge.

While some courses are available these do not substitute for a competency based training or experience gained during practice and this may differ markedly across boards depending on ongoing projects. Some consideration may be given in smaller boards to centralising or regionalising part or all of this function through service level agreements in order to maintain competence whereas large boards will usually have enough ongoing projects to warrant dedicated IPCD resource. Succession planning for this function is vital.

While the involvement of the IPCD in large new build projects has been a particular focus in recent months the IPCD input with regards to older estate should also not be under-estimated and never more so than during the challenges of the Covid-19 pandemic. Understanding the complexities and differences of the older and aging estate with regards their impact on the prevention and control of infection for a broad range of clinical specialities is a significant part of the role of the IPCD and a good working relationship with the estates and facilities team is vital. In health boards with PFI buildings this interaction may be different but is still vital.

In terms of decontamination the IPCD works in close partnership with estates, engineering and facilities colleagues and in liaison with national bodies in the interpretation of microbiological testing results either on commissioning of new equipment or in the ongoing management of equipment as well as advising on outbreaks or incidents with a decontamination focus. The IPCD provides expert opinion on the level of clinical risk posed by an incident as well as guiding the adequate decontamination of medical devices.

In both IPC in the built environment and decontamination it is recognised that the multi-disciplinary team is key and the value of the IPCD is in working in collaboration with other professional backgrounds and technical expertise.

2.8 Support

The IPCD must have adequate administrative support to facilitate the organisation and minuting of meetings, reports, policy documents and effective communications.

The IPCD must have access to adequate data and surveillance support.

3. Recommendations for further development

1. A post of speciality adviser to the chief medical officer in Scotland is created for Infection Prevention and Control Doctors.

2. A formal review of training and ongoing CPD requirements for IPCDs should take place with input from training professionals such as NHS Education for Scotland (NES). There should also be particular discussion regarding how to increase training and expertise for infection prevention and control with regards to the built environment.

3. HAI policy unit should give thought to guiding the number of IPCD sessions across health boards using the type of formula described above to provide equity and ensure a proactive rather than reactive service with the aim of driving down HAI and AMR and improving patient care.

4. Enhancements to the pre CCT Infection Prevention and Control training programme for Scotland should be explored and developed along the lines of the currently weekly national teaching for microbiology trainees with the possibility of supplementary training days.

5. A problem based model of experience sharing should be developed and facilitated by the SMVN IPCD network.
6. Some aspects of the role of the IPCD may benefit from being centralised and bodies such as ARHAI and NHS Assure may consider their own IPCD resource in areas such as ventilation and water.
7. The SMVN IPCD subgroup would welcome the opportunity to be involved in early stage policy and guideline discussions regarding IPC.
8. As the roles and responsibilities of the other members of the IPCT are reviewed this should be done in tandem with the roles and responsibilities described here to ensure that the members of the IPCT interact in an efficient way.

4. References

- ECDC Technical document – Core competencies for infection control and hospital hygiene professionals in the European Union. 2014
- Education in Infection Control: A need for European Certification Zingg et al CMI 2015
- Harmonising and supporting infection control training in Europe. Brusaferro et al JHI 2015
- NHS HDL (2005) 8 INFECTION CONTROL: ORGANISATIONAL ISSUES https://www.sehd.scot.nhs.uk/mels/HDL2005_08.pdf
- Proposed national job description for IPCD 31.3.15 Dr G Phillips
- Queen Elizabeth Hospital Independent Review report https://qeuhprodwebsite.blob.core.windows.net/media/yutnag4j/final-report-published-version-458529_sct0220167968-002_queen-elizabeth-university-hospital-independent-review_p3.pdf
- Recommendations on the capacity for care management by hospital hygiene staff in hospitals and other medical institutions. German Commission for Hospital Hygiene and Infection Prevention (KRINKO).
- The Vale of Leven Hospital inquiry report https://www.nls.uk/scotgov/2016/9781784128449.pdf
- https://apps.who.int/iris/bitstream/handle/10665/335821/9789240011656-eng.pdf?sequence=1&isAllowed=y

From: Rae, Janette
Sent: 23 August 2016 16:22
To: Inverarity, Donald; Guthrie, Lindsay; Cameron, Fiona; Kalima, Pota
Subject: RE: For comments

Hi Donald the new RHSC will have 17 of these rooms with isoltion lobbies through out the hospital and there will be some in the new DCN. However to do planned miantenance or if there were a malfunction would mean moving haem/onc patietns to other areas that is why I also think that there should be more than one air handling unit in that area,
Thanks
Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
10 Chalmers Crescent
Edinburgh
EH9 1TS
[redacted]
Link to Infection Control Manual
http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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From: Inverarity, Donald
Sent: 23 August 2016 13:26
To: Richards, Janette; Guthrie, Lindsay; Cameron, Fiona; Kalima, Pota
Subject: FW: For comments

I'm comfortable with air handling units serving more than one room but one unit serving the entire 5 rooms of the paediatric cancer unit seems to be a problem waiting to happen.
I think there needs to be guidance from the paediatric cancer clinical team as to what sort of patients would be managed in these rooms in order to gauge the risk. The risk to a bone marrow transplant patient from not having access to a positive pressure single room would be greater than for a solid organ post chemo patient. If the rooms were occupied and there was a malfunction, where on the site is there capacity for them to be managed (ward 215 springs to mind from a room design perspective but then there would be children on an adult ward). They could not remain in those 5 rooms while corrective work is being undertaken from a patient safety perspective. There needs to be an explicit agreed contingency plan as to where those 5 children would be managed in event of ventilation failure before embarking on a one air handling unit serves all rooms with no redundancy approach.
Pota is included in the reply as this relates to RHSC.
Donald

From: Richards, Janette
Sent: 22 August 2016 13:05
To: Guthrie, Lindsay; Inverarity, Donald
Cc: Cameron, Fiona
Subject: For comments

Dear Both,
Please see for information and comment re ventilation requirements in isolation rooms in the new RHSC/DCN. Could I have your comments back by 29th Aug. please?

Regards
Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
10 Chalmers Crescent
Edinburgh
EH9 1TS

[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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From: Hanley, Dorothy
Sent: 13 February 2017 11:34
To: Brougham, Mark
Cc: Cairney, Ann
Subject: RE: meeting request

☺, no problem. I'm sure Ann does too !!

I have booked ward 2 seminar room for us 2-3pm (shouldn't take that long)

Dorothy

Dorothy Hanley
Children's Services - Service Lead for Redesign and Commissioning
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

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From: Brougham, Mark
Sent: 13 February 2017 11:30
To: Hanley, Dorothy; Kalima, Pota; Richards, Janette
Cc: Cairney, Ann; Henderson, Ronnie
Subject: RE: meeting request

Thanks -I can make it any time from 2pm.
I'm afraid I still use my paper diary –sorry!

Mark

From: Hanley, Dorothy
Sent: 13 February 2017 11:28
To: Kalima, Pota; Richards, Janette
Cc: Brougham, Mark; Cairney, Ann; Henderson, Ronnie
Subject: RE: meeting request

Let's go for that then and hope that when Janette is back tomorrow she can confirm she can make it too

I will send out a meeting request (assuming you all use your outlook diary schedule !)

Dorothy

Dorothy Hanley
Children's Services - Service Lead for Redesign and Commissioning
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

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From: Kalima, Pota
Sent: 13 February 2017 11:24
To: Hanley, Dorothy; Richards, Janette
Cc: Brougham, Mark; Cairney, Ann; Henderson, Ronnie
Subject: RE: meeting request

Dear Dorothy,
Early afternoon would be better for me.
Kr
Pota

From: Hanley, Dorothy
Sent: 13 February 2017 11:20
To: Richards, Janette; Kalima, Pota
Cc: Brougham, Mark; Cairney, Ann; Henderson, Ronnie
Subject: meeting request

Hi Janette and Pota, I wonder if I could prevail on you to attend a meeting with me/ Janice to discuss the ventilation for single rooms within the new haematology/ oncology ward in the new building. There would appear to have been a need for contractors to deviate from an SHTM in order to achieve the output specification signed off at Financial close. Just need to make sure before the contractors proceed further that we are all in agreement around any operational issues/ balance of potential risks to patients.

Having spoken to Mark this morning, and checked Ann's off duty, they would be available on ward 2 late morning or early afternoon on Thursday 23rd Feb. The contractors will give me airflow drawings to share at the meeting so we can be clear on these

Can you please confirm if you are able to make this date and what time might suit you best, within Mark's suggested range

Many thanks

Dorothy

Dorothy Hanley
Children's Services - Service Lead for Redesign and Commissioning
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

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From: Hanley, Dorothy
Sent: 18 September 2019 07:54
To: Guthrie, Lindsay; Mackenzie, Janice; Inverarity, Donald
Cc: Halcrow, Fiona
Subject: RE: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery
Attachments: 20190828 RHSC Patient Areas risk assessment v0 5.docx; 20190909General ventilation IPC risk assessment v0 5.docx

Hi Janice, thanks for forwarding. Couple of very minor suggested changes (made using track changes)

Thanks

Dorothy

From: Mackenzie, Janice
Sent: 18 September 2019 07:16
To: Hanley, Dorothy; Halcrow, Fiona
Subject: FW: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

FYI

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France Project Team

Royal Hospital for Children & Young People and Department of Clinical Neurosciences 4th Floor Clinical Management Office Little France Crescent Edinburgh
EH16 4TJ
[redacted]

E: janice.mackenzie[redacted]
[PHNC cyan secondary FOR SIG]
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From: Guthrie, Lindsay
Sent: 09 September 2019 15:02
To: Mackenzie, Janice; Inverarity, Donald
Cc: Kalima, Pota; Gillies, Tracey; Cosens, Sorrel
Subject: RE: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

All
Please find attached as requested :

· the updated SBAR – reflecting comments received and discussion with Haem/Onc, DCN and CF teams

· the updated risk assessment -which is included as Appendix 1 in the SBAR

Regards
Lindsay

From: Mackenzie, Janice
Sent: 02 September 2019 14:00
To: Inverarity, Donald
Cc: Guthrie, Lindsay; Kalima, Pota; Gillies, Tracey
Subject: RE: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

Hi Donald

Thanks very much for both of these documents which myself, Fiona, Dorothy & Ronnie have done an initial review of and I attach our comments for your consideration.

As yet we have not consulted with the clinical teams but plans in place to start this, as summarised below:-

· Workshop with DCN on Wednesday afternoon

· Meeting with the CF team on Friday

I have a call out to Eddie Doyle to ask how he wants to tackle consultation with the RHSC teams, my view would be that the focus would be on the areas that we have identified as a higher risk and would aim to have a workshop next week with key individuals.

Kind regards

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France Project Team

Royal Hospital for Children & Young People and Department of Clinical Neurosciences 4th Floor Clinical Management Office Little France Crescent Edinburgh
EH16 4TJ
[redacted]

E: janice.mackenzie[redacted]
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From: Inverarity, Donald
Sent: 30 August 2019 16:19
To: Mackenzie, Janice
Cc: Guthrie, Lindsay; Kalima, Pota; Gillies, Tracey
Subject: RE: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

Sorry about that. The document for Appendix 1 is attached now

From: Mackenzie, Janice
Sent: 30 August 2019 16:06
To: Inverarity, Donald
Cc: Guthrie, Lindsay
Subject: RE: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

Thanks Donald, unfortunately I can't open the embedded word document could you possible send that separately. The PDF document is fine.

Kind regards

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France Project Team

Royal Hospital for Children & Young People and Department of Clinical Neurosciences 4th Floor Clinical Management Office Little France Crescent Edinburgh
EH16 4TJ
[redacted]

E: janice.mackenzie[redacted]
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From: Inverarity, Donald
Sent: 30 August 2019 15:53
To: Guthrie, Lindsay; Kalima, Pota; Mackenzie, Janice; Gillies, Tracey
Cc: Inverarity, Donald
Subject: First draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of design ventilation and its delivery

This is what Lindsay and I have compiled so far. Note it does not cover critical care and does not cover risk from hospital water. The focus at present is around providing narrative to describe what the anticipated risks would be in a particular area and how the ventilation delivery may or may not influence such HAI risk.

Please direct any comments or suggested edits back to me and Lindsay.
Thanks
Donald

RHCYP DCN – Accommodation profile and HAI/IPC risk assessment August 2019

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
Dalhousie: Medical Inpatients	23	3x4	3 (transitional care) 4	1 (transitional care) 3	Transitional care – awaiting discharge/home care and step down from critical care Main ward: • Diabetes • Cystic Fibrosis • Rheumatology • Cardiology • Infectious Diseases • Meningitis (non critical care) • End of life care	Immunocompromised patients Drug induced neutropaenia (Rheum patients) • Known alert organism colonisation • Respiratory infection • Loose stool or diarrhoea • Febrile Rash • Febrile returning traveller	Transitional care not used for CF patient care
Kildrummy: Sleep Lab	2	0	2	0	Sleep studies Elective only - well children		
Lochranza: Haematology/ Oncology	17*	0	12	5	Solid organ cancers Haematology ID immunocompromised	Mixture of solid organ cancer & haematology Fluctuating demand for haematology beds	In pt – *only 10 funded opened at any one time (any configuration of multi/single/isolation

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
Lochranza: day case		1x3 (TCT) 1x6	0	0	patients (e.g. HIV) – protective isolation **Same patient profile as for in patient ward** Chemo/bloods/LP	5 rooms for seriously neutropaenic patients Immunocompromised patients • Neutropaenia/Neutropaenic sepsis • Known alert organism colonisation • Respiratory infection • Loose stool or diarrhoea	rooms) Have separate treatment room – clean utility etc
Dunvegan: Surgical short Stay	14	2x4	6	0	**(Elective, CEPOD & Trauma)** All surgical specialities: • Burns/Plastics • Orthopaedics • ENT • General Surgery • Oncology surgical procedures	• Known alert organism colonisation Less control over non elective patient risk factors Immunocompromised patients (inc short gut babies)	≤72 hrs length of stay Elective patients- cancelled if 'infectious'
Tantallon: Surgical Long	15	2x4	7	0	**(Elective, CEPOD & Trauma)**	• Known alert organism	Community midwife referrals as well as

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
Stay					• Orthopaedic & Spinal patients – #femur and ortho trauma • Oncology surgical procedures • Neonates (<10 days) requiring UV treatment (non infectious jaundice) post discharge from Simpsons (very small numbers)	colonisation Neonates –unclear if single rooms. Non infectious jaundice. Immunocompromised patients	Simpsons
Dirleton: Programmed investigations		1x 4 (trolleys) 1x 5 (chairs)	3	0	Semi elective- inc. GP referral Medical day case Rash Specialist nurse clinics Diabetes **Excludes** • oncology patients	• Known alert organism colonisation Immunocompromised patients (IgG clinic)	Separate waiting area to segregate any child with potential infection
Castle Mey: Paediatric Acute	34	3 x 4	21	1	• All medical specialties **Excludes**	• Known alert organism colonisation	Single room accommodation

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
Receiving Unit (PARU)					• Cystic Fibrosis • Diabetics	• Respiratory infection • Loose stool or diarrhoea • Febrile Rash • Febrile returning traveller	
Crichton: Surgical Admissions Unit	18	9x recovery trolley 6x pre theatre 3x chair ~~day case~~ discharge lounge	3		All surgical specialities: • Burns/Plastics • Orthopaedics • ENT • General Surgery • Oncology surgical procedures • Medical elective procedures (GI) • Oncology day care (Weekly Intrathecal list; line replacement) • Oncology CEPOD or urgent cases	• Known alert organism colonisation	Elective & CEPOD Includes Oncology patients
Borthwick: Paediatric Neurosciences	12	2 x 4	3 - 2 x telemetry rooms	1	• Neurosurgery • Neuro-oncology	Elective & non • Known alert organism	Paediatric Neuro-oncology neutropaenic patients would be

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
					• Neurology	colonisation • Respiratory infection • Loose stool or diarrhoea • Febrile Rash • Febrile returning traveller • Meningitis	managed in Lochranza ward
Critical Care & Neonatal Unit					Critical Care Neonates		See separate risk assessment
Plastic Dressings Clinic					• Complex dressing changes • Burns dressing changes (very low numbers)	• Known alert organism colonisation	ARJO bath for soaking dressings – water safety plan to apply
ED					Accident and Emergency	• Known alert organism colonisation	Cubicles. Short length of stay (<4 hr)
Ward 130: Adult Neurosciences acute care	24	2x4	15	1	• LOS ≤72 hrs • Emergency admission (“new”/unknown pt) SAH, trauma • Recovered craniotomy patients	• Known alert organism colonisation • Respiratory infection • Loose stool or diarrhoea	No level 2 or 3 capacity – go to RIE 118 (Adult Critical Care) SOP to guide appropriate boarding

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
					e.g. de-bulking of tumours • Spinal surgery e.g. anterior decompression • New cancers (undiagnosed)	• Febrile Rash • Febrile returning traveller • Immunocompromised patients • Repatriated Neurosciences patients with MDRO/CPE risks	from RIE to be developed in conjunction with IPCT, clinical services & site management team.
DCN theatres: Adult Day of surgery area		5 x couches			• admission/prep for surgery		Elective only Return to ward 230 post recovery
Ward 230: Adult Neurosurgery	24	0	23	1	• Step down from RIE 118 and 130 • Post operative patients (recovering) • Some direct elective admission	• Known alert organism colonisation	Single room accommodation
Ward 231: Adult Neurology	19*		18- 4 x telemetry	1	• Existing DCN patients – emergency admissions • Planned elective investigations	• Known alert organism colonisation • Respiratory infection • Loose stool or diarrhoea	*15 funded beds Single room accommodation

August 2019Ward	Total Beds	Multi bed Room	Single Room	Isolation Room	Clinical Specialties/Patient type/Procedure type	HAI/IPC Risk	Comments/Mitigation
	4	3 x chair 1 x trolley			PIU – neurology pt for investigations		PIU Monday-Friday elective day case only

SBAR- Draft Risk Assessment regarding Impact of Design Ventilation on managing HAI risk in RHCYP & DCN clinical areas (not including Paediatric Critical Care)

1. Situation:

NHS Lothian are required by the National Oversight Group "*to consider its clinical service model in light of the ventilation arrangements in place for general wards and other non critical areas (incorporating literature review and design information not yet available)*".

This relates to the project design provided which aims to deliver the 6 air changes required by SHTM 03-01 Part A to shared bed spaces and single room accommodation through mechanical supply for 4 air changes and 2 air changes through natural ventilation (although investigation is underway to establish if this is deliverable through window opening as had been designed).

Independent verification (by IOM) of the ventilation system has highlighted some areas where the ventilation performance requires further review and adjustment to ensure this performs in line with the design specification outlined above. This includes shared bed spaces and single room accommodation. NHS Lothian have been asked to demonstrate through risk assessment, that the Board is assured that the provision of 4 air changes per hour on mechanical supply, rather than 6 air changes per hour on mechanical supply does not compromise patient safety by introducing either an increased risk of transmission of infection or acquisition of healthcare associated infection.

2. Background:

In line with mandatory guidance (SHPN04-01 Adult In-patient facilities; HBN 23 Hospital accommodation for children and young people), RHCYP & DCN building provides a high percentage (greater than 50%) of single room accommodation for both children and adults. RHCYP provides 62% single room accommodation, and DCN 88% single room accommodation. This represents a significant increase in single room capacity over that which is currently available.

SHTM 03-01 part A (appendix 1) and SHPN 04 Supplement 1: Isolation facilities in acute settings define the air change rates, filter requirements, mode of delivery and pressure differentials required for hospital ventilation systems. The ventilation system at RHCYP & DCN was designed to deliver the following ventilation

	SHTM 03-01 requirement	Design specification	Current performance	Comments
General ward (multi-bedded bays)	6 air changes per hour (Ach/hr) – mix of supply and natural at balanced or slightly negative pressure	4 air changes per hour supply	Awaiting clarification from IOM	
Single en-suite rooms	6 air changes per hour - mix of supply, extract and natural	4 air changes per hour supply	Awaiting clarification from IOM	

	ventilation Balanced or negative pressure	Balanced or negative pressure		
Isolation rooms (Positive pressure ventilated lobby-PPVL)	10 air changes per hour Lobby at 10 Pascals positive pressure	10 air changes per hour Lobby at 10 Pascals positive pressure	Compliant	
Treatment Room	10 air changes per hour Positive pressure		Awaiting clarification from IOM	

The ventilation design and performance for some multi-bedded bays and single rooms does not conform to SHTM 03-01 part A, in terms of supply ventilation[Independent verification (by IOM) of the ventilation system has highlighted some areas where the ventilation performance requires further review and adjustment to ensure this performs in line with the design specification .

Lochranza ward (Haematology Oncology) does not have HEPA filters in the air supply ventilation to the single rooms which is indicated for rooms where neutropenic patients would be managed. The grade of air filter fitted in the supply air for these rooms (F9) is of a higher standard than the filters advocated for general ward areas or single rooms in SHTM 03-01 Part A Appendix 1 (G4 filter). As such the supply air in the single rooms of Lochranza is of a “cleaner” quality than a general ward but is not of a High Efficiency Particulate Air (HEPA) standard and this benefit would be immediately removed by opening a window to outside air as windows in the single rooms will open. The supply air ventilation in the 5 PPVL isolation rooms does pass through HEPA filters in the room lobbies. The 5 PPVL rooms do perform to the parameters set in SHTM 03-01 for rooms where all neutropenic patients can be safely placed. Windows in the PPVL isolation rooms are sealed units and do not open.

It is understood that all multi bedded bays and single rooms which do not have an opening window are provided with 6 air changes per hour (achieved through mechanical supply and extract) and positive pressure maintained to the corridor. This will be confirmed on receipt of the IOM report on the performance of all rooms against the design specification.

Assessment:

3.1 A review of all clinical departments was undertaken by the clinical leads from the project team (Janice Mackenzie, Dorothy Hanley, Fiona Halcrow); lead infection prevention and control nurse (Lindsay Guthrie) and lead infection control doctor & consultant microbiologist (Dr Donald Inverarity). This was discussed with key clinical colleagues in paediatrics and neurosciences for comment and input prior to submission to the NHS Lothian Executive Steering Group: Royal Hospital for Children and Young People and Department of Clinical Neurosciences for approval.

3.2 In view of planned revision of ventilation systems in Critical Care & Neonatal Unit to meet conformance with SHTM 03-01, it was agreed that these locations did not require to be part of this review, and will not be considered further in this paper.

3.3 A summary table of all wards, bed configuration and clinical service types which informed this risk assessment is provided in appendix 1. This outlines the risk profile of patients being cared

for in each area based on the clinical speciality, known patient risk factors and type of treatment or interventions provided. It also identifies anticipated HAI/IPC risks associated with each clinical area.

3.4 The highest risk patient groups are defined as:

- Any haematology/oncology patient
- Any neutropenic patient
- Any other immunocompromised patient (related to underlying disease process or treatment induced)
- Any patient with Cystic Fibrosis
- Any patient with a complex wound dressing or burn treated in the Plastics Dressing Clinic (or Dunvegan Ward)
- Any patient with a known infection alert (known colonisation or history of infection with alert organism)
- Any patient presenting with a suspected or confirmed infection transmitted by contact, droplet or airborne transmission

This categorisation of patient risk is in line with the definitions provided in Scottish Health Facilities Note 30 Part B: HAI Scribe Implementation strategy and assessment process; Health Protection Scotland interim guidance for routine sampling of Pseudomonas in augmented care areas (2018); and HPS National Infection Prevention and Control Manual.

3.5 Paediatric renal dialysis is not provided at RHCYP. Any child or young person requiring this is referred to QEUH in Glasgow.

3.6 Paediatric organ transplantation is not provided at RHCYP. Any child or young person requiring this is referred to QEUH in Glasgow or specialist services in NHS England. The number of patients requiring transplantation are small, but following treatment they may be admitted to RHCYP to either a surgical ward (Tantallon) or medical ward (Dalhousie).These patients would be considered immunocompromised and managed in line with the NHS Lothian Prioritisation of Isolation Guidance (attached as Appendix 2).

3.7 Within Lochranza (Haematology/Oncology), although the five PPVL isolation rooms provide 10 Air Changes/hour and 10 Pascals positive pressure from lobby to corridor, none of the single rooms available meet the specification for 'Neutropenic patient ward' defined in SHTM 03-01 Appendix 1 (also 10 Air Changes plus 10 Pascals positive pressure). Based on current occupancy, it is estimated by clinicians that currently there may be 5-10 neutropenic patients being cared for in RHSC on any given day. Although it is acknowledged that not all chemotherapy regimens result in the same intensity of immunosuppression and neutropenia, within the new facility, there may be a shortfall in the number of rooms which meet the SHTM 03-01 standard for safe placement of all neutropenic patients.

3.8 Appropriate patient placement and management is considered against the HPS National Infection Prevention and Control Manual (Appendix 11) and NHS Lothian Prioritisation of Isolation Guidelines. The latter was developed by the IPCT in Lothian to assist clinical teams to risk assess and provide safe, effective patient care where demand for isolation or single room accommodation is exceeded by demand. Paediatric and Neuroscience teams have previously been directed to use this document which is applicable for placement of both paediatric and adult patients.

3.9 The review group agreed that the wards with the highest perceived overall risk of demand for isolation exceeding capacity (and thereby potential risk of onward transmission of infection) are: Castle Mey ward (Paediatric acute receiving unit); Dalhousie ward (Medical in-patients); Lochranza ward (Haematology/Oncology)

3.10 Ventilation in healthcare premises is designed to achieve a number of objectives including management of temperature and humidity, removal of odour (particularly required in wards with cancer patients receiving chemotherapy), provide a clean air path directing flow from 'clean' to 'dirty' and dilution of airborne contaminants. These latter two points are of most significance from infection prevention & control perspective.

3.11 The burden of seasonal respiratory viruses is recognised as a risk, particularly for RHCYP. This risk is however mitigated via the provision of a significantly increased availability of en-suite single room accommodation with doors. HPS National Manual Appendix 11 advocates that patients are cared for in such rooms. The risk of droplet transmission is greatest within 3 feet/1 metre of the patient. The primary protection therefore offered by en-suite single rooms is physical separation greater than 1 metre and containment of infectious patients by means of a closed door. The impact on transmission risk of a reduced air exchange rate from 6 to 4 air changes per hour in each shared bed space is unknown.

3.12 A review of all alert organism reports in the past 2 years for the current wards at RHSC and DCN demonstrates that the Paediatric Acute Receiving Unit (Castle Mey) is likely to experience the highest burden of patients with presentations due to respiratory viral infections, loose stool or diarrhoeal illness and will have both the highest turnover of patients and the highest demand on isolation and single rooms.

3.13 The risk of transmission of infection is also mitigated by application of other aspects of transmission based precautions i.e. enhanced cleaning with chlorine 1000ppm av chlorine, use of dedicated or single use equipment, use of appropriate facial or respiratory protection The application of standard infection prevention and control measures such as personal protective equipment used optimally, optimal hand hygiene and access to alcohol based hand rub across all clinical areas will also mitigate some risk of transmission of infection.

3.14 HFS have also asked that NHS Lothian risk assess and define the actions required if one or more air handling unit fails resulting in the loss of isolation room supply ventilation, noting that between 1 and 5 isolation rooms are provided off single air handling units in the new building. This specifically affects both Lochranza and Dalhousie wards. Taking cognisance of the above assessment, in the absence of an infectious disease of high consequence, and providing all other standard and transmission based precautions required by HPS NIPCM are in place, the risk of infection to patients, staff or visitors is likely to be low as SICPs would remain in use and physical isolation in a single room with doors would be maintained. Additionally an air flow from room to toilet air extract would likely continue even if supply air ventilation failed rendering the rooms at slight negative pressure or balanced pressure to the corridor with doors shut.

3.15 Depending on the nature and duration of the AHU failure, and in line with NHS Lothian Prioritisation of Isolation Guidance, a clinical risk assessment would be required in conjunction with the IPCT to determine any further actions required on a case by case basis. This would take account of: the patient's overall clinical condition, the ward type, the infection risk and mode of transmission, the risk profile of adjacent patients and isolation room capacity unaffected by the outage. Additional mitigating actions specific to infectious diseases of high consequence (such as

MERS or Multi Drug Resistant TB) would also be required in the event of supply ventilation failure.

3.16 In discussion with the senior Paediatric Haematology/Oncology clinical and management team, it was agreed that based on the changing risk appetite in NHS Scotland and changes in clinical practice which mean some children are rendered neutropaenic by palliative treatment, that it would be appropriate to bring all single room ventilation to the required specification for managing neutropenic patients. This is possible due to the delay in the migration of paediatric services onto the site. NHS Lothian instructed this additional work through a board change request on 6th September 2019.

3.17 In discussion with senior clinicians who care for children with Cystic Fibrosis, it was agreed that a service specific SOP will be developed in conjunction with IPCT to guide appropriate CF patient placement and management of transmissible infections affecting this patient group (including Mycobacterium abscessus). This will include patient placement, ventilation requirements and environmental decontamination. It is anticipated this will be concluded at a meeting on September 23rd.

3. Recommendations

4.1 Staff at RHCYP and DCN should refer to and implement the NHS Lothian Prioritisation of Isolation Guidelines to ensure that all patients with a suspected or known infection risk, or who are vulnerable to opportunistic infections, are placed appropriately within all clinical care environments.

4.2 All NHS Lothian staff should continue to implement standard and transmission based precautions in line with national policy. This includes, but is not limited to, ensuring that patients with known or suspected infections are cared for in single or isolation room accommodation and the door to the room remains closed.

4.3 All children, young people or adults cared for in RHCYP & DCN who are receiving chemotherapy, radiotherapy or who are considered to be immunosuppressed should be prioritised for single room or isolation room accommodation where possible.

4.4 In line with national policy, co-horting of children with confirmed respiratory viral illness should be considered where this is clinically appropriate and demand for single room isolation has been exceeded. Strict application of standard and transmission based precautions is required for the duration of this

Appendix 1: Risk assessment patient profile, clinical activity & HAI risk

20190829 General ventilation IPC risk as

Appendix 2: NHS Lothian Prioritisation of Isolation Guideline (2017)

20170112 Prioritisation of Isolat

Haematology Oncology provision in RHCYP

Situation

The events in Glasgow and the delayed move into RHCYP has led to questions and discussion about the room specifications in Lochranza, the designated ward for Haematology Oncology patients in the new building

Background

This ward is designed as a 17 bedded ward, with all single rooms. There are 5 isolation rooms and 12 single rooms, around a courtyard. The single rooms are to the standard ward specification (of 6 air changes/hour) rather than the specification for neutropaenic patients (of 10 air changes/ hour at 10 Pa positive pressure with a HEPA filter). The isolation rooms meet the current standards.

It was known in 2017 that the SHTM was not met and this was progressed to Project Co through the normal routes. They were not able to change the design or build and it was accepted that this would need to be managed by clinical risk assessments to support the preferential placement of certain patients in the isolation rooms (those with the most severe neutropaenia and those at most risk of fungal infections). This was agreed and signed off by the clinical team, the project team and Infection Control colleagues as the only option at the time.

Assessment

The situation has changed as of mid 2019 with the following developments:

- The building has not been occupied as planned, so there will be a time window of opportunity prior to occupation in which to undertake rectifications and bring the 12 single rooms up to the required standard.
- The risk appetite across NHS Scotland has changed with regard to the care in hospital of neutropaenic patients with an increasing recognition of the potential impact of the environment. For example, the refurbishment of the adult haematology ward at WGH will deliver this standard for all rooms, and it would be hard to explain why this is not also delivered for children requiring inpatient care in a state of the art new facility.
- The current chemotherapy regimes in use are more effective but in doing so induce more neutropaenia, and are used in clinical situations where previously there was no therapeutic option.
- Increasing numbers of children from the East Coast are managed for inpatient care in Edinburgh where they might previously have received care in Grampian or Tayside
- The helipad is by the courtyard and there is a risk of downdraughts blowing particles into the air inlets and windows.

Recommendation

A board change should be developed and progressed to bring the 12 single rooms up to the required specification for the care of neutropaenic patients. This will involve:

- Increase the air changes from 6 to 10 per hour

- Increase the positive pressure to 10pa
- Fit HEPA filters to the air inlets for the rooms (H12 grad)
- Seal windows and trickle vents

TG 030919

From: Richards, Janette
Sent: 29 September 2016 09:23
To: Laurenson, Ian
Cc: Conroy, Michael; Cameron, Fiona; Inverarity, Donald; 'Macrae, Colin'; Henderson, Ronnie; Sansbury, Jackie
Subject: RE: CT AIR CHANGE RATES
Attachments: 1360855592-SHTM 03-01 Part A Feb 2013[1].pdf; CT AIR CHANGE RATES

Importance: High

Dear Ian,
Thank you for agreeing to look at this in Donald's absence a response is required as soon as possible. We have had information from HFS re air changes in this type of room with regards to a requirement of more than 8 air changes per hour that has been suggested. There are needle biopsies planned to be carried out in the area, there are Thr pendants with nitrous oxide for use and there will be ventilated cases transferred from DCN or RHSC respectively.

Guidance from SHTM 03-01 Ventilation attached pgs 141-142 states requirements for various clinical areas. We have been advised that there will be savaging in the CT rooms for when gas is in use but I have to re iterate that this is **a Health and Safety issue**. If comparing the CT scanner room to a treatment room then at least 10 air changes are required.

HFS have commented and so has the consultant M&E person along with the external expert person who is responsible for ventilation for NHS Lothian.

Ronnie has Health and safety been asked?

Regards
Janette

Janette Richards

Lead HAISCRIBE Infection Prevention and Control Nurse

NHS Lothian

10 Chalmers Crescent

Edinburgh

EH9 1TS

[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

From: Sansbury, Jackie
Sent: 27 September 2016 15:35
To: Richards, Janette; 'Macrae, Colin'; Henderson, Ronnie
Cc: Conroy, Michael; Currie, Brian; Kolodziejczyk, Kamil K; Gordon, Kelly J; Cameron, Fiona; Inverarity, Donald
Subject: RE: CT AIR CHANGE RATES

Thanks, that would be good.
Ronnie if following up with the C/N about the procedures and the use of medical gases.

Jackie

From: Richards, Janette
Sent: 27 September 2016 15:21
To: Sansbury, Jackie; 'Macrae, Colin'; Henderson, Ronnie
Cc: Conroy, Michael; Currie, Brian; Kolodziejczyk, Kamil K; Gordon, Kelly J; Cameron, Fiona; Inverarity, Donald
Subject: RE: CT AIR CHANGE RATES

Dear Jackie
Unfortunately Donald is on A/L until 10th Oct. Can I suggest that Health and Safety comment and I will ask Lindsay and Fiona who else would be able to comment from IPC Dr point of view
Regards Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
14 Rillbank Terrace
Edinburgh
EH9 1LL
[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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From: Sansbury, Jackie
Sent: 27 September 2016 15:10
To: 'Macrae, Colin'; Henderson, Ronnie
Cc: Conroy, Michael; Currie, Brian; Kolodziejczyk, Kamil K; Gordon, Kelly J; Cameron, Fiona; Richards, Janette; Inverarity, Donald
Subject: RE: CT AIR CHANGE RATES

Colin, thank you for that.
Donald, can you give us your views on that please?
Many thanks
Jackie

From: Macrae, Colin [redacted]
Sent: 27 September 2016 14:43
To: Henderson, Ronnie
Cc: Conroy, Michael; Sansbury, Jackie; Currie, Brian; Kolodziejczyk, Kamil K; Gordon, Kelly J; Cameron, Fiona; Richards, Janette; Inverarity, Donald
Subject: RE: CT AIR CHANGE RATES

Ronnie

I would remind you that anaesthetic gas scavenging (AGSS) is provided in the CT rooms to deal with the exhaust from the anaesthetic machine when in use and this should not require the wholesale increase in room ventilation rate above those stated in SHPN guidance, unless there is a specific clinical requirement when AGSS is not sufficient.

Regards

Colin

Colin Macrae
Senior Building Services Engineer

[redacted]

Mott MacDonald
1 Atlantic Quay
Broomielaw
Glasgow G2 8JB
United Kingdom

Website | **Twitter** | **LinkedIn** | **Facebook** | **YouTube**

From: Richards, Janette [redacted]
Sent: 27 September 2016 13:26
To: Henderson, Ronnie; Inverarity, Donald
Cc: Conroy, Michael; Sansbury, Jackie; Currie, Brian; Macrae, Colin; Kolodziejczyk, Kamil K; Gordon, Kelly J; Cameron, Fiona
Subject: RE: CT AIR CHANGE RATES
Importance: High

Dear Ronnie,
The requirement for 15 air changes is in relation to the use of anaesthetic gases e.g. Nitrous Oxide., and as such is a Health and Safety issue. I strongly recommend that you consider that a decision is about to be made against the advice of HFS, IPCT and suggest you have input from health and safety. I attach Donald's response for those who may not have been aware of his considerations.

Regards
Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
14 Rillbank Terrace
Edinburgh
EH9 1LL
[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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From: Henderson, Ronnie
Sent: 27 September 2016 12:01
To: Richards, Janette; Inverarity, Donald
Cc: Conroy, Michael; Sansbury, Jackie; Currie, Brian; Macrae, Colin; Kolodziejczyk, Kamil K; Gordon, Kelly J
Subject: CT AIR CHANGE RATES
Importance: High

All,

In an attermpt to progress this to conclusion we have collectively looked at available current guidance and can conclude that the maximum quoted anywhere for a CT room is 10 ac/hr (SHPN 06, Engineering Requirements Para 7.4) and as such is the maximum that Multiplex can/will design to with available guidance.

If the decision by IPCN is that it must be 15ac/hr, this will need to be submitted as a formal change request that may result in significant cost increase and programme delay, please confirm that you wish me to submit this change request.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

Our Values Into Action

Quality | Dignity and Respect | Care and Compassion | Openness, Honesty and Responsibility | Teamwork

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NHS National Services Scotland

Scottish Health Technical Memorandum 03-01

Ventilation for healthcare premises
Part A – Design and validation

Health Facilities Scotland
Engineering and Environment

February 2013

Contents

Acknowledgements

Health Facilities Scotland would like to thank the principal contributors and the Steering Group led by the Department of Health for their efforts in producing the HTM 03-01 Part A document.

HTM 03-01 Part A has been updated and amended by Health Facilities Scotland for use in NHSScotland as SHTM 03-01 Part A and the contribution from the National Heating & Ventilation Advisory Group is gratefully acknowledged.

Preface

About Scottish Health Technical Memoranda

Engineering Scottish Health Technical Memoranda (SHTMs) 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 Scottish 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.

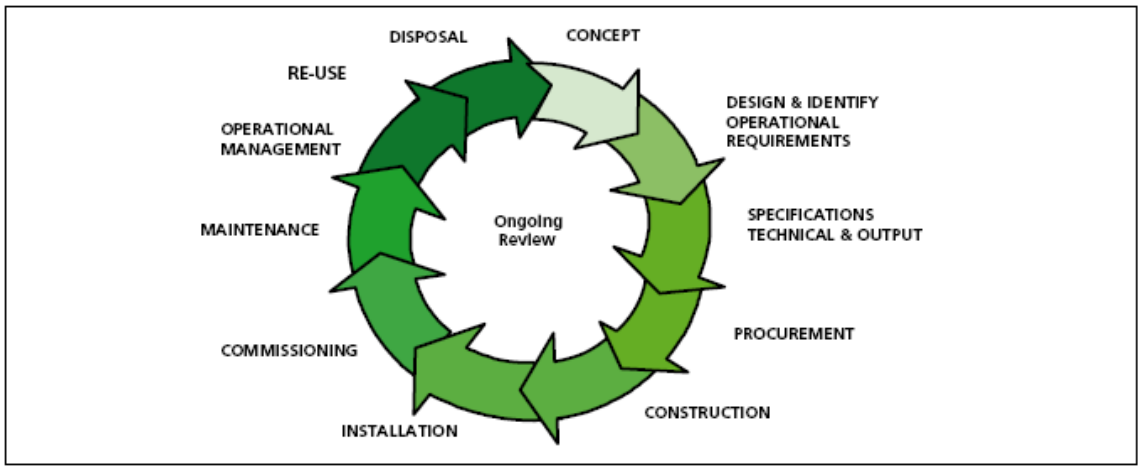
Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to repeat unnecessarily 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. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

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

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



Healthcare building lifecycle

Structure of the Scottish Health Technical Memorandum suite

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

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

Scottish Health Technical Memorandum 01: Decontamination.

Scottish Health Technical Memorandum 02: Medical gases.

Scottish Health Technical Memorandum 03: Heating and ventilation systems.

Scottish Health Technical Memorandum 04: Water systems.

Scottish Health Technical Memorandum 05: Reserved for future use.

Scottish Health Technical Memorandum 06: Electrical services.

Scottish Health Technical Memorandum 07: Environment and sustainability.

Scottish 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.

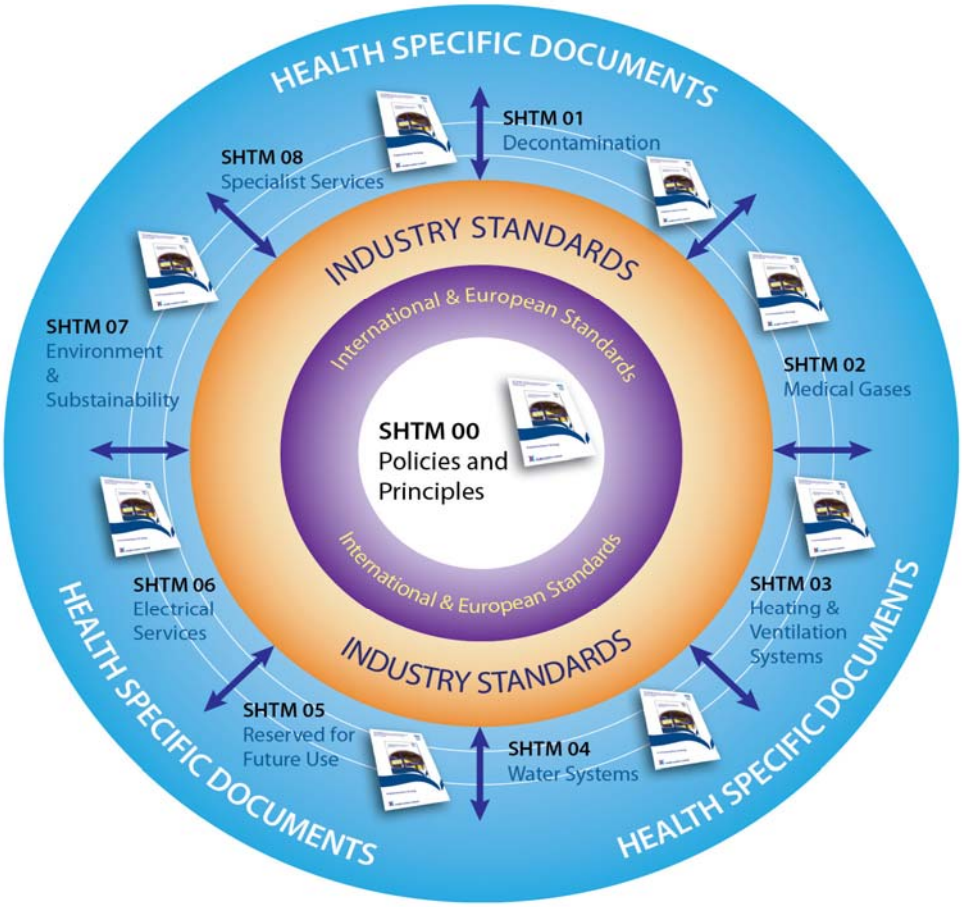
Example: Scottish Health Technical Memorandum 06-02 Part A will represent: Electrical Services – Electrical safety guidance for low voltage systems.

In a similar way Scottish Health Technical Memorandum 07-02 will simply represent:

Environment and Sustainability – EnCO_2de.

All Scottish Health Technical Memoranda are supported by the initial document Scottish 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.



Engineering guidance

1. Introduction

1.1 Ventilation is used extensively in healthcare premises or primary patient treatment in operating departments, high dependency units and isolation facilities. It is also installed to ensure compliance with quality assurance of processed items in pharmacy and sterile supply departments and to protect staff from harmful organisms and toxic substances, for example, in laboratories.

1.2 This edition of Scottish Health Technical Memorandum 03 'Ventilation in healthcare premises' is published in two sections. It is equally applicable to both new and existing sites. It gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design implications, maintenance and operation of general and specialised ventilation in all types of healthcare premises.

1.3 Current statutory legislation requires both 'management' and 'staff' to be aware of their collective responsibility.

1.4 'Ventilation' is also provided in healthcare premises for the comfort of the occupants of buildings. More specialised ventilation will also provide comfort but its prime function will be to control closely the environment and air movement of the space that it serves in order to contain, control and reduce hazards to patients and staff from airborne contaminants, dust and harmful micro-organisms.

1.5 Ventilation systems in themselves present little danger to patients or staff. However, they do possess the ability to transmit hazards arising from other sources to large numbers of people. The danger may not become apparent until many patients and staff have been affected.

1.6 The sophistication of ventilation systems in healthcare premises is increasing. Patients and staff have a right to expect that it will be designed, installed, operated and maintained to standards that will enable it to fulfil its desired functions reliably and safely.

1.7 The Health and Safety at Work etc Act 1974 (HSW Act 1974) is the core legislation that applies to ventilation installations and these installations are intended to prevent contamination, control closely the environment, dilute contaminants or contain hazards. Their very presence indicates that risks to health have been identified.

Statutory requirements

1.8 The Control of Substances Hazardous to Health (COSHH) regulations place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised

ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and safety cabinets.

1.9 The existing requirements to provide ventilation, implicit under HSW Act 1974 and COSHH, have been made explicit by the Management of Health and Safety at Work Regulations 1999, the Workplace (Health, Safety and Welfare) Regulations 1992 and the Provision and Use of Work Equipment Regulations 1998, all issued as a result of European Directives.

1.10 Where specialised ventilation plant is provided as part of the protection measures there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of the COSHH regulations requires that the plant be inspected and tested at least every 14 months by an independent organisation and that management maintain comprehensive records of its performance, repair and maintenance.

1.11 Certain substances have Occupational Exposure Limits (OEL) set out in Guidance Note EH 40 published annually by the Health and Safety Executive. If special ventilation systems are provided in order to achieve these standards they will be subject to the COSHH regulations as above.

1.12 All ventilation systems should conform to the principles set out in the Approved Code of Practice and guidance document entitled “Legionnaires’ disease: the control of *Legionella* bacteria in water systems” (commonly known as ‘L8’) published by the Health and Safety Executive and Scottish Health Technical Memorandum SHTM 04-01: The control of *Legionella*, hygiene, “safe” hot water, cold water and drinking water systems.

1.13 Special ventilation plants installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified organisms, may be subject to particular legislation with regard to their operation in addition to that mentioned above. Further information is given by the Health and Safety Executive Health Services Advisory Committee in:

- safe working and prevention of infection in clinical laboratories;
- safe working and prevention of infection in clinical laboratories: model rules for staff and visitors;
- safe working and prevention of infection in clinical laboratories in the mortuary and post-mortem room.

1.14 Plants installed in units manufacturing medicinal products to the standards set out in the current European Guide to Good Manufacturing Practice may also be subject to particular legislation with regard to their operation in addition to that mentioned above.

1.15 Records should be kept of equipment design and commissioning information. The Health and Safety Executive, Medicines Inspectorate and other interested bodies have a statutory right to inspect them at any time. All records should be kept for at least five years.

1.16 The fire regulations require that if ventilation ductwork penetrates the fabric of a building it should be designed and installed so as to contain the spread of fire. (for further information refer to Firecode Series SHTMs 81, 83 and 85)

1.17 Increased health risks to patients will occur if the more specialised ventilation systems installed to supply high quality air to operating departments do not achieve and maintain the required standards. The link between post-operative infection and theatre air quality has been well established. Plants serving conventional operating departments, for instance, will be required to ensure the separation of areas within the suite by maintaining a specific direction of air flow between rooms, even when doors are opened. They will also maintain the selected operating department environmental conditions regardless of changes in the outside air conditions or activities within the space. In addition ultra-clean operating ventilation systems that are designed to provide an effectively particle-free zone around the patient while the operation is in progress, have been shown to reduce significantly post-operative infection in patients undergoing deep wound surgery. Their use for other forms of surgery may well be required.

1.18 Ventilation systems that can be shown to be inappropriate, inadequate or ineffective and that give rise to proven failures can result in a civil suit by the patient against the operators.

1.19 If the plant has been installed to dilute, extract or contain harmful substances (the definition of which now includes microorganisms) its failure may expose people to unacceptable levels of hazard. Proven failures can give rise to a civil suit against the designers and operators by the individuals who have been affected. This would be in addition to the actions brought as a result of breaching the statutory requirements.

1.20 There is a statutory requirement to provide ventilation in all enclosed workspaces. It may be provided by either natural or mechanical means. The following are some of the factors that determine the ventilation requirements of a workspace:

- human habitation (minimum fresh air requirement);
- the activities of the department, that is, extraction of odours, aerosols, gases, vapours, fumes and dust – some of which may be toxic, infectious, corrosive, flammable, or otherwise hazardous (see Control of Substances Hazardous to Health (COSHH) regulations;
- dilution and control of airborne pathogenic material;
- thermal comfort;
- the removal of heat generated by equipment (e.g. catering, wash-up, sterilising areas, electrical switch rooms, uninterruptible power supply (UPS) cupboards and some laboratory areas);
- the reduction of the effects of solar heat gains where other forms of reducing the solar effect is not available or practical, i.e. solar blinds;

- the reduction of excessive moisture levels to prevent condensation (for example Hydrotherapy pools);
- combustion requirements for fuel burning appliances (see BS5376, BS5410 and BS5440);
- 'make-up' supply air where local exhaust ventilation (LEV) etc., is installed.

Mechanical ventilation systems are expensive in terms of capital and running costs, and planning solutions should be sought which take advantage of natural ventilation either where the use of the area in question is not critical to airflow patterns or pressures, or where backup systems are available when natural ventilation cannot be achieved.

1.21 When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure.

Requirement	Reason	Application
Statutory	Health and Safety at Work etc Act	Operating department Laboratories Pharmacy
	COSHH regulations	Areas containing identified biological or chemical hazards Areas containing oxygen displacing gases
	Local Exhaust Ventilation (LEV)	Enclosed work-spaces Workshops
Functional	Comfort	Situations where the quality of the environment for staff and patients is critical to their general performance and well-being
Clinical	Post-operative infection reduction	Operating suites used for general surgery, casualty, obstetrics/gynaecological and maternity procedures
	Reduction of deep wound sepsis	Ultra-clean operating suites for transplant, deep wound surgery, hip replacement, bone grafting and bone marrow transplant procedures
	Isolation from contact with bio hazards	Isolation units for patients who present a biological, chemical or radiation hazard to others. Isolation units for patients with a reduced immune system

Table 1: Reasons for providing ventilation

Functional overview – Terms in use

1.22 The terms 'ventilation' and 'air-conditioning' are often incorrectly used to describe the same equipment. A general explanation of the terms is given below.

Ventilation

1.23 Ventilation is a means of removing and replacing the air in a space. In its simplest form this may be achieved by opening windows and doors. Mechanical ventilation systems provide a more controllable method. Basic systems consist of a fan and either collection, (extraction) or distribution (supply) ductwork. More complex systems may include the ability to heat and filter the air passing through them. Ventilating equipment may be required in order to remove smells, dilute contaminants and ensure that a supply of 'fresh' air enters a space.

Air-conditioning and mechanical cooling

1.24 Air-conditioning is the ability to heat, cool, dehumidify and filter air. For full air-conditioning, humidification may also be provided. This means that the climate within a space being supplied by an air-conditioning plant can be maintained at a specific level regardless of changes in the outside air conditions or the activities within the space. Mechanical cooling may be provided where close control of 'comfort conditions' within a space is required but humidity control is not needed.

Special ventilation

1.25 In healthcare premises, certain activities will necessitate the provision of ventilation equipment with additional special features in order to achieve and maintain specific conditions. These may be needed in order to assist with the treatment of patients or maintain the health and safety of staff. The precise reason for providing special ventilation will depend upon the intended application. The list below indicates some of the more typical reasons:

- to remove, contain or dilute specific contaminants and fumes;
- to ensure the isolation of one space from another;
- to preserve a desired air flow path from a 'clean' to a 'less clean' area;
- to provide control of the cleanliness of a space;
- to provide 'close' control of temperature;
- to provide 'close' control of humidity.

1.26 The following departments will usually have specialised ventilation requirements, either for a single room or throughout a suite of rooms:

- operating department;
- laser surgery unit;
- intensive treatment unit;
- infectious diseases isolation unit;
- manufacturing pharmacy;
- specialised imaging, X-ray and scanning unit;

- pathology containment laboratories;
- mortuary and dissection suite;
- research laboratory;
- sterilising and disinfecting unit (SDU);
- endoscopy unit;
- renal dialysis suite;
- ultrasound facilities;
- audiology room.

1.27 Ventilation may be provided in a wide variety of ways. These will include:

- extensive purpose-built air-conditioning units housed in their own plant rooms;
- proprietary 'packaged' systems often sited outside on a roof or;
- wall-mounted electric fans located at the point of use.

1.28 A fixed volume of air may be supplied, often expressed in terms of the resulting number of air changes per hour (ac/h) within the space being ventilated. It may also be expressed in terms of litres/second/person. Alternatively the volume of air supplied may be varied in order to maintain a specific pressure relationship between the area supplied and other surrounding areas. In some situations a combination of both methods may be adopted.

1.29 Modern plants are fitted with the means to recover energy from the extract air where this can be justified without causing contamination of the incoming supply air.

1.30 Ultra-clean systems use the same basic plant and equipment as standard air-conditioning but are in addition fitted with a terminal device that supplies the air in a unidirectional manner to the working area. Their standard of filtration will be capable of delivering air with a very low particle count to the space that they serve.

Local exhaust ventilation

1.31 Local exhaust ventilation (LEV) is a term used to describe systems installed to prevent hazardous substances from entering the general atmosphere of the room in which they are being used. Their primary function is to protect staff from the effects of their work activity.

1.32 Simple LEV systems comprise a capture hood, extract ductwork and fan. These are used to contain industrial types of hazard such as fumes from welding processes, gas discharges from standby battery banks and dust from woodworking machinery. The vapour given off when large quantities of chemicals are decanted into ready-use containers and fumes from X-ray film processing units are further examples of chemical hazards often controlled by LEV systems.

1.33 In laboratories, pharmaceutical manufacturing facilities and operating suites, LEV systems usually take the form of semi-open fronted cabinets within which the hazardous substance is manipulated. These cabinets either have their own filtered air supply or are fed with air from the room. The air extracted from the cabinet is passed through a high-efficiency filter before being discharged either to the atmosphere or back into the room. Microbiological safety cabinets, laboratory fume cupboards, cytotoxic drug cabinets and fixed or mobile disinfection enclosures are all examples of this type of facility.

1.34 Mortuaries and dissection suites may have LEV systems incorporated within the dissection table, specimen bench and bone saw.

Management action

1.35 The guidance contained in this SHTM should be applied in full to new installations and major refurbishments of existing installations.

1.36 Ventilation will need to be provided:

- as a requirement for patient care;
- in order to fulfil a statutory duty.

1.37 In assessing the need for more specialised ventilation and the standards desired for patient care, managers will need to be guided by their medical colleagues and by information published by Health Facilities Scotland.

1.38 The statutory need for ventilation falls into two categories:

- in the first, the need for specialised ventilation and the standards to be adopted are clearly set out in specific pieces of legislation. An excellent example of this is the current legislation surrounding the manufacture of medicinal products in the European Community. The managers of the departments affected by this type of legislative requirement should be aware of their needs and be able to advise on the standards to be achieved;
- the second type of statutory requirement arises due to the interpretation of both the Health and Safety at Work etc Act and the Control of Substances Hazardous to Health (COSHH) regulations. The person tasked with conducting COSHH assessments will be able to advise as to the need for, and standard of, ventilation in each particular case.

Design and validation process

1.39 It is essential when undertaking the design of a specialised ventilation system that the project be considered as a whole. The process model set out below should ensure that all relevant factors are considered.

Step	Question	Design statement and information required	Comment
1	Why is the system required?	Healthcare applications Statutory elements Non-healthcare applications	
2	What is the required system performance?	Room air flow pattern Air change rate Differential pressures Air quality Room air condition Noise limits	
3	What are the constraints on the distribution system?	Location, Size, Materials Dampers, Access, Insulation Fire considerations Room terminals	
4	What are the minimum requirements for the AHU(s)?	Intake / Discharge positions *Legionella*, Health and Safety Access, Fire, Electrical safety Leaks, Insulation, Cleanliness Filtration, Drainage	
5	What control functions are required?	User control requirements Estates control functions Energy management Environmental conditions Control sequence logic Run, Set back, Off philosophy	
6	How will the system performance be validated?	Validation methodology Instruments used Design information required [*Design air flow rates* *Design air velocities* *Pressure differentials* *Noise levels* *Air quality* *Installation standard*]	
7	The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.		
8	Handover to client	Basic design information Commissioning results Validation report	

Table 2: Design and Validation process model

Use and function of typical equipment used in ventilation plant

1.40 Typical equipment used in ventilation systems is listed below together with a brief description of both function and use.

General

1.41 The equipment built into the ventilation system and its ductwork should be of a type that will neither cause nor sustain combustion. No materials that could sustain biological activity should be used in the construction or assembly of the system.

Air Intake

1.42 An uncontaminated air supply to the system is essential. In order to achieve this, the air intake will be positioned so that air discharged from extract systems or other dubious sources cannot be drawn in. Exhaust fumes from vehicles can present particular problems. The area surrounding the intake will need to be kept clean and free of vegetation and waste material in order to reduce the possibility of biohazards or fire. The intake itself will be protected by a louvre and mesh screen to prevent rainwater, vermin and insects etc from entering the system.

Damper

1.43 Several types may be fitted:

- automatic dampers fitted immediately behind the air intake and extract louvres. They will automatically close when the system is shut down in order to prevent an uncontrolled circulation of air;
- balancing dampers are fitted into each branch of the air distribution ductwork system so that the design air flow rate can be set during the commissioning process;
- where ductwork passes through a fire compartment wall, ceiling or floor a fire and/or smoke damper may be required;
- plant isolating dampers are fitted so that the main plant can be isolated from its air distribution duct system. They are manually operated and enable cleaning and maintenance of the air-conditioning equipment to be carried out.

Ducting

1.44 The means by which air is conveyed from the intake to its point of use. Ducting is usually constructed of galvanised steel and will normally be insulated to reduce noise and conserve energy. Ducts can also be formed in concrete, brickwork, stainless steel or plastic and may be rigid or flexible.

Fan

1.45 A series of rotating blades that move the air in the direction required. Fans are usually powered by electric motors either directly connected to them or driven through belts and pulleys. A fan may be arranged either to force air into or draw air from a ductwork system.

Attenuator / silencer

1.46 A device that will contain and absorb the noise emitted by a fan. They may be required to reduce disturbance caused by noise breaking out through the air intake and also noise transmitted along the ductwork to the conditioned space.

Filter

1.47 A filter consists of a labyrinth of fibrous material contained in a frame. It is designed to capture and hold particles being carried in the airstream. Because of the size range and number of particles that exist in air no filter can remove them all. The purpose of filtration is to reduce their number and size range to an acceptable level. Filters of progressively higher grades are fitted through the ventilation system:

- primary filters (coarse) are designed to collect the larger particles and are intended to keep the air-conditioning plant clean;
- secondary filters (fine) will remove the staining particles from air and keep the conditioned space visibly clean;
- high efficiency particulate air filters (HEPA/absolute) will remove virtually all particles from air. These may be required in order to reduce contamination in the working area either biologically or in terms of particle count.

Filters may be fitted to extract systems to protect energy recovery devices. They may also be fitted to remove biological, radiation or chemical hazards and if so, are often contained in a ‘safe change’ facility in order to protect those carrying out maintenance.

Activated carbon filters will reduce odours in extracted or recirculated air.

Heater battery / heater coils

1.48 A series of heater batteries or heating coils with or without fins through which steam or hot water is circulated. Heat is given up to the air passing over the battery thus increasing its temperature. Heating is usually carried out in stages, the final battery being controlled by the end user. Small batteries may be electric.

Humidifier

1.49 A device for increasing the humidity of air by adding moisture. For ventilation in healthcare premises this is normally achieved by releasing ‘clean’ steam into an

air supply duct. The steam will be completely absorbed into the air, increasing its humidity. The level of humidity may be preset or controlled by the end user.

Cooler battery / cooling coil

1.50 A series of finned coils mounted in the air supply duct. Either chilled water or refrigerant is circulated through the coils causing heat to be removed from the air. This will reduce its temperature and may also condense moisture out of the air. As free moisture in a duct can be a source of contamination the coil will be fitted with an eliminator and drainage system.

Eliminator

1.51 A device for catching and removing water droplets from an air stream. It may form part of a cooling coil or be a separate device.

Drainage system

1.52 A means of removing water from ductwork and disposing of it safely. Typically it will consist of a tray mounted in the duct to catch moisture, a glass water seal trap, continuously falling drainage pipework and an air break in the drain run to prevent waste water returning and contaminating the duct.

Access doors and observation ports

1.53 Doors and removable panels providing access for routine maintenance and cleaning. The doors should be fitted with glazed ports and suitable lighting provided so that the correct operation of devices such as cooling coils, humidifiers and filters can be easily observed without needing to switch off the plant.

Energy recovery

1.54 Many plants are fitted with the means to recover energy from the extract air without causing contamination of the incoming supply air. These devices will be fitted with a drainage system and may incorporate an eliminator. Several types of energy recovery systems are available.

1.55 Precise definitions of ventilation and air-conditioning terms are given in the Chartered Institution of Building Services Engineers (CIBSE) Guide B.

Typical plant

1.56 The layout of a typical plant that conforms to the requirements for healthcare applications is shown in Figure 1 overleaf. It contains most of the equipment described above.

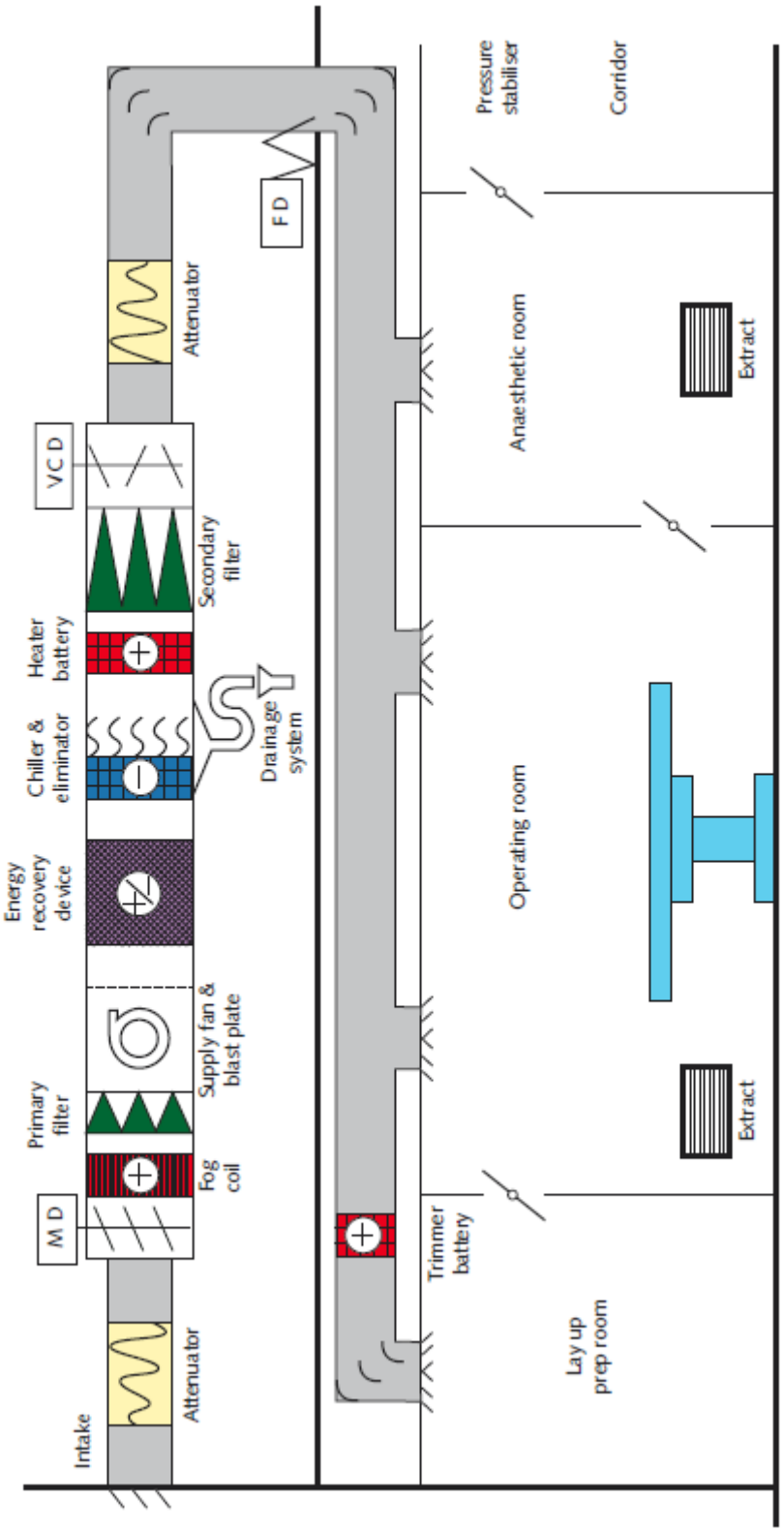


Figure 1: Design and Validation process model

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2. Provision of ventilation in healthcare buildings

2.1 It is acknowledged that planning constraints imposed by the building shape and/or functional relationships of specific areas will invariably result in some measure of deep planning thus reducing the opportunity for natural ventilation. However, ventilation costs can be minimised by ensuring that where practicable, core areas are reserved for rooms that have a functional requirement for mechanical ventilation. Examples are sanitary facilities, dirty utilities and those rooms where clinical or functional requirements have specific environmental needs; and where for reasons of privacy, absence of solar gain etc., windowless accommodation is acceptable. Other spaces appropriate to core areas are those that have only transient occupation and therefore require little or no mechanical ventilation, for example circulation and storage areas.

Natural ventilation

2.2 Natural ventilation is usually created by the effects of wind pressure. It will also occur if there is a temperature difference between the inside and the outside of the building. The thermo-convective effect frequently predominates when the wind speed is low and will be enhanced if there is a difference in height between inlet and outlet openings. Ventilation induced by wind pressures can induce high air change rates through a building provided air is allowed to move freely within the space from the windward to the leeward side.

2.3 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 areas including office accommodation, general wards, staff areas, libraries rooms, dining rooms and similar areas which should, where possible, be provided with opening windows of a design that facilitates natural ventilation.

2.4 Current guidance restricts the amount windows can be opened for safety reasons and as many designs are top-hung, their ability to permit natural ventilation is limited. It may therefore be necessary to provide dedicated ventilation openings in the fabric of the building to allow a sufficient natural flow of air into and out of the space. Paragraph 2.20 also refers.

2.5 In all cases, excessive heat gain, indoor air quality requirements or external noise may limit or preclude the use of natural ventilation.

Extract ventilation systems

2.6 Separate extract ventilation will be required for sanitary facilities, lavage areas, dirty utilities and in rooms where odorous, but non-toxic fumes are likely, in order to ensure air movement into the space. 10 air changes per hour have been found necessary, particularly in geriatric and psychogeriatric

accommodation. This will assist with infection control procedures. A single fan/motor unit can be suitable for individual rooms, but multi-room systems should be provided with duty and standby fans or motors to meet this need.

2.7 Toilets should have an extract ventilation rate as set out in the building regulations. Where WC's are located in shower and bathroom spaces, the ventilation required for the WC will normally be adequate for the whole space.

Supply only ventilation

2.8 Mechanical supply ventilation will be required in areas where it is important to maintain a positive pressure in order to prevent the ingress of less clean air, e.g. in pharmacy aseptic suites, sterile supply packing rooms, operating theatres and their preparation rooms (air change rates are given in Table A1).

Supply and extract ventilation

2.9 Mechanical supply and extract ventilation should be provided in rooms where there is a need to control room pressure in relation to adjacent spaces. Intensive Care Units, (ICU), isolation suites and treatment areas are typical applications.

Mechanical or comfort cooling

2.10 Cooling is very expensive in terms of energy costs and should be provided only where necessary to maintain a comfortable environment for staff and patient, or to ensure satisfactory operation of equipment. The imaging department in particular may require cooling to offset the equipment load.

2.11 Calculations and thermal modelling should be undertaken to ensure that during the summertime, internal temperatures in patient areas do not exceed 28ºC (dry bulb) for more than 50 hours per year taking into account the level of design risk for the application.

2.12 Certain non-patient areas may also require cooling and will typically include some laboratories, central wash-up and other areas that are subject to high equipment heat gains.

2.13 Where deep planning of other continuously occupied spaces, for example offices, is unavoidable, there will also be occasions when acceptable levels of comfort can only be maintained by cooling. Planning solutions of this type however will be exceptional.

2.14 Refrigeration plant should be of sufficient capacity to offset heat gains and maintain areas at a temperature that does not exceed the external design shade temperatures by more than about 3ºC taking into account the level of design risk for the application.

Air-conditioning

2.15 Full air-conditioning is only required in a very small number of areas within healthcare buildings and due to the capital and running cost its inclusion should be kept to a minimum. Paragraphs 3.14 - 3.15 and 4.91 - 4.93 also refer.

2.16 Areas whose functions may warrant the installation of air-conditioning include operating departments, intensive therapy units, manufacturing pharmacies and areas with particularly sensitive equipment.

Specialised ventilation

2.17 Due to the nature and extent of activities carried out in healthcare buildings, there will be a need for a wide range of specialised ventilation systems. The types of system which are generally required in individual departments and typical arrangements are given in Section 7.

2.18 The activities within some departments will require the provision of local exhaust ventilation (LEV). This is a statutory requirement under COSHH wherever the escape of chemicals, toxic fumes, biological material or quantities of dust into the general area would present a hazard to the occupants.

Ventilation for general areas

2.19 Table A1provides recommended air change rates, temperatures and pressures for general areas that require mechanical ventilation in healthcare buildings.

Use of natural ventilation

2.20 The air tightness of new buildings has improved to the point that infiltration through building leakage can no longer be relied upon to provide sufficient air-flow. Attention must therefore be given to the provision of purpose-made ventilation openings to achieve the necessary flow rates. The air entering the openings may need to be controlled by motorised dampers linked to temperature and / or occupancy sensors in the ventilated space.

2.21 Internal partitions, fire compartment walls and closed doorways can often impede the flow path, and when this happens, the process will be more dependent on single-sided ventilation. Nevertheless, even with this degree of compartmentation, acceptable ventilation may still be achieved without window openings that would prejudice safety, security or comfort.

2.22 Some types of window, for example, vertical sliding, can enhance single sided air change by temperature difference, and these will improve the overall rate of natural ventilation in protected or sheltered areas where the effect of wind pressure is likely to be minimal.

2.23 It is generally considered that natural cross-flow ventilation is able to give reasonable air distribution for a distance of up to 6 metres inwards from the

external façade, provided that reasonably clear air paths are maintained. Beyond this distance in areas where clear air paths cannot be maintained and in areas where high minimum air change rates are specified, mechanical ventilation should be provided.

2.24 Further information can be found in SHTM 55 'Windows', BS5925 'Code of practice for ventilation principles and designing for natural ventilation' and CIBSE Applications Manual AM10: 'Natural ventilation in non-domestic buildings'.

Mixed mode ventilation

2.25 This comprises an assisted form of natural ventilation. Fans are fitted in the purpose made damper-controlled ventilation openings. Alternatively a separate ventilation unit may be installed. In both cases the dampers and fans are controlled under the dictates of temperature and occupancy sensors to ensure a minimum air flow rate while taking advantage of natural ventilation effects when present.

2.26 Where natural or mixed mode ventilation is adopted with complex air paths, the designer should produce an air flow diagram in order to ensure correct provision of air transfer devices. CIBSE Applications Manual AM13: 'Mixed mode ventilation in non-domestic buildings' gives guidance.

Mechanical extract ventilation

2.27 General extract systems can vary in complexity from a single wall-mounted fan to a ducted air system with dual extract fans.

2.28 Replacement air is generally provided by a central supply system (as described below). Unless special precautions are taken, the latter may result in an unacceptable level of draughts occurring in winter, and possible risk of unacceptable levels of noise transmission.

2.29 If individual systems are used, the ventilation can be operated intermittently, provided it continues to run for at least 15 minutes after the room is vacated, as with light switch-operated fans in individual toilets.

2.30 If general exhaust systems are used; it is recommended that filtered and tempered replacement air is provided via a central supply plant to adjoining lobbies or corridors, to prevent the risk of discomfort caused by the ingress of cold air. Fire compartmentation requirements must be maintained.

2.31 Information on specialised extract systems is given in Section 7.

Mechanical supply systems

2.32 Where mechanical supply systems are required, the fresh air should be tempered and filtered before being delivered to the space, to avoid discomfort.

2.33 The air should be heated using a constant or variable temperature source, but generally only to the space air temperature. In most instances, the low-pressure hot water heating (LPHW) should offset any fabric loss, so that setback room temperatures can be maintained during unoccupied periods without the need for the ventilation system to operate.

Balanced ventilation

2.34 Balanced ventilation systems are merely a combination of a supply and extract systems of equal volume; and either a single space or a whole building may be considered to be balanced. A balanced system is necessary in instances where it is essential to maintain consistent air movement within an area, for example, treatment rooms.

Cascade ventilation

2.35 In operating departments it is normal practice to supply air to the operating room, and allow it to pass through less clean areas – corridors, utility rooms etc. (from where it is eventually extracted).

Recirculation systems

2.36 Due to the nature of the use of mechanical ventilation systems within healthcare buildings, there are few opportunities for the application of recirculation air systems. They are however normally used for HEPA filtered clean room applications where the extract air is significantly cleaner than the outside supply. Recirculation is also routinely used in the canopy section of Ultra Clean Operating theatre ventilation systems.

2.37 Where the designer is considering the installation of a recirculation air system, due account must be taken of:

- minimum fresh air supply volume required by the Building (Scotland) Regulations 2004 (currently 20%);
- prevention of contamination of supply air from vitiated air in extract systems;
- prevention of stratification occurring within plenum chambers and mixing boxes which may result in freezing of downstream coils;
- ensuring sufficient velocities through control dampers (ideally 5-6m/s) to provide suitable authority; and good shut-off;
- modulating control of mixing to provide optimum on-plant conditions;
- use of ‘free cooling’ by cycling the dampers to minimum fresh air when the enthalpy of the outside air is above that of the extract air under conditions when cooling is required.

Chilled beams

2.38 The use of chilled beams for the provision of heating, cooling and ventilation is increasingly common in healthcare premises. The use of Active Chilled Beams providing tempered filtered air to a heating / cooling device within the room can provide effective local control of environmental conditions.

2.39 Care should be taken in positioning chilled beams to ensure the avoidance of cold draughts particularly when used in the cooling mode. The control settings should ensure that the external elements of the beam are always above dewpoint.

2.40 Consideration should be given to the ease with which specific types of chilled beam units can be accessed for cleaning having regard to the need to control the infection risk. The impact of maintenance requirements on room availability should also be considered.

Split comfort air-conditioners

2.41 Split comfort air-conditioners, room conditioners or cassette units are used increasingly where there is a small local requirement for cooling for operational purposes. They can provide an effective economic solution to cooling needs, where a central refrigeration system is not practicable.

2.42 The units re-circulate room air so provision for a fresh air make up, either by natural or mechanical means, to the standard required by the Building (Scotland) Regulations must be provided.

2.43 The recirculation of room air presents problems with indoor air quality (IAQ) and may increase the risk of healthcare associated infection (HAI). Split units should not therefore be used in critical patient areas.

2.44 Split units may be used for single room applications or as multiple linked units that can independently provide either heating or cooling, all served by a single outdoor unit. These systems enable good temperature control of a number of rooms with maximum energy efficiency.

2.45 Whether single or multiple systems are used, it is essential that the designer gives due consideration to the source of electrical supply, location of the heat rejection unit, environmental effects to the refrigerant used and drainage provision for the cooling coil condensate.

2.46 The units will require routine maintenance for filter change and cleaning; they should therefore be installed in an accessible position.

Dilution ventilation and clean air flow paths

2.47 Dilution ventilation has in the past been used to control levels of hazardous substances in a space. This approach is no longer considered acceptable. The COSHH Regulations require that known hazardous substances should

be substituted by safe alternatives. If this is not possible then they should be controlled at source by the use of closed systems such as anaesthetic gas scavenging units or exhaust protective enclosures such as fume cupboards.

2.48 The exposure of staff to casual spillages of substances such as medical gases in anaesthetic rooms should in the first instance be dealt with by establishing a clean airflow path. Air should be supplied at high level and extracted at low level directly behind the anaesthetic equipment position. The philosophy of establishing a clean air-flow path from the supply point; to the staff; on to the patient and out via a low level extract would also apply in recovery rooms and maternity delivery rooms including labour, delivery, recovery & post partum (LDRP) Rooms. A suitable air change rate will provide dilution ventilation as an additional safeguard; see Table A1, Table A2 and Note c.

2.49 In operating theatres the patient will be on a closed breathing circuit in a room with a high air change rate. Under these circumstances the dilution effect would be considered sufficient to control any casual exposure to anaesthetic gases.

Mechanical ventilation systems

System selection

2.50 Natural ventilation is always the preferred solution for a space, provided that the quantity and quality of air required, and the consistency of control of ventilation to suit the requirements of the space, are achievable with this method. If this is not the case, a mechanical ventilation system will be required.

Choice of central/local plant

2.51 Mechanical ventilation is expensive to operate, and as such, should be controlled to operate when the space being served requires to be ventilated. In addition, loads on refrigeration plant are rarely constant owing to changes in solar gain, occupancy and use of heat-generating equipment and lights, therefore control of temperature is critical.

2.53 If the ventilation loads throughout a department or building are in phase, or are not significant, a central plant with single zone control can be adopted. However, this is rarely the case, and elsewhere, the condition or quantity of supply air to different areas or zones of the building must be varied accordingly. This can be done by providing either individual plants to each zone, or separate zone terminal control. Where there is a high density of rooms with similar ventilation requirements in an area of a building or department, it is usually economical to combine them into a central system.

2.54 In large buildings, a choice between a single distribution system and multiple smaller systems may arise. Large distribution systems and their plant can have the advantage of lower operating costs, but require more space for vertical shafts and horizontal distribution. In general, very long runs of ducting should be avoided to prevent undue heat losses or gains, excessive leakage, and difficulties in balancing during commissioning. As the pressure losses in the

long runs will be greater and a higher initial static pressure will be required, this will lead to a more expensive class of ductwork. Multiple smaller distribution systems may be more expensive in capital and operating costs but they avoid long runs, large ducts and vertical shafts, and this may reduce overall building costs. They also provide a more robust service as the failure of an individual system does not prevent the use of the rest of the building.

Zoning of the building

2.55 The efficiency and effectiveness of any ventilation or air-conditioning installation depends largely on the zoning and control of the installation. The factors to consider when determining the zoning of a ventilation system for a building or department are:

- periods of occupancy;
- fresh air/ventilation requirements;
- smoke control.

2.56 Where the ventilation system is not merely tempering the air, but also providing the heating and/or cooling requirements, the following additional factors will need to be considered:

- internal or peripheral location;
- orientation of windows;
- variation in internal loads;
- level of control required.

2.57 For single zone plant in staff areas, local control (with a run-on timer if required) is recommended, as this can be turned off when the space is not in use, thus saving both thermal and electrical energy. Most supply and extract systems, conversely, are required to operate continuously while the department is occupied, thus some form of time or use control is necessary.

2.58 The control of individual plant items is covered in Section 4, with examples of typical control strategies in Section 6. For control of particular specialised ventilation and air-conditioning systems refer to Section 7 of this document.

2.59 On very rare occasions a duplicate standby air handling plant may be justified. If installed it must be provided with a gas-tight damper at its junction with the supply distribution duct, so that no back-flow can occur. Standby plants can become sources of contamination if warm moist air is allowed to dwell within them. Their design and control system must ensure that this cannot happen.

Specific requirements for hospital departments

2.60 Specific requirements for individual spaces and departments are included in the Health Building Notes (HBNs) and Activity Database (ADB) A-Sheets, or Scottish Health Planning Notes (SHPNs).

3. Assessment of service requirement

Selection of design criteria

External design conditions

3.1 The most accurate data that is available for the summer and winter conditions at the site should be used. The Metrological office can supply data for the United Kingdom.

3.2 Healthcare mechanical ventilation systems will normally be 'full fresh air'.

3.3 Local adjustments such as for height above sea level, exposure factor, or other climate peculiarities, should be made as appropriate.

Internal design conditions

3.4 The design conditions selected within patient areas must strike a balance between the comfort requirements of staff and patients, who often have very different levels of clothing and activity.

3.5 Recommendations for the dry resultant temperature and humidity of individual spaces are shown on Activity Database (ADB) A-Sheets. Table A1 gives a summary.

Minimum fresh air requirements

3.6 For most applications involving human occupancy, the dilution of body odours is the critical factor in determining ventilation requirements. Where natural ventilation or mechanical full fresh-air systems are used, all ventilation air will be fresh.

3.7 Where odour dilution is the overriding factor, it is recommended that 10 litres/second/person should be taken as the minimum ventilation rate.

3.8 Smoking is not permitted in healthcare premises. If permitted for example in residential care, it will be confined to designated areas. It therefore follows that these areas will contain a high percentage of smokers so the ventilation rate would be at least 36 litres/second/person for these applications (CIBSE Guide A; Table 1.10 refers).

3.9 In non-standard applications such as laboratories, aseptic suites, operating departments, etc., the particular requirements for each area should be considered independently in order to determine the overriding minimum requirement for ventilation.

Limiting supply air conditions

3.10 For most applications in healthcare buildings, it is the temperature differential between the supply and room air, rather than the actual temperature of the supply air which is the critical factor. The maximum recommended supply-to-room air temperature differential is:

summer cooling: - 7K

winter heating: + 10K

3.11 It is also necessary to keep supply air humidity below 70% during winter in order to minimise risks associated with condensation.

Air purity

3.12 In healthcare premises, the standard of filtration will depend on the activities within the occupied spaces. With the exception of special areas, (for example manufacturing pharmacies), the requirement for aerobiological needs is not stringent and filtration is only required to:

- maintain hygienic conditions for the health and welfare of occupants, or for processes such as food preparation;
- protect finishes, fabrics and furnishings; to reduce redecoration costs;
- protect equipment either within the supply air system; that is, to prevent blocking of coils, or in the space itself to prevent dust collection.

3.13 Given that almost all viable particles will originate from the occupants of a space and not from the incoming air, dilution is the more important factor aerobiologically. Therefore, for general areas a G4 filter will be suitable. More critical areas will require a F7 filter. HEPA filters will only be required in Ultra Clean systems.

Humidity control requirements

3.14 Providing humidification is expensive in terms of plant, running costs and maintenance, and therefore its use should be restricted to where it is necessary for physiological or operational reasons.

3.15 Humidification was originally required for some healthcare applications, e.g. operating theatres, in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased. Humidification is therefore no longer required unless there is a very specific application requirement.

Maximum noise levels

3.16 Noise will be generated in an air distribution system by the fan, ductwork fittings, dampers and grilles. The specified maximum noise level will depend on the activities within the occupied spaces.

3.17 The overall noise levels should not exceed the values given in Scottish Health Technical Memorandum 08-01: 'Acoustics', although general requirements are given in Table 3.

3.18 Attenuation should be incorporated into the ductwork system or plant arrangement as necessary to reduce noise from fans and plant items in order to achieve the acceptable limits within the rooms at the design air flows.

3.19 Plant noise should not be greater than 80dB(A) within the plant room from the fans, coolers, heaters, humidifiers etc. when starting up or running, and should be reduced to lower noise levels where the plant is near to departments sensitive to noise.

3.20 Attention must be given to the reduction of tonal components. High tonal components from air diffusers etc. can seriously disturb concentration over longer periods even when the overall noise level is low. Broadband noise causes less annoyance. Reference should be made to SHTM 08-01: 'Acoustics'.

3.21 The designer requires knowledge of the total hospital layout and operational policies, to assign acceptance magnitudes to all the possible noise sources, in order to arrive at the correct rating.

Room	Overall noise level - NR	Ventilation plant commissioning - NR	Ventilation plant design - NR
Operating department	50 (55)	45	40
Ward areas	33	30	30
Sanitary facilities	45	40	35
Industrial areas	50	45	40
Circulation areas	50	45	40

Table 3: Interior noise level

3.22 In Table 3, above, the overall noise level takes account of all internal and external noise sources. The commissioning noise level is the level measured with a sound level meter in the unoccupied room, taking account of the external noise together with the noise generated by the ventilation system. When occupied and in use, this commissioning level will constitute a continuous background noise which will allow the overall noise level to be achieved. The ventilation plant design noise level is that generated by the plant alone with no other noise source being considered. The levels suggested make recognised allowance for the ingress of environmental noise that must be considered in the overall design, that is, in specifying the attenuation of walls, partitions, ceilings, etc.

3.23 The recommended criterion is measured as the "A" weighted sound pressure level expressed in decibels, which should not be exceeded for more than 10% of the time.

3.24 The designer must also consider noise escaping to the external environment and this must not be unacceptable to occupants of adjacent buildings.

Calculation of building loads

Air infiltration

3.25 Air infiltration occurs due to a complex combination of wind pressure, thermal effects, location relative to other features and the construction standard of the building. The infiltration rate is governed by the size and number of openings in the building envelope and the complexity of internal air paths.

3.26 CIBSE Guide A (2006) Section 4 provides information and formulae for the calculation of air infiltration and natural ventilation of buildings. In all cases the requirements of the appropriate section of the Building (Scotland) Regulations must be met.

Summertime temperatures

3.27 The calculation method for determining the summertime temperature is described CIBSE Guide A (2006) Section 5. However, it is very important to select the time of day and time of year of peak loadings for the calculations. These will be dependent on the orientation and proportion of solar to total heat gain. In establishing outside design values, the design risk having regard to the function and occupancy of the building should be considered.

3.28 Where calculations indicate that internal temperatures will frequently exceed the selected design external shade temperature by more than 3K for a period that exceeds the building design risk, methods of reducing temperature rise should be implemented. Options include: - reducing solar and casual gains, the use of chilled beams or ceilings, increasing ventilation rates or providing mechanical cooling. In some situations it may be possible to alter the thermal mass of the structure to 'move' the peak temperature event time so that it occurs outside of the occupancy period. Calculations and thermal modelling should be undertaken to ensure that during the summertime internal temperatures in patient areas do not exceed 28°C dry bulb for more than 50 hours per year. It has been found that there is a relationship between preferred indoor temperatures and mean outside temperature. Fig A2 in CIBSE Guide A indicates this relationship.

Peak heating load

3.29 Peak heating local calculations are necessary on all mechanical supply systems to establish the size of heater batteries and subsequently the central plant.

3.30 Where ventilation systems provide tempered air to spaces that have supplementary LPHW to offset the building fabric losses, the plant heating load should be calculated based on the external winter design temperature, the design internal air temperature, and the calculated total air volume (including a suitable allowance for leakage).

3.31 Where the ventilation system is the only means of heating a space, an increase in load equivalent to the calculated fabric heat losses from the space should be added to the ventilation load. A check of supply temperature difference should be made. If it exceeds 10K the ventilation supply volume should be increased to suit.

Condensation risk

3.32 A check should be made to ensure that the selected air condition will not lead to surface condensation on low-temperature elements of the ventilated space.

3.33 Where there are local sources of moisture that would require excessive levels of ventilation to avoid condensation, the designer should consider the capture and removal of moisture at the source of the evaporation via an exhaust hood or similar device.

3.34 In intermittently heated buildings, it is necessary to consider the condensation risk at night setback conditions as well as during normal operation. Calculation methods for this assessment are given in CIBSE Guide A.

Peak cooling load

3.35 In addition to the base data of airflow rates and temperatures, when calculating cooling loads, the designer must take into account:

- solar cooling loads;
- surface conduction cooling loads;
- internal gain cooling loads;
- cooling loads due to high-level humidity control;
- method of control of internal conditions;
- fluctuations in internal temperatures.

3.36 When the peak internal loads have been assessed and a suitable allowance made for non-coincidence, the supply temperature can be calculated.

3.37 Once the lowest required supply temperature of the air handling unit has been established, and an allowance made for temperature rise through the fan and ductwork (usually 1K for low pressure systems), the off-plant enthalpy can be established from a psychrometric chart or table.

3.38 The cooling loads for all plants on the chilled water system should be calculated at each of the individual peak times in order to establish accurately the required (diversified) capacity of the chiller.

Annual energy consumption

3.39 Annual energy consumptions of heating-only ventilation systems are simple to calculate based on supply-to-external air temperature rise, and frequency of occurrence of external temperatures as given in CIBSE Guide A.

3.40 Minimum air volumes are usually fixed by the room loads or fresh air requirements. However, the designer may increase airflow to some rooms or zones in order to balance loads, as detailed in the following paragraphs on "Calculation of plant requirements."

3.41 The method of zoning and control can significantly influence energy consumption.

3.42 The nature of air-conditioning operation, comprising cooling and reheating for humidity or zonal temperature control, makes prediction of energy consumption very complex. It is imperative that these calculations are performed to ensure optimum energy efficiency.

3.43 The concept of load and plant operation charts is outlined in the CIBSE Guide A. The method requires the designer to establish the minimum and maximum loads on all zones across the range of external temperatures between winter and summer design conditions. Once the load chart is complete, the plant chart converts the loads to supply temperatures, which are then superimposed on external air temperatures.

3.44 When all temperatures for all zones are plotted on the plant operation chart, set points and resetting schedules can be established. From this information, the outputs of individual heaters, coolers and humidifiers can be established at any given external temperature. When those loads are computed against annual frequency of occurrence of external temperatures as given in CIBSE Guide A, the annual energy consumption of individual elements, and thus the air-conditioning system, can be established.

3.45 In order to prevent surface condensation occurring, it is necessary to provide sufficient ventilation to maintain the maximum and ambient dew-point temperature below the lowest surface temperature, the coldest usually being the glazing. Paragraphs 3.33 and 3.34 also refer.

Calculation of plant requirements

Air supply volumes

3.46 The minimum air supply volume for a room is determined by the greatest of these three criteria:

- the minimum fresh-air requirement;
- the minimum supply volume for the room load as determined by the maximum heating or cooling supply temperature differential;
- the desired/required air change rate.

Plant sizing

3.47 Once the design airflow has been established the cross-sectional area of the air-handling unit can be calculated based on a maximum coil face velocity of 2.0 m/s.

3.48 In order to establish the length of the air-handling unit, it will be necessary to refer to manufacturers' literature, ensuring all necessary access panels and components are included as detailed in Section 4.

3.49 The fan duty should be calculated by adding the resistances of all elements that contribute to the pressure drop of the index circuit.

3.50 The main elements that must be considered are:

- inlet or discharge louvres;
- plant entry and discharge;
- attenuators;
- components within the air-handling unit;
- duct-mounted heaters and filters (including a dust allowance);
- ductwork distribution;
- ductwork fittings, including: fire dampers, volume control dampers, bends and sets, tees, changes of section;
- air terminal device;
- discharge velocity.

3.51 Where packaged air-handling units are installed, the fan pressure drop is usually quoted as external plant resistance, and thus the designer does not need to calculate the resistances of individual plant items. The designer should, however, ensure that an allowance has been made for filter clogging; and confirm whether the fan pressure quoted is fan total or static pressure.

3.52 Resistances of ductwork and fittings may be obtained from the CIBSE Guide A. However, the designer should exercise some care when using tabulated pressure loss information for fittings that are relatively close together.

3.53 Upon completion of the resistance calculation exercise, the designer should make allowances for calculation and construction tolerances as indicated in Table 4.

Criteria	Low pressure systems	Medium/high pressure systems
Volume flow rate margin for leaking and balancing requirements	+5%	+5%
Total pressure loss margin A. for increase in volume flow rate (above)	+5%	+5%
B. for uncertainties in calculation	+5%	+10%
Combined total pressure loss margin	+10%	+15%

Table 4: Typical fan volume and pressure margins

Plantroom size and location

3.54 The ventilation plant and associated equipment should be positioned to give maximum reduction of noise and vibration transmitted to sensitive departments; while at the same time, achieve an economic solution for the distribution of services.

3.55 It is not recommended that noise and vibration generating plant be housed either directly above or below sensitive areas (for example, operating or anaesthetic rooms) unless there is no alternative, in which case, additional care and attention must be given to the control measures.

3.56 The plant must also be located so that it is remote from possible sources of contamination, heat gains and adverse weather conditions. The design should ensure that wind speed and direction have a minimal effect on plant throughput.

3.57 Safe access to and around plant is essential to facilitate inspection, routine maintenance, repair and plant replacement.

Provision of primary services

3.58 Where more than one air-handling plant requires cooling, remote central cooling plants with piped chilled water are preferred. In the case of a single plant, a multi-stage direct-expansion cooling coil with refrigerant piped from an adjacent compressor/condensing plant could be considered. If this option is selected, a refrigerant gas detector mounted in the base of the duct and an alarm system audible to the end-user will also need to be provided (as dictated by COSHH Regulations).

3.59 Clean dry steam is preferred for humidification, provided that the boiler water treatment does not render the steam unusable for direct humidification.

3.60 If a suitable supply of steam cannot be obtained from the steam main, a steam generator should be provided locally, or a self-generating humidifier installed. Electric humidifiers require considerable electrical loads and if a gas supply can be derived, this would be preferable. The location of a local steam generator is critical if condensate is to drain back into it.

Inlet and discharge sizing and location

3.61 Air intakes and discharge points should preferably be located at high level, to minimise the risks of noise nuisance to surrounding buildings, contamination and vandalism.

3.62 Intakes and discharges should be designed and located so that wind speed and direction have a minimal effect on the plant throughput.

3.63 Helicopter landing pads in the vicinity of ventilation intakes and discharges can result in large short-term pressure changes. This can cause pressure surges in supply systems and reverse airflows in extracts. Exhaust fumes from the helicopter may also be drawn into intakes. For general information, refer to Health Building Note (HBN) 15-03 – Hospital helipads.

3.64 Intake points should also be situated away from cooling towers, boiler flues, vents from oil storage tanks, fume cupboards and other discharges of contaminated air, vapours and gases, and places where vehicle exhaust gases may be drawn in.

3.65 Where intakes have necessarily to be sited at or near ground level, the area around them should be paved or concreted to prevent soil or vegetation being drawn in. They should also be caged or located within a compound to prevent rubbish being left in the vicinity. The likely proximity of vehicle exhausts should also be taken into account when determining the protected area around the intake.

3.66 The discharge from an extract system must be located so that vitiated air cannot be drawn back into the supply air intake or any other fresh-air inlet. Ideally, the extract discharge will be located on a different face of the building from the supply intake(s). In any event, there must be a minimum separation of 4 metres between them, with the discharge mounted at a higher level than the intake.

3.67 Discharges from LEV systems should preferably be vertical and usually not less than 3m above roof level. They should not be fitted with a cowl that could cause the discharge to be deflected downwards.

3.68 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain. Louvres should be sized based on a maximum face velocity of 2 m/s in order to prevent excessive noise generation and pressure loss.

3.69 The inside of the louvres should be fitted with a mesh of not less than 6mm and not more than 12mm to prevent leaves being drawn in and infestation by vermin.

3.70 The duct behind louvres should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system.

3.71 Cleaning access must be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door.

Heat rejection devices

3.72 The design conditions given in Section 2 make no allowance for the elevated temperatures that can occur on the roof of buildings. Refrigeration condensers should, if practicable, be shaded from direct solar radiation, or the design adjusted to take account of the gain.

3.73 Air-cooled condensers must always be the first choice for heat rejection from any refrigeration plant. Evaporative cooling systems must not be used in healthcare premises.

3.74 Reference should be made to Scottish Health Technical Memorandum 04-01: 'The Control of *Legionella*, hygiene, 'Safe' hot water, cold water and drinking water systems, Part A: Design, Installation and Testing, and Part B: Operational Management, published by Health Facilities Scotland, 2011.

4. Air handling unit design and specification guidance

General requirements

Location and access

4.1 Air-handling units should be located in an accessible area secured from unauthorised entry. Siting units in ceiling voids above occupied spaces is not appropriate.

4.2 Units located on roofs must have a safe means of access together with suitable precautions to prevent personnel or equipment falling or being blown off during maintenance activities.

4.3 Units located at ground level should be secured within a locked compound to prevent unauthorised access. Measures should be taken to exclude vehicles from the vicinity to ensure that exhaust fumes will not be drawn into intakes.

4.4 Units may have a working life of approximately 20 years. It can be anticipated that over this period there will be a need to access every element within the unit for deep cleaning. It is also quite possible that the main fan and individual heater and chiller batteries will need replacement. Suitably positioned service connection joints and adequate spacing should permit these items to be withdrawn without the need to dismantle other installed plant or equipment. Batteries significantly wider than 1 metre should be split to permit withdrawal from both sides.

4.5 It is essential that air-handling units are positioned so that all parts are easily and safely accessible for routine inspection and service. If a unit is located against a wall or backs onto another unit then access to all parts must be available from the front. Units greater than 1 metre wide should preferably have access from both sides or access doors large enough to permit the full and safe entry of maintenance personnel.

4.6 Water may be used during routine cleaning or spilt when maintenance is being undertaken. The area around the unit should be tanked to prevent water penetration to adjacent areas and adequately drained.

4.7 Fire precautions should be incorporated in accordance with Firecode. Guidance is available in BS5588: Part 9 and Sections 5 and 6 of this document.

4.8 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.

Technical requirements

4.9 The basic technical requirements of the whole of the ventilation system should meet the relevant clauses of the Model Engineering Specification. It should be noted that the Specification contains a menu of clauses that cover a wide range of applications, so it is important to select only those that are relevant to the specific application.

Note 1: At the time of writing, Model Engineering Specification C04 was listed for revision in order to bring it into line with the revised standards as set out in this Scottish Health Technical Memorandum. Where conflicts in specification arise, the Scottish Health Technical Memorandum takes precedence.

4.10 It is essential that the main plant/ductwork is located far enough above the floor to permit the correct installation of drainage systems for cooling coils, humidifiers and heat recovery systems. Easy access for maintenance of drainage systems and their associated pipework must be provided.

4.11 Organic materials or substances that can support the growth of microorganisms must not be used in the construction of the plant or its distribution system. The water fittings and materials directory lists suitable materials for sealants and gaskets.

4.12 The plant and its distribution system must not contain any material or substance that could cause or support combustion.

4.13 Plants should have a high standard of air-tightness. The double-skin method of construction with insulation sandwiched between two metal faces is recommended. The panels may be available in a variety of colours at no additional cost. This can aid identification by colour coding of units in a plant room (for example green for general ventilation; blue for theatres; red for laboratories and isolation facilities; grey for extract etc).

4.14 The inside of the plant should be as smooth as possible. Channels, rolled angles or formed sections that could trap or hold moisture should be kept to a minimum. If stiffeners are required, they should be fitted externally. If internal bracing has to be fitted it must be of a design that will not trap or hold moisture.

4.15 Airflow across air treatment components such as filters, heat exchangers and humidifiers will be influenced by the pattern of the approaching airstream. If unsatisfactory conditions are created, the performance of the component will be reduced.

4.16 Access to items that require routine service such as filters, frost batteries and chiller batteries should be via hinged doors. The doors should be large enough (for example 500mm minimum) to allow easy access. Items requiring infrequent access such as attenuators may be via bolted-on, lift-off panels. All doors and panels should be close-fitting and without leaks.

4.17 Care should be taken during installation to ensure that electrical and mechanical services are not installed in positions that will reduce or impede access.

4.18 It can be difficult to turn off AHUs in order to inspect filters and drainage trays. Viewing ports and internal illumination will therefore facilitate routine inspection of such items. 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 should be positioned so that they provide both illumination for inspection and task lighting. All of the lights in a unit should be operated by a single switch.

4.19 Access to AHUs and items in the distribution system such as filters or heater / chiller batteries should be via fixed ladders and platforms or pulpit-style moveable steps. The installation of distribution ductwork and other electrical or mechanical services should provide sufficient clearance to allow the pulpit steps to be easily wheeled into position.

AHU drainage system

4.20 All items of plant that could produce moisture must be provided with a drainage system. The system will comprise a drip tray, glass trap, air break and associated drainage pipework.

4.21 The drip-tray should be constructed of a corrosion-resistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent 'pooling', it is essential that the drain connection should not have an upstand; and that a slope of approximately 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.

4.22 Each drip tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed thus giving an early indication of corrosion, biological activity or contamination within the duct. The trap should have a means for filling and incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework connecting it to the drainage tray should have a continuous fall of not less that 1 in 20.

4.23 Traps fitted to plant located outside or in unheated plant rooms may need to be trace-heated in winter. The trace-heating must not raise the temperature of water in the trap above 5°C.

4.24 Water from each trap must discharge via a clear air gap of at least 15mm above the unrestricted spill-over level of either an open tundish connected to a foul drainage stack via a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish providing each has its own air break.

4.25 Drainage pipework may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22mm and a fall of at least 1 in 60 in the direction of flow. It should be well supported and located so as not to inhibit access to the AHU.

Layout of air handling unit

4.26 The AHU should 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. A recommended layout is given in schematic from in Figure 3.

4.27 A separate extract unit will generally be required for the area served by each supply unit.

4.28 An energy recovery system will normally be fitted between the supply and extract units.

Provision of dampers

4.29 Fire- or smoke-actuated dampers shall be provided at the locations required by Firecode. (See Paragraphs 5.17 - 5.21).

4.30 Motorised low-leakage shut-off dampers should be located immediately behind the intake and discharge of each supply and extract system respectively. They should 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.

4.31 The quality of motorised dampers is critical. They should 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%.

4.32 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.

4.33 Good practice will require the fitting of a main volume control damper so that the design airflow rate can be set at commissioning. The damper should be lockable in any position. If it will also be used for plant isolation, it should be capable of being reset to give the design airflow without the need for re-measurement.

4.34 Internal plant isolating dampers or provision for the fitting of shut-off plates between items within a unit are not required.

Vibration

4.35 Vibration from a remote plantroom can be transmitted by the structure of the building, may be regenerated and may sometimes be magnified many times. Units should be selected to have the minimum vibration generation and installed on suitable anti-vibration mounts. Pipe and ductwork should incorporate anti-

vibration couplings, preferably in two planes at right angles, as close to the vibration source as possible. Consideration should be given to the use of anti-vibration pipe hangers and supports.

Sequence of components

4.36 The following arrangement of plant components is typical although in many instances not all elements will be required:

- fresh air intake;
- motorised isolation damper;
- frost / fog coil;
- pre-filter;
- energy-recovery device;
- attenuator;
- fan;
- blast plate;
- attenuator;
- chiller battery;
- eliminator;
- heater battery;
- humidifier;
- final filter;
- isolation / volume control damper.

Note 2: Attenuators may be located in the intake and discharge duct if they are of a suitable type (See Paragraphs 4.159 - 4.162)

There may be instances where the above arrangement is not appropriate and the plant arrangement should be planned accordingly.

Fans

General requirements

4.37 The fan should be selected for good efficiency and minimum noise level, but the overriding factor should be the selection of a fan characteristic such that the air quantity is not greatly affected by system pressure changes due to filters becoming dirty or external wind effects.

Acceptable types

4.38 Fans can be of the axial, centrifugal, cross-flow, mixed-flow or propeller type, depending upon the requirements of the system.

4.39 Where used, centrifugal fans should preferably be of the backward-blade type. Alternatively, where noise levels are more critical and pressure requirements are lower, forward-curved blade fans are acceptable. For high-power applications, aerofoil-blade fans may be appropriate.

Selection

4.40 Generally, large ventilation systems will use centrifugal fans due to their efficiency, non-overloading characteristics, and developed pressures.

4.41 Forward curved centrifugal fans can overload if allowed to handle more air than they are designed for.

4.42 Alternatively, it may be appropriate to use mixed flow fans in high-pressure systems.

4.43 Axial flow or propeller fans are generally only used in local through-the-wall systems, or systems with very low pressure requirements.

4.44 Cross-flow fans have very low operating efficiencies, and thus their use is restricted to applications such as fan coil units.

Location and connection

4.45 Fans are normally positioned to ‘blow through’ the central plant so that the cooling coil and humidifier drains will be under positive pressure.

4.46 The fan performance figures given by manufacturers in their catalogue data are based on tests carried out under ideal conditions, which include long uniform ducts on the fan inlet/outlet. These standard test connections are unlikely to occur in practice, the designer should therefore ensure as far as is practical that the fan performance will not be significantly de-rated by the system. This objective can be approached by ensuring that the fan inlet flow conditions comprise uniform axial flow velocities with low levels of turbulence.

4.47 Where the outlet duct is larger than the fan discharge connections, there should be a gradual transition, with a following section of straight duct, having a length equivalent to three duct diameters.

4.48 The design of the fan intake connection must be carefully considered to avoid swirl in the airstream. When the air spins in the same direction as the impeller, the performance and power consumption of the fan are reduced. When the air spins in the opposite direction to the impeller the power consumption and noise will increase with hardly any pressure increase. Airstream swirl is usually induced by large variations across the fan intake caused by the air passing round a tight bend immediately before the intake.

4.49 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.

4.50 Airtight flexible joints should be provided at fan inlet and outlet connections. They should be equal in cross-section to the points of connection and be neither longer than 200mm nor shorter than 100mm.

4.51 For centrifugal fans, a diffuser screen / blast plate should be fitted immediately downstream of their discharge.

Supply fan drive arrangements

4.52 Where the fan drive is via a motor-driven belt and pulley, it should be external to the air stream. This arrangement has the following advantages:

- the fire risk is reduced;
- the drive is visible so it is simple to check that the belt is still there;
- particles shed from the drive belt are outside of the air stream;
- if the belt slips, the “burning rubber smell” is not transmitted down into occupied areas of the premises;
- noise generated by the motor and drive will not be transmitted along the ductwork;
- waste heat is excluded from the system;
- the drive may be through a vee or toothed belt and pulley. The latter have the advantage of eliminating belt squeal on start up and have a longer service life. They are particularly suitable where the fan drive motor is fitted with a soft start and should be located external to the air stream.

4.53 The drive train should be easily visible without the need to remove access covers. Protecting the drive train with a mesh guard is the preferred option. For weatherproof units designed to be located outside, the fan drive will be external to the duct but enclosed. It should be easily visible through a viewing port with internal illumination and access via a lockable hinged door.

4.54 For direct-coupled fan and motor units, the motor should be out of the air stream.

4.55 For induction drive ‘plug’ motor arrangements (where the motor is fitted within the fan and is integral to it) and in line axial fans with a pod motor; the fan / motor combination may be within the air stream provided the motor windings are protected from over temperature by a thermister and lockout relay.

Extract fan drive arrangements

4.56 The preferred method where the fan drive is via a motor driven belt and pulley arrangement will be to locate it external to the air stream.

4.57 The fan drive and motor may be located inside the duct within the air stream provided the motor windings are protected from over-temperature by a thermister and lockout. The drive train should be easily visible through a viewing port, have internal illumination and access via a lockable hinged door.

4.58 Where the system air is explosive, aggressive or has high moisture content, the extract fan motor must be located outside the air stream. This is generally achieved with axial fans by using a bifurcated unit.

Control

4.59 Fans in healthcare applications are normally either single or two-speed. Where there is a requirement for two-speed operation, this is generally via a local user control (for example, in a hood extract system to provide a boost facility) or via a time schedule for energy saving during unoccupied periods.

4.60 Normally only a single motor is required with a standby motor available for fitting as necessary or fitted but not belted. Twin, run and standby motors - with the standby being jockeyed around - are not required.

4.61 Where there is a specified requirement for standby fans, the system should incorporate an automatic changeover facility activated via an airflow sensor. Fault indication should be provided.

4.62 The control of fans in terms of start-up and run is increasingly being vested in computer software. Inverter-drive, variable-speed, soft-start systems are becoming a standard approach. It should be remembered that most healthcare applications require known amounts of air to be delivered while the system is in use. Constant volume systems that deliver specified air-change rates are therefore the norm. Duct- or room-pressure-controlled, variable-speed systems have a very limited application in healthcare.

4.63 It is necessary to ensure that - should the computer control system or its software develop a fault - then the fan can be switched to a direct-start, fixed-speed, manual operation. This is particularly important for critical care systems serving operating suites, high-dependency care units of any type, patient isolation facilities, laboratories and pharmaceutical production suites. Off-site software support is no substitute for the ability of on site staff to override the automatic control and keep the system operating in an emergency. Under these circumstances actions that may shorten the life of the plant are considered of secondary importance to that of preserving the health and safety of patients and staff.

Heater batteries / heater coils

General requirements

4.64 Frost batteries are installed to protect the downstream filters from low-temperature, high-humidity intake air conditions. As they handle unfiltered air they should be constructed of plain tubing without fins and be as near to the outside as possible to minimise condensation during cold weather. Access for cleaning will need to be provided to both sides of the coil.

4.65 Where steam coils are used for a frost battery, they may be constructed using spiral-finned copper tube. As they will be prone to fouling the tube layout and spacing should permit easy access for regular cleaning.

4.66 Main and branch heater-batteries should be constructed of solid-drawn copper-tube coils with copper fins, generally connected in parallel.

4.67 Where there is a wet heating system in the areas served, the main heater-battery should be sized for the ventilation requirements only, and not for the fabric loss.

4.68 Access for cleaning must be provided to both sides of all frost batteries and heater-batteries.

Acceptable types

4.69 Electric, water or steam heater-batteries may be considered. However, electric heater-batteries are expensive to operate and where there are alternatives, their use should be restricted to low-power use (for example trimming control).

4.70 Where steam-supplied heater-batteries are used, their control, venting and trapping systems should be designed so that a vacuum cannot occur within the coil. The condensate drainage arrangements should not allow pressure to build in the main resulting in a back-up of condensate in the coil.

Location

4.71 Where possible, wet-trimmer heater-batteries should be located in plant areas.

4.72 Where it is necessary to locate heater-batteries in false ceilings etc, consideration should be given to the use of electric heaters. If this is not practicable, drip-trays should be installed under both the battery and the control valve assembly to protect the ceiling. A moisture sensor and alarm should be fitted in the tray. In any event, to facilitate maintenance access, they should be located above corridors or other non-critical areas and never above patient occupied spaces.

4.73 Auxiliary fan coil units should not be installed in the ceiling above an occupied space. They should be accessible for routine maintenance and cleaning without the need to cause significant disruption to the operation of the department that they serve.

Control

4.74 LPHW frost coils should be controlled by an off-coil temperature sensor operating a motorised valve to provide a minimum plant "on temperature" of between 2°C and 5°C. The off-coil temperature of the frost coil is generally sensed by a serpentine thermostat downstream of the coil or upstream of the next plant item. This thermostat will shut the fan down if any part of the air stream is below the minimum set-point.

4.75 Steam-supplied frost coils should be fitted with an on/off control operated by a temperature sensor mounted upstream of the battery. These are normally set to open the control valve fully when the outside temperature drops to +1°C. This will ensure that there is no standing condensate in the base of the coil.

4.76 The main heater-battery should be controlled in the same manner under the dictates of either an off-coil temperature sensor, or a room temperature sensor, depending on the plant configuration and method of control. Trimmer heater-batteries are generally controlled by one or more averaging temperature sensors within the room or rooms in the zone.

4.77 Heater-battery control valves should drive to a closed position on system shutdown or fan failure. The control system should then automatically set to provide frost protection.

Cooling coils

General requirements

4.78 Cooling coils will need to be decontaminated periodically. They must have good access both up and downstream. Hinged access doors with viewing ports and illumination inside the duct should be provided both sides of the coil.

4.79 An eliminator will be required downstream of all cooling coils. The eliminator may take the form of an extension of the coil fins or be a separate device. If a separate device it should be removable as a unit to permit cleaning of the coil face.

4.81 4.80 All cooling coils must be fitted with their own independent drainage system as specified above. A baffle or similar device must be provided in the drip tray to prevent air bypassing the coil. The tray should be large enough to capture the moisture from the eliminator, bends and headers. Where coils are greater than 1m high, intermediate drip-trays will be required.

4.82 Condensate traps manufactured from Borosilicate Glass will allow easy visual inspection and incorporate a self-cleaning smooth non-porous internal surface, complying with ISO 3585 and BS2589 Part 1.

Selection

4.83 Cooling coils supplied with chilled water are the preferred option. For small loads or where chilled water is not available, direct expansion coils may be used.

4.84 Care must be taken in selection to minimise electrolytic action resulting from condensation on the airside. Coils constructed from copper tubes with copper fins extended on the downstream side in the form of an eliminator and electro-tinned after manufacture are preferred. Aluminium fins should only be used if vinyl-coated.

4.85 All parts of the coil and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials. Pressed steel coil headers, even if treated, have been shown to be prone to corrosion over time and should not be used. Steel mounting frames and casings present similar problems hence stainless steel is preferred.

Location

4.86 Microorganisms that multiply in moisture cannot be avoided when the coil is dehumidifying. However, locating the final filter downstream of the coils will reduce the risk of infection.

4.87 Cooling coils in AHUs should be located upstream of the final filter.

4.88 Where any cooling coil has to be located above a ceiling, drip-trays should be installed under both the coil and the control valve assembly to protect the ceiling. A moisture sensor and alarm should be fitted in the tray. To facilitate maintenance access, they should be located above corridors or other non-critical areas and never above patient occupied spaces.

Control

4.89 There are two basic methods of control for cooling coils:

- off-coil control – used in multi-zone systems or single-zone systems where close humidity control is required, to provide a constant maximum off-plant condition which satisfies the temperature and high humidity requirements of the zone with the highest load;
- sequential control – used in single-zone systems, or multi-zone systems with averaging sensors where close control is not required. A room or duct temperature sensor controls the cooling coil and heater battery in sequence to maintain constant room conditions.

4.90 The advantage of off-coil control is that accurate humidity control can be provided without relying on humidity sensors, which are prone to inaccuracy and drift. Off-coil control is however, expensive to operate in terms of energy consumption, due to the fact that there is no feedback of room loads, and thus

at low loads and in systems where there are large zonal variations, significant over-cooling and reheating will occur.

4.91 On systems with two-speed operating, it is usual to isolate the cooling coil upon selection of low speed. In addition, on system shutdown, low airflow or fan failure, the cooling coil must be isolated.

Humidifiers

Design need

4.92 Humidification was originally required for some healthcare applications in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased. Humidification is therefore no longer required unless there is a very specific application requirement.

4.93 Operating-theatre AHUs do not generally require humidifiers but provision for their retrofitting in terms of space provision and a capped drainage system should be provided.

4.94 Where humidification is required, it will be subject to the specific requirements set out below. These are intended to ensure that the unit will operate safely and not become a source of contamination.

General requirements

4.95 The most important requirement for a humidifier is to create complete mixing of the steam with the air. The manufacturers' instructions should be followed regarding minimum distances which should be allowed before bends or other components. This is particularly important with respect to a filter mounted downstream. If it becomes saturated by the humidifier, organisms can grow through the filter and be released into the duct. These may then be carried on the airstream into an occupied space.

4.96 The section of ductwork containing the humidifier may need to be periodically decontaminated. Hinged access doors with viewing ports and internal illumination should be provided. A label warning that the device emits live steam and should be isolated prior to opening should be affixed to the access door.

4.97 All parts of the humidifier and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials. Stainless steel is preferred.

4.98 The electrodes of self-generating electrode-boiler type humidifiers should be stainless steel.

4.99 All humidifiers must be fitted with their own independent drainage systems as detailed in Paragraphs 4.20 - 4.25 or 4.72 and 4.87.

4.100 For self- and locally-generated steam humidifiers, the cleanliness of the water supply is essential for their safe operation. Provision should be made for draining down supply pipework and break tanks for periodic disinfection and cleaning during periods when they are not required in service.

4.101 The addition of treatment chemicals for continuous control of water quality for humidifier/air handling units should be avoided. Consideration could be given to installing a UV system to control microbiological growth. Given the limitations of UV systems, however, this will require filtration to high quality to ensure the effectiveness of exposure of organisms to the UV irradiation. As with all water treatment systems the unit should be of proven efficacy and incorporate UV monitors so that any loss of transmission can be detected.

Acceptable types

4.102 Only steam-injection manifold-type humidifiers are considered suitable for use in health building air-conditioning systems. Water humidifiers of any type should not be used.

4.103 Steam may be derived from the central steam supply provided that it does not contain any treatment carry-over, or generated locally either within or adjacent to the humidifier.

4.104 The introduction of steam should be by an appliance specially designed to discharge dry steam into the air-conditioning system without objectionable noise or carry-over of moisture.

4.105 During the design stage, consideration should be given to the proposed methods for the regular cleansing of the humidifier(s) and their components.

Selection

4.106 The number and length of steam-injection manifolds to be used is dependent on various factors such as duct cross-sectional area, air velocity, dry-bulb temperature and manifold design. Guidance from the manufacturer should be followed closely.

4.107 A mains steam humidifier can be noisy and will be difficult to control if it is operated at an excessive steam pressure. It should be sized for an operating pressure of approximately 1 bar. The pipework supplying it should be provided with a dirt pocket, pressure reducing valve and steam trap installed as close as practicable to the humidifier, so that the steam condition at entry is as dry as possible. A temperature switch on the condensate line (or equivalent design provision by the humidifier manufacturer) should be incorporated to prevent 'spitting' on start-up.

4.108 Most operational problems with mains steam humidifiers arise because of back-pressure in the condensate discharge line which will result in flooding into the duct. Unless the condensate from the device can be discharged and collected at atmospheric pressure, it should be discharged directly to drain.

4.109 A local steam generator, where used, must be fed with potable quality water. Additional water treatment to the standard set out above may be required. If the humidifier is unused for a period exceeding 48 hours, it must automatically drain its water content, including that contained in the supply pipework, right back to the running main and leave itself empty.

4.110 Some steam generators are of a type that requires regular cleaning and descaling. The design must allow for them to be installed such that they can be physically isolated from the air duct in order to prevent contamination of the supply by cleaning agents while this is taking place.

Location

4.111 Careful siting of the humidifier injection manifold is required to prevent the steam impinging onto the side(s) of the duct, condensing and generating excess moisture.

Control

4.112 Accurate humidity control can only be provided on single-zone systems, or multi-zone systems with zonal humidifiers. In the above systems, humidity sensors control the humidifier for low-level humidity control, and override the temperature controls to open the cooling coil valve for high-limit humidity control.

4.113 Multi-zone systems are more usually controlled by a minimum humidity sensor located in the supply duct(s) following the last heater-battery.

4.114 Overriding controls separate from the normal plant humidistat should be installed. Their purpose is to prevent excessive condensation in the conditioned space when starting up. A time delay should 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 should be installed to limit the output of the humidifier so that the saturation in the duct does not exceed 70%. This humidistat is to control the added moisture. It is not necessary to install a de-humidifier to reduce the humidity of the incoming air if it already exceeds 70%. The humidifier control system should ensure that the humidifier is switched off when the fan is not running.

4.115 On systems with two-speed operating, it is usual to isolate the humidifier upon selection of low speed. In addition, on system shutdown, low airflow or fan failure, the humidifier should be isolated.

Filtration

General requirements

4.116 The purpose of filtration is to reduce the level of airborne contamination in an air stream. It is generally carried out in stages.

4.117 Filters must be securely housed and sealed in well-fitting frames that minimise air by pass. Air by pass significantly reduces filter efficiency, the higher the filter grade the greater the effect. Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass. Mounting frames that withdraw so that the filter can be changed without having to reach into the unit are preferred.

4.118 Neither the filter media, nor any material used in the construction of the filters, should be capable of sustaining combustion. The filter media should be such that particles of it do not detach and become carried away by the airflow.

4.119 Filters need to be readily accessible for replacement so a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

4.120 All filters should be provided with a means of visually checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

4.121 A complete spare set of filters must be provided at handover.

Definition of filter terms

4.122 Particulate air filters are divided into four categories:

- general ventilation filters grades G1 to G4;
- fine filters grades F5 to F9;
- high efficiency particulate filters (HEPA) graded H10 to H14;
- ultra-low particulate air filters (ULPA) graded U15 to U17.

4.123 General filters are graded in terms of their ‘Synthetic dust weight ‘Arrestance’. This represents the percentage of a test dust captured by a filter. ‘Arrestance’ provides a good indication of a filter’s ability to remove the larger, heavier particles found in outdoor air. These are of a size to block finned batteries and large enough to settle out in the air distribution system.

BS EN 779 grade (Eurovent grade)	% Arrestance	Notes and typical healthcare application
G1 - (EU1)	< 65	Metal mesh grease filter
G2 - (EU2)	65 to < 80	Coarse primary filter
G3 - (EU3)	80 to < 90	Primary air intake; return air; energy recovery device protection
G4 - (EU4)	> 90	General purpose tempered air supply

Table 4: General Filters

4.124 Fine filters are graded in terms of their ‘Atmospheric dust spot Efficiency’. This is a measure of the filter’s ability to remove the very fine staining particles found in outdoor air. It will indicate how ‘visibly’ clean a filter will keep a ventilated space. The staining particles are approximately the same size as most

common bacteria so it is also a rough measure of the filter's ability to remove microorganisms.

BS EN 779 grade (Eurovent grade)	% Efficiency	Notes and typical healthcare applications
F5 - (EU5)	40 to 60	General purpose panel / bag filter
F6 - (EU6)	60 to < 80	Basic grade bag filter
F7 - (EU7)	80 to < 90	Medium grade bag or pleated paper Conventional operating theatre supply air
F8 - (EU8)	90 to < 95	High grade bag or pleated paper
F9 - (EU9)	> 95	Basic HEPA filter – Level 8 clean rooms

Table 5: Fine Filters

4.125 High efficiency filters (HEPA and ULPA) are graded in terms of their ability to capture their 'Most Penetrating Particle Size' (MPPS). High-efficiency filters self-select the particle that they are least able to trap, hence the MPPS. They are then tested against that size of particle. These filters are designed to provide very high-efficiency filtration of particles in the sub-micron size range.

BS EN 1822 grade (Eurovent grade)	% Efficiency @ MPPS	Notes and typical healthcare application
H10 - (EU10)	85	Ultra-clean theatre terminal
H11 - (EU11)	95	
H12 - (EU12)	99.5	
H13 - (EU13)	99.95	
H14 - (EU14)	99.995	Pharmacy aseptic suite Category 3 room extract
U15 – U17	-	Not generally used in healthcare

Table 6: High Efficiency (HEPA) Particulate Filters

Selection primary filters

4.126 All filters should be of the dry type. Panel filters are cheap and disposable with relatively low dust-holding capacity. They are generally used as pre-filters to eliminate large particles that would otherwise clog or cause damage to the fan and finned heating and cooling batteries. Stainless steel frames that hold disposable pre-cut filter pads are preferred.

4.127 General ventilation supply plant should incorporate primary air filters of grade G3, sized for a maximum face velocity of 2.0 m/s. Additional coarse pre-filters may be justified where the intake air is exceptionally polluted. They are sometimes fitted as a temporary measure when building work is being carried out in the vicinity of the air intake.

Secondary filters

4.128 Where a higher standard of filtration is required, secondary bag or pleated paper panel filters would be used. Rigid frame filters incorporating pleated

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paper elements are preferred over bag filters for critical care applications such as operating theatres.

4.129 In urban or other areas of high atmospheric pollution, a higher standard of filtration may be justified to reduce the level of staining to internal finishes.

Extract air filters

4.130 Extract filtration will generally only be required where heat-recovery devices are installed. There are a very limited number of specialised applications (microbiological safety cabinets and similar LEV systems) where contaminated air is required to be filtered prior to discharge to atmosphere. If it is safe for staff to work in a room without wearing respiratory protective equipment, it is safe to discharge the room air to atmosphere without filtration.

Return-air filters

4.131 They are used to reduce the load on HEPA filters in recirculating applications such as Ultra Clean operating suite ventilation canopies and pharmacy aseptic suites.

High-efficiency filters – HEPA and ULPA

4.132 HEPA filters are expensive so their use should be kept to a minimum. Applications requiring HEPA filters include the air supply to aseptic suites in manufacturing pharmacies, the discharges from microbiological safety cabinets and isolation facilities.

4.133 If used, HEPA filters should be of the replaceable panel type with leak-proof seals. They should be installed in a manner that permits on-site validation of the filter and its housing. This may 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. Alternatively a particle-counting method may be used.

4.134 HEPA filters are sometimes fitted in extract systems to capture hazardous substances or organisms. Design provision must be made for the subsequent safe handling of contaminated filters by maintenance staff. This may be achieved by:

- sealing the hazardous substance into the filter before it is removed;
- providing a system to fumigate the filter to kill any organisms;
- housing it in a ”safe change” unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.

4.135 In view of the costs and problems associated with placing HEPA filters in extracts, it is recommended that a full risk assessment be carried out at the design stage. This should include defining the true need for HEPA filters in an

extract; validation of its performance at installation; the method of safely changing a contaminated filter; and its subsequent disposal.

4.136 ULPA filters are very expensive and are designed to remove particles below a size that are either surgically or aerobiologically significant. There would have to be exceptional circumstances in order to justify their use in healthcare ventilation systems.

Activated carbon filters

4.137 Activated carbon filters are able to remove gases and vapours from an air stream and are graded according to the range of substances they can remove. They are not normally fitted in air-conditioning supply systems.

4.138 They are occasionally fitted retrospectively because the main air intake has been poorly sited and is drawing in traffic fumes. Where used they must be protected by a particulate air filter.

4.139 Activated carbon filters are more commonly used in specialised fume extraction systems when the location of the discharge means that dilution cannot be relied upon to disperse noxious fumes.

Location

4.140 The primary filter should be positioned on the inlet side of the supply fan, downstream of the frost coil. The secondary filter, when fitted, should be on the positive-pressure side of the fan. This will prevent air being drawn into the system after the filter and capture any particles shed by items of equipment within the AHU.

4.141 The filter installation must be arranged to provide easy access to filter media for cleaning, removal or replacement, with side or front withdrawal as required.

Control

4.142 Differential-pressure transducers should be provided to monitor and alarm remotely on excessive filter pressure drop. In critical areas dirty-filter indication lights should be provided at the point-of-use.

Energy-recovery

General requirements

4.143 Energy recovery will normally be fitted to all healthcare ventilation systems. It may be omitted only where it would clearly be uneconomic. Where the economic case is marginal, space should be allowed for the retrofitting of an energy recovery system.

4.144 For systems in healthcare premises, a plate heat exchanger or ‘run-around coil’ system is suitable. Thermal wheels may be used providing they are fitted with a

purge sector. The small amounts of air leakage across those devices are not considered significant. Other systems such as heat pumps or heat pipes are

also suitable. Selection should be based on relative locations of the supply and extract units, ease of maintenance and practicality. Cleaning access will be required to both sides of any energy-recovery device.

4.145 The following are the minimum energy transfer efficiencies required for devices handling equal air volumes:

- run-around coil – 45%;
- plate heat exchanger – 50%;
- thermal wheel – 65%;
- any other energy-recovery device – 50%.

4.146 If a plate heat exchanger is chosen, the plates should be constructed of metal. Plastic should not be used for internal bypass dampers and drive gears.

4.147 Whichever energy-recovery device is chosen the extract side will need to be protected by a G3 filter and provided with a drainage system as described in Paragraphs 4.20 - 4.25, to remove condensate.

Location

4.148 Energy-recovery devices should be located downstream of the frost battery and pre-filter, prior to the cooling coil or main heater battery on the supply side.

Control

4.149 It is essential to consider the control of both the energy recovery device and the frost battery when assessing the economics of recovery, as all energy provided by the frost battery will directly reduce the heat exchange of the recovery device. To this end, the off-coil setting of the frost coil should be the minimum possible to protect the primary filter (for example +2°C).

4.150 The energy-recovery device should be controlled in sequence with the main heater battery, and should incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the required plant set point.

4.151 In instances where the plant is cooling the air, it may be possible to remove heat from the supply air at high ambient conditions, under the dictates of enthalpy sensors in the intake and extract ducts.

Attenuation

General requirements

4.152 Noise will be generated in an air distribution system by the fan, plant items and airflow. The ductwork is a very effective transmitter of this noise hence there is generally a need to limit the noise transmission to meet the requirements of the building. This normally involves the provision of sound attenuation treatment as part of the overall ductwork system design.

4.153 A thorough assessment of the design should be made to assess the noise impact. This should take into account the following primary factors:

- fan- and plant-noise generation;
- air-flow generated noise in ductwork fittings and dampers;
- noise generated at grilles, diffusers and other terminals;
- noise break-in and break-out of ductwork;
- cross-talk and similar interference;
- the noise limitations for the building and surrounding areas;
- external noise generation.

4.154 A method of assessment of these factors and the sound attenuation requirements of ductwork systems is given in CIBSE Guide B.

4.155 The fan is usually the main source of system noise. The sound power that it generates varies as the square of the fan pressure, and thus to limit the fan noise level the system resistance should be kept as low as economically possible. As a general rule the selected fan should operate close to its point of maximum efficiency to minimise its noise generation. Where there is disturbance to the airflow at the fan inlet, the manufacturer's stated fan noise levels should be increased by up to 5 dB(A). More precise guidance on this aspect may be available from the manufacturers.

4.156 Fans radiate noise through both the inlet and outlet connections and it may be necessary to provide attenuation to limit the noise from both of these connections. It is always preferable and more economic to control noise and vibration at source, or as close to source as possible. It should be noted that attenuators offer a resistance to airflow. The resistance must be included in the fan and ductwork calculations.

4.157 Provided care is taken in the design and construction of low-pressure systems to avoid significant noise generation in the ductwork, attenuation should only be needed to absorb fan noise.

4.158 Noise breakout from all equipment housed in the plantroom must be taken into consideration if control is to be satisfactory. Any ductwork within the plantroom after the silencer should be acoustically insulated to prevent noise break-in or the silencer relocated at the point of entry or exit of ductwork to and from the plant room.

4.159 There is no complete means of control over external noise generation from such as road traffic, aircraft, factory and community noise. Consideration must be given to this at the design and planning stage.

Acceptable types and location

4.160 The noise levels produced by ventilation and other plant should be reduced by either lining the inside of the duct with sound-absorbing material or fitting bespoke attenuator units.

4.161 In supply systems, sound-absorbing material should not be applied to the inside surface of a duct system downstream of the final filter, owing to the risk of mechanical damage and the subsequent dispersal of the media into the ventilation system.

4.162 In supply and extract systems, sound-absorbing material must not be applied to the inside of a duct within 1 metre of a fire damper. The material should be non-particle-shedding and fire-resistant (further guidance can be found in SHTM Firecode suite of documents). Where sound-absorbing material is applied in a section of duct that will be routinely exposed during maintenance activities it should be protected from mechanical damage.

4.163 Bespoke attenuator units with a sound-absorbing infill suitable for the quality of air being handled and protected by a perforated sheet metal casing are the preferred option for critical systems. Absorption of moisture, dirt and corrosive substances into the ‘in-fill’ and the release of fibrous particles into the airstream should be prevented by the use of a membrane. The membrane material should have a declared service life of at least 25 years. If these conditions can be met then the attenuator may be located in the supply ductwork downstream of the final filter. When so located, cleaning access should be provided at both ends of the attenuator unit.

5. Air distribution system

Air distribution arrangements

Ductwork distribution systems

5.1 Ductwork systems for ventilating and air-conditioning applications are referred to by their velocity or pressure category, that is, as low, medium or high velocity (or pressure) systems. Heating & Ventilating Contractors Association (HVCA) limits are up to 10 m/s or 1,000 Pa; 20 m/s or 1,750 Pa: and 40 m/s or 3,250 Pa in the case of conventional low, medium and high pressure systems respectively. High-pressure systems are disappearing because of the constraints of the Building Regulations but existing systems may sometimes need to be altered or extended.

5.2 For normal applications in healthcare buildings, low velocity systems are recommended. The use of higher velocities than those recommended is not likely to be economical. Future trends are likely to be towards even lower optimum duct velocities; however, velocities below 2 m/s are unlikely to be justified.

5.3 The site will often dictate the main routing of ductwork systems, but in general, the design should seek to make the layout as symmetrical as possible; that is, the pressure loss in each branch should be as nearly equal as possible. This will aid regulation and may reduce the number and variety of duct fittings that are needed.

5.4 Main distribution ductwork should not be routed above sleeping areas. Where there is no alternative route, additional acoustic insulation will be required.

5.5 Where auxiliary cooling units, fans, filters or trimming devices are installed in the distribution system, they must be independently supported and fitted with a suitable drainage system where appropriate. If they are a source of vibration they should be linked to the distribution ductwork via flexible connections.

5.6 The fan of a Local Exhaust Ventilation (LEV) system provided under the COSHH Regulations should be located outside of the building so that all of the ductwork within the building is under negative pressure. Where the fan has to be within the building it should be located as close as practicable to the outside with an absolute minimum run of discharge ductwork within the building. The discharge ductwork within the building will be under positive pressure so it must not be penetrated by test holes or inspection hatches.

Ductwork materials and construction

5.7 The choice of duct material should take account of the nature of the air or gas being conveyed and the environment in which the duct will be placed.

5.8 Galvanised-sheet-steel is generally suitable and most economical for normal ventilating and air-conditioning applications. Its inherent mechanical strength renders it resistant to casual damage both during the construction phase and throughout its service life when mechanical and electrical services around it are altered. It also readily withstands the impacts sustained when rotary equipment is used to for internal cleaning.

5.9 In instances where moisture levels and/or corrosive elements in the air being conveyed are very high, aluminium, stainless steel, PVC or GRP (glass-reinforced plastic) ducts should be used. Stainless or black steel are the only suitable materials for high-temperature ductwork.

5.10 In inherently wet areas, such as the base of fresh air inlet ducts and some extract systems, the ductwork may require draining to prevent a build-up of standing water. The layout of the drains should be as specified in Paragraphs 4.20 - 4.25.

5.11 Where builderwork plenum chambers or ducts are used, these may be constructed of various materials. However all such ducts must be rendered and sealed to prevent dust shedding. A greater allowance may need to be made for leakage.

5.12 Galvanised, black and stainless steel ductwork should be manufactured and installed to the current HVCA specification for sheet metal ductwork DW144, but excluding the use of bolt-through supports.

5.13 GRP and PVC ductwork should be manufactured and installed to the current HVCA specification for plastic ductwork DW154.

5.14 Where phenolic-board ductwork is considered, care should be taken to ensure that it is fabricated to a quality standard and installed strictly in accordance with the manufacturers' instructions. Its pressure rating and degree of support should be suitable for the application and ducts should be fitted with mechanical protection where required. Designers should be fully conversant with installation techniques and Installers should be experienced having received training in the techniques required and certified to this effect by the manufacturers. Due consideration should be given to the impact on ductwork pressures created by the closing of dampers. Phenolic-board ducting should not be installed in plant rooms or any other areas where it could be vulnerable to impact damage. Internal cleaning using mechanical (rotary) means is also liable to cause damage to the integrity of surfaces.

5.15 Flexible ductwork is unsuitable for air distribution in healthcare applications. It should only be used to make the final connection to a terminal (See Paragraphs 5.54 and 5.55).

5.16 The inside of the ductwork should be free from structural projections and as smooth as possible. Flanged, gasketed joints are preferred.

Fire aspects, damper types and locations

5.17 It is essential that all relevant fire aspects of ducting systems are agreed with the fire officer before the design is finalised.

5.18 Ductwork must be fire-stopped where it penetrates fire compartment walls, floors and enclosures, cavity barriers and sub-compartment walls or enclosures, and provided with weatherproof collars where roofs or external walls are penetrated.

5.19 Fire/smoke dampers shall be provided at the locations required by SHTM Firecode. The fire-damper mounting frame must be securely attached to the building fabric. Where a fire-damper is not mounted directly in a fire compartment wall, it must be correctly supported and the ductwork between it and the firewall must posses the same fire rating as the firewall that it penetrates. The fire-rated portion of ductwork must not be penetrated by test holes or inspection hatches. All fire/smoke dampers shall be capable of remote re-setting via the Building and Energy Management System (BEMS) or equivalent, after periodic testing procedures.

5.20 An access hatch shall be provided adjacent to each fire damper so that its correct operation can be directly observed.

5.21 Smoke-diverting dampers must be provided on recirculation air systems to divert automatically any smoke-contaminated return air to the outside of the building in the event of a fire; and arranged so that the normally open smoke-diverting damper on the return-air branch to the input unit closes and all the return air is exhausted through the extract fan. Guidance is available in SHTM 81 and BS5588: Part 9.

Duct sections

5.22 Ducting is generally available in rectangular, circular and flat oval sections, although other sections may be made for special situations.

5.23 Rectangular ducting is most common on low-pressure systems, for the following reasons:

- it can readily be adapted to fit into the space available;
- fittings are cheaper than those for circular or flat oval ductwork;
- it can readily be joined to such component items as heating and cooling coils, and filters.

5.24 When sizing ductwork, the designer should take into account:

- both installation and operating costs;
- space limitations imposed by the structure and other services;
- operating noise levels;

- requirements of regulation at the commissioning stage.

5.25 For overall economy and performance, the aspect ratio should be close to 1:1, since high aspect ratios increase the pressure loss, heat gains or losses and overall cost (for example, changing the aspect ratio from 1:1 to 1:4 can typically increase the installed cost of the ductwork by 40% and add 25% to the heat gains or losses).

5.26 Rectangular ducting should not be the first choice for high pressure systems, and should be avoided in systems operating at high negative pressures, because the strengthening of the flat sides and the sealing requirements necessary to make rectangular ducts suitable for these high pressures are costly.

5.27 Circular ducting is preferable for high-pressure systems, and for systems operating at high negative pressures. In the case of the latter, additional stiffening rings may be necessary. Machine-formed spirally-wound ducting and a standard range of pressed and fabricated fittings can sometimes make circular ducting more economical, particularly in low pressure systems having a relatively low proportion of fittings.

5.28 Flat oval ducting provides an alternative to circular ducting, principally where there is a limitation on one of the dimensions in the space available for the duct run.

5.29 Other sections may be used, such as triangular sections to pass through roof trusses. Such sections present difficulties in the provision of fittings, and connections to standard plant items, and are likely to be more expensive than traditional sections.

Standard ductwork fittings

5.30 All fittings should conform to current HVCA specification DW144. Wherever possible, long radius bends, large radius main branches, not more than 45° angle sub-branches and long-taper transformations should be used.

5.31 Fittings should be arranged with vanes in sub-branches connected directly to grilles and diffusers, and turning vanes in square bends (when used). When vanes are used, additional cleaning access will be required.

5.32 The number of duct fittings should be kept to a minimum and there should be a conscious attempt to achieve some standardisation of types and sizes. Increasing the number and variety of fittings in a system can markedly raise its overall cost.

5.33 Bad design in relation to air flow can lead to vibration of flat duct surfaces, increases duct-generated noise and pressure loss, unpredictable behaviour in branch fittings and terminals, and adverse effects on the performance of installed plant items (such as trimmer batteries).

Branches

5.34 There are many designs of branches and junctions in use. The important features are that the flow should be divided (or combined) with the minimum interference and disturbance. Changes in duct sizes should not be made at the branch but a short distance downstream (or upstream). A good dividing branch design cannot be effective if the flow entering the branch is not uniform across the section.

Changes of section

5.35 The expansion of a duct section should be formed with sides having a total included angle of no more than 30°, and preferably less than 20°. If the angle of expansion is greater, the flow is not likely to remain attached to the walls of the duct and large eddies will be formed with flow reversal at the walls. This leads not only to a high-pressure loss, but also to non-uniform velocity pattern at the outlet. Where there is insufficient space for a gentle expansion and a greater angle is necessary, internal splitters should be used.

5.36 A contraction in a duct section is less critical, but the total included angle of the taper should not exceed 40° (or 20° where the contraction is made on one side of the duct only)

5.37 The most economical way to change the section of a rectangular duct is to restrict the change of duct size to one side only. If the calculated reduction or increase to the side dimension is 50mm or less, it is usually not economical to change the size at the position. The minimum size of a rectangular duct should usually be 150mm x 100mm.

Other fittings

5.38 As a general rule, fittings should avoid abrupt changes in direction and also sharp edges that cause the flow to separate and form eddies, thus limiting pressure loss and causing noise generation. If the fitting leads to the flow preferentially attaching to one side of the outlet, then a significant length of straight downstream duct is necessary before the next branch or fitting; this length should be greater than five equivalent diameters.

Thermal insulation

5.39 Thermal insulation is applied to ductwork to reduce heat exchange, and to prevent condensation.

5.40 In a duct system, the air temperature changes can be significant, especially when passing through untreated space, and these have the effect of reducing the heating or cooling capacity of the air and of increasing the energy input to the system. The heat transmission to and from the surrounding space can be reduced by effective insulation of the ducts. Extract ductwork conveying air from which heat recovery will be derived should be thermally insulated to the same standard as with associated supply ventilation ductwork.

5.41 Condensation can arise in ductwork systems conveying cooled air and, apart from creating conditions conducive to corrosion of ductwork, condensation affects the heat and vapour-resisting properties of insulating materials themselves which may induce further condensation.

5.42 In normal circumstances, the insulation thickness for heat resistance is sufficient to prevent surface condensation, but in extreme conditions the insulation thickness for vapour resistance may be greater than that for heat resistance. When cold ducts pass through areas of high dew-point, carefully selected vapour barriers should be applied externally to the insulation.

Noise generation within the ductwork

5.43 Noise is generated in ductwork at sharp edges, by tie rods, damper blades, duct obstructions and sharp bends etc. This air-flow-generated noise becomes an important factor if it is about the same or greater level than the upstream noise level. (Air-flow-generated noise is often referred to as “regenerated noise”).

5.44 The noise level generated by airflow in ductwork is very sensitive to the velocity. The sound power of this noise is approximately proportional to the sixth power of the velocity; that is, a doubling of the duct velocity will increase the sound power by a factor of 64. The duct velocities should therefore be kept as low as possible. In general, duct fittings that have lower pressure loss factors in similar flow conditions will generate less noise.

5.45 Ductwork serving quiet areas should not be routed through noisy areas where noise break-in can occur and increase the noise level in the ductwork.

5.46 Grille, register and louvre noise should be kept to the minimum by selecting types having low noise-producing characteristics, without high tonal noise, and should be fitted with acoustically treated external inlet and outlet louvres.

5.47 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where individual room confidentiality is required. They will normally be of the ‘through-the-ceiling, ‘up-and-over’ type and may include a fire damper if required.

Volume control damper locations

5.48 Manually operated balancing dampers are needed generally:

- in the main duct downstream of the fan;
- in branches of zone ducts;
- in sub-branch ducts serving four or more terminals;
- at terminals not covered by the previous item.

5.49 Dampers integral with terminals should only be used for final trimming of air volumes, otherwise noise and air distribution problems may ensue.

5.50 Dampers in rectangular ducts should be single-bladed when the longer side is up to 450mm but be of the opposed-blade multi-leaf type above this size. In circular ducts, iris-type dampers are recommended. Dampers must be accessible, incorporate a position indicator and means of locking in the commissioned position. Dampers should be located as far away as possible from adjacent branches or plant items.

Cleaning and access door locations

5.51 Cleaning and access doors are required to facilitate access to plant items and ductwork components for inspection, maintenance, cleaning and replacement, and must be of sufficient size to permit safe access for the required functions. Consideration should also be given to the number of doors to be provided. Older installations may be deficient in the provision of access doors and consideration will be necessary to have these incorporated in the course of any refurbishment in the accommodation served.

5.52 Recommended locations for access doors are given in the current HVCA specification DW144 and are generally provided to give access to:

- every regulating damper;
- every fire and motorised damper;
- filter (to facilitate filter withdrawal);
- both sides of cooling/heating coils;
- humidifiers;
- fans; and
- motors and impellers.

5.53 Care should be taken when siting access doors to ensure that no other services to be installed will prevent reasonable access.

Flexible ducting

5.54 Flexible ductwork may be used for final connections to grilles and diffusers provided it is constructed to meet the fire precautions recommended in BS8313. It must not pass through fire compartment walls, floors or enclosures of sub-compartment walls or enclosures, or through cavity barriers.

5.55 Flexible ducting will cause a significant frictional loss and may be difficult to clean and should never be used in lieu of a bend. Where installed it should take the most direct route and be as short as possible, never exceeding 1 metre in length.

Diffuser and grille selection and sizing

5.56 The effectiveness of all ventilation and air-conditioning systems depends on the methods by which air is introduced to, and vitiated air is removed from, the

space. The usual results of poor air-terminal selection and/or positioning are: draughts, stagnation, poor air quality, large temperature gradients and excessive noise.

5.57 Air can be supplied to a space in a number of ways, although any device can be broadly placed into one of two categories: that producing a diffused supply, or that producing a perpendicular jet. Diffusers may be radial or linear, and normally utilise the Coanda effect (that is, adhesion of the air stream to an adjacent surface), to reduce the risk of excessive room-air movement. A perpendicular jet is formed by discharging air through grilles, louvres or nozzles, which are generally adjustable.

5.58 Air-flow patterns produced by both types of terminal are dependent to a large extent on the presence of the Coanda effect.

5.59 Supply air terminals can be incorporated into any room surface, for example, floors, walls (high or low level), desktop etc.

5.60 As they operate on the jet principle, the use of sidewall and linear grilles is restricted to areas where air change rates are low, that is, less than 10 per hour. Perforated rectangular diffusers can provide acceptable conditions within the occupied zone at up to 15 air changes per hour. In areas where a higher air change rate is required, square or circular ceiling mounted diffusers should be used.

5.61 The performance of supply air terminal devices is provided, based on three criteria: throw, spread and drop.

- **throw** is defined as perpendicular or parallel distance from the terminal to the point at which the air velocity is 0.5 m/s isovel;
- **spread** is defined as the width of the 0.5 m/s isovel; and
- **drop** is defined as the vertical distance from the centre line of the terminal to the bottom edge of the 0.25 m/s isovel.

5.62 It is necessary to consider each of these parameters in both summer and winter conditions to ensure satisfactory operation of the air-terminal device, as warm jets behave very differently from cold jets.

5.63 A warm jet tends to rise until it attaches itself to a horizontal surface, while a cold jet falls. Care must be taken to ensure that this does not lead to unacceptable temperature gradients in winter or excessive air velocities in the occupied zone in summer.

5.64 In order to ensure satisfactory air movement within a space, it is necessary to consider interaction between air movement from adjacent terminals, and ceiling mounted fixtures (light fittings etc), as well as interaction between air movement and room surfaces.

5.65 If the supply and extract terminals are too close, short-circuiting may occur, while if they are too far apart, stagnant zones may be formed. Where two

opposing air streams meet, the individual velocities must not be greater than 0.25 m/s.

5.66 Supply and extract grilles and diffusers should be fitted with opposed-blade dampers for fine balancing purposes.

5.67 Further guidance on the selection of grilles and diffusers is given in the CIBSE Guide B.

5.68 In operating theatres, the supply terminals must be able to produce a down-flow movement of air in the operating zone 1 metre above floor level. Ceiling mounted diffusers with fixed directional vanes that provide a downward turbulent airflow are the preferred option. Plenum boxes fitted with perforated screens to produce a parallel downward flow are also acceptable. Nozzles or jets of any type are not acceptable. Sidewall-mounted linear diffusers that utilise the Coanda effect to send air across the ceiling and 'drop' it into the operating zone are also not suitable. However linear ceiling mounted diffusers that provide a direct downward airflow around the operating zone may be used.

Transfer grille - size and location

5.69 Air-transfer grilles in walls, partitions or doors form an integral part of the building's air distribution system. Modern doorsets have very low leakage rates so cannot be relied upon to permit even quite small airflows. Failure to make adequate provision for air to move from room to room will result in excessive pressure differentials and 'door whistle'.

5.70 Transfer grilles are required in locations where there is a significant imbalance between the supply and extract rates in a room. They will relieve any pressure differentials that may affect the operation of the spaces and/or the ventilation system and permit airflow in a known direction. However, transfer grilles are vulnerable to damage and, in many instances, as long as the equivalent free area is provided, they can be substituted with undercut door.

5.71 Care needs to be taken to ensure that the positioning of transfer grilles does not interfere with the fire or smoke integrity of the building. In general, the air-transfer grilles should not be installed within fire-resisting boundaries, although if this is unavoidable, they should be fitted with fire- or smoke-dampers.

5.72 Where installed, transfer grilles should be of the non-vision type, sized for a maximum face velocity of 1.5 m/s.

5.73 In photographic dark rooms, lightproof transfer grilles will be required.

5.74 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where individual room confidentiality is required. (See also Paragraphs 5.43 - 5.47).

Pressure stabilisers - size and location

5.75 Pressure stabilisers are required in lieu of air-transfer grilles in areas where it is necessary to maintain pressure differentials between adjacent rooms to prevent reversal of airflows for example, in operating suites, isolation facilities and clean rooms. (See also Paragraphs 7.24 - 7.28).

5.76 Fire precautions for pressure stabilisers are the same as for transfer grilles. For sizing criteria, refer to Paragraph 7.23

5.77 Pressure stabilisers should be of the balanced-blade type, with the facility to make fine adjustment of the pressure setting. They should be silent in operation and give a seal as tight as practicable when closed. The materials of construction and method of assembly should allow for cleaning and disinfection.

5.78 Pressure stabilisers should be installed in a visible location so that their operation can be readily observed.

5.79 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where confidentiality is required. In these cases, the pressure stabiliser and cross-talk attenuator should be mounted in a short length of ductwork within the ceiling void.

5.80 Pressure stabilisers may need to be fitted with a stand-off baffle on their discharge side to prevent a sight line in situations where a laser will be used. Baffles may also be required to preserve privacy or prevent discharge air causing draughts or disturbing the air distribution pattern in the adjoining room. They are also useful in low-level locations to prevent the airflow path being obstructed by portable equipment.

6. Automatic controls

6.1 Various options for control of single and multi-zone air-conditioning systems are given in CIBSE Guide B.

General requirements

6.2 The basic requirements for an automatic control system are as follows:

- facilities to start, set-back and stop the plant;
- facilities to control the volumetric air-flow;
- facilities to control the system or room pressure;
- temperature control and indication;
- humidity control and indication;
- devices to monitor and indicate the plant's operating state;
- alarms to indicate plant failure, low air-flow, and filter state.

The control functions actually provided will depend on the purpose of the ventilation system.

6.3 There will also be a need to determine the control strategy in the event of a fire either within the zone being served or within an adjoining zone.

6.4 The designer should consider whether it is necessary for the supply and extract fans to be interlocked, either so that the supply fan will not operate unless air-flow is established within the extract system, or vice-versa depending on the required pressures within the rooms being served.

6.5 The sequence switching of units in order to prevent transient reverse airflows will be particularly important in laboratory and pharmacy areas that also contain fume cupboards, safety cabinets and other LEV systems.

6.6 Alarms should be provided to show 'filter fault' and 'low air-flow'. The "filter fault" alarm should be initiated by a predetermined increase of pressure differentials across the filter. The 'low air-flow' alarm should be initiated when the supply air quantity falls to 80% of the design value.

Objectives of control system

6.7 The primary objective of ventilation plant control system is to maintain the space served within the required environmental control limits, at the appropriate times, regardless of external conditions or internal loads and with the minimum energy consumption.

6.8 Often, it is not possible to predict accurately building load variation at the design stage, and thus optimum set points cannot be assessed. Information provided by monitoring the operation of the plant via a Building and Energy Management System (BEMS) will enable optimum set points to be established and energy consumption reduced. Control of most systems will be via a BEMS. This will enable the operating conditions and control tolerances to be set and monitored. The BEMS may also be set to log the actual energy consumed by the system together with that recovered by the energy-recovery device. This will provide a useful check on overall operating efficiency and provide evidence that energy targets are being achieved.

6.9 BEMS incorporating self-adaptive control algorithms that automatically adjust the set-point to the suit the usage and load are preferred. The provision of movement sensors within the controlled space in order to determine the actual occupancy will facilitate this process.

6.10 The failure of specialised ventilation systems can have grave consequences for the delivery of healthcare. Control systems should therefore be simple, robust and reliable.

6.11 Computer-software-driven control systems are becoming the norm in building services. However, it should be remembered that healthcare ventilation systems need to be available to operate outside of normal working periods when software support is not available. Should the software fail, it will be left to site staff, who may have little knowledge of the control algorithms to restart the ventilation system. It is therefore essential to ensure that a simple means of re-starting critical systems in the event of a software failure is provided (see also Paragraphs 4.62 - 4.63)

Location of controls

6.12 Whether within the plant, duct or room, sensors should be located to provide accurate measurement of the condition of the air being monitored.

6.13 Sensors and control items such as control valves should be located close to the element being sensed or plant item being controlled, in order to minimise time lags within the system which may create over-shoot of conditions beyond the design envelope and result in additional energy consumption.

6.14 There are practical advantages in locating all control valves for an air-handling unit in a bank (at a convenient height) at one end of the unit. (This will not normally result in an undue additional control lag.)

6.15 Some applications require intermittent mechanical ventilation, frequently at a high air-change rate, (for example, in bathrooms and treatment rooms.) Local controls to facilitate this mode of operation should be placed in a prominent position to encourage economical use.

6.16 Local controls that enable the user to select more than one mode of operation should be clearly labelled to identify the particular mode selected. Where the system allows different room pressures to be selected then a direct-reading

pressure gauge should be fitted within the eye line of the users to provide an independent confirmation of the resultant mode of operation. A clear description of the selectable modes of operation should be mounted adjacent to the control switch.

Fire aspects

6.17 A fire control panel should be mounted at the entrance of the area that the ventilation serves. The panel should have restricted access for the fire officer and include independent on/off controls and indication of the supply and extract systems.

6.18 In certain critical care departments it is preferable to maintain the supply ventilation in case of a fire within the area. For example, in an operating department, while undergoing surgery, the patient cannot always be easily moved without significant risk. In the event of a fire in a staff or support area of the department, or adjoining zone, 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. This will allow time for the patient to be stabilised so that he/she can be safely evacuated if necessary. A similar situation occurs for patients in ITU and other critical care units. In all of these cases the ventilation to the critical area should continue to operate unless the AHU starts to draw in smoke. For these departments, a notice should be affixed to the fire control panel drawing attention for the need to liaise with departmental staff before switching off fan units.

6.19 All supply AHUs should 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, it should cause the supply air fire damper to close and shut down the AHU.

Time switching

6.20 Facilities to start, set-back and stop the plant should be provided in the plantroom. Remote start and set-back control and indication, if required, should be provided at a manned staff location, for example, at the reception or staff base or, in theatres, within the Surgeon's Panel.

6.21 Many ventilation systems may be completely shut down when the area served is not in active use. Alternatively, where there is a need to maintain a background condition, the ventilation output can be reduced by "setting back" the system. This will significantly reduce energy consumption and extend the life of filters and other system components.

Start-up control

6.22 The plant's start control should contain a control logic that will start the plant in the sequence set out in the following algorithms, Figures 2 - 5

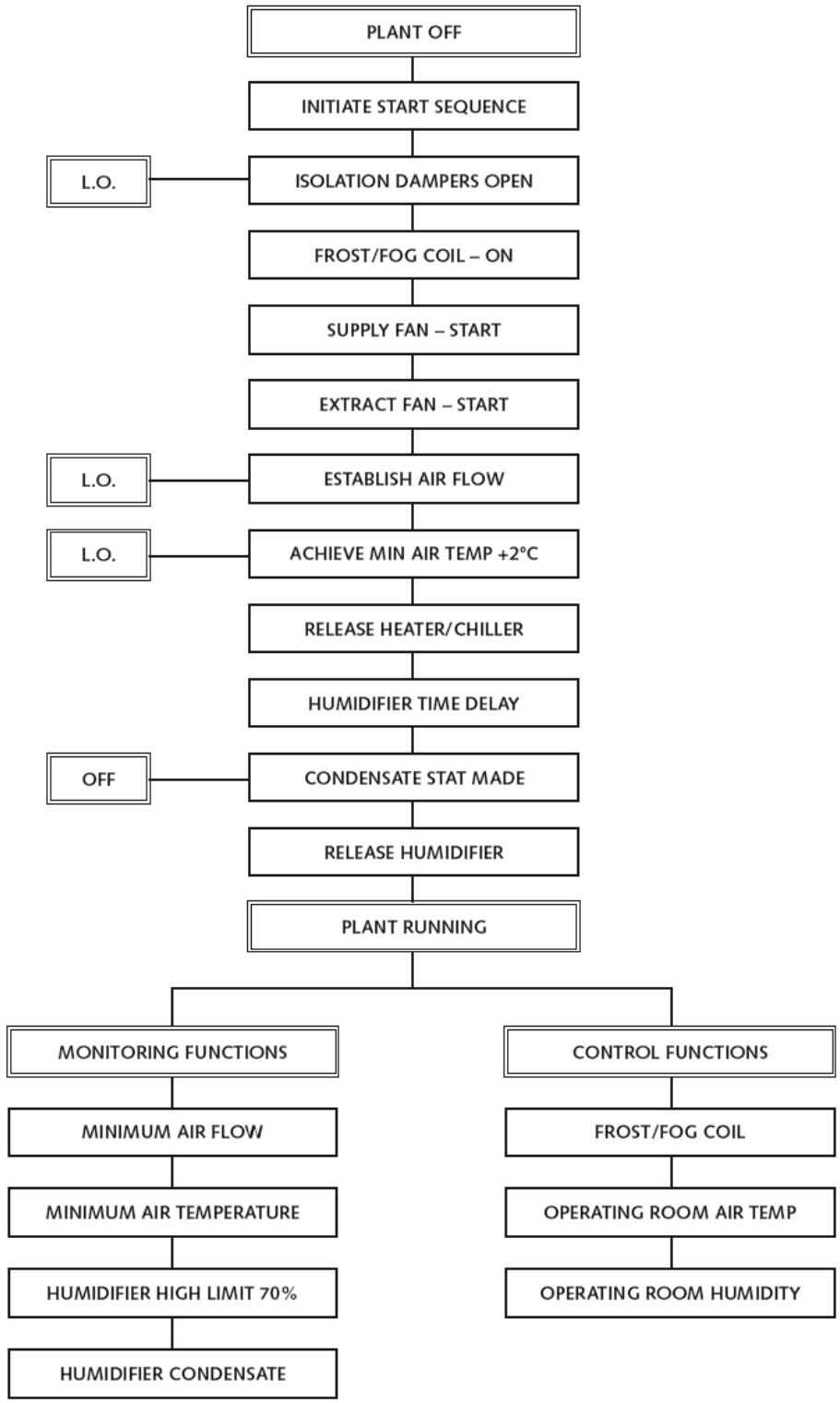

Figure 2: Typical plant control algorithm – normal start-up sequence

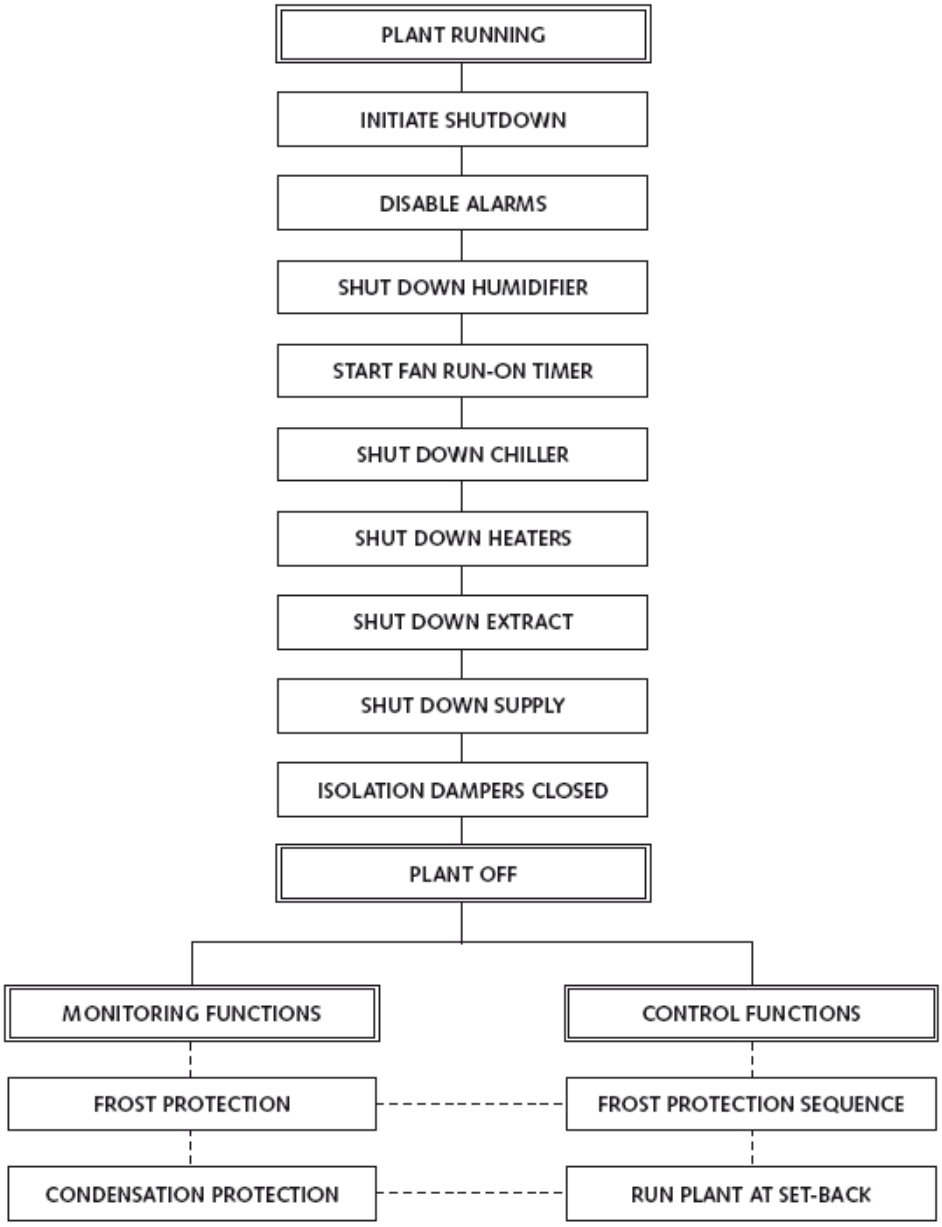

Figure 3: Plant control algorithm – normal shutdown sequence

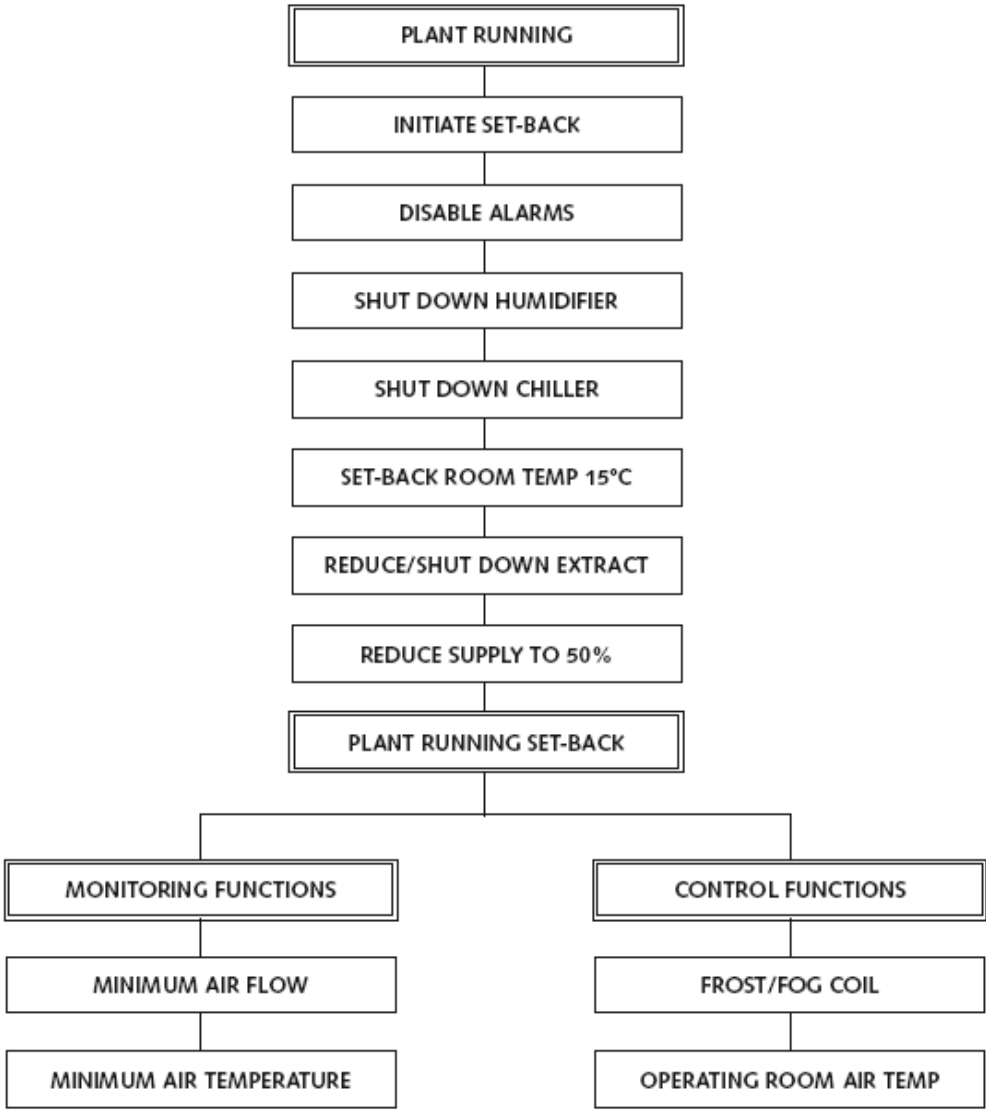

Figure 4: Plant control algorithm – set back sequence

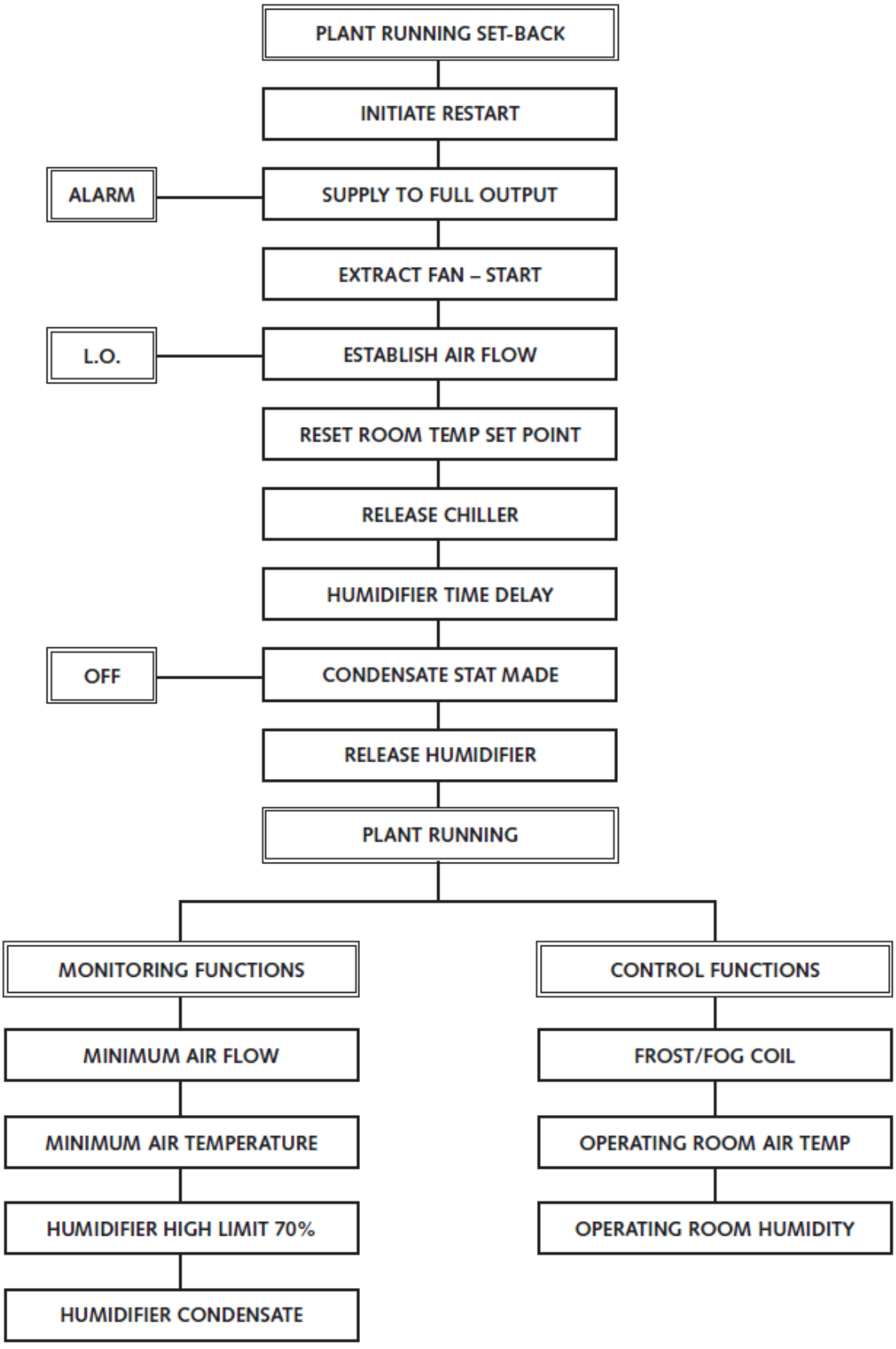

Figure 5: Plant control algorithm – restart from set-back

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Set-back control

6.23 Where variable speed controls are installed, the setback facility for each plant should depress the control temperature to around 15°C; exclude any humidification and cooling from the system; and reduce the supply and extract air volumes to around 50%. The extract fan can also be turned off as long as the desired direction of air movement from clean to less clean will be maintained (See also Figures 2 - 5).

Use control

6.24 The installation of movement detectors allows for “use control” of ventilation systems. A simple control logic that reduces the system to a “set-back” condition if there has been no movement detected in the space for, say, 30 minutes and that switches the system “off” if no movement is detected for one hour is recommended for many applications, including operating suites.

6.25 A variation on this can be provided by linking ventilation controls to lighting. For example, in an operating theatre, the system may be off outside of working hours, could run at set-back when the general lighting was switched on and increase to full speed when the operating lamp is switched on. As with movement detection, a 30-minute run-on should be provided at each stage when the lights are turned off.

6.26 Either of the above control strategies may be refined by linking to the BEMS to provide a control logic related to normal working hours and associated ‘real-time’ movement within the zone being controlled. This should result in significant energy savings.

Environmental control

Temperature control methods and application

General

6.27 All control valves must fail safe, that is, close in the event of power or air-flow failure, with the exception of the fog/frost battery control valve, which should open upon power or airflow failure.

6.28 Control valves should be located in an accessible position. Isolation valves should be provided to enable the control valve to be removed for service without the need to drain-down the system.

6.29 Care should be taken to ensure that the installation of control valves and their associated pipework do not obstruct access to the AHU inspection doors and hatches.

Room temperature control

6.30 The limits for room temperature set point are generally between 16°C and 25°C depending on the particular application, and in some specialised instances (for example, operating departments) are adjustable within a predetermined range by the user.

6.31 The selection of temperature set point for each room or zone may be by a control facility in the room / zone, or remotely at the control panel or BEMS. Where the control device is mounted within the room / zone and adjustable by the user, it should be marked either 'raise' and 'lower' or '+' and '-'. It should control within a specified temperature range to suit the user requirement with a control tolerance of ±1K. All other control set-points should be selectable either on the control panel or at the BEMS interface.

6.32 Where local control is provided, an indication of temperature will be required locally, or at a staff base (if appropriate), using an analogue or digital indicator. The indicator should be large enough to be read from the normal working position (for example, at the operating table in a theatre). This may be mounted in a supervisory or, 'surgeon's' control panel, with the signal repeated on the main system control panel or BEMS. It is important that this indicator displays the actual measured temperature and not the selected temperature.

6.33 Where the supply and extraction systems are designed for ventilation only and there is a wet heating system to provide background heating, care must be taken to avoid one system trying to heat the space while the other system is trying to cool the area.

Frost battery control

6.34 Steam-supplied frost batteries must be operated as on/off devices with their sensor mounted upstream of the battery. This will give 'open loop' control. A set point of +1°C is recommended.

6.35 Low pressure hot water (LPHW)-supplied frost batteries should be controlled using the proportional mode. Their sensor should be located downstream of the battery to give 'closed loop' control. A set point of between 2°C and 5°C is recommended.

6.36 If the temperature downstream of the frost battery, as sensed by a serpentine thermostat, falls below the required set point over any part of the coil, the plant must automatically shut down in order to prevent damage to the other batteries. The serpentine thermostat must not be in direct contact with the coil.

Off-plant control

6.37 The control logic must prevent the chiller and pre-heater being on at the same time.

Humidity control methods and application

6.38 In order to prevent excessive condensation when starting up from a total plant shut-down, a time delay should be incorporated into the control system such that the humidifier does not start until 30 minutes after the ventilation plant starts up.

6.39 Irrespective of the method of control, a high-limit humidistat should be installed to ensure that when the humidifier operates, the condition of the air in the duct does not exceed 70% saturated, particularly during plant start-up.

6.40 With certain types of steam humidifiers, it may be necessary to install a thermostat in the condensate line from the humidifier's steam supply, to ensure that the steam at the control valve is as dry as possible before it is injected into the air supply.

6.41 The humidifier and cooling-coil control must be interlocked so that they cannot be on at the same time.

6.42 The humidifier control system should ensure that it is switched off with the fan. It is preferable to design the control system so that the humidifier is isolated for an adequate time before the fan is turned off so as to purge humid air from the system.

6.43 All control valves must fail safe (that is, close in the event of power failure) and the humidifier must be interlocked with the low airflow switch.

Multi-zone control methods and application.

6.44 Close control of all air-conditioning parameters may be difficult to achieve with multi-zone systems, since each zone will in theory require a re-heater and humidifier to give total control of humidity if that is what is required. In reality such close control is rarely required in practice. It is therefore usual with multi-zone systems to provide control of zonal temperature only, with humidity control where fitted being based on average conditions within all zones, or minimum conditions within one zone.

6.45 Where there is a requirement for close control of air-conditioning parameters in a number of zones (e.g. an operating department) separate plants should be provided for each zone in order to avoid the need for expensive over-cooling and reheating of individual zones.

6.46 Most multi-zone systems within healthcare premises are controlled based on off-coil control within the central plant, with trimmer heater batteries on individual zones.

Alarms and indication

6.47 Supply and extract systems should include indicator lamps on the control panels to confirm the operational status of each system. Where the usage is on

a regular daily pattern, time control with a user-operated timed manual over-ride should be provided.

6.48 Where a system is provided for a particular space, the indicator should be in, or immediately adjacent to, that space and local controls should be provided with labels clearly defining their function (eg. isolation suites.)

6.49 The 'plant failure' and 'low air-flow' alarms should be initiated by a paddle switch or other device located in the main air supply duct. This should operate when the air quantity fails to reach or falls to around 80% of the design value and will give indication of fan failure, damper closed, access door left open, or any other eventuality that could cause a reduction of air quantity. Monitoring the current drawn by the fan motor is not a substitute for a sensing device that is directly affected by the air-flow.

6.50 The 'filter fault alarm' should be initiated by a predetermined increase of pressure differential across the filters, thereby indicating a dirty filter.

6.51 Direct-reading gauges or manometers should be installed across filters to give maintenance staff an indication of their condition.

6.52 Visual indication should be provided at a manned staff location (for example, the reception or staff base) and on the main control panel and BEMS to show 'plant failure' and 'low air flow'.

BEMS

6.53 Control of most systems will be via a Building Energy Management System (BEMS). This will enable the operating conditions and control tolerances to be set and monitored. The BEMS may also be set to log the actual energy consumed by the system and recovered by the energy recovery system. This will provide a useful check on the overall operating efficiency and provide evidence that energy targets are being achieved.

7. Specialised ventilation systems

7.1 This section contains design information for a range of healthcare ventilation applications.

7.2 The following departments will require a degree of specialised ventilation.

- the Operating department;
  - treatment rooms;
  - endoscopy, day case and minimum invasive suites;
  - cardiology and operative imaging suites;
  - conventional operating theatres;
  - Ultra-clean ventilation (UCV) operating theatres;
  - barn theatres;
  - recovery and ancillary areas.
- Obstetrics;
  - maternity theatres;
  - birthing rooms;
  - LDRP Rooms;
  - SCBU.
- critical areas and high-dependency units of any type;
- Isolation facilities;
  - infectious diseases units;
  - bone marrow and other transplant units;
  - chemotherapy and oncology units.
- Sterile Supply and Decontamination Units;
  - wash rooms;
  - inspection and packing rooms;
  - sterile pack stores.
- the Pharmacy departments;
  - aseptic suites;
  - extemporaneous preparation areas;
  - radio pharmacies.
- the Pathology department;
  - laboratories;

  - cat 3 and 4 rooms.
- the Mortuary and Post mortem suite;
  - mortuaries;
  - post-mortem rooms;
  - specimen stores.
- Hydrotherapy units;
- Burns units;
  - burns theatres;
  - treatment rooms;
  - isolation rooms;
  - tissue banks.
- Emerging specialties;
  - gene therapy units;
  - stem-cell laboratories.
- Infrastructure;
  - plant rooms housing combustion equipment;
  - welding facilities;
  - wood working workshops;
  - electric vehicle charging areas.

7.3 Design information for many of these applications is given in Appendix 1 Table A1, Appendix 2 and in the following Chapters within this section.

7.4 It is not possible within this existing document to give definitive guidance for every healthcare specific ventilation application. Additional detailed guidance may be issued in due course in the form of supplements.

General information

7.5 The section on operating theatres is the most extensive and contains much information that is common to other applications. Each theatre suite should have its own dedicated air-handling unit and extract fan. Where no specific guidance is given the principles set out below should be followed:

- the foregoing sections of the document contain general information on healthcare-specific aspects of ventilation system design and specification;
- a set of standard solutions for the design of general operating theatre suites to conform to past and new standards is given in new standard layouts Nos 1, 3, 5 and 7 and those for UCV theatres in new standard layouts Nos 2, 4, 6 and 8 within Appendix 3;

- the CIBSE Guides A & B contain basic information on ventilation design that can be applied to most applications;
- where a British or European standard exists that is specific to the application (for example, a clean room) it should be used as the basis of the design requirement;
- air should always move from clean to less-clean areas. A hierarchy of room cleanliness is given in Table A2;
- differential pressure will prevent contamination between areas when doors are closed. Information on air leakage through closed doors and hatches for a range of differential pressures is given in Table A3;
- the flow of air will prevent contamination between areas when doors are open. Information on air leakage through open doors and hatches for a range of differential pressures is given in Table A4;
- if anaesthetic gases are used, 15 air changes per hour will be required;
- a methodology for calculating a design solution for a non-standard suite of operating rooms is given in Appendix 4. This may be adapted as necessary to suit other less complex applications where air is required to cascade from clean to less clean areas.

7.6 The supply of air to a room has four main functions:

- to dilute airborne contamination;
- to control air movement within such that the transfer of airborne contaminants from less clean to cleaner areas is minimized;
- to control the temperature and if necessary the humidity of the space;
- to assist the removal of and dilute waste gases where used.

7.7 Because of the complexities of controlling air-movement patterns, much design effort will be required for this aspect. It is important that the design makes the best possible use of the air available, as excessive supply airflows for the control of air movement should not be used. The amount of air supplied will be determined by the number of doors and desired air-change rate.

7.8 There are four routes whereby airborne contaminants may appear in a room:-

- through the supply air;
- shed directly by the room occupants;
- arising as a result of the work activities;
- transferred from adjacent spaces.

7.9 Particles entering with the supply air can be controlled by the selection of suitable filter grades.

7.10 Particles shed directly by the room occupants can be controlled by:

- restricting access to essential persons only;

- the choice of the occupants' clothing;
- the room's air-change rate.

7.11 Particles arising as a result of the work activity can be controlled by:

- enclosing, semi-enclosing or otherwise controlling the work-based source;
- the room air-change rate.

7.12 The transfer of particles from adjacent spaces can be controlled by:

- differential pressure;
- air-flow paths.

7.13 Air change rates are given in Table A1. These figures have been found to give sufficient dilution of airborne contaminants, provided the mixing of room air is reasonably uniform.

7.14 A downward-displacement turbulent air distribution is generally preferred. The supply and extract diffusers should be positioned to ensure that all parts of the room are actively ventilated and that where necessary the staff will be in a clean air-flow path. (See Section 5 for additional guidance on supply terminals).

7.15 Horizontal-flow room-air distribution with or without a Coanda effect can be a source of draughts and difficult to set up correctly. Its use should be confined to non-critical areas.

Air movement control

7.16 The design of the system should seek to minimise the movement of contaminated air from less clean to cleaner areas. Transfer grilles enable air to pass in either direction between rooms of equal class and pressure. Pressure stabilisers operate in one direction only; they allow excess air to be directed to the area desired and assist in maintaining room pressure differentials. When closed they prevent significant reverse air-flow.

7.17 The relative locations of supply and extract terminals and their design air-volume rates will determine the basic airflow between adjacent spaces. Transfer grilles and pressure stabilisers will permit and control the flow of air between spaces ensuring a flow from the clean to less clean areas. Failure to provide such devices will lead to uncontrolled air flows when personnel move between rooms. They may also result in doors being held partially open by air pressure

Temperature and humidity control

7.18 To achieve the required room conditions, supply flow rates are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air. In most applications the base heating load will be provided by a heating

system. In critical systems the room or suite being considered will be within the heated building envelope so the ventilation will be sized to suit the casual gains or losses.

7.19 Temperature differences of up to 10K for winter heating and 7K for summer cooling must not be exceeded.

7.20 It is acceptable for the humidity to swing uncontrolled between 35% and 70% saturation.

Removal and dilution of waste anaesthetic gases

7.21 Anaesthetic gases are subject to occupational exposure limits. Waste anaesthetic gas must be contained and removed by a suitable gas-scavenging system. Some leakage from the anaesthetic equipment and the patient's breathing circuit will occur with all systems, particularly during connection and disconnection; and from the interface with the patient. The air movement scheme should ensure that this leakage is diluted and removed from the room. Anaesthetic agents are heavier than air so placing the supply terminal at high level with an extract at low level, adjacent to the anaesthetic gas terminal units will ensure that staff are in a clean air-flow path.

7.22 In LDRP and delivery rooms the use of anaesthetic gas is controlled on demand by the patient. This may result in significant leakage which, in order to reduce staff exposure, will need to be controlled by establishing a clean airflow path. A supply at high level at the foot-end of the bed with extract at low level at the head-end will provide such a path.

Fire aspects

7.23 When considering the overall airflow movement, careful thought needs to be given to the operation of the ventilation system, to limit smoke spread in the event of a fire.

Door protection

7.24 Air should flow from the cleaner to the less clean areas as shown in Table A2. There are several factors that affect the likelihood of a reverse air- flow through doorways:

- when a person passes through a doorway, both the passage of the person and the movement of the door flap cause a transfer of air between the areas separated by the door;
- when a door is left open there is a transfer of air between the two areas separated by the doorway. This is caused by air turbulence, but is greatly increased by any temperature differential between the areas (a 1.4m wide doorway may allow the transfer of 0.19 m^3/s of air in each direction when there is no temperature difference, but when the temperature differential increases to say 2K, the volume transferred may increase to 0.24 m^3/s).

7.25 Two methods of door protection are used in order to reduce the likelihood of contamination of clean area by a reverse air-flow from a less clean area:

- closed door protection – a pressure differential is created across a closed door so that any air leakage is from the clean to the less clean area. Table A3 gives details of closed door leakage rates for a range of differential pressures;
- open door protection – the pressure differential drops (See Table A5) and is effectively replaced by a flow of air through the doorway from the clean to the less clean area. The flow of air needs to be sufficiently large to ensure that significant reverse airflow cannot occur and will be related to the relative cleanliness of the areas being considered. Table A4 gives air-flow rates for open door protection related to door / opening size and classification of the adjoining areas.

7.26 Pressure stabilisers enable the room differential pressure to be set when the doors are shut, thus providing closed-door protection. When a door is opened the stabilisers will close, forcing air to be directed through the doorway thus providing open-door protection.

7.27 The recommended air-flow rates to achieve this are given in Table A3. Provided that the dilution criteria in Table A1 are met, the occasional small back-flows created (when two doors are opened simultaneously; or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

7.28 In applications where it is critical to maintain a specific airflow and /or pressure regime (for example isolation rooms) all windows in the zone should be locked shut or sealed. Trickle vents, if fitted, will also need to be sealed.

Systems design

7.29 The design of the ventilation system for an area depends on the overall configuration of the department. Where the department is served by more than one AHU, the control of the units may need to be interlocked so that reverse air-flow patterns do not occur.

7.30 Dual-duct high velocity systems have advantages, but are noisy, costly and may give rise to unacceptable values of humidity. Single-duct, low velocity/pressure systems are preferred.

7.31 Extract grilles should be sited and balanced to promote air movement in the desired direction.

7.0 (a) Operating department ventilation systems

7.32 The information given in this section relates to general operating suites. It will be applicable to other types of theatre suite such as maternity, burns, cardiac, etc. The standard values given may need to be adjusted to reflect non-standard room sizes, pressure regimes and air change rates.

7.33 A method of obtaining a design solution for non-standard theatres is given in Appendix 4.

7.34 Additional information for Ultra-clean ventilation (UCV) theatres is given in Section 7.0 (b).

General

7.35 The supply of air to an operating room has four main functions:

- to dilute airborne contamination;
- to control air movement within the suite such that the transfer of airborne contaminants from less clean to cleaner areas is minimized;
- to control the temperature and if necessary the humidity of the space;
- to assist the removal of, and dilute, waste anaesthetic gases.

7.36 Because of the complexities of controlling air-movement patterns, much design effort will be required for this aspect. It is important that the design makes the best possible use of the air available, as excessive supply airflows for the control of air movement should not be used. The amount of air supplied to the operating room will be determined by the number of doors and desired air-change rate.

7.37 The detailed considerations upon which the supply air-flow rate is based are as follows.

Dilution of airborne bacterial contaminants

7.38 There are four routes that airborne contaminants may appear in an operating room:

- through the supply air;
- shed by operating staff;
- produced by the surgical activities;
- transferred from adjacent spaces.

7.39 Supply flow rates for the main rooms of the operating suite are given in Appendix 3. For the other areas where room sizes and activities vary from site to site, air-change rates are given in Table A1. These figures have been found to give sufficient dilution of airborne bacterial contaminants, provided the mixing of room air is reasonably uniform.

7.40 A downward-displacement air distribution is preferred; it may be either turbulent or laminar flow. For turbulent flow the supply-air diffusers should be positioned either in the centre of each quadrant of the ceiling or along a line between the centres of each quadrant. This should ensure that all parts of the room are actively ventilated and that there will be adequate air movement at the operating table. Laminar flow would be provided by a perforated plenum terminal centred

above the operating table. (See Section 5 for additional guidance on supply terminals).

7.41 Suspended articulated equipment is usually fitted in theatres. These require significant structural steelwork in the ceiling void to cater for the loads imposed by the resulting bending moments. It is important to ensure that the void is deep enough to accommodate both the steelwork and the ventilation ducts. The location of the steelwork must not prevent a suitable layout of the ventilation ductwork and correct positioning of the supply air terminals. It needs to be recognised that the correct ventilation of an operating theatre plays a significant part in controlling healthcare acquired infections and is not subordinate to the desire to make equipment easy to move.

7.42 Horizontal flow distribution with or without a Coanda effect can be difficult to set up correctly and are unlikely to be as effective in Theatre applications. It should not be used in new installations. However space constraints may force its retention or replacement when refurbishing existing installations. Where fitted, the supply grilles will require a means of directional adjustment.

7.43 For general operating theatres, the air supply would be filtered in the AHU. Terminal HEPA filters are not generally required.

Control of air movement within the suite

7.44 The design of the system should seek to minimise the movement of contaminated air from less clean to cleaner areas. Transfer grilles enable air to pass in either direction between rooms of equal class and pressure. In older designs suitably dimensioned door undercuts were often used in lieu of transfer grilles. Pressure stabilisers operate in one direction only; they allow excess air to be directed to the area desired and assist in maintaining room-pressure differentials.

7.45 The relative locations of supply and extract terminals and their design air-volume rates will determine the basic air-flow between adjacent spaces. Transfer grilles and pressure stabilisers will permit and control the flow of air between spaces ensuring a flow from the clean to less-clean areas of the suite. Failure to provide such devices will lead to uncontrolled airflows when personnel move between rooms and doors being held partially open by air pressure.

Temperature and humidity control

7.46 Supply flow rates to achieve the required room conditions, are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air. In most applications the room being considered will be within the heated building envelope.

7.47 Temperature differences of up to 10K for winter heating and 7K for summer cooling must not be exceeded.

7.48 It is acceptable for the humidity to swing uncontrolled between 35% and 60% saturation.

Removal and dilution of waste anaesthetic gases

7.49 Anaesthetic gases are subject to occupational exposure limits. The air-movement scheme should ensure that staff are in a clean air-flow path. (See Paragraph 7.21).

7.50 Air extracted from operating suites should not be re-circulated, as it may contain malodorous contaminants. However an energy recovery system should be fitted in the extract in order to reduce the plant energy consumption. (See Paragraphs 4.142 - 4.147).

Fire aspects

7.51 When considering the overall air-flow movement, careful thought needs to be given to the operation of the ventilation system, to limit smoke spread in the event of a fire. However, this is a highly staffed department with a low fire risk/load status and these factors need to be recognised when developing the fire strategy. It is considered satisfactory to treat the complete operating department as a single fire compartment providing there are at least two exits from it. Over-compartmentalisation can lead to difficulties in establishing clean air-flow paths and room-air dilution rates. This will lead to an increased risk of healthcare-associated infections. Staff areas within the department should be treated as a sub-compartment. (See Paragraph 6.18).

Door protection

7.52 Air should flow from the cleaner to the less clean areas as shown in Table A2. The factors that affect the likelihood of a reverse airflow through doorways are discussed in Paragraphs 7.24 - 7.26.

7.53 It is not possible to design an air-movement scheme, within the restraints of the amount of air available that will protect the operating room when two doors are simultaneously opened. The design process that has been used considers that each door is opened in turn and ensures that the direction and rate of air-flow through any open doorway is sufficient to prevent any serious back-flow of air to a cleaner area.

7.54 Provided that the air-change rates in Table A1 are met, dilution will be sufficient to ensure that the occasional small back-flows created (when two doors are opened simultaneously; or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

7.55 The following general points should be taken into consideration during the design of operating suites:

- Number of exits – the fewer the number of rooms (and therefore doorways) leading from the operating room the better, as traffic is reduced and less complicated air-movement control schemes are required.
- Scrub and hand-wash facilities – these may be a part of the operating room, often in a bay. The bay would count as part of the operating room volume and should have a low-level active or passive extract to remove the moisture-laden air. Should a separate room be required for the scrub area, a door between the scrub-up room and the operating room is an inconvenience to scrubbed staff, and could be replaced by an opening. This opening should be larger than a normal single doorway, but the scrub would not, in these circumstances, be considered part of the operating room volume.
- If an alcohol scrub regime is employed, individual theatre scrubs may not be required and would be replaced by a common departmental pre-/post-operation scrub position in the corridor. This would require local extract to prevent a build-up of moisture.
- Preparation 'Sterile Pack Store' (SPS) – if it is intended to 'lay-up' instruments in the operating room, the preparation room is then used simply as a sterile pack store. The nominal room pressure can therefore be the same as that of the operating room and the airflow between the two rooms in either direction. Air supplied to the preparation room may be directed into the operating room either through a door mounted transfer grille or if no door is fitted, through the opening. Alternatively, stock ready-use sterile items can be located in a bay within the theatre. In this case, a portion of the total theatre supply air should be provided in the bay to ensure it is actively ventilated.
- Preparation room 'lay-up' – when the preparation room is used as an instrument 'lay-up' room, it should be regarded as being of greater cleanliness than the operating room, and the design should minimise the transfer of air from the operating room to the preparation room. Air supplied to the room may be directed to the operating room through a pressure stabiliser taking care not to compromise the airflow pattern in the operating room. The air may also be directed into a corridor;
- Service corridor – if materials to be disposed of are placed in impervious material for transportation, it is not necessary to have a separate corridor for this purpose. However, a service corridor has many operational advantages it terms of the flow of materials through the theatre suite. It also permits routine service and maintenance access without compromising the use of adjacent theatre suites.

Standard air-movement control schemes

7.56 In the previous versions of this guidance standard air movement control schemes were given that provided a range of design solutions to typical operating suite layouts. These were satisfactory design solutions for 'standard' sized rooms within the suite but were never intended to be universal for any sized room or suite. Guidance on operating suites contained in HBN 26 (2004) has increased the recommended size of operating room from approximately

35m^2 to 55m^2. Associated room sizes and air change rates have also increased. This means that the original standard solutions are no longer appropriate for new-build installations.

7.57 Because of the resulting increase in the volume of air supplied to the theatre, provision needs to be made either to actively remove it or allow it to escape passively through pressure stabilisers. The increase in room size has also made the number and position of air-supply terminals critical to the effective ventilation of the room.

7.58 Four new standard solutions have been developed to reflect the current guidance on theatre suite layout and room sizes given in HBN 26 (2004) as well as the general increase in air-change rates.

7.59 The most commonly used original standard solutions have been revised and updated. They have been retained in this guidance, as they will remain applicable to older theatre suites that are being refurbished to their original performance standards. They will also be applicable in existing departments where space constrains do not permit the upgrading of suites to the latest standard of performance or where a pre-built "shell" is being fitted out.

7.60 It is important to recognise that in any situation where a "non-standard" room size or theatre suite layout is being considered, the designer must return to first principles when developing a solution. Examples of non-standard configurations would be:

- cardiac theatres that typically have an operating room half as big again as normal, a perfusion laboratory and no anaesthetic room;
- operating departments served by a central instrument lay-up preparation area rather than individual prep rooms;
- balanced-flow theatres for infectious cases.

Appendix 4 contains a methodology for assisting the designer to arrive at a suitable solution.

7.61 The new and revised standard design solutions are as follows:

No 1 – Typical Conventional theatre – room sizes as HBN 26;

No 2 – Typical UCV theatre – room sizes as HBN 26;

No 3 – HBN 26 illustrated Conventional theatre;

No 4 – HBN 26 illustrated theatre with UCV terminal fitted;

No 5 – Pre-2006 Conventional theatre, single corridor (former SHTM 2025; 1b);

No 6 – Pre-2006 UCV theatre, single corridor (former SHTM 2025; 1a);

No 7 – Pre-2006 Conventional theatre, two corridor (former SHTM 2025; 5b);

No 8 – Pre-2006 UCV theatre, two corridor (former SHTM 2025; 5a).

7.62 Details of these standard solutions are given in Appendix 3. They contain diagrams that show the relationship of rooms and the various doors and transfer devices between them, **but should not be regarded as architectural layouts.** The schemes have been developed using the calculation procedure described in Appendix 4. Important features of the solutions are:

- Zone trimmer heaters – a trimmer heater battery is advocated when calculations indicate that the temperature differential between rooms may be greater than 2K. Generally this will only be the case in the preparation room when designated as a lay-up.
- The preparation room (sterile pack store)/operating room interface – these rooms are deemed to be of equal cleanliness, and thus a transfer grille is required between these rooms or the door can be replaced with an opening wider than a standard door.
- Preparation (lay-up)/disposal room interface – pressure relief dampers are recommended here to provide an air path when doors are closed, while preventing back-flow when a door is opened elsewhere.
- Operating room/anaesthetic room interface – pressure stabilisers, or in some cases, carefully sized transfer grilles are recommended here, and between the anaesthetic room and corridor, and between the operating room and corridor.
- Operating room/scrub room interface – an opening is provided between these rooms. The flow of air through the opening provides protection, and gives bacterial dilution within the scrub room; the air is then exhausted to the corridor via a pressure stabiliser.

7.63 No mechanical supply or extract ventilation is provided in the scrub room, and thus when a door is opened elsewhere in the suite, the stabiliser will close, allowing the air to be re-directed to help protect the doorway. If the scrub is a bay within the theatre then a suitably positioned pressure stabiliser and / or active extract should be provided to ensure air movement and prevent a local build-up of moisture.

7.64 Any other scheme may be used and the standard solutions applied, if the following conditions are met:

- room relationships in air network terms are as shown in the plans;
- door-gap measurements approximate to those given in Scottish Health Technical Memorandum 58: ‘Internal doorsets’, (but see also Table A3 and Note 3);
- casual heat gains are accounted for;
- a trimmer battery is installed in the air supply system to the preparation room;
- leakage through the structure is kept to a minimum.

Note 3: It should be noted that many doors are now fitted with cold smoke seals as standard. These will significantly reduce the door leakage rate when new and undamaged. It is therefore recommended that provision for the design door leakage is factored into the sizing of the appropriate transfer grille or pressure stabiliser. Failure to do this will result in air gap whistles and doors being held partially open by air pressure.

7.65 It is recommended that every effort should be made to adopt one of the schemes described above.

Air terminals and air distribution within rooms

7.66 The selection and sighting of air diffusers will be critical in establishing an efficient pattern of mixing. To this end the diffusers selected must be fit for purpose. Ceiling mounted circular 'air master' style, square 'four-way blow' or similar diffuser designs that provide a downward displacement, turbulent airflow are the preferred option. (See Paragraph 5.68).

7.67 Plenum-type 'laminar'-flow-style diffusers with a footprint that encompasses the operating site are acceptable but may be prone to buoyancy effects as a result of temperature difference. Manufacturers' type-test data should be consulted to ensure that the terminal will achieve the required performance envelope. Note that these are not true laminar-flow systems in the strict sense of the word but produce a downward-displacement parallel-flow style of air distribution.

7.68 The diffuser equipment chosen should not cause 'dumping' and it should provide a velocity 1 metre above floor level at the operating position of between 0.2 m/s and 0.3 m/s.

7.69 In the operating room, the supply air terminals must be at high level, and should all be adjustable for rate of flow as well as being easily cleaned and silent in operation.

7.70 In order to ensure that all parts of the operating room are actively ventilated, there should be an air-out path on each face or in each corner of the theatre. This may be provided by a pressure stabiliser, transfer grille, active or passive extract terminal. A minimum of three, but preferably four, air-out paths - approximately equally spaced - should be provided.

Automatic control

7.71 The automatic control of ventilation in operating suites needs to be simple and robust. Over-reliance on complex room pressure and flow relationships linked to automatic fan speed control is unnecessary and in the long term have been shown to be unreliable. Complex software algorithms that can only be accessed and interpreted by off-site specialists should not be used. Whichever control strategy is chosen it is important that on-site staff have the facility to override the control system and keep the ventilation operating at least until the surgical procedure is complete. (See also Paragraph 6.11)

7.72 Theatre air-conditioning control sensors should be actively ventilated. They would typically be located in a sampling extract duct mounted in the surgeon's panel, positioned at normal working height (1.8m above finished floor level) and be accessible for cleaning and the removal of fluff and lint.

7.73 Wall-mounted passive-temperature and humidity sensors are not recommended.

7.74 Controls should be provided to enable operating department ventilation plants to be closed down when the operating suites are unoccupied. (See also Paragraphs 6.24 - 6.26)

7.75 When in the 'off' mode, the control system should ensure that the ventilation plant is automatically reinstated if the space temperature falls below 15°C.

7.76 The theatre control panel should include plant status indication; clearly-readable temperature and humidity indicating gauges; and means of adjusting the set point for temperature. Theatre ventilation plant status indication should be located at the staff control base.

7.77 Where it is considered necessary to fit a humidifier, it should be selected to humidify to 40% saturation at 20°C during the design winter outside conditions. The cooling coil should be able to remove sufficient moisture so that 60% saturation at 20°C is not exceeded during the design summer outside conditions.

7.78 Each operating suite should be served by an independent supply and extract plant.

Ventilation of operating department ancillary areas

General

7.79 There are advantages in providing mechanical ventilation to all areas of the department. Maintaining operating suite airflow patterns is simpler and grilles and diffusers can be sited to eliminate condensation on windows. Where radiators or embedded wall or ceiling panels are installed they should be confined to the corridors and staff-only areas of the department.

Ventilation requirements

7.80 Table A2 gives guidance on the operating department areas in descending order of cleanliness, and this should be considered in the overall design of the department ventilation systems. The specified flow rates of air through doors given in Table A4 for the operating suite are not necessary for other areas of the department. However, the air-flow directions must be maintained from the clean to the less clean areas.

7.81 All windows in the department should be double-glazed and hermetically-sealed in order to ensure that the desired airflow pattern is maintained under all

external environmental conditions and to avoid infestation. Trickle vents if fitted will need to be sealed.

Systems design

7.82 The design of the ventilation system for the ancillary rooms depends on the overall configuration of the department. The plant for the ancillary rooms may need to be interlocked to the theatre suite plants so that reverse air-flow patterns do not occur.

7.83 Extract grilles should be sited and balanced to promote air movement along the clean and access corridors towards the reception/transfer areas. This should not affect the air distribution in the operating suite(s).

Reception

7.84 The aim in these areas is to provide comfortable conditions having regard to the movement control requirements of the department as a whole. The number of air changes will depend on the particular design.

Sterile pack bulk store

7.85 The store needs to be maintained at a positive pressure in order to preserve the cleanliness of the outside of the packs; 6 air changes are recommended.

Recovery

7.86 The air-change rate in the recovery room will be rather higher than that needed merely to provide clean, comfortable conditions, as it is necessary to control the level of anaesthetic gas pollution; 15 air changes are recommended, with a balanced air flow.

7.87 The supply air terminals should be ceiling mounted above the foot-end of the recovery bed positions. Extract should be at low (bed height or below) level behind the bed head positions or in the corners. This will establish a clean airflow path so that staff do not inhale anaesthetic gases exhaled by recovering patients.

7.0 (b) Ultra-clean ventilation systems

General requirements

7.88 The design philosophy of a conventionally ventilated operating suite is based on the need to dilute contaminants and control both the condition and movement of air in an operating suite. Ultra-clean ventilation (UCV) is a means of significantly increasing the dilution effect by providing a large volume of clean filtered air to the zone in which an operation is performed and sterile items are exposed. Air is discharged above the operating zone and while not truly laminar, its downward displacement purges the clean zone of contaminants and

particles generated by the activities within it. The airflow in and around the clean zone also serves to prevent particles originating outside the zone from entering it. The resulting reduction in contaminants has been shown to reduce significantly post-operative sepsis following certain orthopaedic procedures.

7.89 The number of bacteria that are present in the air at the wound site and exposed surgical items is dependent on the operating team, their procedural discipline, choice of clothing and the type of UCV system. Ultra-Clean air is defined as that containing not more than 10 CFU/m^3.

7.90 UCV systems are very successful in reducing contaminants at the wound site so it is often considered that there is no need for complex air movement control schemes in the rest of the suite. However, when designing the ventilation scheme, it should be noted that the users may switch the UCV terminal to "set-back" when non-orthopaedic surgery is taking place. This is because the high airflow rates can cause increased moisture evaporation of exposed tissue that may be detrimental to the surgical outcome. In recognition of this, the ventilation scheme should be capable of providing operating conditions to at least a "conventional" theatre standard throughout the suite with the UCV in set-back mode. It should also be remembered that suitable levels of ventilation will always be required in the peripheral rooms.

7.91 UCV systems can be designed and built from first principles or a range of bespoke modular units of varying shapes and sizes are available with each manufacturer having a slightly different approach to UCV design. Some systems are fitted with partial or full walls to delineate the clean zone and direct a laminar or exponential downflow of air within it. Other designs utilise slotted linear supply terminals to produce an air curtain around the clean zone together with laminar-flow diffusers to provide a downward-displacement supply within it. **Notwithstanding any variation in the design philosophy, all UCV systems will be required to achieve completely the performance standard set out in the "Validation" section of this document**. (Section 8)

7.92 As with conventional theatres, each UCV operating suite should have its own dedicated air handling unit (AHU) to the standard set out in Section 4 of this document. To ensure operational flexibility and permit routine maintenance, air handling units should not be shared between suites.

7.93 In retrofit installations, site conditions may preclude individual AHUs for each suite. In these circumstances an AHU may be shared between not more than two operating suites providing each suite has its own control of temperature. An accessible airflow measurement test point should be provided in the supply branch duct to each theatre so that the primary air volume to each UCV canopy can be determined. In addition the branch supply and extract should be capable of being physically isolated and the main air-flow rate reduced so that either suite can be taken out of use without detriment to operating conditions in the other.

7.94 An inherent feature of a UCV system is its large airflow so it is essential to re-circulate the air supplied to the operating theatre and/or to recover its energy in order to optimise operating costs.

7.95 The primary fresh-air volume supplied to a UCV suite will be the same as in a conventional suite and it should be dispersed to the rooms in the suite in the same manner. This is an important aspect of the design and requests by UCV suppliers for increased primary air-supply volumes should be resisted.

7.96 Laying-up in the clean zone is preferable for infection control reasons. Where a Sterile Pack Store (SPS) Preparation room is provided a transfer grille will be required in the preparation room / theatre door.

7.97 If the Preparation room is intended to be used for laying-up instruments, a pressure stabiliser will be required between the prep room and theatre. It should be fitted with a stand-off baffle to prevent air transfer interfering with the ultra-clean airflow distribution.

7.98 Separate scrub-up or disposal facilities are not necessary for air cleanliness although operational policy may prefer such a provision. A separate anaesthetic room should, however, be provided.

7.99 There is no aerobiological reason why two or more UCV systems should not be installed in a common area as long as adequate spacing is provided. These are known as “barn theatres” and require special design considerations and operational discipline. The relative positions of the UCV units, temperature control range and location of doors and openings to other areas will all significantly affect the airflow at the operating positions.

Types of UCV system

Remote plant systems

7.100 In a remote plant system, all the air-conditioning equipment is located outside of the operating room, except for the unidirectional air-flow terminal, terminal filter, air diffuser and the return-air grilles (see Figure 6).

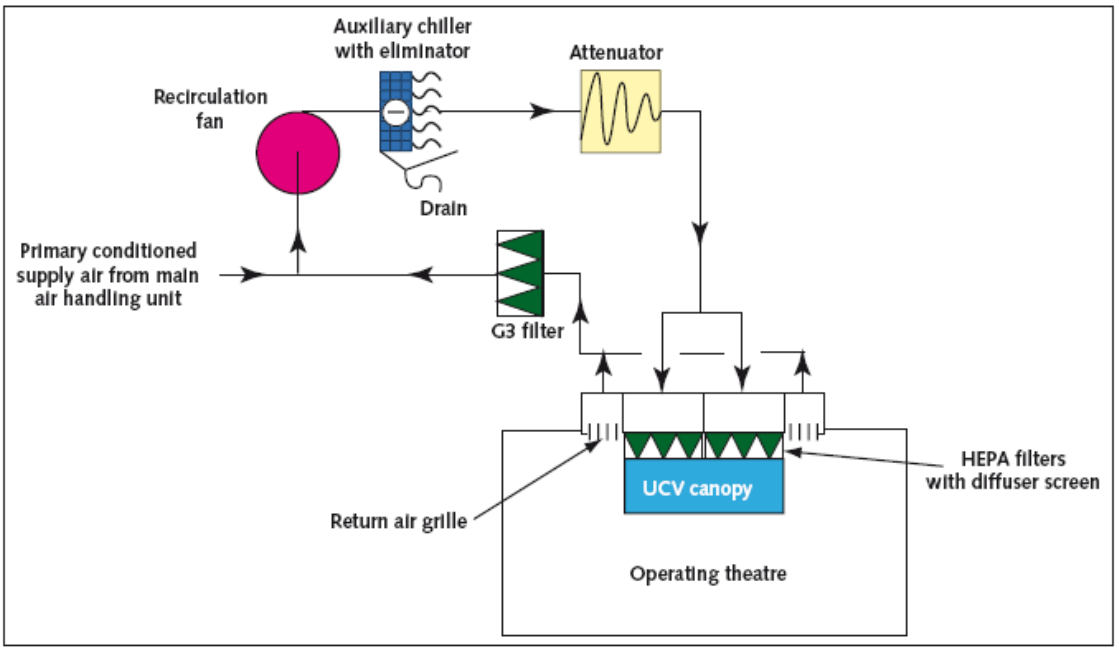

Figure 6: UCV theatre with remote air recirculation

7.101 This arrangement is the preferred option for new installations as it has the following advantages:

- the recirculation fans are out of the theatre thus reducing noise. Multiple recirculation fans can be replaced by a single fan unit with its drive out of the air stream;
- casual heat gains from recirculation fan(s), canopy lights, equipment and people within the theatre can be removed by a chiller battery in the return air stream. This will prevent heat build-up in the theatre;
- the return-air filters can be changed without needing access to the theatre making routine maintenance more feasible;
- the opportunity exists to locate the HEPA filter in the primary supply duct rather than the theatre terminal. This will reduce the number of filters required and allow them to be changed without entering the theatre.

Modular systems

7.102 Modular systems are frequently used in retrofit applications. Vertical or horizontal units are available.

7.103 Vertical-flow modular units comprise a ceiling-mounted air-terminal module containing return-air filters, return-air fans, final filter and air diffuser. Primary air is supplied by a remote air-conditioning unit at the volume and to the standard required for a conventional operating suite. (see Figure 7)

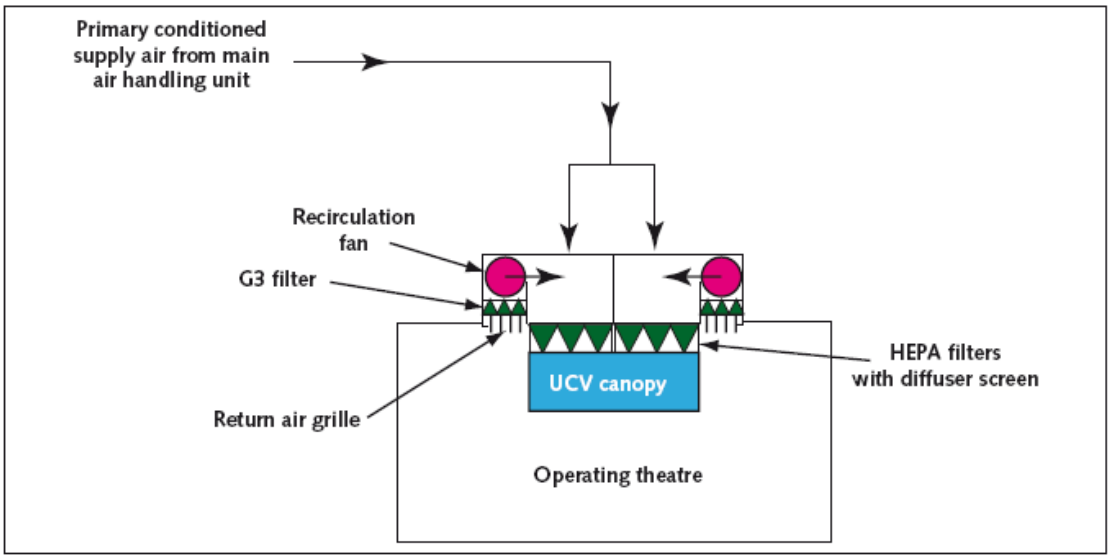

Figure 7: UCV theatre with modular system

7.104 Horizontal or cross-flow modular units comprise a wall-mounted air-terminal module standing vertically to produce a horizontal flow of air and containing final filter/diffuser, return-air filters and fans. The module may incorporate a cooling unit or be supplied with 'fresh air' from a separate primary cooling system.

Vertical flow UCV systems

7.105 Vertical-flow systems have a superior performance and are more effective at reducing infection risks. Air-curtain or partial-wall systems are acceptable, but are known to be more susceptible to problems arising from performance deterioration, poor operating-team discipline and high occupancy rates than is the case with full-wall systems. A full-wall is considered to be any wall terminating not more than one metre above the finished floor level.

7.106 Because of the large volume of air being moved in a relatively small space, the siting of the return-air grilles can cause short-circuiting of the air discharged through the UCV terminal. If the return-air grilles are positioned at high level, partial walls should be provided to control short-circuiting. The partial-walls shall be not less than 1m from the operating room walls and terminate at least 2m above floor level. The clearance should be increased proportionally for larger terminals (that is, 1.15m for 3.2m x 3.2m units and 1.25m for 3.5m x 3.5m units). In all cases, the sidewalls should terminate at 2m above floor level.

7.107 Siting the return-air grilles around the periphery of the theatre at low level will eliminate short-circuiting, remove the need for partial walls and give an improved airflow path. In any event there should be an air-out path on each face or in each corner of the theatre. These may be provided by combination of pressure stabilisers and passive or active low level extract grilles. Failure to provide air-out paths on all faces of the theatre may result in the surplus air causing entrainment into the clean zone.

7.108 Vertical systems should have a clean zone large enough to encompass the operating site and all of the instrument trays likely to be needed for the surgical procedures to be undertaken. Ophthalmic and minor hand surgery would

typically require a 1·4m circular or rectangular terminal. For major orthopaedic procedures a minimum size of 2·8m x 2·8m will be required. This is the area projected on the floor under the supply air terminal within the partial walls, full walls or air curtain. Any air outside this zone cannot be guaranteed to be ultra-clean although given the dilution factor the level of microbiological contamination will be much lower than the general level in a conventional operating room. The use of lines or a coloured area on the floor delineating the extent of the clean zone will assist staff and is therefore essential.

7.109 When upgrading an existing conventional theatre to an ultra-clean standard the only solution may be the installation of a modular system. In these units, the heat gains from the return-air fans and terminal lights may warrant the inclusion of supplementary cooling within the module although modern luminaries contribute substantially less unwanted heat. However issues of cooling coil drainage, condensate removal and maintenance access within the space constraints of the module may make this option impracticable. The additional cooling load should then be catered for by conditioning the primary air to compensate.

7.110 If an existing AHU is to be retained, it may require modification to ensure that it achieves the minimum standards set out in Section 4 of this document. The fan may need re-rating to accommodate the change in system resistance. The cooling coil may also need to be upgraded to cater for the increased load resulting from the return air fans and terminal lights. Failure to make adequate provision for this may make the theatre unusable during prolonged warm spells.

7.111 A factor affecting the air-flow pattern is the supply or room air temperature difference. When the supply-air temperature is significantly above room temperature, buoyancy effects will reduce the volume of air reaching the operating zone. If it is anticipated at design stage that this will be a regular occurrence, then a system incorporating full-walls should be used. Demountable extensions that convert a partial-wall to a full-wall unit are available.

7.112 Convection up-currents from the surgical team and operating lamp tend to counter the movement of clean air towards the operating site, hence the air velocity reaching the operating level is critical. The minimum velocity given below has been selected to take account of these factors and is greater than the theoretical minimum value.

7.113 For all vertical UCV systems the design discharge velocities will be as follows:

Air velocity 2 metres above floor level:

- partial-wall system = 0.38 m/s average;
- full-wall system = 0.30 m/s average.

Air velocity 1 metre above floor level:

- all systems = 0·2 m/s minimum within the operating zone.

The validation Paragraphs 8.75 – 8.86, gives details of the method of measurement.

7.114 Variable-speed recirculation fans with differential pressure control may be the most suitable solution for maintaining consistent performance and energy saving.

Horizontal UCV systems

7.115 Horizontal UCV air-flow systems have been shown to be less effective than vertical systems and are not the preferred solution. There may be occasions, however, where architectural, engineering, economic or workload considerations prevent the installation of a vertical-flow system and only a horizontal-flow system can be installed.

7.116 Horizontal- or cross-flow modular units comprise a wall-mounted air terminal standing vertically to produce a horizontal flow of air across the operating field. The terminal module contains the final filters, air diffuser, return-air grilles, filters and fans. The module may incorporate a full air-conditioning unit or be supplied with 'fresh-air' from a separate primary air-conditioning system. In the latter case the return-air fan power may warrant the inclusion of a supplementary cooling coil within the module.

7.117 The system should have sidewall panels at least 2·4m apart. The panels may fold to facilitate cleaning of the theatre. The minimum height of the terminal should be 2·1m and a deflector at the top of the filter/diffuser will be acceptable as an alternative to a full roof. These dimensions reflect currently available equipment and may impose operational constraints in addition to a lower level of performance common to these systems.

7.118 In the horizontal flow systems, personnel working between the filter and surgical wound will disperse bacteria that are more likely to contaminate exposed surgical instruments and enter the wound. This may be minimised by the use of improved clothing and operating procedure to reduce dispersion of bacteria. The use of lines on the floor delineating the extent of the clean zone and hatching or colour coding the 'no-entry' zone between the air diffuser and patient will serve to prompt staff and are therefore essential.

7.119 The air discharge velocity as measured 1m from the diffuser face should have a mean value of 0·4 m/s. The validation Section 8 gives details of the method of measurement.

Filters

7.120 The main plant primary and secondary filters should be to the standards and in the location set out in Section 4.

7.121 Terminal filters should be provided within the airflow terminal or in the air supply to it. High efficiency particulate air (HEPA) filters grade H10 as specified in BS EN 1822 will be required as a minimum. There is no aerobiological benefit in

fitting filters of a higher grade than this, although for practical reasons most UCV manufacturer recommend the fitting of H12-grade filters.

7.122 In some modular UCV units, the terminal filter is used as a pressure equaliser to balance airflow and filters of a higher grade with a greater pressure drop may be recommended by their manufacturer. The increased resistance may affect the velocity of air reaching the operating level and there will be penalties in terms of installed fan power and higher noise levels.

7.123 The final filters should 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 will be carried out during commissioning to prove the effectiveness of the complete installation.

7.124 Where UCV units are constructed in sections, a means of measuring the pressure drop across the terminal filters in each section should be provided. The pressure test-points should be located outside of the partial wall, capped to prevent air leakage and accessible within the theatre without the need to open the unit inspection panels. Alternatively direct-reading pressure gauges should be fitted.

7.125 The UCV system will require a return-air filter to capture the relatively coarse particles that would otherwise significantly reduce the life of the final filter. This should be at least a G3 grade to BS EN 779. In remote recirculation systems there may be advantages in fitting a higher grade return air filter, as it will reduce the load on the terminal HEPA filters and extend their life.

Noise level

7.126 If sound-attenuating material is used to line any portion of the inside of the UCV unit it should be non-particle-shedding and fire-resistant. (Further guidance can be found in SHTM Firecode suite of documents).

7.127 The maximum noise level in an operating room fitted with a UCV terminal of any type shall not exceed 50 NR. The validation section gives details of the method of measurement.

Lighting and operating lights

7.128 CIBSE lighting guide LG2 and BS EN 12464-1 give detailed information of lighting requirements. Operating luminaires should comply with the photometric requirements detailed in relevant sections of BS EN 60601.

7.129 The position of the UCV light fittings and style of partial walls, where fitted, should neither adversely disturb the airflow nor result in significant spatial variations in illuminance levels.

7.130 In vertical units, specialised task lighting should be provided by toroidal, cruciform or small multiple dome-shaped luminaires as they have good aerodynamic properties. The ideal luminaire will have a minimal effect on the airflow regardless of where it is positioned. Large-diameter saucer-shaped

luminaires should not be used in vertical-flow systems as they will occlude the airflow in the critical central zone. It is important to consider the suitability of existing luminaires when retrofitting UCV systems.

7.131 In vertical UCV installations a minimum of 2·75m from floor to underside of the diffuser is required to allow for supporting mechanisms and lamp articulation. When upgrading existing systems this dimension may not be achievable. However, when parked, the lowest point of the central light stem, luminaire and articulation arms should never be less than 2m above floor level.

7.132 The traditional means of light support is a central column that passes through the UCV terminal and is rigidly fixed to the building structure. The position of the support therefore prevents air being supplied at the centre of the terminal. Separate supports displaced from the centre of the clean zone would lead to improved airflow. This approach was advocated in the 1994 version of HTM 2025 but at the time of writing no UK manufacturer has chosen to adopt this solution.

7.133 In horizontal units the size or shape of the specialised task luminaire has little effect on the air-flow pattern.

Controls and instrumentation

7.134 The functions of the supply AHU and extract ventilation should be continuously monitored by a BEMS control unit. The controls and instrumentation for the main plant are set out in Section 6.

7.135 UCV systems will additionally require:

- a set-back facility that can reduce the air supplied through the UCV terminal to a volume that equates to not less than 25 air changes per hour of the operating room gross volume whilst still leaving the supply AHU operating at full speed;
- a facility to turn the entire system, supply AHU and UCV terminal, off. (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 will illuminate when either the supply AHU or the UCV terminal fails, either or both are switched off or are at set-back;
- an amber indicator light that will illuminate when the UCV terminal is at set-back and the supply AHU is running;
- a green indicator light that will illuminate when both the supply AHU and UCV terminal are operating at full speed;
- a blue indicator light that will illuminate when the UCV terminal air flow, as detected by a differential pressure sensor, falls below 80% of the design flow rate.

AHU	UVC terminal	Indicator light	Comment
Off or Fault	Off or Fault	Red	Ventilation not operating at a suitable level to commence surgical procedures
Off or Fault	On (set-back)		
Off or Fault	On (full speed)		
On (set-back)	Off or Fault		
On (full speed)	Off or Fault		
On (set-back)	On (set-back)		
On (full speed)	On (set-back)	Amber	Ventilation provided to at least conventional theatre standard
On (full speed)	On (full speed)	Green	Full UCV standard conditions
-	-	Blue	HEPA-filter resistance causing low air flow

Table 7: Indicator light logic table

7.136 The switching devices and indicators should be incorporated in the surgeon's panel and their functions clearly labelled. In retrofit installations an auxiliary panel for the UCV may be the most practical option. If fitted it should be mounted adjacent to the surgeon's panel and their control functions interlocked as necessary.

7.137 When a system is designed to have partial walls with full-wall extensions, a volume control facility may be incorporated to allow the system to be run with reduced velocity when the demountable full-walls are in place. It would be the responsibility of the user to ensure correct operation of the system. To assist the user an explanatory notice should be included on the theatre control panel.

7.138 A direct-reading gauge should be fitted in the theatre to show a representative pressure drop across the final filters. If the UCV control box is located out of the theatre and has a means of manually adjusting the return air-fan speed then it should also be fitted with a direct-reading differential pressure gauge. The means of adjusting the return-air fan speed should be lockable to prevent casual adjustment. The direct-reading gauges should be fitted with a means of indicating the correct operating pressure range.

7.139 The UCV-unit manufacturer's control box should be located in an accessible position preferably in the operating department adjacent to the operating theatre that it serves. A service corridor, if provided, is an ideal location. The control box should be clearly labelled with the identity of the operating theatre that it serves.

7.0 (c) Extract systems

7.140 Extracts may be provided for a variety of reasons including:

- simple odour control (for example in a WC or mortuary);
- to receive and remove moisture-laden air (for example, in a kitchen);
- as part of a combined supply/extract balanced system (for example, in an operating suite);

- to capture a hazardous substance at source (for example a safety cabinet).

7.141 Devices that use an inflow of air to control exposure of staff to hazardous substances are classified as Local Exhaust Ventilation (LEV) systems under the COSHH Regulations.

7.142 An LEV system may comprise a self-contained unit incorporating its own carbon filter such as a simple bench-top fume cupboard. Alternatively it may be a complete "ventilation system" comprising a make-up air supply, multiple-exhaust-protected work stations, branch and central extract ductwork, duplex extract fans and a high-level discharge terminal. It may also incorporate a special filtration system appropriate to the hazardous substance being controlled. Such systems could be required for workshops containing woodworking machinery or large centralised pathology laboratories housing multiple safety cabinets, dissection benches, fume cupboards and specimen stores.

7.143 It is important to recognise at the design stage whether an extract is being provided for comfort or as an LEV system. Typical systems in healthcare include:

- microbiological safety cabinets and Category 3 containment rooms;
- fume cupboards;
- welding-fume extracts;
- woodworking machinery duct collectors;
- battery-charging bay extracts;
- powered plaster and bone saws;
- pharmaceutical preparation cabinets and tablet machines;
- dissection benches, cut-up tables and some specimen stores;
- medium- and high-risk infectious disease isolation facilities;
- decontamination facilities;
- dental furnaces, grinders and polishers.

7.144 General design information and guidance for LEV systems is produced by the Health and Safety Executive (HSE) as HS(G)37. Information on the design and installation of microbiological safety cabinets is given in BS5726 and that for fume cupboards is given in BS EN 14175. Their recommendations should be closely followed.

7.145 LEV systems are statutory items that will be subject to an independent inspection every 14 months.

Hood extract systems

Special requirements

7.146 Extract canopies will be required over steam-and-heat-emitting appliances, for example sterilisers, catering and washing equipment; and for the extraction of toxic fumes over benches used for mixing, sifting and blending procedures.

7.147 Perimeter-drain gulleys and corrosion-proof grease eliminators should be provided on kitchen hoods.

Typical arrangements

7.148 The air-flow rate must be sufficient to ensure an adequate capture velocity in the vicinity of the process; typical values are as follows:

- evaporation of steam and like vapours 0.25 m/s to 0.5 m/s;
- chemical and solvent releases 1.0 m/s;
- vapour of gases 5 m/s to 6 m/s;
- light dusts 7 m/s to 10.0 m/s.

Excessive velocities will be wasteful of power and generate noise.

7.149 The lowest edge of the canopy should be 2m above finished floor level, with a minimum of 300mm overhang beyond the edge of the equipment on all sides.

7.150 A compact arrangement of equipment (but with access for maintenance) will minimise the canopy area, and hence reduce the air volume necessary to achieve the optimum capture velocity.

7.151 Hoods required for the control of heat gain and vapours may be connected to the general extract system when it is convenient to do so, but where non-corrosive ductwork materials are necessary, a separate discharge is preferred.

7.152 Lighting and internal divider plates are often required to be built into the perimeter of large canopies. However, built-in shelving systems are not recommended, as they interfere with the air-flow, and constitute a maintenance problem.

Control of hood extracts

7.153 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the hood extract and any associated supply can be shut down. To this end, local control should be provided.

Bench extract systems

Special requirements

7.154 Bench extract ventilation is required in departments such as pathology and mortuary, where activities involve the release of malodorous or toxic fumes that should not be inhaled. Where hazardous substances are being controlled, the system should be designated an LEV.

Typical arrangements

7.155 Each ventilated position will usually be accommodated in a continuous run of benching, which should not be more than 650mm from front to rear and which should be provided with a continuous upstand at the rear. Each position should have a 1200mm x 150mm linear extract grille mounted on a purpose-designed plenum box (incorporating guide vanes as necessary), with its face flush with the upstand. The bottom of the grille should be as close as practicable to the level of the working surface (usually 75mm above, to allow for cleaning). The minimum velocity across any part of the grille should be 1 m/s. The grille should be readily demountable to allow for cleaning.

Control of bench extract systems

7.156 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the bench extract and any associated make-up supply can be shut down. However, a run-on timer with a minimum setting of 30 minutes must be provided. To this end, local or automatic-use control should be provided.

7.157 Processes that produce hazardous vapours, fumes, dusts or noxious vapours should be enclosed or semi-enclosed in a suitable cabinet or exhaust protected workstation.

Safety cabinet and fume-cupboard extract systems

7.158 Safety cabinets and fume cupboards are devices that use an inflow of air to control exposure of staff to hazardous substances. The units, their exhaust systems, filters, fans and discharge terminals are all classified as Local Exhaust Ventilation (LEV) systems under the COSHH Regulations. The make-up air system to a room that contains an LEV system should also be considered as an essential part of the system and be included in the LEV classification. Information on the design and installation of microbiological safety cabinets is given in BS5726 and that for fume cupboards is given in BS EN 14175. Their recommendations should be closely followed.

7.159 The Advisory Committee on Dangerous Pathogens (ACDP) publishes 'The Management, Design and Operation of Microbiological Containment Laboratories' covering the general environment in which they are used and operational considerations.

Special requirements

7.160 The supply-air system should not distort the unidirectional and stable air pattern required for fume cupboards and microbiological safety cabinets. In general, supply-air ceiling diffusers should not discharge directly towards fume cupboards or safety cabinets, unless the terminal velocity is such that the air-flow pattern of the cabinet is unaffected. The design should ensure that high air-change rates, and/or the opening and closing of doors do not have any adverse effect on the performance of safety cabinets or fume cupboards. A damped door-closure mechanism may help.

7.161 In order to safeguard the user, all safety cabinets and fume cupboards must be fitted with a clear indication that they are operating correctly. Direct-reading gauges or falling-ball indicators are preferred (in addition to electronic pressure indicators). The system should be set to alarm audibly if the face velocity falls below the minimum safe operating level.

Arrangements for safety cabinet installations

7.162 The manufacture and installation of microbiological safety cabinets must be in accordance with the relevant national standards and guidance issued by the Advisory Committee on Dangerous Pathogens (ACDP).

7.163 A Class 1 microbiological safety cabinet must be specified for routine work involving Group 3 pathogens. It should be housed in a Category 3 containment room. Specific design information on containment rooms is issued by ACDP in conjunction with the Health and Safety Commission.

7.164 Siting and installation of microbiological safety cabinets are of particular importance because:

- the protection afforded to the operator by the cabinet depends on a specific and stable unidirectional air flow through the open front;
- the protection to the environment by the cabinet depends on the high efficiency particulate air (HEPA) filters. The exhaust air should never be considered as totally free from microbiological hazard.

7.165 Microbiological safety cabinet is HEPA filtered prior to being discharged to outside. The extract ductwork should as far as practicable be kept under negative pressure while inside the building.

7.166 Current standards permit the installation of microbiological safety cabinets with integral fans, provided that the extract ductwork can be kept short (that is, less than 2m); such an installation however, is likely to be noisy and is not recommended for use in new buildings.

7.167 The discharge from the cabinet should be fitted with a back-draft damper. In multiple installations where several cabinets discharge into a common extract and discharge duct, it must be possible to isolate each cabinet from the system when not in use.

7.168 Roof-level discharge, wherever practicable, is preferred since it removes much of the uncertainty over air re-entering the building through ventilation inlets and/or windows. In such an installation, the extract fan should be situated separately from the cabinet and close to the discharge outlet, to maintain the duct within the building under negative pressure. The discharge point on a flat roof should be through a 3m high terminal. This is required to safeguard staff who may need to access the roof periodically for maintenance. This requirement will also be applicable to fume-cupboard discharges.

7.169 Where this is impracticable, discharge into the room via a double HEPA filter has been accepted. The preferred method, however, is to discharge 3m above the roofline in line with the similar standard for fume cupboard designs.

Arrangements for fume cupboard installations

7.170 The manufacture and installation of fume cupboards must be in accordance with the relevant national standards and associated guidance.

7.171 The primary factors that contribute to the effective performance of fume cupboards include:

- an adequate volume of supply air;
- an effective exhaust system to promote the safe dispersal of waste products to atmosphere.

7.172 The air velocities through sash openings must be sufficient to prevent hazardous materials from entering the laboratory while avoiding excess flow rates that interfere with the investigation process. Average face velocities should be between 0.5 and 1.0 m/s, with a minimum at any point within 20% of the average, the upper end of the range being applicable to the containment of materials of high toxicity. The design velocity must be maintained irrespective of whether the sash opening is varied, or whether doors or windows are open or closed. Variable Air Volume (VAV) cupboards are available which offer a reduction in energy use.

7.173 The possibility of a fire or explosion that may not be contained by a fume cupboard must always be considered. A fume cupboard should not, therefore, be sited in a position where exit to an escape route will necessitate passing directly in front of it.

7.174 Fume-cupboard fans should be installed as near as possible to the termination of the duct, thus maintaining the maximum amount of ductwork at negative pressure.

7.175 Where there are adjacent buildings with opening windows, or where downdraughts occur, it may be necessary to increase the height of discharge ducts in order to achieve adequate dispersal. In complex locations, airflow modelling or wind tunnel tests may be required to determine the optimum height of the stack (see also Paragraph 7.167).

7.176 Fume-cupboards for certain processes must have separate extract systems. However, where appropriate, individual fume-cupboard exhaust systems may discharge via non-returning dampers into a single collection duct rather than having a large number of separate stacks. The collection duct should have a large cross-sectional area to minimise its effect on the individual exhaust systems; be open to atmosphere upstream of the first connection; and be designed to discharge a total air volume at least equal to the combined individual extract systems.

7.177 Individual fume-cupboard extract systems, discharging either directly to atmosphere or into a collection duct, do not require duplex fans. However, a collection duct designed to provide dispersal of effluent from a number of individual extracts, should have duplex fans with automatic changeover.

7.178 Some fumes are particularly corrosive, so the choice of material for the ductwork, and type of extract fan fitted should reflect the nature of the fume being conveyed.

Control of extract systems

7.179 It is desirable to provide local control of safety cabinets in order to maximise the life of the HEPA filter, and to permit the sealing of the cabinet and room for fumigation if spillage occurs.

7.180 To cope with the risk of an accident or spillage outside safety cabinets, a 'panic button' should be provided to switch off the supply to that area; and discharge all extracted air to atmosphere.

7.181 In pathology departments, it will be necessary to have one or more microbiological safety cabinets and one or more fume cupboards available for use at all times, including weekends, therefore, local overriding controls for all these items and any associated ventilation plant will be necessary.

7.0(d) Plantroom ventilation

General requirements

7.182 Plant rooms are required to be ventilated in order to maintain acceptable temperatures for satisfactory operation of the plant and controls, and for maintenance activities. In the case of plant rooms housing combustion equipment, a secondary function of the ventilation is to provide make-up air for the combustion process.

7.183 The air required for these purposes should be introduced into the space through inlets positioned to minimise the discomfort to occupants; they should be unlikely to be blocked, closed deliberately (except in the case of fire shutters if required), or rendered inoperative by prevailing winds.

7.184 Plantroom ventilation air should not be used for any other purposes, such as make-up air for extract; and where the plantroom contains combustion equipment, the appliance pressure must not fall below the outside air pressure.

7.185 Specialised healthcare air handling equipment must not be located in a fire compartment that houses combustion equipment.

7.186 Statutory regulations for plantroom ventilation are contained in the Scottish Building Regulations, and further guidance is given in CIBSE Guides A & B.

Assessment of ventilation levels

7.187 Ventilation requirements must take into account all heat sources within a plantroom, and where there are large glazing areas, solar gains. The ventilation rate should limit the maximum temperature within the plantroom to 32°C.

7.188 As the level of equipment operating during mid-season and summer is often lower than the winter condition, and the cooling effect of the outside air is reduced, it is necessary to calculate the minimum volume for each season of operation, and the inlet and outlet grilles or fan sizes should be chosen to cater for the largest seasonal air volume.

7.189 Replacement air should not be drawn through pipe trenches or fuel service ducts. Where metal ducts penetrate walls and floors, effective sealing should be provided to confine the ventilation to the boiler room and to meet fire protection requirements. Penetration of fire barrier walls by ventilation ducts should be avoided if possible.

7.190 Fire dampers in plant room ventilation ducts should be electrically interlocked with the boiler plant.

7.191 Care must be taken to prevent any noise generated in the boiler room emerging from natural or mechanical ventilation openings to the detriment of the surrounding environment. Particular care is necessary with mechanical flue draughts and fan-diluted flue systems.

7.192 Information on required air volumes in contained in the CIBSE Guide A & B.

7.193 Where combustion plant is installed, the high-level (outlet) openings should be sized to cater for the total ventilating air quantity; and the low-level (supply) openings sized to cater for the total combined ventilating and combustion air quantity.

Choice of ventilation system

7.194 Ventilation air may be introduced and exhausted by either natural or mechanical means or a combination of both. However, natural systems are preferred where possible.

7.195 Generally, small installations at or above ground level should have their combustion and ventilation air provided by natural means, employing both high- and low-level openings.

7.196 Basement, internal and large installations at or above ground level will usually require a combination of natural and mechanical ventilation. If the airflow rate is difficult, both supply and extract may require mechanical means.

7.197 Whether natural or mechanical, the system should be designed to avoid both horizontal and vertical temperature gradients. Both inlet and outlet openings should be placed on opposite or adjacent sites of the building to reduce the effect of wind forces.

7.198 Where mechanical air supply is employed, electrical interlocks with the boiler plant should be provided to prevent damage in the event of failure of the supply fan(s) once the air volume is established.

7.199 The necessary free opening areas for a naturally ventilated plantroom may be calculated using either the method in A4 of the CIBSE Guide A or the table in section B13 of CIBSE Guide B.

7.200 A combined natural and mechanical ventilation system should allow for natural extract at high level, to take advantage of convective forces in the room, with mechanical supply at low level. The high level natural ventilators should be sized to cope with the total quantity of ventilation air, as above.

7.201 To prevent leakage of flue gases and to ensure that the flue draught is not impeded at any time, the air pressure in the boiler room must not exceed the prevailing outside pressure. Therefore, the fan duty should exceed the calculated total combined combustion and ventilation air quantity by at least 25%. Fan-powered inlets should be arranged to flow outside air into the space at a point where cross-ventilation will ensure pick-up of heat without causing discomfort to occupiers.

7.202 Where it is impractical to provide sufficient natural ventilation to remove the heat emitted by the plant, both mechanical supply and extract will be required.

7.203 The high-level extract should be sized to cater for the total ventilating air quantity and the low-level supply should exceed the total combined combustion and ventilating air quantity by at least 25%, as above.

7.0(e) Ventilation of hydrotherapy suites

General requirements

7.204 In a hydrotherapy suite heat recovery should be via heat pump.

7.205 The quantity of supply air should be calculated as 25 litres/sec/m^2 wetted surface, with the wetted surface taken as 110% of the pool water surface area.

7.206 A re-circulation plant is recommended, with a minimum of 20% fresh air.

7.207 As far as practicable, re-circulated pool air should be provided to the ancillary changing and recover accommodation, with the only extract from the toilets, laundry/utility room and pool hall.

7.208 Supply air to the pool hall should be introduced at high level and directed towards the perimeter to mitigate condensation, with extract air taken from directly over the pool. Dampers should not be located over the pool water.

Control of hydrotherapy pool installations

7.209 The supply and extract fans should be interlocked so that the supply fan does not operate until flow is established within the extract system.

7.210 Time-clock control should be provided, with a local override switch to extend the normal operating period as required.

7.211 Night setback temperature (in the range of 21°C -25°C) and high humidity control (in the range of 60-75% sat) should be provided to override the time clock in order to prevent condensation. The exact set points should be ascertained post-installation.

7.212 A remote indication panel should be provided in the pool hall, giving a visual display of the pool water and pool air temperature.

8. Validation of specialised ventilation systems

Definitions

Commissioning - Commissioning is the process of advancing a system from physical completion to an operating condition. It will normally be carried out by specialist commissioning contractors working in conjunction with equipment suppliers. Commissioning will normally be the responsibility of the main or mechanical services contractor.

Validation - A process of proving that the system is fit for purpose and achieves the operating performance originally specified. It will normally be a condition of contract that "*The system will be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.*"

Note: Commissioning is often sub divided into sections e.g. air handling unit, automatic controls, airside balance, building fabric and fittings. Each section may be commissioned by its specialist installer and they are often accepted in isolation. Validation differs from commissioning in that its purpose is to look at the complete installation from air intake to extract discharge and assess its fitness for purpose as a whole. This involves examining the fabric of the building being served by the system and inspecting the ventilation equipment fitted as well as measuring the actual ventilation performance.

It is unlikely that 'in house' staff will possess the knowledge or equipment necessary to validate critical ventilation systems such as those serving operating suites, pharmacy clean rooms and local exhaust ventilation systems. Validation of these systems should therefore be carried out by a suitably qualified independent Authorised Person appointed by the NHS Board.

It is anticipated that training in the validation of specialised healthcare ventilation systems for independent Authorised Persons will become available during the life of this SHTM.

Commissioning general

8.1 Commissioning is an essential process for ventilation systems. It is therefore important that adequate provision for the process be made at the design stage of the project. Procedures for commissioning air-handling systems are given in CIBSE Commissioning Codes and BSRIA Application Guide Set COMPAK 1.

8.2 The duct-sizing procedure should take into account the requirements of system balancing, and the position and number of regulating dampers included in the design should be sufficient for this purpose.

Location of dampers and test holes

8.3 Balancing/commissioning dampers will be required in each branch of the distribution ductwork.

8.4 Test holes for the measurement of air-flow will be required at carefully selected points in main and all branch ducts. The number and spacing of holes are given in the BSRIA Application Guide Set COMPAK 1. Their positions must be identified at the design stage.

8.5 The test positions need to be accessible for commissioning to take place. They may also be required for subsequent annual verification of the system performance, so they should not be covered by permanent lagging.

8.6 The measurement point should be in a straight length of duct as far away as possible from any upstream bends, dampers or other elements that could cause disturbance to the airflow. The actual location should be:

- at least 1.5 duct diameters upstream of sources of turbulence such as dampers and bends;
- if this is not possible, 10 diameters downstream of dampers, bends or tees, and 5 diameters downstream of eccentric reducers;
- where there is enough space round the duct to insert the pitot tube and take readings;
- where the duct has a constant cross-sectional area.

8.7 Test holes for measuring total airflow from a fan should be located either 4 diameters upstream or 10 diameters downstream of the fan. Provision should also be made for measuring the speed of rotation.

Information to be provided

8.8 It is essential that the designer should pass on his intentions fully to the commissioning engineer by indicating which parts of the system are high, medium and low pressure, and by providing:

- relevant parts of the specification;
- schematic drawings indicating performance data as indicated in Table 8;
- equipment schedules;
- controller and regulator schedule;
- fan performance curves;
- wiring diagrams for electrical equipment, including interlock details.

Items in system	Information to be provided
Fans	Fan total pressure Volume flow rate at high and low speed Maximum motor current
Plant items	Type and identification numbers from equipment schedules Fluid and air volume flow rates Fluid and air side pressure losses Dry bulb temperatures Wet bulb temperatures Humidity
Dampers, including motorised and fire dampers	Identification numbers from equipment schedules Location Identification number Volume flow rate
Main and branch ducts	Dimensions Volume flow rates and velocities Identification numbers from equipment schedules
Terminal	Location Identification number Grille or diffuser factor Volume flow rate and neck velocity Operating static pressure
Test holes and access panels	Location Identification number
Controllers	Set points

Table 8: Information to be provided on schematic drawings

Notes: For Table 8

1. Fan total pressure is the difference between the total pressure (static pressure + velocity pressure) at the fan outlet and the total pressure at the fan inlet.

2. Where volume flow rates are variable, maximum and minimum values should be provided.

Commissioning personnel

8.9 As one individual is unlikely to possess all of the required commissioning skills, a commissioning team is therefore usually needed. The objective of commissioning is to ensure that the necessary performance and safety requirements are met.

8.10 During the commissioning process a great deal of information will be generated which will form an invaluable future source of reference about the plant. It is essential to ensure that it is collected together in the form of a commissioning manual and handed over to the client on completion of the contract together with the 'as fitted' drawings. This information should be both in hard copy and electronic format.

8.11 In order to be successful the commissioning process must start before achieving practical completion as many parts of the system will become progressively less accessible. The correct installation of those parts will need to be witnessed and leak-rate tests carried out as construction proceeds. Failure to establish responsibility for commissioning early enough will delay the completion of the project or lead to unsatisfactory plant performance.

Commissioning brief

8.12 The commissioning team will require a detailed brief from the system designer. This should include:

- a 'user' brief comprising a description of the installation and its intended mode of operation;
- the precise design requirements with regard to the scheme of air movement, room static pressures, supply and extract air-flow rates and acceptable tolerances;
- full details of the design conditions both inside and out, for winter and summer together with the control strategy;
- equipment manufacturer's type test data, commissioning, operation and maintenance recommendations;
- drawings showing the layout of the system, positions of air-flow measurement test points, dampers, regulating devices and filters within the duct runs, together with sizes of ducts and terminal fittings. It will save time if these drawings are annotated with the design volumes and static pressures required at each branch and outlet point;
- wiring diagrams for all electrical equipment associated with the air handling systems including motor control circuit details and any interlocking and safety devices such as emergency-stop buttons adjacent to the item of plant.

8.13 The CIBSE Commissioning Code, Series 'A' – "Air Distribution", provides full guidance on the information that will be required by the commissioning team.

8.14 The designer should include in the contract document instructions on verifying the accuracy of test instruments that should be supported by reference to relevant calibration certificates.

8.15 The system, on completion, should be operated by the contractor as a whole and subject to performance tests in accordance with the contract requirements.

For critical systems, these may include independent validation of the system performance on behalf of the client.

8.16 Prior to dynamic commissioning, it is essential that builders' work in the area served by the system is complete, all rubbish and dust is removed, concealed plumbing (IPS-type) panels are in position and ceiling tiles are in place and clipped. Floors should be mopped and visible dust removed from all other surfaces.

8.17 Once the system is shown to meet the design intent the handover documentation should be completed. In the event of performance not being acceptable, the matter should be dealt with in accordance with the contract arrangements.

Pre-commissioning checks

8.18 The pre-commissioning checks consist of visual inspection, manual operation of equipment, static measurements and functional tests of individual components. They should be carried out prior to setting the system to work and undertaking the dynamic commissioning process set out in Paragraph 8.29 onwards of this guidance.

Standard of installation

8.19 During the installation of the system the following must be witnessed:

- that the plant and installations have been provided and installed in accordance with the design specification and drawings;
- that only approved sealants have been used in the installation;
- that all components function correctly;
- that the satisfactory sealing of access doors and viewing ports have been carried out;
- that air pressure tests and air-leakage tests on ventilation ducting have been carried out in accordance with the methods set out in the HVCA's DW/143: Ductwork Leakage Testing. It is usual to carry out these tests, a section at a time, as the ductwork is installed and before its insulation is applied. The results must be recorded in the commissioning manual;
- that gaps around doors and hatches are as specified in the design;
- that the correct operation of pressure stabilisers, control dampers, isolating and non-return dampers have been checked and installed in the correct orientation for air-flow;
- that test holes have been provided in their specified locations and are sealed with suitable grommets;
- that control dampers are secured and their quadrants fitted correctly;
- that any interlocks are operative and in accordance with specification;

- that the electric circuits are completed, tested and energised;
- that electric motors have been checked for correct direction of rotation both at full speed and set-back;
- that cooling and heating media are available at correct temperatures and pressures and in specified quantities;
- that the air-conditioning plant components and controls function correctly;
- that the air-conditioning plant interlocks and safety controls function correctly;
- that the plant is physically complete, insulation is applied and all ducts and pipework are identified as specified;
- that the building housing the ventilation plant is generally in a fit condition for commissioning and performance tests to commence, that is, windows, doors, partitions etc are completed, surfaces sealed and their final finish applied;
- that the areas containing the ventilation plant and those being served by it are clean;
- that access to all parts of the system is safe and satisfactory.

Cleanliness of installation

8.20 During installation it must be established that ductwork is being installed to the 'advanced level' as defined in the HVCA (2005) 'TR/19 – Guide to good practice: internal cleanliness of ventilation systems'. This specifically includes ensuring that ductwork sections arrive on site and are stored with their open ends sealed and that open ends remain sealed during installation to prevent the ingress of builders' dust.

8.21 Should any doubt exist whether the guidance has been observed, the ducts must be cleaned internally to restore them to this standard before being taken into use.

8.22 "Builders work" ducts of brick or concrete must be surface sealed to prevent the release of dust before being taken into use.

8.23 The area around the supply air intake must be free of vegetation, waste, rubbish, builders' debris or any other possible source of contamination.

Certification of equipment

8.24 The following test certificates should be assembled by the commissioning team and be available for inspection at any time during the contract period. They will form part of the handover information and should be placed in the commissioning manual:

- type-test performance certificates for fans;
- pressure-test certificates for:

  - heater-batteries;
  - cooling coils;
  - humidifiers (if appropriate);
- type-test certificates for attenuators;
- type-test certificates for primary and secondary filters;
- individual test certificates for high efficiency particulate air (HEPA) filters.

Equipment tests

8.25 Prior to setting the system to work, the checks in Paragraphs 8.26 - 8.28 should be witnessed, and proving tests should be carried out as detailed.

Filters

8.26 The quality of filter housing and in particular, the seals is a critical factor in maintaining the efficacy of the filtration system by ensuring that air does not bypass the filter panels. Therefore, the following checks should be made:

- filter seals should be fitted and in good condition;
- filters should be installed correctly with respect to air flow;
- bag filters should be installed so that the bags are vertical and their pockets free;
- HEPA filters should be installed in a sealed housing and their seals tested to DIN 1946 if specified;
- all filters should be checked to ensure they are free of visible damage;
- the differential pressure indicators should be checked for accuracy and that they are marked with the initial and final filter resistance.

Drainage arrangements

8.27 The drain should conform in all respects to the “Design considerations” of this SHTM. In addition the following must be proved:

- that the drain tray is easily removable;
- that a clear trap is fitted and is easily removable;
- that the drain has a clear air gap of at least 15mm;
- that the pipework is supported so that the air break cannot be reduced;
- that the drain system from each drain tray is independent up to the air break;
- that the operation of the drainage system is proved by introducing water into the duct at the drain tray and observing that it completely drains out. This check is to be repeated both at normal speed and set back once the fans

have been commissioned. At this time the clear trap can be marked to indicate the normal water level with the fan running.

Fire dampers

8.28 The following must be witnessed and proving tests should be carried out as detailed:

- the operation of all fire dampers;
- the access provided to enable the dampers' to be visually inspected and / or re-set should be sufficient for the purpose;
- indication should be provided of the dampers' position (open/tripped);
- indication of the fire dampers' location should be provided both on the ductwork and at a visible point on the building fabric if the ductwork is concealed.

Dynamic commissioning

Air-handling and distribution system

8.29 The fan drive, direction of rotation, speed and current drawn should be set in accordance with their manufacturer's instructions.

8.30 After the installation has been checked to ensure that it is in a satisfactory and safe condition for start-up, it should be set to work and regulated to enable the plant to meet its design specification. The proportional balancing method described in the CIBSE Commissioning Code "A" must be followed. The air-flow rates must be set within the tolerances laid down in the design brief. This will normally be the design airflow rate +10% -0%.

8.31 When combined supply and extract systems are to be balanced and the area that they serve is to be at or above atmospheric pressure then the supply should be balanced first with the extract fan switched off, and then the extract balanced with the supply fan(s) on.

8.32 For combined systems where the area that they serve is to be below atmospheric pressure then the extract should be balanced first with the supply fan switched off and then the supply balanced with the extract fan on.

8.33 On completion of the balance all volume air-flows in supply and extract ducts and from grilles and diffusers must be measured and recorded. The true air change rate can them be calculated from the data obtained.

8.34 The main supply and extract duct volume control dampers must be locked and their position marked.

8.35 All grille and diffuser volume control registers must be locked to prevent alteration and their final position marked.

Room air distribution

8.36 The pressure-relief dampers and pressure stabilisers must be set to achieve the specified room static pressures and locked. The grille direction control vanes and diffuser cones must be set to give the specified air-movement pattern. Visualisation techniques may need to be employed in order to prove that the required air-flow pattern is being achieved. This may be a potential requirement when commissioning LEV systems or rooms that contain them.

Air-conditioning plant

8.37 The specified flow rate and/or pressure drops must be set for all heater batteries, cooling coils and humidifiers. The methods described in the CIBSE Commissioning Codes "W" and "R" should be followed. On completion their regulating devices must be locked to prevent alteration.

Control system

8.38 The control system should not be commissioned until both the air distribution system and air-conditioning equipment have been commissioned.

8.39 Because of the specialised nature of control systems and the fact that each manufacturer's system will contain its own specialist components and settings, the commissioning should be completed by the supplier and witnessed by a representative of the user.

8.40 The location of all control and monitoring sensors should be checked and their accuracy proved.

8.41 The control system's ability to carry out its specified functions must be proved.

8.42 If the plant is provided with a "user's" control panel in addition to the one located in the plantroom then the operation of both must be proved. This will typically apply to operating departments and laboratory systems.

Specific performance standards

Air movement

8.43 The performance of the system should be measured and compared with information provided by the designer.

Plant capacity and control

8.44 When setting to work and proving the design, both the manufacturer of the air-handling plant and the control specialist should attend site together and jointly commission the system.

8.45 If any doubt exists as to the capacity of the installed system, then its ability to achieve the specified inside design conditions with the plant operating at winter

and summer outside design conditions must be proved. Artificial loads will be required in order to simulate the internal gains/losses and the outside design conditions.

8.46 On completion of the plant performance test, recording thermo-hygrographs should be placed in each room/area served by the plant and also the supply air duct upstream of the frost battery. The plant should be run for 24 hours with all doors closed. During this period the inside conditions must stay within the tolerances specified. The BEMS should be used to obtain the information required wherever possible. Periodic tests will be required during the defects liability period.

Noise levels - general

8.47 The commissioning noise level is the level measured with a sound-level meter in the unoccupied room and taking account of the external noise together with the noise generated by the ventilation system. When occupied and in use this commissioning level will constitute a continuous background noise that will allow the overall noise level to be achieved. The ventilation plant design noise level is that generated by the plant alone with no other noise source being considered. The levels suggested make recognised allowance for the ingress of environmental noise.

8.48 The noise levels apply at the maximum velocity for which the system is designed to operate. Acoustic commissioning tests should be carried out with all plant and machinery running normally and achieving the design conditions of airflow, temperature and humidity.

8.49 An industrial-grade sound-level meter to BS3489 or IEC 651 Type 2 will normally be sufficient to check the noise level.

8.50 The noise level readings are to be taken at typical normal listening position 1.5m above floor level and at least 1m from any surface and not on any line of symmetry. In critical rooms the noise should be measured at the centre of the room and at the centre of each quarter. The mean of the 5 readings should then be calculated.

8.51 In the event of a contractual deficiency, a Type 1 precision-grade sound-level meter should be used and the noise level determined by the procedure given in Scottish Health Technical Memorandum 08-01 (2011).

Filter challenge

General ventilation filters

8.52 In-situ performance tests will not normally be required for primary and secondary filters and their housings. However the filters should be visually inspected for grade, tears, orientation and fit within their housing. Filters should be clean and a replacement set available. Bag filters should be installed so that

their bags are vertical and spaced so that air can move through them freely. Any filter found to be wet should be replaced and the cause investigated.

HEPA filters (for exhaust protective enclosures and laboratories)

8.53 Pathogenic material may be discharged through damaged or badly installed HEPA terminal filters. The complete installation must be tested using the method set out in BS EN: 14644 'Method of Testing for the Determination of Filter Installation Leaks'.

8.54 The challenge tests may be carried out using either of the following techniques:

- use Dispersed Oil Generator (DOP) to provide the challenge and a photometer to detect leaks;
- use a Discrete Particle Counter (DPC) to detect leaks. (In order to obtain a sufficient challenge it may be necessary to remove temporarily the supply AHU secondary filters).

8.55 In both cases the upstream challenge should be measured. A measurement of particle penetration through a representative section of the HEPA filter media is then taken and used as the reference background level. These two readings enable the range of the detecting instrument to be set.

8.56 A challenge aerosol of inert particles of the type produced by a DOP generator should be introduced into the air, upstream of the HEPA filter. The downstream face of the filter, its mounting seal and housing would then be scanned for leakage using a photometer. A leak should be deemed to have occurred if a steady and repeatable reading on the photometer at any point exceeds 0.01% of the upstream reading.

8.57 Alternatively a Discrete Particle Counter (DPC) may be used. For the Discrete Particle Counter method the filter face is sampled at several points to establish the smallest non-penetrating particle size. If particles at or above this size are detected when subsequent scans of the filter face, its seal and housing are made, then there is deemed to be a significant leak at, or near, the test position.

8.58 Should the HEPA filter fail this test it must be replaced. Should the filter mounting seal or housing fail this test it may be repaired and the test repeated.

Bacteriological sampling

General ventilation systems

8.59 Bacteriological sampling will not normally be required for either general or local exhaust ventilation (LEV) systems unless otherwise specified.

Conventional operating rooms

8.60 The level of airborne bacteria introduced by the supply air can be checked by closing all doors and leaving the operating room empty with the ventilation system running for 15 minutes. An active air sampler set to 1 cubic metre and mounted on the operating table should then be activated remotely. Aerobic cultures on non-selective media should not exceed 10 bacterial and/or fungal colony forming units per cubic metre (CFU/m^3).

8.61 The results should be examined to establish the broad category of organisms present. A high preponderance of fungal organisms may be an indication of inadequate filtration for the particular installation. Precise guidance is inappropriate and will depend on local circumstances.

8.62 It may be appropriate to carry out a check of airborne bacteria during a surgical operation. If required this should be carried out as soon as possible after handover. Unless there are unusually high numbers of personnel or extensive activity in the room, the number of airborne bacterial and/or fungal CFU averaged over any five-minute period, would be unlikely to exceed 180 per cubic metre.

8.63 Information on the additional validation testing of UCV Operating suites is given in Section 8.0(a).

Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:

- the user department;
- infection control (where required);
- estates and facilities.

8.0(a) Validation of UCV operating suites

General

8.66 Commissioning of a UCV terminal will normally be carried out by its supplier. Commissioning of the air-handling unit, fire dampers, distribution ductwork and control systems may be undertaken by different teams. It is therefore important to recognise that the UCV terminal is only one element of the specialised ventilation system serving the operating suite and it cannot be accepted in isolation.

8.67 In order to ensure that the complete system operates correctly it will be necessary to validate the system as a whole from the air intake through to the extract discharge. It is unlikely that "in house" staff will possess the knowledge or equipment necessary to undertake this process. Validation of Ultra-Clean operating theatre ventilation systems should therefore be carried out by a suitably qualified independent Authorised Person appointed by the client.

8.68 It is anticipated that training in the validation of specialised healthcare ventilation systems for independent Authorised Persons will become available during the life of this SHTM.

8.69 The following regime of inspection and testing should be applied to the validation of new installations designed to provide Ultra-Clean conditions in an Operating suite. The test regime has been devised to ensure that the system as installed fully achieves the design requirement for these systems as set out in Section 7.0(b) of this document.

Basic requirement

8.70 The operating suite to be validated should be physically complete with final finishes applied. All ventilation systems serving it should be operating correctly and delivering the design air-flow rates.

8.71 In order to avoid pre-loading the UCV terminal's recirculation ducts and HEPA filters, the Operating suite should be free of any obvious dust and at least "builders clean" before the recirculation fans are set to work.

8.72 The validation procedure for a conventional theatre suite should have been satisfactorily completed to the standard set out in Section 8 prior to attempting to validate the UCV unit. In particular:

- the supply AHU will have achieved the minimum standard;
- the operation of all fire dampers will have been proved;
- the supply and extract air-flow rates as measured in ducts and at room terminals will achieve their design values +10%; -0%;
- room differential pressures will be correct.

Evidence of the satisfactory achievement of the foregoing standard should be available for inspection and independently measured as necessary *prior to validating the UCV unit.*

UCV unit validation procedure

8.73 Tests to validate the suitability and performance of an ultra-clean operating suite should be undertaken in the order that they appear below. Should an item fail to meet the required standard it should be rectified and successfully retested before passing on to the next test.

Summary of test regime

- Challenge tests to ensure that:
  - the UCV terminal unit is correctly assembled and sealed so that no air will bypass the filters;
  - the terminal filters are correctly sealed in their housings;
  - the terminal filters are of the same grade, of uniform quality and undamaged.
- Air velocity measurements to ensure that
  - a sufficient quantity of air is being delivered by the terminal;
  - the terminal quadrants are in balance;
  - the air flow has sufficient velocity to reach the working plane.
- An entrainment test to ensure that contaminants arising outside of the UCV terminal footprint are not drawn into it.
- Visualisation techniques to gain an understanding of the overall system performance.
- Noise measurement to ensure that working conditions are satisfactory.
- Control system checks to ensure that the system operates as specified.
- Biological monitoring to determine how effective the system is in use.

Test and measuring conditions

8.74 While validating the UCV terminal, the conditions in the Operating room shall be stable and within the given ranges.

temperature: – 19°C - 23°C dry bulb.

humidity: – 30 – 65% relative humidity.

Test and measuring equipment

8.75 Any test or measuring equipment used should have a certificate to prove that it has been validated within the previous 12 months at a calibration facility using traceable national standards.

8.76 In the case of a noise meter, its “matched sound source” should have a certificate to prove that it has been validated within the previous 12 months at a calibration facility using traceable national standards. The noise meter should be calibrated to the sound source on each occasion that it is used.

Test grid – vertical units

8.77 A test grid should be constructed on the floor within the ultra-clean terminal footprint as projected by the inside dimensions of the sidewalls or boundary air

curtain. A suitably marked test sheet will provide a consistent standard of test grid.

8.78 The test grid should comprise test squares of 280mm each side.

8.79 The test grid should be aligned along the centre lines of the terminal footprint with its centre under the centre point of the terminal.

8.80 Any test square with 80% of its area within the UCV footprint should be used as a test position.

8.81 An inner zone should be designated that is not less than 36% of the total footprint. It should be made up of a number of test squares distributed symmetrically about the terminal footprint centre line. Regardless of the shape of the terminal footprint, the inner zone should comprise a minimum grid of 6 x 6 test squares.

8.82 Unless specified otherwise, a test position should be in the geometric centre of a test square.

8.83 Test position 1 should be the leftmost test square in the row nearest to the operating room wall that houses the surgeon's panel.

(For an example of a grid for a 2.8 x 2.8 metre terminal see Figure 8)

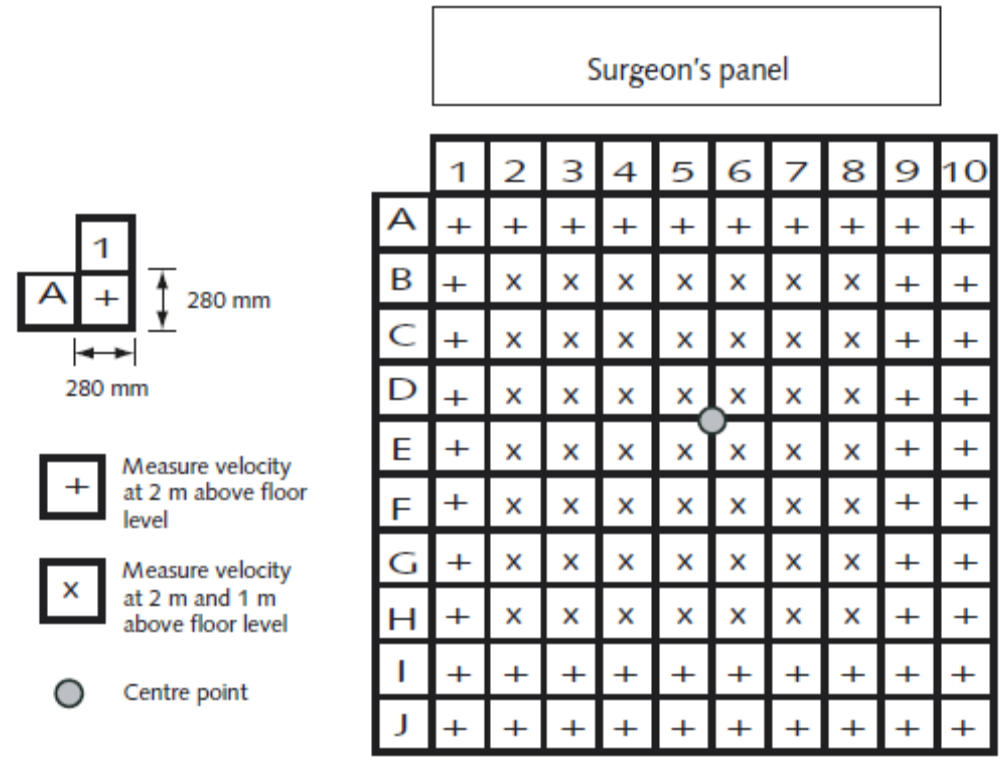

Figure 8: Example of a Test Grid for a 2.8m x 2.8m UCV Terminal

Test grid – horizontal units

8.84 A line of test positions should be marked on the floor 1m in front of the face of the UCV terminal.

8.85 A test position should be marked in the centre of the line. Additional test positions should be marked at 280mm spacing along the line either side of the centre position, up to the full-face width of the unit.

UCV terminal challenge tests (Vertical and horizontal systems)

8.86 The diffuser screen fitted below the face of the terminal HEPA filters should be lowered or removed while the challenge tests are being carried out.

8.87 The installed HEPA filters should be checked to ensure that their grade accords with the design specification and that their performance has been certified by the manufacturer.

8.88 The challenge tests may be carried out using either of the following techniques:

- use DOP to provide the challenge and a photometer to detect leaks;
- use a DPC to detect leaks. In order to obtain a sufficient challenge it may be necessary to remove temporarily the supply AHU secondary filters.

8.89 In both cases the upstream challenge should be measured. A measurement of particle penetration through a representative section of the HEPA filter media is then taken and used as the reference background level. These two readings enable the range of the detecting instrument to be set.

8.90 For the DOP test this should be set as the reference level and a leak will be declared significant if penetration greater than 0.01% of the range is detected. (See Paragraph 8.56 for details).

8.91 For the DPC method the filter face is scanned to establish the smallest non-penetrating particle size. If significant particles at or above this size are detected when subsequent scans are made then there is deemed to be a significant leak at, or near, the test position. (See Paragraph 8.57 for details)

UCV terminal unit clean zone leak test

8.92 This test will confirm that there is no unfiltered air bypassing the HEPA filter.

8.93 The joints and service penetration points under the UCV terminal within its side walls or boundary air curtain should be scanned to prove that there are no leaks.

8.94 A leak is defined as a significant rise above the background level.

Terminal HEPA filter seal leak test

8.95 The test will confirm that there is no unfiltered air bypassing the HEPA filter's seal.

8.96 Each HEPA filter's seal should be scanned to prove that there are no leaks.

8.97 A leak is defined as a significant rise above the background level.

Terminal HEPA filter media leak test

8.98 The test will confirm that the HEPA filters have not sustained damage while being installed.

8.99 The face of each HEPA filter should be scanned to prove that there are no leaks.

8.100 A leak is defined as a significant rise above the background level.

Vertical UCV terminal air velocity tests

Test set up

8.101 The terminal face diffuser screen should be in place for these tests.

8.102 Take spot readings to establish that the room is within the specified temperature and humidity test conditions.

8.103 Set out the test grid as described previously.

8.104 Swing the operating lamp arms and any other stem arms so that they align to present the least resistance to air flow, are perpendicular to the front edge of the test sheet and face the back edge. Any lamp and equipment heads should as far as practicable be outside of the UCV terminal footprint.

Test instrument

8.105 The measuring instrument should be a hot-wire anemometer with a digital read-out. The instrument resolution should be at least 0·01m/s, have a tolerance of ±0·015 m/s or 3% of that reading and be calibrated down to 0·15 m/s or lower. An alternative instrument may be used providing it is of no lesser specification.

Test method

8.106 The instrument should be mounted on a test stand and set to take a mean reading over a ten-second sample interval.

8.107 It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. Alternatively they could be downloaded to a computer or data logger at the end of the test.

8.108 The test stand to be positioned on each test point in turn and the reading taken when the instrument has stabilised.

8.109 When taking a reading the test person should not stand within the same quadrant as the test instrument.

8.110 Readings are to be taken at the test positions with the instrument probe facing the wall housing the surgeon's panel, commencing at the first test position.

Readings are taken working along the row from left to right and back, or for all text positions in one quadrant at a time.

8.111 When all test positions under one half of the terminal have been covered, readings of temperature and humidity are then taken at the specified height in the centre of the terminal. The read-outs on the surgeon's panel should be recorded at the same time.

8.112 Having completed one half of the test grid, the operating lamp arms and any other stem arms should be swung round through 180º and the test stand reversed so that the wall housing the surgeon's panel is behind the test person. Readings are recommenced starting at the right of the test row and working from right to left a quadrant at a time, as above.

UCV high-level discharge velocity test

8.113 Measurements of air velocity are to be taken at every test position 2m above floor level and the results averaged.

8.114 The average of the total readings taken is to be not less than:

0.38 m/s for a partial-wall system;

0.30 m/s for a full-wall system.

The average air velocity for each quadrant should not exceed ±6% of the measured average velocity for the terminal

UCV low-level air velocity test

8.115 Measurements of air velocity are to be taken at each of the inner zone test position 1m above floor level.

8.116 The measured velocity at every test position in the inner (operating) zone shall be not less than 0·2 m/s.

Horizontal UCV terminal air velocity test

Test set up

8.117 Set out the line of test positions as described previously.

8.118 Swing the operating lamp arms and any other stem arms so that they align to present the least resistance to air flow and are perpendicular to the line of test positions.

Test instrument

8.119 See that specified for vertical systems (Paragraph 8.105 refers).

Test method

8.120 The instrument should be mounted on a test stand and set to take a mean reading over a ten-second sample interval.

8.121 It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. Alternatively, they could be downloaded to a computer or data-logger at the end of the test.

8.122 The test stand should be positioned on each test point in turn and the reading taken when the instrument has stabilised.

8.123 When taking readings the test person should stand well downstream of the instrument.

8.124 Readings are to be taken at the test positions with the instrument probe facing the UCV terminal, commencing at the first test position on the left and working along the row from left to right at the specified height.

8.125 The instrument should be reset to the next specified height and the test repeated and so on.

8.126 Readings of temperature and humidity should be taken at the specified height in the centre of the terminal. The read-outs on the surgeon's panel should be recorded at the same time.

UCV discharge velocity test

8.127 Measurements of air velocity are to be taken at all test positions at 1m, 1·5m and 2m above floor level.

8.128 The average of the total readings taken should be no less than 0·4 m/s.

UCV entrainment test (Vertical systems only)

Rationale for the entrainment test

8.129 The performance of UCV systems may be compromised by room air being drawn into the ultra-clean airflow, a phenomenon known as "entrainment." Significant levels of entrainment could lead to microbial contamination of items left exposed on instrument trolleys laid out beneath the canopy.

8.130 UCV systems having permanently fitted full sidewalls do not need to be tested, as the sidewalls physically prevent entrainment.

Principle of the test

8.131 A source of particles is produced outside of the UCV terminal and is used to challenge the system. A detector is placed within the ultra-clean airflow and used to determine the percentage penetration of the test particles at predefined

locations under the UCV terminal footprint. The source and detector are moved in tandem around the UCV canopy and pairs of readings taken, from which the percentage penetration at specified locations is calculated. The degree of penetration should be below specified maximum limits if entrainment is to be declared not significant.

8.132 The entrainment test may be carried out using either of the following techniques:

- use DOPs to provide the challenge source at the specified release position and a photometer to measure the entrainment; or
- duct non-HEPA-filtered air to the specified release position and use a DPC to measure the entrainment.

Test set-up

8.133 The terminal face diffuser screen should be in place for these tests.

8.134 The test should be performed without any equipment in place beneath or closely adjacent to the UCV terminal.

8.135 The theatre lights should be moved to a central position beneath the terminal and raised to 2m above floor level, so as not to interfere with the peripheral airflows.

8.136 Take spot readings at the centre of the canopy, one metre from floor level, to establish that the room is within the specified temperature and humidity test conditions.

8.137 Set out the test grid as described previously.

8.138 For either of the following entrainment tests, a measurement of particle penetration through a representative section of the HEPA filter media is to be taken and used as the reference background level.

Test equipment, challenge source, measuring instrument and detector head

8.139 The challenge and detector equipment should be chosen so that:

- the tracer particles are mainly within the size range 0.3 to 5 microns and thus capable of remaining airborne for a substantial time;
- the particles used should not be able to penetrate the terminal filters in sufficient numbers to cause a background count that is more than 0.1% of the challenge count;
- the choice of particle and detector will enable a minimum of a three-logarithm (1,000-fold) range of counts to be recorded between the highest (that is, source) and lowest (that is, background) readings expected. (A concentration of approximately 10^5 particles per cubic metre of source air has been shown to be adequate.)

Source – Dispersed Oil Particles (D.O.P.)

8.140 The DOP generator should be able to produce a cloud of test particles in the form of a visible smoke. The test smoke should be delivered via an aperture so that it flows vertically downward from the lowermost edge of the partial wall, on the outside of the UCV canopy.

8.141 The test smoke is to be delivered via an aperture.

Note 4: To prevent undue contamination of the theatre and filters with deposits of oil, DOP should only be released for the minimum amount of time necessary to complete the test.

Challenge source – natural particles

8.142 The source unit should be a fan/blower or other method that takes non-HEPA-filtered air and expels it via a delivery head at the specified release position to provide the particle challenge. The challenge air should be delivered vertically downwards from the lowermost edge of the partial wall, on the outside of the UCV canopy, parallel to the airflow coming from the diffusers. The challenge air velocity should be the same as the measured average velocity at 2m from the terminal under test.

Note 5: The use of DOP for testing is gradually being phased out and replaced by a natural challenge measured with a DPC. At the time of writing research is under way to define more precisely a challenge source unit for natural particles. It is anticipated that such a unit, together with a matching test methodology, will become available during the life of this Scottish Health Technical Memorandum.

The detector (defined in terms of range and resolution)

8.143 This may be a photometer or a DPC. It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. The instrument should be capable of sampling a minimum a 28.3 litres of air per minute and in the case of the DPC, provide readings for particle size ranges from 0.3 microns to 5.0 microns and greater. The instrument should be compliant with the requirements of BS EN ISO 14644-1. An alternative instrument may be used providing it is of no lesser specification.

Test positions and orientation of source and detector

8.144 The test positions should be at the centre of each test square, as defined for the velocity test.

8.145 For rectangular UCV terminals, measurements of penetration are to be taken at the four corner test squares of the test grid and at intermediate positions along the line of test squares between the corners. The number of intermediate test positions will be as equally spaced as possible around the periphery with no fewer than 3 and no more than 5 complete test squares between test positions.

8.146 A further series of measurements are to be obtained around the periphery of the inner zone. Measurements of penetration are to be taken at the four corner test squares of the inner zone of the test grid and if necessary at intermediate positions along the line of test squares between the corners as equally spaced as possible, with no fewer than 3 and no more than 5 complete test squares between test positions.

8.147 A single measurement should be taken at the geometrical centre of the UCV terminal footprint. The centre measurement will be taken with the detector head mounted vertically upwards 1 metre above floor level.

8.148 The centre of the challenge particle source should be aligned with the centre of the designated test square, with its longer edge against the outer edge of the partial wall and delivering the challenge from the lower edge of the partial wall. The air containing challenge particles is directed vertically downwards from the lower edge of the partial wall, in a plane parallel to the adjacent partial wall. Where there is physical interference due to obstructions such as gas pendants, the source will be moved to the next available non-obstructed test-square location nearest to the stipulated sampling position. The detector should then also be moved to remain opposite the source.

8.149 In the case of non-rectangular terminals, an interpretation of the above strategy should be adopted that will yield a no less searching examination of the unit's ability to control entrainment.

Test method

8.150 The sampling head of the detector instrument is mounted on a test stand with its sampling orifice facing outwards horizontally from the centre of the UCV canopy, 1m above floor level. The sampling head should be orientated at right angles to the partial wall when sampling along the sides of the test grid but will be set to bisect the angle when measuring at the corner test positions (Figure 88 illustrates the challenge and detector orientations when evaluating a 2.8m x 2.8m UCV terminal).

8.151 The test will commence at the first test position, this being designated the leftmost corner of the test grid when facing the wall housing the surgeon's panel. The penetration will also be measured at the corresponding test point on the inner zone commencing at the corner nearest to the first test position. When these tests have been completed, the source and detector equipment should be moved to the next test positions, working around the test grid in a clockwise direction.

8.152 The test stand should be positioned on each test point in turn and a pair of readings (challenge, then penetration) taken when the instrument has stabilised. The detector should be set to take a reading over a 15 second sample interval.

8.153 When taking a reading the test person should stand within the UCV terminal footprint but not in the same quadrant as the detector head.

Analysis and interpretation

8.154 The following standard is to be achieved:

- penetration to be not greater than 10% of the challenge at each test position in the outer zone;
- penetration to be no greater than 1% of the challenge at each test position in the inner zone;
- penetration to be no greater than 0·1% of the challenge at the centre of the test grid.

If a result is close to, or above the given limits, then a further reading must be obtained using a longer time base (1 minute) and the penetration must not exceed the given limit.

Basis of the test

8.155 Whyte W, Shaw BH, Freeman MAR. An evaluation of a partial-walled laminar-flow operating room. *J Hyg Camb* 1974; 73: 61 – 75.

Whyte W, Lidwell OM, Lowbury EJL, Blowers R. Suggested bacteriological standards for air in ultraclean operating rooms. *J Hosp Infect* 1983; 4: 133 – 139.

UCV visualisation

8.156 The use of smoke to gain an understanding of the overall performance of the system may prove useful at this stage in the validation process but cannot be relied on to produce a contractually definitive measure of performance.

UCV noise level

8.157 An industrial-grade sound-level meter to BS EN 61672 Type 2 fitted with a muff should be used to check the noise level. The instrument should be calibrated using a matched sound source prior to each set of readings.

Vertical systems

8.158 The noise level readings should be taken at typical normal listening positions 1·5m above floor level and at least 1m from any surface and not on any line of symmetry. Measurements should be taken under the centre of each quadrant of the UCV terminal and the four readings averaged.

Horizontal systems

8.159 The noise level readings are to be taken at typical normal listening positions 1·5m above floor level on the test line. The width of the unit should be divided

in two and a measurement taken in the centre of each half but avoiding any line of symmetry. The two readings should be averaged.

8.160 Measurements should also be taken in each room of the suite.

8.161 In the event of a contractual deficiency a Type 1 precision-grade sound-level meter complying with BS EN 61672 should be used. Readings should be taken at the positions specified above and in each case the logarithmic mean of the results should be calculated in order to determine the noise level. Further information can be found in SHTM 08-01 (2011).

8.162 For vertical or horizontal systems, the noise level shall not exceed:

- 50NR [55dB(A)] – for UCV operating rooms and spaces without doors that open directly on to it (for example the scrub);
- 40NR [45dB(A)] – for all other peripheral rooms of the suite.

UCV control system checks

Temperature

8.163 The readings of temperature taken under or in front of the UCV unit should be within ±1 K of each other and the read-out on the surgeon's panel.

Humidity

8.164 The readings of humidity taken under or in front of the UCV unit should be within ±5% of each other and the read-out on the surgeon's panel.

Direct-reading differential pressure gauges

8.165 The differential pressure across the terminal filter(s) should be measured to confirm the accuracy of the indicated reading of any gauge.

Control functions

8.166 The operation of all control functions provided on the surgeon's panel should be proved for conformity with the design specification.

8.167 If an auxiliary panel has been fitted then its interlocking with the main surgeon's panel control functions must be proved to conform to the design specification.

Panel indicator lights

8.168 The panel indicator lights should illuminate as appropriate when the control functions are selected or warning levels are reached

BEMS interface

8.169 The operation, monitoring and alarm functions must be proved to conform to those set out in the design specification.

UCV theatre microbiological tests

8.170 There is little value in performing microbiological sampling in a new theatre supplied with ultra-clean ventilation. The foregoing filter challenge tests, air velocity measurements and entrainment test should have proved that the system operates satisfactorily and achieves the contracted level of performance. The HEPA filters will remove bacteria-sized particles from the air supplied through the UCV terminal. Therefore there will be an insignificant number of bacterial and/or fungal CFUs present until the Theatre is actually used.

8.171 Once the theatre has been taken into use, microbial sampling during a surgical procedure should help to confirm the satisfactory performance of the system and discipline of the users. Before commencing bacteriological testing, the room and its ventilation system should have achieved a steady state condition: (see also Paragraph 8.74)

8.172 The installation should be tested during surgical procedure at intervals between the time of the first incision and final closure of the wound. On average, the air sampled within 300mm of the wound should not contain more than 10 CFU/m^3.

UCV validation report

8.173 Following validation a full report detailing the findings should be produced. The report shall conclude with a clear statement as to whether the UCV theatre suite achieved or did not achieve the standard set out above.

8.174 A copy of the report should be lodged with the following groups:

- operating department;
- infection control;
- estates and facilities.

Appendix 1: Table A1: 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 Room	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 UCV 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

Table A1

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Application	Ventilation	ac/Hour	Pressure (Pascals)	Supply Filter	Noise (NR)	Temp (°C)	Comments For further information see Section 6
Recovery room	S & E	15	0	F7	35	*18-25*	Provide clean air-flow path
Cardiac catheterisation lab	S	15	+ve	F7	40	*18-22*	
Endoscopy room	S	15	+ve	F7	40	*18-25*	
Endoscopy cleaning	E	>10	-ve	-	40	-	
Day case theatre	S	15	+ve	F7	40	*18-25*	
Treatment room	S	10	+ve	F7	35	*18-25*	
Pharmacy aseptic suite	S	20	#	H14	-	*18-22*	# See EGGMP (Orange guide) a
Cat 3 or 4 containment room	#	>20	#	H14*	-	*18-22*	# See ACDP guide; *Filter in extract
Post mortem room	S & E	S = 10 E = 12	-ve	G4	35	*18–22*	Provide clean air-flow path
Specimen store	E	-	-ve	-	-	-	Fan accessible from outside of store

Table A1 continued

Notes: 18°C-22°C indicates the range over which the temperature may float

18°C-22°C indicates the range over which the temperature should be capable of being controlled

S = supply N = natural ventilation

E = extract [a] – European guidelines on good manufacturing practice published by the Medicines and Healthcare products Regulatory Authority (MHRA)

Appendix 2: Hierarchy of cleanliness

			Air-flow rate for bacterial contaminant dilution	
Class	**Room**	**Nominal pressure (Pa) a**	**Flow in or supply m^3/s**	**Flow out or extract m^3/s**
Sterile	Preparation room (a) lay-up (b) sterile pack store Operating room Scrub bay b	 35 25 25 25	See standard schemes in Appendix 3 for recommended design values	
Clean	Sterile pack bulk store Anaesthetic room c Scrub room	 +ve 14 c 14	6 ac/h The greater of 15 ac/hr or 0.15 -	- The greater of 15 ac/hr or 0.15 0.10
Transitional	Recovery room Clean corridor General access corridor Changing rooms Plaster room	3 0 0 3 3	15 ac/hr d e e 7 ac/hr 7 ac/hr	15 ac/hr d 7 ac/hr 7 ac/hr 7 ac/hr 7 ac/hr
Dirty	Service corridor Disposal room	0 -5 or 0	- -	f 0.41 or 0.10

Table A2

Notes (applicable to Table A2):

a. Nominal room pressures are given to facilitate setting up of pressure relief dampers, the calculation process, and the sizing of transfer devices. In practice, the resultant pressures are not critical, provided the desired airflow rates and movement are achieved.

b. An open or semi-open bay is considered to be part of the operating room; provided air movement is satisfactory, no specific extract is required. However if the layout means that air movement is poor, a local extract may be required to control local condensation on the building surfaces, which can result in mould growth.

c. For design purposes, anaesthetic should be assumed to be at 14Pa. When commissioning 10Pa is considered suitable.

d. 15 ac/hr are considered necessary for the control of anaesthetic gas pollution.

e. Supply airflow rate necessary to make up 7 ac/hr after taking into account secondary air from cleaner areas.

f. No dilution requirement. Temperature control requirements only.

Type	Pressure difference - Pa						
	5	10	15	20	25	30	40
Single door (CDB Size 2.4.3.2.6.)	.03	.05	.06	.06	.07	.07	.08
Double door (CDB)	.04	.08	.10	.11	.12	.13	.14
High permanent length of 3mm gap	.004	.008	.010	.011	.012	.012	.013

Table A3: Leakage flows in m^3/s through closed door gaps

Note: CDB = Component Data Base

It should be noted that many doors are now fitted with cold smoke seals as standard. These will significantly reduce the door leakage rate when new and undamaged. It is therefore recommended that provision for the design leakage is factored into the sizing of the appropriate transfer grille or pressure stabiliser. Failure to do this will result in air gap whistles and doors being held partially open by air pressure.

Factory-assembled door-sets with a steel frame and pre-hung leaves have become common. There is effectively no leakage across these doors when closed. Therefore, when this type of door assembly is fitted, the door leakage can be ignored and the design airflow into the room reduced accordingly. The design airflow would then become that required either (i) for open door

protection, or (ii) to achieve the specified air-change rate - whichever is the greater.

Room class		Dirty	Transitional	Clean	Sterile
Sterile	Hatch	0.3	0.24	0.18	
	Single door	0.47	0.39	0.28	0 or 0.28 a
	Double door	0.95	0.75	0.57	0 or 0.57 a
Clean	Single door	0.39	0.28	0 or 0.28 a	
	Double door	0.75	0.57	0 or 0.57 a	
Transitional	Single door	0.28	0 or 0.28 a		
	Double door	0.57	0 or 0.57 a		
Dirty	Single door	0	Open single door = 0.80m x 2.01m high		
	Double door	0	Open double door = 1.80m x 2.01m high		

Table A4: Recommended air flow rates in m^3/s through a doorway between rooms of different cleanliness to control cross-contamination

Designer's Notes:

a. The degree of protection required at an open doorway between rooms is dependent upon the degree of difference in cleanliness between them.

b. Flow rate required between rooms within the same class tends to zero as class reduces.

c. If two rooms are of equal cleanliness, no flow is required (in practice there will be an interchange in either direction) and the design of the air movement will assume zero air-flow. In certain cases, however, interchange is not permitted and protection airflow of 0.28 is assumed in the design, for example, in the case of a preparation room used as a "lay up".

		Effect on other rooms	
Door open between	Resultant pressure in these rooms (Pa)	Room	Pressure (Pa)
Operating room and corridor or Scrub bay and corridor	0	Anaesthetic Preparation – lay up Disposal Preparation – sterile pack store	0 12 -6 5
Operating room and anaesthetic room (or other series room with double doors)	17	Preparation – lay up Disposal Preparation – sterile pack store	26 -9 22
Operating room and disposal room or Operating room and preparation room	25	No change	
Anaesthetic room and corridor (or other series room with double doors)	0	Preparation – lay-up Disposal Operating room Preparation – sterile pack store	30 -6 20 25
Preparation room – corridor Disposal room & corridor	0	No change	
Disposal room & outer corridor	0	No change	

Table A5: Typical pressures in an operating suite when a given door is open

Notes: 1. The room differential pressure protects against reverse flows when the door is closed.

2. The flow of air through a doorway protects against reverse airflow when the door is open.

3. Pressure stabilisers control flow and ensure a known air-flow path between rooms when doors are closed and reduce back-flow between rooms when doors to other rooms are open.

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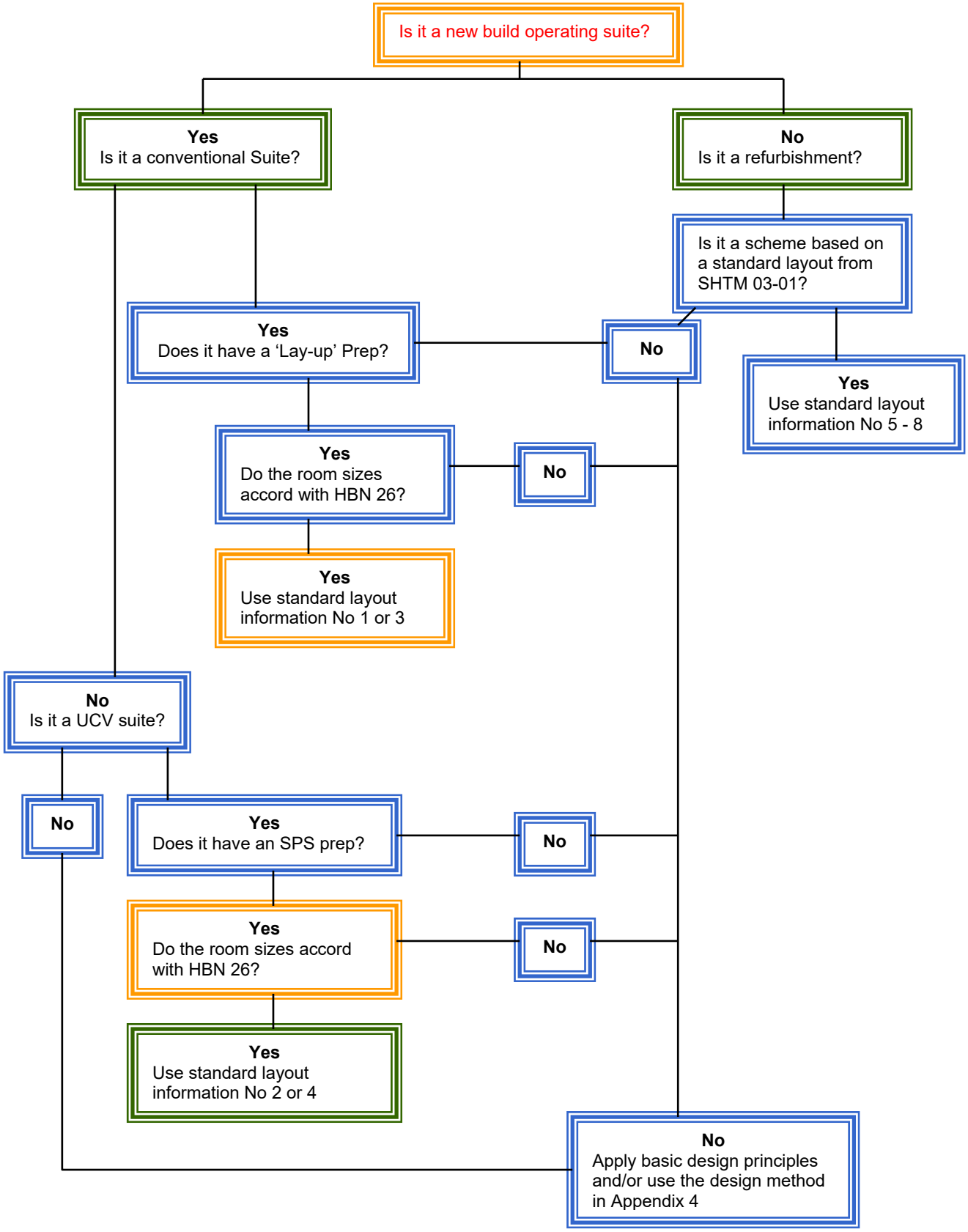
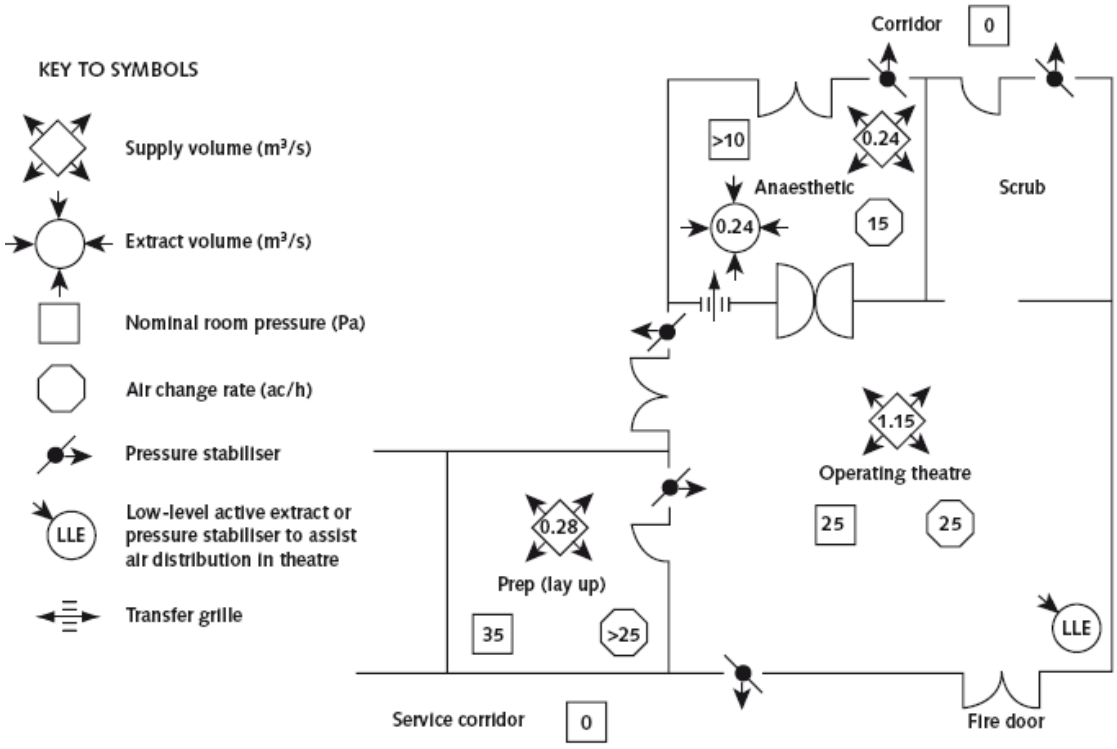
Appendix 3: Operating suite design logic



New Standard Layout N^{o} 1 - Suitable for a typical conventional theatre suite (Room sizes as specified in HBN 26)



Room	Size m^3 Derived from HBN26	Air-Change Rate per hour	Nominal Pressure Pa	Flowrate m^3/s
Theatre	165	25	25	1.15
Anaesthetic	57	15	>10	0.24
Lay-Up-Prep	36	>25	35	0.28**
Scrub	*	-	25	-

*This is a separate scrub and is not considered as being part of the theatre volume.

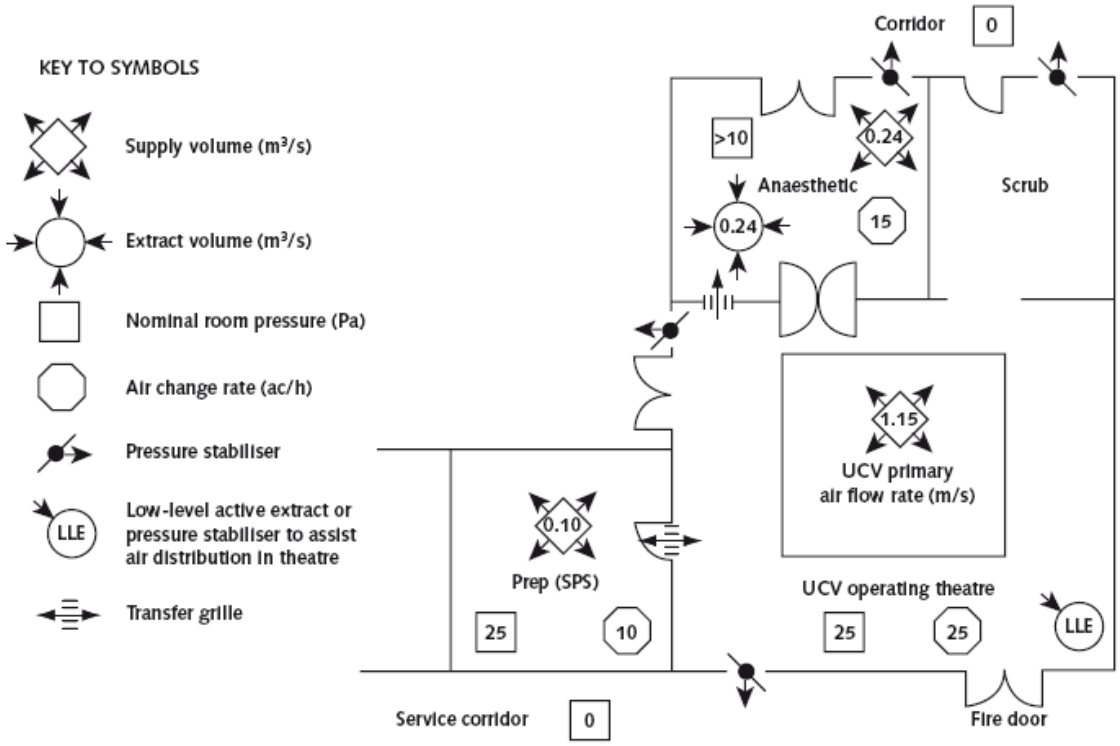
**Interchange is not permitted between the theatre and lay-up prep; therefore an airflow protection of 0.28 + 0.06 closed-door airflow is required as a minimum.

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the exits from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should be

located at low level and positioned to promote the ventilation of all areas of the space.

New standard layout N° 2 - Suitable for a typical UCV theatre suite (Room sizes as specified in HBN 26)



Room	Size m³ Derived from HBN26	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m³/s
Theatre	165	25	25	1.15**
Anaesthetic	57	15	>10	0.24
Sterile Prep	36	25	25	0.10
Scrub	*	-	25	-

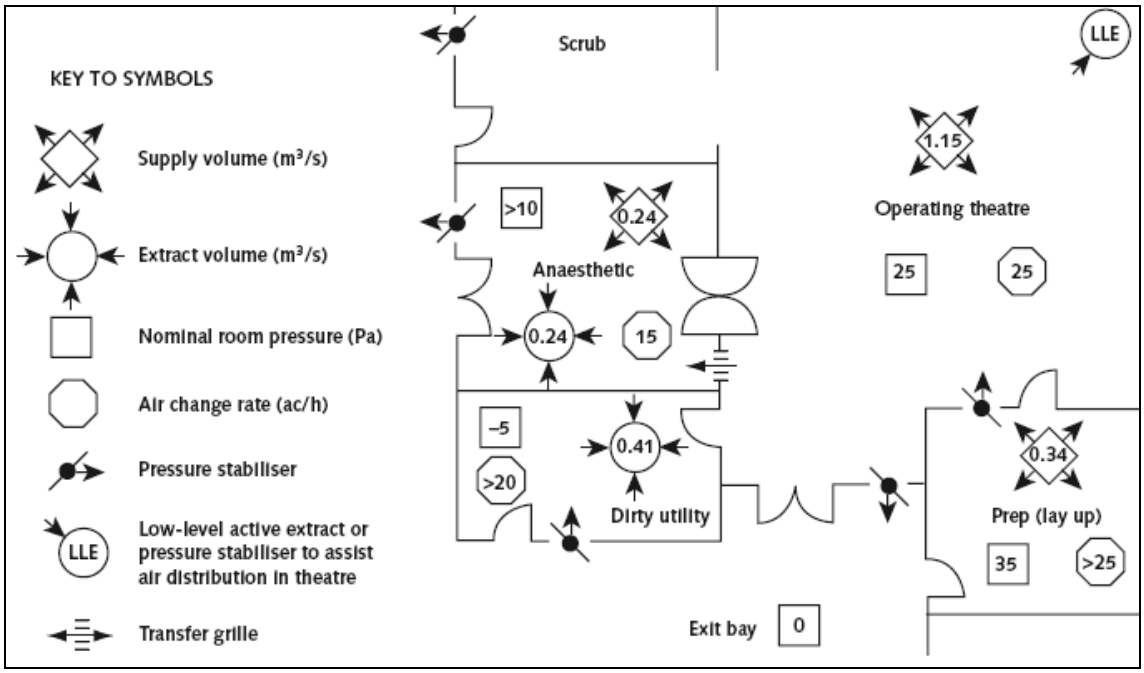
*Separate scrub and not considered as part of theatre volume

**Primary Fresh air Volume Only

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the exits from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilizers or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space.

New standard layout N° 3 - Suitable for a typical Conventional theatre suite (Layout and room sizes are as illustrated in HBN 26)



Room	Size m³ Derived from HBN26	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m³/s
Theatre	165	25	25	1.15
Anaesthetic	57	15	14	0.24
Lay-Up Prep	36	>25	35	0.34**
Scrub	*	-	25	-
Dirty Utility	36	-	-5	0.41

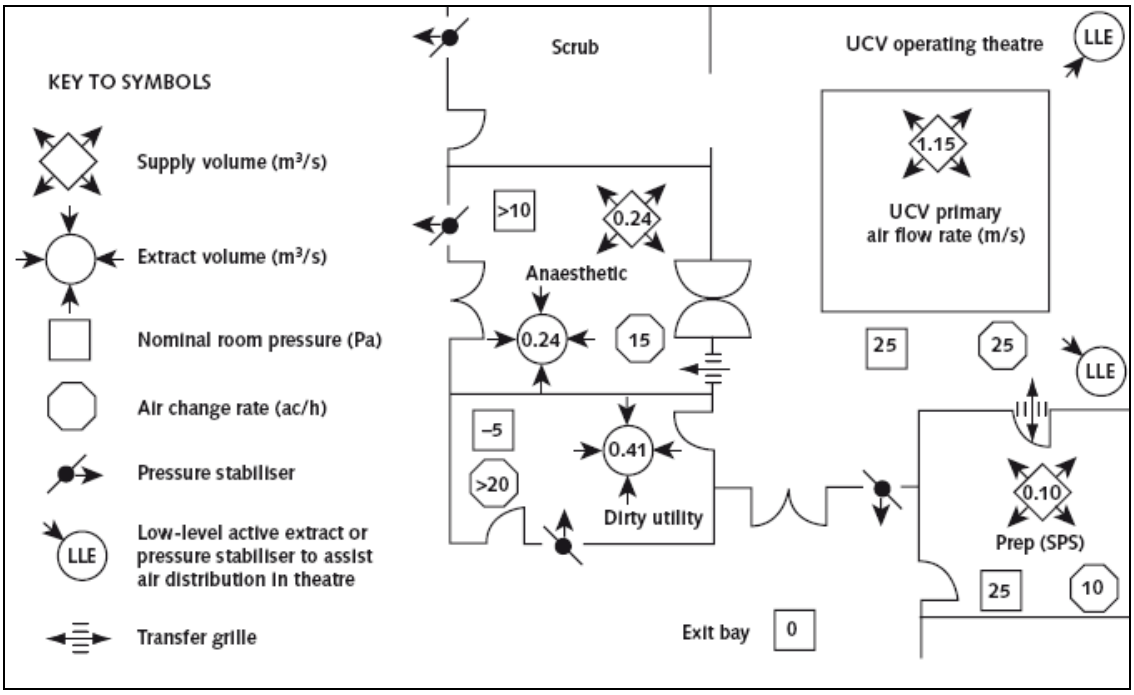
*Separate scrub not considered part of theatre volume.

**Interchange is not permitted between the theatre and lay up prep therefore as Table 4 an airflow protection of 0.28 + 0.06 closed door air flow is required as a minimum.

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the exits from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilizers or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space.

New standard layout N° 4 - Suitable for a typical UCV theatre suite (Layout and room sizes are as illustrated in HBN 26)



Room	Size m³ Derived from HBN26	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m³/s
Theatre	165	25	25	1.15**
Anaesthetic	57	15	>10	0.24
Sterile Pack Prep	36	10	25	0.10
Scrub	*	-	25	-
Dirty Utility	36	-	-5	0.41

* Separate scrub not considered part of theatre volume

**Primary Fresh air Volume Only

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the exits from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilizers or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space.

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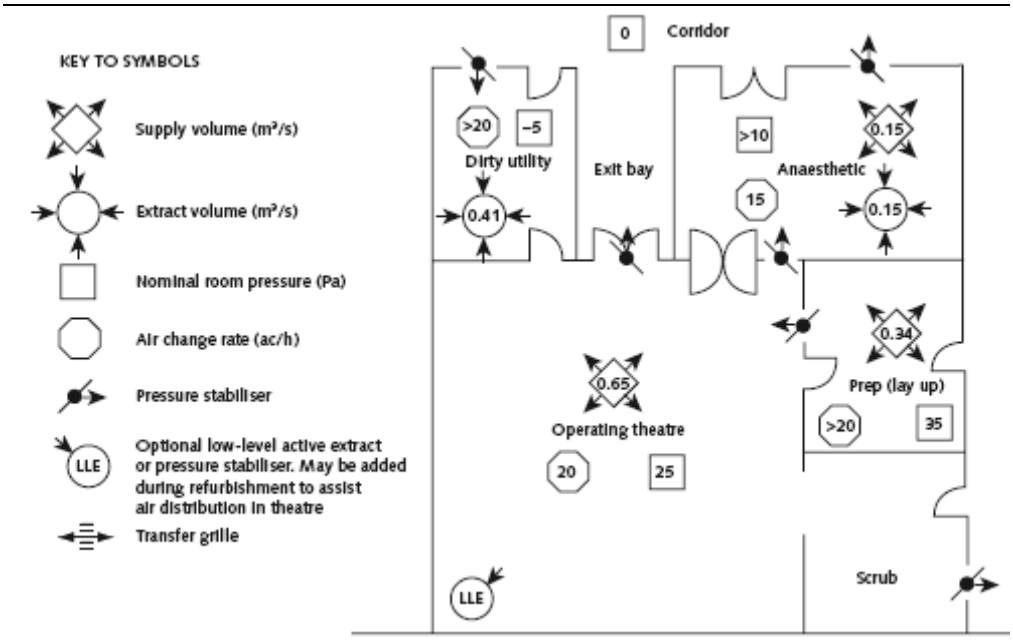
New standard layout N° 5 - SHTM 2025 Existing standard plan '1b' typical layout for a conventional theatre suite

This layout and data is for historical purposes only. The information is to be used for the evaluating of existing systems or rebalancing following ventilation system cleaning.

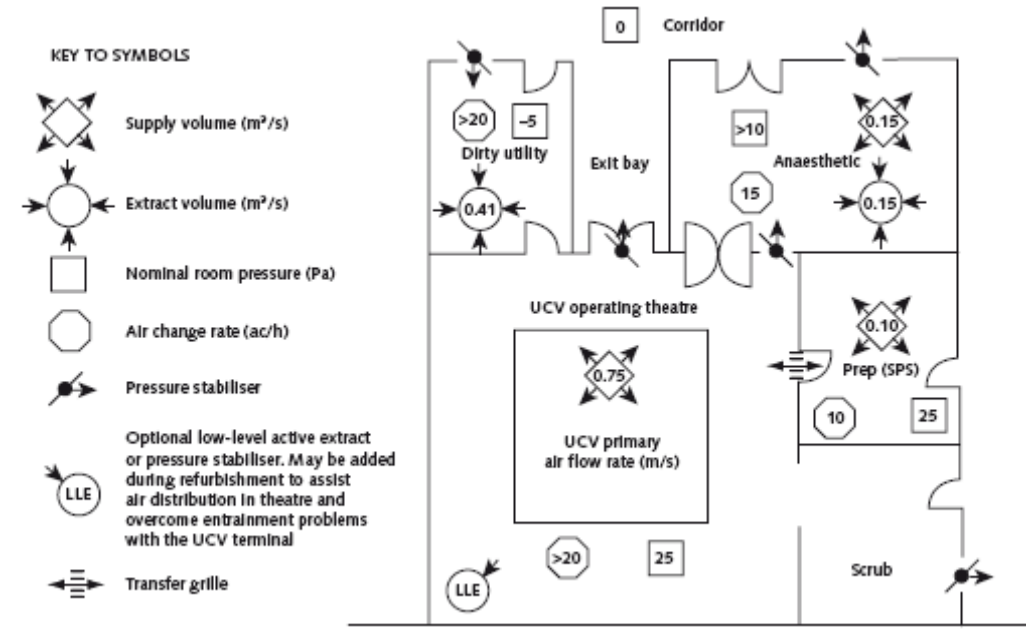


Room	Size m^3	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m^3/s
Theatre	Existing Theatre Suite to Be measured on site	20	25	0.65
Anaesthetic		15	14	0.15
Lay-Up Prep		-	35	0.34
Scrub		-	25	Included within theatre
Disposal		-	-5	0.41

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor.

Standard layout No 6 - SHTM 2025 Existing standard Plan '1a' Typical layout for a UCV theatre suite

This layout and data is for historical purposes only. The information is to be used for the evaluating of existing systems or rebalancing following ventilation system cleaning.



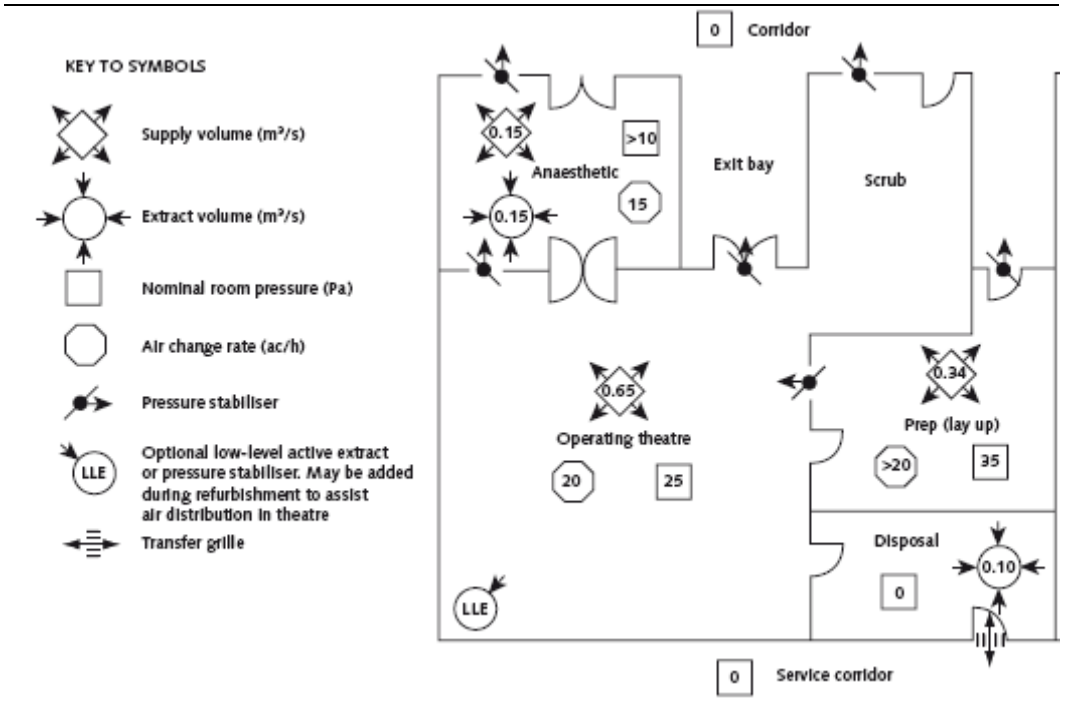
Room	Size m^3	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m^3/s
Theatre	Existing Theatre Suite to be measured on site	20	25	0.75*
Anaesthetic		15	>10	0.15
Sterile Pack Prep		10	25	0.1
Scrub		-	25	Included within theatre
Disposal		-	-5	0.41

*Primary fresh airflow volume

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor.

Standard layout N° 7 - SHTM 2025 Existing standard Plan '5b' Typical layout for a conventional theatre suite

This layout and data is for historical purposes only. The information is to be used for the evaluating of existing systems or rebalancing following ventilation system cleaning.

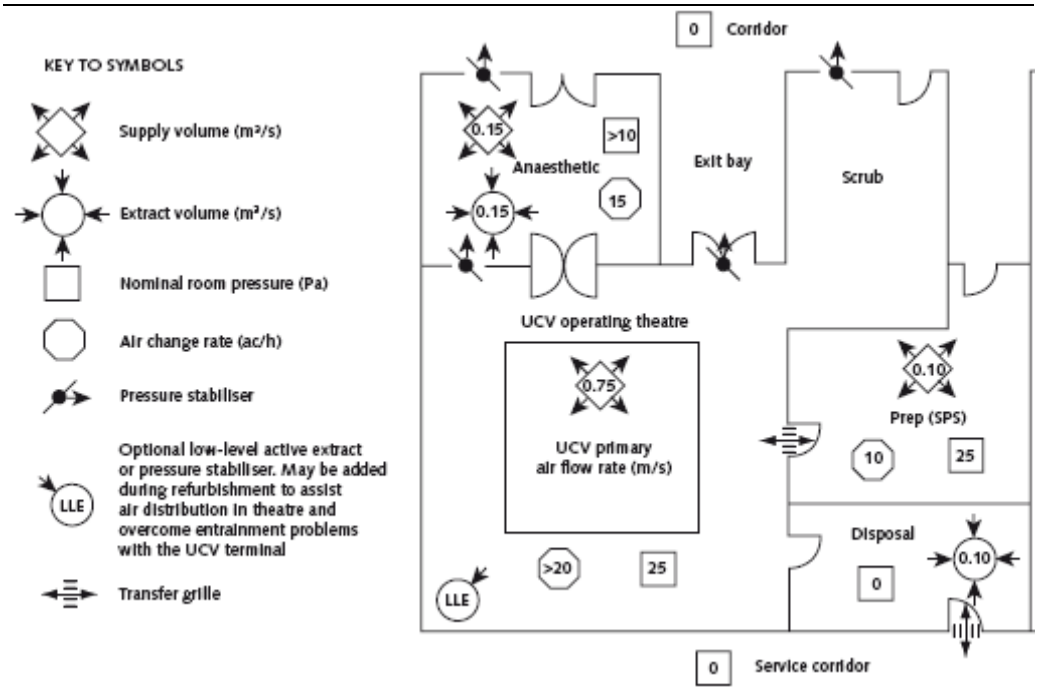


Room	Size m³	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m³/s
Theatre	Existing Theatre Suite to be measured on site	20	25	0.65
Anaesthetic		15	>10	0.15
Lay-Up Prep		>20	35	0.34
Scrub		-	25	Included within theatre
Disposal		-	0	0.1

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor. Alternatively the disposal room could be omitted and replaced with a disposal hatch between the theatre and corridor.

Standard layout N° 8 - SHTM 2025 Existing standard Plan '5a' Typical layout for a UCV theatre suite

This layout and data is for historical purposes only. The information is to be used for the evaluating of existing systems or rebalancing following ventilation system cleaning.



Room	Size m³	Air Change Rate per hour	Nominal Pressure Pa	Flowrate m³/s
Theatre	Existing Theatre Suite to be measured on site	20	25	0.75*
Anaesthetic		15	>10	0.15
Sterile Prep		10	25	0.1
Scrub		-	25	Included within theatre
Disposal		-	0	0.1

*Primary fresh air-flow volume only

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor. Alternatively the disposal room could be omitted and replaced with a disposal hatch between the theatre and corridor.

Appendix 4: Design of air-movement control schemes for operating theatres.

General

A4.1 Standard operating suite design solutions are given in Appendix 3. If these standard solutions cannot be used, the following procedure should be adopted, which will result in an acceptable design. Note that the method employed can equally be used to provide a design solution to a ventilated suite of rooms for any application.

A4.2 The method is concerned with the calculation of airflow rates to ensure that correct air movement occurs between rooms when any one door is open. Under most circumstances, the air quantities required for air-movement control will approximate to those for either temperature control or bacterial contaminant dilution. This flow rate is sufficient to control the effects of any slight reverse flows occurring when a door is opened.

A4.3 The progression through the design procedure is shown in the airflow design procedure chart (Figure A4/3) and is supported by worksheets WS1 to WS7 described in Paragraph A4.4. It is recommended that a plan of the suite and an airflow network be made (Figure A4/2) to collate all information. Flow rates, air-transfer devices etc should be entered as required. The remainder of this Appendix may be treated as reference data to assist in the various steps. The following symbols are used:

S_S – supply airflow rate for summer temperature control;

S_W – supply airflow rate for winter temperature control;

S_D – supply airflow rate for dilution of bacterial contaminants;

S_L – supply airflow rate for heat loss;

S_G – supply airflow rate for heat gain;

E_D – extract airflow rate for dilution of bacterial contaminants;

S_F – final supply airflow rates;

E_F – final extract flow rates;

S_{AMC} – air-supply flow rate for air-movement control;

E_{AMC} – air-extract flow for air-movement control;

L_{OUT} – leakage airflow rate outward;

L_{IN} – leakage airflow rate inward;

$\sum_{OUT}$ – total airflow rate outward;

$\sum_{IN}$ – total airflow rate inward.

A4.4 To simplify the procedure, standard worksheets (WS1 to WS7) have been devised. For each operating suite, a set is required comprising one each of WS1, WS3, WS5, WS6a, WS6b and WS7, one WS4 for each corridor and one WS2 to cover each peripheral room. WS2 has five versions:

- WS2a single flow;
- WS2b parallel/series multi-flow;
- WS2c parallel multi-flow or series multi-flow (unbalanced);
- WS2d series multi-flow (balanced); and
- WS2e bay (semi-open).

Peripheral room type

A4.5 The rooms in the operating suite other than the operating room and corridor are referred to as peripheral rooms. Peripheral rooms have been classified according to the flows in and out. These room classifications are defined below in Paragraphs A4.6 – A4.11.

Single flow

A4.6 This is a room with only one door and a net surplus of supply or extract air.

Parallel multi-flow

A4.7 This is a room with two or more doors through each of which the air-flows either outwards (high-pressure) or inwards (low-pressure) (for example the Prep (lay-up) in standard layout 5).

Parallel/series multi-flow

A4.8 This is a room having a net surplus of supply or extract and with two or more doors. One or more doors will be to an area of equal cleanliness and need not be protected; hence, the flow may vary between inwards and outwards, the remaining door being to an area of greater or lesser cleanliness (for example the Prep (SPS) in standard layout 6).

Series multi-flow (unbalanced)

A4.9 This is a room having a net surplus of supply or extract and with two or more doors. Air flows inwards through one or more doors and outwards through one or more doors.

Series multi-flow (balanced)

A4.10 This is a room as in Paragraph A4.9 above, but having either no mechanical ventilation or no net surplus of supply or extract. (for example an anaesthetic room).

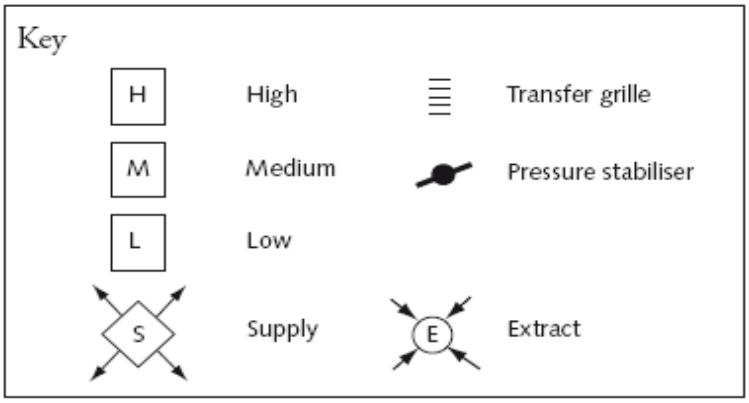
Bay

A4.11 A room that has a permanent opening to the operating room may be considered as a bay off the latter (for example a scrub). Two categories exist:

- open bay – the opening is larger than a normal single door opening. The bay may be considered as part of the main room;
- semi-open bay – the opening is no larger than a normal single door opening. In this case it is possible to protect the bay from the main room by provision of air supply or extract in the bay, or by passing air to or from another area.

Air-movement control in peripheral rooms

A4.12 For the design of air-movement control, two types of air-transfer device are considered. These are transfer grilles and pressure stabilisers. Each has a particular field of application within the design, as described in Paragraphs A4.34 – A4.43. Air movement is controlled in each of the different room types described in Paragraphs A4.13 – A4.31.



Note: This key applies to each diagram in A4.13 - A4.27.

Single flow rooms

A4.13 An appropriately sized transfer grille should be located in or adjacent to the door of each single flow room to relieve the pressure differences across the door when closed.

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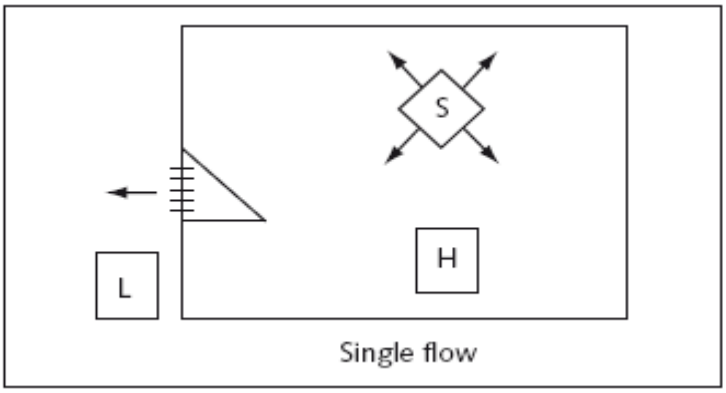
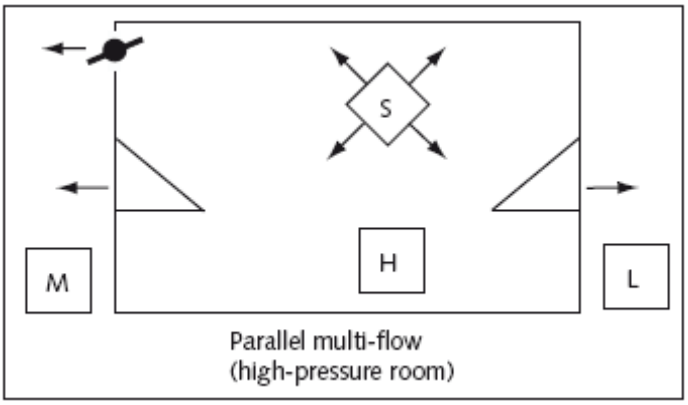
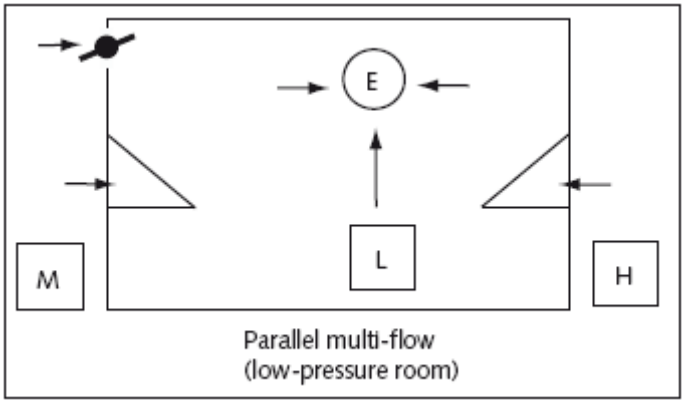


Parallel multi-flow rooms

A4.14 The pressure difference across the closed doors must be relieved, but transfer grilles are not appropriate where two doors lead to areas of different pressures, because reverse flow could occur when the other door is open. For this reason, pressure stabilisers are used.





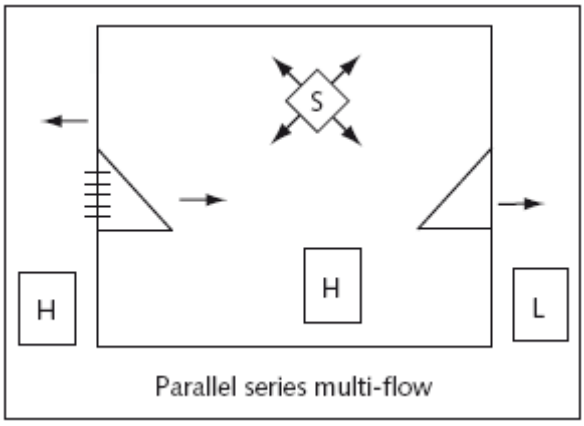
A4.15 These rooms will be either high-pressure or low-pressure with respect to the adjacent areas (see preparation lay-up room and disposal room, respectively, in standard layout 5). The pressure-relief damper is always situated between the room and area, which results in the smaller differential pressure to ensure best use of air.

A4.16 Just as reverse flow can occur if transfer grilles are used, it can similarly occur via door gaps when the other door is opened. It is not possible to avoid this,

except by using air locks, but due to the low flow rates and short durations involved, this is not considered to be of importance.

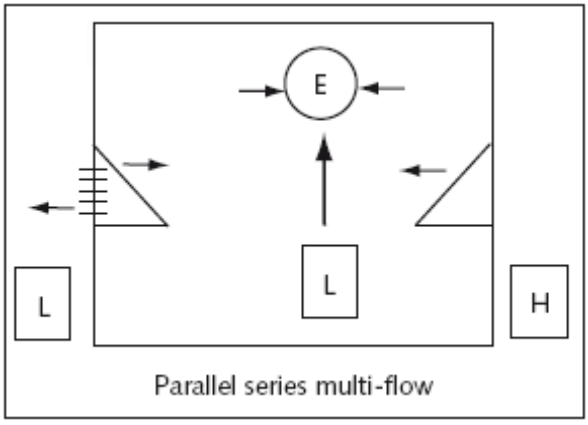
Parallel-series multi-flow rooms

A4.17 These rooms are similar to those in Paragraph A4.14 above, but because the room is of equal cleanliness to one of the adjacent rooms the nominal pressures will be equal and air may flow through the adjoining doorway in either direction. (for example the Prep (SPS) in standard layout 6).



Parallel series multi-flow

A4.18 Where the nominal room pressure equals that of the higher-pressure adjacent room, the best use of air is by supplying air required for bacterial dilution only and allowing this to exhaust via a transfer grille to the area of equal cleanliness. The doorway to the lower pressure area is protected by the combination of the supply air and the air that will flow inwards through the transfer grille from the area of equal cleanliness.

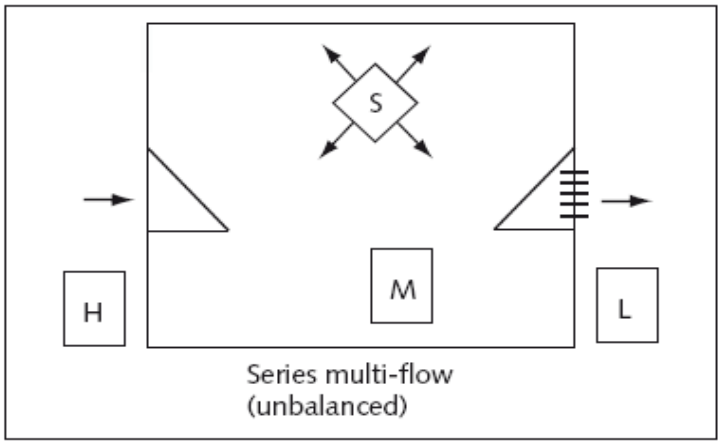


Parallel series multi-flow

A4.19 Conversely, where the nominal pressure equals that of the lower-pressure adjacent room, extract ventilation and a transfer grille to the lower pressure adjacent room should be provided. (for example, the disposal room in standard layout 8).

Series multi-flow (unbalanced)

A4.20 These rooms are somewhat similar to those in Paragraph A4.15 above, but because the pressure lies between that of the rooms on either side, the back-flow problem does not exist.



Series multi-flow (unbalanced)

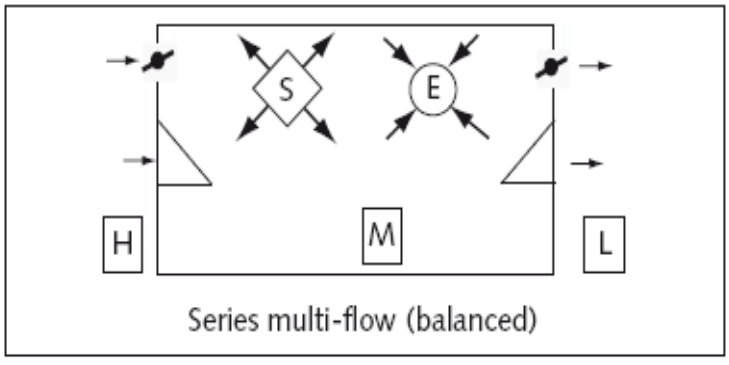
A4.21 Where the room has a net surplus of mechanical supply air, a transfer grille should be located in or adjacent to the door through which air flows outwards, and the mechanical supply flow rate to the room should be chosen to give protection when this door is open.

A4.22 Where the room has a net surplus of mechanical extract air, a transfer grille should be located adjacent to the door through which the air flows inwards, and the mechanical extract flow rate to the room should be chosen to give protection when this door is open.

A4.23 The grille must be sized for the protection requirement of the opposing door when open. When the room on the high-pressure side depressurises, there is a possibility of back-flow through gaps around the door, but this problem may be ignored.

Series multi-flow (balanced)

A4.24 In these rooms, a transfer device adjacent to each doorway is required in order to provide a flow path for the air required to protect the opposing door when opened.



Series multi-flow (balanced)

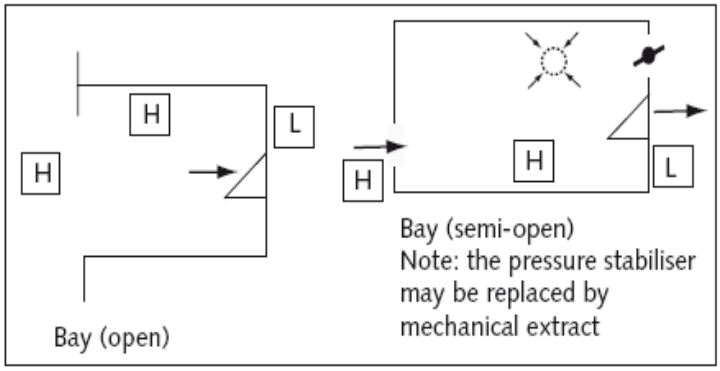
A4.25 These transfer devices will normally be pressure stabilisers, although transfer grilles may be used where a large amount of excess air is to be exhausted from the operating room when all doors are closed. (for example, anaesthetic rooms).

A4.26 The calculation procedure is to assume that pressure stabilisers are being used; then (if there is sufficient excess air) change to transfer grilles as described in Paragraph A4.50.

Bay

Open bay

A4.27 A bay of the open type (for example scrub-up) is considered to be part of the operating room. Provided air movement is satisfactory, no specific extract is required.



Semi-open bay

A4.28 In a bay of the semi-open type, protection of one area from the other is possible. (For example scrub-up).

A4.29 As stated previously, the need for protection between operating room and scrub-room is not very great. Better use of air can therefore be achieved in this case by installing a pressure stabiliser between the scrub-room and clean corridor. This will allow a flow of air through the scrub-room at all times, except when a door is opened elsewhere in the suite. The pressure stabiliser will then close and the air will be diverted to the other door. When it is considered necessary to protect the scrub-room at all times, either a transfer grille to the corridor or mechanical extract in the scrub-room should be provided.

Operating room

A4.30 Once the peripheral rooms have been considered, the operating room requirements may then be decided and the supply flow rate required for air-movement control calculated. This flow rate should be such that, with any one door open, the correct air movement directions are maintained. There will be one door in the suite that will require the largest supply flow rate to the

operating room for protection when open. This is called the “key door” and is discussed separately in Paragraph A4.33. Use of this concept avoids repetitive calculations for each door in turn. Having established the required supply flow rate, a relief route must be provided to the clean corridor for any excess air when the doors are closed. This would be via transfer grilles or pressure stabilisers through a series-flow room or via pressure stabilisers to the clean corridor directly.

Corridors

A4.31 All surplus air from the suite, except that lost through structure leakage and any passing to the outer corridor, will arrive in the patient/staff corridor. Should this air be insufficient to achieve the required air-change rate (see Appendices 1 and 2), some additional air supply should be provided. (The air balance should take account of structural leakage.)

Door opening

A4.32 Whereas the resulting pressures are dependent on ductwork layout, room relationships and characteristics of the fan, the generalisations shown in Appendix 2 can be used to estimate the change in room pressure when a door is opened.

A4.33 The “key door” will be the open double door which leaves the operating room at the highest pressure, and/or requires the largest air flow. This should be determined using the procedure in worksheet WS3.

Transfer grilles

A4.34 These may be used to limit the pressure differences across the closed door of a single-flow room or, in some instances, for protection of a series-flow or parallel-series-flow room. They allow airflow in both directions and may not be suitable for all applications.

A4.35 The free area of a grille is calculated from the following equation:

$$A = \frac{Q}{0.84\sqrt{\Delta P}}$$

where:

A is free area (m^2)

Q is flow rate (m^3/s)

P is pressure difference (Pa).

A4.36 The flow through a grille at a different pressure may be found from the following equation:

$$Q_2 = Q_1\sqrt{\frac{\Delta P_1}{\Delta P_2}}$$

where:

Q_1 and P_1 are original flow and differential pressure

Q_2 and P_2 are new flow and differential pressure.

A4.37 The transfer grille may be replaced by carefully proportioned door undercuts of the equivalent free area.

A4.38 The function of the transfer grille is to provide a means of airflow control by which the volume and pressure loss can be established. If a grille is used, it should have an easily removable core to facilitate cleaning.

Pressure-relief dampers

A4.39 The functions of a pressure-relief damper are now carried out by pressure stabilisers. Accordingly, all further mention of them has been removed from this document.

Pressure stabilisers

A4.40 Pressure stabilisers can be adjusted to hold the pressure constant over a wide range of flow rates. They are used where requirements exist for accurate room-pressure control or rapid shut-off on pressure fall.

A4.41 The installation of a grille or baffle in association with a stabiliser will alter the operating characteristics. It is recommended that a location be chosen to avoid the need for visual screening, for example, at high level. The location should be chosen to minimise the likelihood of damage.

A4.42 The stabilisers used should be virtually silent in operation, adjustable on site, maintenance-free and of a type that cannot be wrongly inserted. They should not be used in external walls or where the pressure difference is less than 5 Pa. The required size of a pressure stabiliser is dependent on the design pressure difference across it and flow rate through it. The manufacturer should provide data relating pressure difference to mean velocity (or flow rate per unit area). From this, the required area can be calculated and then rounded-up to the nearest size manufactured or nearest combination of smaller sizes.

A4.43 It is sometimes possible to arrange for a pressure stabiliser to perform two tasks. In an anaesthetic room, for example, the two pressure stabilisers may be made to pass the open door protection air, and also control the operating and anaesthetic room pressures with the door closed. To achieve this, the

stabilisers are sized for the flow rate required with one of the doors open, but the pressure setting is adjusted to be the value required with the doors closed. This is shown in Figure A4/1.

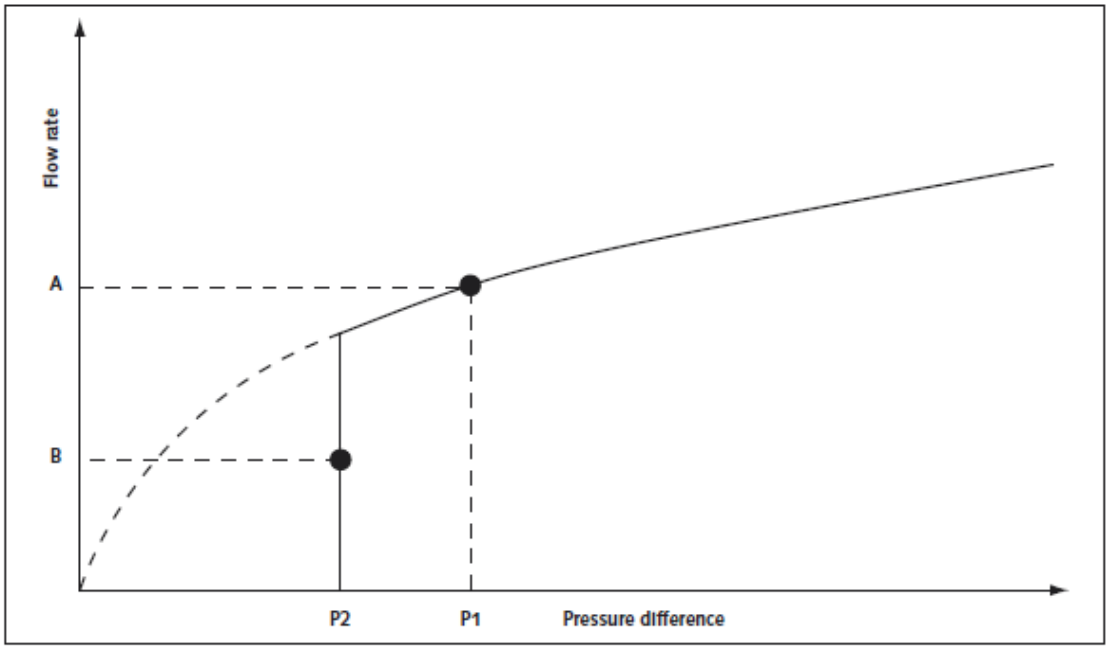


Figure A4/1

Door leakage flows

A4.44 For an air-movement control scheme to work satisfactorily, it is essential that the estimates of door-gap leakage made at the design stage are closely related to those which are achieved in practice. The calculation of gap-flows is complicated by the fact that such flows generally fall into the transition region between laminar and turbulent flow and hence do not follow the normal flow equations. The gaps assumed are 4mm along the bottom, 3mm at the top and sides, and 2mm between double leaves. Doors should not have wider gaps than these. Tighter gaps would result in lower flow-rate requirements and hence lower fan power, but care should be taken to ensure that all doors in the suite have similar gap dimensions. It may be possible to ignore the door leakage and so reduce the airflow requirement (see the notes in Appendix 3).

Room temperature estimation

A4.45 The air-flow rate required to prevent back-flow through an open door is dependent on the temperature difference across the door. The design figures shown in Appendix 3 are based on the temperature differences that will normally occur in practice, assuming heat gains and losses in accordance with Appendix 2.

A4.46 In accordance with the airflow design process, the temperature differences across the doors of all rooms classed as “sterile” is calculated. Worksheet WS6 is recommended for the calculations, using the following criteria:

- assume that the operating room is being controlled at 20°C and calculate the incoming air-supply temperature as shown on worksheet WS6;
- the calculation should be repeated for both summer and winter conditions, with an operation in progress;
- assume all doors are closed;
- use the room supply flow rates from WS1;
- use the inward air flows through air-transfer devices and closed door leakages from WS2a to WS2e;
- the formula used in worksheet WS6 is as follows:

$$T = \frac{(t_1Q_1 + t_2Q_2 + \cdots + t_nQ_n) + 0.828H}{(Q_1 + Q_2 + \cdots Q_n)}$$

where:

Q = flow rate from source (m^3/s)

t = the temperature of source (°C)

H = the room heat gain (kW).

A4.47 If the evaluated temperature differences between rooms do not exceed 2°C, the solution is satisfactory; otherwise proceed as follows:

- check the assumption on which the heat gains are based;
- take steps to reduce the heat gains;
- if the door is to a corridor, the flow through the open door will be larger than the value given in Appendix 2. Calculate on WS3, assuming it is the "key door" with door-flow unknown, and the supply as known;
- if the door leads to a room with mechanical supply, install a trimmer heater in the supply to the room controlled by either a differential thermostat or a thermostat slaved to the operating room thermostat to ensure that T is minimized.
- If the door leads to a room with no mechanical supply, increase the door protection flow as follows:

$$Q_{new} = Q_{old}\left[\frac{\Delta T + 1}{2}\right]$$

A4.48 These options should be considered in the above order, and the first three should be investigated thoroughly before proceeding to the latter two. The mechanical supply may need to be increased in order to achieve the desired air-change rates.

Relief of excess air from operating room when all doors are closed

A4.49 As the mechanical supply to the operating room is sized to provide an appropriate flow outward through any door that is opened, it follows that when all doors are closed, there will be more air supplied to the operating room than can exit from it via leaks etc. This "excess" air can be relieved by either of the two methods described in Paragraphs A4.50 - 4.54.

By transfer devices via the anaesthetic room

A4.50 For door protection, the transfer devices in the anaesthetic room are typically designed to pass 0.47 m^3/s at a differential pressure of 14 Pa. When the doors are closed, the differential pressure will change to 11 Pa between theatre and anaesthetic room, and 14 Pa between anaesthetic room and corridor; the volume of air passed by the transfer devices will be modified as shown in the following formula:

$$Q = Q_1\left(\frac{\Delta P_1}{\Delta P_2}\right)^{1/2}$$

$$= 0.47\left(\frac{11}{14}\right)^{1/2}$$

$$= 0.42\ m^3/s$$

where:

Q = "excess" air to be vented with doors closed;

Q_1 = air-flow required for door protection through transfer device;

ΔP_1 = nominal differential pressure with door to operating room closed and door to corridor closed;

ΔP_2 = nominal differential pressure between either the anaesthetic room and corridor when the operating room door is open, or the anaesthetic room and operating room when the corridor is open. This differential pressure is used when selecting size of both devices.

A4.51 If the "excess" air is less than 0.42 m^3/s, a pressure stabiliser is required to ensure that the correct protection airflow is available to pass through the door.

A4.52 If the "excess" air is greater than 0.42 m^3/s, a transfer grille is acceptable because at all times the airflow will exceed the flow required for door protection.

By pressure stabilisers to the corridor

A4.53 If it is undesirable to pass operating room air through the anaesthetic room, it may be passed directly to a corridor via a separate pressure stabiliser.

A4.54 If there is sufficient "excess" air, the transfer grille solution at Paragraph A4.52 should be adopted, as it provides the simplest solution and, once set up, will require no further maintenance. With less excess air, it is recommended that the air be passed through the anaesthetic room via the pressure stabilisers as at Paragraph A4.51, thus keeping the number of pressure stabilisers to a minimum. Both these solutions increase the air-change rate in the anaesthetic room, but care should be taken to avoid passing excessive amounts through that would cause discomfort to the occupants.

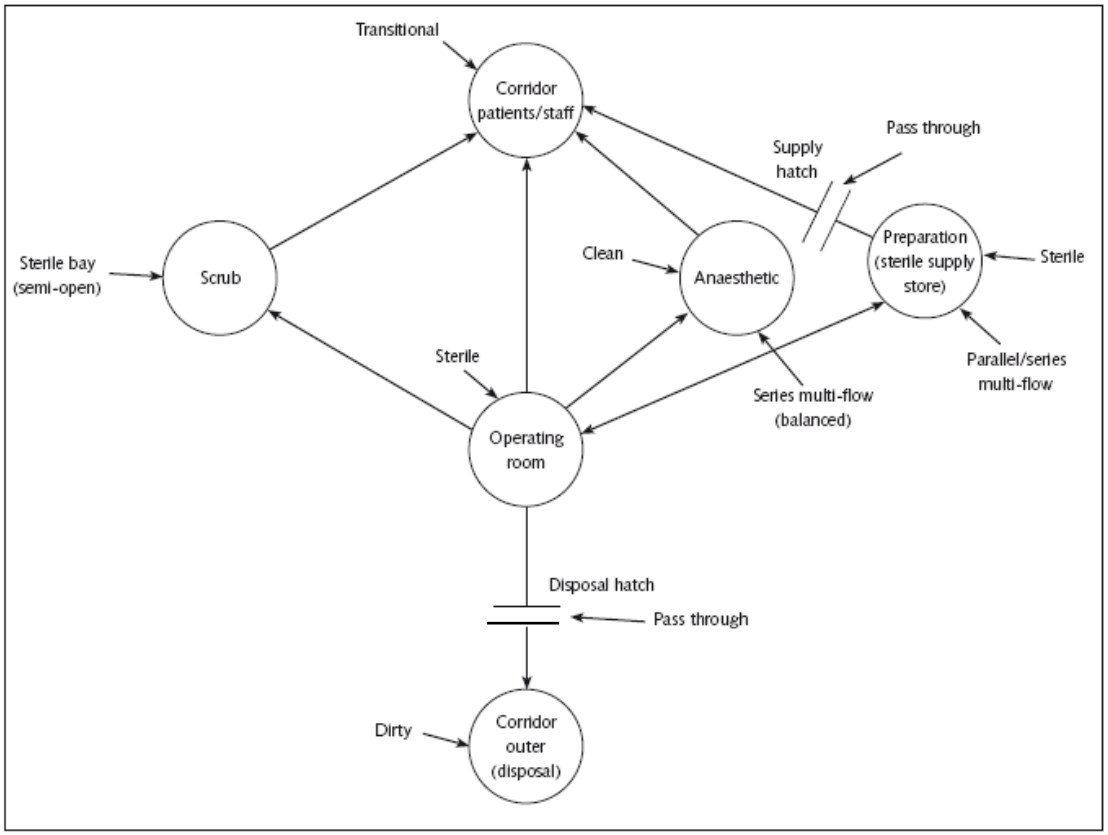
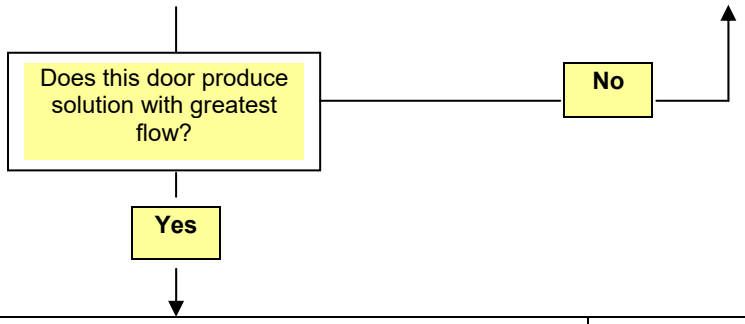
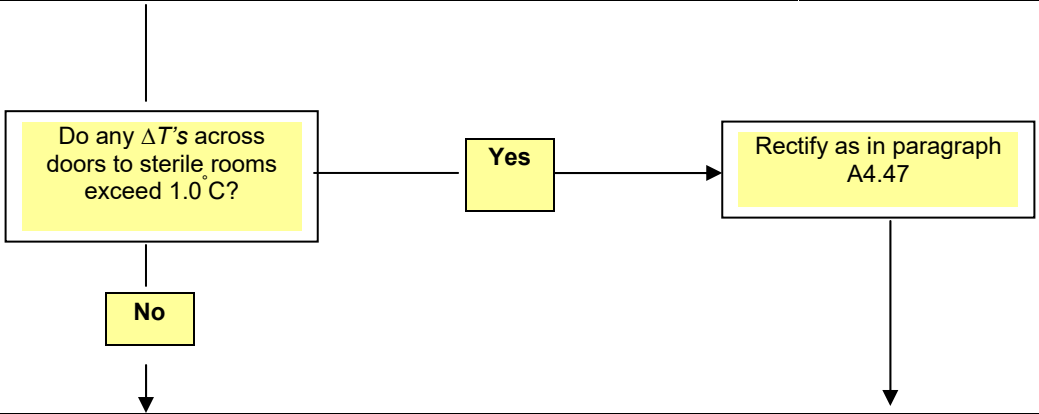


Figure A4/2: An example of an airflow network

Step	Description	Worksheet
1	Show nominal room pressures and air flow directions on the plan of the theatre suite and WS1	WS1
2	Enter heat/loss/gain data and calculate supply airflow rates for temperature control only. Categorise room types e.g. sterile, clean etc.	WS1
3	Enter airflows required for bacterial contamination control or air change rate whichever is the greater, add supply and extract volumes (S_D, E_D) on the plan.	WS1
4	Define peripheral room types, see paragraphs A4.5 - A4.11, and select appropriate worksheets.	Select from WS2a - WS2e
5	Locate air transfer devices, enter details on worksheets and locate on the plan and Figure A4/2	Selected worksheets from WS2a - WS2e
6	For each peripheral room, determine air flows through doors when open and calculate mechanical supply or extract and transfer device flows	As above
7	Select "Key Door" and calculate air supply for operating room	WS3



8	Transfer to WS1 and select final rate S_F and E_F	WS1. WS3
9	Make provision for relief of excess air with doors closed	Selected Worksheets and WS3
10	Calculate supply and extract flow rates for corridor(s)	WS4, WS5
11	Calculate room temperatures (all doors closed) and ΔT's	WS4, WS5



12	Make summary of flows	WS6a and WS6b
13	Size transfer devices, size ductwork, central plant etc	WS7
14	Design ductwork layout, control plant etc	

Figure A4/3: Airflow design procedures

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Calculation sheet for						**Worksheet WS1** **Reference:**
Room Name:						
1. Summer Temperature Control Heat Gain	kW					
2. Acceptable Δt	°C					
3. Air flow rate (S_G) $= \frac{\text{Gain}}{\Delta t \times 1.2}$	m^3/s					
4. Winter Temperature Control Heat Loss	kW					
5. Acceptable Δt	°C					
6. Air flow rate (S_L) $= \frac{\text{Loss}}{\Delta t \times 1.2}$	m^3/s					
7. Dilution of bacterial contaminations Air flow rate	m^3/s					
S_D or E_D						
8. Desired air change rate	ac/hr					
$\frac{\text{AC/hr x room volume } (m^3)}{3600}$	m^3/s					
9. Maximum of S_G, S_L, S_D or E_D or air change rate from Step 8	m^3/s					
10. Air movement control	S m^3/s					
Air flow for air movement control S_{AMC} or E_{AMC} (from WS2, WS3, or WS4)	E m^3/s					
11. Final Supply Flow Rate (S_F)	m^3/s					
12. Final Extract	m^3/s					
13. Total Supply	m^3/s					
14. Total Extract	m^3/s					

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Air Movement Control **Peripheral Room ..... type, single flow**	**Worksheet WS2a** **Reference:** **Nominal Pressure: ..... Pa**

Consider door to ..... open

Flow required through doorway to give protection	Pa	Δt	Air flow, m^3/s Out	In	Remarks
Total					

S_{AMC} $(\sum_{OUT} - \sum_{IN})$ _____ m^3/s

or

E_{AMC} $(\sum_{OUT} - \sum_{IN})$ _____ m^3/s

Transfer S_{AMC} or E_{AMC} to WS1

Consider door to .....closed

Closed door leakage	Pa	Δt	Out	In	Remarks
Total					

Return S_F and E_F to WS1 _____ _____

Flow through transfer grille outward ($S_F - E_F - L_{OUT}$ _____

or

Flow through transfer grille inward ($E_F - S_F - L_{IN}$) _____

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Air movement control **Peripheral Room ..... type, parallel/series multi-flow**	**Worksheet WS2b** **References:** **Nominal Pressure: Pa**

Door from this room to ..... (room of equal cleanliness) is not to be protected.
A transfer grille is located in, or adjacent to, this door.

Consider door to ..... open

Room pressure now becomes [ ] or [ ] or [ ] Pa (see Appendix 6)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
Mechanical supply or extract (S_F/E_F)					
		Total			

X ($\sum_{OUT} - \sum_{IN}$) [ ] Or Y ($\sum_{IN} - \sum_{OUT}$) [ ]

Transfer grille required:

or from high-pressure zone Flow = *X* [ ] at [ ] ΔPa

to low-pressure zone Flow = *Y*

Size of transfer grille (free area) A1 [ ]

Consider doors and hatch closed – room pressure becomes [ ] Pa (nominal)

Closed door leakage from Appendix 4 (assuming no transfer grille)	Pa	ΔP	Out	In	Remarks
Mechanical supply or extract					
		Total			

Air flow required through transfer grille = IN – OUT = Z' [ ]

or OUT – IN = Z'' [ ]

Transfer grille required flow *Z' or Z''* [ ] @ [ ] ΔP

Size of transfer grille (free area) A2 = [ ]

Select larger of A1 or A2 [ ]

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Air movement control **Peripheral Room ..... type, parallel multi-flow high/low or series multi-flow (unbalanced)**	**Worksheet WS2c** **References:** **Nominal Pressure: Pa**

Consider door from this room to ..... open.

Room pressure now becomes [ ] or [ ] or [ ] Pa (see Appendix 6)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
		Total			

S_1 ($\sum_{OUT} - \sum_{IN}$) [ ] Or E_1 ($\sum_{IN} - \sum_{OUT}$) [ ]

Consider door from this room to ..... open

Room pressure then becomes [ ] or [ ] or [ ] Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
		Total			

S_2 ($\sum_{OUT} - \sum_{IN}$) [ ] Or E_2 ($\sum_{IN} - \sum_{OUT}$) [ ]

Consider doors closed. Closed doors leakage from Appendix 4

Door to:	Pa	ΔP	Out	In	Remarks
		Total			

Return S_F and E_F to WS1 [ ] [ ]

Flow through transfer grille outward ($S_F - L_{OUT}$) [ ] to .....

or

Flow through transfer grille inward ($E_F - L_{IN}$) [ ] from.....

Transfer grille [ ] Pressure relief damper [ ]

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Air movement control **Peripheral Room ..... type, parallel/series multi-flow**	**Worksheet WS2d** **References:** **Nominal Pressure:** **Pa**

Note: In this type of room the supply and extract air flow rates are equal and take no part in the air movement control (AMC)

First, open door to higher pressure area.

Room pressure then becomes [ ] or [ ] or [ ] Pa (see Appendix 2)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
Total					

Q_1 ($\sum_{IN} - \sum_{OUT}$) [ ] (+ve inwards)

Next, open door to lower pressure area.

Room pressure then becomes [ ] or [ ] or [ ] Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

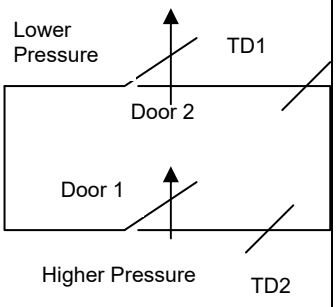
Q_1 ($\sum_{IN} - \sum_{OUT}$) [ ] (+ve inwards)

Flow through transfer device (TD1) to protect Door 1 = Q1 [ ] at resultant

ΔP .....

Flow through transfer device (TD2) to protect Door 2 = Q2 [ ] at resultant

ΔP .....



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Air movement control **Peripheral Room ..... type bay (semi-open)**	**Worksheet WS2e** **References:** **Nominal Pressure:** **Pa**

Note: If the room is of the open bay type (i.e. opening is larger than normal single doorway), then room should be considered part of the main room. No air movement control considerations need then be made, and this sheet can be discarded. Supply and/or extract flow ill be based on air distribution considerations.

Consider permanent opening

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
		Total			

E_{AMC} _____ or flow outward through transfer ($\sum_{IN} - \sum_{OUT}$) _____

Transfer S_{AMC} or E_{AMC} to WS1

Transfer device – transfer grille _____

– pressure stabiliser _____

Size select transfer device for flow rate _____ @ ΔP _____

Note: A door from the bay is considered with the peripheral room to which it leads or, if it leads to the corridor, it is considered with the main room.

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Air movement control **Operating Room**	**Worksheet WS3** **References:** **Nominal Pressure:** **Pa**

Note: To avoid considering each door open in turn, the "key door" concept is introduced. This is the door which requires the greatest mechanical flow when open. See paragraph A4.33

Select "key door" (see above).

Consider this door open – room pressure now becomes _____ Pa (See Appendix 2)

See Appendix 3 for room pressures

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Air flow "out" or "in" via doors, transfer devices etc.	Pa	ΔP			
Mechanical extract					
Total					

S_{AMC} $(\sum_{OUT} - \sum_{IN})$ _____ Transfer S_{AMC} to WS1

Consider all doors closed.

Return S_F and E_F to WS1 _____ Room pressure now _____ Pa (nominal)

Air flow "out" or "in" via door leakage, transfer devices etc	Pa	Δt	Out	In	Remarks
Mechanical extract					
Total					

Flow $(\sum_{IN} - \sum_{OUT})$ through transfer device _____ @ ΔP _____ to……

For final selection of transfer device see paragraphs A4.50 – A4.54

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Air movement control **Corridor**			**Worksheet WS4** **References:** **Nominal Pressure:** **Pa**		
Consider all doors closed					
			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Leaks through closed doors, transfer devices, permanent openings etc.	Pa	ΔP			
Total flow inwards (S_1)					
Add mechanical input (S_2) if necessary to increase S_1 to give 7 AC/hr					
Total Flow Outwards and Inwards					
$S_{AMC} = (\sum_{OUT} - \sum_{IN} + S_2)$		Transfer to WS5			
or $E_{AMC} = (\sum_{IN} - \sum_{OUT} + S_2)$		Transfer to WS5			

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Air movement control **Corridor**	**Worksheet WS5** **References:**

Summary of Air Supply and extract for an Operating Suite

Consider all doors closed

Air Flow to Corridor	All Doors Closed	Anaesthetic (key door open)
	m^3/s	m^3/s
From Preparation		
From Operating Room		
From Scrub		
From Anaesthetic		
Total (a)		
Air Flow to Corridor from Disposal		
From other source		
Total (b)		
Other Room Supplies.....Total (c)		
Total Air Supply (a) + (b) + (c)		

Consider corridor ventilation (see Appendix 2) and calculate air volume required, based on 7 ac/hr (see Note 1)

	m^3/s
Additional Air to Ventilate Corridor	
Additional Air to Ventilate Service Corridor (see Note 2)	
Air Extract The size of the extract plant should be of the order of 10% below the supply to assist in maintaining the department under positive pressure relative to the outside departments.	
	m^3/s
Extract Plant = Supply less Leakage	
Less 10% of Supply	
Total Extract (see Note 3)	

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Room Temperature - Summer | **Worksheet WS6a**

References:

Find summer supply temperature T_{SS} = 20 – 0.828 H/(O/R) _____ = T_{SS} _____ °C

Q(O/R) _____

Note: The temperature of a space may be calculated from

$$T = \frac{t_1 Q_1 + t_2 Q_2 + \ldots\ldots\ldots\ldots + t_n Q_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source (1°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space (kW)

Summary of Air Supply and extract for an Operating Suite

Consider all doors closed

Room	Heat Gain kWh	Supply		Flows Inwards										Temperature °C T
		Q	T_{SS}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check Doors to Sterile Areas

Door Between	Calculated Room ΔT (°C)	Maximum ΔT *Permitted*	Remarks

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Room Temperature - Winter | **Worksheet WS6b**

References:

Find winter supply temperature T_{SW} = 20 – 0.828 H/(O/R) _____ = T_{SW} _____ °C

Q(O/R) _____

Note: The temperature of a space may be calculated from

$$T = \frac{t_1 Q_1 + t_2 Q_2 + \ldots\ldots\ldots\ldots + t_n Q_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source (1°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space (kW)

Summary of Air Supply and extract for an Operating Suite

Consider all doors closed

Room	Heat Gain kWh	Supply		Flows Inwards										Temperature °C T
		Q	T_{SW}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check Doors to Sterile Areas

Door Between	Calculated Room ΔT (°C)	Maximum ΔT *Permitted*	Remarks

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Transfer Grilles, Pressure Relief Dampers and Pressure Stabilisers	**Worksheet WS7** **Reference:**

Transfer Grilles – see paragraphs A4.34 – A4.38

Check Doors to Sterile Areas

No	Location	Pressure Difference Pa	Flow Rate m^3/s	Free Area m^2	Model	Resultant Δp Pa	Remarks

Pressure Relief Dampers – see paragraph A4.39

No	Location	Pressure Difference Pa	Flow Rate m^3/s	Free Area m^2	Pressure Setting Pa	Remarks

Pressure Stabilisers –see paragraphs A4.40 – A4.43

Note: where a stabiliser is acting both as series room door protection and operating pressure control, "pressure difference" and "flow rate" are from WS2d; "pressure setting" is from WS3

No	Location	Pressure Difference Pa	Flow Rate m^3/s	Free Area m^2	Pressure Setting Pa	Remarks

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From:	Henderson, Ronnie
To:	Richards, Janette; Inverarity, Donald
Cc:	Conroy, Michael; Sansbury, Jackie; Currie, Brian; Macrae, Colin; Kolodziejczyk, Kamil K; Gordon, Kelly J
Subject:	CT AIR CHANGE RATES
Date:	27 September 2016 12:00:24
Importance:	High

All,

In an attermpt to progress this to conclusion we have collectively looked at available current guidance and can conclude that the maximum quoted anywhere for a CT room is 10 ac/hr (SHPN 06, Engineering Requirements Para 7.4) and as such is the maximum that Multiplex can/will design to with available guidance.

If the decision by IPCN is that it must be 15ac/hr, this will need to be submitted as a formal change request that may result in significant cost increase and programme delay, please confirm that you wish me to submit this change request.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Mackenzie, Janice
Sent: 07 July 2017 07:57
To: Sansbury, Jackie; Currie, Brian
Cc: Halcrow, Fiona; Hanley, Dorothy; Henderson, Ronnie; 'kelly.Bain[redacted]
'Kamil.Kolodziejczyk@[redacted] Greer, Graeme
Subject: RE: Risk Assessment re 4 bedded room Ventilation
Attachments: Record of General Risk Assessment ventilation _combined.doc

Thanks Jackie. I have added the context for the scores at the end of the table of individual scores.

Janice

From: Sansbury, Jackie
Sent: 06 July 2017 17:30
To: Mackenzie, Janice; Currie, Brian
Cc: Halcrow, Fiona; Hanley, Dorothy; Henderson, Ronnie; 'kelly.Bain[redacted]
'Kamil.Kolodziejczyk[redacted]; Greer, Graeme
Subject: RE: Risk Assessment re 4 bedded room Ventilation

Janice, Fiona and Dorothy thanks for this. I think it would be good to add the context to the scores – i.e. 25 being the worst. It shows that this is a serious risk.
Jackie

From: Mackenzie, Janice
Sent: 06 July 2017 17:16
To: Sansbury, Jackie; Currie, Brian
Cc: Halcrow, Fiona; Hanley, Dorothy; Henderson, Ronnie; 'kelly.Bain[redacted]
'Kamil.Kolodziejczyk[redacted]; Greer, Graeme
Subject: Risk Assessment re 4 bedded room Ventilation

Dear Both

Please find the clinical risk assessment in relation to the above as requested, which Dorothy, Fiona and I have pulled together.

The issue only really affects Children's Services, but we have discussed with Hester. We consulted with Children's CMT representatives this morning (Fiona Mitchell, Eddie Doyle, Lynda Cowie, Peter Campbell & Sharon Russell) and the risk assessment fully reflects their views. They are clear, as we also are, that we cannot have a new facility that does not give us the option of cohorting patients with air-borne infections. We have suggested an overall compromise position of only some of the 4 bedded rooms in the facility having the ventilation changed (in summary – all in PARU & Medical Inpatients and one of the 4 bedded areas within Critical Care), however the Children's CMT did say that to achieve this, there would be a delay to programme then they questioned whether we should not be changing all of the 4 bedded rooms to allow for future proofing and flexibility.

Infection Control have also confirmed they are happy with our risk assessment.

I am off next week, so Dorothy is around to answer queries ad we are both here tomorrow.

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

[redacted]

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ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie, Clinical Director Dorothy Hanley, RHSC Commissioning Lead Fiona Halcrow, Project Manager	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Janice MacKenzie		
Department:	RHSC & DCN Reprovision Project		

Subject of Assessment: Consider Task or Environment.

Bedroom Ventilation design in 4 bedded rooms does not meet the recommendations of SHTM 03-01, as the current design has the 4 bedded rooms as being positive pressure.

To allow cohorting of patients with the same air-borne infections these rooms require to be balanced or negative pressure.

Whilst the Board can rationalise the number of 4 bedded rooms where the ventilation needs to change it should be noted that this does reduce overall flexibility and future-proofing. Given the different patient groups related to specific wards, separate risk assessments have been undertaken (see attached). Individual risk assessments have identified that the need for cohorting of patients is only an issue for the Children's Service.

The risk assessments have been discussed with the Children's CMT and Infection Control & Prevention who have confirmed that not having the ability to cohort patients is not acceptable from a patient safety perspective. In addition the Children's CMT highlighted that if the programme is going to be delayed in order to achieve compliance with the SHTM 03-01 in the 4 bedded rooms then should we not be considering achieving this in all 4 bedded rooms. As opposed to the ones that have been identified to reach a compromise solution which would ensure future proofing and flexibility within the building for service changes and avoid the need to retro-fit.

Step 1: What are the Hazards?

Overall Risks:-

- The inability to cohort patients with air-borne infections in a clinically safe environment
- Clinical risk to isolating babies and children under two years of age with airway compromise i.e RSV
- Need for increased staffing requirements due to the observation and interventions required in this patient group if nursed in singe rooms
- Reduction in overall flexibility and future proofing would be limited if change of use of a ward/s was required
- Reputational risk as one of the key drivers, as outlined in the FBC, is to provide improved modern facilities that overcome the challenges currently faced within the existing facilities that cannot be adapted to provide the best services possible.

See separate risk assessments for inpatient ward/s as the risk rating for each ward/s is different dependent upon the patient group and clinical risk

Step 2: Who might be harmed and how?

See separate risk assessments for specific ward/s

Step 3: What are you already doing? (Existing Precautions)

Generic Precautions

- Isolation rooms have positive pressure lobby which acts as an air curtain and also have a hepa-filter to prevent the transfer of air-borne infection from the corridor into the room or the room into the corridor.
- All single rooms have balanced or slightly negative pressure.
- Increase in the number of single and isolation rooms (See separate risk assessment for the number of isolation and single rooms by ward) from 30% to 62%.
- Within RHCYP wards there will be technology to remotely monitor patient oxygen saturation levels and heart rate

Summary of Risk by Ward/s

Ward/s	Proposed Action	Risk Rating If No Change	Risk Rating if Change Implemented
RHCYP - PARU	All three 4bedded rooms to have ventilation changed	15	4
RHCYP – Medical Inpts	All two 4bedded rooms to have ventilation changed	10	3
RHCYP – Critical Care	One 4 bedded room (B1-063) ventilation changed	9	3
RHCYP – Surgical Wards	No change to ventilation in 4 bedded rooms	3	
RHCYP - Neurosciences	No change to ventilation in 4 bedded rooms	3	
RHCYP – Haematology/Oncology	No change to ventilation in day care	3	
DCN – Inpatient Wards	No change to ventilation in 4 bedded rooms	1	

NB – Risk Scoring range is 1-25 (with 25 indicating an extreme consequence)

Step 4: Action Plan			
What further action is necessary?	**Action By Whom**	**Action by when (dd/mm/yy)**	**Action completed. (dd/mm/yy)**
Clear Guidance in the Building Users Guide as to what 4 bedded rooms can be used to cohort patients with air-borne infections See separate risk assessments for specific actions by ward/s	Jane Campbell	September 2017	

Step 5: Review Table			
Date (dd/mm/yy)	**Reviewer**	**Reasons for review**	**Approved/Not Approved by (dd/mm/yy)**

ID:

NHS Lothian

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project - **RHCYP PARU (A2)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within PARU

Step 1: What are the Hazards?

Significant clinical risk to isolating babies and children under two years of age with airway compromise, some of whom may have co-morbidities where isolation in single room carries additional clinical risk.

If PARU has no cohort areas the hazards are:-

- There is a risk that the 6 shelled beds would require to be opened and additional staffing resource would be required
- Additional staffing would be required to safely care for these patients in single rooms due to the level of observation and intervention required. This has not been accounted for in the agreed workforce plan.
- Reduction in the overall capacity within RHCYP as more single rooms would be required to be used to board patients potentially resulting on the cancellation of elective patients.
- Reliance on remote patient monitoring for oxygen saturation and heart rate to ensure patient safety is increased

The Children's CMT have confirmed that all three of the 4 bedded rooms to have negative/balanced pressure

Step 2: Who might be harmed and how?

Patients: -

- Boarding of patients into other specialities is a recognised clinical risk.
- Patients from whom cohorting may be safest clinical option despite the availability of a single room e.g a child under two years of age with respiratory infection plus co-morbidity (cardiac or neurological) who because of their complex underlying condition need constant observation.

Step 3: What are you already doing? (Existing Precautions)

PARU has 34 beds:-

- 3 x 4 bedded rooms
- I x isolation room
- 21 x single rooms

Increased number of beds in single rooms and 4 bedded rooms as opposed to 6 bedded rooms (in existing hospital).

Procuring a remote monitoring system for oxygen saturation and heart rate to alert staff to a potential deterioration in patient's condition

Level of Risk with no cohort area 15

Level of Risk with cohort area 4

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Careful selection of patients for boarding	Nursing & Medical Teams	Ongoing	
Use of remote technology to assist with monitoring of patients in single rooms	Nurse in Charge & Consultant	Ongoing	
Clear guidance in the Building Users Guide regarding cohorting of patients with air-borne infections	Jane Campbell	September 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director		
Department:	RHSC & DCN Reprovision Project – **RHCYP Medical Inpatients (C1.1)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Medical Inpatients

Step 1: What are the Hazards?

Despite the fact it is planned that PARU will take all of the acute general admissions, reliance on a cohort area within this ward is only marginally reduced, particularly in times of peak activity when PARU would be unable to accommodate all of the RSV patients.

The Board feel a compromise is not possible in the 4 bedded rooms.

Step 2: Who might be harmed and how?

Patients from whom cohorting may be safest clinical option despite the availability of a single room e.g a child under two years of age with respiratory infection plus co-morbidity (cardiac or neurological).

Step 3: What are you already doing? (Existing Precautions)

Increased number of single and isolation rooms within medical inpatients:-

- 2 x 4 bedded bays
- 4 x Isolation Rooms
- 11 x single rooms

Procuring a remote monitoring system for oxygen saturation and heart rate to alert staff to a potential deterioration in patient's condition

Level of Risk if no change made 10

Level of Risk with Cohort Areas 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Careful selection of patients for boarding	Nursing & Medical Teams	Ongoing	
Use of remote technology to assist with monitoring of patients in single rooms	Nurse in Charge & Consultant	Ongoing	
Clear guidance in the Building Users Guide regarding cohorting of patients with air-borne infections	Jane Campbell	September 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP Critical Care (B1)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Critical Care Unit

Step 1: What are the Hazards?

Clinical risk is still relatively high if no cohort area available and therefore operationally to retain the ability to cohort within B1-063 (low acuity HDU) would be clinically and operationally highly advantageous.

Step 2: Who might be harmed and how?

Patients through spread of infection.
Potential cancellation of elective surgical cases as staff group will be required to deliver 1:1 care who potentially could be cared for within a cohort area

Step 3: What are you already doing? (Existing Precautions)

Critical Care (B1) – 24 beds

- 3 x 4 bedded rooms (intensive care, high acuity & low acuity)
- 1 x 3 bedded room (surgical neonates)
- 4 x isolation rooms
- 5 x single rooms

The increased number of single rooms and a higher nurse to patient ratio within the Critical Care Unit will help mitigate the risk of nursing patients in single rooms

Level of Risk if no cohort area 9

Level of Risk if cohort retained 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that two 4 bedded rooms (ITU & high acuity high dependency) and one three bedded room (surgical neonates) cannot be used to cohort patients with air-borne infections	Jane Campbell	September 2017	
Careful placement of patients within the designated areas	Senior Nurse in Charge & Consultant	Ongoing	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP – Surgical Wards (C1.2 & C1.8)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients with air-borne infections within the Surgical Wards

Step 1: What are the Hazards?

- Clinical risk is low as increased number of single rooms within Medical wards reduces the need to board patients into the surgical wards from the medical wards
- Compromise possible in not altering ventilation in the 4 bedded rooms but reduces flexibility and future proofing

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

There are two surgical wards:-

Surgical Short Stay has 14 beds:-

- 2 x 4 bedded rooms
- 6 x single rooms

Surgical Long Stay has 15 beds:-

- 2 x 4 bedded rooms
- 7 x single rooms

Increased number of beds within PARU and medical inpatients to reduce the need to board patients

Level of Risk 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	September 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP – Neurosciences (C1.3)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Neurosciences Ward

Step 1: What are the Hazards?

- Clinical risk is low as increased number of single rooms within Medical wards reduces the need to board patients into the neuroscience ward from the medical wards
- Compromise possible in not altering ventilation in the 4 bedded rooms but reduces flexibility and future proofing

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

The Neurosciences Ward has 12 beds

- 2 x 4 bedded rooms
- 1 x isolation room
- 3 x single rooms

Increased number of single rooms including one isolation room within this ward to allow the ward to care for neurosciences patients with an infection within the ward and not board in other wards which is the case in the existing hospital.

Level of Risk 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	September 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP Haematology/Oncology Ward (C1.4)**		

Subject of Assessment: Consider Task or Environment.

Patient pathway for day care patients with a known infection

Step 1: What are the Hazards?

This is a combined inpatient and day care facility, however the design separates these two areas. Operationally the clinical team have already agreed a compromise where patients with infections coming to day care would be dealt with in the consulting room within day care or the inpatient facility. The Board have previously accepted that they can operationally manage these areas without a change in ventilation to the 2 day care rooms.

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

Haematology/Oncology Ward has 17 inpatient beds and 9 day care beds/trolleys:-

- 5 x isolation rooms
- 12 x single rooms
- 1 x 6 bedded day care room
- 1 x 3 bedded day care room

Operational policy has been agreed for the management of day care patients with an infection

Level of Risk 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state the type of pressure in the Day Care areas	Jane Campbell	September 2017	
Written patient pathway and operational policy for the management of day care patients with an infection	Charge Nurse & Lead Consultant	October 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Hester Niven, Clinical Nurse Manager DCN		
Department:	RHSC & DCN Reprovision Project – **DCN Wards**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients with air-borne infections within DCN wards

Step 1: What are the Hazards?

The Board have previously accepted that they can operationally manage these wards due to the number of single rooms and types of patients and the need for cohorting of infectious patients would be extremely rare

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

DCN has three wards:-

DCN Acute Care (L1) – 24 beds
- 2 x 4 bedded rooms
- 1 x isolation room
- 15 x single rooms

DCN Inpatients Wards (L2) – 43 beds
- 2 x isolation room
- 41 x single rooms

Significant increase in the number of single rooms as compared to existing facility

Level of Risk 1

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	September 2017	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

From: Rae, Janette
Sent: 24 August 2018 09:32
To: Inverarity, Donald
Subject: RE: Independent verification of theatres and isolation room ventilation

Thank you for this Donald,
I am sure Ronnie Henderson , Estates Commissioning Manger, should be saying the same.
Janette

From: Inverarity, Donald
Sent: 24 August 2018 09:28
To: Sansbury, Jackie; Rae, Janette; Henderson, Ronnie; Kalima, Pota; Henderson, Naomi
Subject: RE: Independent verification of theatres and isolation room ventilation

Dear Jackie,

Thanks for your e-mails. This is absolutely an issue we need to get right given the recent experiences of my microbiology colleagues in Glasgow with their new children's hospital.

It would be useful for us to use St Johns Theatres 11,12 as a Lothian example of the process we have used as a board before.
You will know that last year theatres 11 (Ultraclean theatre for hand surgery) and 12 (Conventional theatre for eye surgery) were built and put through a validation and verification. Initially there was some confusion regarding what the "validation" and "verification" requirement would be require, particularly for Theatre 11.

The approach we took was as follows.

We insisted that the requirements of SHTM 03-01 were met in that Infection Control required a formal validation summary report (and not a collection of documents with uninterpreted particle count and pressure results which we were initially delivered).
The non-negotiable expectation from SHTM 03-01 is we need evidence of compliance with parts 8.170-8.174 on pages 136-138 of the attached.
So we should be being provided with a validation report as indicated below.

UCV validation report

8.173 Following validation a full report detailing the findings should be produced. The report shall conclude with a clear statement as to whether the UCV theatre suite achieved or did not achieve the standard set out above.
8.174 A copy of the report should be lodged with the following groups:

- operating department;
- infection control;
- estates and facilities.

The validation process, particularly for an ultraclean theatre depends on assessment on a battery of physical and engineering parameters and "microbiological" testing i.e. culturing is not part of that process –air quality being assessed by particle counts using standardised methodology.
Taking this on board, the project manager, involved in the theatre 11, 12 commissioning arranged for a company (which was not involved in the theatre construction) to do the assessment and produce the validation report. I've attached a copy of that report in the e-mail trail attached.

As you can see, it is a concise and easy to read document that clearly states the theatres are fit for use. However you will also see from the e-mails that a number of snagging issues were identified that needed correction first – hence why having the report produced by another company is very useful. So I would very much propose we look for independent verification based on 1. We have done it before at SJH and 2. Glasgow have identified many issues since accepting their building that they are in the process of retrospectively addressing and we should avoid finding ourselves in that position.

I find it a bit perturbing that we are being asked such questions by the builders which are very clearly answered by SHMT 03-01 which they should be very familiar with and working to.

With regards to the isolation rooms, it would seem intuitive to take the same approach of independent verification. Although this does not appear from SHTM 03-01 to be mandatory (as it is in theatres). Crucially important given the discussions we have been having about their design are the air flows, pressures and air changes achieved per hour and I would propose that smoke testing is going to be crucial in assessing that air flows are going in the correct direction (particularly if a door is open). From a verbal discussion with a colleague in Glasgow smoke testing of the isolation rooms in their new building identified that air flows were not as intended. It is a crucial bit of the design that we need evidence is correct.

Multiplex as the builder should be performing a "validation" but that is unlikely to be unbiased and may miss issues that need addressed. More crucially I think we should be asking for independent verification and a clear validation summary report indicating that all aspects of these areas are functioning as intended which is supported by SHTM 03-01.

Please note I am on annual leave next week. Drs Kalima and Henderson are included for information in case their input is required while I am away. I'm back on Sept 3rd.

Best wishes
Donald

From: Sansbury, Jackie
Sent: 23 August 2018 17:10
To: Rae, Janette; Inverarity, Donald; Henderson, Ronnie
Subject: Independent verification of theatres and isolation room ventilation

Dear all, at the commissioning meeting with Multiplex yesterday they asked me what verification we wanted to carry out for theatres and isolation rooms.
They were at great pains to separate out validation from verification.
It appears in Glasgow the same person did both. It also appears that in Dumfries and Galloway they insisted on an independent verification.
Can you advise me what we wish to do?

Also what do we wish to do for the UV canopies? They thought we would wish to do microbiological checks.

I would be grateful for your advice.
Many thanks
Jackie

Jackie Sansbury
Head of Commissioning
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh EH16 4TJ

[redacted]

Inverarity, Donald

From: Inkster Teresa (NHS GREATER GLASGOW & CLYDE) [redacted]
Sent: 20 May 2016 12:43
To: Peters Christine (NHS GREATER GLASGOW & CLYDE); Morris Keith (NHS FIFE); Batchelor Linsey (NHS DUMFRIES AND GALLOWAY); Connor Martin (NHS DUMFRIES AND GALLOWAY); Cooke Benjamin (NHS FORTH VALLEY); James Ed (NHS BORDERS); Gillespie Thomas (NHS LANARKSHIRE); Inverarity, Donald; Jamdar Sara (NHS FORTH VALLEY); Karcher Annemarie (NHS GRAMPIAN); Laidlaw Susan (NHS SHETLAND); Laurenson, Ian; MacDonald Alan (NHS AYRSHIRE AND ARRAN); Marek Aleksandra (NHS GREATER GLASGOW & CLYDE); Hanson, Mary; Mills Jonathan (NHS HIGHLAND); Orange Gillian (NHS TAYSIDE); Phillips Gabby (NHS TAYSIDE); Sarah.Whitehead[redacted] Venkatesh Priya (NHS FIFE); Wilson Becky (NHS GRAMPIAN)
Subject: ventilation query

Hi all

I am dealing with a ventilation issue at the moment and following on from Christine's Q2 can I ask specifically about ? MERs and MDRTB patients . Where would you place these patients in your hospital - negative pressure rooms, PPVL rooms or SSR with ensuite?

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]

From: Peters, Christine [redacted]
Sent: 12 May 2016 15:48
To: Morris Keith (NHS FIFE); Batchelor Linsey (NHS DUMFRIES AND GALLOWAY); Connor Martin (NHS DUMFRIES AND GALLOWAY); Cooke Benjamin (NHS FORTH VALLEY); James Ed (NHS BORDERS); Gillespie Thomas (NHS LANARKSHIRE); Inkster Teresa (NHS GREATER GLASGOW & CLYDE); Inverarity Donald (NHS LOTHIAN); Jamdar Sara (NHS FORTH VALLEY); Karcher Annemarie (NHS GRAMPIAN); Laidlaw Susan (NHS SHETLAND); ian.laurenson[redacted]; MacDonald Alan (NHS AYRSHIRE AND ARRAN); Marek Aleksandra (NHS GREATER GLASGOW & CLYDE); mary.hanson[redacted] Mills Jonathan (NHS HIGHLAND); Orange Gillian (NHS TAYSIDE); Phillips Gabby (NHS TAYSIDE); Sarah.Whitehead@[redacted]Venkatesh Priya (NHS FIFE); Wilson Becky (NHS GRAMPIAN)
Subject: RE: Framework to Support Staff Development in the Decontamination of RMDs

Hi All!

I have a serious of questions to pick your collective networked brains about:

1. Education in IC of Doctors _ do you have mandatory training for consultant level ? Is it linked to appraisal? Any success stories?

2. Isolation rooms for source isolation : what do you have in place just now re ventilation parameters and ante rooms etc and can I come to see them ?
3. Isolation for protective isolation : same as above .

Look forward to hearing from you all,
Bw
Christine

From: Morris Keith (NHS FIFE) [redacted]
Sent: 11 May 2016 16:35
To: Balfour, Alison; Bagrade, Linda (NHSmail); Batchelor Linsey (NHS DUMFRIES AND GALLOWAY); Connor Martin (NHS DUMFRIES AND GALLOWAY); Cooke Benjamin (NHS FORTH VALLEY); James Ed (NHS BORDERS); Gillespie Thomas (NHS LANARKSHIRE); Inkster, Teresa (NHSmail); Inverarity Donald (NHS LOTHIAN); Jamdar Sara (NHS FORTH VALLEY); Karcher Annemarie (NHS GRAMPIAN); Laidlaw Susan (NHS SHETLAND); ian.laurenson@[redacted]MacDonald Alan (NHS AYRSHIRE AND ARRAN); Marek, Aleksandra (NHSmail); mary.hanson@[redacted]; Mills Jonathan (NHS HIGHLAND); Morris Keith (NHS FIFE); Orange Gillian (NHS TAYSIDE); Peters, Christine; Phillips Gabby (NHS TAYSIDE); Sarah.Whitehead@[redacted]Venkatesh Priya (NHS FIFE); Wilson Becky (NHS GRAMPIAN)
Subject: FW: Framework to Support Staff Development in the Decontamination of RMDs

Please see email from Mary. It maybe of interest to those involved in decontamination

R
Keith

Keith Morris FRCPath, FRCP(Edin)
Consultant Microbiologist & Infection Prevention Doctor
North Laboratory
Victoria Hospital
Hayfield Road
Kirkcaldy
Fife
KY2 5AG
Tel [redacted]

From: Hanson, Mary [redacted]
Sent: 11 May 2016 15:53
To: Morris Keith (NHS FIFE); f.m.mackenzie@[redacted]
Subject: FW: Framework to Support Staff Development in the Decontamination of RMDs

Dear Keith and Fiona

If you feel this would be of interest to ICD Network and SMVN can you please circulate?

Many thanks

Mary

From: Elaine Thompson [redacted]
Sent: 10 May 2016 17:15
To: Gill Walker; Fiona McMillan; John McKay; Abigail.Mullings[redacted] Hanson, Mary; Edward.James[redacted] laura.imrie[redacted] neil.redhead[redacted]

margaret.tannahil[redacted]; jacqueline.sneddon[redacted] Sheena Greco; Nicola.taylor[redacted]
Rosalyn.murphy[redacted] Rosalyn.murphy[redacted]; ian.gentlman[redacted]
paulinehogg2[redacted] edward.james[redacted] paulinehogg2[redacted]
edward.james[redacted]; ian.gentlman[redacted] ann.scobie[redacted] alisonsolley[redacted]
kim.jackobsen[redacted] Susancameron[redacted] acorker[redacted] hpagan[redacted]; Sue.storrar[redacted]
Iain.Gorman[redacted] Rebecca.Reid2[redacted] Ann.TraquairSmith[redacted]
Stephen.Boyd[redacted] Alexander.Connel[redacted]; Irene.Gillespie[redacted]
Marie.Peat[redacted] Anne.Caldwel[redacted] Tracy.Ward[redacted]
Andrew.Hamilton2[redacted] David.Shaw[redacted] Jacqui.McCormick[redacted]
Ian.McIvor[redacted] phyllis.watt[redacted]; alan.stewart[redacted]
Frances.mclinden[redacted]; elainehutchison[redacted] rosemary.waters[redacted]
Fiona.MacKenzie3[redacted] Elizabeth.mclaughlin[redacted]; lisa.neil2[redacted]
anne.frame[redacted] Joan.barclay[redacted]; claira.chisholm[redacted] yvonne.trotter[redacted] ellis.cosh[redacted]
Mike.devine[redacted]; Leane.smith[redacted] Lorraine.hinton[redacted]
Alison.kerr[redacted]; jean.kerr[redacted] Nicola.tracey[redacted]
Frances.queen[redacted]; margaret.jamieson1[redacted] noreenmacdonald[redacted]
kenny.macleod[redacted] ericmacdonald[redacted] annamacfarlane[redacted]; annette.rankin[redacted]
Heatherwallace1[redacted]; Gillian Dougan

Subject: Framework to Support Staff Development in the Decontamination of RMDs

Sent on behalf of Christine Young

For Information

Dear Colleague

Here is the link to the recently published framework to support staff development in the decontamination of RMDs:

http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/healthcare-associated-infections/training-resources/framework-to-support-staff-development-in-the-decontamination-of-re-usable-medical-devices.aspx

Flyers to support local promotion of the framework have also been published and we are happy to send copies of these on request. If you would like copies of these, then please contact[redacted] and identify how many you require.

This framework was developed to support staff who undertake, manage or are responsible for decontamination activities in decontamination units throughout Scotland. It aims to help staff to develop their existing knowledge, understanding and skills in the complex area of decontamination. It links with KSF, PDPs and the personal development review process.

The next stage of this project is framework implementation and this involves evaluating the most useful and effective methods for implementation by staff working in decontamination. NES will be looking to establish pilot sites incorporating health boards with diverse decontamination structures. These pilot sites will be the focus of the implementation strategy and evaluation results will be shared across NHSScotland to maximise the benefit to staff when using the framework.

An invitation for health boards to volunteer to be a pilot site for local (dental and podiatry), endoscopy and central decontamination will soon be issued.

I would be grateful if you could share this information as widely as possible to the most relevant persons in your area and apologise if I've inadvertently missed anyone from this circulation list.

Please let me know if you have any queries.

Best wishes.

Christine

Elaine Thompson
Project Administrator (HAI)
NHS Education for Scotland
2nd Floor
West Port 102
EDINBURGH EH3 9DN
[redacted]

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NSS Health Facilities Scotland

Managing the Risk of Contamination of Ventilation Systems by Fungi from Bird Droppings

Interim Guidance

March 2019

A47310563

Background

The production of this guidance is prompted by recent experience of infection, and the presence of fungal spores, in areas occupied by immunocompromised patients. Investigations are ongoing and updates may be issued as further evidence emerges. This guidance should be read in conjunction with Scottish Health Technical Memorandum (SHTM) 03-01 - Ventilation for healthcare premises, Scottish Health Facilities Note 30 Part A: Manual - Information for Design Teams, Construction Teams, Estates & Facilities and Infection Prevention & Control Teams and Part B: HAI-SCRIBE - Implementation strategy and assessment process.

Fungi are ubiquitous in the external environment and, whilst generally harmless to healthy people, susceptible patients can be infected by various fungi, not just those associated with bird droppings. For that reason ventilation systems serving areas housing patients susceptible to fungal infection are designed to minimise the risk of transmission of spores into the occupied space by means of appropriate filtration and pressure differentials between relatively clean and less clean environments.

Airborne fungal spores can enter general healthcare environments via opening or poorly sealed windows and doors, apertures in building fabric, supplies, plants and flowers etc. Although the filtration in non specialised ventilation systems is not intended to eliminate fungal spores, keeping plant areas free of vermin and bird droppings is good practice and helps prevent spores entering the occupied space.

Ventilation systems serving general patient and non patient areas are primarily designed to dilute contaminants in the occupied space and maintain comfort conditions. Although the filters used will reduce contamination from external sources, they are not designed to eliminate fungal spores. More detailed information is given in SHTM 03-01. The guidance contained herein is intended to reduce the challenge ventilation systems face from fungi and to reduce the risks, particularly recognising that patients in general hospital environments may have reduced immunity for a number of reasons. It is not intended to make areas served by non-specialised ventilation systems safe for patients who should be accommodated in specialised protective environments but it does recognise that people with increased susceptibility can be present in other areas.

Specialised advice on the management of ventilation systems, including the protection of plant from contamination from bird droppings should be sought as needed from the Board's appointed Authorising Engineer (Ventilation). Boards should satisfy themselves that appropriate vermin control measures have been implemented.

Plantrooms

To minimise the risk of contamination of ventilation systems with fungal sporesi, plant rooms should be maintained clean and free of vermin. Where bird droppings are found, the entry points for birds should be found and blocked and the area cleaned and decontaminated under controlled conditions. This should be done in such a way as to prevent further dispersal of spores and contamination of surrounding clinical environments and taking care not to produce dust or aerosol, and an investigation commenced into the source of the contamination.

External ventilation plant

External plant areas are more difficult to protect and measures should reflect the risks involved. NHS Boards should have records of all external ventilation plant, which should identify the areas and patient groups served. The inspection and maintenance of external ventilation plant should be in accordance with the requirements of SHTM 03-01 and should include steps to reduce the risks from fungal contamination from bird droppings.

Where external plant serves areas where patients are considered to be susceptible to fungal infection, or housing immunocompromised patients, measures to minimise the risk of contamination by fungi from bird droppings should be considered, including bird netting, anti roost devices, partial enclosure combined with bird netting, enclosing the plant in a fabricated housing and/or regular inspection and cleaning as appropriate to the risk. Solutions will need to take account of local conditions such as layout, weather exposure, roof loading and maintainability. The integrity of any solution needs to be taken into account as a poorly designed or maintained solution might increase roosting risk.

Bird dropping contamination at air intakes

Bird droppings, in areas where they might be able to produce airborne fungal spores which might be drawn into the system, should be cleaned and decontaminated under controlled conditions. This should be done in such a way as to prevent further dispersal of fungal spores and contamination of surrounding clinical environments and taking care not to produce dust or aerosol.

Where droppings are not likely to be disturbed and not close to air intakes, they are unlikely to shed spores in greater quantities than that present in outside air. If regular inspection identifies places where contamination repeatedly builds up and needs to be cleaned, then appropriate steps should be taken to deter birds from using that place, such as by placement of anti roosting devices or netting. Prevention of bird dropping contamination is preferred to cleaning and the contents of this guidance should be reflected in pest control policies.

The measures adopted should be determined by risk assessment involving appropriate clinical, microbiology, infection prevention and control and estates disciplines, and should take account of patient placement, patient susceptibility, filtration, location of plant, practicability of protective measures and other issues identified by those undertaking the assessment. HAI-SCRIBE has been developed as a framework for disciplines to work together to identify, manage and mitigate built environment infection prevention and control risks.

Removal of bird droppings

The fungi associated with bird droppings presents a risk to those engaged in its removal and any associated work should only be carried out following an appropriate risk assessment and following a procedure developed to control the risks. The risk assessment should identify the appropriate personal protective equipment (PPE) to be used. Microorganisms such as fungi may be substances hazardous to health as in the Control of Substances Hazardous to Health Regulations 2002 http://www.hse.gov.uk/coshh/. Staff with compromised immune systems should not undertake the work of removing bird droppings.

Whether specialist contractors or in house staff are used to remove bird droppings, they should be appropriately trained and use appropriate methods and equipment, including personal protective equipment as identified in the risk assessment and procedure above. A permit to work system should be used to control the timing, methodology and extent of work. The route to and from the work site should also be considered to ensure fungi are not spread to adjoining clinical areas, and should be collaboratively signed off by estates and infection control. Clothing, equipment and tools should be appropriately decontaminated or disposed of at the end of work in accordance with the risk assessment and procedure. All contaminated waste should be disposed of with due regard to the pathogens present. Further information is available on the HSE web site, http://www.hse.gov.uk/construction/healthrisks/hazardous-substances/harmful-micro-organisms/other-diseases.htm.

Health and safety assessments, records and other documentation should be updated in accordance with decisions made, risk assessments and work procedures.

Bird droppings should be removed using techniques designed to minimise the risk of releasing airborne fungi. As the risk of releasing airborne fungi increases when droppings are dry and can produce dust when disturbed, HEPA filtered vacuuming and/or wet removal techniques are likely to be best. Pressure washing should be avoided as this will aerosolise and spread the droppings. When droppings are being removed, the associated ventilation systems should be off and isolated where practicable and indicated by risk assessment. Chemical inactivation of fungi, once the affected area is physically clean, should be used although this should not be relied on as a substitute for other protective measures.

Bird management

This guidance does not set out to address bird management in general, which is a complex multifactorial issue, although it should be noted that management of the bird population in the vicinity of buildings can affect the accumulation of droppings and the risk of contamination from Fungi should be part of a bird management strategy.

All wild birds in Great Britain are protected under the Wildlife and Countryside Act 1981 (as amended). This includes even common species like pigeons and blackbirds. Further information is available from Scottish Natural Heritage here.

Cryptococcus Briefing for AE(V)'s, AP(V)'s & Estates Professionals

Acknowledgments

Lead Author(s) Andrew Poplett

Harry Evans

Contributing Parties

IOM Consulting Ltd

Ray Hughes

Joe Hughes

The following individuals and organisations were consulted during the preparation of this document. Their contribution is gratefully acknowledged.

All members of the Specialist Ventilation for Healthcare Society

Introduction

Following recent press coverage regarding an incident of two patient deaths at a Glasgow hospital, reported as 'due to infections of cryptococcus', the following information summary has been prepared to provide guidance and proportional advice to estates professionals, regarding any additional actions to consider to minimise or address estates ventilation related issues.

Cryptococcus is a pathogenic yeast fungus whose spores are ubiquitous in the environment, normally found in air (including hospital ventilation systems), soil, decaying plant matter, and bird excrement. This makes it extremely difficult if not impossible to control at the point of source.

- The fungal spores produced by the fungi have an effective diameter of between (1 to 2µm)
- Infection is mainly via inhalation although direct wound contamination is also possible.
- Multiplication and growth are strongest in warm and/or damp environments

Whilst Cryptococcus rarely poses a threat to normal healthy people, it is recognised as a potential cause of severe illness and mortality in highly immunocompromised patients.

Cryptococcosis has a number of identified strains including neoformans, gattii, albidus, and uniguttulatus which have all been identified in cases of human infection, there are also a total of fourteen non-infectious species. For the purposes of this briefing paper it is Cryptococcus neoformans that is referenced, as research suggests that this strain is the primary source for the majority of human infections.

Characteristics

Cryptococcus neoformans is a spherical yeast fungus, 3 µm in diameter when desiccated and 5 to 10µm in diameter when hydrated), that produces a capsule containing glucoronoxylomannan (GXM), extending the overall diameter to 25 µm or more.

The problem is the spores from the Cryptococcus are so small, like many other fungal spores such as 'aspergillus' etc., they can pass through the majority of filter grades with the exception of HEPA filters, and enable the spores to penetrate the alveoli within the lung more efficiently than other yeast organisms.

Mode of Transmission

Humans and animals can get the infection after inhaling the microscopic fungal spores from the environment. Cryptococcus neoformans infections are not contagious (human to human), although some research suggests that people may be exposed to Cryptococcus in the environment when they are children. Most people who breathe it in never get sick from it. However, in people who have weakened immune systems, Cryptococcus can stay hidden in the body and cause infection later when the immune system becomes too weak to fight it off.

Incubation Period

Unknown, Cryptococcus neoformans can colonize in the host respiratory tract for months to years without causing any clinical symptoms

How common are Cryptococcus neoformans infections?

Cryptococcus infections are rare among people who have healthy immune systems; however, Cryptococcus can be a major cause of illness in people with HIV/AIDS or patients who have severely weakened immune systems (transplant/oncology).

Pathology

Infection with Cryptococcus neoformans is termed Cryptococcosis. Most infections with Cryptococcus neoformans occur in the lungs. However, fungal meningitis and encephalitis, especially as a secondary infection for severely immunocompromised patients, are often caused by Cryptococcus, making it a particularly dangerous fungus. Infections with this fungus are rare in those with fully functioning immune systems

Infection starts in lungs, disseminates via blood to meninges and then to other parts of the body. Cryptococcus can cause a systemic infection, including fatal meningitis known as meningoencephalitis in normal, diabetic and immunocompromised hosts. The infection from Cryptococcus neoformans in the brain can be fatal if untreated. CNS (central nervous system) infection may also be present as a brain abscess known as Cryptococcomas, subdural effusion, dementia, isolated cranial nerve lesion, spinal cord lesion, and ischemic stroke. If Cryptococcal meningitis occurs, mortality rate is between 10–30%.

Potential Risk Groups

- Organ Transplants
- Oncology / Caner treatment
- Patients on high dose steroids
- Haematology
- I.C.U. / P.I.C.U.
- S.C.I.D.S. / B.M.T.
- HIV Positive patients
- Laboratory Facilities

Suceptibility to Disinfectants

Cryptococcus neoformans is effectively killed by 70% ethyl alcohol and is susceptible to phenolic compounds, formaldehyde, glutaraldehyde, iodophors, and sodium hypochloride (1%)

Potential Additional Maintenance Precautions

- Ensure all plantrooms and air handling unit air intake areas are clear and secured.
- All air intakes should be clear of debris and where practical the immediate surrounding area should be clear of vegetation and any accumulation of bird faeces should be cleaned at regular intervals.
- In all cases where bird ingress to plant areas is evident, it should be dealt with and cleaned up immediately upon discovery.
- Birds must be prevented from nesting or congregating close to any AHU intake. If anti-roosting netting has been recently installed, birds will be displaced and nest elsewhere, special attention should be given to ensure that they do not nest near AHU air intakes.

- All filters should be subject to routine inspection and changed when indicated by pressure drop.
- All anti-roost netting should be inspected as part of the existing quarterly inspection protocol for all critical ventilation AHU plant.
- The IPC team and estates team should establish a regular review meeting to identify clinical areas where patient susceptibility may be high and immunocompromised patients are treated. In extreme cases of known risk consideration should be given to provision of temporary or permanent HEPA filtered positive pressure ventilation systems, however this is not anticipated to be a routine requirement for the majority of healthcare environments.

For specific issues or concerns the Trust Authorising Engineer (Ventilation) should be contacted to work with all estates and clinical stakeholders to agree additional precautionary measures.

References & Further Reading

Health & Safety Executive, Controlling Harmful Substances, Harmful Micro-organisms – Infection at Work, Controlling the Risks, HMSO 2003

Health Facilities Scotland - Interim guidance on managing the risk of fungal contamination from bird droppings in air, February 2019

Pathogen Safety Data Sheet: Infectious Substances – Cryptococcus neoformans, Public Health Agency of Canada, Copyright © 2018

R Rajasingham et al., Lancet Infectious Diseases 2017

Sorrell TC, Ellis DH. Ecology of Cryptococcus neoformans. Rev Iberoam Micol. 1997 Jun

Michael R. Botts, Steven S. Giles, Marcellene A. Gates, Thomas R. Kozel, and Christina M. Hull
Isolation and Characterization of Cryptococcus neoformans Spores Reveal a Critical Role for Capsule Biosynthesis Genes in Spore Biogenesis
Department of Biomolecular Chemistry and Department of Medical Microbiology & Immunology, School of Medicine and Public Health, University of Wisconsin, Madison, Wisconsin 53706, and Department of Microbiology and Immunology, University of Nevada School of Medicine, Reno, Nevada, USA Copyright © 2009, American Society for Microbiology.

Center for Disease Control and Prevention What is Cryptococcus infection (cryptococcosis)? April 28, 2010. Retrieved 8 March 2012.

CDC Centers for Disease Control and Prevention, US Department of Health & Human Services, USA

"What Makes Cryptococcus neoformans a Pathogen? - Volume 4, Number 1—March 1998 - Emerging Infectious Diseases - CDC". wwwnc.cdc.gov. Retrieved 2017-04-18

Inverarity, Donald

From: Evans, Stephen
Sent: 11 February 2019 09:40
To: Sutherland, SarahJane
Cc: Guthrie, Lindsay; Inverarity, Donald; Munro, Anna; Bathgate, Clare; Mackenzie, Janice; Halcrow, Fiona
Subject: RE: Air testing MRI intra-operative scanning room

Dear Sarah,
Thanks for the e-mail.
No need for Dr Inverarity to attend.
I was seeking final clarification as Jackie has now left the project, and I wanted to remove the item from the agenda.
Regards
Stephen

From: Sutherland, SarahJane
Sent: 11 February 2019 09:05
To: Evans, Stephen
Cc: Guthrie, Lindsay; Inverarity, Donald; Munro, Anna; Bathgate, Clare; Mackenzie, Janice; Halcrow, Fiona
Subject: Air testing MRI intra-operative scanning room

Dear all,

I note that the MRI minutes from the meeting on 23.01.2019 appear to have an ongoing action in relation to air testing within the MRI intra-operative scanning room and Stephen has asked Anna for clarification around this.

Both Anna Munro and Lead IPCN Lindsay Guthrie had a previous discussion with Dr Inverarity Consultant Microbiologist and ICD for NHS Lothian in relation to this question. My understanding was that Anna had discussed this with Jackie whom also requested clarification from myself. Please see Dr Inverarity's advice below:

I have previously been asked about this scenario and advised not to perform microbiological air testing because there are no microbiological parameters by which to interpret the result in this context.
I would not usually advise performing a microbiological test when the result is not interpretable.

In such a scenario, the assessment of the adequacy of the ventilation rests on the visual inspection of the area and confidence that air changes and room pressures are adequate.
Donald.

Dr Inverarity has advised that If it would be helpful and he is available, he would be happy to attend the next meeting to explain theatre microbiological air testing (and its limitations).

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian Infection Prevention & Control Servces

[redacted]

For more information visit the IPCT
http://intranet.lothian.scot.nhs.uk/Directory/InfectionPreventionAndControl/Pages/NHSLothianInfectionPreventionandControl.aspx

Inverarity, Donald

From: Sutherland, SarahJane
Sent: 04 April 2019 13:02
To: McDonald, Jane
Cc: Inverarity, Donald; Khatamzas, Elham
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Jane,

I have attached a fairly recent paper I received in relation to the effects of Laminar Flow (neurosurgery) however, unfortunately I do not have a great deal of experience with theatre ventilation and Laminar Flow (hopefully I will after I have attended an engineering course later in the year!).

Perhaps my Microbiology colleagues may be able to point you in the right direction of the best resource as I am aware there has been recent discussion in relation to DCN theatres.

Donald/Elham would you be able to assist Jane?

Kind regards
Sarah

From: McDonald, Jane
Sent: 04 April 2019 08:22
To: Sutherland, SarahJane
Subject: FW: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hello Sarah Jane,

I'm GM for the adult theatres across Lothian – would you be able to point me in the direction of any of the developing evidence about risks with laminar flow.

Thank you
Jane

From: Hull, Ashley
Sent: 04 April 2019 07:34
To: McDonald, Jane
Subject: FW: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

See below
Ashley

From: Khatamzas, Elham
Sent: 03 April 2019 17:23
To: Halcrow, Fiona; Inverarity, Donald
Cc: Fitzpatrick, Michael; Hull, Ashley; Fouyas, Ioannis; Niven, Hester; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Dear Fiona

Many thanks. That's really helpful.

It is reassuring to know that the laminar flow ventilation can be switched to conventional ventilation for cranial procedures. I assume the theatre design and environment and all other issues would be captured in the HAI-Scribe and there would be clear protocols and education around that?

There is an increasing awareness about potential risks of laminar flow ventilation, for instance when patient body temperature is not maintained, which could be the case in prolonged procedures. There is a multicentre trial presently looking at the risks of different warming techniques on infection rates.

I think it would be useful to address all the potential issues and pitfalls that may arise far in advance involving surgeons, theatre staff, anaesthesists and estates to minimize risks and delays.

Happy to discuss further.

Elham

From: Halcrow, Fiona
Sent: 02 April 2019 18:06
To: Khatamzas, Elham; Inverarity, Donald
Cc: Fitzpatrick, Michael; Hull, Ashley; Fouyas, Ioannis; Niven, Hester
Subject: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Both

I have read through the emails below with regard to the question being raised by both of you with regard to clinicians in DCN requesting ultraclean laminar flow ventilation in the 4 theatres.

The senior DCN clinician involved in the design of theatres early doors was Mr James Steers. Miss Lynn Myles and Mr Jerard Ross were also involved (Mr Ross does not now work with NHSL)

I have information dating back as early as 2009/2010 on the DCN Theatres specifications which included the need for laminar flows in their theatres. One of the key rationales for DCN theatres have laminar flows is that the majority of surgery undertaken in DCN is spinal related.

The laminar flow specification at the procurement stage was also reviewed by clinicians – Mr Sokol and Mr Demetriades from DCN was involved.

One key element was for the units control system that it permitted the Ultra Clean Ventilation System to be set-back to a reduced speed. *So this would be utilised when cranial surgery is being undertaken. Does this help to address your concerns?*

If you wish to meet up to discuss I am usually down at the WGH on a Friday.

Regards

Fiona

From: Khatamzas, Elham
Sent: 01 April 2019 16:51
To: Halcrow, Fiona
Subject: FW: question re theatres in new RIE site

Hi Fiona

I just had a discussion with Mike Fitzpatrick who was unaware of the issues I have raised as below and certainly did not know that the new theatres have been fitted with laminar flow ventilation that would not be standard practice in neurosurgery. Are you aware of the background decisions leading to this and hwat the rationale was?

Many thanks
Elham

Dr Elham Khatamzas
Consultant in Infectious Diseases and Microbiology, NHS Lothian
Honorary Senior Clinical Lecturer, University of Edinburgh

Office [redacted]
Mobile via switchboard

From: Hull, Ashley
Sent: 29 March 2019 11:44
To: Khatamzas, Elham; Niven, Hester
Subject: RE: question re theatres in new RIE site

Good Morning

As you are aware planning for this new build was quite a few years ago. My understanding was that the initial design of the theatres it was agreed with the services/clinicians that ultra clean theatre was required.

If I find out any other information why the services / clinicians had asked for this I will update you.

Kind Regards
Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Khatamzas, Elham
Sent: 29 March 2019 10:54
To: Niven, Hester
Cc: Hull, Ashley
Subject: RE: question re theatres in new RIE site

Thanks

Dear Ashley could you please explain why the theatres are fitted with ultraclean laminar flow ventilation?

Elham

From: Niven, Hester
Sent: 29 March 2019 10:49
To: Khatamzas, Elham
Cc: Hull, Ashley
Subject: Re: question re theatres in new RIE site

Hi Elham

Ashley Hull is the commissioning lead for theatres.

Hester

Sent from my BlackBerry 10 smartphone on the EE network.

From: Khatamzas, Elham
Sent: Friday, 29 March 2019 10:34
To: Niven, Hester
Subject: FW: question re theatres in new RIE site

Hi Hester

Would you know who'd know about this (see below)?

Thanks
Elham

From: Khatamzas, Elham
Sent: 28 March 2019 09:38
To: Fouyas, Ioannis; Fitzpatrick, Michael
Subject: question re theatres in new RIE site
Importance: High

Hi

Donald Inverarity has inspected theatres in the new site and it appears that all operating suites are fitted with ultraclean laminar flow ventilation. It is unusual for theatres where cranial procedures are carried out to use laminar flow so we

are both puzzled. We wanted to check if you were aware of this? Or even if this was based on specific request by neurosurgeons?

Best wishes
Elham

Inverarity, Donald

From: Sutherland, SarahJane
Sent: 15 April 2019 09:51
To: Halcrow, Fiona
Cc: Guthrie, Lindsay; Kalima, Pota; Horsburgh, Carol; Munro, Anna; Inverarity, Donald
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Fiona,

Apologies, working my through emails.

The policy Donald is referring to sits within the Infection Control page on the Intranet. Staff will also find The National Infection Prevention and Control Manual (NIPCM) via the Infection Control pages - Appendix 11 of this document also provides advice on which patients require Isolation and where an Isolation Suite is required.

Staff should be aware of these/familiarise themselves with both documents and where to locate these on the intranet as these are the documents that they should make reference to for guidance.

I have attached the links below however any hard copies of these documents should not be printed and kept as policies/guidance may be updated electronically at any given time.

http://intranet.lothian.scot.nhs.uk/Directory/InfectionPreventionAndControl/Policies/Isolation%20Guidance.pdf

http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-11-best-practice-aide-memoire-for-optimal-patient-placement-and-respiratory-protective-equipment-rpe-for-infectious-agents-whilst-a-patient-is-in-hospital/#

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian

[redacted]

From: Halcrow, Fiona
Sent: 10 April 2019 17:08
To: Inverarity, Donald; Sutherland, SarahJane
Cc: Guthrie, Lindsay; Kalima, Pota
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hello Donald

We have been shown how these rooms work and understand the alarm system etc.

As you know RHSC and DCN do not have isolation rooms just now so they need to be aware of the NHSL document you mention below.

Could someone send that through to me?

Regards

Fiona
Fiona Halcrow
Project Manager

RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Inverarity, Donald
Sent: 10 April 2019 16:55
To: Halcrow, Fiona; Sutherland, SarahJane
Cc: Guthrie, Lindsay; Kalima, Pota
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Fiona,
I think guidance that explains how to work the isolation room and monitor that it is working correctly is really the remit of Facilities. Until the builders or facilities explain and demonstrate how it works to us I don't think anyone in the IPCT would be in a position to write anything useful. I also think ownership of such a document really should be through involvement with the clinical teams who will occupy those areas and using the rooms.

All the best
Donald

From: Halcrow, Fiona
Sent: 10 April 2019 16:46
To: Inverarity, Donald; Sutherland, SarahJane
Cc: Guthrie, Lindsay; Kalima, Pota
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi All

Can I please leave this with you to develop this SOP.

What is a realistic timeline for you.

We have been trying to have SOPS done by the end of April but this might be an unrealistic timeline for you.

Query end of May?

Regards

Fiona

Fiona Halcrow
Project Manager

RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Inverarity, Donald
Sent: 10 April 2019 16:13
To: Sutherland, SarahJane; Halcrow, Fiona
Cc: Guthrie, Lindsay; Kalima, Pota
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

There is an NHS Lothian policy document that outlines which types of patient require isolation but the design of the isolation rooms in the new building are unique in NHS Lothian with positive pressure HEPA filtered anterooms separating the room from corridor and I suspect we would need to write a protocol regarding how staff would know that they are working correctly once occupied.
Thanks
Donald

From: Sutherland, SarahJane
Sent: 10 April 2019 15:59
To: Halcrow, Fiona
Cc: Guthrie, Lindsay; Inverarity, Donald; Kalima, Pota
Subject: Re: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Fiona,

I have had a look within the RIDU web page and cannot locate an SOP for isolation rooms. Is it instructions on how to work the functions of negative/positive pressure settings within the suite you are looking for?

Regards
Sarah

Sent from my BlackBerry 10 smartphone on the O2 network.

From: Halcrow, Fiona
Sent: Wednesday, 10 April 2019 15:47
To: Khatamzas, Elham; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Both

Could you send on what you already have as this may meet every ones needs.

Regards

Fiona

Fiona Halcrow
Project Manager

RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Khatamzas, Elham
Sent: 10 April 2019 15:41
To: Halcrow, Fiona; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Fiona

We have isolation rooms across all sites so not sure if we need to create any new SOP. Unless there are some surprisingly new aspects to the isolation rooms that we don't know about? I think Sarah will capture all areas as part of the HAI scribe.

Elham

From: Halcrow, Fiona
Sent: 09 April 2019 16:29
To: Khatamzas, Elham; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Elham

Okay that is fine.

Also, as you know we have many isolation rooms in this building, does NHSL have a SOP re use of isolation rooms and if not I presume microbiology and infection control would want to take a lead on this?

Regards

Fiona

Fiona Halcrow
Project Manager

RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Khatamzas, Elham
Sent: 09 April 2019 16:25
To: Halcrow, Fiona
Cc: Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Fiona

Yes would like to be involved in reviewing the protocols to minimize risks

Thanks
Elham

From: Halcrow, Fiona
Sent: 03 April 2019 17:53
To: Khatamzas, Elham; Inverarity, Donald
Cc: Fitzpatrick, Michael; Hull, Ashley; Fouyas, Ioannis; Niven, Hester; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Elham

See response below in relation to your questions.

Regards

Fiona

Fiona Halcrow
Project Manager

RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Khatamzas, Elham
Sent: 03 April 2019 17:23
To: Halcrow, Fiona; Inverarity, Donald
Cc: Fitzpatrick, Michael; Hull, Ashley; Fouyas, Ioannis; Niven, Hester; Sutherland, SarahJane
Subject: RE: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Dear Fiona

Many thanks. That's really helpful.

It is reassuring to know that the laminar flow ventilation can be switched to conventional ventilation for cranial procedures. I assume the theatre design and environment and all other issues would be captured in the HAI-Scribe and there would be clear protocols and education around that? During the familiarisation and induction period there will be training provided to theatre staff with regard to the lamina Flow and how it functions. Protocols to aid staff when the laminar flow unit should be used and not be used will need to be drawn up and suggest also part of a tick list preparation for the theatre per theatre list.

Would you be keen to be involved in these protocols to ensure they address the issues you mention below?

There is an increasing awareness about potential risks of laminar flow ventilation, for instance when patient body temperature is not maintained, which could be the case in prolonged procedures. There is a multicentre trial presently looking at the risks of different warming techniques on infection rates.

I think it would be useful to address all the potential issues and pitfalls that may arise far in advance involving surgeons, theatre staff, anaesthesists and estates to minimize risks and delays.

Happy to discuss further.

Elham

From: Halcrow, Fiona
Sent: 02 April 2019 18:06
To: Khatamzas, Elham; Inverarity, Donald
Cc: Fitzpatrick, Michael; Hull, Ashley; Fouyas, Ioannis; Niven, Hester
Subject: Ultraclean laminar flow venitilation in DCN new theatres - new RHSC and DCN Building

Hi Both

I have read through the emails below with regard to the question being raised by both of you with regard to clinicians in DCN requesting ultraclean laminar flow ventilation in the 4 theatres.

The senior DCN clinician involved in the design of theatres early doors was Mr James Steers. Miss Lynn Myles and Mr Jerard Ross were also involved (Mr Ross does not now work with NHSL)

I have information dating back as early as 2009/2010 on the DCN Theatres specifications which included the need for laminar flows in their theatres. One of the key rationales for DCN theatres have laminar flows is that the majority of surgery undertaken in DCN is spinal related.

The laminar flow specification at the procurement stage was also reviewed by clinicians – Mr Sokol and Mr Demetriades from DCN was involved.

One key element was for the units control system that it permitted the Ultra Clean Ventilation System to be set-back to a reduced speed. *So this would be utilised when cranial surgery is being undertaken. Does this help to address your concerns?*

If you wish to meet up to discuss I am usually down at the WGH on a Friday.

Regards

Fiona

From: Khatamzas, Elham
Sent: 01 April 2019 16:51
To: Halcrow, Fiona
Subject: FW: question re theatres in new RIE site

Hi Fiona

I just had a discussion with Mike Fitzpatrick who was unaware of the issues I have raised as below and certainly did not know that the new theatres have been fitted with laminar flow ventilation that would not be standard practice in neurosurgery. Are you aware of the background decisions leading to this and hwat the rationale was?

Many thanks
Elham

Dr Elham Khatamzas
Consultant in Infectious Diseases and Microbiology, NHS Lothian
Honorary Senior Clinical Lecturer, University of Edinburgh

Office [redacted]
Mobile via switchboard

From: Hull, Ashley
Sent: 29 March 2019 11:44
To: Khatamzas, Elham; Niven, Hester
Subject: RE: question re theatres in new RIE site

Good Morning

As you are aware planning for this new build was quite a few years ago. My understanding was that the initial design of the theatres it was agreed with the services/clinicians that ultra clean theatre was required.

If I find out any other information why the services / clinicians had asked for this I will update you.

Kind Regards
Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Khatamzas, Elham
Sent: 29 March 2019 10:54
To: Niven, Hester
Cc: Hull, Ashley
Subject: RE: question re theatres in new RIE site

Thanks

Dear Ashley could you please explain why the theatres are fitted with ultraclean laminar flow ventilation?

Elham

From: Niven, Hester
Sent: 29 March 2019 10:49
To: Khatamzas, Elham
Cc: Hull, Ashley
Subject: Re: question re theatres in new RIE site

Hi Elham

Ashley Hull is the commissioning lead for theatres.

Hester

Sent from my BlackBerry 10 smartphone on the EE network.

From: Khatamzas, Elham
Sent: Friday, 29 March 2019 10:34
To: Niven, Hester
Subject: FW: question re theatres in new RIE site

Hi Hester

Would you know who'd know about this (see below)?

Thanks
Elham

From: Khatamzas, Elham
Sent: 28 March 2019 09:38
To: Fouyas, Ioannis; Fitzpatrick, Michael
Subject: question re theatres in new RIE site
Importance: High

Hi

Donald Inverarity has inspected theatres in the new site and it appears that all operating suites are fitted with ultraclean laminar flow ventilation. It is unusual for theatres where cranial procedures are carried out to use laminar flow so we are both puzzled. We wanted to check if you were aware of this? Or even if this was based on specific request by neurosurgeons?

Best wishes
Elham

From: Little, Kerryann
Sent: 13 May 2019 08:46
To: Gillies, Tracey
Subject: RE: Theatre Validation

Thank you Tracey

From: Gillies, Tracey
Sent: 11 May 2019 13:40
To: Inverarity, Donald; Curley, George; Henderson, Ronnie; Currie, Brian
Cc: Little, Kerryann
Subject: RE: Theatre Validation

Answering for Alex as he is on leave
I think all your points are valid Donald, and it should not be difficult to close the gap between what has been presented and the standard it is being measured against if this is all presentational.
Surely it just needs a list of what we need to know to be completed.
It may well be that the IT had access to a document management system that allowed them to see the evidence but you are right, in the current climate and potentially in future, saying signed off by IT will not be sufficient
Tracey

Executive Medical Director
NHS Lothian
Waverley Gate
PA Audrey Trotter [redacted]
mobile [redacted]

From: Little, Kerryann **On Behalf Of** McMahon, Alex
Sent: 10 May 2019 15:51
To: Gillies, Tracey
Subject: FW: Theatre Validation

Hi Tracey

Copying to you in Alex absence – Can you help with this please?

Thanks
Kal

Kerryann Little
PA to Professor Alex McMahon
Executive Director, Nursing, Midwifery and AHPs
Executive Lead for REAS and Prison Healthcare
NHS Lothian|2 - 4 Waterloo Place|Edinburgh|EH1 3EG[redacted]

From: Inverarity, Donald [redacted]
Sent: 10 May 2019 15:47
To: Henderson, Ronnie [redacted]
Cc: Currie, Brian [redacted]>; Curley, George [redacted]

McMahon, Alex [redacted]
Subject: RE: Theatre Validation

Hi Ronnie,

The Multiplex document doesn't indicate what size the theatres are, what the air pressures are in the theatre areas (anaesthetic room, prep area, theatre etc) or what number of air changes per hour are achieved and neither does it mention what, if any, microbiological assessment of air quality has been performed (that box is blank so I'm presuming none has been performed). Although you are being assured that it "conforms" it isn't explicitly stated what standard it "conforms" to –presumably SHTM 03-01 ?
The statement:
"The theatre suite ventilation system has been commissioned and validated in accordance with the required regulations and has achieved the required standard."
might be factually correct but there is nothing to back it up and it tells us absolutely nothing about how the theatre performs at baseline. It is essentially asking us to taking everything on trust that its all okay. That makes me a little uncomfortable in the current political climate of scrutiny. Does it achieve the required standard with a wide safety margin or did it barely achieve it empty without any operations in progress?
At validation the report should tell us at baseline how it actually "performs" so that if there are problems in the future we have some baseline parameters of air pressures and air changes per hour to compare it against.
I see that "all test documentation is located on Zutec." I don't know what Zutec is or whether anyone in NHS Lothian has access to that information so essentially I can't provide any assurance to myself or NHS Lothian by assessing it myself. But in my role as infection control doctor I shouldn't need to go to source documents and extract that information to interrogate and interpret it myself, it should be clearly and explicitly included in the validation report.

Section 8.64 of SHTM 03-01 says:
Ventilation system commissioning/validation report
8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

Personally I don't think we are being provided with a "full report" detailing the validation findings and there is not enough detail for me to know if the theatre is," fit for purpose and will only require routine maintenance in order to remain so for its projected life." I don't think the Validation checklist provided fulfils point 8.64 of SHTM 03-01 whereas the validation reports we were issued when the SJH theatres were commissioned did and were very easy to read and be assured by.

I'm happy to be over-ruled but, for me, I'm not assured by this checklist that theatre 30 is fit for purpose because the information I would be looking for to allow me to have that assurance is not provided and not accessible by me. I'm happy to hear other views.
Thanks.
All the best.
Donald

From: Henderson, Ronnie
Sent: 10 May 2019 14:49
To: Inverarity, Donald
Cc: Currie, Brian; Curley, George
Subject: Theatre Validation

Hi Donald,

Multiplex have provided us with their validation report for Theatre 30 as an example of what they intend to provide for each individual theatre. You will note it differs from the example you sent from St Johns although there is a

declaration that it conforms. I can confirm that these have been reviewed and signed off by the independent tester which provides us with reassurance of compliance. If however you have any doubts or concerns, happy to discuss with a view to appointing someone from outwith the project to give an additional layer of assurance if required.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

From: Henderson, Ronnie
Sent: 13 May 2019 14:26
To: Inverarity, Donald
Cc: Currie, Brian; Curley, George; McMahon, Alex; Gillies, Tracey
Subject: RE: Theatre Validation

Hi Donald,

As you know through our previous discussions it is neither our desire nor intention to provide something you are not 100% happy to accept as a suitable record or report. It is true to say that all the relevant information is available on the project data management system 'Zutec', I will ask our AE (ventilation) to review and independently validate and to provide the type of report you expect. For completeness, I do think it would be beneficial for yourself to view the kind of records held on the Zutec system and I would be happy to demonstrate this say during a one hour session.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Inverarity, Donald
Sent: 10 May 2019 15:47
To: Henderson, Ronnie
Cc: Currie, Brian; Curley, George; McMahon, Alex
Subject: RE: Theatre Validation

Hi Ronnie,

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Personally I don't think we are being provided with a "full report" detailing the validation findings and there is not enough detail for me to know if the theatre is," fit for purpose and will only require routine maintenance in order to remain so for its projected life." I don't think the Validation checklist provided fulfils point 8.64 of SHTM 03-01 whereas the validation reports we were issued when the SJH theatres were commissioned did and were very easy to read and be assured by.

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All the best.
Donald

From: Henderson, Ronnie
Sent: 10 May 2019 14:49
To: Inverarity, Donald
Cc: Currie, Brian; Curley, George
Subject: Theatre Validation

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Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

[redacted]

From: Rae, Janette
Sent: 29 December 2016 12:01
To: Hull, Ashley
Cc: Olson, Ewan; Inverarity, Donald
Subject: RE: THEATRES NEW BUILD
Attachments: SHTM 03 01 ventilation part b operational management.pdf

Dear Ashley,
Here are the documents that provide the info required re the commissioning etc of Theatres.

Ewan and Donald do you have any other information to add?
Regards
Janette

https://www.his.org.uk/files/5213/7338/2929/Microbiological_Commissioning_and_Monitoring.pdf

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
14 Rillbank Terrace
Edinburgh
EH9 1LL
[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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From: Hull, Ashley
Sent: 29 December 2016 11:46
To: Richards, Janette
Subject: RE: THEATRES NEW BUILD

Hi Janette

Thank you for getting back to me so quickly.

Much appreciated

Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

MOBILE [redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Richards, Janette
Sent: 29 December 2016 11:37
To: Hull, Ashley
Subject: RE: THEATRES NEW BUILD

Dear Ashley
I had a lovely Christmas thank you hope you did too.

Air sampling will have to be done at commissioning before you let staff go in and out putting in equipment etc. As this will be part of the assurance protocol that the air handling units are working. As for frequency after that prior to the theatres actually becoming functional I will have to look up and get back to you,
Regards
Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
14 Rillbank Terrace
Edinburgh
EH9 1LL
[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

From: Hull, Ashley
Sent: 29 December 2016 10:21
To: Richards, Janette
Subject: THEATRES NEW BUILD

Good Morning Janette

Hope you had a rest over Christmas. I take it you have been busy.

Just a quick question in relation to air sampling new theatres.

My thoughts are :

The plan is to move RHSC first and then DCN .

When would the appropriate time to air sample these theatres . I am proposing that all staff start to wear scrubs as from January 1st 2018.

I do not want to find issues a few days before the move and find that the move would be delayed. So when do you advise us to start remembering that we want no delays and would DCN be completed at the same time. All the

equipment should be in before Christmas 2017 .Only the transfer equipment to follow. Which is not as much as you think except for instrument trays, microscopes , stacks etc.

My other plan is that there is one delivery point DCN recovery this will allow us to control traffic as DCN will be the last in to theatres.

The plan for critical care is once the building clean is completed. Our domestics will start to clean them on a regular basis i.e. daily.

Kind Regards

Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

Our Values Into Action

Quality | Dignity and Respect | Care and Compassion | Openness, Honesty and Responsibility | Teamwork

For more information visit: http://www.nhslothian.scot.nhs.uk/values

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NHS National Services Scotland

Scottish Health Technical Memorandum 03-01:

Ventilation for healthcare premises
Part B: Operational management and performance verification

Health Facilities Scotland
Engineering and Environment

October 2011

Health Facilities Scotland

NHS National Services Scotland

Contents

Health Facilities Scotland

NHS National Services Scotland

Disclaimer

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Acknowledgements

Health Facilities Scotland would like to thank the principal contributors and the Steering Group led by the Department of Health for their efforts in producing the HTM 03-01 Part B document.

HTM 03-01 Part B has been updated and amended by Health Facilities Scotland for use in NHSScotland as SHTM 03-01 Part B. The contribution made by the National Heating & Ventilation Advisory Group is gratefully acknowledged.

Health Facilities Scotland

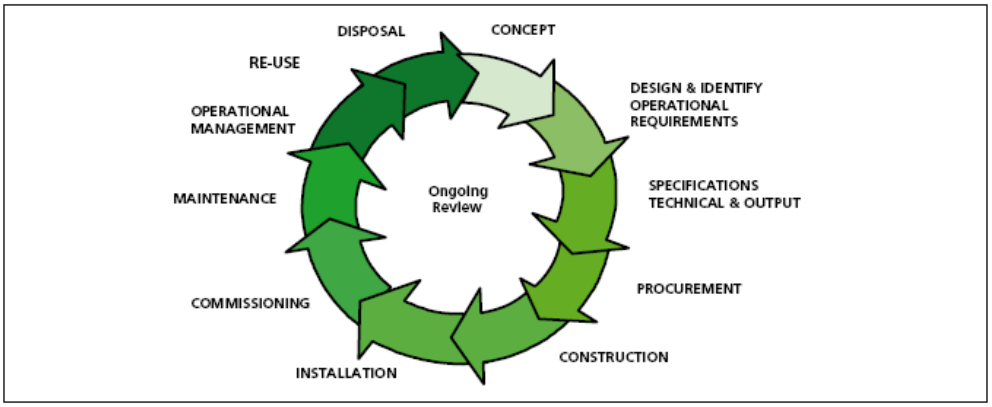
NHS National Services Scotland

Preface

About Scottish Health Technical Memoranda

Scottish Engineering Health Technical Memoranda (SHTMs) 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 Scottish 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.



Healthcare building life-cycle

Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Scottish Engineering 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 repeat unnecessarily 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. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

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

- is more streamlined and accessible;

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

Structure of the Scottish Health Technical Memorandum suite

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

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

Scottish Health Technical Memorandum 01: Decontamination

Scottish Health Technical Memorandum 02: Medical gases

Scottish Health Technical Memorandum 03: Heating and ventilation systems

Scottish Health Technical Memorandum 04: Water systems

Scottish Health Technical Memorandum 05: Reserved for future use.

Scottish Health Technical Memorandum 06: Electrical services

Scottish Health Technical Memorandum 07: Environment and sustainability

Scottish Health Technical Memorandum 08: Specialist services

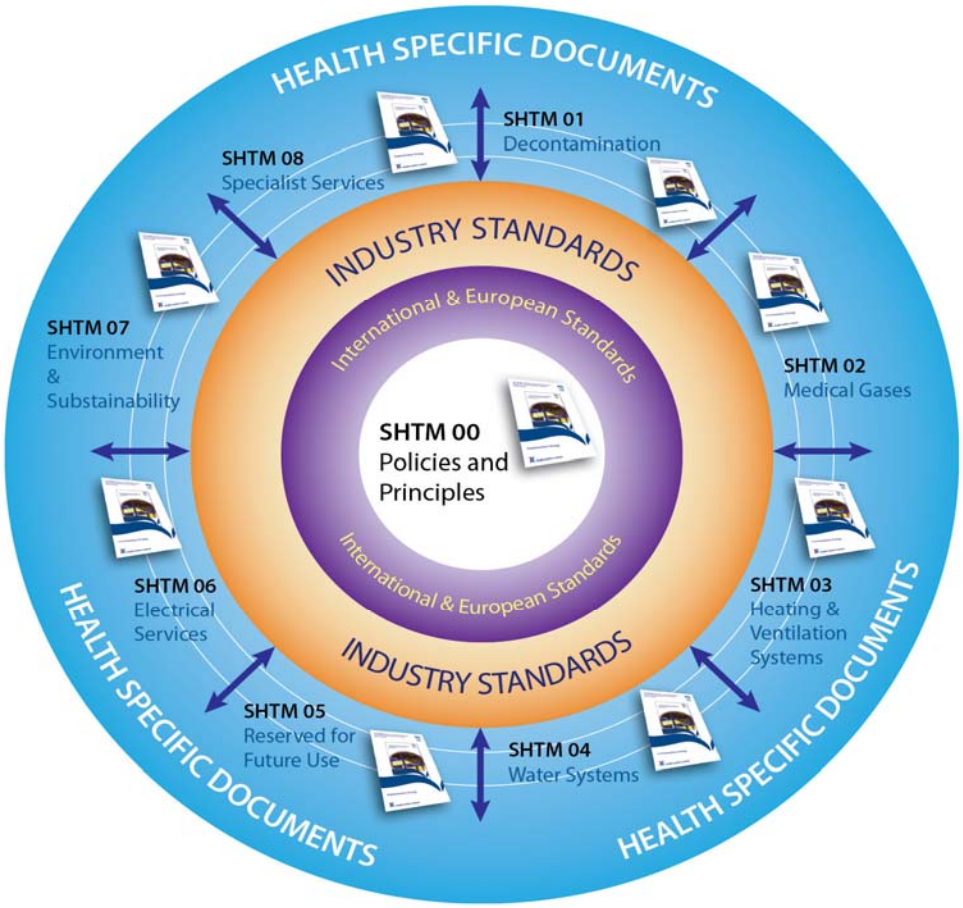
Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

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

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

All Scottish Health Technical Memoranda are supported by the initial document Scottish 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.



Engineering guidance

Health Facilities Scotland

NHS National Services Scotland

Executive summary

Scottish Health Technical Memorandum 03-01: 'Ventilation in healthcare premises' is published in two parts. Part A deals with the design and installation of ventilation systems; Part B covers operational management.

The document gives comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

The guidance contained in this Scottish Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

Scottish Health Technical Memorandum 03-01 supersedes all previous versions of Scottish Health Technical Memorandum 2025: 'Ventilation in healthcare premises'.

Who should use this guidance?

This document is aimed at healthcare management, estates managers and operations managers.

Main recommendations

- all ventilation plant should meet a minimum requirement in terms of the control of *Legionella* and safe access for inspection and maintenance;
- all ventilation plant should be inspected annually;
- the performance of all critical ventilation systems (such as those servicing operating suites) should be verified annually.

1. Introduction

1.1 Scottish Health Technical Memorandum 03-01: 'Ventilation in healthcare premises' is published in two parts. Part A deals with design and validation of general and specialised ventilation; Part B covers operational management.

1.2 The document gives comprehensive advice and guidance to healthcare management, design engineers, estates managers and operations managers on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

1.3 The guidance contained in this Scottish Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

1.4 Scottish Health Technical Memorandum 03-01 supersedes all previous versions of Scottish Health Technical Memorandum 2025: 'Ventilation in healthcare premises'.

Ventilation in healthcare premises

1.5 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. More specialised ventilation is provided in areas such as operating departments, critical care areas and isolation facilities for primary patient treatment.

1.6 It is also installed:

- to ensure compliance with the quality assurance requirements of items processed in pharmacies and sterile services departments;
- to protect staff from harmful organisms and toxic substances (for example in laboratories).

Statutory requirements

1.7 Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established.

If the ventilation plant has been installed to dilute or contain harmful substances, its failure may expose people to unacceptable levels of contamination. Proven breaches of the statutory requirements can result in prosecution and may also give rise to a civil suit against the operators.

Health and Safety at Work etc Act 1974

1.8 The Health and Safety at Work etc Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent

contamination, control closely the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

COSHH

1.9 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.

1.10 Where specialised ventilation plant is provided as part of the protection measures, there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the system be examined and tested at least every 14 months by a competent person and that management maintain comprehensive records of its performance, repair and maintenance.

1.11 Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's Guidance Note EH40 – 'Workplace exposure limits: containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended)'. If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above.

Fire regulations

1.12 The Fire Regulations require that if ventilation ductwork penetrates the fabric of a building, it should be designed and installed so as to contain the spread of fire (see Firecode: SHTM 81: 'Fire Precautions in New Hospitals, Version 3' and the requirements of the Scottish Technical Handbooks, Non-Domestic, Section 2: Fire, published by the Scottish Building Standards Agency).

1.13 It is management's responsibility to ensure that the standards applied during the design and installation are not reduced during the subsequent operation and maintenance of the equipment.

Plants installed in units manufacturing medicinal products

1.14 Plants installed in units manufacturing medicinal products to the standards set out in the current European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/ eudralex/homev4.htm) may also be subject to particular legislation with regard to their operation and maintenance.

1.15 There are specific requirements under the Medicines Act 1968 to maintain accurate records of plant performance, room conditions and maintenance

events. Such records would need to be preserved for up to 35 years as part of a quality assurance audit trail.

Plants installed in laboratories

1.16 Specialised ventilation plants installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified organisms, may be subject to particular legislation with regard to their operation in addition to that mentioned above.

Codes of practice and guidance

1.17 All ventilation systems should conform to the principles set out in the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8), and Scottish Health Technical Memorandum 04-01: 'The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems'.

1.18 Scottish Health Facilities Note 30: 'Infection Control in the Built Environment, Design and planning' guides and stimulates thinking on the planning of and execution of new construction and refurbishment works in all types of healthcare facilities. Ventilation systems (covered in this guidance) play an important role in reducing the risk of Healthcare Associated Infection.

Management responsibilities – general

1.19 It is a management responsibility to ensure that inspection, service and maintenance activities are carried out safely without hazard to staff, patients or members of the public.

1.20 Those required to monitor and/or maintain ventilation equipment will need to show that they are competent to do so (see Section 2).

1.21 Maintenance procedures should be reviewed periodically to ensure that they remain appropriate.

System information

1.22 When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure.

1.23 In many existing systems, original design and commissioning information will not be available. It will therefore be necessary to determine a suitable level of system performance based on the function, purpose and age of the installation.

1.24 Part A of this Scottish Health Technical Memorandum gives design parameters for new installations.

1.25 Section 3 of this document sets out the minimum standards for all air-handling units (AHUs) and their air distribution systems.

1.26 Ventilation system records and logbooks should be kept of the commissioning information, operational management routine, monitoring and maintenance. The Health and Safety Executive and other interested bodies have a statutory right to inspect them at any time. All records should be kept for at least five years.

Note 1: In the event of a reportable incident connected with ventilation equipment or the area that it serves; all records and plant logbooks will need to be collected as evidence.

1.27 A set of specimen maintenance checklists is given in Appendix 1.

Frequency of inspections and verifications

1.28 All ventilation systems should be subject to, at least, a simple visual inspection annually.

1.29 Ventilation systems serving critical care areas should be inspected quarterly and their performance measured and verified annually. The quarterly inspection should be a simple visual check; the annual verification will be a more detailed inspection of the system together with the measurement of its actual performance.

1.30 The LEV section of the COSHH Regulations contains a statutory requirement that systems installed to contain or control hazardous substances be examined and tested at least every 14 months by a competent person.

1.31 Regular tests, at intervals agreed with the local fire prevention officer, will need to be carried out in order to demonstrate the continuing efficiency of the fire detection and containment systems. These may be in addition to the inspections detailed above. Records of these tests should be kept.

Implications of PPP/PFI Procurement

1.32 While the ultimate responsibilities as set out in this SHTM in terms of overall management remain with NHS Boards, when a new or recent hospital has been procured via the Public-Private Partnership (PPP) or Private Finance Initiative (PFI) routes, there are changes in the chain of responsibilities.

1.33 More often than not, the operator of the facility will subcontract or enter into partnership with a Facilities Management (FM) Provider who will maintain and operate mechanical and electrical installations, including ventilation systems. It is not unknown for the FM provider to be the NHS Board's own estates staff. Whichever organisation carries out the functions set out in this SHTM, it will be

necessary for the same practice and procedures to be carried out, records maintained and reports prepared to maintain an audit trail. These have to be submitted to the NHS Board for which the hospital has been established. The NHS Board will retain in-house estates staff and/or technical advisers to monitor these records and reports, having the right to comment where performance standards are not being achieved, inspect installations, and seek to ensure that remedial measures are put in hand and monitored as to their effect.

In the event that a civil suit is served on a NHS Board, they would seek redress from the operator of the Hospital, where appropriate.

1.34 Issues related to control of infection where mechanical ventilation systems are implicated will be the remit of the NHS Board's control of infection teams set up for the purpose and representation should be arranged for estates staff or the FM Provider so that any remedial action agreed can be can be set in motion without delay.

Health Facilities Scotland

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2. Functional responsibilities

Management responsibilities

2.1 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.

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

2.3 Those required to inspect, verify or maintain 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.

2.4 It is anticipated that training in the validation and verification of specialised healthcare ventilation systems for Authorised Persons and Competent Persons will become available during the life of this Scottish Health Technical Memorandum.

Designated staff functions

2.5 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.

Management

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

Designated Person

2.7 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.

Authorising Engineer (Ventilation) (AE(V))

2.8 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.

Authorised Person (Ventilation) (AP(V))

2.9 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.

Competent Person (Ventilation) (CP(V))

2.10 The CP(V) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of ventilation systems.

Infection Control Officer

2.11 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.

2.12 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 Authorised Person).

Plant Operator

2.13 The Plant Operator is any person who operates a ventilation installation.

User

2.14 The User is the person responsible for the management of the unit in which the ventilation system is installed (for example head of department, operating theatre manager, head of laboratory, production pharmacist, head of research or other responsible person).

Contractor

2.15 The Contractor is the person or organisation responsible for the supply of the ventilation equipment, its installation, commissioning or validation. This person may be a representative of a specialist ventilation organisation or a member of the general manager/chief executive's staff.

Records

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

2.17 Substitute or replacement staff should be designated in order to cover for sickness, holidays and staff transfers.

Training

2.18 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.

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

2.20 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.

Specific health and safety aspects

2.21 Staff engaged in the service and maintenance of extract ventilation systems from pathology departments, mortuaries, laboratories, source-protective isolation facilities and other areas containing a chemical, biological or radiation hazard may be particularly at risk. In these cases, the risk should be identified and assessed.

2.22 The means by which the system can be rendered safe to work on should be determined, and a permit-to-work on the system implemented.

2.23 Training in the exact procedures should be given to all staff involved.

2.24 Some healthcare facilities may contain specialised units that are subject to access restrictions (for example pharmacy aseptic suites). Estates or contract staff requiring access may need additional training or to be accompanied when entering the unit.

Note 2: See also the following guidance published by the Health and Safety Commission's Health Services Advisory Committee:

- 'Safe working and the prevention of infection in clinical laboratories and similar facilities';
- 'The management, design and operation of microbiological containment laboratories';
- 'Safe working and prevention of infection in the mortuary and post-mortem room'.

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3. Ventilation systems – minimum requirements

General requirements

3.1 All ventilation systems should be inspected annually to ensure conformity with minimum requirements, which are designed to:

- ensure safe access when carrying out routine service and maintenance activities;
- prevent or control risks associated with *Legionella* and other potential hazardous organisms;
- check that the system remains fit for purpose;
- maintain records of outcomes.

3.2 Every effort should be made to ensure that all AHUs achieve the minimum requirement set out below.

Location and access

3.3 AHUs should be secured from unauthorised access.

3.4 Units located on roofs must have a safe and permanent means of access. Suitable precautions must be in place to prevent personnel or equipment from falling during maintenance activities.

3.5 Units located outside at ground level should be secured within a compound to prevent unauthorised access. Vehicles should be excluded from the vicinity to ensure that exhaust fumes will not be drawn into intakes.

3.6 All parts of the AHU should be easily and safely accessible for routine inspection and service.

3.7 The area around an AHU within a building should be tanked to prevent water penetration to adjacent areas, and should be adequately drained.

3.8 Fire precautions should be in accordance with Firecode.

3.9 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.

3.10 Plantrooms that house AHUs must not be used for general storage. Care should be taken to ensure that combustible material is not kept in the plantroom.

Basic requirements

3.11 The plant must not contain any material or substance that could support the growth of microorganisms.

3.12 The plant must not contain any material or substance that could cause or support combustion.

3.13 Access to items that require routine service, such as filters, coils and chiller batteries, should be via hinged doors.

3.14 Items requiring infrequent access such as attenuators may be via clipped or bolted-on lift-off panels.

3.15 All doors and panels should be close-fitting and without leaks.

3.16 Every effort should be made to ensure that access is via fixed ladders and platforms or pulpit-style movable steps.

3.17 Electrical and mechanical services should not restrict or impede access to those parts of the AHU that require inspection.

3.18 Viewing ports and internal illumination should be fitted in order to inspect filters and drainage trays.

3.19 Internal illumination should be provided by fittings to at least IP55 rating. Fittings should be positioned so that they provide both illumination for inspection and task lighting.

3.20 A single switch should operate all of the lights in a unit.

AHU intakes and discharges

3.21 Intake and discharge points should not be situated where they will cause vitiated air to be drawn into a system (see paragraphs 3.61-3.71) in Part A, which give detailed information). In existing systems, it may be necessary to extend the intake or discharge point to a suitable position.

3.22 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain. The inside of the louvres should be fitted with a mesh of not less than 6mm and not more than 12mm to prevent infestation by vermin and prevent leaves being drawn in.

3.23 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system. Cleaning access must be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door.

AHU drainage system

3.24 All items of plant that could produce moisture must be provided with a drainage system. The system will comprise a drip-tray, glass trap, air break and associated drainage pipework.

3.25 Some existing units may not have been mounted far enough above the floor to permit the correct installation of a drainage system. If the AHU cannot be raised to an adequate height, an alternative arrangement (such as a pump-out system) must be provided.

3.26 The drip-tray should be constructed of a corrosion-resistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent 'pooling', it is essential that the drain connection should not have an upstand and that a slope of approximately 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.

3.27 Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct (Part A, Section 4, paragraphs 4.20-4.25 refer and paragraph 3.29 of this Part B).

3.28 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 will 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.

3.29 Traps fitted to plant located outside or in unheated plantrooms may need to be trace-heated in winter. The trace heating should be checked for operation and must not raise the temperature of water in the trap above 5°C.

3.30 Water from each trap must discharge via a clear air gap of at least 15mm above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish, providing each has its own air break.

3.31 Drainage pipework may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22mm and have a fall of at least 1 in 60 in the direction of flow. It should be well supported, and located so as not to inhibit access to the AHU.

Dampers

3.32 AHUs serving critical areas and those areas that are shut down out of hours should be fitted with motorised low-leak shut-off dampers located immediately behind the intake and discharge of each supply and extract system.

Fan drives

3.33 Fan-drive trains, whether supply or extract, should be easily visible without the need to remove access covers. Protecting the drive train with a mesh guard is the preferred option. For weatherproof units designed to be located outside, the fan drive should be enclosed. It should be easily visible through a viewing port with internal illumination and be accessed via a lockable, hinged door.

3.34 The motor windings of induction-drive 'plug' motor arrangements and in-line axial fans having a pod motor within the air stream must be protected from over-temperature by a thermistor and lockout relay.

3.35 It is necessary to ensure that – should the computer control system or its software develop a fault – the fan can be switched to a direct start with fixed speed and manual operation. This is particularly important for critical care systems serving operating suites, high dependency care units of any type, isolation facilities, laboratories and pharmaceutical production suites.

Heater & Frost batteries

3.36 Access for cleaning must be provided to both sides of frost batteries and heater-batteries.

3.37 Where auxiliary wet heater-batteries are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray. Placing wet heater batteries in ceiling voids should be avoided if at all possible.

Cooling coils

3.38 Each cooling coil – whether within the AHU or within a branch duct – must be fitted with its own independent drainage system as specified above. 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.

3.39 The cooling-coil control valve should close upon selection of low speed, system shutdown, low air-flow or fan failure.

3.40 Where auxiliary wet-cooling coils are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Humidifiers

3.41 Humidifiers are not generally required. Where they are fitted, but have been out of use for a significant period of time, they should be removed. All associated pipework should also be removed back to its junction with the running main.

3.42 Where humidifiers are fitted and their use is still required, they should fully conform to the installation standard set out in Section 4 of Part A.

3.43 The section of ductwork containing the humidifier may need to be periodically decontaminated. Hinged access doors with viewing ports and internal illumination should be provided.

3.44 All humidifiers must be fitted with their own independent drainage system as detailed above.

3.45 Only steam-injection humidifiers, whether mains fed or locally generated, are suitable for use in air-conditioning systems within healthcare facilities. Water humidifiers, if fitted, should be removed.

3.46 Self- and locally-generated steam humidifiers must be supplied with potable water. The installation should be capable of being isolated, drained and cleaned. Section 4 in Part A of this Scottish Health Technical Memorandum gives further details.

3.47 Some steam generators are of a type that requires regular cleaning and descaling. The installation should enable them to be physically isolated from the air duct in order to prevent contamination of the air supply by cleaning agents.

3.48 The humidifier control system should fully conform to the standard set out in Sections 4 and 6 of Part A.

Filtration

3.49 Filters must be securely housed and sealed in well-fitting frames that minimise air bypass. Air bypass significantly reduces filter efficiency: the higher the filter grade, the greater the effect. Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass.

3.50 All filters should be of the dry type. Panel filters are generally used as pre-filters and should be positioned on the inlet side of the supply fan, downstream of the frost battery. Where required, secondary filters (these will be bags or pleated paper) should be on the positive-pressure side of the fan.

3.51 The filter installation should provide easy access to filter media for cleaning, removal or replacement; therefore, a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

3.52 All filters should be provided with a means of checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

High-efficiency filters – HEPA and ULPA

3.53 Where fitted, HEPA filters should be of the replaceable-panel type with leak-proof seals. Their installation should permit the validation of the filter and its housing.

3.54 HEPA filters are sometimes used in extract systems for the containment of hazardous substances or organisms. They may be fitted with pre-filters to extend their service life.

3.55 When used for the containment of hazardous substances, the installation should incorporate design provision for the subsequent safe removal and handling of contaminated filters by maintenance staff.

Energy recovery

3.56 Energy recovery, where fitted, will require cleaning access to both sides of the device.

3.57 Whichever type of energy recovery device is fitted, the extract side should be protected by a G3 filter and provided with a drainage system to remove condensate.

3.58 The heat-recovery device should be controlled in sequence with the main heater-battery, and may need to incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the plant's required set point.

Attenuation

3.59 Cleaning access should be provided at both ends of any attenuator unit.

Identification and labelling

3.60 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 50mm 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.

3.61 The direction of air-flow should be clearly marked on all main and branch ducts.

3.62 All air-flow test-points should be clearly identified and the size of the duct given.

Pressure stabilisers

3.63 Pressure stabilisers should be unobstructed and silent in operation.

4. Annual inspection and verification requirements

Ventilation systems inspection

4.1 All ventilation systems should be subject to at least a simple visual inspection annually.

4.2 The purpose of the inspection is to establish that:

- the system is still required;
- the AHU conforms to the minimum standard (see 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.

4.3 It is recommended that a simple check sheet be used to record the result of the inspection. Examples are given in Appendices 1 and 2.

Critical ventilation systems

4.4 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.

4.5 The quarterly inspection should be as detailed in paragraphs 4.1 – 4.3.

4.6 The purpose of the annual verification will be to ensure additionally that the system:

- achieves minimum standards specific to the application;
- is operating to an acceptable performance level;
- remains fit for purpose.

Definition of a critical system

4.7 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;

- 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.

4.8 The loss of service from such a system would seriously degrade the ability of the premises to deliver optimal healthcare.

Annual verification

4.9 The annual verification is intended to establish that:

- the system is still required;
- the AHU conforms to the minimum standard (see Section 3);
- the fire containment has not been breached;
- the general condition of the ventilation system is adequate;
- the fabric of the area served is satisfactory;
- the system performance is adequate with respect to the functional requirement – this will require:
  - a full measure of the supply and extract air-flow rates;
  - the calculation of room air-change rates if applicable;
  - the measurement of room differential pressures if applicable;
  - the measurement of room noise levels;
  - air-quality checks if appropriate;
  - a check on the control functions.

4.10 An assessment should then be made as to whether the system overall is fit for purpose and operating in a satisfactory manner.

Fabric of the area served

4.11 The building elements in the room or rooms served by a critical ventilation system should also be suitable for the function. As an example, in a suite of rooms comprising an operating theatre complex, the following elements should be checked:

- the ceiling should be complete and, if tiled, all tiles should be clipped down and sealed;

- the walls and floors should be free from significant construction and finish defects;
- windows and their trickle vents should be sealed and locked shut;
- the doors should close completely and the door closers should be correctly adjusted to hold them against the room pressure;
- all service penetrations and access panels should be sealed to prevent uncontrolled air flow between rooms and service voids;
- steps should have been taken (if necessary) to prevent portable equipment and stock items from obstructing low-level supply, transfer or extract airflow paths.

4.12 Failure to achieve a suitable standard will render even the most sophisticated ventilation system ineffective.

4.13 All fire dampers should be tested as part of the annual verification.

4.14 LEV systems will be subject to an examination and test by a competent person at least every 14 months.

4.15 Table 1 overleaf provides a model for the verification of critical ventilation systems.

Critical ventilation systems – verification standards

4.16 Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in Appendix 1 of Part A, or its original design parameters.

4.17 The pressure regime should achieve not less than 75% of the design value given in Appendix 1 of Part A, or its original design parameters; and the pressure gradient relationships with regards to surrounding areas must be maintained.

4.18 The sound levels given in Table 2 overleaf are maximum permissible levels and should not be exceeded. Measurements should be made using at least a Type 2 sound meter fitted with a muff. Its accuracy should be checked using a calibration sound source before use.

Step	Question	Information/standard required	Comment
1	Is the system still required?	Why was it installed?	Is that function still required?
2	Does the AHU achieve the minimum standard?	Health and safety aspects Intake/discharge positions Inspection access *Legionella* control and drainage Fire and electrical safety Leaks, cleanliness and insulation Filtration	Inspect to ascertain compliance with minimum standards set out in Section 3 Part B of this SHTM
3	Is the air distribution system satisfactory?	Access Fire dampers Cleanliness Insulation Identification Room terminals Pressure stabilisers	Inspect to ascertain continued fitness for purpose
4	Does the measured system performance still accord with the design intent and achieve a minimum acceptable standard?	Design air velocities Design air-flow rates Room air-change rates Pressure differentials Noise levels Air quality	Establish the design values Measure the system output to verify its performance
5	Does the control system function correctly?	Desired environmental conditions Control sequence logic Run; set back, off philosophy	Establish the design requirement Inspect/test to verify performance
6	Having regard to the foregoing, is the system 'fit for purpose' and will it only require routine maintenance in order to remain so until the next scheduled verification?		Yes or No
7	What routine service and maintenance will be required for the system to remain fit for purpose and function correctly until the next scheduled verification?	Filter changes System cleaning Performance indication Performance monitoring Performance measurement	Decide inspection frequency and maintenance schedule

Table 1: Operational management and routine verification process model

Location	Design sound level (NR)	Measured sound level (dB (A))
Ultra-clean operating room	50	55
Conventional operating room	40	45
All other non-specified rooms	40	45
Corridors	40	45
Recovery room	35	40
Ward areas, sleeping areas	30	35

Table 2: Maximum sound levels (service noise only)

Vertical ultra-clean operating theatres

4.19 The following additional measurements should be taken:

- the average air velocity at the 2m level under the canopy: it should achieve a minimum average of 0.38 m/s for a partial wall system and 0.3 m/s for a full wall system;
- the air velocity within the inner zone at the 1m level: every reading should achieve a minimum velocity of 0.2 m/s.

4.20 The air velocity measurements are to be taken using the equipment, test grid and method set out in Section 8 of Part A.

Note 3: There is no requirement to carry out filter scanning or entrainment tests at the annual verification unless the HEPA filters or recirculating air fans are changed, or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the ultra-clean ventilation (UCV) unit.

4.21 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Section 8 of Part A.

Note 4: Scottish Health Technical Memorandum 08-01 (2011) gives detailed guidance on acoustics and the measurement of sound.

Horizontal ultra-clean operating theatres

4.22 The following additional measurements should be taken:

- the discharge velocity test at 1m, 1.5m and 2m in front of the terminal: the average velocity should be not less than 0.4 m/s.

4.23 The measurements are to be taken using the equipment, test grid and method set out in Section 8 of Part A.

4.24 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Section 8 of Part A.

Category 3 and 4 laboratories and rooms

4.25 These areas should conform to the requirements of current information published by the Advisory Committee on Dangerous Pathogens and the Health and Safety Executive:

- 'The management, design and operation of microbiological containment laboratories';
- 'Biological agents: managing the risks in laboratories and healthcare premises'; and
- 'Biological agents: the principles, design and operation of Containment Level 4 facilities'.

Pharmacy aseptic suites

4.26 Pharmacy aseptic suites should conform to the requirements of the European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) and the requirements of the Medicine Inspectorate if a licensed manufacturing unit.

Sterile services department – inspection and packing rooms

4.27 Inspection and packing rooms should conform to the requirements of BS EN ISO 14644 and any additional requirements for the processing of medical devices, if applicable (see also Scottish Health Planning Note 13: 'Sterile services department').

LEV systems

4.28 LEV systems should conform to the Health and Safety Executive's 'The maintenance, examination and testing of local exhaust ventilation'.

Critical system verification failure

4.29 Should a critical system be unable to achieve the standard set out above, it should be taken out of service. If healthcare provision needs prevent the system being taken out of service, the senior manager of the user department should be informed in writing that the system performance is suboptimal. A copy of the notice should be sent to the infection control committee.

4.30 If a critical system is refurbished in order to bring it to a suitable standard, it should be subject to the full validation procedure set out in Section 8 of Part A or other application-specific guidance as appropriate.

5. Inspection and maintenance

General

5.1 Inspection and maintenance activities should be assessed to ensure that they do not create a hazard for those who undertake the work or for those who could be affected by it.

5.2 The degree and frequency of maintenance should relate to the function of the system, its location, its general condition and the consequence of failure.

5.3 Specimen inspection and maintenance checklists are given in Appendices 1 and 2.

Inspection and maintenance of critical systems

5.4 The loss of service of these systems would seriously degrade the ability of the premises to deliver optimal healthcare. In order to ensure reliable service provision, it is essential to inspect, verify and maintain these systems at appropriate intervals.

5.5 For many of these systems a permit-to-work will need to be completed to ensure that taking the ventilation system out of service does not compromise the activities of the user department. In any event, it will be necessary to liaise with the user department when switching the system off to carry out routine inspection and maintenance.

AHU drainage

5.6 AHU drainage systems comprise a drainage tray, glass trap, connecting pipework and an air break. The system should be inspected to ensure that it is clean and operating correctly. The cleanliness of the drainage tray and colour of the water in the trap will give an indication of a fault condition (see Table 3 overleaf).

Colour of water	Probable cause and comment
Normal	Satisfactory.
Green	Copper corrosion of pipework Possible leak in battery tubing.
White	Aluminium corrosion of battery fins.
Black	General dirt Filter faulty allowing air bypass System is overdue for a thorough clean Urgent action required.
Brown/red	Iron corrosion (rust) within the duct May indicate a specific *Legionella* hazard Immediate action required.
Bubbly/slimy	Microbiological activity within the duct May indicate a specific *Legionella* hazard Immediate action required.

Table 3: Colour of water in glass trap

Filter changing

5.7 Dirty supply air filters may pose a general dust hazard when being changed.

5.8 Dirty extract- and return-air filters may pose an increased level of hazard. This will relate to the particular contamination within the air that they have filtered. Filters handling extract air from general areas are unlikely to present a significantly greater hazard than that posed by dirty supply air filters.

5.9 Care should be taken to protect staff from inhaling the dust. If there is a need to enter the duct when changing filters, a dust mask should be worn.

5.10 Dirty filters should be carefully removed and placed in the box that contained the replacement filters or in a plastic bag. On completion of the work, the dirty filters should be removed from the plantroom and disposed of appropriately.

5.11 The duct in the area of the filter housing should be carefully vacuumed before fitting the replacement filters. This will prevent particles (that is, those that are shed when the dirty filters are disturbed) being blown into the system downstream.

5.12 It is important to ensure that replacement filters are fitted the right way round. Most panel filters are manufactured with a membrane or wire support mesh on their downstream side. Alternatively they may be colour-coded. The manufacturer's instructions regarding fitting should be followed.

5.13 Bag filters should be fitted with the pockets vertical. Care should be taken to remove any transit tapes and to ensure that the individual pockets are separate and free to inflate.

Changing extract filters containing hazardous substances

5.14 Filters handling extract air from an LEV system will obviously present a hazard and should be subject to a safe system of work.

5.15 Filters used in an extract system for the containment of hazardous substances or organisms should incorporate design provision for their safe removal when so contaminated. This may be achieved by:

- sealing the hazardous substance into the filter before it is removed;
- a system to fumigate the filter to kill any organisms;
- housing it in a 'safe change' unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.

5.16 The method chosen should reflect the nature of the hazard.

5.17 Filters fitted to remove hazardous substances from extract air are classed as hazardous waste and should be handled and disposed of accordingly.

Ventilation system cleaning

5.18 The intake section of a ventilation system should be vacuumed-out as necessary to remove visible particles.

5.19 AHUs should be vacuumed-out and/or washed down internally as necessary to remove obvious dust and dirt.

5.20 Chiller batteries, humidifier units, energy-recovery batteries or plates and their drainage systems should be washed down with hot water annually to remove visible contamination.

5.21 Supply air distribution ductwork conveys air that has been filtered. It will require internal cleaning only when it becomes contaminated with visible dirt. The frequency of cleaning will depend on the age of the system and grade of the AHU final filter but will typically be in excess of ten years. There is no requirement to clean ductwork annually. A rapid build-up of visible dirt within a supply duct is an indication of a failure of the filtration or its housing.

5.22 Extract air systems handle unfiltered air. They should be cleaned as frequently as necessary in order to maintain their operating efficiency. Room extract terminals, particularly those sited at low level in critical care areas, will need regular cleaning.

5.23 On completion of cleaning, the ductwork should not be 'fogged' with chemicals. This treatment has no lasting biocidal effect and is responsible for initiating the breakdown of the galvanised coating of ductwork. This will result in accelerated corrosion of the inside of the duct, with the products of corrosion being shed into the air stream. It will also significantly shorten service life.

5.24 Following duct cleaning, all service hatches should be checked to ensure that they have been correctly replaced and do not leak.

5.25 Duct-cleaning equipment that uses rotating brushes or a vacuum unit can easily damage flexible sections of ductwork. On completion of cleaning, all flexible duct sections should be checked for rips and tears. The straps that secure them to rigid duct sections and air terminals should also be checked to ensure that there is no air leakage.

Chilled beams

5.26 The efficiency of these units will rapidly decline if they become blocked with fluff/lint. They should be inspected every six months and cleaned as appropriate.

Split and cassette cooling units

5.27 These units incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The systems should be inspected and cleaned every three months.

Portable room cooling units

5.28 Portable units are sometimes kept in store or hired-in to cope with temporary local situations giving rise to excessive temperatures. They typically incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. Units employing an internal water reservoir and wick to promote evaporative cooling must not be used in healthcare premises.

5.29 The infection control team must be consulted before these types of unit are deployed.

5.30 The units should be inspected and thoroughly cleaned before being taken into use. Units that are to be used in areas containing immunocompromised patients will, unless new, need to be fumigated before use.

5.31 All portable units should be inspected and cleaned every week that they remain in use.

Self-contained mobile filter and/or ultraviolet (UV) light units

5.32 The efficacy of these units is directly related to their cleanliness. In this respect, the manufacturer's instructions regarding service/maintenance and lamp and filter replacement should be closely followed.

5.33 Units that have been used in isolation rooms or areas containing infective patients will need to be fumigated before being used in other locations, or returned to store or to the hirer.

5.34 Filters fitted to remove hazardous substances from the recirculated room air are classed as hazardous waste and should be handled and disposed of accordingly (see also Scottish Health Technical Note 3: NHS Scotland Waste Management Guidance Parts A-D).

Inspection and maintenance records

5.35 Records of inspection and maintenance activities should be kept for at least five years.

Health Facilities Scotland

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Appendix 1: Annual inspection of critical ventilation systems – AHU and plantroom equipment

Definition of terms used on survey form

General condition

End of useful life
This should be clear from the condition of the AHU and its associated services and plant. The main indicators will be: • extensive internal and/or external corrosion of the AHU casing; • failure of filter housings to prevent air bypass; • general corrosion of heater and cooling battery fins, attenuator surfaces etc; • significant failure to meet minimum standards; • associated plant services and control elements in a poor condition or not able to fulfil their purpose; • AHU aged 20 years or more.
Action: **Urgent replacement indicated.**

Poor
Should be fairly apparent but should 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 prolonged 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 equipment.

Compliance with minimum standards (questions 2 to 23, 32 and 33)

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

Average
No more than 3 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.

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Annual inspection of critical ventilation systems – AHU and plantroom equipment

Hospital ☐

Plantroom ☐

Air-handling unit ☐ **Age of unit** ☐

Area served by unit ☐

Date of survey ☐ **Name** ☐

General condition: End 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, 34 to 40)

No	Survey question	Yes	No	Comments
1	Plant running?			
2	Are the unit and its associate 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 the fan motor(s) outside of the air stream?			

No	Survey question	Yes	No	Comments
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 of Section 3 of Scottish Health Technical Memorandum 03-01, Part B?			
12	Are drainage traps clean and filled with water? (see Table 3 in SHTM 03-01, Part B)			
13	Is the drain trap air break at least 15mm?			
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 safely?			
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 to isolator.

No	Survey question	Yes	No	Comments
26	Did the motorised dampers close on plant shutdown?			
27	Is the vermin/insect screen clean?			
28	Is the intake section including the fog coil clean?			
29	Are the pre-filters correctly fitted with no air by-pass?			
30	Are all drive belts correctly aligned and tensioned?			
31	Is the cooling-coil matrix cleaned?			
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 the drainage traps free of water?			
36	Is the matrix clean for each heater-battery?			
37	Have the main filters been correctly fitted with no air by-pass?			
38	Are AHU and its associated main ductwork clean internally?			
Remove padlock and Re-start plant.				
39	Did unit restart satisfactorily?			
Test automatic fan-motor change-over, if fitted				
40	Did automatic changeover operate satisfactorily?			

Additional comments
(For example: air leaks from access doors; control valves leaking or passing; general cleanliness of the area around the unit; or any other items of concern.)

Competent person/Authorised person……

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Appendix 2: Operating suite annual verification

Definition of terms used on survey form

Assessment of compliance with Scottish Health Technical Memorandum 03-01 (all questions relevant to the type of theatre)

Poor
• air volumes and hence air-change rates 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; • 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 pressure 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

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Annual verification of theatre ventilation systems - Theatre suite information

Hospital ☐

Theatre name/no. ☐ **Type of Theatre** ☐

Date of survey ☐ **AHU location & ID** ☐

Name ☐

Compliance with SHPN & SHTM **Poor** ☐ **Average** ☐ **Good** ☐

Maintenance quality **Poor** ☐ **Average** ☐ **Good** ☐

No	Survey question	Yes	No	Comments
1	Has the annual verification of the AHU been carried out?			
2	Are windows hermetically sealed?			
3	Is the theatre /are the theatre and prep room complete and sealed?			
4	Are there any significant faults in the fabric of the rooms in the suite?			
5	Are room light fittings correctly sealed?			
6	Do all doors close completely and hold against the room pressure?			
7	Are the pressure stabilisers operating correctly and silently?			
8	Are the supply and extract air terminals and pressure stabilisers visibly clean?			
9	Measure and record the operating room temperature			
10	Does this accord with that displayed on the surgeon's panel?			

No	Survey question	Yes	No	Comments
11	Measure and record the operating room relative humidity.			
12	Does this accord with that displayed on the surgeon's panel?			
13	Measure and record the supply and extract airflow in the principal ducts.			
14	Measure and record the airflow at all supply and extract terminals.			
15	Does the derived air-change rate achieve at least 75% of the design?			
16	For UCV units, also measure and record the air velocities within the canopy using the method set out in Section 8 of Scottish Health Technical Memorandum 03-01 (Part A)			
17	Do the air velocities achieve the standard appropriate for the type of canopy?			
18	Measure and record the room differential pressures			
19	Do the room differential pressures ensure a flow of air from the clean to the less clean areas?			
20	Measure and record the noise levels in the principal rooms of the suite.			
21	Do the noise levels fall below the limits set out in Table 2 of SHTM 03-01 Part B			
22	Check the operation of all ventilation control functions represented on the surgeon's panel.			
23	Do the indicators accurately represent the operational state of the ventilation system(s)?			

No	Survey question	Yes	No	Comments
24	For UCV systems: are the UCV and AHU interlocked to ensure that the AHU runs at full speed when the UCV is at operating speed or at set-back? (see Table 7 in Scottish Health Technical Memorandum 03-01, Part A)			
25	With the UCV running at setback, does the system maintain the standard of a conventional operating room?			
26	For all theatres: with the system running at set-back, does it maintain a flow of air from the clean to the less clean areas?			

Additional comments
(For example: the general décor; are the suite and its ventilation systems suitable for their designated functions?)

Competent person/Authorised person……

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Inverarity, Donald

From: Sutherland, SarahJane
Sent: 24 May 2019 14:09
To: Khatamzas, Elham; Hull, Ashley
Cc: Inverarity, Donald; Kalima, Pota; Guthrie, Lindsay
Subject: Re: Theatres Air sampling

Hi Elham,

Thank you for your reply in relation to air sampling for theatre commissioning

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian
[redacted]

From: Khatamzas, Elham
Sent: Thursday, 23 May 2019 14:32
To: Sutherland, SarahJane; Hull, Ashley
Cc: Inverarity, Donald; Kalima, Pota; Guthrie, Lindsay
Subject: RE: Theatres Air sampling

I agree with Sarah's comments and her interpretation of the guidance and would be keen to see the results as part of the validation report

Kind regards

Elham Khatamzas
Consultant in Clinical Infection NHS Lothian and Honorary Clinical Lecturer University of Edinburgh
[redacted]
Mobile via switchboard

From: Sutherland, SarahJane
Sent: 21 May 2019 21:10
To: Hull, Ashley
Cc: Inverarity, Donald; Khatamzas, Elham; Kalima, Pota; Guthrie, Lindsay
Subject: RE: Theatres Air sampling

Hi Ashley,

My understanding from SHTM 03-01 Part A - Ventilation Validation (attached) and as per Dr Inverarity's advice below, is that any sampling for theatre commissioning whether particle counting or microbiological air sampling should be carried out by an accredited independent company (to that of the builders) and should be reported within the theatre ventilation validation report. Please note the highlighted area in Dr Inverarity's response below.

As discussed last Friday with Lindsay, following the Stage 4 HAI Scribe review, NHSL would only require to carry out further microbiological air sampling following validation if there were any works carried out which caused disturbance to fabric of the theatre suite and this would not include the 'setting up of theatre' (putting in theatre equipment).

I have copied in relevant parties who may wish to comment on the above, and correct me if I am wrong in my interpretation of the guidance..

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian

[redacted]

From: Inverarity, Donald
Sent: 02 May 2019 16:48
To: Hull, Ashley; Hutcheson, Allison
Cc: Sutherland, SarahJane; Halcrow, Fiona; Mackenzie, Janice; Henderson, Ronnie
Subject: RE: Air Sampling Theatres

Hi Ashley,

Commissioning of ultraclean theatres is done by particle counting and there is no role for microbiological air culture.
Commissioning of conventional theatres is done by microbiological air culture and not particle counting.
For the neurosurgical theatres that may have the laminar flow switched off for some surgeries the commissioning should include both particle counting and microbiological air testing.
These results should feature as part of the theatre validation report and be performed by an accredited company that is independent to the builders.
Hope that clarifies
Donald

From: Hull, Ashley
Sent: 21 May 2019 11:20
To: Guthrie, Lindsay; Sutherland, SarahJane
Subject: Theatres Air sampling

Good Morning

Please can you advise that we will still require to carry out our own sampling and who will carry this out.

Kind Regards
Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

Inverarity, Donald

From: Sutherland, SarahJane
Sent: 16 June 2019 18:02
To: Hull, Ashley; Inverarity, Donald; Hutcheson, Allison
Cc: Halcrow, Fiona; Mackenzie, Janice; Henderson, Ronnie
Subject: RE: Air Sampling Theatres

Hi Ashley,

I believe that you have spoken with Dr Inverarity in relation to the sampling process.

In regards to cleaning in these areas, (and all other areas on completion of work) the contractors should carry out a builders clean then the domestic services should carry out a 'terminal clean' using Chlorclean.

It is important following the terminal clean, and before samples are obtained that the project team carry out a visual inspection of the rooms to ensure that the level of cleaning is optimal and there is no dust/debris remaining , particularly in high reach areas such as pendants etc as this would potentially affect sample results.

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian

[redacted]

From: Hull, Ashley
Sent: 11 June 2019 12:14
To: Inverarity, Donald; Hutcheson, Allison
Cc: Sutherland, SarahJane; Halcrow, Fiona; Mackenzie, Janice; Henderson, Ronnie
Subject: RE: Air Sampling Theatres

Good Afternoon
Please can I have clarification for cleaning theatres ,imaging(MRI'S) and isolation rooms.
We are having an independent tester next week. I understand that we carry out both for ultra clean theatres.

My question is what type of clean will our own domestics need to carry before the independent tester arrives next week.
Following the independent tester will NHS Lothian carry out their own.
Kind Regards
Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Inverarity, Donald
Sent: 02 May 2019 16:48
To: Hull, Ashley; Hutcheson, Allison
Cc: Sutherland, SarahJane; Halcrow, Fiona; Mackenzie, Janice; Henderson, Ronnie
Subject: RE: Air Sampling Theatres

Hi Ashley,
Commissioning of ultraclean theatres is done by particle counting and there is no role for microbiological air culture.
Commissioning of conventional theatres is done by microbiological air culture and not particle counting.
For the neurosurgical theatres that may have the laminar flow switched off for some surgeries the commissioning should include both particle counting and microbiological air testing.
These results should feature as part of the theatre validation report and be performed by an accredited company that is independent to the builders.
Hope that clarifies
Donald

From: Hull, Ashley
Sent: 02 May 2019 13:02
To: Inverarity, Donald; Hutcheson, Allison
Cc: Sutherland, SarahJane; Halcrow, Fiona; Mackenzie, Janice; Henderson, Ronnie
Subject: Air Sampling Theatres

Good Afternoon

Following my conversation with Sarah this morning re air sampling of the new RHSCYP/DCN theatres. Which in total are 10 theatres 7 ultra clean and 3 standard theatres.

Please can you advise what is required for air sampling.

My understanding MAT (Medical Air Technologies) who have supplied the Ultra clean theatres come in and commission. Ronnie can you confirm what this may entail.

Kind Regards
Ashley

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

RHCYP Critical Care Ventilation

Summary of Discussion on 10th & 11th July 2019

10th July Attendees

Julie Freeman	Consultant Critical Care
Laura Reilly	Critical Care Clinical Nurse Manager
Pat Smith	Critical Care Charge Nurse
Janice MacKenzie	Project Clinical Director
Ronnie Henderson	Project Hard FM Commissioning Manager
Donald Inverarity	Consultant Microbiologist
Carol Calder	IPCN

11th July Attendees

Julie Freeman	Consultant Critical Care
Laura Reilly	Critical Care Clinical Nurse Manager
Pat Smith	Critical Care Charge Nurse
Janice MacKenzie	Project Clinical Director
Ronnie Henderson	Project Hard FM Commissioning Manager
Donald Inverarity	Consultant Microbiologist
Carol Calder	IPCN
William Evans	IPCN
Pota Kalima	Consultant Microbiologist
Catherine McDougall	Medical Consultant

We discussed the current proposals for improving the critical care ventilation to ensure that it is compliant with SHTM 03-01 with 10 air changes and 10 Pa positive pressure in the single rooms and 4 bedded bays. We also reviewed the ventilation requirements in the 4 bedded bays to allow you to cohort patients with the same infections.

<u>Current Proposal for Critical Care Ventilation Improvements</u>
We visited the Unit, specifically 1-B1-031 which will be impacted on with one of the proposals to review the bed space.
Ronnie updated as follows
Of the 5 initial proposals considered, only two now being considered:-

1. Utilise existing plant or replace in existing location, upsize fans and upsize ducting in critical care – Design team assessing but unlikely to be possible
2. Install new plant external and duct in via window in 4 bed bay, connect ducting to serve approx 50% of critical care
   Note – in both options isolation rooms are unaffected

See attached marked up drawing for the space affected:-

- One window would be blocked to allow the duct work to come in and it would be boxed out no further than the start of the vision panel at the side to the adjoining room.
- We placed the pendants in the positions they would be in and considered the equipment that would be at the top of the bed and confirmed that there would be sufficient circulating space. Ronnie took some photos of the pendant positions and he will pass these onto MPX
- We noted that no further windows in the bay could be affected as this would then affect the natural light coming into the area

- The additional plant would be on the grass roof area outside the window. Once size of the unit and orientation is known need to ensure that it does not adversely affect the light coming into the area.
- The Critical Care team asked that both the boxed out area within the bay and the plant would have some form of enhancement to make it more aesthetically pleasing e.g. graphics

Compliance with SHTM 03- 01

- Currently the 4 bedded rooms and single rooms have 4 air changes and this needs to increase to 10 air changes to ensure compliance with SHTM. It was acknowledged that the SHTM was more focused on adult critical care where the patient profile is different and the need to cohort patients was extremely rare
- It was noted that previously a decision had been made to derogate from the SHTM for the 4 bedded areas to allow patients to be cohorted with the same air-borne infection and following consultation with the clinical team and IPCT at the time the decision was made that these areas should be balanced or slightly negative. The SHTM states that both the 4 bedded areas and single rooms should have 10 air changes and 10Pa (positive pressure)
- It was confirmed that the Isolation Rooms were compliant with SHTM 03-01
- IPCT view was that you could cohort patients with the same air-borne infection in the 4 bedded areas that were 10 air changes and 10Pa and that there is no reason that this would result in an increased risk of spread of infection. A design of balanced or slightly negative pressure approaches the issue of spread of infection from a cohort from a different direction but it was agreed that neither approach increases the risk of infection spread but that the SHTM 03-01 compliant design has additional benefit for neutropenic patients who could be in single rooms at 10Pa positive pressure.
- It was acknowledged that the design of the Unit also provided additional control measures to prevent spread of infection and the barriers to transmission included:-
    - Bed space size
    - Distance between single room doors, isolation room doors and 4 bedded bay doors as range of droplet spread is generally considered to be between 1-3 metres
    - Patients on ventilators less of a risk of generating aerosols from coughing
    - Direction of air flow in corridor space directs any air borne contaminants towards an air extract vent and away from other patient rooms. Extract ventilation may need to be improved in corridor area to take account of increased pressure
    - Turn over of air dilutes any airborne organisms in patient rooms and corridors.
- It was noted that if a patient with an infection was in a 4 bedded bay or single room or a neutropenic patient in a single room the windows should not be opened and increased room cleaning would likely be required
- Confirmed that Isolation Rooms should be used for patients with infections transmitted by aerosols e.g. measles, chicken pox, TB
- Single rooms and cohort areas would be suitable for droplet infections e.g. RSV, Influenza
- Confirmed that the single cubicle in neonatal Unit will have 10Pa and 10 air changes and as it has an en-suite it will need a transfer grille on the en-suite door
- Confirmed the entire neonatal area was at 10Pa and 10 air changes with respect to the corridor.
- Because the single cubicle is within the neonatal unit it was confirmed that the single cubicle is at a balanced pressure or slightly negative with respect to the open neonatal bed bay.
- Confirmed that any 'dirty' rooms e.g. Dirty Utility, toilets have extract and any 'clean' rooms e.g. clean utility have supply and extract
- We discussed the Positive Pressure Ventilation Lobby (PPVL) isolation rooms in relation to ventilation in QEUH, specifically in relation to Multi-Drug Resistant TB, however Donald was very cautious about making any comparisons as the context was different (paediatric critical

care versus adult infectious diseases isolation ward) . It was suggested that this was something that could be discussed further with HFS

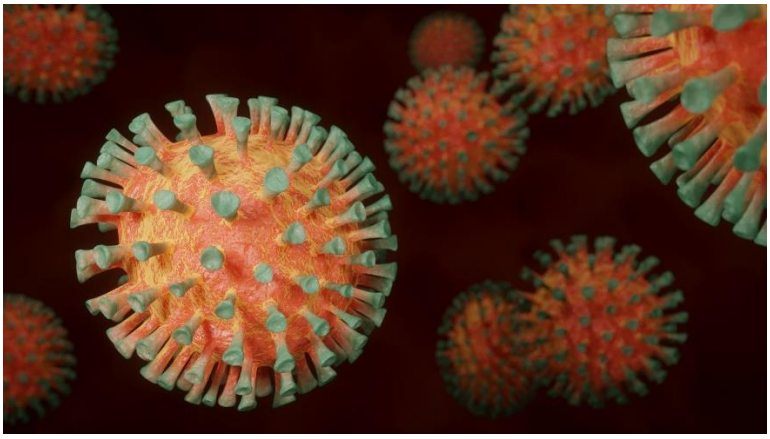
- We discussed a number of different patient groups and scenarios in relation to the use of the Isolation rooms, Single Rooms and 4 bedded bays and in light of these discussions and the points above all agreed that the SHTM 03-01 was a safe design for ventilation within the Paediatric Critical Care Unit in conjunction with the design of the unit and good practice in relation to infection control measures which all worked together as a package to achieve best outcome for patients

We also briefly discussed:-

- Cystic Fibrosis patients and the areas that they would be treated in and whether CF patients with different infections would be treated in the same ward as currently they would be treated in different wards as the existing hospital does not have Isolation Rooms. It was confirmed that Dalhousie ward(Medical Inpatients) have 4 PPVL Isolation room. It was felt by IPCT that provided appropriate measures were in place about the placement of patients within the ward then this could happen. Also Castle Mey (Acute Receiving Unit) has 1 PPVL isolation room. It was noted that currently Dalhouisie Ward is classed as an Augmented Care Area but Castle Mey not. This lead to a discussion about other areas in the hospital where CF patients could be treated, this includes OPD, Cardio Respiratory OPD and Dirleton (Medical Day Care) and therefore whether these areas should also be classed as Augmented Care as far as water sampling is concerned. It was felt that the risk was greater in Inpatient areas. Further discussion to be had with IPCT acknowledging that the water testing regime may need a bit of tweaking when hospital occupied

Specialised Ventilation for Healthcare Society

Updated Briefing & Guidance on Considerations for the Ventilation Aspects of Healthcare Facilities for Coronavirus



Updated 27th April 2020

Document SVHSoc.03-V4.

The Specialised Ventilation for Healthcare Society (SVHSoc.)

The Society was formed in November 2014 with the aim of bringing together those who were practicing or wished to become Authorising Engineers (Ventilation) (AE(V)) or who have a more general interest in Ventilation in the Healthcare setting.

- The SVHSoc. meet several times a year at various locations around the UK.
- Full membership of the Society is open to registered AE(V)'s.
- The Society "Code of Conduct" is issued with all quotations for AE(V) services.
- The Society maintains a register containing details of practicing AE(V)s.
- A set of competencies have been drawn up for prospective AE(V)s.

- Associate membership is open to anyone interested in Ventilation for Healthcare.
- A significant portion of the Society meetings is given over to discussing and clarifying interpretation of HTM03-01 and other healthcare ventilation standards.

Further information concerning the SVHSoc. may be obtained from:-

Malcolm Thomas - President SVHSoc. - [redacted]

Graham Powell – Chair SVHSoc. – [redacted]

John Rayner – Secretary SVHSoc. – [redacted]

The following documents have been issued by SVHSoc. to help clarify Healthcare Ventilation requirements

SVHSoc.01-V3.0 **Operating Theatres - Energy Control Strategies and the Surgeon's panel**

SVHSoc.02-V1.0 **Change in Air Filter Test and Classification standards**

SVHSoc.03-V4.0 **Coronavirus COVID-19 Guidance**

Coronavirus COVID-19

Acknowledgments

Lead Author - Andrew Poplett
Principal contributor - Graham P. Taylor

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SVHSoc. Members & Associates		
	Malcolm Thomas	Ray Hughes
	Graham Powell	Jez Beales
	John Rayner	Richard Harris
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	Tim Buckell	Joe Gill
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	David Livingstone	Stephen Morris
	Colin Gaffney	James Dagnall
	Ian Storrar	Paddy Fitzpatrick
	Siggi Volkmann	Edward Wright
	Lynn Rodgers	James Draycott
	Eddie McLaughlan	Lester Stuart
	Harry Evans	Graham Stuart
	John Adamson	
Consultant Microbiologists		
	Professor Rob Townsend	
	Dr Robert Porter	
University of Birmingham		
	Mr Andrew Thomas	Orthopaedic Consultant
PHE	Peter Hoffman	

Specialised Ventilation for Healthcare Society

SVHSoc.03-V4.0 (27th April 2020)

Contents

Introduction

Following peer review, recent feedback and experience from SVH Society members, and advice from Public Health England (Peter Hoffman) the briefing and guidance from the SVHSoc has been updated to reflect the current official guidance and to provide a range of options and areas for consideration for healthcare estates professionals to provide enhanced levels of protection for patients, staff, and visitors.

The briefing is intended to provide an overview of the issues and points to consider when assessing the ventilation strategy and options. It has also been updated to provide some initial maintenance considerations and precautions which may need to be considered. It is intended that this briefing and guidance will be subject to regular review and updates as details, information, and the situation continues to develop.

Current guidance on the lifespan of the virus once outside the body is still to be fully established, however current estimates are that it could survive anywhere between a few hours up to 3 to 4 days on hard surfaces and is spread by both primary direct exposure (breathing in droplets expelled from an infected person from coughing or sneezing) and secondary contact by touch (touching a surface which has been contaminated and transferring this contamination by touch to the mouth, nose or eyes). “Coronaviruses are mainly transmitted by large respiratory droplets and direct or indirect contact with infected secretions. They have also been detected in blood, faeces and urine and, under certain circumstances, airborne transmission is thought to have occurred from aerosolised respiratory secretions and faecal material”. That level of airborne transmissibility is specifically associated with certain aerosol generating procedures (AGPs).

That COVID-19 has been termed an airborne infection is an indication that it is capable of transmitting via an airborne route in certain circumstances, not that its mode of spread is primarily airborne nor that any aerosol remains sufficiently concentrated to be infectious over longer distances other than in the immediate vicinity of a dispersing patient.

The PHE guidance is under constant review and updated as necessary. The current guidance can be found at:

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control

Ventilation can contribute to an isolation or protection strategy to assist in minimising the spread of the virus, however a number of factors need to be considered, not least of all the provision of adequate ventilation to provide dilution of any airborne contamination, with other factors including;

- Area / rooms where isolation can be established
- Physical / fabric of the room construction / air permeability rates (e.g. solid ceilings)
- Surrounding areas of clinical activity
- Room volume and airflow / room pressure differentials (dilution effects)
- Provision and location of ventilation (e.g. ceiling mounted supply with low level extract)

- Point of discharge and filtration of any extracted air
- Levels of isolation and practical considerations
- Decontamination of the area between patients
- Protection of all potentially exposed staff groups (clinical, cleaning, and estates)
- Potential risks associated with oxygen enriched atmospheres

Standards and Technical Specifications

HTM 03-01 sets out the overall guidance for ventilation of healthcare premises with addition specific guidance on isolation facilities being contained within HBN 04-01 Supplement and HBN 04-02 for critical care units (it should be noted that the HBN's can be interpreted as containing some conflicting advice for ventilation strategies, however the objectives are similar). These documents should be used as the basis for all ventilation strategies in conjunction with advice from the Infection Prevention Control (IPC) team, WHO & PHE support. Overall it needs to be an issue where IPC set the room criteria and then estates can look to see how it can be provided.

Note/commentary from PHE - Standards and technical specifications within the UK we are rapidly moving to a position where COVID patients will be cohorted on bays in wards. Beyond specific "aerosol generating procedures" (AGPs) there is not thought to be an airborne risk and staff do not require respirators. This can be seen from the "general ward" guidance for AGPs in the PHE guidance.

Table 1: Transmission based precautions (TBPs): Personal protective equipment (PPE) for care of patients with pandemic COVID-19

	*Entry to cohort area (only if necessary) no patient contact**	*General ward **	*High risk unit ICU/ITU/HDU*	*Aerosol generating procedures (any setting)*
Disposable Gloves	*No*	*Yes*	*Yes*	*Yes*
Disposable Plastic Apron	*No*	*Yes*	*Yes*	*No*
Disposable Gown	*No*	*No*	*No*	*Yes*
Fluid-resistant (Type IIR) surgical mask (FRSM)	*Yes*	*Yes*	*No*	*No*
Filtering face piece (class 3) (FFP3) respirator	*No*	*No*	*Yes*	*Yes*
Disposable Eye protection	*No*	*Risk assessment*	*Risk assessment (always if wearing an FFP3)*	*Yes*

Notwithstanding the above, in the SVHSoc's opinion, a standard for any facility used, should strive to achieve the following performance criteria;

- The room/area should achieve between 6 to 12 air changes per hour. The greater the air changes provided the more effective the dilution effect provided that it does not interfere with other critical elements.
- The room/area ideally should be at least neutral to the surrounding areas (0 to -10 Pa)
- If achievable the room/area should have sufficient air supply and extract to achieve open door protection, however this may not be possible other than in a PPVL room or air-locked facility.
- The room should ideally have a protected lobby (if possible) with barrier or isolation nursing care and PPE worn by all staff
- Immediately outside but adjacent to the room there should be a wash hand basin and an area for de-gowning. If the room has a lobby (PPVL) then de-gowning should take place within the lobby.

Droplet Transmission & Airborne Dilution / Clearance

The PHE have stated that in their opinion there is very little to no risk of any viable virus transfer beyond the immediate clinical area through air gaps in doors or via pressure stabilisers as the water droplets would not survive the distance or routes without very significant dilution and desiccation. This is especially true for a patient who is anesthetised and on a closed breathing circuit. All staff within a critical care environment should be wearing full PPE. There is however emerging anecdotal evidence that the concentration of exposure may have a direct correlation to the severity of any subsequent infection and therefore dilution of aero-microbiological contamination is considered an essential precaution, even where PPE is worn.

Definitive scientific evidence that the infection is not airborne is not yet clear, and on a precautionary principle it should be assumed that it can be airborne on droplet nuclei, until proved otherwise, certainly for short distances within confined or poorly ventilated environments. Droplets expelled during AGP's can be anywhere from 1 µm to 2mm in size with an estimated average size of 50 µm. A droplet of 100 µm will fall to the floor at around 30cm/s and a droplet of 30 µm will fall at a rate of around 3cm/s, so droplets ejected from a patient by coughing/breathing are estimated to travel around 1 – 4 metres and with a downward displacement ventilation system in operation are likely to fall/be pushed to the floor very quickly. Added to this is the fact that patients are in a horizontal position typically 1m above the floor level and if ventilated on a closed breathing circuit making release of droplets less likely.

After any treatment or surgical procedure any residual airborne particles are cleared from a room at a rate of 63% per air change, therefore within 6 air changes 99.8% of any airborne contaminates will have been removed. In an operating department achieving the recommended air change rate of 25 air changes per hour (HTM 03-01 standard) the room will be effectively clear of residual airborne particles within 15 minutes or 20 minutes if achieving 20 air changes per hour (HTM 2025 standard). A similar effect will be achieved within a treatment or CCU space although these will typically achieve between 15-10 ACH and will correspondingly achieve the required 6 air changes within 24-36 minutes.

The practical implication of this guidance is that the current supply and extract ventilation systems offer a significant dilution effect to a facility and should remain in use and are unlikely to offer any risk to building occupants / users.

General Options and Considerations

A negative pressure or PPVL room with lobby is the likely preferred locally achievable option. Extract filtration, provided the air is discharged in an appropriate location, is not likely to be required as it is likely to significantly impact on the airflow performance and it will be necessary to undertake a risk based assessment on the use of extract filtration and consider system upgrades to maintain overall airflow performance. The point of discharge of any extract ventilation system should be assessed to ensure that it does not provide a route of cross contamination.

If however multiple PPVL rooms are not available then a side room with a lobby and its own en-suite is likely to be the next best option. The extract from the en-suite will provide some degree of pressure cascade / regime although it is unlikely to provide open door protection and the point of discharge location will again require to be assessed. If a side room has supply air then this should provide a minimum fresh air rate of at least 6 ACH but ideally be less than the extract air volume to maintain the room at a neutral/negative pressure, whilst not compromising dilution effect.

In most clinical care environments the vast majority of openable windows have security/restrictor arrangements to enhance user safety. In order to improve ventilation, it may be possible to undertake a risk assessed review to enable some windows to open more fully.

If an air scrubber/filtration unit is considered it will not provide any dilution or fresh air supply into the room, but may remove some contamination from the air, however the issue of how to de-contaminate and dispose of the filter unit between patients will need consideration (see maintenance considerations below).

As the spread of the virus has continued hospitals have been required to identify and consider designating entire ward areas or even buildings as isolation facilities. This cohorting of cases has been driven by clinical risk assessment based upon risk of cross contamination (between patients within the isolation space) and the need for clinical support/treatment.

In these circumstances it is likely that the capacity of the electrical and medical gas infrastructure (oxygen, medical air, and vacuum) systems has been the greatest challenge and ventilation has been a secondary issue, however some basic principles should still be considered;

- Wards with single bedrooms with en-suite facilities are likely to offer the best solution.
- Maintaining a good air change rate of between 6 - 12 ACH is considered appropriate to maintain a dilution effect for both patients and staff protection.
- The extract rate should ideally be greater than the supply where practical, to create an appropriate pressure cascade to surrounding areas, ideally with supply in corridors and extract by means of en-suite facilities and dirty extract systems, in all cases ward doors to circulation spaces MUST be kept closed as far as reasonably practical.

- If open plan/multi-bed bay wards are used then a clinical assessment of risk relating to cross contamination will be needed, however areas with low level extract by each bed space are preferable.
- If the ventilation system (AHU) serves more than a single ward then the supply aspect is less critical as the airflow direction provides a level of protection, however an ACR of around 6 ACH should be considered as a minimum. Shared extract systems are less ideal and consideration should be given to separating or closing off non-essential extracts if practical. Extract systems should be inter-locked with supply systems to ensure that if the supply fails the extract continues to operate, however if the extract fails then the supply should also switch off, only as a short term measure until the extract system can be repaired / re-instated. If a failure is likely to be over 1 hour then the supply can be reinstated to provide both thermal comfort and dilution provided that it does not create a cross contamination risk.
- If an area or room is identified as being potentially suitable to be used as a temporary isolation facility it is advisable if possible to undertake a 'room air permeability or leakage test' to ensure air is contained within the room and does not leak to adjacent areas through suspended ceiling or service penetrations, (this may not be practical to achieve, given the urgency of demand).
- Any room used as a temporary holding or isolation facility should be stripped of all non-essential materials and soft furnishings.
- If you can locate an increased extract unit to provide a negative pressure environment then care will be needed when considering the distribution ducting and the exhaust air discharge point. Ducting and extract grilles should be located to ensure an even draw of air from around bed spaces and not rely on a single point at the end of the unit which draws air over adjacent patients and staff. The exhaust discharge however providing it is discharging to a safe external space (ideally at high level 3m above roof level) then HEPA filtration is unlikely to be required. Consider sealing any openable windows in the immediate vicinity (around 4m) of any low level discharges and avoid discharge over pedestrian paths/walkways.

Use of Theatres as CCU's

As the need for critical care beds has increased some hospitals have identified areas which are suitable and have the required engineering and medical services to provide an appropriate and safe clinical environment. In many cases where patient ventilation / life support is required the theatre and associated recovery suites (freed up from elective procedures from mid-April) are considered as ideal. If kept for the exclusive use by non-infected patients the ventilation system is likely to need little modification or adjustment, however consideration may be given to lowering both supply and extract rates to save energy and ensure patient comfort (reducing ACRs to around 10 ACH would be appropriate).

Recovery areas are preferable to theatres in the first instance as the ventilation strategy of these spaces provides a good air change rate (15ACH) with neutral pressure cascade to surrounding areas and bedhead low level extract to provide a clean air path for staff protection.

Typically 2 CCU bed spaces could be provided per theatre with an addition bed located in the anaesthetic room if needed, (medical gases, adequate ventilation and electrical outlets are typically all present in these rooms). Recovery spaces are designed to provide 12-15 ACH and should be neutral to surrounding areas so no modifications to the ventilation system should be needed.

If it is proposed to use theatres as spaces to treat COVID 19 infectious patients then the airflows would need to be very carefully reviewed and adjusted to maintain a safe air change rate and provide an ideally neutral pressure regime to surrounding clinical and staff areas.

Use of Theatres for COVID 19 infected patients Including Emergency Maternity Theatres

The following information reflects the current guidance from the centre for the use of theatres for known or suspected infected (COVID19) patients;

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control

It is recommended that ventilation in both laminar flow and conventionally ventilated theatres should remain fully on during surgical procedures where patients may have COVID-19 infection. Air passing from operating theatres to adjacent areas will be highly diluted and is not considered by PHE to represent a significant risk.

- Theatres must be informed in advance of a patient transfer of a confirmed or possible COVID-19 positive case, the patient should be transported directly to the operating theatre and should wear a surgical mask if it can be tolerated.
- The patient should be anaesthetised and recovered in the theatre. Staff should wear protective clothing but only those at risk of exposure from aerosol generating procedures, i.e. during intubation need to wear FFP3 respirators and full gowns. Those closest to aerosol generation procedures are most at risk. The rapid dilution of these aerosols by operating theatre ventilation should minimise the exposure to operating room staff.
- Instruments and devices should be decontaminated in the normal manner in accordance with manufacturers' advice
- Both laryngoscope handle and blade should either be single use or reprocessed in the Sterile Supply Department. Video laryngoscope blades should be single use and scope/handle decontaminated as per manufacture instructions.
- Instruments must be transported safely to decontamination, following use.
- The theatre and all associated support areas should be cleaned as per local policy for infected cases, paying particular attention to hand contact points.
- Theatres should not be used by staff or patients for 20 minutes after the patient leaves.
- Possible or confirmed cases of COVID-19 should be placed at the end of the list where feasible

The follow information is provided to support or supplement this initial guidance.

Neutral Pressure Theatres

With the current COVID19 infection issues there may be a requirement for an operating suite to be used for an infected or suspected patient. If airborne micro-organisms liberated from a patient during the surgical procedure are allowed to cascade out into the adjacent corridors, they could contaminate surfaces or infect other patients or the staff within the surrounding operating department. Although air passing from operating theatres to adjacent areas will be highly diluted and this is not considered by PHE to represent a significant risk.

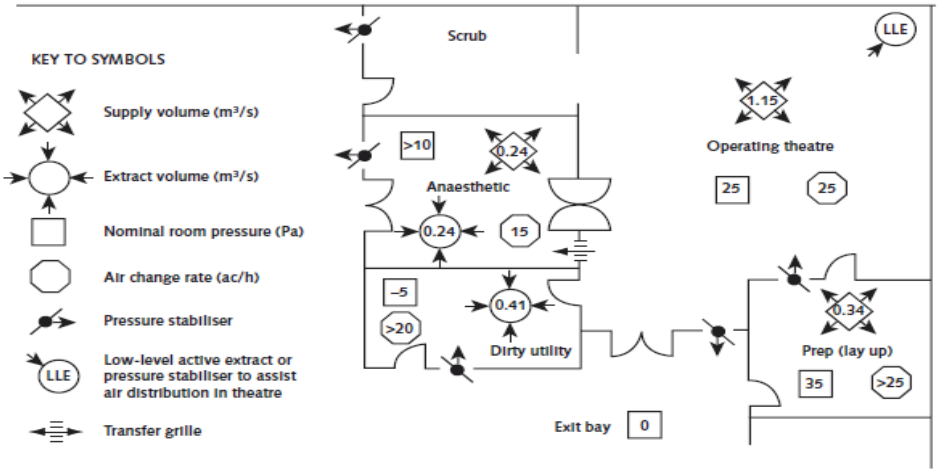
The concept of a neutral pressure or infectious theatre is to maintain an appropriate and safe air change rate to the theatre space but instead of the traditional cascade arrange of air from the theatre suite to the surrounding areas it is based on a balanced air flow of both supply and extract from ideally within the theatre itself or as a minimum within the individual theatre suite.

The room provision and layout will be as for a conventional operating suite with the following variation to the ventilation scheme:

- The operating theatre will have a balanced supply and extract so that it is at the same pressure as the corridor.
- Air should not cascade from the theatre to the surrounding rooms so pressure stabilisers and / or transfer grilles will not be fitted.
- The preparation room could be dispensed with to avoid having stock that could become pre-contaminated. Sterile packs, instruments and consumables would be delivered to the theatre on a case by case basis. If a preparation room is required, then it should be maintained at 10Pa to both the theatre and corridor.
- The anaesthetic room should have a supply in excess of extract so that is maintained at 10Pa above both the corridor and theatre. There should be a pressure stabiliser between the anaesthetic and corridor but no transfer between the anaesthetic and theatre.
- The scrub should have an active extract as for a conventional operating suite but no pressure stabiliser between it and the corridor.
- The utility should be at -5Pa to the theatre and its corridor.
- The corridor extract will be sized to cater for the air leakage from the anaesthetic room only.

Overall the ventilation scheme should ensure that all air supplied to the operating theatre is removed in the theatre suite. The theatre should be neutral (at the same pressure) to the corridor so that when the theatre exit door is open there is effectively no interchange of air between them. Ideally when the preparation or anaesthetic doors are opened airflows from them into the theatre and not the other way.

The traditional theatre suite layout typically as below (or a variation thereof);



If sites are required to endeavour to transform existing positive pressure cascade theatres to create a neutral pressure theatre the following areas will need to be considered.

In line with guidance the patient should be brought into and out of the theatre through the anaesthetic room, but anaesthetised and recovered in theatre. The doors and any pressure stabilisers from the theatre to the corridor should be sealed and not used.

The lay-up prep area should only hold the minimum stock required for the given procedure, however the air cascade from the lay-up prep to theatre should be maintained as a positive differential.

The pressure stabilisers from both the scrub area to the corridor and the anaesthetics room to corridor should be sealed.

The dirty utility room should remain at a negative pressure differential to both the theatre and corridor.

Ideally the anaesthetics room should be positive pressure to the theatre, however this may not be practical, in which case the anaesthetics room should only have all surfaces as clear as practical and all surplus or spare equipment held elsewhere.

A full re-balance of the supply and extract systems will be required and the provision of addition theatre extract is also likely. This will have to be assessed and designed on a theatre by theatre basis.

The same considerations apply to both conventional and UCV theatres. The UCV canopy is a re-circulation canopy and as such should have minimal impact on the theatres pressure regime, however due care should be taken not to disturb the canopies clean airflow area with excessive localised air movement and prevent perturbation of the UCV canopy air pattern.
It may be necessary to consider a relaxation of minimum air change rates to achieve a neutral pressure cascade however these should not be lower than 18ACH and MUST be agreed with clinical and IPC teams based on clinical risk assessment.

All non-essential materials and equipment should be removed from the theatre and surrounding corridor areas to ensure all cleaning can be undertaken as easily as possible. Specific patient and staff procedures and flows will need to be considered and agreed.

An alternative approach may be to designate a suite of theatre suites within a single location (floor or building) as infectious at which point the entire theatre complex could be isolated from any surrounding clinical areas and used exclusively for only infectious patients. In this case provided the extracted air was discharged to a safe location and all staff wear PPE whenever within the theatre area no or limited modification to ventilation strategies would be necessary.

NHS Nightingale Units - Potential Viral load risk and test methodologies

One of the founding principles of healthcare ventilation is the dilution and removal of airborne contaminants from the patient environment with particular requirements for the air change rates, by room volumes (as specified in HTM 03-01 (2007), via clean airflow paths. In addition to the issue of aero-microbiological loading, there is also the additional risk of oxygen enrichment of the general environment due to the potentially high concentration of patients on ventilators or receiving oxygen based therapy/ treatments.

Both of these issues are addressed by the use of good general ventilation through air changes of the occupied volume of the treatment/ patient space.

The spaces being used generally appear to benefit from very high ceiling void spaces and there is likely to be a high degree of thermal air movement from the bed areas into the open void above, where the existing ventilation system will be located.

It is not possible to know what specific ventilation strategy is deployed into any proposed space, however it is likely that the facility will have some degree of forced mechanical ventilation (both supply and extract) and provided that this does not utilise re-circulation airflows, and achieves in excess of 5 air changes per hour (preferably 10-12ach), the space should have sufficient ventilation. However it may not be practical to provide a fully ducted exhaust ventilation by each bedhead. If recirculation of air is used as part of the existing ventilation/energy strategy then this needs to be assessed and where practical adjusted to maximise fresh air supply.

In order to test and certify the effectiveness of the patient environment, it would be ideal if a two stage approach were adopted;

- Stage 1: pre-occupation
- Stage 2: appropriate intervals during the operational phase of the facility.

Stage one (pre-occupation) ventilation test approach.

Active air sampling for microbiological activity will be of little use prior to patient occupation, it is therefore suggested that a simple test of air movement and dilution be completed at a number of sample bed spaces. This would involve:

- Use of cold smoke (Draeger Smoke Test Puffer) to demonstrate the time taken to clear and general direction of airflow paths - ideally this should occur within a few seconds of release.

- Additionally, a Kata Test Thermometer can be used to produce an accurate air velocity performance reading at the bedhead - ideally this should be in excess of 0.2m/s.

A vane or thermal anemometer is unlikely to produce a reliable test reading at these low velocity levels.

Stage two (occupied) ventilation test approach.

Once occupied, a regular air monitoring regime could be employed to establish and monitor both 'oxygen concentration' levels (using a suitably calibrated and certified oxygen monitor, to BS EN 50104:2019), to enable action to be taken if high levels are found and, 'active air sampling' in the form of occupational environmental air sampling (HSE G409 and Monitoring strategies for toxic substances HSG173 (Second edition) HSE Books 2006 ISBN 0 7176 6188 1) of staff to ensure adequate dilution is being achieved in use.

Community Healthcare Ventilation systems

The practical implication of the guidance is that the current supply and extract ventilation systems offer a dilution effect to the facility and should remain in use and are unlikely to offer any risk to building occupants / users.

Recirculating air conditioning units (also known as split systems) should not be used within clinical care environments as they incorporate both air filtration and water / condensation 'open' trays. These units can provide a location where micro-organisms can become concentrated and proliferate. This is not a specific COVID-19 risk but a general consideration for the use and installation of these units.

Environmental cleaning following a possible case
Once a possible case has been transferred from the primary care premises, the room where the patient was placed should not be used, the room door should remain shut, with windows opened and the air conditioning switched off until it has been cleaned with detergent and disinfectant. Once this process has been completed, the room can be put back in use immediately.

Note - The air conditioning referred to is understood to be any room mounted 'split' air conditioning unit which only circulates the air within the space and cools or in some models heats the air. As this does not provide fresh air, nor does it remove air to outside the advice to switch it off is related to it not being used whilst windows are open.

Non ventilation Considerations

In addition to the ventilation issues associated with the current COVID 19 pandemic, other healthcare related engineering services and operational considerations will need to be assessed and considered. These are likely to include;

- Medical gas capacities and flow rates to deliver required clinical treatments (oxygen, medical air & vacuum).
- Number and location of electrical outlets on essential power supplies, for clinical and medical electronics.
- Provision of suitable emergency lighting
- Patient access and egress / transportation routes through other clinical / public areas.
- A minimum separation distance of between 1 – 2 metres should be maintained between beds
- If temporary separation / partition walls or barriers are constructed to create segregated bed spaces, the fire strategy and fire evacuation plans MUST be reviewed to ensure they remain appropriate. This should involve identification of evacuation routes and places to provide both an immediate safe refuge and a place to continue care and treatment.
- Provision of adequate hand washing facilities.
- Waste collection and storage capacities and locations and transfer routes.
- Surrounding clinical services to avoid close proximity to other 'at risk' patient groups.
- Adequate staff welfare and rest areas if staff numbers are increased to meet clinical needs.

Estates staff are recommended to give consideration to all of the above and where considered necessary review the PHE guidance and consult with their appropriate Authorising Engineer for the associated engineering specialty.

Additional guidance is available in the NHS&I – Novel coronavirus (COVID-19) standard operating procedure – Design Note: COVID-19 ward for intubated patients version 1.0 published 22/03/2020 (Publications approval ref 001559).

Ventilation Maintenance Considerations

Ventilation breakdowns and repairs

Any potential contamination risk associated with extract ductwork, fans and filters is likely to be very low. The ventilation system acts to dry out any droplets that are drawn out of a room and if these droplets settle on ductwork or fan surfaces they will very quickly desiccate and are likely to be inactive. Notwithstanding this it is advised that enhanced precautions should be taken by maintenance staff when working on such systems both as a precautionary measure and to provide re-assurance to those undertaking the work.

If a breakdown or internal inspection is required to an extract system from a potentially contaminated area then the following issues should be considered;

- Minimise the tools taken into the area during any period when a system is 'opened up' for maintenance or inspection.
- Following work being completed old or redundant materials / components should be bagged and removed as clinical waste.
- Tools used during the work should be washed / disinfected where practical or wiped down with alcohol based steri-wipes or similar.
- Minimise the number of workers in the immediate area of the work, whilst maintaining safe working conditions and staffing levels (two man working may be necessary if working at height or if moving and handling issues exist).
- All staff should wear appropriate PPE and dress, remove, and dispose of it as detailed below.

Other maintenance activities not directly relating to extract ventilation maintenance such as fire damper drop testing, or ductwork cleanliness inspections will need to be managed so as to ensure that no potential contaminated extract ductwork is opened accidentally. Smoke and fire dampers on extract systems will need to be assessed to ensure routine fire alarm testing does not interrupt or involve extract ductwork ventilation system operation, if being used for isolation protection.

The precautions and method statement detailed above should be adapted / applied to all maintenance staff working in areas where potentially or known infectious patient are or have been located whether working on ventilation systems or any building / estates related element / equipment.

Filter changing

There are two typical types of filters installed in extract ventilation systems, Safe change types in systems designed to handle toxic or contaminated air (LEV's or HCID units) also known as Bag In Bag Out BIBO type filter units and general filtration (primarily designed to protect fan components and heat exchangers).

Safe change filter units as specifically designed to enable removal and replacement without exposing the maintenance worker to direct contact with the dirty filter. The design of these units can vary so the manufacturers' guidance notes and method statements should be followed to ensure safe removal and disposal.

General filters will not be of a grade that is designed to capture all particles, but will capture some and should be treated carefully. Prior to opening up a unit to remove a general filter a disposal bag should be available. The unit should be switched off and any backflow dampers allowed to close (or if manual – closed) prior to opening up the filter access door. The filter should be removed carefully to minimise the release of any dust/contamination on the filter surfaces and placed directly into the disposal bag. The filter frame should be cleaned ideally with a HEPA filter vacuum cleaner or wiped down with and alcohol based steri-wipe, the used wipes should also be disposed of in the filter disposal bag.

Once clean the new replacement filter can be installed, the unit re-assembled and the fan switch on, once any manual dampers have been re-opened.

PPE - Putting on and removing personal protective equipment

Putting on PPE

Before donning, healthcare maintenance workers should, remove all nonessential items and tools from overalls and tool bags, ensure they are hydrated, and perform hand hygiene.
Staff should wear the following PPE, put on in the following order:

- Disposable boiler suit/coveralls
- FFP3 respirator and fit check
- eye protection (goggles or face shield)
- disposable gloves

The order given above is practical but the order for putting on is less critical than the order of removal given below. During donning each item must be adjusted as required to ensure it fits correctly and interfaces well with other PPE items.

Removal of PPE

PPE should be removed in an order that minimises the potential for cross-contamination.
If working within a clinical space after leaving the side room gloves, disposable boiler suit and eye protection should be removed (in that order, where worn) and disposed of as clinical waste. The respirator can be removed and the filters disposed of as clinical waste with the mask being wiped clean with alcohol based steri-wipes or similar.
If working in a plantroom or service area (on remote located ventilation equipment associated with an isolation facility then the PPE should be removed and bagged prior to leaving the plantroom area. Other staff should not be working in the area whilst the maintenance work to extract ventilation systems is being undertaken.
The order of removal of PPE is suggested as follows, consistent with WHO guidance:

- peel off gloves and dispose in clinical waste
- perform hand hygiene
- remove boiler suit by using a peeling motion, fold in on itself and place in clinical waste bin
- remove goggles or visor only by the headband or sides and dispose in clinical waste
- remove respirator from behind and dispose of filters as clinical waste
- Clean respirator mask housing using alcohol based steri-wipes or similar.
- perform hand and face hygiene

For additional guidance see the PHE COVID-19: Guidance for infection prevention and control in healthcare settings. Version 1.0. Appendix 3 – Best Practice - Putting on and taking off PPE.

Endnote

Any healthcare organisation which is undertaking works or modifications to their ventilation systems should seek to obtain specialist advice both internally from the organisations own multi-disciplinary team (estates (AP(V)), IPC, Clinical leads, Decontamination leads, Medical Gas AP(MPGS), etc.…) but also from an appropriately qualified and experienced Authorising Engineer (Ventilation) or other suitable professional design consultant.

References

Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises Parts A & B (2007)

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

Health Building Note 04-02 Critical Care Units (2013)

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings - *Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee*
Guidance Wuhan novel coronavirus (nCoV) infection prevention and control guidance Updated 31st January 2020 - Gov.UK Public Health England

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The Use of Engineering Measures To Control Airborne Pathogens In Hospital Buildings, Dr Clive Beggs, School of Civil Engineering, University of Leeds, Leeds LS2 9JT, UK

Updated Briefing & Guidance on Considerations for the Ventilation Aspects of Healthcare Facilities for Coronavirus – Updated 24th March 2020

Revision Number 3.3 (24-03-2020)

Acknowledgments

Lead Author - Andrew Poplett IEng, MSVHSoc, MIHEEM, ACIBSE, AffIFE

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- Members of the Specialist Ventilation for Healthcare Society

Introduction

Following a review and advice from Public Health England (Peter Hoffman) the briefing and guidance from the SVHSoc has been updated to reflect the current official guidance and to provide a range of options and areas for consideration for healthcare estates professionals to provide enhanced levels of protection for patients, staff, and visitors.

The briefing is intended to provide an overview of the issues and points to consider when assessing the ventilation strategy and options. It has also been updated to provide some initial maintenance considerations and precautions which may need to be considered. It is intended that this briefing and guidance will be subject to regular review and updates as details, information, and the situation continues to develop.

Current guidance on the lifespan of the virus once outside the body is still to be fully established, however current estimates are that it could survive anywhere between a few hours up to 3 to 4 days on hard surfaces and is spread by both primary direct exposure (breathing in droplets expelled from an infected person from coughing or sneezing) and secondary contact by touch (touching a surface which has been contaminated and transferring this contamination by touch to the mouth, nose or eyes). Coronaviruses are mainly transmitted by large respiratory droplets and direct or indirect contact with infected secretions. They have also been detected in blood, faeces and urine and, under certain circumstances, airborne transmission is thought to have occurred from aerosolised respiratory secretions and faecal material". That level of airborne transmissibility is specifically associated with certain aerosol generating procedures (AGPs).

That COVID-19 has been termed an airborne infection is an indication that it is capable of transmitting via an airborne route in certain circumstances, not that its mode of spread is primarily airborne nor that any aerosol remains sufficiently concentrated to be infectious over longer distances other than in the immediate vicinity of a dispersing patient.

The PHE guidance is under constant review and updated as necessary. The current guidance can be found at:

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/wuhan-novel-coronavirus-wn-cov-infection-prevention-and-control-guidance

Ventilation can contribute to an isolation or protection strategy to assist in minimising the spread of the virus, however a number of factors need to be considered, not least of all the provision of adequate ventilation to provide dilution of any airborne contamination, with other factors including;

- Area / rooms where isolation can be established
- Physical / fabric of the room construction / air permeability rates (e.g. solid ceilings)
- Surrounding areas of clinical activity
- Room volume and airflow / room pressure differentials (dilution effects)
- Provision and location of ventilation (e.g. ceiling mounted supply with low level extract)
- Point of discharge of any extracted air and filtration of same
- Levels of isolation and practical considerations
- Decontamination of the area between patients
- Protection of all potentially exposed staff groups (clinical, cleaning, and estates)

Standards and Technical Specifications

HTM 03-01 sets out the overall guidance for ventilation of healthcare premises with addition specific guidance on isolation facilities being contained within HBN 04-01 Supplement. These documents should be used as the basis for all ventilation strategies in conjunction with advice from the Infection Protection Control (IPC) team, WHO & PHE support. Overall it needs to be an issue where IPC set the room criteria and then estates can look to see how it can be provided.

Note/commentary from PHE - Standards and technical specs; We (PHE) are rapidly moving to a position where COVID patients will be cohorted on bays in wards. Beyond specific "aerosol generating procedures" (AGPs) there is not thought to be an airborne risk and staff do not require respirators. This can be seen from the "general ward" guidance for AGPs in the PHE guidance.

Table 1: Transmission based precautions (TBPs): Personal protective equipment (PPE) for care of patients with pandemic COVID-19

	*Entry to cohort area (only if necessary) no patient contact**	*General ward **	*High risk unit ICU/ITU/HDU*	*Aerosol generating procedures (any setting)*
Disposable Gloves	*No*	*Yes*	*Yes*	*Yes*
Disposable Plastic Apron	*No*	*Yes*	*Yes*	*No*
Disposable Gown	*No*	*No*	*No*	*Yes*
Fluid-resistant (Type IIR) surgical mask (FRSM)	*Yes*	*Yes*	*No*	*No*
Filtering face piece (class 3) (FFP3) respirator	*No*	*No*	*Yes*	*Yes*
Disposable Eye protection	*No*	*Risk assessment*	*Risk assessment (always if wearing an FFP3)*	*Yes*

Notwithstanding the above, in the SVHSoc's opinion, a standard for any facility used, should strive to achieve the following performance criteria;

- The room ideally should be neutral or negative to the surrounding areas (-5 to -10 Pa)
- The room should achieve between 6 to 12 air changes per hour
- If achievable the room should have sufficient air supply and extract to achieve open door protection, however this may not be possible other than in a PPVL room.
- The room should ideally have a protected lobby (if possible) with barrier nursing and PPE worn by all staff
- Immediately outside but adjacent to the room there should be a wash hand basin and an area for de-gowning. If the room has a lobby (PPVL) then de-gowning should take place within the lobby.

General Options and Considerations

A negative pressure or PPVL room with lobby is the likely preferred locally achievable option. Extract filtration is not likely to be required as it is likely to significantly impact on the airflow performance and it will be necessary to undertake a risk based assessment on the use of extract filtration and consider system upgrades to maintain overall airflow performance. The point of discharge of any extract ventilation system should be assessed to ensure that it does not provide a route of cross contamination.

If however multiple PPVL rooms are not available then a side room with a lobby and its own en-suite is likely to be the next best option. The extract from the en-suite will provide some degree of pressure cascade / regime although it is unlikely to provide open door protection and the point of discharge location will again require to be assessed. If a side room has supply air then this should be re-balanced to provide a minimum fresh air rate but be less than the extract air volume to maintain the room at a negative pressure, whilst not compromising dilution effect. Negative pressure units (NPU) are readily available in the asbestos removal industry, they come with DOP test HEPA filters and could be considered to create a negative pressure room on a temporary basis.

If an air scrubber/filtration unit is considered it will not provide any dilution or fresh air supply into the room, but may remove some contamination from the air, however the issue of how to de-contaminate and dispose of the filter unit between patients will need consideration (see maintenance considerations below).

As the spread of the virus continues it is likely that hospitals will be asked to identify and consider designating entire ward areas or even buildings as isolation facilities. This cohorting of cases will be driven by clinical risk assessment based upon risk of cross contamination (between patients within the isolation space) and the need for clinical support/treatment. In these circumstances it is likely that the capacity of the electrical and medical gas infrastructure (oxygen, medical air, and vacuum) systems will be the greatest challenge and ventilation will be a secondary issue, however some basic principles should be considered;

- Wards with single bedrooms with en-suite facilities are likely to offer the best solution.
- The extract rate should be greater than the supply where practical, to create a negative pressure cascade to surrounding areas, ideally with supply in corridors and extract by means of en-suite facilities and dirty extract systems, in all cases ward doors to circulation spaces MUST be kept closed as far as reasonably practical.
- Maintaining a good air change rate of between 6 - 12 ACH is considered appropriate to maintain a dilution effect for both patients and staff protection.

- If open plan/multi-bed bay wards are used then a clinical assessment of risk relating to cross contamination will be needed, however areas with low level extract by each bed space would be preferable.
- If the ventilation system (AHU) serves more than a single ward then the supply aspect is less critical as the airflow direction provides a level of protection, however an ACR of around 6 ACH should be considered as a minimum. Shared extract systems are less ideal and consideration should be given to separating or closing off non-essential extracts if practical. Extract systems should be inter-locked with supply systems to ensure that if the supply fails the extract continues to operate, however if the extract fails then the supply should also switch off, only as a short term measure until the extract system can be repaired / re-instated. If a failure is likely to be over 1 hour then the supply can be reinstated to provide both thermal comfort and dilution provided that it does not create a cross contamination risk.
- If an area or room is identified as being potentially suitable to be used as a temporary isolation facility it is advisable if possible to undertake a 'room air permeability or leakage test' to ensure air is contained within the room and does not leak to adjacent areas through suspended ceiling or service penetrations, (this may not be practical to achieve, given the urgency of demand).
- Any room used as a temporary holding or isolation facility should be stripped of all non-essential materials and soft furnishings.
- If you can locate an increased extract unit to provide a negative pressure environment then care will be needed when considering the distribution ducting and the exhaust air discharge point. Ducting and extract grilles should be located to ensure an even draw of air from around bed spaces and not rely on a single point at the end of the unit which draws air over adjacent patients and staff. The exhaust discharge however providing it is discharging to a safe external space (ideally at high level 3m above roof level) then HEPA filtration is unlikely to be required. Consider sealing any openable windows in the immediate vicinity (around 4m) of any low level discharges and avoid discharge over pedestrian paths/walkways.

Use of Theatres as CCU's

As the need for critical care beds increases hospitals will need to identify areas which are suitable and have the required engineering and medical services to provide an appropriate and safe clinical environment. In many cases where patient ventilation / life support is required the theatre and associated recovery suites (freed up from elective procedures from mid-April) could be considered as ideal. If kept for the exclusive use by non-infected patients the ventilation system is likely to need little modification or adjustment, however consideration may be given to lowering both supply and extract rates to save energy and ensure patient comfort (reducing ACRs to around 10 ACH would be appropriate). Typically 2 CCU bed spaces could be provided per theatre with an addition bed located in the anaesthetic room if needed, (medical gases, adequate ventilation and electrical outlets are typically all present in these rooms). Recovery spaces are designed to provide 12-15 ACH and should be neutral to surrounding areas so no modifications to the ventilation system should be needed.

If it is proposed to use theatres as spaces to treat COVID 19 infectious patients then the airflows would need to be very carefully reviewed and adjusted to maintain a safe air change rate and provide an ideally neutral pressure regime to surrounding clinical and staff areas.

Use of Theatres for COVID 19 infected patients Including Emergency Maternity Theatres

The following information reflects the current guidance from the centre for the use of theatres for known or suspected infected (COVID19) patients;

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control

18. Theatres

- theatres must be informed in advance of a patient transfer of a confirmed or possible COVID-19 positive case
- the patient should be transported directly to the operating theatre and should wear a surgical mask if it can be tolerated
- the patient should be anaesthetised and recovered in the theatre. Staff should wear protective clothing but only those at risk of exposure from aerosol generating procedures, ie during intubation need to wear FFP3 respirators and full gowns. considerations about the use of respiratory/anaesthetic equipment are addressed in the critical care section above
- instruments and devices should be decontaminated in the normal manner in accordance with manufacturers' advice
- both laryngoscope handle and blade should either be single use or reprocessed in the Sterile Supply Department. Video laryngoscope blades should be single use and scope/handle decontaminated as per manufacture instructions.
- instruments must be transported safely to decontamination, following use
- the theatre should be cleaned as per local policy for infected cases, paying particular attention to hand contact points on the anaesthetic machine
- theatres should not be used by staff or patients for 20 minutes after the patient leaves if conventionally ventilated, or 5 minutes if ultraclean ventilation is used
- possible or confirmed cases of COVID-19 should be placed at the end of the list where feasible

The follow information is provided to support or supplement this initial guidance.

Neutral Pressure Theatres

With the current COVID19 infection issues there may be a requirement for an operating suite to be used for an infected or suspected patient. If airborne micro-organisms liberated from a patient during the surgical procedure are allowed to cascade out into the adjacent corridors, they could contaminate surfaces or infect other patients or the staff within the surrounding operating department.

The concept of a neutral pressure or infectious theatre is to maintain an appropriate and safe air change rate to the theatre space but instead of the tradition cascade arrange of air from the theatre suite to the surrounding areas it is a based on a balanced air flow of both supply and extract from ideally within the theatre itself or as a minimum within the individual theatre suite.

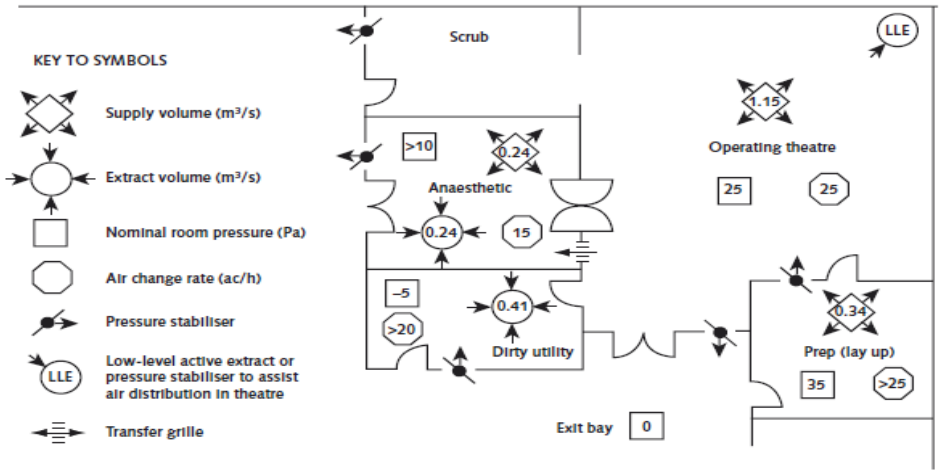
The room provision and layout will be as for a conventional operating suite with the following variation to the ventilation scheme:

- The operating theatre will have a balanced supply and extract so that it is at the same pressure as the corridor.
- Air should not cascade from the theatre to the surrounding rooms so pressure stabilisers and / or transfer grilles will not be fitted.

- The preparation room could be dispensed with to avoid having stock that could become pre-contaminated. Sterile packs, instruments and consumables would be delivered to the theatre on a case by case basis. If a preparation room is required, then it should be maintained at 10Pa to both the theatre and corridor.
- The anaesthetic room should have a supply in excess of extract so that is maintained at 10Pa above both the corridor and theatre. There should be a pressure stabiliser between the anaesthetic and corridor but no transfer between the anaesthetic and theatre.
- The scrub should have an active extract as for a conventional operating suite but no pressure stabiliser between it and the corridor.
- The utility should be at -5Pa to the theatre and its corridor.
- The corridor extract will be sized to cater for the air leakage from the anaesthetic room only.

Overall the ventilation scheme should ensure that all air supplied to the operating theatre is removed in the theatre suite. The theatre should be neutral (at the same pressure) to the corridor so that when the theatre exit door is open there is effectively no interchange of air between them. Ideally when the preparation or anaesthetic doors are opened airflows from them into the theatre and not the other way.

The traditional theatre suite layout typically as below (or a variation thereof);



If sites are required to endeavour to transform existing positive pressure cascade theatres to create a neutral pressure theatre the following areas will need to be considered.

In line with guidance the patient should be brought into and out of the theatre through the anaesthetic room, but anaesthetised and recovered in theatre. The doors and any pressure stabilisers from the theatre to the corridor should be sealed and not used.

The lay-up prep area should only hold the minimum stock required for the given procedure, however the air cascade from the lay-up prep to theatre should be maintained as a positive differential.

The pressure stabilisers from both the scrub area to the corridor and the anaesthetics room to corridor should be sealed.

The dirty utility room should remain at a negative pressure differential to both the theatre and corridor.

Ideally the anaesthetics room should be neural pressure to the theatre, however this may not be practical, in which case the anaesthetics room should only have all surfaces as clear as practical and all surplus or spare equipment held elsewhere.

A full re-balance of the supply and extract systems will be required and the provision of addition theatre extract is also likely. This will have to be assessed and designed on a theatre by theatre basis.

The same considerations apply to both conventional and UCV theatres. The UCV canopy is a re-circulation canopy and as such should have minimal impact on the theatres pressure regime, however due care should be taken not to disturb the canopies clean airflow area with excessive localised air movement and prevent perturbation of the UCV canopy air pattern.

It may be necessary to consider a relaxation of minimum air change rates to achieve a neutral pressure cascade however these should not be lower than 18ACH and MUST be agreed with clinical and IPC teams based on clinical risk assessment.

All non-essential materials and equipment should be removed from the theatre and surrounding corridor areas to ensure all cleaning can be undertaken as easily as possible.

Specific patient and staff procedures and flows will need to be considered and agreed.

An alternative approach may be to designate a suite of theatre suites within a single location (floor or building) as infectious at which point the entire theatre complex could be isolated from any surrounding clinical areas and used exclusively for only infectious patients. In this case provided the extracted air was discharged to a safe location and all staff wear PPE whenever within the theatre area no or limited modification to ventilation strategies would be necessary.

Summary

Any healthcare organisation which is undertaking this assessment or provision should seek to obtain specialist advice both internally from the organisations own multi-disciplinary team (estates (AP(V), IPC, Clinical leads, Decontamination leads, Medical Gas AP(MPGS), etc…) but also from an appropriately qualified and experienced Authorising Engineer (Ventilation) or other suitable professional design consultant.

Non ventilation Considerations

In addition to the ventilation issues associated with the current COVID 19 pandemic, other healthcare related engineering services and operational considerations will need to be assessed and considered. These are likely to include;

- Medical gas capacities and flow rates to deliver required clinical treatments (oxygen, medical air & vacuum).
- Number and location of electrical outlets on essential power supplies, for clinical and medical electronics.
- Provision of suitable emergency lighting
- Patient access and egress / transportation routes through other clinical / public areas.
- A minimum separation distance of between 1 – 2 metres should be maintained between beds
- If temporary separation / partition walls or barriers are constructed to create segregated bed spaces, the fire strategy and fire evacuation plans MUST be reviewed to ensure they remain appropriate. This should involve identification of evacuation routes and places to provide both an immediate safe refuge and a place to continue care and treatment.
- Provision of adequate hand washing facilities.
- Waste collection and storage capacities and locations and transfer routes.
- Surrounding clinical services to avoid close proximity to other 'at risk' patient groups.
- Adequate staff welfare and rest areas if staff numbers are increased to meet clinical needs.

Estates staff are recommended to give consideration to all of the above and where considered necessary review the PHE guidance and consult with their appropriate Authorising Engineer for the associated engineering specialty.

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If a breakdown or internal inspection is required to an extract system from a potentially contaminated area then the following issues should be considered;

- Minimise the tools taken into the area during any period when a system is 'opened up' for maintenance or inspection.
- Following work being completed old or redundant materials / components should be bagged and removed as clinical waste.
- Tools used during the work should be washed / disinfected where practical or wiped down with alcohol based steri-wipes or similar.
- Minimise the number of workers in the immediate area of the work, whilst maintaining safe working conditions and staffing levels (two man working may be necessary if working at height or if moving and handling issues exist).
- All staff should wear appropriate PPE and dress, remove, and dispose of it as detailed below.

Other maintenance activities not directly relating to extract ventilation maintenance such as fire damper drop testing, or ductwork cleanliness inspections will need to be managed so as to ensure that no potential contaminated extract ductwork is opened accidentally. Smoke and fire dampers on extract systems will need to be assessed to ensure routine fire alarm testing does not interrupt or involve extract ductwork ventilation system operation, if being used for isolation protection.

The precautions and method statement detailed above should be adapted / applied to all maintenance staff working in areas where potentially or known infectious patient are or have been located weather working on ventilation systems or any building / estates related element / equipment.

Filter changing

There are two typical types of filters installed in extract ventilation systems, Safe change types in systems designed to handle toxic or contaminated air (LEV's or HCID units) also known as Bag In Bag Out BIBO type filter units and general filtration (primarily designed to protect fan components and heat exchangers).

Safe change filter units as specifically designed to enable removal and replacement without exposing the maintenance worker to direct contact with the dirty filter. The design of these units can vary so the manufacturers' guidance notes and method statements should be followed to ensure safe removal and disposal.

General filters will not be of a grade that is designed to capture all particles, but will capture some and should be treated carefully. Prior to opening up a unit to remove a general filter a disposal bag should be available. The unit should be switched off and any backflow dampers allowed to close (or if manual – closed) prior to opening up the filter access door. The filter should be removed carefully to minimise the release of any dust/contamination on the filter surfaces and placed directly into the disposal bag.

The filter frame should be cleaned ideally with a HEPA filter vacuum cleaner or wiped down with and alcohol based steri-wipe, the used wipes should also be disposed of in the filter disposal bag.

Once clean the new replacement filter can be installed, the unit re-assembled and the fan switch on, once any manual dampers have been re-opened.

PPE

Putting on and removing personal protective equipment

Putting on PPE

Before donning, healthcare maintenance workers should, remove all nonessential items and tools from overalls and tool bags, ensure they are hydrated, and perform hand hygiene.

Staff should wear the following PPE, put on in the following order:

- Disposable boiler suit/coveralls
- FFP3 respirator and fit check
- eye protection (goggles or face shield)
- disposable gloves

The order given above is practical but the order for putting on is less critical than the order of removal given below. During donning each item must be adjusted as required to ensure it fits correctly and interfaces well with other PPE items.

Removal of PPE

PPE should be removed in an order that minimises the potential for cross-contamination.

If working within a clinical space after leaving the side room gloves, disposable boiler suit and eye protection should be removed (in that order, where worn) and disposed of as clinical waste. The respirator can be removed and the filters disposed of as clinical waste with the mask being wiped clean with alcohol based steri-wipes or similar.

If working in a plantroom or service area (on remote located ventilation equipment associated with an isolation facility then the PPE should be removed and bagged prior to leaving the plantroom area. Other staff should not be working in the area whilst the maintenance work to extract ventilation systems is being undertaken.

The order of removal of PPE is suggested as follows, consistent with WHO guidance:

- peel off gloves and dispose in clinical waste
- perform hand hygiene
- remove boiler suit by using a peeling motion, fold in on itself and place in clinical waste bin
- remove goggles or visor only by the headband or sides and dispose in clinical waste
- remove respirator from behind and dispose of filters as clinical waste
- Clean respirator mask housing using alcohol based steri-wipes or similar.
- perform hand and face hygiene

For additional guidance see the PHE COVID-19: Guidance for infection prevention and control in healthcare settings. Version 1.0. Appendix 3 – Best Practice - Putting on and taking off PPE.

References

Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises Parts A & B (2007)

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

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings - *Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee*

Guidance Wuhan novel coronavirus (nCoV) infection prevention and control guidance Updated 31st January 2020 - Gov.UK Public Health England

Guidance COVID-19: infection prevention and control guidance PHE.Gov.UK

NHS&I – Novel coronavirus (COVID-19) standard operating procedure – Design Note: COVID-19 ward for intubated patients version 1.0 published 22/03/2020 (Publications approval ref 001559).

COVID-19 Guidance for infection prevention and control in healthcare settings Adapted from Pandemic Influenza: Guidance for Infection prevention and control in healthcare settings 2020 Issued jointly by the Department of Health and Social Care (DHSC), Public Health Wales (PHW), Public Health Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England as official guidance.

From: Mackenzie, Janice
Sent: 12 July 2019 12:51
To: Inverarity, Donald; Freeman, Julie; Reilly, Laura; Smith, Pat; Calder, Carol A; Evans, William; McDougall, Catherine; Kalima, Pota
Cc: Hull, Ashley; Henderson, Ronnie; McFadzean, Jillian; Currie, Brian
Subject: Critical Care Ventilation
Attachments: 20190712070843502.pdf; RHCYP Critical Care Ventialtion Summary of DiscussionsJuly19.docx

Dear All

Please find attached a summary of our discussions at the two meetings this week along with a marked up drawing showing the 4 bedded bay affected by the proposed ventilation works. Hopefully I have captured the key points but if there is anything I have missed then please let me know

The feedback from these discussions will now be feed into the design meetings currently being held involving HFS which Donald and Ronnie attend.

Kind regards

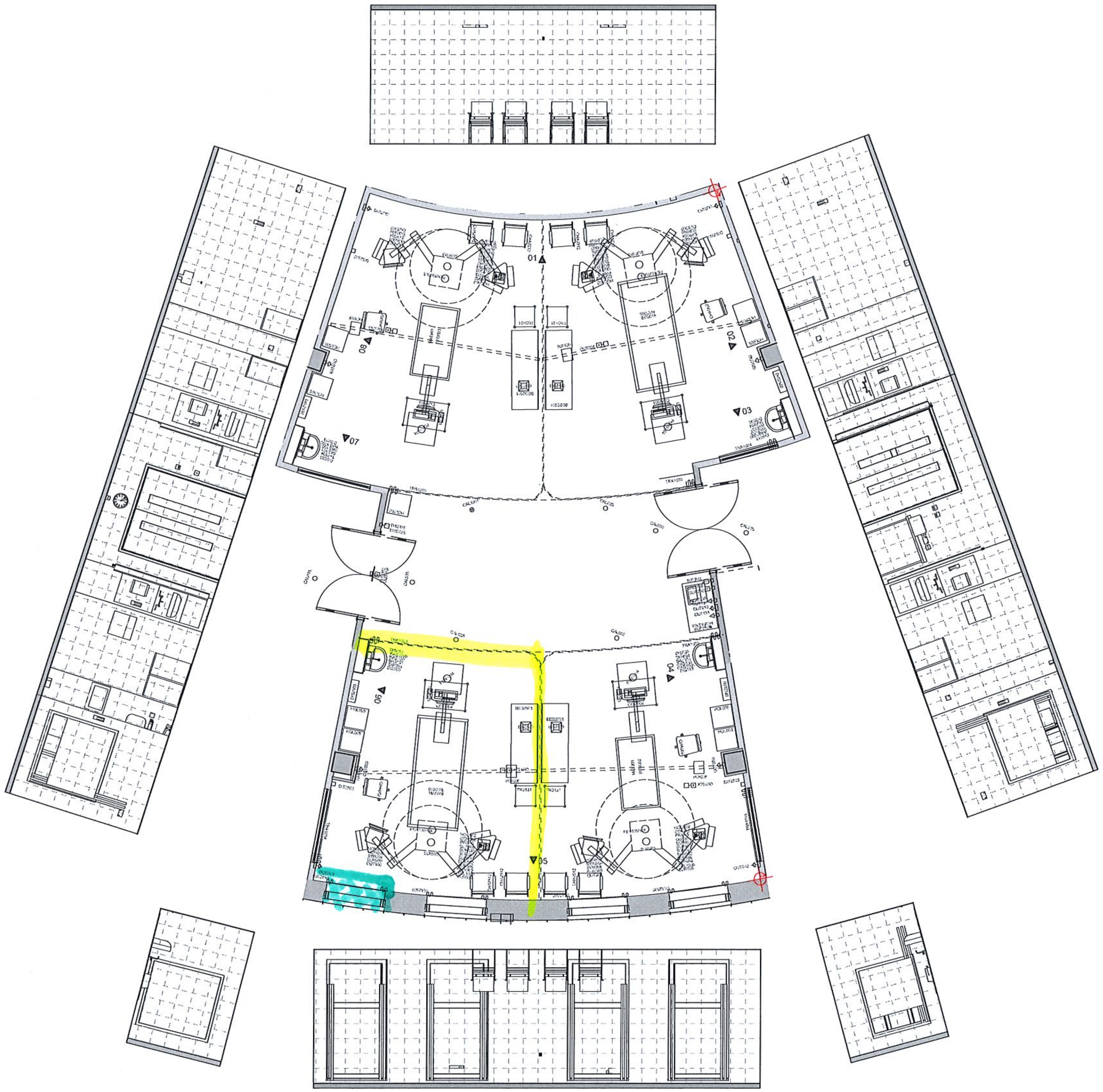
Janice

PLEASE NOTE MY TELEPHONE NUMBER HAS CHANGED to [redacted]

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France Project Team

Royal Hospital for Children & Young People and Department of Clinical Neurosciences 4th Floor Clinical Management Office Little France Crescent Edinburgh
EH16 4TJ
[redacted]

[redacted]
[PHNC cyan secondary FOR SIG]
www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters



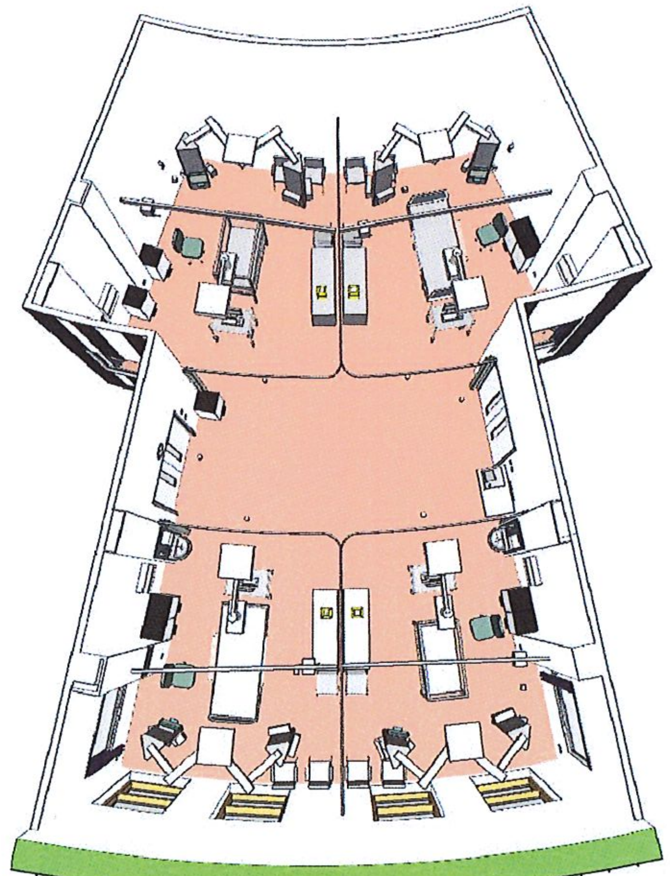
Quantity	Code	Description
4	BAS101	BASIN, medium, hospital pattern, vitreous china, no tap holes, no overflow, integral back outlet, 600W 400D
2	BED003	BED; cot, baby; dropside, standard size
2	BED016	BED, COT/IFC, radio translucent lying backrest, two-way tilt, height adjustable (900-600), on castors
4	BED2501	Mobile bed divider 1600W 1350H
4	BIN2503	BIN, sharps disposal
1	BMS999	BMS Sensor
7	CAL035	LAMP repeat call (patient/staff or staff emergency or Cardiac call), ceiling mounted
1	CAL1001	CALL, lamp time unit, ceiling mounted
4	CHA002	CHAIR; height adjustable; medium back, swivel, 5 star base; on castors
8	CHA2512	CHAIR, upright with arms; vinyl plastic; stacking
1	CLO003	CLOCK synchronous with second sweep hand, wall mounted
1	COM038	COMPUTER PRINTER, laser, A4, 250H 350W 385D
4	COM904	CIS CART; with CPU ; screen; keyboard & mouse
4	CON902	Remote monitor control (cabling integrated into the pendant or WiFi)
4	DIS013	DISPENSER, paper towel, wall mounted
4	DIS030	DISPENSER, soap, disposable single cartridge, lever action, wall mounted
4	DIS2500	DISPENSER, dispenser; combined glove/apron,
4	DIS2503	DISPENSER; alcohol gel, disposable single cartridge, wall mounted,
1	EBB001	Equipotential Bonding Busbars
4	HOI005	HOIST PATIENT, with washable slings, electric; 24v; straight track ceiling mounted (Length of the track to suit the individual needs)
9	HOL005	HOLDER, bin, medium, capacity 70 litres, freestanding.
4	HOO002	Hook for suction support. Upper Medirail mounted,
2	MAT005	MATTRESS, ITU/CCU bed, extra care
2	MAT901	MATTRESS, reliever
4	MON904	MONITOR, High end multi-functionality for ITU/Theatre/High Acuity
4	MON909	MONITOR; Transport monitor for ITU/Theatre/High Acuity
4	OUT004	OUTLET cable, fused, 13 amp, ceiling mounted
4	OUT005	SOCKET outlet, switched, 13amp, single
5	OUT010	SOCKET outlet, switched, 13amp, twin
1	OUT059	CONNECTION UNIT switched 13amp, indicator light
2	OUT121	SOCKET outlet double data/voice; wall/trunking mounted.
8	OUT900	Data Input Box for CIS with 16 input channels (Lantronix): uses 1 plug, 1 data point
4	PEN1000LR	PENDANT; critical care; twin arm; multi movement, with sockets, equipotential sockets, dtd data, oxygen, vacuum, medical air, AGSS, nurse call, light swc, lamp, uplighter, medirails, infusion poles, shelves as detailed in ME-XX-AX-DC-400-002
4	PEN1004	PENDANT, critical care, CIS; single arm with elbow joints; multi movement with 4 sockets & 2 data points as detailed in ME-XX-AX-DC-400-002
4	PRI015	PRINTER, label, portable
2	SUP2500	SUPPORT LEG; for 920 high worktop
4	SUR955	Humidifier. 1 plug, 1 Data (Lantronix) cable
4	SUR965	Docking station with 7 volumetric pumps. 1 plug, 1 Data (Lantronix) cable
4	SUR987	Nebuliser mounted on Medirail . 1 plug
8	SUR989	Alaris volumetric pumps. 2 plugs
4	SUR991	Double oxygen flow meter. Upper Medirail mounted
4	SUR992	Air flow meter. Upper Medirail mounted
4	SUR993	Airway pressure monitor. Upper Medirail mounted
4	SUR999	Enteral feed pump
1	SWC025	SWITCH, light
4	SYR004	SYRINGE pump; anaesthetic use, with diffusor, 115H 400W 180D
4	TAP804	TAP bib, hospital pattern, integral thermostatic mixer, HTM64
4	TEL1000	TELEPHONE, handset,
2	THE005	THERMOSTAT
4	TRA1003	TRACK, curtain, bed/trolley; length and shape as drawn.
3	TRA1004	TRACK, curtain, to internal screens
4	TRA2500	TRACK; curtain; window, length to suit
4	TRO151	TROLLEY, dressing/instrument, stainless steel, buffered, 870H 450W 450D
4	UPS003	Uninterrupted power supply (UPS).
4	WAS100	WASTE, unslotted flush-grated, metal, 1.1/4 in
4	WAS1000	TRAP; concealed waste, for back outlet basins,
1	WKT1003H	WORKTOP; 900 high 600 deep 40mm thick, with 60mm upstand, length as drawn.

Notes

Check all dimensions on site. Do not scale from this drawing.
Report any discrepancies and omissions to drawing originator.

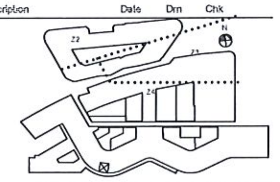
Designer Identification of Hazard Risk

- 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



Rev	Description	Date	Drn	Chk
E	Room Name Updated in line with LVC071A	08/09/17	JCD	HLM
D	BMS added in line with M&E design EBB added in line with CI-000824	24/04/17	JCD	HLM
C	Updated in line with LVC074	22/08/15	HLM	HLM
B	Updated M&E requirements	22/08/15	HLM	HLM
A	Updated in line with NHSL comments - refer to HLM-SZ-01-SH-400-112	19/02/15	HLM	HLM
01	Preliminary issue for comment	05/11/15	HLM	HLM

Revisions



Project

Re-provision of RHSC and DCN at Little France

Client

NHS Lothian

Title

BAY 2 1-B1-031

Drawing No.: HLM-Z4-01-AS-400-041

Revision: E

Scale @ A1: 1:50

Date: 21/09/15

Status: FOR CONSTRUCTION

IHS LOTHIAN INTEGRATED HEALTH SOLUTIONS

A47310563

RHCYP Critical Care Ventilation

Summary of Discussion on 10th & 11th July 2019

10th July Attendees

Julie Freeman	Consultant Critical Care
Laura Reilly	Critical Care Clinical Nurse Manager
Pat Smith	Critical Care Charge Nurse
Janice MacKenzie	Project Clinical Director
Ronnie Henderson	Project Hard FM Commissioning Manager
Donald Inverarity	Consultant Microbiologist
Carol Calder	IPCN

11th July Attendees

Julie Freeman	Consultant Critical Care
Laura Reilly	Critical Care Clinical Nurse Manager
Pat Smith	Critical Care Charge Nurse
Janice MacKenzie	Project Clinical Director
Ronnie Henderson	Project Hard FM Commissioning Manager
Donald Inverarity	Consultant Microbiologist
Carol Calder	IPCN
William Evans	IPCN
Pota Kalima	Consultant Microbiologist
Catherine McDougall	Medical Consultant

We discussed the current proposals for improving the critical care ventilation to ensure that it is compliant with SHTM 03-01 with 10 air changes and 10 Pa positive pressure in the single rooms and 4 bedded bays. We also reviewed the ventilation requirements in the 4 bedded bays to allow you to cohort patients with the same infections.

<u>Current Proposal for Critical Care Ventilation Improvements</u>
We visited the Unit, specifically 1-B1-031 which will be impacted on with one of the proposals to review the bed space.
Ronnie updated as follows
Of the 5 initial proposals considered, only two now being considered:-

1. Utilise existing plant or replace in existing location, upsize fans and upsize ducting in critical care – Design team assessing but unlikely to be possible
2. Install new plant external and duct in via window in 4 bed bay, connect ducting to serve approx 50% of critical care
   Note – in both options isolation rooms are unaffected

See attached marked up drawing for the space affected:-

- One window would be blocked to allow the duct work to come in and it would be boxed out no further than the start of the vision panel at the side to the adjoining room.
- We placed the pendants in the positions they would be in and considered the equipment that would be at the top of the bed and confirmed that there would be sufficient circulating space. Ronnie took some photos of the pendant positions and he will pass these onto MPX
- We noted that no further windows in the bay could be affected as this would then affect the natural light coming into the area

- The additional plant would be on the grass roof area outside the window. Once size of the unit and orientation is known need to ensure that it does not adversely affect the light coming into the area.
- The Critical Care team asked that both the boxed out area within the bay and the plant would have some form of enhancement to make it more aesthetically pleasing e.g. graphics

Compliance with SHTM 03- 01

- Currently the 4 bedded rooms and single rooms have 4 air changes and this needs to increase to 10 air changes to ensure compliance with SHTM. It was acknowledged that the SHTM was more focused on adult critical care where the patient profile is different and the need to cohort patients was extremely rare
- It was noted that previously a decision had been made to derogate from the SHTM for the 4 bedded areas to allow patients to be cohorted with the same air-borne infection and following consultation with the clinical team and IPCT at the time the decision was made that these areas should be balanced or slightly negative. The SHTM states that both the 4 bedded areas and single rooms should have 10 air changes and 10Pa (positive pressure)
- It was confirmed that the Isolation Rooms were compliant with SHTM 03-01
- IPCT view was that you could cohort patients with the same air-borne infection in the 4 bedded areas that were 10 air changes and 10Pa and that there is no reason that this would result in an increased risk of spread of infection. A design of balanced or slightly negative pressure approaches the issue of spread of infection from a cohort from a different direction but it was agreed that neither approach increases the risk of infection spread but that the SHTM 03-01 compliant design has additional benefit for neutropenic patients who could be in single rooms as 10Pa positive pressure.
- It was acknowledged that the design of the Unit also provided additional control measures to prevent spread of infection and the barriers to transmission included:-
    - Bed space size
    - Distance between single room doors, isolation room doors and 4 bedded bay doors as range of droplet spread is generally considered to be between 1-3 metres
    - Patients on ventilators less of a risk of generating aerosols from coughing
    - Direction of air flow in corridor space directs and air borne contaminants towards and air extract vent and away from other patient rooms.
    - Turn over of air dilutes any airborne organisms in patient rooms and corridors.
- It was noted that if a patient with an infection was in a 4 bedded bay or single room or a neutropenic patient in a single room the windows should not be opened and increased room cleaning would likely be required
- Confirmed that Isolation Rooms should be used for patients with infections transmitted by airosols e.g. measles, chicken pox, TB
- Single rooms and cohort areas would be suitable for droplet infections e.g. RSV, Influenza
- Confirmed that the single cubicle in neonatal Unit will have 10Pa and 10 air changes and as it has an en-suite it will need a transfer grille on the en-suite door
- Confirmed that any ‘dirty’ rooms e.g. Dirty Utility, toilets have extract and any ‘clean’ rooms e.g. clean utility have supply and extract
- We discussed the Positive Pressure Ventilation Lobby (PPVL) isolation rooms in relation to ventilation in QEUH, specifically in relation to Multi-Drug Resistant TB, however Donald was very cautious about making any comparisons as the context was different (paediatric critical care versus adult infectious diseases isolation ward) . It was suggested that this was something that could be discussed further with HFS
- We discussed a number of different patient groups and scenarios in relation to the use of the Isolation rooms, Single Rooms and 4 bedded bays and in light of these discussions and the points above all agreed that the SHTM 03-01 was a safe design for ventilation within the

Paediatric Critical Care Unit in conjunction with the design of the unit and good practice in relation to infection control measures which all worked together as a package to achieve best outcome for patients

We also briefly discussed:-

- Cystic Fibrosis patients and the areas that they would be treated in and whether CF patients with different infections would be treated in the same ward as currently they would be treated in different wards as the existing hospital does not have Isolation Rooms. It was confirmed that Dalhousie ward(Medical Inpatients) have 4 PPVL Isolation room. It was felt by IPCT that provided appropriate measures were in place about the placement of patients within the ward then this could happen. Also Castle Mey (Acute Receiving Unit) has 1 PPVL isolation room. It was noted that currently Dalhouisie Ward is classed as an Augmented Care Area but Castle Mey not. This lead to a discussion about other areas in the hospital where CF patients could be treated, this includes OPD, Cardio Respiratory OPD and Dirleton (Medical Day Care) and therefore whether these areas should also be classed as Augmented Care as far as water sampling is concerned. It was felt that the risk was greater in Inpatient areas. Further discussion to be had with IPCT acknowledging that the water testing regime may need a bit of tweaking when hospital occupied

Inverarity, Donald

From: POYNER, Jennifer (NHS LOTHIAN) [redacted]
Sent: 11 July 2019 14:56
To: Inverarity, Donald; Guthrie, Lindsay; Sutherland, SarahJane
Cc: Calder, Carol A
Subject: Re: SHTM 03-01 Critical Care

Hi Donald,

Overall with this one we think its not really an issue. The fact that there is a door that can be closed on the 4 bed room will in itself reduce infection spread by 80%. Changing to a negative pressure facility in that room area will not necessarily add anything. Will look over again later in more detail and get back to you if we think of anything else. Will have an evening session again tonight with Peter where we might be able to ask him some more questions.

I'm sorry you're feeling a little brain fried, but I'm not surprised! We are starting to feel that way too after these 12 hour plus days of learning.

Kind regards,

Jen.

Get Outlook for iOS

On Wed, Jul 10, 2019 at 3:54 PM +0100, "Inverarity, Donald" [redacted] wrote:

> Any views from Falfield please?
> Essentially Carol and I spent a couple of hours talking through each room of RHCYP ITU/HDU with the critical care medical and nursing team and why the design parameters set in SHTM 03-01 did not put patients at risk outwith a 4 bedded cohort from RSV etc based on air flow to extract in corridor, closed doors, distance to next patient > 3metres, need to overcome 10Pa pressure for aerosol to enter another room.
> Discussion was detailed but crucial to get their agreement for us to have an SHT 03-01 compliant design. The current design of balanced or slightly negative 4 bedded rooms (deviation from SHTM 03-01) seems to have arisen from clinical teams rightly wanting to protect patients outwith a potential cohorted area and so much of this concern is to convince them that this is still possible with an SHTM 03-01 compliant design.
> Thanks. My brain is fried!
> Donald
>
> **From:** Freeman, Julie
> **Sent:** 10 July 2019 15:42
> **To:** Mackenzie, Janice; Inverarity, Donald
> **Cc:** Reilly, Laura; Smith, Pat
> **Subject:** SHTM 03-01 Critical Care
>
> Dear Janice and Donald,
>
> The bit I am struggling with is the pressures with respect to the single rooms and the 4 bed bays.

Everything on Appendix 1 of SHTM 03-01 that is infectious or a “dirty” area is negative pressure and everything that is “clean” is positive pressure. It is also about flow between areas.

The need to cohort RSV in the 4 bed bays was the reason we went for balanced pressures.

So Questions:

- From the HTM a neutropenic patient or patient awaiting transplant would only require to be in a single room if the pressure was at 10 Pa above the corridor is this correct?
- If the 4 bed bay is at 10Pa above the corridor does this confer any advantageous with respect to balanced pressures in protecting the patients in the bay from each other or not?
- Will the air changes per hour in the critical care corridor circulation space be 10 as well?
- Are our clean and dirty utilities at the correct pressures and air changes?

I will sleep on it and get back to you if I have more questions.

Regards
Julie

****

****

Inverarity, Donald

From: Mackenzie, Janice
Sent: 11 July 2019 10:05
To: Inverarity, Donald
Cc: Henderson, Ronnie
Subject: FW: SHTM 03-01 Critical Care

Importance: High

Hi Donald

Can you phone me regarding Julie's emails as she has also phoned me and she is now feeling very uncomfortable about this and reversing a decision that was made several years ago in conjunction with Pota and is very keen to meet to discuss further which I think we do need to do as a matter of urgency.

She has said that she is available today and tomorrow (although I appreciate that you are very tied up tomorrow with meetings)

Look forward to hearing from you, if I am not at my desk give me a call on my mobile.

Janice

PLEASE NOTE MY TELEPHONE NUMBER HAS CHANGED to [redacted].

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France Project Team

Royal Hospital for Children & Young People and Department of Clinical Neurosciences
4th Floor Clinical Management Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

[redacted]

PROUD HISTORIES | NEW CHAPTERS

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From: Freeman, Julie
Sent: 11 July 2019 09:37
To: Freeman, Julie; Mackenzie, Janice; Inverarity, Donald
Cc: Reilly, Laura; Smith, Pat
Subject: RE: SHTM 03-01 Critical Care

Hi Janice and Donald,

More questions:

- P 92 section 7.6 talks about balanced flow theatres for infectious cases. Is this not the same situation as cohorting patients in our 4 bed bays?
- We will have immunocompromised patients in our cubicles or infectious patient albeit of lower infectivity.
- Does the design with respect to pressure differential (balanced or positive) affect how the increase in air exchanges is engineered?
- Past events described at burn meetings where theatre has been the common location of transmission of acinetobacter between patients makes me nervous and influences the pressure decision.
- Do the single rooms have both supply and extract ventilation as well as the 4 bed bays?
- The SHTM 03-01 for Critical Care has supply ventilation only with the positive pressure in Appendix 1. Is balanced pressure with both supply and extract ventilation not better than that?
- Is the neonatal cubicle balanced pressure? Does it have supply and extract ventilation?
- Does positive or balanced pressures make any difference to whether Option 1 works?

I think it would be helpful to meet to discuss these questions face to face with the same group of people. I know some issues were discussed yesterday but there was a lot of information to take in. I not clear on all aspects of on the current situation is and less clear on the planned solution. Inherently cohorting infectious disease in a positive pressure area does not feel right to me.

I am freely available this week and next and I think now is the time to have further discussion. Ronnie and Carol may also be helpful. I'd rather be sure we are making the right decision rather than a decision based on a table that does not fully describe our position.

Regards
Julie

From: Freeman, Julie
Sent: 10 July 2019 15:42
To: Mackenzie, Janice; Inverarity, Donald
Cc: Reilly, Laura; Smith, Pat
Subject: SHTM 03-01 Critical Care

Dear Janice and Donald,

The bit I am struggling with is the pressures with respect to the single rooms and the 4 bed bays.

Everything on Appendix 1 of SHTM 03-01 that is infectious or a "dirty" area is negative pressure and everything that is "clean" is positive pressure. It is also about flow between areas.

The need to cohort RSV in the 4 bed bays was the reason we went for balanced pressures.

So Questions:

- From the HTM a neutropenic patient or patient awaiting transplant would only require to be in a single room if the pressure was at 10 Pa above the corridor is this correct?
- If the 4 bed bay is at 10Pa above the corridor does this confer any advantageous with respect to balanced pressures in protecting the patients in the bay from each other or not?
- Will the air changes per hour in the critical care corridor circulation space be 10 as well?
- Are our clean and dirty utilities at the correct pressures and air changes?

I will sleep on it and get back to you if I have more questions.

Regards
Julie

From: Henderson, Ronnie
Sent: 27 September 2019 17:07
To: David Wilson
Cc: Currie, Brian; Curley, George; STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND); 'Jerry Slann'; 'Brodie, Ian S'; Inverarity, Donald; Kalima, Pota; Guthrie, Lindsay; 'Craig Noble'; 'GORDON, David'; 'HERKES, Alan'
Subject: AHU 02-06 Inspection
Attachments: AHU 02-06 Inspection 190927.docx

Importance: High

Tracking:

Recipient	Read
David Wilson	
Currie, Brian	Read: 30/09/2019 08:00
Curley, George	
STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND)	
'Jerry Slann'	
'Brodie, Ian S'	
Inverarity, Donald	
Kalima, Pota	Read: 30/09/2019 11:08
Guthrie, Lindsay	Read: 30/09/2019 08:52
'Craig Noble'	
'GORDON, David'	
'HERKES, Alan'	

Hi David,

Thanks for hosting today's inspection. See attached checklist for summarised comments against each item in red, can you please update and respond. Can I ask everyone to confirm that all comments raised are covered.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

NHSL OUTCOMES EXPECTED FROM AHU RELATED WORKS: AHU 02-06 REVIEW 27/09/19

Numbers in brackets represent corresponding number on IOM issues log, letters in brackets represent items identified communicated during HFS audit walkround

1. (29) Cabling inside AHU's – NHSL preference is for these to be removed in compliance with SHTM 03-01, Part A clause, 4.12. IHSL to demonstrate that any alternative solution meets or betters this requirement.
    - Does any of this work affect or invalidate any warranties
    - Does the containment of the cables produce thermal risk to the insulation of the cables or connectors particularly in the vicinity of the heater battery
    - Electrical safety labelling to be applied to the containment
    - Has electrical testing been carried out with the containment in place
    - What maintenance will be in place to check and repair seals around the edges on a regular/frequent basis
    - Can consistency of workmanship be guaranteed for all units
    - Does the method of sealing present an additional infection risk
    - Is there a potential for condensation to form within the containment
    - Local isolator in difficult to reach location
2. (30) Filter pleat orientation – To be rectified as part of AHU works
    - **CLOSED**
3. (31) Pre filters showing signs of bypass – To be rectified as part of AHU works
    - Provide means to secure pre filters in place that does not allow gaps to form between each column of filters and minimises gap at end of filter tray
4. (39) Motorised dampers take a long time to close – To be rectified as part of AHU works
    - MPX to confirm when this will be done
5. (40) Plant labelling incorrect – To be rectified as part of AHU works
    - **CLOSED**
6. (43) Motors running 95% – MPX to provide report showing actual versus max capacity, if issues arise a new scope of works is required for item.
    - Await report from MPX
7. (50) AHU Pressure controls – With IOM for review, if issues arise a new scope of works is required for item.
    - IOM to issue written feedback, however verbally acknowledged that this item can be **CLOSED**
8. (52) Temperature control – NHSL await temperature log report and confirmation that all passing valves have been repaired or replaced. If issues arise a new scope of works is required for item.
    - Await report from MPX
9. (57) Inverters – NHSL await demonstration of proposal to remove inverters from inside AHU
    - Provide means of local isolation
    - Provide protection against ingress
    - Confirm containment is appropriately bonded and is of a standard equivalent to electrical trunking

10. (58) Dampers (backdraught) – To be rectified as part of AHU works. NHSL require demonstration that fixing method is appropriate given the number of failures
    - One damper damaged during inspection, BYES to consider implications of continued failure of these components
    - Visible dust on blades of damper
11. (60) Cleaning – NHSL await confirmation and evidence that bird droppings have been removed from the surface of AHU's and associated infrastructure (cable trays, pipework etc)
    - No evidence of droppings at this review, BYES to confirm this is complete at the specific location to which this refers
12. (61) Cleaning – NHSL await confirmation and evidence that dead rodent/bird has been removed from AHU inlet
    - No evidence of this issue at this review, BYES to confirm this is complete at the specific location to which this refers
13. (62) Cleaning – NHSL await confirmation that the internals of all AHU's have been cleaned to an appropriate standard
    - Evidence of dust on internal surfaces, ensure all AHU's are cleaned prior to inspection
14. (64) Inlet section – NHSL await confirmation that drains have been fitted to allow self draining.
    - **CLOSED**
15. (A) Air tightness – To be rectified as part of AHU works. All penetrations for pipework, cables hoses etc should be sealed to prevent air leakage
    - Evidence of leakage from various points, please review and rectify
16. (B) AHU access – NHSL require confirmation that all access doors to AHU's are free from opening restrictions
    - **CLOSED**
17. (C) Position of light switches – NHSL require that light switches installed at high level are re-positioned to a convenient height from floor level.
    - MPX have confirmed that they will not move this item, BYES to confirm that they have accepted this
18. (D) Ductwork section changes – NHSL require confirmation that ductwork section changes comply with SHTM 03-01, Part A, paras 5.35 and 5.36
    - Not applicable on this unit, MPX to confirm impact on other units
19. (E) AHU Intake Louvres – NHSL require confirmation that access to intake louvre complies with SHTM 03-01, Part B, para 3.23
    - Not applicable on this unit, MPX to confirm impact on other units
20. (F) AHU Drainage – NHSL require confirmation that the borosilicate traps have been suitable cleaned and that a maintenance regime is in place to inspect and clean
    - **CLOSED**
21. (G) AHU Drainage – NHSL require confirmation that AHU drainage has appropriate fall to drain and that there is a minimum air gap of 15mm
    - Fall OK, air gap should be immediately downstream of trap

22. (H) AHU 04-07 drainage – NHSL require confirmation that brackets and impediments to the appropriate installation of drainage pipework have been removed and that pipe runs have been installed correctly
    - Not applicable on this unit, MPX to confirm work complete on unit referenced
23. (I) Air flow test points – NHSL require confirmation that appropriate and correctly labelled airflow test points are available on major branches to main ducts
    - **CLOSED**

General comment – the foregoing applies to the inspection carried out today only. It is envisaged that the same checklist will apply to each unit.

Please ensure that all future units have all above elements rectified if possible and that they have been cleaned prior to presentation for inspection

Using personal protective equipment (PPE) to control risks at work

2. Managing risk using PPE

As part of your risk assessment you should decide whether PPE is needed. Use the hierarchy of controls to make this decision.

Hierarchy of controls

PPE should be the last resort to protect against risks. Consider controls in the following order, with elimination being the most effective and PPE being the least effective:

- Elimination – physically remove the hazard
- Substitution – replace the hazard
- Engineering controls – isolate people from the hazard
- Administrative controls – change the way people work
- PPE – protect the worker with equipment

You must select equipment carefully. Make sure all workers are trained to use it properly and know how to detect and report any faults.

← Previous
Overview

Next →
Selection and use

Resources

- Changes to PPE law
- Respiratory protective equipment
- Guidance on PPE Regulations - L25
- Product safety

Related content

- PPE at Work Regulations 1992
- PPE at Work (Amendment) Regulations 2022
- Regulation 2016/425 (as incorporated into UK law)
- Construction and PPE
- COSHH
- Treework and chainsaws

Queen Elizabeth University Hospital

Isolation Rooms

Report 2016 D 0.05

Ian Storrar

1. Introduction

1. Health Facilities Scotland (HFS) were contacted by Mr D Loudon , Director of Facilities and Capital Planning of NHS Greater Glasgow and Clyde (NHS GGC), to give an opinion on the suitability of the isolation rooms at the isolation rooms at the Queen Elizabeth University Hospital (QEUH) in Glasgow, with reference to the scope noted below.
2. HFS and NHS GGC met at QEUH on 13th June 2016 to discuss the scope of this report and visit an isolation room.
3. The scope was agreed as follows:-
    - Review client briefing information
    - Review design documentation
    - Review as installed information
    - Review commissioning information
    - Engage colleagues from Health Protection Scotland (HPS) as necessary
    - Comment on the isolation room designs with respect to published guidance and the client briefing information
    - 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?
        - Multi Drug Resistant TB (MDRTB)
        - MERS
        - H1N1
4. The two main design guidance documents current at the time of design for isolation rooms are
    - SHPN 04 Supplement 1 dated September 2008
    - HBN 04-01 Supplement 1 dated 2005. (Note: this document is superseded by the 2015 version, specifically the guidance therein that relates to rooms used for source isolation. It does not supersede the guidance on protective isolation). Most of the documents cite HBN 04 Supplement 1 as the design guidance and the 2005 version will be used to check the various aspects of the design and as installed information as this was current at the time of design. It should be noted that Scottish Design Guidance should take precedence over any equivalent English (or other) Design Guidance if it is available.

5. Both HPN 04-01 supplement 1 (2005) and SHPN 04 supplement 1 (2008) advise "This supplement does not describe the specialist facilities required in infectious disease units or on wards where severely immuno-compromised patients are nursed. Guidance for these facilities will follow in a further supplement to HBN 4". The Department of Health (DoH) has not provided this additional documentation to date.
6. To enable this report to be concluded in full some additional information is required from NHS GGC to allow a more comprehensive assessment of the physical and environmental conditions. The suggested additional information is noted in Appendix 2.
7. HPS have provided commentary on this report based on the information received from NHS GGC and the notes contained within this report. To provide expert opinion on the possible use of the isolation rooms for highly infectious patients would require further work by HPS in collaboration with HFS and NHSGGC.

2. Review of Documentation provided by NHS GGC

1. The documents provided by NHS GGC for review are listed in Appendix 1
2. From the information provided there are a combination of single isolation rooms without lobbies and isolation suites with lobbies. Additionally there appears to be rooms noted as isolation rooms which do not have en-suite facilities.
3. The document "NSGACL Critical Care NSG_iss1_rev - Clinical Output Spec" clause 2.1.1 notes that the Intensive Care Unit (ICU) shall have 20 beds in two pods of ten, 2 of which are single rooms with gowning lobbies and the remainder of which (18) are single bed rooms with glass frontage. This clause also notes that the facility will "need to meet all current Scottish Health Planning / Health Building Note on radiological protection issues and Health Board Radiological Protection Officer advice." Clause 2.1.1 also notes that all patient rooms must have access to natural light. Clause 7.2 notes that the Environmental and Services Requirements "should correspond to the relevant SPHNs, HTMs and other technical guidance and the technical output specification for this project." The specific requirements of the isolation rooms from a clinical perspective are outlined in Clause 8. Clause 8.1 notes that for intensive care (level 3) single rooms and lobbies are required for isolation.
4. The room datasheet (RDS) document RDS - NA-SZ-01-RD-400-CCW_B, details the specific requirements for the isolation rooms amongst others. This notes that the mechanical services ventilation provision should be to HBN 04-01 Supplement 1.
5. Considering the drawings provided for the isolation room lobby (NA-SZ-XX-AS-400-126 and NA-SZ-XX-AS-400-126_Z1) against the requirements of HBN 04-01 Supplement 1, it is noted that whilst the majority of items are provided, the following are not:
    - Storage for "other" clean PPE (plastic apron, glove and mask storage provided)
    - Storage for room cleaning equipment
    - Facilities for completing and storing log books
6. Detailed drawings for isolation rooms with en-suites were not provided therefore no comment can be made.
7. Considering the drawings for the isolation rooms which were provided (NA-SZ-XX-AS-400-127-01 and NA-SZ-XX-AS-400-127-01_Z1), they show rooms with no en-suite as part of the design. This arrangement is also shown on schematic ZBP-XX-XX-SC-524-707 B. This

arrangement is not part of HBN 04-01 Supplement 1, which notes that an en-suite is a key consideration and provides a simple cost effective way to provide isolation. It is not clear from the information provided where these rooms are, as those isolation rooms identified in 2.2 above have en-suites.

8. In general, the air handling units serving the isolation rooms supply and extract air from other rooms (non-isolation rooms). A common supply is permissible under the guidance in HBN 04-01 Supplement 1; there is no information provided on the control strategy to ensure that the supply system will deliver constant volume depending on the demand.
9. The ventilation extract from the isolation room en-suites and the isolation rooms themselves are extracted via a separate system which would appear to terminate at a louver on the side of the building. HBN 04-01 Supplement 1 notes that this extract should terminate at roof level at least 3m above the building height. It is not clear from the information provided if all the extract fans are supplied from the "essential" side of the electrical distribution or if they have any safe change housings for changing filters.
10. The recoded magnehelic gauges for the isolation rooms, with the exception of Lobby ID GW3-051 (Bed 16) read 10 Pa or above. The noted unit was recorded as 9.0 Pa. HBN 01 Supplement 1 permits a positive pressure between 8Pa and 12 Pa.
11. The room leakage test carried out and reported by the specialist contractor, RSK Environment Limited, indicate that they meet the leakage parameters set out in HBN 04-Suppliemnt 1.
12. There is no confirmation in the commissioning data provided that the rooms or the en-suites meet the required air change rates.

3. Conclusions and recommendations

1. It is clear that in HBN-04 Supplement 1 that the design of the isolation suits is based on a validated design, which was carried out by BSRIA for DoH. The drawings provided appear to show that the isolation rooms at QEUH do not, in some instances, meet the requirements of the guidance in the following respects :-
    - Some isolation suite extract ventilation would appear to terminate behind louvers on the facade
    - Some extract ventilation would appear to terminate in formed turrets above plant rooms.
    - Isolation suites may have been provided without en-suite facilities.
    - Log books not available in lobbies

Recommendations

2. As stated in both HBN 04-01 Supplement 1 (and SHPN 04 Supplement 1), "this supplement does not describe the specialist facilities required in infectious disease units or on wards where severely immuno-compromised patients are nursed. Guidance for these facilities will follow in a further supplement to HBN 4." The Department of Health (DoH) have confirmed that the additional guidance noted was never produced and there are no plans in place for it to be produced as part of their guidance review. Therefore, to provide a more detailed

response to the safe nursing of patients with certain conditions this additional guidance may be required. In conjunction with colleagues from HPS we are preparing a SBAR and bid to Scottish Antimicrobial Resistance and Healthcare Associated Infection group (SARHAI) to provide advice and guidance for these patients.

3. Without complete information on the isolation rooms to be reviewed it is not possible for HPS to provide a comprehensive response to NHSGGC regarding the suitability of the rooms to care for highly infectious or infectious patients. With the limited information available HPS would recommend;
    - That the isolation rooms with positive pressure lobbies and en-suites are not used for highly infectious/infectious patients. The positive pressures recorded in the lobby meets the parameters laid out in HBN 04-01 Supplement 1. Leak tests also confirmed met the leakage parameters set out in HBN 04-01 Suppliement 1. However no air changes information is available for the room and en-suite itself so we cannot advise if the rooms meet expected or safe standards.
    - That rooms without lobbies are not used for highly infectious/infectious patients. At this time as we do not have air changes information and cannot be confident that the risk of cross transmission of infection from the room via the ventilation system cannot be excluded.
    - That rooms without en-suite facilities are not used for the care of highly infectious/infectious patients as advised within the HBN 04-01 Supplement 1, which notes that an en-suite is a key consideration and provides a simple cost effective way to provide isolation. Using rooms without en-suite facilities risks possible cross transmission of infection as alternative methods for toilet facilities and personal hygiene must be made.
    - That NHSGGC provide the requested information to allow HPS/HFS to provide a more detailed appraisal of the current isolation room facilities and suitability for use, which may include some on-site collaborative working.
    - That HPS and HFS, in line with previous work, visit NHSGGC and review the isolation rooms in question and all associated building and commissioning information to provide an SBAR on the suitability of the rooms as requested by NHSGGC.
    - Caring for highly infectious/infectious patients within the QEUH should be undertaken using a risk assessment for patient placement until a full appraisal of the isolation rooms is complete and recommendations provided.

Appendix 1

Documents provided by NHS GGC

General

Locations of Isolation rooms

Client briefing

Bed glass dividers – PMI (Project Manager Instruction)

Handles – PMI (Project Manager Instruction)

NSGACL Critical Care NSG_iss1_rev - Clinical Output Spec

Room data sheets

Room Data Sheets RDS - NA-SZ-01-RD-400-CCW_B

Signed off drawings

NA-SZ-XX-AS-400-126 - gowning lobby

NA-SZ-XX-AS-400-127-01 - Single room isolation

ZBP-XX-XX-SC-524-701 - Ventilation Schematic AHU 01

ZBP-XX-XX-SC-524-703 - Ventilation Schematic AHU 03

ZBP-XX-XX-SC-524-704 - Ventilation Schematic AHU 04

ZBP-XX-XX-SC-524-705 - Ventilation Schematic AHU 06

ZBP-XX-XX-SC-524-707 - Ventilation Schematic AHU 08 – 17

ZBP-XX-XX-SC-524-708 - Ventilation Schematic AHU 18

ZBP-XX-XX-SC-524-709 - Ventilation Schematic AHU 19

ZBP-XX-XX-SC-524-871 - Ventilation Schematic AHU 41

ZBP-ZD-01-PL-524-014_J - Ventilation Layout First Floor Critical Care

ZBP-ZG-01-PL-524-017_M - Ventilation Layout First Floor Critical Care

As installed information

ME-ZD-01-PL-500-521_Z1 - First Floor CCU As Built Domestic Water Pipe Work

ME-ZD-01-PL-500-522_Z1 - First Floor CCW As Built Domestic Water Services

ME-ZD-01-PL-524-521_Z1 - First Floor CCU As Built Ventilation Ductwork Layout

ME-ZD-01-PL-524-522_Z1 - First Floor CCU As Built Ventilation Ductwork Layout

NA-SZ-XX-AS-400-126_Z1 – Gowning lobby : Single Bedroom

NA-SZ-XX-AS-400-127-01_Z1 - Critical Care Bed Area

Commissioning information

QEUH isolation room summary

NSGH Isolation Rooms - Mag Calibration and room pressure set

Extract fan commissioning results for EF 08, 09, 10,11,12,13,14,15,16 and 17

Supply fan commissioning results for AHU 08, 09, 10,11,12,13,14,15,16 and 17

524395 South Glasgow Hospital Isolation Room Test Results (00) 23.11.20...

524395 South Glasgow Hospital Isolation Room Test Results (01) 24 11 20

Appendix 2

Additional information requested from NHS GGC

- Client brief
- Design parameters
- Designers drawings
- Designers specification
- Contractors proposals
- As installed schematics
- As installed room drawings
- Initial commissioning results (air flows, pressure regime, etc)
- Any subsequent test results post commissioning/handover
- O&M information on the plant and equipment for the isolation rooms
- Is the document "NSGACL Critical Care NSG_iss1_rev - Clinical Output Spec" effectively the ACR or was there any other document produced to advise of the design parameters?
- Did the contractor provide any written proposals?
- Has there been any post commissioning test/commissioning results taken?
- How does the isolation room AHU extract duct work terminate?
- To allow the room diffusers to match up to the commissioning documents can you please advise of the room names/references for the following and what drawing they are on please

room	**Fan ref**	**Terminal ref**
	8/EF01	TG06
	8/EF01	TG07
	AHU 08	SG009
	9/EF01	TG009
	9/EF01	TG010
	AHU 9	SG025
	10/EF01	TG013
	10/EF01	TG014
	AHU10	SG005
	11/EF01	TG015
	11/EF01	TG016
	AHU 11	SG038

room	Fan ref	Terminal ref
	12/EF01	EG014
	AHU 12	SG014
	13/EF01	EG013
	AHU 13	SG023
	14/EF01	EG001
	AHU 14	SG001
	15/EF01	EG020
	AHU 15	SG027
	16/EF01	EG045
	16/EF01	EG046
	AHU 16	SG054
	17/EF01	EG041
	17/EF01	EG042
	AHU 17	SG048

NICE National Institute for Health and Care Excellence

NICE guideline

Tuberculosis

NICE guideline
Published: 13 January 2016
Last updated: 12 September 2019

www.nice.org.uk/guidance/ng33

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guideline replaces CG117 and PH37.

This guideline is the basis of QS141.

Overview

This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It aims to improve ways of finding people who have TB in the community and recommends that everyone under 65 with latent TB should be treated. It describes how TB services should be organised, including the role of the TB control board.

Who is it for?

- Healthcare professionals and TB multidisciplinary teams
- Substance misuse services, prisons and immigration removal centres
- Local government and commissioners
- TB control boards, directors of public health and public health consultants
- Public Health England and NHS England
- Voluntary sector workers
- People with TB and their carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Preventing TB

1.1.1 Raising and sustaining awareness of TB

Among health professionals and those working with high-risk groups

1.1.1.1 Multidisciplinary TB teams (in collaboration with Public Health England, primary care, the voluntary sector and Health Education England) should identify and support an ongoing TB education programme for local professionals in contact with the general public, and at-risk groups in particular. This includes, for example, staff in emergency departments, GPs and wider primary care staff, people who work in housing support services, staff who support migrants and those working in walk-in centres, hostels, substance misuse projects and prisons. **[2012, amended 2016]**

1.1.1.2 Multidisciplinary TB teams should ensure the education programme increases other professionals' awareness of the possibility of TB and reduces the stigma associated with it. The programme should include detail on:

- causes of TB, how it is transmitted, and the signs and symptoms
- lifestyle factors that may mask symptoms

- local epidemiology, highlighting under-served groups, other high-risk groups and the fact that TB also occurs in people without risk factors
- principles of TB control:
  - early diagnosis and active case-finding
  - how to support treatment (including directly observed therapy)
  - drug resistance
  - awareness of drug interactions (including factors such as effect on contraception efficacy)
  - contact investigation after diagnosing an active case
  - the importance of adhering to treatment
  - treatment for TB is free for everyone (irrespective of eligibility for other NHS care)
  - social and cultural barriers to accessing health services (for example, fear of stigma and staff attitudes)
  - local referral pathways, including details of who to refer and how
  - the role of allied professionals in awareness-raising, identifying cases and helping people complete treatment
  - misinformation that causes fear about TB, including concerns about housing people with the condition
- the best ways to effectively communicate all the above topics with different groups. **[2012, amended 2016]**

1.1.1.3 Statutory, community and voluntary organisations and advocates working with the general public, and under-served and high-risk groups in particular, should share information on TB education and awareness training with all frontline staff. (They should get information on this from the local multidisciplinary TB team.) **[2012, amended 2016]**

1.1.1.4 If possible, statutory, community and voluntary organisations should ensure peers from under-served groups and anyone else with experience

of TB contribute to, or lead, awareness-raising activities. (Peers who lead such activities will need training and support.) **[2012, amended 2016]**

Among high-risk groups

1.1.1.5 Multidisciplinary TB teams should help professionals working in relevant statutory, community and voluntary organisations to raise awareness of TB among under-served and other high-risk groups. These professionals should be able to explain that treatment for TB is free and confidential for everyone (irrespective of eligibility for other NHS care). They should also be able to provide people with details of:

- how to recognise symptoms in adults and children
- how people get TB
- the benefits of diagnosis and treatment (including the fact that TB is treatable and curable)
- location and opening hours of testing services
- referral pathways, including self-referral
- the potential interaction of TB medication with other drugs, for example, oral contraceptives and opioids (especially methadone) and HIV treatment
- TB/HIV co-infection
- how to address the myths about TB infection and treatment (for example, to counter the belief that TB is hereditary)
- how to address the stigma associated with TB
- the risk of migrants from high-incidence countries developing active TB, even if they have already screened negative for it
- contact tracing. **[2012, amended 2016]**

1.1.1.6 Multidisciplinary TB teams and others working with at-risk groups should use high quality material to raise awareness of TB (see section 1.1.2). **[2012, amended 2016]**

1.1.1.7 Multidisciplinary TB teams and others working with the general public, and with under-served and other high-risk groups in particular, should include information on TB with other health-related messages and existing health promotion programmes tailored to the target group. **[2012, amended 2016]**

1.1.1.8 Multidisciplinary TB teams should work in partnership with voluntary organisations and 'community champions' to increase awareness of TB, in particular among under-served groups at risk of infection but also in the general population. If possible, peers who have experience of TB should contribute to awareness-raising activities and support people in treatment. **[2012, amended 2016]**

1.1.2 Providing information for the public about TB

1.1.2.1 National organisations (for example, National Knowledge Service: Tuberculosis, TB Alert, Public Health England, Department of Health and NHS Choices) should work together to develop generic, quality-assured template materials with consistent up-to-date messages. These materials should be made freely available and designed so that they can be adapted to local needs. **[new 2016]**

1.1.2.2 Multidisciplinary TB teams should use these templates for general awareness raising and targeted activities in under-served and other high-risk groups. Involve the target group in developing and piloting the materials. **[new 2016]**

1.1.2.3 The content of any materials should:

- be up-to-date and attractively designed, including pictures and colour if possible
- be culturally appropriate, taking into account the language, actions, customs, beliefs and values of the group they are aimed at
- be tailored to the target population's needs
- include risks and benefits of treatment, and how to access services, advice and support

- dispel myths
- show that, by deciding to be tested and treated for TB, a person can be empowered to take responsibility for their own health
- use language that encourages the person to believe that they can change their behaviour
- be simple and succinct. **[new 2016]**

1.1.2.4 Make the material available in a range of formats such as written, braille, text messages, electronic, audio (including podcasts), pictorial and video. Make them freely available in a variety of ways, for example, online, as print materials or on memory sticks. **[new 2016]**

1.1.2.5 Disseminate materials in ways likely to reach target groups, for example, via culturally specific radio or TV stations, at shelters, and at community, commercial or religious venues that target groups attend regularly. **[new 2016]**

1.1.3 BCG vaccination

1.1.3.1 To improve the uptake of BCG vaccination, identify eligible groups (in line with the Department of Health's Green Book) opportunistically through several routes, for example:

- new registrations in primary care and with antenatal services, or other points of contact with secondary or tertiary care
- people entering education, including university
- links with statutory and voluntary groups working with new entrants and looked-after children and young people
- during contact investigations. **[new 2016]**

1.1.3.2 When BCG vaccination is being recommended, discuss the benefits and risks of vaccination or remaining unvaccinated with the person (or, if a child, with the parents), so that they can make an informed decision. Tailor this discussion to the person, use appropriate language, and take into account cultural sensitivities and stigma. **[2006]**

1.1.3.3 If people identified for BCG vaccination through occupational health, contact tracing or new entrant screening are also considered to be at increased risk of being HIV-positive, offer them HIV testing before BCG vaccination. **[2006]**

BCG vaccination in neonates (0 to 4 weeks)

1.1.3.4 Identify babies eligible for vaccination (in line with the Green Book) before birth, ideally through antenatal services. **[new 2016]**

1.1.3.5 Discuss neonatal BCG vaccination for any baby at increased risk of TB with the parents or legal guardian. **[2006]**

1.1.3.6 Preferably vaccinate babies at increased risk of TB before discharge from hospital or before handover from midwifery to primary care. Otherwise, vaccinate as soon as possible afterwards, for example, at the 6-week postnatal check. **[new 2016]**

1.1.3.7 Incorporate computer reminders into maternity service (obstetrics) IT systems for staff, to identify and offer BCG vaccination to babies eligible for vaccination. **[new 2016]**

1.1.3.8 Provide education and training for postnatal ward staff, midwives, health visitors and other clinicians on identifying babies eligible for vaccination, local service information and providing BCG vaccination, including:

- case definition for at-risk groups to be offered vaccination
- information about the local BCG vaccination policy that can be given verbally, in writing or in any other appropriate format (see sections 1.1.1 and 1.1.2) to parents and carers at the routine examination of the baby before discharge
- local service information about BCG vaccination, such as pre-discharge availability of neonatal vaccination, local BCG clinics and referral for BCG vaccination if this is not available in maternity services
- administration of BCG vaccination and contraindications. **[new 2016]**

1.1.3.9 Primary care organisations with a high incidence of TB should consider vaccinating all neonates soon after birth. **[2006]**

1.1.3.10 In areas with a low incidence of TB (see Public Health England's TB rate bands, published in their annual tuberculosis report), primary care organisations should offer BCG vaccination to selected neonates who:

- were born in an area with a high incidence of TB **or**
- have 1 or more parents or grandparents who were born in a high-incidence country **or**
- have a family history of TB in the past 5 years. **[2006, amended 2016]**

BCG vaccination for infants (0 to 5 years) and older children (6 to 15 years)

1.1.3.11 Routine BCG vaccination is not recommended for children aged 10 to 14 years.

- Healthcare professionals should opportunistically identify unvaccinated children older than 4 weeks and younger than 16 years at increased risk of TB who would have qualified for neonatal BCG (see recommendation 1.1.3.4) and provide Mantoux testing (see the section on diagnosing latent TB in children and young people) and BCG vaccination (if Mantoux-negative).

  At the time of publication (January 2016) the BNF states: 'The Mantoux test is recommended for tuberculin skin testing, but no licensed preparation is currently available.' For further guidance, see immunisation against infectious disease (the Green book).

- This opportunistic vaccination should be in line with the Green Book. **[2006, amended 2016]**

1.1.3.12 Mantoux testing should not be done routinely before BCG vaccination in children younger than 6 years unless they have a history of residence or prolonged stay (more than 1 month) in a country with a high incidence of TB. **[2006]**

BCG vaccination for new entrants from high-incidence areas

1.1.3.13 Offer BCG vaccination to new entrants who are Mantoux-negative who:

- are from high-incidence countries **and**

- are previously unvaccinated (that is, without adequate documentation or a BCG scar) **and**
- are aged:
  - younger than 16 years **or**
- 16 to 35 years from sub-Saharan Africa or a country with a TB incidence of 500 per 100,000 or more. **[2006, amended 2016]**

Encouraging uptake among infants, older children and new entrants

1.1.3.14 Deliver the following interventions in primary care settings to improve uptake of BCG vaccination in people from eligible groups (as outlined in the Green Book):

- education and support for practice staff, including:
  - raising awareness of relevant guidelines and case definition for at-risk groups
  - promoting BCG and TB testing in eligible groups
- incorporating reminders for staff (prompts about eligibility for BCG) on practice computers (for example, embedded in medical records)
- consider financial incentives for practices for identifying eligible groups for BCG and TB testing
- reminders ('immunisations due') and recall ('immunisations overdue') for people who are eligible for vaccination or for parents of infants and children who are eligible, as outlined in the Green Book. (This could include written reminders, telephone calls from a member of staff or a computerised auto dialler, text messages or a combination of these approaches.) **[new 2016]**

1.1.3.15 Use home visits to give information and advice to people who are disadvantaged on the importance of immunisation. This should be delivered by trained lay health workers, community-based healthcare staff or nurses. **[new 2016]**

BCG vaccination for healthcare workers

1.1.3.16 Offer BCG vaccination to healthcare workers and other NHS employees as advised in the Green Book. **[2006, amended 2016]**

BCG vaccination for contacts of people with active TB

1.1.3.17 Offer BCG vaccination to Mantoux-negative contacts of people with pulmonary and laryngeal TB (see the section on diagnosing latent TB in all age groups) if they:

- have not been vaccinated previously (that is, there is no adequate documentation or a BCG scar) **and**
- are aged 35 years or younger **or**
- are aged 36 years and older and a healthcare or laboratory worker who has contact with patients or clinical materials. **[2006, amended 2016]**

BCG vaccination for other groups

1.1.3.18 Offer BCG vaccination to previously unvaccinated, Mantoux-negative people aged 35 years or younger in the following groups at increased risk of exposure to TB, in accordance with the Green Book:

- veterinary and other staff such as abattoir workers who handle animal species known to be susceptible to TB, such as simians
- prison staff working directly with prisoners
- staff of care homes for older people
- staff of hostels for people who are homeless and facilities accommodating refugees and asylum seekers
- people going to live or work with local people for more than 3 months in a high-incidence country. **[2006, amended 2016]**

1.1.4 Preventing infection in specific settings

Healthcare environments: new NHS employees

1.1.4.1 Employees new to the NHS who will be working with patients or clinical specimens should not start work until they have completed a TB screen or health check, or documentary evidence is provided of such screening having taken place within the preceding 12 months. **[2006]**

1.1.4.2 Employees new to the NHS who will not have contact with patients or clinical specimens should not start work if they have signs or symptoms of TB. **[2006]**

1.1.4.3 Health checks for employees new to the NHS who will have contact with patients or clinical materials should include:

- assessment of personal or family history of TB
- asking about symptoms and signs, possibly by questionnaire
- documentary evidence of TB skin (or interferon-gamma release assay) testing within the past 5 years and/or BCG scar check by an occupational health professional, not relying on the applicant's personal assessment. **[2006]**

1.1.4.4 See the section on healthcare workers for screening new NHS employees for latent TB. **[2006, amended 2011]**

1.1.4.5 Employees who will be working with patients or clinical specimens and who are Mantoux- or interferon-gamma release assay-negative (see section 1.2.1) should have an individual risk assessment for HIV infection before BCG vaccination is given. **[2006, amended 2016]**

1.1.4.6 Offer BCG vaccination to employees of any age who are new to the NHS and are from countries of high TB incidence, or who have had contact with patients in settings with a high TB prevalence, and who are Mantoux-negative. **[2006, amended 2011]**

1.1.4.7 If a new employee from the UK or other low-incidence setting, who has not had a BCG vaccination, has a positive Mantoux test and a positive

interferon-gamma release assay, they should have a medical assessment and a chest X-ray. They should be referred to a TB clinic to determine whether they need TB treatment if the chest X-ray is abnormal, or to determine whether they need treatment of latent TB infection if the chest X-ray is normal. **[2006, amended 2011, amended 2016]**

1.1.4.8 If a prospective or current healthcare worker who is Mantoux-negative (see the section on healthcare workers) declines BCG vaccination, explain the risks and supplement the oral explanation with written advice. If the person still declines BCG vaccination, he or she should not work where there is a risk of exposure to TB. The employer will need to consider each case individually, taking account of employment and health and safety obligations. **[2006, amended 2016]**

1.1.4.9 Screen clinical students, agency and locum staff and contract ancillary workers who have contact with patients or clinical materials for TB to the same standard as new employees in healthcare environments, according to the recommendations set out above. Seek documentary evidence of screening to this standard from locum agencies and contractors who carry out their own screening. **[2006]**

1.1.4.10 NHS trusts arranging care for NHS patients in non-NHS settings should ensure that healthcare workers who have contact with patients or clinical materials in these settings have been screened for TB to the same standard as new employees in NHS settings. **[2006]**

Healthcare environments: occupational health

1.1.4.11 Include reminders of the symptoms of TB, and the need for prompt reporting of such symptoms, with annual reminders about occupational health for staff who:

- are in regular contact with TB patients or clinical materials **or**
- have worked in a high-risk clinical setting for 4 weeks or longer.

Give one-off reminders after a TB incident on a ward. **[2006]**

1.1.4.12 If no documentary evidence of previous screening is available, screen

staff in contact with patients or clinical material who are transferring jobs within the NHS as for new employees (see recommendations 1.2.1.5 to 1.2.1.7 in the section on healthcare workers). **[2006]**

1.1.4.13 Assess the risk of TB for a new healthcare worker who knows he or she is HIV-positive at the time of recruitment as part of the occupational health checks. **[2006]**

1.1.4.14 The employer, through the occupational health department, should be aware of the settings with increased risk of exposure to TB, and that these pose increased risks to HIV-positive healthcare workers. **[2006]**

1.1.4.15 Healthcare workers who are found to be HIV-positive during employment should have medical and occupational assessments of TB risk, and may need to modify their work to reduce exposure. **[2006]**

1.2 Latent TB

1.2.1 Diagnosing latent TB in adults

1.2.1.1 Offer Mantoux testing to diagnose latent TB in adults aged 18 to 65 who are close contacts of a person with pulmonary or laryngeal TB.

- If the Mantoux test is inconclusive, refer the person to a TB specialist.
- If the Mantoux test is positive (an induration of 5 mm or larger, regardless of BCG history) assess for active TB (see the sections on diagnosing active TB in all age groups, diagnosing pulmonary (including laryngeal) TB in all age groups, diagnosing pulmonary (including laryngeal) TB in adults and diagnosing extrapulmonary TB in all age groups).
- If the Mantoux test is positive but a diagnosis of active TB is excluded, consider an interferon gamma release assay if more evidence of infection is needed to decide on treatment. This could be, for example, if the person needs enhanced case management or if there could be adverse events from treatment.

- If the Mantoux is positive, and if an IGRA was done and that is also positive, offer them treatment for latent TB infection (see the sections on managing latent TB in all age groups and managing latent TB in adults).

  At the time of publication (January 2016) the BNF states: 'The Mantoux test is recommended for tuberculin skin testing, but no licensed preparation is currently available.' For further guidance, see immunisation against infectious disease (the Green book).**[2011, amended 2016]**

Adults who are immunocompromised

1.2.1.2 In adults who are anticipated to be or are currently immunocompromised, do a risk assessment to establish whether testing should be offered, taking into account their:

- risk of progression to active TB based on how severely they are immunocompromised and for how long they have been immunocompromised
- risk factors for TB infection, such as country of birth or recent contact with an index case with suspected infectious or confirmed pulmonary or laryngeal TB. **[new 2016]**

1.2.1.3 For adults who are severely immunocompromised, such as those with HIV and CD4 counts of fewer than 200 cells/mm^3, or after solid organ or allogeneic stem cell transplant, offer an interferon-gamma release assay and a concurrent Mantoux test.

- If either test is positive (for Mantoux, this is an induration of 5 mm or larger, regardless of BCG history), assess for active TB.
- If this assessment is negative, offer them treatment for latent TB infection. **[new 2016]**

1.2.1.4 For other adults who are immunocompromised, consider an interferon-gamma release assay alone or an interferon-gamma release assay with a concurrent Mantoux test.

- If either test is positive (for Mantoux, this is an induration of 5 mm or larger, regardless of BCG history), assess for active TB.

- If this assessment is negative, offer them treatment for latent TB infection. **[new 2016]**

Healthcare workers

1.2.1.5 Offer a Mantoux test to new NHS employees who will be in contact with patients or clinical materials, if the employees:

- are not new entrants from high-incidence countries **and**
- have not had BCG vaccination (for example, they are without a BCG scar, other documentation or a reliable history).

  If the Mantoux test is positive, offer an interferon-gamma release assay. If this is positive, assess for active TB; if this assessment is negative, offer them treatment for latent TB infection. **[2011, amended 2016]**

1.2.1.6 Offer a Mantoux test to new NHS employees who are from a high-incidence country.

- If the Mantoux test is positive (5 mm or larger, regardless of BCG history), assess for active TB; if this assessment is negative, offer them treatment for latent TB infection.
- If Mantoux testing is unavailable, offer an interferon-gamma release assay. **[new 2016]**

1.2.1.7 Offer an interferon-gamma release assay to new NHS employees who have had contact with patients in settings where TB is highly prevalent:

- If the interferon-gamma release assay is positive, assess for active TB **and**
- if this assessment is negative, offer them treatment for latent TB infection. **[2011, amended 2016]**

1.2.1.8 Healthcare workers who are immunocompromised should be screened in the same way as other people who are immunocompromised (see recommendations 1.2.1.2 to 1.2.1.4). **[2011]**

1.2.2 Diagnosing latent TB in children and young people

1.2.2.1 Only consider using interferon-gamma release assays alone in children and young people if Mantoux testing is not available or is impractical. This includes for example, situations in which large numbers need to be tested (see the section on incident and outbreak response and recommendation 1.2.3.2). **[new 2016]**

1.2.2.2 Refer children younger than 2 years and in close contact with people with smear-negative pulmonary or laryngeal TB to a specialist to determine what testing strategy for latent TB should be done. This should be a paediatrician with experience and training in TB, or a general paediatrician with advice from a specialised clinician. **[new 2016]**

1.2.2.3 If a neonate has been in close contact with people with smear-positive pulmonary or laryngeal TB who have not had at least 2 weeks of anti-TB treatment:

- Assess for active TB (see the sections on diagnosing active TB in all age groups, diagnosing pulmonary (including laryngeal) TB in all age groups and diagnosing pulmonary (including laryngeal) TB in children and young people).
- Start isoniazid (with pyridoxine).
- Carry out a Mantoux test after 6 weeks of treatment.
- If the Mantoux test is inconclusive, refer the child to a TB specialist.
- If the Mantoux test is positive (5 mm or larger, regardless of BCG history), reassess for active TB; if this assessment is negative, continue isoniazid (with pyridoxine) for a total of 6 months.
- If the Mantoux test is negative, reassess for active TB and consider an interferon-gamma release assay:
  - if the interferon-gamma release assay is negative then stop isoniazid (and pyridoxine) and give a BCG vaccination
  - if the interferon-gamma release assay is positive, reassess for active TB; if this assessment for active TB is negative, continue isoniazid (with pyridoxine) for a total of 6 months. **[new 2016]**

1.2.2.4 If a child aged between 4 weeks and 2 years has been in close contact with people with smear-positive pulmonary or laryngeal TB who have not had at least 2 weeks of anti-TB treatment:

- Assess for active TB.
- Start treatment for latent TB (see the sections on managing latent TB in all age groups and managing latent TB in children and young people) and carry out a Mantoux test.
- If the Mantoux test is inconclusive, refer the child to a TB specialist.
- If the Mantoux test is positive (5 mm or larger, regardless of BCG history), reassess for active TB; if this assessment is negative, complete treatment for latent TB.
- If the Mantoux test is negative, continue treatment for latent TB, reassess for active TB after 6 weeks and repeat the Mantoux test:
  - if the Mantoux test is negative, consider an interferon-gamma release assay
  - if the interferon-gamma release assay is negative, treatment for latent TB may be stopped; give a BCG vaccination if the child has not already had one
  - if either test is positive, reassess for active TB; if this assessment is negative, complete treatment for latent TB. **[new 2016]**

1.2.2.5 If a child or young person aged between 2 and 17 years has been in close contact with people with pulmonary or laryngeal TB:

- Offer Mantoux testing.
- If the Mantoux test is inconclusive, refer the child or young person to a TB specialist.
- If the Mantoux test is positive (5 mm or larger, regardless of BCG history), assess for active TB; if this assessment is negative, offer them treatment for latent TB infection.

- If the initial Mantoux test is negative, offer an interferon-gamma release assay after 6 weeks and repeat the Mantoux test. **[new 2016]**

Immunocompromised children and young people

1.2.2.6 If latent TB is suspected in children and young people who are anticipated to be or are currently immunocompromised (for example, if they are from a high incidence country or have been in close contact with people with suspected infectious or confirmed pulmonary or laryngeal TB), refer to a TB specialist. **[2016]**

1.2.3 Diagnosing latent TB in all age groups

New entrants from high-incidence countries

1.2.3.1 Offer Mantoux testing as the initial diagnostic test for latent TB infection in people who have recently arrived from a high-incidence country who present to healthcare services. If the Mantoux test is positive (5 mm or larger, regardless of BCG history):

- assess for active TB (see recommendations 1.3.1 to 1.3.5 in the section on active TB) **and**
- if this assessment is negative, offer them treatment for latent TB infection (see the section on managing latent TB in all age groups to the section on managing latent TB in children and young people).

  If Mantoux testing is unavailable, offer an interferon-gamma release assay. **[new 2016]**

Contacts: incident situation

1.2.3.2 In an incident situation when large numbers of people may need to be screened, consider a single interferon-gamma release assay for people aged 18 to 65 years. For children and young people, follow the recommendations in the sections on diagnosing latent TB in children and young people and immunocompromised children and young people. **[2011, amended 2016]**

Under-served groups

1.2.3.3 Offer people younger than 65 years from under-served groups a single interferon-gamma release assay. **[2011, amended 2016]**

1.2.3.4 Substance misuse services with access to an interferon-gamma release assay should provide testing for people younger than 65 years who misuse substances if they:

- live in a high incidence area
- are likely to be involved with substance misuse services or other support services on a regular basis (for example, for opioid substitution therapy), when support should be available for directly observed preventive therapy. **[2012, amended 2016]**

1.2.3.5 In high incidence areas (and at prisons that receive prisoners from high incidence areas), prison health services should offer an interferon-gamma release assay for TB to inmates younger than 65 years who are in regular contact with substance misuse services or other support services. This is provided arrangements have been made for this support to continue after release. **[2012, amended 2016]**

1.2.3.6 Substance misuse services and prison health services should incorporate interferon-gamma release assay testing with screening for hepatitis B and C, and HIV testing. They should refer prisoners and people who misuse substances with positive interferon-gamma release assays to local multidisciplinary TB teams for further clinical investigations. For prisoners, these investigations should be done in the prison if practically possible. **[2012, amended 2016]**

1.2.3.7 If the interferon-gamma release assay is positive, assess for active TB (see the sections on diagnosing active TB in all age groups to diagnosing extrapulmonary TB in all age groups); if this assessment is negative, offer them treatment for latent TB infection (see sections on managing latent TB in all age groups to managing latent TB in children and young people). **[new 2016]**

1.2.4 Managing latent TB in all age groups

1.2.4.1 Be aware that certain groups of people with latent TB are at increased risk of going on to develop active TB, including people who:

- are HIV-positive
- are younger than 5 years
- have excessive alcohol intake
- are injecting drug users
- have had solid organ transplantation
- have a haematological malignancy
- are having chemotherapy
- have had a jejunoileal bypass
- have diabetes
- have chronic kidney disease or receive haemodialysis
- have had a gastrectomy
- are having treatment with anti-tumour necrosis factor-alpha or other biologic agents
- have silicosis. **[new 2016]**

1.2.4.2 For people, including those with HIV, aged younger than 65 years with evidence of latent TB who have been in close contact with people who have suspected infectious or confirmed active pulmonary or laryngeal drug-sensitive TB, offer either of the following drug treatments:

- 3 months of isoniazid (with pyridoxine) and rifampicin **or**
- 6 months of isoniazid (with pyridoxine). **[new 2016]**

1.2.4.3 Base the choice of regimen on the person's clinical circumstances. Offer:

- 3 months of isoniazid (with pyridoxine) and rifampicin to people younger than 35 years if hepatotoxicity is a concern after an assessment of both liver function (including transaminase levels) and risk factors
- 6 months of isoniazid (with pyridoxine) if interactions with rifamycins are a concern, for example, in people with HIV or who have had a transplant. **[new 2016]**

1.2.4.4 Clearly explain the risks and potential benefits of each treatment regimen. In discussion with the person, select a suitable regimen if they wish to proceed with preventive treatment. **[new 2016]**

1.2.4.5 If a person also has severe liver disease, for example, Child-Pugh level B or C, work with a specialist multidisciplinary team with experience of managing TB and liver disease. **[new 2016]**

1.2.4.6 Manage treatment with caution, ensuring careful monitoring of liver function, in:

- people with non-severe liver disease
- people with abnormal liver function (including abnormal transaminase levels) before starting treatment for latent TB infection
- people who misuse alcohol or drugs. **[new 2016]**

1.2.4.7 Ensure people having treatment for latent TB who also have social risk factors, such as misusing alcohol or drugs or being homeless, are linked to support services. They should also have an assessment of social needs and stability, including potential barriers to adherence or treatment completion (see the section on adherence, treatment completion and follow-up). **[new 2016]**

1.2.4.8 People in the groups listed in recommendation 1.2.4.1 who do not have treatment for latent TB, as specified in recommendations 1.2.4.2 to 1.2.4.8, for any reason should be advised of the risks and symptoms of TB (on the basis of an individual risk assessment), usually in a standard letter of the type referred to as 'Inform and advise' information (see section 1.1.2). **[new 2016]**

1.2.5 Managing latent TB in adults

1.2.5.1 For adults between the ages of 35 and 65 years, offer drug treatments only if hepatotoxicity is not a concern. **[new 2016]**

1.2.5.2 Offer testing for HIV before starting treatment for latent TB. See the NICE guidelines on increasing the uptake of HIV testing among black Africans in England and increasing the uptake of HIV testing among men who have sex with men. **[new 2016]**

1.2.5.3 Offer adults testing for hepatitis B and C before starting treatment for latent TB. See the NICE guidelines on hepatitis B and C: ways to promote and offer testing to people at increased risk of infection and hepatitis B (chronic): diagnosis and management of chronic hepatitis B in children, young people and adults. **[new 2016]**

1.2.6 Managing latent TB in children and young people

1.2.6.1 Consider testing children and young people for hepatitis B and C before starting treatment for latent TB. See the NICE guidelines on hepatitis B and C: ways to promote and offer testing to people at increased risk of infection and hepatitis B (chronic): diagnosis and management of chronic hepatitis B in children, young people and adults. **[new 2016]**

1.3 Active TB

1.3.1 Diagnosing active TB in all age groups

1.3.1.1 If TB is a possibility, microbiology staff should consider carrying out TB culture on samples (see recommendations 1.3.2.2 and 1.3.2.3), even if it is not requested. **[2006, amended 2016]**

1.3.1.2 If there are clinical signs and symptoms consistent with a diagnosis of TB, start treatment without waiting for culture results. **[2006]**

1.3.1.3 Consider completing the standard recommended regimen (see recommendations 1.3.7.2 and 1.3.7.3 in the section on standard

treatment), even if subsequent culture results are negative. **[2006, amended 2016]**

1.3.2 Diagnosing pulmonary (including laryngeal) TB in all age groups

1.3.2.1 Take a chest X-ray; do further diagnostic investigations (as detailed below and summarised in table 1) if chest X-ray appearances suggest TB. **[2016]**

1.3.2.2 Send multiple respiratory samples (3 deep cough sputum samples, preferably including 1 early morning sample) for TB microscopy and culture. **[2016]**

- This should be before starting treatment if possible or, failing that, within 7 days of starting treatment in people with life-threatening disease. **[2006, amended 2016]**
- Obtain spontaneously-produced, deep cough sputum samples if possible, otherwise use:
  - 3 gastric lavages or 3 inductions of sputum in children and young people (see recommendation 1.5.1.10 in the section on infection control in healthcare settings) **[new 2016] or**
  - induction of sputum or bronchoscopy and lavage in adults. **[2006, amended 2016]**
- Laboratory practices should be in accordance with the UK's Standards for Microbiology Investigations. **[new 2016]**

1.3.2.3 Send samples for TB culture from autopsy samples if pulmonary or laryngeal TB is a possibility. **[2006, amended 2016]**

1.3.3 Diagnosing pulmonary (including laryngeal) TB in adults

1.3.3.1 Request rapid diagnostic nucleic acid amplification tests for the *M. tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum*) on primary specimens (listed in table 1) if there is clinical suspicion of TB

disease, and:

- the person has HIV **or**
- rapid information about mycobacterial species would alter the person's care **or**
- the need for a large contact-tracing initiative is being explored. **[new 2016]**

1.3.4 Diagnosing pulmonary (including laryngeal) TB in children and young people

1.3.4.1 In children aged 15 years or younger with suspected pulmonary TB, offer rapid diagnostic nucleic acid amplification tests for the *M. tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum*). Usually only 1 nucleic acid amplification test is needed per specimen type (for example, spontaneous sputum, induced sputum or gastric lavage; see table 1). **[new 2016]**

1.3.4.2 In young people aged 16 to 18 years use the same criteria as in adults to decide whether to request rapid diagnostic nucleic acid amplification tests (see table 1). **[new 2016]**

Table 1 Diagnostic investigations for pulmonary TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests (if it would alter management)
Pulmonary (adult)	X-ray (Routine test, see recommendation 1.3.2.1.) CT thorax Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	3 respiratory samples: • preferably spontaneously-produced, deep cough sputum samples, otherwise induced sputum or bronchoscopy and lavage • preferably 1 early morning sample	Microscopy Culture Histology	Nucleic acid amplification test
Pulmonary (young people aged 16 to 17 years)	X-ray (Routine test, see recommendation 1.3.2.1.) CT thorax Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	3 respiratory samples: • preferably spontaneously-produced, deep cough sputum samples, otherwise induced sputum or gastric lavage • preferably 1 early morning sample	Microscopy Culture Histology	Nucleic acid amplification test

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests (if it would alter management)
Pulmonary (children aged 15 years or younger)	X-ray (Routine test, see recommendation 1.3.2.1.) CT thorax Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	3 respiratory samples: • preferably spontaneously-produced, deep cough sputum samples, otherwise induced sputum or gastric lavage • preferably 1 early morning sample	Microscopy Culture Histology Nucleic acid amplification tests (1 per specimen type)	Interferon-gamma release assay and/or tuberculin skin test (with expert input)

1.3.4.3 Either a paediatrician with experience and training in TB or a general paediatrician with advice from a specialised clinician should investigate and manage TB in children and young people. **[new 2016]**

1.3.4.4 An expert in paediatric TB may request interferon-gamma release assays and tuberculin skin tests. Interpret these together with other diagnostic tools (such as history taking, clinical examination and imaging). **[new 2016]**

1.3.5 Diagnosing extrapulmonary TB in all age groups

1.3.5.1 Discuss the advantages and disadvantages of both biopsy and needle aspiration with the patient, with the aim of obtaining adequate material for diagnosis. **[2006]**

1.3.5.2 Do not place part or all of any of the samples in formalin (or other fixative agent) when sending for TB culture. **[2006, amended 2016]**

1.3.5.3 Think about a diagnosis of extrapulmonary TB even if rapid diagnostic tests in, for example, cerebrospinal fluid, pleural fluid or ascitic fluid are negative. **[new 2016]**

1.3.5.4 Offer all patients presenting with extrapulmonary TB a chest X-ray and, if possible, culture of a spontaneously-produced respiratory sample to exclude or confirm coexisting pulmonary TB (see recommendations 1.3.1 to 1.3.3 in the section on active TB). Also, consider site-specific tests as described below to exclude or confirm additional sites of TB. **[new 2016]**

1.3.5.5 Refer to an expert for sites not listed here, including TB of the eye and other rare sites of disease. **[new 2016]**

Pleural TB

1.3.5.6 Use the site-specific investigations listed in table 2 to diagnose and assess pleural TB.

Table 2 Site-specific investigations for pleural TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Pleural	X-ray Bronchoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	3 respiratory samples: • preferably spontaneously-produced, deep cough sputum samples, otherwise induced sputum or gastric lavage • preferably 1 early morning sample Pleural biopsy	Microscopy Culture Histology	-
Pleural	X-ray Bronchoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Pleural fluid	Microscopy Culture Cytology	Adenosine deaminase assay

[new 2016]

Central nervous system TB

1.3.5.7 Use the site-specific investigations listed in table 3 to diagnose and assess central nervous system TB.

Table 3 Site-specific investigations for central nervous system TB

Suspected site of disease	Possible imaging techniques[a]	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Central nervous system	CT (Routine test, see recommendation 1.3.5.8) MRI (Routine test, see recommendation 1.3.5.8) Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy of suspected tuberculoma	Microscopy Culture Histology	-
Central nervous system	CT (Routine test, see recommendation 1.3.5.8) MRI (Routine test, see recommendation 1.3.5.8) Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Cerebrospinal fluid	Microscopy Culture Cytology	Adenosine deaminase assay

Suspected site of disease	Possible imaging techniques[a]	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Meningeal	CT (Routine test, see recommendation 1.3.5.8) MRI (Routine test, see recommendation 1.3.5.8) Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Cerebrospinal fluid	Microscopy Culture Cytology	Nucleic acid amplification test Adenosine deaminase assay

[new 2016]

1.3.5.8 Offer a CT or MRI scan to people in whom central nervous system involvement is suspected. **[2016]**

1.3.5.9 Offer treatment for TB meningitis if clinical signs and other laboratory findings are consistent with the diagnosis, even if a rapid diagnostic test is negative. **[new 2016]**

Lymph node TB (including intrathoracic mediastinal adenopathy)

1.3.5.10 Use the site-specific investigations listed in table 4 to diagnose and assess lymph node TB (including intrathoracic mediastinal adenopathy).

Table 4 Site-specific investigations for lymph node TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Lymph node (including intrathoracic mediastinal adenopathy)	Ultrasound CT MRI Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy	Microscopy Culture Histology	Nucleic acid amplification test
		Aspirate	Microscopy Culture Cytology	Nucleic acid amplification test

[new 2016]

Pericardial TB

1.3.5.11 Use the site-specific investigations listed in table 5 to diagnose and assess pericardial TB.

Table 5 Site-specific investigations for pericardial TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Pericardial	Echocardiogram Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy of pericardium	Microscopy Culture Histology	-
Pericardial	Echocardiogram Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Pericardial fluid	Microscopy Culture Cytology	Nucleic acid amplification test Adenosine deaminase assay

[new 2016]

Gastrointestinal TB

1.3.5.12 Use the site-specific investigations listed in table 6 to diagnose and assess gastrointestinal TB.

Table 6 Site-specific investigations for gastrointestinal TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Gastrointestinal	Ultrasound CT Laparoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy of omentum Biopsy of bowel Biopsy of liver	Microscopy Culture Histology	-
Gastrointestinal	Ultrasound CT Laparoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Ascitic fluid	Microscopy Culture Cytology	Adenosine deaminase assay

[new 2016]

Genitourinary TB

1.3.5.13 Use the site-specific investigations listed in table 7 to diagnose and assess genitourinary TB.

Table 7 Site-specific investigations for genitourinary TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Genitourinary	Ultrasound Intravenous urography Laparoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Early morning urine	Culture	-
Genitourinary	Ultrasound Intravenous urography Laparoscopy Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy from site of disease, such as endometrial curettings or renal biopsy	Microscopy Culture Histology	-

[new 2016]

Bone and joint TB

1.3.5.14 Use the site-specific investigations listed in table 8 to diagnose and assess bone and joint TB.

Table 8 Site-specific investigations for bone and joint TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional test on primary specimen (if it would alter management)
Bone or joint TB	X-ray CT MRI Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment	Biopsy or aspirate of paraspinal abscess Biopsy of joint Aspiration of joint fluid	Culture	-

[new 2016]

Disseminated TB

1.3.5.15 Use the site-specific investigations listed in table 9 to diagnose and assess disseminated TB.

Table 9 Site-specific investigations for disseminated TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Disseminated	CT of the thorax and head MRI Ultrasound of the abdomen Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Biopsy of site of disease, including lung, liver and bone marrow	Microscopy Culture Histology	Additional tests appropriate to site
Disseminated	CT of the thorax and head MRI Ultrasound of the abdomen Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Aspirate bone marrow Bronchial wash Cerebrospinal fluid	Microscopy (if sample available) Culture Cytology	Additional tests appropriate to site
Disseminated	CT of the thorax and head MRI Ultrasound of the abdomen Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment.	Blood	Culture	Additional tests appropriate to site

[new 2016]

Skin TB

1.3.5.16 Use the site-specific investigations listed in table 10 to diagnose and assess skin TB.

Table 10: Site-specific investigations for skin TB

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Skin	-	Biopsy	Microscopy Culture Histology	-

[2016]

Localised tuberculous abscess

1.3.5.17 Use the site-specific investigations listed in table 11 to diagnose and assess TB in a localised, tuberculous abscess at a site other than a lymph node.

Table 11: Site-specific investigations for localised tuberculous abscess

Suspected site of disease	Possible imaging techniques	Specimen	Routine test	Additional tests on primary specimen (if it would alter management)
Abscess outside of the lymph nodes	Ultrasound or other appropriate imaging Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment	Aspirate	Microscopy Culture Cytology	-
Abscess outside of the lymph nodes	Ultrasound or other appropriate imaging Taking into account, for example, the exact site of suspected disease and the availability of the test at the time of assessment	Biopsy	Microscopy Culture Histology	-

[2016]

1.3.6 Rapid-access radiology and other investigation results: referral to multidisciplinary TB team process

1.3.6.1 Local hospitals, clinical commissioning groups and the local multidisciplinary team should consider developing a local pathway for people with imaging highly suggestive of active TB. The pathway should enable them to be referred by the radiology department by the next working day to multidisciplinary TB teams. Consider including the following in the pathway:

- Agreed standardised radiology codes to identify imaging investigations highly suggestive of active TB.

- Regular liaison between multidisciplinary TB teams and the radiology department (for example, weekly) to ensure all patients have been referred to the multidisciplinary team for triage using the agreed local mechanism or pathway. **[new 2016]**

1.3.6.2 Report results of all pathology or other diagnostic results suggesting TB to the multidisciplinary TB team and clinicians who ask for them. **[new 2016]**

Direct referral from emergency departments to multidisciplinary TB teams

1.3.6.3 Commissioners and multidisciplinary teams should consider working with emergency departments to develop direct referral pathways for people with suspected active TB so that:

- the local multidisciplinary team is informed of all suspected cases of TB using the appropriate process

- referral is accepted from any appropriate healthcare professional, for example an on-call radiologist. **[new 2016]**

1.3.6.4 Emergency department clinicians should ensure first-line diagnostic tests for TB are performed on anyone presenting with suspected TB (see table 1 on diagnostic investigations for pulmonary TB). **[new 2016]**

1.3.6.5 Emergency departments should consider carrying out audits of their direct referrals because of suspected active TB and the outcomes of diagnosis. **[new 2016]**

1.3.6.6 Multidisciplinary TB teams should consider training emergency department staff in:

- using approaches that do not stigmatise people with TB

- giving people with TB appropriate advice (see recommendations 1.1.1 and 1.1.2 in the section on raising and sustaining awareness of TB and the section on infection control). **[new 2016]**

1.3.7 Managing active TB in all age groups

Standard treatment

1.3.7.1 Once a diagnosis of active TB is made:

- the clinician responsible for care should refer the person with TB to a clinician with training in, and experience of, the specialised care of people with TB
- the TB service should include specialised nurses and health visitors
- active TB in children should be managed by a TB specialist (see recommendation 1.3.4.3 in the section on diagnosing pulmonary (including laryngeal) TB in children and young people), and by paediatric trained nursing staff, where possible.

  If these arrangements are not possible, seek advice from more specialised colleagues throughout the treatment period. **[2016]**

1.3.7.2 For people with active TB without central nervous system involvement, offer:

- isoniazid (with pyridoxine), rifampicin, pyrazinamide and ethambutol for 2 months **then**
- isoniazid (with pyridoxine) and rifampicin for a further 4 months.

  Modify the treatment regimen according to drug susceptibility testing. **[2016]**

1.3.7.3 For people with active TB of the central nervous system, offer:

- isoniazid (with pyridoxine), rifampicin, pyrazinamide and ethambutol for 2 months **then**
- isoniazid (with pyridoxine) and rifampicin for a further 10 months.

  Modify the treatment regimen according to drug susceptibility testing. **[2016]**

1.3.7.4 Test people with active spinal TB who have neurological signs or symptoms for central nervous system involvement (see recommendation

1.3.5.8 in the section on central nervous system TB). Manage direct spinal cord involvement (for example, a spinal cord tuberculoma) as TB of the central nervous system. **[2016]**

1.3.7.5 For people with active spinal TB without central nervous system involvement, do not extend treatment beyond 6 months for residual effects (for example, persistent bending of the spine or vertebral loss). **[2016]**

1.3.7.6 Test people with disseminated (including miliary) TB who have neurological signs or symptoms for central nervous system involvement. If there is evidence of central nervous system involvement, treat as for TB of the central nervous system. **[2016]**

1.3.7.7 Treat active peripheral lymph node TB in people who have had an affected gland surgically removed with the standard recommended regimen. **[new 2016]**

1.3.7.8 For people with active TB of the lymph nodes, do not routinely extend treatment beyond 6 months for newly enlarged lymph nodes or sinus formation, or for residual enlargement of the lymph nodes or sinuses. **[new 2016]**

Dosing of regimens

1.3.7.9 Use fixed-dose combination tablets as part of any TB treatment regimen. **[2006]**

1.3.7.10 Do not offer anti-TB treatment dosing regimens of fewer than 3 times per week. **[2006, amended 2016]**

1.3.7.11 Offer a daily dosing schedule to people with active pulmonary TB. **[2006, amended 2016]**

1.3.7.12 Consider a daily dosing schedule as first choice in people with active extrapulmonary TB. **[2006, amended 2016]**

1.3.7.13 Consider 3 times weekly dosing for people with active TB only if:

- a risk assessment identifies a need for directly observed therapy and enhanced case management (see section on adherence, treatment completion and follow-up) **and**
- daily directly observed therapy is not possible. **[2006, amended 2016]**

People with comorbidities or coexisting conditions

1.3.7.14 If the person has a comorbidity or coexisting condition such as:

- HIV **or**
- severe liver disease, for example, Child-Pugh level B or C **or**
- stage 4 or 5 chronic kidney disease (a glomerular filtration rate of <30 ml/minute/1.73m^2) **or**
- diabetes **or**
- eye disease or impaired vision **or**
- pregnancy or breastfeeding **or**
- a history of alcohol or substance misuse

work with a specialist multidisciplinary team with experience of managing TB and the comorbidity or coexisting condition. **[new 2016]**

1.3.7.15 For people with HIV and active TB without central nervous system involvement, do not routinely extend treatment beyond 6 months. **[new 2016]**

1.3.7.16 For people with HIV and active TB with central nervous system involvement, do not routinely extend treatment beyond 12 months. **[new 2016]**

1.3.7.17 Take into account drug-to-drug interactions when co-prescribing antiretroviral and anti-TB drugs. **[new 2016]**

Adjunctive corticosteroids

Central nervous system TB

1.3.7.18 At the start of an anti-TB treatment regimen, offer people with active TB of the central nervous system dexamethasone or prednisolone, initially at a high dose with gradual withdrawal over 4 to 8 weeks. An example of a suitable regimen is listed in table 12.

Table 12 Example of suitable corticosteroid regimen for adults

Dose of dexamethasone by week	Stage 1	Stage 2 or 3
Week 1	0.3 mg/kg/day (intravenous)	0.4 mg/kg/day (intravenous)
Week 2	0.2 mg/kg/day (intravenous)	0.3 mg/kg/day (intravenous)
Week 3	0.1 mg/kg/day (oral)	0.2 mg/kg/day (intravenous)
Week 4	3 mg/day (oral)	0.1 mg/kg/day (intravenous)
Week 5	2 mg/day (oral)	4 mg/day (oral)
Week 6	1 mg/day (oral)	3 mg/day (oral)
Week 7	-	2 mg/day (oral)
Week 8	-	1 mg/day (oral)

According to the modified British Medical Research Council criteria for disease severity:

Stage 1: Glasgow coma score of 15 without focal neurological deficits; alert and oriented.

Stage 2: Glasgow coma score of 14 to 11 or 15 with focal neurological deficits.

Stage 3: Glasgow coma score of 10 or less, with or without focal neurological deficits.

[new 2016]

1.3.7.19 At the start of an anti-TB treatment regimen, offer children and young people with active TB of the central nervous system dexamethasone or prednisolone. This should initially be at a high dose with gradual withdrawal over 4 to 8 weeks in line with the British National Formulary for Children. **[new 2016]**

Pericardial TB

1.3.7.20 At the start of an anti-TB treatment regimen, offer adults with active pericardial TB oral prednisolone at a starting dose of 60 mg/day, gradually withdrawing it 2 to 3 weeks after starting treatment. **[2016]**

1.3.7.21 At the start of an anti-TB treatment regimen, offer children and young people with active pericardial TB oral prednisolone in line with the British National Formulary for Children. Gradually withdraw prednisolone 2 to 3 weeks after starting treatment. **[2016]**

Adjunctive surgery

1.3.7.22 If surgery is indicated, the surgeon should fully explain what is involved to the person, either with or after consulting a TB specialist. Discuss the possible benefits and risks with the person and their family members or carers, as appropriate, so that they can make an informed decision. **[new 2016]**

Central nervous system TB

1.3.7.23 Consider referring people with TB of the central nervous system for surgery as a therapeutic intervention only if there is evidence of raised intracranial pressure. **[new 2016]**

Spinal TB

1.3.7.24 Do not routinely refer people with spinal TB for surgery to eradicate the disease. **[new 2016]**

1.3.7.25 Consider referring people with spinal TB for surgery if there is spinal instability or evidence of spinal cord compression. **[new 2016]**

1.4 Drug resistant TB

1.4.1 Multidrug-resistant TB

1.4.1.1 For people with clinically suspected TB, a TB specialist should request rapid diagnostic nucleic acid amplification tests for rifampicin resistance on primary specimens if a risk assessment for multidrug resistance identifies any of the following risk factors:

- history of previous TB drug treatment, particularly if there was known to be poor adherence to that treatment
- contact with a known case of multidrug-resistant TB
- birth or residence in a country in which the World Health Organization reports that a high proportion (5% or more) of new TB cases are multidrug-resistant.

Start infection control measures (see section 1.5). **[new 2016]**

1.4.1.2 If the rapid diagnostic nucleic acid amplification test for rifampicin resistance is positive:

- continue infection control measures until pulmonary or laryngeal disease has been excluded
- manage treatment along with a multidisciplinary team with experience of managing multidrug-resistant TB (see the section on service organisation)
- offer a treatment regimen involving at least 6 drugs to which the mycobacterium is likely to be sensitive
- test for resistance to second-line drugs. **[new 2016]**

1.4.1.3 If the rapid diagnostic nucleic acid amplification test for the *M. tuberculosis* complex is positive but rifampicin resistance is not detected, treat as drug-susceptible TB with the standard regimen (see the section on managing active TB in all age groups). **[new 2016]**

1.4.1.4 If the rapid diagnostic nucleic acid amplification test for the *M. tuberculosis* complex is negative in a person at high risk of

multidrug-resistant TB:

- obtain further specimens for nucleic acid amplification testing and culture, if possible
- use rapid rifampicin resistance detection on cultures that become positive for the *M. tuberculosis* complex
- consider waiting for the results of further tests before starting treatment if the person is well
- if urgent treatment is needed, consider managing as multidrug-resistant TB until sensitivity results are available. **[new 2016]**

1.4.1.5 When definitive phenotypic susceptibility results are available, modify treatment as needed (see sections on managing active TB in all age groups and drug-resistant TB). **[new 2016]**

1.4.1.6 Consider more intensive clinical follow-up for people with multidrug-resistant TB. This includes people having directly observed therapy (see the section on adherence, treatment completion and follow-up) throughout treatment because of the complexity of treatment and risk of adverse events. **[new 2016]**

1.4.1.7 Discuss the options for organising care for people with multidrug-resistant TB with clinicians who specialise in this. Seek the person's views and take them into account, and consider shared care (see the section on service organisation). **[2006]**

1.4.1.8 Consider surgery as a therapeutic intervention in people with potentially resectable multidrug-resistant disease if:

- optimal medical therapy under direct observation has not worked **or**
- medical therapy is likely to fail because of extensively drug-resistant TB. **[new 2016]**

1.4.2 Drug-resistant TB (excluding multidrug- and extensively drug-resistant TB)

1.4.2.1 For people with TB, without central nervous system involvement, that is resistant to just 1 drug consider the treatments in table 13.

Table 13 Treatment regimen for people with TB that is resistant to 1 drug

Drug resistance	First 2 months (initial phase)	Continue with (continuation phase)
Isoniazid	Rifampicin, pyrazinamide and ethambutol	Rifampicin and ethambutol for 7 months (up to 10 months for extensive disease)
Pyrazinamide	Rifampicin, isoniazid (with pyridoxine) and ethambutol	Rifampicin and isoniazid (with pyridoxine) for 7 months
Ethambutol	Rifampicin, isoniazid (with pyridoxine) and pyrazinamide	Rifampicin and isoniazid (with pyridoxine) for 4 months
Rifampicin	As for multidrug-resistant TB	As for multidrug-resistant TB

[new 2016]

1.4.2.2 For people with drug-resistant TB and central nervous system involvement, involve a TB specialist with experience in managing drug-resistant TB in decisions about the most appropriate regimen and the duration of treatment. **[new 2016]**

1.5 Infection control

NICE has also produced general guidelines on the prevention and control of healthcare-associated infections in primary and community care, and the prevention and control of healthcare-associated infections.

1.5.1 Healthcare settings

1.5.1.1 Ensure healthcare settings can promptly identify people with suspected infectious or confirmed pulmonary or laryngeal TB before or at

presentation. Ensure people working in the settings follow the recommendations about testing and treatments (see the sections on latent TB, active TB and drug resistant TB*).* **[new 2016]**

1.5.1.2 Put people with suspected infectious or confirmed pulmonary or laryngeal TB who will remain in a hospital setting (including emergency, outpatients or inpatient care) in a single room. If this is not possible, keep the person's waiting times to a minimum. This may involve prioritising their care above that of other patients. **[new 2016]**

1.5.1.3 Minimise the number and duration of visits a person with TB makes to an outpatient department while they are still infectious. To minimise the risk of infection, people with infectious TB should be seen at times or in places away from other people. **[new 2016]**

1.5.1.4 In hospital settings, risk assess people with suspected infectious or confirmed pulmonary TB for multidrug-resistant TB *(*see the section on multidrug-resistant TB). Care for people deemed to be at low risk in a single room, as a minimum. For people deemed to be at high risk:

- provide care in a negative pressure room **and**
- have specimens sent for rapid diagnostic tests, such as nucleic acid amplification tests. **[new 2016]**

1.5.1.5 Unless there is a clear clinical or public health need, such as homelessness, people with suspected infectious or confirmed pulmonary TB should not be admitted to hospital for diagnostic tests or for care. **[2006, amended 2016]**

1.5.1.6 Do not admit people with suspected infectious or confirmed pulmonary TB to a ward containing people who are immunocompromised, such as transplant recipients, people with HIV and those on anti-tumour necrosis factor alpha or other biologics, unless they can be cared for in a negative pressure room on the same ward. **[new 2016]**

1.5.1.7 Assess any visitors to a child with suspected active TB in hospital for symptoms of infectious TB, and keep them separate from other people until they have been excluded as a source of infection (see

recommendations 1.2.1 to 1.2.3 in the section on latent TB and the section on contact tracing). **[new 2016]**

1.5.1.8 Care for people with a continuing clinical or public health need for admission with pulmonary TB in a single room (as a minimum) until they have completed 2 weeks of the standard treatment regimen (see the section on managing active TB in all age groups) if they:

- are unlikely to be rifampicin resistant (that is, do not have risk factors for multidrug-resistant TB) **or**
- have negative rifampicin resistance on nucleic acid amplification test or culture. **[new 2016]**

1.5.1.9 Consider de-escalating isolation after 2 weeks of treatment, taking into account the risks and benefits, if:

- the person is showing tolerance to the prescribed treatment
- there is agreement to adhere to treatment
- there is resolution of cough
- there is definite clinical improvement on treatment; for example, remaining afebrile for a week
- there are not immunocompromised people, such as transplant recipients, people with HIV and those on anti-tumour necrosis factor alpha or other biologics, in the same accommodation
- the person's initial smear grade was not high; for example, 2 or less
- there is not extensive pulmonary involvement, including cavitation
- there is no laryngeal TB. **[new 2016]**

1.5.1.10 In people who may have TB, only carry out aerosol-generating procedures such as bronchoscopy, sputum induction or nebuliser treatment in an appropriately engineered and ventilated area (ideally a negative pressure room). **[new 2016]**

1.5.1.11 Consider discharging from hospital people:

- who do not have a continuing clinical or public health need for admission with pulmonary TB **and**
- who are unlikely to be rifampicin resistant (that is, do not have risk factors for multidrug-resistant TB) **or**
- who have negative rifampicin resistance on nucleic acid amplification test or culture.

If discharged, the person should avoid congregate settings for the first 2 weeks of their treatment. **[new 2016]**

1.5.1.12 Explain to inpatients with suspected infectious or confirmed pulmonary or laryngeal TB that they will need to wear a surgical mask in the hospital whenever they leave their room. Ask them to continue wearing it until they have had at least 2 weeks of treatment. **[2016]**

1.5.1.13 Offer people advice on simple respiratory hygiene measures. **[new 2016]**

1.5.2 Non-healthcare settings

1.5.2.1 In non-healthcare settings catering for large numbers of people and populations at high risk of TB (such as detention settings, residential hostels and day centres):

- promote simple respiratory hygiene
- ensure awareness of symptoms of potentially infectious TB to enable prompt healthcare referral
- work with the local public health team and the local authority to ensure accommodation for people with TB
- ensure adequate ventilation. **[new 2016]**

1.5.2.2 In prisons or immigration removal centres, everyone with X-ray changes indicative of active TB, as well as those with symptoms who are awaiting X-ray, should be isolated in an adequately ventilated individual room or cell. Prisoners and detainees should be retained on medical hold until they have:

- proven smear-negative and had an X-ray that does not suggest active TB **or**
- had a negative risk assessment for multidrug-resistant TB and completed 2 weeks of the standard treatment regimen. **[2012, amended 2016]**

1.5.3 Multidrug-resistant TB

1.5.3.1 If people with suspected or known infectious multidrug-resistant TB are admitted to hospital, admit them to a negative pressure room. If none is available locally, transfer them to a hospital that has these facilities and a clinician experienced in managing complex drug-resistant cases. Carry out care in a negative pressure room for people with:

- suspected multidrug-resistant TB, until non-resistance is confirmed
- confirmed multidrug-resistant TB, until they have 3 negative smears at weekly intervals and ideally have a negative culture. **[new 2016]**

1.5.3.2 As soon as possible, explore options to reduce the psychosocial impact of prolonged isolation. For example, through providing free access to internet, telephone and television, and accompanied walks in the open air. **[new 2016]**

1.5.3.3 Consider earlier discharge for people with confirmed multidrug-resistant TB, if there are suitable facilities for home isolation and the person will adhere to the care plan. **[new 2016]**

1.5.3.4 For people with confirmed multidrug-resistant TB whose symptoms have improved and who are unable to produce sputum, discharge decisions should be taken by the multidisciplinary team and the health protection team. **[new 2016]**

1.5.3.5 Staff and visitors should wear filtering face piece (FFP3) masks during contact with a person with suspected or known multidrug-resistant TB while the person is thought to be infectious. **[2016]**

1.5.3.6 Before deciding to discharge a person with suspected or known multidrug-resistant TB from hospital, agree with the person and their carers secure arrangements for supervising and administering all anti-TB

therapy. **[2016]**

1.5.3.7 Discuss the decision to discharge a person with suspected or known multidrug-resistant TB with:

- the infection control team **and**
- the local microbiologist **and**
- the local TB service **and**
- the health protection team. **[2016]**

1.5.3.8 Ensure negative pressure rooms used for infection control in multidrug-resistant TB meet the standards of the Interdepartmental Working Group on Tuberculosis, and are clearly identified for staff, for example by a standard sign. Keep such signs up to date. **[2016]**

1.6 Case finding

1.6.1 Contact tracing

Human to human transmission

1.6.1.1 Once a person has been diagnosed with active TB, the diagnosing physician should inform relevant colleagues so that the need for contact tracing can be assessed without delay. Contact tracing should not be delayed until notification. **[2006]**

1.6.1.2 Offer screening to the close contacts of any person with pulmonary or laryngeal TB. **[2006, amended 2016]**

1.6.1.3 Assess symptomatic close contacts for active TB (see recommendations 1.3.1 to 1.3.4 in the section on active TB). **[new 2016]**

1.6.1.4 In asymptomatic close contacts younger than 65 years, consider standard testing for latent TB (see recommendations 1.2.1 to 1.2.3 in the section on latent TB), followed by consideration of BCG vaccination in

line with the section on BCG vaccination or treatment for latent TB infection (see recommendations 1.2.4 to 1.2.6 in the section on latent TB) once active TB has been ruled out for people who:

- are previously unvaccinated **and**
- are contacts of a person with smear-positive pulmonary or laryngeal TB **and**
- are Mantoux-negative.

  At the time of publication (January 2016) the BNF states: 'The Mantoux test is recommended for tuberculin skin testing, but no licensed preparation is currently available.' For further guidance, see immunisation against infectious disease (the Green book). **[2006, amended 2016]**

1.6.1.5 In asymptomatic close contacts older than 65 years, consider a chest X-ray (if there are no contraindications), possibly leading to further investigation for active TB. **[2006, amended 2016]**

1.6.1.6 Do not routinely assess social contacts of people with TB, who will include most workplace contacts. **[2006, amended 2016]**

1.6.1.7 Assess the need for tracing social contacts of people with pulmonary or laryngeal TB if:

- the index case is judged to be particularly infectious (for example, evidenced by transmission to close contacts) **or**
- any social contacts are known to possess features that put them at high risk of going on to develop active TB. **[2006, amended 2016]**

1.6.1.8 Offer 'inform and advise' information to close and social contacts of people with smear-positive TB (see section on providing information for the public about TB). **[2006]**

Cases on an aircraft

1.6.1.9 After diagnosis of TB in an aircraft traveller, do not routinely carry out contact tracing of fellow passengers. **[2006, amended 2016]**

1.6.1.10 The notifying clinician should inform the relevant consultant in communicable disease control or health protection if:

- less than 3 months has elapsed since the flight and the flight was longer than 8 hours **and**
- the index case is smear-positive **and either**
  - the index case has multidrug-resistant TB **or**
  - the index case coughed frequently during the flight. **[2006]**

1.6.1.11 The consultant in communicable disease control or health protection should provide the airline with 'inform and advise' information to send to passengers seated in the same part of the aircraft as the index case. **[2006, amended 2016]**

1.6.1.12 If the TB index case is an aircraft crew member, contact tracing of passengers should not routinely take place. **[2006]**

1.6.1.13 If the TB index case is an aircraft crew member, contact tracing of other members of staff is appropriate, in accordance with the usual principles for screening workplace colleagues. **[2006]**

Cases in schools

1.6.1.14 After diagnosis of TB in a school pupil or member of staff, the consultant in communicable disease control or health protection should be prepared to explain the prevention and control procedures to staff, parents and the press. Advice on managing these incidents and their public relations is available from the Public Health England health protection team and the local authority. **[2006, amended 2016]**

1.6.1.15 If a school pupil is diagnosed with smear-positive TB, carry out a risk assessment of the need to test the rest of his or her class (if there is a single class group), or the rest of the year group who share classes, as part of contact tracing. **[2006]**

1.6.1.16 If a teacher has smear-positive TB, assess the pupils in his or her classes during the preceding 3 months as part of contact tracing. **[2006]**

1.6.1.17 Consider extending contact tracing in schools to include children and teachers involved in extracurricular activities, and non-teaching staff, on the basis of:

- the degree of infectivity of the index case
- the length of time the index case was in contact with others
- whether contacts are unusually susceptible to infection
- the proximity of contact. **[2006, amended 2016]**

1.6.1.18 Treat secondary cases of smear-positive TB as index cases for contact tracing. **[2006]**

1.6.1.19 If the index case of a school pupil's TB infection is not found, and the child is not in a high-risk group for TB, contact tracing and screening (by either symptom enquiry or chest X-ray) should be considered for all relevant members of staff at the school. **[2006]**

Cases in community childcare

1.6.1.20 When an adult who works in childcare (including people who provide childcare informally) is diagnosed with smear-positive TB, follow recommendations 1.6.1.1 to 1.6.1.8. **[2006, amended 2016]**

Cases in hospital inpatients

1.6.1.21 If TB is diagnosed in a hospital inpatient, do a risk assessment. This should take into account:

- the degree of infectivity of the index case
- the length of time before the infectious patient was isolated
- whether other patients are unusually susceptible to infection
- the proximity of contact. **[2006, amended 2016]**

1.6.1.22 Carry out contact tracing and testing only for patients for whom the risk is regarded as significant. **[2006]**

1.6.1.23 Regard patients as at risk of infection if they spent more than 8 hours in the same bay as an inpatient with smear-positive TB who had a cough. Document the risk in the contact's clinical notes, for the attention of the contact's consultant. Give the contact 'inform and advise' information, and inform their GP. **[2006]**

1.6.1.24 If patients were exposed to a patient with smear-positive TB for long enough to be equivalent to close contacts (as determined by the risk assessment), or an exposed patient is known to be particularly susceptible to infection, manage their TB risk in the same way as close contacts. **[2006, amended 2016]**

1.6.1.25 If an inpatient with smear-positive TB is found to have multidrug-resistant TB, or if exposed patients are HIV positive, trace contacts following the Interdepartmental Working Group on Tuberculosis guidelines. **[2006]**

1.6.1.26 In cases of doubt when planning contact tracing after diagnosing smear-positive TB in an inpatient, seek further advice from the local or national Public Health England or Wales unit or people experienced in the field. **[2006, amended 2016]**

1.6.2 Opportunistic case finding

New entrants from high incidence countries

1.6.2.1 Assess and manage TB in new entrants from high incidence countries who present to healthcare services as follows:

- assess risk of HIV, including HIV prevalence rates in the country of origin, and take this into account when deciding whether to give a BCG vaccination
- offer testing for latent TB (see recommendations 1.2.1 to 1.2.3 in the section on latent TB)
- assess for active TB if the test for latent TB is positive (see recommendations 1.3.1 to 1.3.5 in the section on active TB)

- offer treatment to people aged 65 years or younger in whom active TB has been excluded but who have a positive Mantoux test or a positive interferon-gamma release assay for latent TB infection (see recommendations 1.2.4 to 1.2.6 in the section on latent TB)

- consider offering BCG for unvaccinated people who are Mantoux- or interferon-gamma release assay-negative (see the section on BCG vaccination)

- give 'inform and advise' information to people who do not have active TB and are not being offered BCG or treatment for latent TB infection (see the section on providing information for the public about TB). **[2006, amended 2011 and 2016]**

1.6.2.2 Primary care services should support local, community-based and voluntary organisations that work with vulnerable migrants to ensure they:

- register with a primary care provider

- know how to use NHS services (emergency or primary care). **[2012]**

1.6.2.3 Healthcare professionals, including primary care staff, responsible for testing new entrants should test all vulnerable migrants who have not previously been checked. This is regardless of when they arrived in England. People born in countries with an incidence of more than 150 per 100,000 per year should be made a priority for latent TB testing when they arrive here. **[2012, amended 2016]**

People using homeless or substance misuse services

1.6.2.4 In areas of identified need (see the section on local needs assessment), including major urban centres with a high incidence of TB, commissioners should:

- ensure there is a programme of active case-finding using mobile X-ray in places where homeless people and people who misuse substances congregate (this includes: homeless day centres, rolling shelters, hostels and temporary shelters established as part of cold weather initiatives and venues housing needle and syringe programmes)

- base the frequency of screening at any 1 location on population turnover
- where local demand does not warrant a mobile X-ray team, consider commissioning mobile X-ray capacity from another area. **[2006, amended 2012]**

1.6.2.5 Multidisciplinary TB teams should consider using simple incentives, such as providing hot drinks and snacks, to encourage people to attend for testing. **[2006, amended 2012, amended 2016]**

1.6.2.6 Commissioners of TB prevention and control programmes should consider offering people who are homeless and people who misuse substances other health interventions when they are screened for TB at a mobile X-ray unit. (Examples may include blood-borne virus screening, dentistry and podiatry services.) **[2012]**

1.6.2.7 Multidisciplinary TB teams should work closely with mobile X-ray teams and frontline staff in hostels and day centres to promote TB screening and to ensure appropriate onward referrals and follow-up. **[2012]**

1.6.2.8 Multidisciplinary TB teams should consider using peer educators to promote the uptake of TB screening in hostels and day centres. **[2012]**

1.6.2.9 Multidisciplinary TB teams should provide routine data to TB control boards on: screening uptake, referrals and the number of active TB cases identified. **[2012]**

People in prisons or immigration removal centres

1.6.2.10 Healthcare professionals in prisons and immigration removal centres should ensure prisoners and detainees are screened for TB within 48 hours of arrival. **[2012]**

1.6.2.11 Prisons with Department of Health-funded static digital X-ray facilities for TB screening should X-ray all new prisoners and detainees (including those being transferred from other establishments) if they have not had a chest X-ray in the past 6 months. This should take place within 48 hours of arrival. **[2012]**

1.6.2.12 Prison and immigration removal centre health staff should report all suspected and confirmed TB cases to the local multidisciplinary TB team within 1 working day. **[2012]**

1.6.2.13 Multidisciplinary TB staff should visit every confirmed TB case in a prison or immigration removal centre in their locality within 5 working days. **[2012]**

1.6.2.14 If a case of active TB is identified, the local Public Health England unit, in conjunction with the multidisciplinary TB team, should plan a contact investigations exercise. They should also consider using mobile X-ray to check for further cases. **[2012]**

1.6.3 Active case finding in under-served groups

1.6.3.1 Multidisciplinary TB teams should follow NICE recommendations on contact tracing (see the section on contact tracing).They should coordinate contact investigations at places where the person with TB spends significant amounts of time. Examples could include pubs, crack houses, parks and community centres. The aim is to help identify people who have been living with them and people they frequently socialise with. **[2012]**

1.6.3.2 Multidisciplinary TB teams dealing with someone from an under-served group should work alongside health and social care professionals known to them to help trace relevant contacts. They should also work in partnership with voluntary, community and statutory organisations to conduct outreach contact investigations. **[2012]**

1.6.3.3 Multidisciplinary TB teams should, if available and appropriate, encourage peer educators or TB programme support workers to help with contact investigations involving under-served people who have complex social networks. **[2012]**

1.6.3.4 Multidisciplinary TB teams in discussion with local Public Health England health protection teams should consider using digital mobile X-ray for active case-finding in settings identified by looking at social networks as places where under-served people at risk congregate. They should also

provide the necessary support so that multidisciplinary TB teams can use strain-typing and social network analysis to ascertain where transmission is occurring in the community. (Examples of transmission sites may include pubs, crack houses, hostels and day centres.) They should focus on active case-finding in the settings identified. **[2012, amended 2016]**

1.6.4 Incident and outbreak response

1.6.4.1 Multidisciplinary TB teams should coordinate incident or outbreak contact investigations at places where the person with active TB spends significant amounts of time. Examples include workplaces, schools, colleges, universities, childcare settings. Identify people that the person with TB frequently spends substantial time with, as outlined in the section on contact tracing. **[new 2016]**

1.6.4.2 Multidisciplinary TB teams should refer any incident in a congregate setting to the local Public Health England health protection team for risk assessment within 5 working days of suspicion of a potential incident. **[new 2016]**

1.6.4.3 TB control boards working with local health protection teams should, through local arrangements, mobilise existing staff or have access to an incident team that will:

- undertake an incident risk assessment and provide advice
- support or undertake contact investigations
- provide information and communication support to the multidisciplinary TB team, the local director of public health, the setting in which the incident has occurred and the people affected including:
  - written advice, printed or by email
  - question and answer sessions
  - telephone advice
  - media engagement

- gather and collate data, and report on outcomes to measure the effectiveness of the investigation (for example, offering testing to all people identified at risk and monitoring uptake)

- report back to TB control boards at appropriate times. This includes when outcomes of initial investigation of people classified as close contacts are available. It also includes when a decision is made to broaden the investigation to the next stage using the concentric circle method for risk assessment. **[new 2016]**

1.6.4.4 When incidents have been identified, multidisciplinary TB teams in discussion with local Public Health England health protection teams should consider providing support for strain-typing and other analysis to ascertain where transmission is occurring. (Examples of transmission sites may include workplaces, schools, colleges, universities, childcare settings.) **[new 2016]**

1.6.4.5 In all types of contact investigation scenarios (active case finding, incident or outbreak investigations) multidisciplinary TB teams should investigate all people who have been in contact with children who have pulmonary or extrapulmonary TB to identify the primary source of infection. If necessary, they should look beyond immediate close contacts to find the source. **[2012, amended 2016]**

1.7 Adherence, treatment completion and follow-up

1.7.1 Improving adherence: case management including directly observed therapy

1.7.1.1 Allocate a named TB case manager to everyone with active TB as soon as possible after diagnosis (and within 5 days). The clinical team should tell each person who their named TB case manager is and provide contact details. **[2006, 2012 amended 2016]**

1.7.1.2 The TB case managers should work with the person diagnosed with TB to develop a health and social care plan, and support them to complete

therapy successfully. The TB case manager should:

- offer a risk assessment to every person with TB, to identify their needs and whether they should have enhanced case management including directly observed therapy
- educate the person about TB and the treatment
- develop an individual care plan after discussion with the person
- gain the person's consent to the plan and agree a review date (for example, when moving from initiation to maintenance, or at each contact to ensure the person's needs are being met)
- coordinate discharge planning, especially for people on directly observed therapy
- involve representatives from other allied professions and key workers from all organisations who work with the person, if appropriate
- explore appropriate ways that peers and voluntary organisations can provide support. **[2006, 2012, amended 2016]**

1.7.1.3 Offer directly observed therapy as part of enhanced case management in people who:

- do not adhere to treatment (or have not in the past)
- have been treated previously for TB
- have a history of homelessness, drug or alcohol misuse
- are currently in prison, or have been in the past 5 years
- have a major psychiatric, memory or cognitive disorder
- are in denial of the TB diagnosis
- have multidrug-resistant TB
- request directly observed therapy after discussion with the clinical team
- are too ill to administer the treatment themselves. **[2012, amended 2016]**

1.7.1.4 In children whose parents are members of any of the above groups, offer directly observed therapy as part of enhanced case management and include advice and support for parents to assist with treatment completion. **[2016]**

1.7.1.5 Re-evaluate the need for directly observed therapy throughout the course of TB treatment whenever the person's (or in the case of children, parents') circumstances change. **[new 2016]**

1.7.1.6 TB case managers should ensure the health and social care plan (particularly if directly observed therapy is needed) identifies why a person may not attend for diagnostic testing or follow a treatment plan, and how they can be encouraged to do so. It should also include ways to address issues such as fear of stigmatisation, support needs and/or cultural beliefs, and may include information on:

- demographics (for example, age, nationality, place of birth, length of time in UK)
- all current prescribing regimens
- housing needs and living situation, including looked-after children
- substance misuse (drugs or alcohol)
- any contact with the criminal justice system
- the need for hepatitis B and C or HIV testing (see recommendations 1.2.5.2 and 1.2.5.3 in the section on managing latent TB in adults and recommendation 1.2.6.1 in the section on managing latent TB in children and young people)
- HIV status
- other health conditions (physical or mental)
- communication factors (for example, language and literacy levels)
- ability to access treatment (mobility and transport needs)
- employment or entitlement to benefits

- legal or immigration status (including risk of removal or relocation within the UK)
- any enablers or incentives to overcome anything that is stopping diagnosis or treatment. **[2012, amended 2016]**

1.7.1.7 The health and social care plan should:

- state who will be observing treatment and where (if the person is having directly observed therapy this should be provided at a location that is convenient and accessible to them, for example, at a methadone clinic) **[2012, amended 2016]**
- include actions to take if contact with the person is lost (for example, keeping details of people who might be able to help re-establish contact) **[2012]**
- refer to, and be coordinated with, any other care plan already established for the person **[2012]**
- define the support needed to address any unmet health and social care needs (for example, support to gain housing or other benefits, or to help them access other health or social care services) **[2012, amended 2016]**
- include a commitment from the person to complete their TB treatment **[2012, amended 2016]**
- be supported by frequent contact with any key workers who work with the person. **[2006 amended 2011, amended 2016]**

1.7.1.8 Multidisciplinary TB teams should aim to find people with active TB who are lost to follow-up, or who stop using services before completing diagnostic investigations. They should report all those lost to follow-up to local Public Health England teams, GPs, the referring organisation and specialist outreach teams. **[2012]**

1.7.2 Other strategies to encourage people to follow their treatment plan

1.7.2.1 To encourage people to follow their treatment plan, involve people in treatment decisions for active or latent TB from the start. Emphasise the importance of following the treatment plan when agreeing the regimen.

[2016]

1.7.2.2 Multidisciplinary TB teams should implement strategies for active and latent TB to encourage people to follow the treatment plan and prevent people stopping treatment early. These could include:

- reminder letters, printed information, telephone calls, texts and apps using an appropriate language **[2006, amended 2016]**
- health education counselling and patient-centred interviews **[2006, amended 2016]**
- tailored health education booklets from quality sources (see section on providing information for the public about TB) **[2006, amended 2016]**
- home visits **[2006]**
- random urine tests and other monitoring (for example, pill counts) **[2006]**
- access to free TB treatment for everyone (irrespective of eligibility for other NHS care) and information about help with paying for prescriptions **[2006, 2012, amended 2016]**
- social and psychological support (including cultural case management and broader social support) **[new 2016]**
- advice and support for parents and carers **[new 2016]**
- incentives and enablers to help people follow their treatment regimen. **[new 2016]**

1.7.2.3 TB control boards should ensure services take into account the barriers facing vulnerable migrants who may need treatment, and in particular the stigma they may face. Other issues include the location of services (both geographically and in terms of opening times) and people's language and cultural needs, in terms of the format of advice and the type of information given. **[2012, amended 2016]**

1.7.3 Strategies in prisons or immigration removal centres

1.7.3.1 On arrival at a prison or immigration removal centre, healthcare

professionals should ask all prisoners and detainees (including those being transferred from other establishments) if they are taking TB medication, to ensure continuity of treatment. **[2012]**

1.7.3.2 All prisoners and immigration removal centre detainees having treatment for active TB should have a named TB case manager. The case manager should be responsible for contingency planning for discharge from prison or detention. **[2012]**

1.7.3.3 Prisons and immigration removal centres should ensure multidisciplinary TB staff have access to prisoners and detainees who need treatment (for example, by being given security clearance). **[2012]**

1.7.3.4 All prisoners having treatment for active TB should have directly observed therapy. **[2012]**

1.7.3.5 Prison health services should have contingency, liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons or released. In addition, other agencies working with prisoners or detainees should also be involved in this planning. **[2012]**

1.7.3.6 Prison and immigration removal centre healthcare services should liaise with the named TB case manager (from the multidisciplinary TB team) to ensure contingency plans for continuation of treatment are drawn up for prisoners and immigration removal centre detainees with TB. **[2012]**

1.7.3.7 Multidisciplinary TB teams should ensure accommodation is available for the duration of TB treatment after the prisoner or detainee's release (see section on Identifying and managing active TB in prisons, custody suites or immigration removal centres: organisational factors). **[2012]**

1.7.3.8 Multidisciplinary TB teams should ensure directly observed therapy is arranged for prisoners or detainees being treated for TB after their release. This should be available close to where they will live in the community. **[2012]**

1.7.4 Re-establishing treatment for active or latent TB after

interruptions because of adverse events

1.7.4.1 In people who have experienced a treatment interruption because of drug-induced hepatotoxicity:

- investigate other causes of acute liver reactions **and**
- wait until aspartate or alanine transaminase levels fall below twice the upper limit of normal, bilirubin levels return to the normal range and hepatotoxic symptoms have resolved **then**
- sequentially reintroduce each of the anti-TB drugs at full dose over a period of no more than 10 days, starting with ethambutol and either isoniazid (with pyridoxine) or rifampicin. **[new 2016]**

1.7.4.2 In people with severe or highly infectious TB who need to interrupt standard therapy because of a reaction, consider continuing treatment:

- for hepatotoxicity, a combination of at least 2 anti-TB drugs of low hepatotoxicity (such as ethambutol and streptomycin, with or without a fluoroquinolone antibiotic, such as levofloxacin or moxifloxacin) and monitor with a liver specialist for further reactions

  See MHRA advice for restrictions and precautions for using fluoroquinolone antibiotics due to very rare reports of disabling and potentially long-lasting or irreversible side effects affecting musculoskeletal and nervous systems. Warnings include: stopping treatment at first signs of a serious adverse reaction (such as tendonitis), prescribing with special caution in people over 60 years and avoiding coadministration with a corticosteroid (March 2019).

  Not licensed for tuberculosis, so use would be off label. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing and managing medicines and devices for further information.

- for a cutaneous reaction, a combination of at least 2 anti-TB drugs with a low risk of cutaneous reactions (such as ethambutol and streptomycin) and monitor with a dermatologist for further reactions. **[new 2016, amended 2019]**

1.7.4.3 If another reaction of a similar or greater severity occurs because of reintroducing a particular drug, do not give that drug in future regimens and consider extending the total regimen accordingly. **[new 2016]**

1.7.5 Follow-up after treatment completion

1.7.5.1 Follow-up clinic visits should not be conducted routinely after treatment completion. **[2006]**

1.7.5.2 Tell patients to watch for symptoms of relapse and how to contact the TB service rapidly through primary care or a TB clinic. Key workers should ensure that patients at increased risk of relapse are particularly well informed about symptoms. **[2006]**

1.7.5.3 Patients who have had drug-resistant TB should be considered for follow-up for 12 months after completing treatment. Patients who have had multidrug-resistant TB should be considered for prolonged follow-up. **[2006]**

1.8 Service organisation

When using the recommendations in this section with under served groups, also check sections 1.1.1 on raising and sustaining awareness, 1.1.2 on providing information for the public, 1.6.2 on opportunistic case finding, 1.6.3 on active case finding in under served groups and 1.7 on adherence, treatment completion and follow up. See also, recommendations on under served groups in section 1.2.3 on diagnosing latent TB in all age groups.

1.8.1 Strategic oversight and commissioning of TB prevention and control activities

1.8.1.1 Public Health England, in partnership with NHS England, should take responsibility for national oversight of TB prevention and control activities. This includes setting up TB control boards (see section 1.8.2). **[2012, amended 2016]**

1.8.1.2 Public Health England and NHS England should consider working together to establish control boards in agreed geographical areas and employ appropriate staff (see recommendation 1.8.2.3). **[new 2016]**

1.8.1.3 Clinical commissioning groups and local authority public health teams working in partnership with Public Health England and NHS England should consider collaborative commissioning arrangements through TB control boards. This could, for example, include working with 1 or more clinical commissioning groups to cover a major metropolitan district, region or TB control board area taking into account:

- local TB incidence
- local at-risk populations and their movements across different geographical areas
- existing service configurations for organisations involved in TB prevention and control
- the need to share services, such as mobile X-ray facilities, and outreach incident teams across different geographical areas. **[2012, amended 2016]**

1.8.1.4 TB control boards should develop TB prevention and control programmes working with commissioners, Public Health England and NHS England. The board could include clinical, commissioning (from clinical commissioning groups, local government and the voluntary sector) and public health leaders and people with TB or groups who advocate on their behalf from across the control board area. This may include identifying a lead clinical commissioning group, which could be led by an executive director of that commissioning group working with the board. Feedback mechanisms between local commissioning groups and the TB control board should be developed. **[new 2016]**

1.8.1.5 An executive director of local commissioning groups, working with the local director of public health or another nominated public health consultant, should lead implementation of the programme in their locality. The lead should ensure a comprehensive prevention and control programme is commissioned to support the level of need (see section on local needs assessment) and that they work with the control board regularly. **[2012, amended 2016]**

1.8.1.6 Working together through TB control boards and local networks, commissioners, local government and Public Health England should ensure TB prevention and control programmes set up multidisciplinary TB teams to provide all TB services (see section on commissioning multidisciplinary TB support). They should ensure that local strategy and service commissioning focuses on an end-to-end pathway. **[2012, amended 2016]**

1.8.1.7 Working together through TB control boards, commissioners and Public Health England should ensure the TB prevention and control programme is informed by relevant NICE guidance and developed in collaboration with clinical services. It should also be informed by the standard minimum data set collected through local needs assessment and service audit. **[2012, amended 2016]**

1.8.1.8 Working together through TB control boards, commissioners and Public Health England should ensure the TB prevention and control programme targets all ages, including children, and covers all aspects of TB prevention and control (see recommendations 1.8.2.1 and 1.8.2.2), including but not limited to:

- active case finding (contact investigations and identifying latent TB in high-risk groups)
- awareness-raising activities
- standard and enhanced case management (including providing directly observed therapy and free treatment)
- finding people lost to follow-up and encouraging them back into treatment
- incident and outbreak control
- monitoring, evaluating and gathering surveillance and outcome data. **[2012, amended 2016]**

1.8.1.9 Working together through TB control boards, commissioners, Public Health England and the voluntary sector should ensure TB prevention and control programmes take account of the need to work with other programmes targeting specific high-risk groups, such as those who are

under-served. Examples include programmes focused on the health of asylum seekers and refugees, under-served children, homelessness and housing, offenders and people who misuse substances. **[2012, amended 2016]**

1.8.1.10 TB control boards should consider integrating TB and HIV services, joint clinics and training opportunities. **[new 2016]**

1.8.1.11 Commissioners should consider commissioning support and advice to all groups diagnosed with TB irrespective of whether they are under-served. **[new 2016]**

1.8.2 Developing the TB prevention and control programme

1.8.2.1 TB control boards should be responsible for developing a TB prevention and control programme based on the national strategy and evidence-based models. **[new 2016]**

1.8.2.2 TB control boards should plan, oversee, support and monitor local TB control, including clinical and public health services and workforce planning. **[new 2016]**

1.8.2.3 TB control boards should assess services in their area, identify gaps in provision and develop plans to meet these, including:

- undertaking a workforce review to support local or regional commissioning of TB services to meet the needs of their population (see sections on local needs assessment and cohort review)
- supporting development of appropriate services and pathways to improve access and early diagnosis (see the sections on rapid-access radiology and other investigation results: referral to multidisciplinary TB team process, non-clinical roles including TB support workers and rapid-access TB services)
- negotiating arrangements to cover the cost of additional services to address specific gaps in current TB control arrangements. **[new 2016]**

1.8.2.4 TB control boards should ensure cohort review is undertaken at least quarterly, and the results are fed back to local clinical and TB networks.

These should be agreed by accountable bodies such as clinical commissioning groups, trust management, regional Public Health England and centre directors and local authority directors of public health as agreed, all of whom should make sure appropriate action is taken. **[new 2016]**

1.8.2.5 TB control boards should enable full and consistent use of national guidelines including:

- ensuring the needs of all people with TB, particularly under-served populations, are addressed
- ensuring contact tracing arrangements are appropriate to the needs of the population (see the section on case finding)
- assuring themselves that TB control in low-incidence areas is established and delivered appropriately (see the section on rural services: organisational and support factors)
- assuring themselves that multidrug-resistant TB is managed appropriately (see the section on multidrug-resistant TB) and mechanisms are in place to ensure:
  - there is sufficient clinical expertise available to manage cases
  - regional multidrug-resistant TB networks take account of expert advice (see section 1.8.3). **[new 2016]**

1.8.2.6 TB control boards should develop links and partnerships and establish agreed relationships and lines of accountability between TB control boards and local clinical and TB networks. This includes engaging with other key stakeholders to ensure universal coverage of TB control efforts. **[new 2016]**

1.8.2.7 TB control boards should collaborate with their local and regional partners. They should agree and establish regular monitoring, surveillance and reporting arrangements with all partners to support needs assessment (see the section on local needs assessment) and regular audit and evaluation. **[new 2016]**

1.8.2.8 TB control board staff should have clearly defined roles and

responsibilities. Their roles and responsibilities could include:

- Establishing the links, partnerships and relationships between all aspects of the control board area within their remit (if necessary across usual geographical commissioning boundaries).
- Developing and supporting adoption and implementation of evidence-based model service specifications for the clinical and public health actions needed to control TB including:
  - improving access and early diagnosis (see the sections on raising and sustaining awareness of TB, providing information for the public about TB, rapid-access radiology and other investigation results: referral to multidisciplinary TB team process and non-clinical roles including TB support workers)
  - diagnostics, treatment and care services (see the sections on latent TB and active TB)
  - contact investigations and tracing (see the sections on diagnosing latent TB in adults and case finding)
  - cohort review
  - vaccination (see the section on BCG vaccination)
  - drug resistance (see the section on multidrug-resistant TB)
  - tackling TB in under-served populations
  - surveillance, monitoring and quality assurance
  - workforce development and commissioning (see the sections on commissioning multidisciplinary TB support and non-clinical roles including TB support workers). **[new 2016]**

1.8.2.9 TB control boards should ensure there is sufficient capacity available to them to manage a sudden increase in demand such as:

- TB contact investigations, (such as incidents in congregate settings)

- large scale active case-finding initiatives in under-served groups in the community
- outbreaks in a variety of settings or sites where transmission risk may be high, including but not limited to schools, workplaces, hostels and prisons. **[new 2016]**

1.8.2.10 To set up, monitor and evaluate a TB control programme, TB control boards should:

- agree plans within their partnerships to assess local services against the service specifications
- develop plans and quality standards to secure improvements
- establish quality assurance mechanisms and regular audits including, but not limited to, cohort review for all aspects of the TB control board partnership plans. **[new 2016]**

Coordinating local TB networks

1.8.2.11 TB control boards should (in collaboration with commissioners) consider the need for a TB network local coordinator, particularly if working across multiple clinical commissioning group areas (see recommendation 1.8.1.3). **[new 2016]**

1.8.2.12 The coordinator should work in close collaboration with clinicians and all relevant multidisciplinary TB teams to develop the network and be responsible for:

- setting up the network and developing it based on needs, reporting back to the TB control board regularly
- establishing the links, partnerships and relationships across their local network (if necessary across usual geographical commissioning boundaries). **[new 2016]**

1.8.3 Regional multidrug-resistant TB network

1.8.3.1 TB control boards should consider setting up a regional multidisciplinary

TB network to oversee management of multidrug-resistant TB. This could:

- Identify and designate regional expert centres.
- Ensure all healthcare professionals who suspect or treat a case of multidrug-resistant TB are informed about and have access to specialist advisory services for multidrug-resistant TB. This includes the designated expert centre in their regional network and may also include the national advisory service for multidrug-resistant TB (currently provided by the British Thoracic Society).
- Ensure all cases of multidrug-resistant TB are discussed at the regional multidisciplinary TB team meeting in the local clinical network.
- Formally consider and record the advice from the specialist advisory services for multidrug-resistant TB provided by the designated regional expert centre or the national advisory service for multidrug-resistant TB. **[new 2016]**

1.8.4 Rural services: organisational and support factors

1.8.4.1 Commissioners in rural areas (working with the TB control board) should consider collaborative approaches to deliver and manage TB services. They could, for example, set up a network including areas with high and low incidence of TB. **[new 2016]**

1.8.5 Local needs assessment

1.8.5.1 Directors of public health, in discussion with local health protection teams, should ensure that TB is part of the joint strategic needs assessment. **[2012, amended 2016]**

1.8.5.2 Directors of public health should provide commissioners of TB prevention and control programmes and TB control boards with local needs assessment information annually using data provided by Public Health England. **[2012, amended 2016]**

1.8.5.3 Commissioners of TB prevention and control programmes should ensure services reflect the needs of their area, identified by needs assessment.

Health and wellbeing boards should ensure that local TB services have been commissioned based on local needs identified through needs assessment. **[2012, amended 2016]**

1.8.5.4 Directors of public health and TB control boards should use cohort review (see section 1.8.6) and other methods to collect data on the following, to inform local needs assessment:

- Number of annual notified TB cases (see Public Health England's enhanced TB surveillance data and annual 'suite of indicators').
- Size, composition (for example, age and ethnicity) and distribution of local at-risk groups.
- Indices of social deprivation.
- Local statutory and non-statutory services working with these groups.
- Organisation of local TB services, including the composition and capacity of the local multidisciplinary TB team(see the results of local audit) and location of services. This may also include data to support evaluating the need for integrated TB/HIV services including joint clinics.
- Numbers needing enhanced case management (see the section on adherence, treatment completion and follow-up).
- Numbers receiving directly observed therapy from the start of, or at any point during, treatment (see Public Health England's enhanced TB surveillance data).
- Evidence of recent transmission (for example, using DNA fingerprinting or surrogate markers such as number of cases in children under 5 years (see UK TB national strain-typing database and local incident and outbreak reports).
- Completeness and yield of contact investigations. This includes: proportion of smear-positive cases with 0, 5 or more contacts identified; proportion of identified contacts clinically assessed; and proportion of contacts with latent TB infection who successfully complete treatment.
- Active case-finding initiatives, incident contact investigations and identification of latent TB infection in high-risk groups.

- Treatment outcomes for everyone grouped according to social risk factors and by the use of directly observed therapy (including rates of loss to follow-up and treatment interruptions, see Public Health England's enhanced TB surveillance data).
- Local education and awareness-raising programmes for under-served groups, professionals and practitioners working with them.
- Views and experiences of people with TB, carers and the services working with them. **[2012, amended 2016]**

1.8.5.5 Local needs assessments should also be equity proofed to assess the potential effect of planning, commissioning and policy decisions on health inequalities (see planning and commissioning services in NICE's local government briefing on health inequalities and population health). **[new 2016]**

1.8.6 Cohort review

1.8.6.1 TB control boards and prevention and control programme leads should initiate, audit and evaluate cohort reviews in their commissioning area. Quarterly cohort review meetings should take place in the area covered by the programme. Combine these meetings with others if possible, or use technology to make it easier for clinicians and case managers to attend. **[2012, amended 2016]**

1.8.6.2 TB case managers should present standardised information on each case, including: demographic information, HIV test results, pre-treatment and ongoing status (clinical, laboratory, radiology), adherence to treatment and the results of contact investigations. **[2012, amended 2016]**

1.8.6.3 TB case managers and key allied professionals from the TB prevention and control programme should attend cohort review meetings. This could include the lead clinician (who may or may not be the case manager). Either a paediatrician with experience and training in the treatment of TB or a general paediatrician with advice from a specialised clinician should be present when cases of children with TB are presented. **[2012, amended 2016]**

1.8.6.4 The chair of the cohort review should not work for any of the TB services included in the review. Examples of possible chairs include a public health consultant, a specialist physician or a senior TB nurse, preferably from a different geographical area. Alternatively the chair could be a representative from the local Public Health England health protection team or the TB control board. **[2012, amended 2016]**

1.8.6.5 Multidisciplinary TB teams, in conjunction with Public Health England units, should collate and present cohort review data on TB treatment and the outcome of contact investigations at the review meetings. In addition, progress towards national, regional and local service targets should be presented. **[2012, amended 2016]**

1.8.6.6 TB control boards, directors of public health and local public health consultants should ensure outputs from the cohort review feed into the needs assessment for TB services. TB control board directors should attend the cohort review at least once a year. **[2012, amended 2016]**

1.8.6.7 TB case managers should feed back promptly to multidisciplinary TB teams on issues identified as a result of cohort review. The results of the cohort review should be collated locally and agreed by the chair before being fed back to TB control boards, commissioners and health and wellbeing boards regularly and via needs assessment. **[2012, amended 2016]**

1.8.6.8 People participating in a cohort review should review the results and evaluate local services (for example, auditing adverse outcomes, rates of culture confirmation, treatment completion rates or time to diagnosis). **[2012, amended 2016]**

1.8.7 Commissioning multidisciplinary TB support

1.8.7.1 Commissioners should ensure multidisciplinary TB teams:

- Have the skills and resources to manage the care of people with active TB who are not from under-served groups. **[2012, amended 2016]**

- Include at least 1 TB case manager with responsibility for planning and coordinating the care of under-served people and those with active TB who receive enhanced case management. **[2012, amended 2016]**
- Have the resources to manage latent TB care in under-served groups and the wider population. **[new 2016]**
- Include a range of clinical specialties in the multidisciplinary TB team, including paediatrics, infection control and respiratory medicine. **[2012]**
- Have regular attendance at these multidisciplinary team and cohort review meetings for all team members included as a programmed activity as part of their work planning. **[new 2016]**
- Have the skills and resources necessary to manage the care of people with complex social and clinical needs (either directly or via an established route). This includes the ability to provide prompt access (or if necessary, referral) to skilled outreach and advocacy workers who can draw on the services of allied practitioners. The aim is to address people's housing, asylum, immigration, welfare, substance dependency and other health and social care needs. (The allied practitioner support should include both a specified housing officer and a social worker.) **[2012]**
- Can provide rapid access TB clinics for all cases, including under-served groups. **[2012]**
- Consider providing administration support for TB nurses and case managers so they have capacity for clinical and case management work. This could include giving TB nurses access to computer hardware and software. **[new 2016]**
- Have the resources to provide a continuous service throughout the year, ensuring the TB service accounts for the following to manage continuity of care:
  - planned absence (for example, professional development, mandatory training, annual, maternity or paternity leave)
  - unplanned absence (such as sickness absence). **[2012, amended 2016]**
- Can provide prompt access to a professional who has training and experience in assessing and protecting children and vulnerable adults at risk of abuse or neglect. **[2012]**

- Have access to funds through local government and clinical commissioning groups that can be used flexibly to improve adherence to treatment among under-served groups. For example, funds could be used to provide transport to clinics, to provide support or enablers for treatment, or for paying outreach workers or community services to support directly observed therapy. Funds may also be used to provide accommodation during treatment. **[2012, amended 2016]**

- Have the resources to provide ongoing TB awareness-raising activities for professional, community and voluntary (including advocacy) groups that work with populations at high risk of TB (see the section on raising and sustaining awareness of TB). These resources could be financed by local government or clinical commissioning groups. **[2012, amended 2016]**

1.8.7.2 Commissioners should ensure NHS England's safe staffing principles are applied when commissioning TB services.

The staffing ratios used in Public Health England and NHS England's collaborative tuberculosis strategy for England (published in 2015) came from NICE's guideline on tuberculosis: identification and management in under-served groups (published in 2012) which has been replaced by this guideline.

NICE's 2012 guideline on tuberculosis: identification and management in under-served groups recommended 1 WTE case manager per 40 incident cases needing standard management and 1 WTE case manager per 20 incident cases needing enhanced case management. **[new 2016]**

1.8.8 Non-clinical roles including TB support workers

1.8.8.1 TB control boards and local TB services should consider employing trained, non-clinically qualified professionals to work alongside clinical teams to agreed protocols, and to contribute to a variety of activities. Examples of this may include awareness raising and supporting people to attend appointments (including other health and social care appointments). They could also help with collecting samples, contact tracing, case management including directly observed therapy and cohort review, or any other aspect of the service if:

- they are trained to deliver the intervention or processes effectively
- they are supported, mentored and supervised by a named case manager, such as a TB nurse
- they have the skills to monitor, evaluate and report on their work practices and outcomes to maintain a process of ongoing evaluation and service improvement in relation to cohort review (see the section on cohort review). **[new 2016]**

1.8.8.2 TB control boards should ensure that people working in the TB service have the right knowledge, engagement, advocacy and communication skills to meet the needs (for example, language, cultural or other requirements) of all the groups they may work with. **[new 2016]**

1.8.8.3 Commissioners should consider taking into account different needs across traditional geographical and organisational boundaries. Put agreements in place so that staff can work across these boundaries, covering the whole service or TB control board area if appropriate. **[new 2016]**

1.8.8.4 Commissioners and TB control boards should ensure they put in place appropriate governance (including clear lines of accountability and extension of scope of practice) and data sharing practices and agreements. This includes ensuring they are part of service level agreements between NHS and non-NHS services, for example, the third sector or local government, and appropriate training has been completed. **[new 2016]**

1.8.9 Rapid-access TB services

1.8.9.1 Multidisciplinary TB teams should establish relationships with statutory, community and voluntary organisations that work with people at risk of TB to develop appropriate TB referral pathways. They should ensure these organisations know how to refer people to local TB services. **[2012]**

1.8.9.2 Multidisciplinary TB teams should accept referrals from healthcare providers and allied organisations working in the community with

under-served groups. This includes voluntary and statutory organisations (for example, mobile X-ray teams or community organisations or outreach workers working with vulnerable migrants). **[2012]**

1.8.9.3 Multidisciplinary TB teams should accept self-referrals to TB clinics by people who suspect they have TB or have recently been in contact with someone with TB. **[2012, amended 2016]**

1.8.9.4 Multidisciplinary TB teams should consider accepting direct referrals from emergency departments (see the section on rapid-access radiology and other investigation results: referral to multidisciplinary TB team process). **[new 2016]**

1.8.9.5 Healthcare professionals should consider urgent referral to TB clinics for people with suspected active TB. They should also ensure the results from first-line diagnostic tests (including a sputum smear and chest X-ray) are available before the person sees a specialist. (Note: this should not delay the referral.) **[2012, amended 2016]**

1.8.9.6 Multidisciplinary TB teams should have pathways to triage referrals, start investigations and collect clinical information before the person is seen by a physician. **[new 2016]**

1.8.9.7 While triaging, multidisciplinary TB teams should ensure everyone is given information about TB as part of the process (see the section on providing information for the public about TB). This should include who the person should contact if they have any questions and how to access advice or information from support groups, national charities such as TB Alert and other sources such as local government (for example, public health or social care teams). **[2016]**

1.8.9.8 Multidisciplinary TB teams should ensure people who have a smear-positive result or imaging features highly suggestive of smear-positive TB (for example, evidence of cavitation on chest X-ray) are assessed the next working day. This is so that case management and infection control procedures start promptly. **[2012, amended 2016]**

1.8.9.9 The multidisciplinary TB team should assess people who are not

smear-positive but have imaging that suggests pulmonary or laryngeal TB as soon as possible. This should be no later than 5 working days after a referral. **[2012, amended 2016]**

1.8.9.10 Multidisciplinary TB teams should, where necessary, be able to provide or arrange outreach services to ensure sputum samples or other assessments such as contact investigations can be arranged in the community. **[2016]**

1.8.10 Identifying and managing active TB in prisons, custody suites or immigration removal centres: organisational factors

1.8.10.1 Multidisciplinary TB teams, prisons, custody suites and immigration removal centre healthcare services should have named TB liaison leads to ensure they can communicate effectively with each other. **[2012, amended 2016]**

1.8.10.2 Prison, custody suites and immigration removal centre healthcare services should develop a TB policy by working with the TB control board and multidisciplinary TB team and the local Public Health England health protection team. **[2012, amended 2016]**

1.8.10.3 Multidisciplinary TB teams, in conjunction with prisons, custody suites and immigration removal centre healthcare services, should agree a care pathway for TB. This is to ensure that any suspected or confirmed cases are reported to, and managed by, the multidisciplinary TB team. **[2012, amended 2016]**

1.8.10.4 Multidisciplinary TB teams, in liaison with prisons, custody suites or immigration removal centre healthcare providers, should manage all cases of active TB. Investigations and follow-up should be undertaken within the prison or immigration removal centre if possible. **[2012, amended 2016]**

1.8.11 Accommodation during treatment

1.8.11.1 Multidisciplinary TB teams should assess the living circumstances of people with TB. Where there is a housing need they should work with

allied agencies to ensure that all those who are entitled to state-funded accommodation receive it as early as possible during their treatment, for example, as a result of a statutory homelessness review and identified need. **[2012, amended 2016]**

1.8.11.2 Multidisciplinary TB teams, commissioners, local authority housing lead officers and other social landlords, providers of hostel accommodation, hospital discharge teams, Public Health England and the Local Government Association should work together to agree a process for identifying and providing accommodation for homeless people diagnosed with active pulmonary TB who are otherwise ineligible for state-funded accommodation. This includes people who are not sleeping rough but do not have access to housing or recourse to public funds. The process should detail the person's eligibility and ensure they are given accommodation for the duration of their TB treatment. **[2012, amended 2016]**

1.8.11.3 Local government and clinical commissioning groups should fund accommodation for homeless people diagnosed with active TB who are otherwise ineligible for state-funded accommodation. Use health and public health resources, in line with the Care Act 2014. **[2012, amended 2016]**

1.8.11.4 Multidisciplinary TB teams should make people who would not otherwise be entitled to state-funded accommodation aware that they may lose this accommodation if they do not comply with treatment. They should ensure plans are made to continue housing people once their TB treatment is completed. **[2012]**

1.8.11.5 Public Health England, working with the Local Government Association and their special interest groups, should consider working with national housing organisations such as the Chartered Institute of Housing, Homeless Link, Sitra and the National Housing Federation to raise the profile of TB. This is to ensure people with TB are considered a priority for housing. **[new 2016]**

1.8.11.6 Consider training housing commissioners and frontline staff on TB and the need for housing support, so that they understand that a stable

home life is a prerequisite to successful TB treatment. **[new 2016]**

Terms used in this guideline

Active case-finding

Systematically identifying people with active or latent TB using tests, examinations or other procedures.

Adherence

The term adherence refers to the person's ability or willingness to keep to a treatment regimen as directed.

Adults

People aged 18 or older.

Case management

Case management involves follow-up of a person suspected or confirmed to have TB. It needs a collaborative, multidisciplinary approach and should start as soon as possible after a suspected case is discovered.

Case manager

Standard and enhanced case management is overseen by a case manager who will usually be a specialist TB nurse or (in low-incidence areas) a nurse with responsibilities that include TB. Depending on the person's circumstances and needs, case management can also be provided by appropriately trained and supported non-clinical members of the TB multidisciplinary team.

Children

People aged 15 or younger.

Children and young people

People aged 17 or younger.

Close contacts

'Close contacts' are people who have had prolonged, frequent or intense contact with a person with infectious TB. For example, these could include 'household contacts', those who share a bedroom, kitchen, bathroom or sitting room with the index case. Close contacts may also include boyfriends or girlfriends and frequent visitors to the home of the index case. Depending in the circumstances, occasionally coworkers are classed as 'close contacts although they are more usually classed as 'social contacts'.

Cohort review

Cohort review is a systematic quarterly audit of the management and treatment of all TB patients and their contacts. The 'cohort' is a group of cases counted over a specific time, usually 3 months. Brief details of the management and outcomes of each case are reviewed in a group setting. The case manager presents the cases they are responsible for, giving the opportunity to discuss problems and difficulties in case management, service strengths and weaknesses, and staff training needs.

Congregate setting

A place where people congregate or an institutional setting such as a workplace, prison, hostel, or childcare or educational setting, where social contacts might have had significant exposure to TB.

Contact

A person who has spent time with someone with infectious TB. See also 'close contact' and 'social contact'.

Contact investigation

Clinical investigations (diagnostic testing) of people identified as having had significant exposure to a case of TB, including tests to diagnose latent or active TB. The aims of

contact investigations are to:

- detect active TB earlier to offer treatment and prevent further transmission
- detect latent TB that may benefit from drug treatment
- detect people not infected but for whom BCG vaccination might be appropriate.

Contact tracing

Identifying people who may have come into contact with a person with infectious TB and assessing them for risk of significant exposure to TB. The aim is to find associated cases, to detect people with latent TB and to identify those not infected but for whom BCG vaccination might be appropriate.

Disseminated TB

Blood-borne spread of TB that may or may not be accompanied by chest X-ray or high resolution CT changes.

Enablers

Methods of helping someone to overcome barriers to completing diagnostic investigations and TB treatment. Examples of barriers include: transport, housing, nutrition and immigration status.

Enhanced case management

Management of TB for someone with clinically or socially complex needs. It starts as soon as TB is suspected. As part of enhanced case management, the need for directly observed treatment is considered, along with a package of supportive care tailored to the person's needs.

Equity proofed

Tools such as health equity audit and health impact assessment have been used systematically to assess the potential effect of all policies, programmes and activities (including those without an explicit health focus) on health inequalities. Equity proofing

helps ensure all policies and programmes address the social determinants of health and health inequalities. Including a health equity audit as part of the joint strategic needs assessment can help local authorities and their partners to:

- develop strategy and plans according to need
- identify and work with community and health partners
- commission activities based on the best available evidence
- implement interventions to tackle inequity.

End-to-end pathway

The pathway from awareness raising and primary prevention, through diagnosis to treatment completion, incorporating all aspects such as contact tracing and other infection control mechanisms, for example, access to isolation facilities. This includes governance and commissioning considerations so that a comprehensive clinical and public health service is developed and delivered across any agreed geographical footprint.

Extrapulmonary TB

Active TB disease in any site other than the lungs or tracheobronchial tree.

Extensively drug-resistant TB

Resistance to at least isoniazid and rifampicin, 1 injectable agent (capreomycin, kanamycin or amikacin) and 1 fluoroquinolone.

High incidence

A high-incidence country or area has more than 40 cases of TB per 100,000 people per year. Public Health England lists high-incidence countries and areas of the UK on its website.

High-risk groups

The term 'high-risk groups' is used in this guideline to mean adults, young people and

children from any ethnic background, regardless of migration status, who are at increased risk of having or contracting TB. This includes people classified as under-served, people identified as contacts according to the case finding recommendations, new entrants from high-incidence countries and people who are immunocompromised.

Homelessness

For the purposes of TB control, a broad and inclusive definition of homelessness has been adopted that incorporates overcrowded and substandard accommodation. It includes people:

- who share an enclosed air space with people at high risk of undetected active pulmonary TB (that is, people with a history of rough sleeping, hostel residence or substance misuse)
- without the means to securely store prescribed medication
- without private space in which to self-administer TB treatment
- without secure accommodation in which to rest and recuperate in safety and dignity for the full duration of planned treatment.

Immigration removal centres

Immigration removal centres are private or prison-run holding centres for migrants waiting to be accepted by, or deported from, the UK. Immigration removal centres are also known as immigration detention centres and pre-departure accommodation.

Immunocompromised

In this guideline, immunocompromised refers to a person who has a significantly impaired immune system. For instance, this may be because of prolonged corticosteroid use, tumour necrosis factor-alpha antagonists, antirejection therapy, immunosuppression-causing medication or comorbid states that affect the immune system, for example, HIV, chronic renal disease, many haematological and solid cancers, and diabetes.

Incident risk assessment

Assessment of risk of exposure to TB in a congregate setting to decide on the need for and extent of contact investigation. The risk assessment would take into consideration factors such as infectiousness of the index case, vulnerability of contacts to TB infection, length of contact with or exposure to an infectious case and the built environment (for example, size of the rooms, ventilation and overcrowding).

Index case

The initial person found to have TB, whose contacts are screened. The source of their infection may be found to be 1 of the contacts, but the person who presents first is regarded as the index case.

Induration

The firm skin reaction occurring after a tuberculin skin test to diagnose latent TB infection. It is measured, and the result used to determine whether the test result is classified as positive or negative. This guideline recommends a threshold of 5 mm for tuberculin skin test positivity.

Infectious TB

Active smear-positive pulmonary TB, that is with acid fast bacilli visible on microscopy. Active TB affecting other parts of the respiratory tract or oral cavity, though rare, is also considered infectious.

Isolation

An infection control measure in which people with infectious TB are kept away from others who may be at risk of infection. This guideline deals with 3 levels of isolation for infection control in hospital settings:

- negative pressure rooms, which have air pressure continuously or automatically measured, as defined by NHS Property Services
- single rooms that are not negative pressure but are vented to the outside of the building

- beds on a ward, for which no particular engineering standards are needed.

Lost to follow-up

People are defined as 'lost to follow-up' if they cannot be contacted within 10 working days of:

- their first missed outpatient appointment (if they are on self-administered treatment)
- their first missed directly observed therapy appointment (if they are on directly observed therapy).

Multidisciplinary TB teams

A team of professionals with a mix of skills to meet the needs of someone with TB who also has complex physical and psychosocial issues (that is, someone who is under-served). Team members will include a social worker, voluntary sector and local housing representatives, TB lead physician and nurse, a case manager, a pharmacist, an infectious disease doctor or consultant in communicable disease control or health protection, a peer supporter or advocate and a psychiatrist.

Multidrug-resistant TB

TB resistant to isoniazid and rifampicin, with or without any other resistance.

Negative pressure room

Used to isolate some patients known or suspected to have infectious TB. A negative pressure room is one where the air from the room is sucked out into dedicated ducting through a filter and into the outside air, at a distance from all other air intakes. The pressure should be 10 pascals below the ambient air pressure.

Neonates

Children aged 4 weeks or younger.

New entrant

Anyone coming to work or settle in the UK. This includes immigrants, refugees, asylum seekers, students and people on work permits. It also includes UK-born people, or UK citizens, re-entering the country after a prolonged stay in a high-incidence country.

Opportunistic case-finding

Opportunistic identification of people with active or latent TB using tests, examinations or other procedures in the course of existing appointments or interactions, rather than identification through formal screening programmes.

Outbreak

There is no robust, widely accepted threshold for an outbreak of a disease, but in practical terms an outbreak is the occurrence of an unusually high number of cases in associated people, in a small geographical area, or in a relatively short period of time.

Peers

Peers are people who may have experienced TB. They are often in a good position to help convey, with empathy, the need for testing or treatment. They may be recruited from specific populations. With support they can communicate health messages, assist with contact investigations or testing and offer people support while they are being tested or treated.

Prisons

Any state prison establishments, including young offender institutions.

Rapid access

In the context of TB services, rapid access refers to timely support from a specialist team.

Smear grade

The number of bacilli found in a sputum sample, believed to relate to the degree of

infectivity of the person. There are several systems but in general recording goes from no mycobacteria in 100 fields (0 or negative) to more than 10 acid-fast bacilli per field in at least 20 fields (grade 3).

Social contacts

Someone who has had contact with a person with infectious TB but has not been in prolonged, frequent or intense contact.

Substance misuse

Substance misuse is defined as intoxication by, or regular excessive consumption of or dependence on, psychoactive substances, leading to social, psychological, physical or legal problems. It includes problematic use of both legal and illegal drugs.

TB control board

A partnership of mixed professionals and lay people who have experience of leading, commissioning, managing or supporting people with TB. Board members are likely to include the voluntary sector, housing representatives, TB specialists and other clinicians, consultants in communicable disease control or health protection, peer supporter and advocate groups, clinical commissioning groups, executive officers, local government commissioners and an independent chair. This list is not intended to be exhaustive; membership should be determined based on an area's needs, agreements and commissioning arrangements.

Treatment interruption

A break in the prescribed anti-TB regimen for 2 weeks or more in the initial phase, or more than 20% of prescribed doses missed intermittently.

Under-served groups

This term is used in this guideline to mean groups of adults, young people and children from any ethnic background, regardless of migration status. They are 'under-served' if their social circumstances, language, culture or lifestyle (or those of their parents or carers) make it difficult to:

- recognise the clinical onset of TB
- access diagnostic and treatment services
- self-administer treatment (or, in the case of children and young people, have treatment administered by a parent or carer)
- attend regular appointments for clinical follow-up.

The groups classified as under-served in this guideline are:

- people who are homeless
- people who misuse substances
- prisoners
- vulnerable migrants.

Under-served children

Groups of children identified as potentially under served include:

- unaccompanied minors
- children whose parents are under served, including vulnerable migrants
- children whose parents are in prison or who abuse substances
- children from Gypsy and Traveller communities
- looked-after children.

Vulnerable migrants

Vulnerable migrants may include undocumented migrants and those with no recourse to public funds. Some refugees, asylum seekers and new entrants to the country may also fall into this category.

Young people

People aged 16 or 17.

Context

Tuberculosis (TB) is a curable infectious disease caused by a type of bacterium called *Mycobacterium tuberculosis* ('M. tuberculosis' or 'M.Tb'), or other bacterium in the M. tuberculosis complex (that is*, M. bovis* or *M. africanum*). It is spread by droplets containing the bacteria being coughed out by someone with infectious TB, and then being inhaled by other people.

The initial infection clears in over 80% of people but, in a few cases, a defensive barrier is built round the infection and the TB bacteria lie dormant. This is called latent TB; the person is not ill and is not infectious. If the immune system fails to build the defensive barrier, or the barrier fails later, latent TB can spread in the lung (pulmonary TB) or develop in the other parts of the body it has spread to (extrapulmonary TB). Only a small proportion of people with latent TB will develop symptoms ('active TB').

Many cases of TB can be prevented by public health measures and, when clinical disease does occur, most people can be cured if treated properly. Taking medication in the wrong dose or combination, irregularly or for too short a time can lead to drug resistance. Drug-resistant strains of TB are much harder to treat and significantly increase a person's risk of long-term complications or death. If left untreated, 1 person with active pulmonary TB may infect as many as 10 to 15 people every year.

TB incidence in the UK has increased since the early 1990s, but has remained relatively stable since 2005. Despite this, it remains high compared with many other western European countries. Cases tend to cluster in urban areas where populations of at-risk groups are high. These include areas with many people born in countries with a high incidence of TB, areas with a high level of homelessness, poor housing or poverty, and areas with high rates of problem drug use.

The NHS and Public Health England, as well as a local authority public health teams and many third sector organisations, have been working to reduce the harm caused by TB to many individuals and communities. TB is a notifiable disease, meaning that clinicians have a statutory duty to notify local authorities or a local Public Health England centre of suspected cases, and efforts have been made to strengthen services and ensure clear lines of accountability and responsibility. However, a stronger approach to TB control is now needed to build on this work. Indicators of TB incidence and TB treatment outcomes have been included in the Public Health Outcomes Framework. In addition, Public Health

England and NHS England have designed a collaborative tuberculosis strategy for England that brings together best practice in clinical care, social support and public health. Agencies at all levels, including national and local government, clinical commissioning groups and third sector partners, are committed to working in partnership to decrease the incidence of TB, fight the spread of drug-resistant forms of the disease, reduce current health inequality and, ultimately, eliminate TB as a public health problem in England.

Recommendations for research

The guideline committee has made the following recommendations for research. The guideline committee's full set of research recommendations is detailed in the full guideline.

1 Universal compared with risk-based approach to using rapid diagnostic tests

In people with suspected TB, what is the relative clinical and cost effectiveness of universal and risk-based use of rapid nucleic acid amplification tests?

Why this is important

The guideline committee noted that there were 2 possible approaches to using rapid nucleic acid amplification tests for suspected TB. The current approach is to use them only if TB is strongly suspected and rapid information about mycobacterial species would alter the person's care. Another approach is to use them in anyone with a possible diagnosis of TB. There is a trade-off between ensuring that all people with active TB are diagnosed and avoiding a large number of false positives, which leads to unnecessary treatment. This trade-off may lead to differences in the cost effectiveness of each approach. NICE's systematic review of the diagnosis of active TB did not identify any robust evidence on this, nor did the health technology assessment on using nucleic acid amplification tests to detect drug resistance. Cost-effectiveness studies are needed to improve understanding in this area.

2 Diagnosis in children

Apart from culture, what other diagnostic tests or combinations of tests are effective in establishing an accurate diagnosis of active respiratory TB in children and young people with suspected active TB?

Why this is important

The guideline committee noted the lack of evidence on the diagnosis of active TB in children. The disease manifests differently in children than in adults, and more evidence

would have been useful to the committee. Cross-sectional studies are needed to examine the relative accuracy of different tests, and the most appropriate specimen type for these tests, compared with tests currently in use. In particular, the poor accuracy of many tests in children means that diagnostic strategies that is, combinations of tests, should be investigated, including both tests with high sensitivity and tests based on host response.

3 Treating isoniazid-resistant TB

For isoniazid-resistant TB, what is the most effective regimen for reducing mortality and morbidity?

Why this is important

There is little evidence for the treatment of isoniazid resistant TB. This is the most common form of drug resistance in the UK, occurring in 7.5% of TB cases. Currently, treatment is not always successful, even when the recommended drugs are given for the recommended time and there are no adherence issues. It is particularly difficult to treat if there are treatment interruptions or if the central nervous system is involved. Randomised controlled trials are needed to compare different anti-TB regimens for isoniazid-resistant TB, assessing mortality, treatment success or treatment failure, rates of relapse and adverse events.

4 Impact of infection control measures on quality of life

What effects does isolation have on the quality of life of people being treated for TB?

Why this is important

Isolation is known to significantly affect a person's quality of life. Despite this, the guideline committee identified no reliable data on the impact of isolation on quality of life. This information is essential in producing economic models that reflect the real costs of isolation. Data on the impact of isolation on quality of life need to be collected and reported.

5 Treatment interruptions caused by adverse

events (specifically hepatotoxicity)

For people with active, drug susceptible TB who experience treatment interruptions because of adverse events, particularly hepatotoxicity, what approach to re-establishing treatment is most effective in reducing mortality and morbidity?

Why this is important

There is little evidence on re-establishing treatment after interruptions because of adverse events. This is key to ensuring treatment success without relapse or the emergence of drug resistance, but avoiding further adverse events is also important. Randomised controlled trials are needed to compare approaches to re-establishing treatment for active, drug susceptible TB after it is interrupted because of adverse events, particularly hepatotoxicity. These trials should assess mortality, treatment success or failure, rates of relapse, the recurrence of adverse events and the emergence of drug resistance. Approaches evaluated could compare, for example, restarting regimens with lengthening their duration, as well as sequential reintroduction. Approaches should vary depending on the proportion of doses missed and the stage of treatment (initial or continuation phase) in which the interruption occurred. Prospective observational cohort studies with multivariable analyses may also be useful.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic pages on tuberculosis and vulnerable groups.

For full details of the evidence and the guideline committee's discussions, see the full guideline. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

Update information

September 2019: Minor wording changes have been made to recommendation 1.7.4.2 and footnotes added to reflect new restrictions and precautions for the use of fluoroquinolone antibiotics. It is labelled **[new 2016, amended 2019]**.

June 2019: Recommendation 1.6.1.8 has been amended to add in more detail about the meaning of contacts.

November 2018: Recommendation 1.1.3.16 on BCG vaccinations for healthcare workers and other NHS employees was updated after a surveillance review.

May 2016: Recommendation 1.2.1.1 was clarified to reflect the sequencing of tests. Reference to IGRA status was removed from recommendations 1.1.3.13; 1.1.3.16-18; 1.1.4.6; 1.1.4.8 and 1.6.1.4.

February 2016: Recommendation 1.1.3.4 has been amended to clarify that the recommendation is about assessing risk for and vaccinating the baby.

January 2016: This guideline was published. It is an update of NICE guideline CG117 (published March 2011) and replaces it. It also incorporates and adapts NICE guideline PH37 (published March 2012).

Through the scoping process we work with stakeholders to identify, prioritise and agree areas of the guideline to update. This means that areas outside the scope were not reviewed during this update and the recommendations may not reflect current practice. Areas that have not been reviewed in this update may be addressed 2 years after publication, when NICE next considers updating this guideline. NICE may undertake an update of discrete areas of the guideline if new and relevant evidence is published.

Recommendations are marked as:

- **[new 2016]** if the evidence has been reviewed and the recommendation has been added or updated
- **[2016]** if the evidence has been reviewed but no change has been made to the recommended action

- **[2006]** if the evidence has not been reviewed since 2006
- **[2006, amended 2011]** or **[2011]** if the evidence has not been reviewed since 2006
- **[2012]** if the evidence has not been reviewed since 2012
- **[2006, amended 2011, amended 2016]** or **[2011, amended 2016]** if the evidence has not been reviewed since 2011, but either changes have been made to the recommendation wording that change the meaning or NICE has made editorial changes to the original wording to clarify the action to be taken (see below).
- **[2006, 2012, amended 2016]** or **[2012, amended 2016]** if the evidence has not been reviewed since 2012, but either changes have been made to the recommendation wording that change the meaning or NICE has made editorial changes to the original wording to clarify the action to be taken (see below).

Recommendations from NICE guideline CG117 that have been amended

Recommendations are labelled **[2011, amended 2016] and [2006, amended 2011, amended 2016]** if the evidence has not been reviewed but either:

- changes have been made to the recommendation wording that change the meaning, or
- NICE has made editorial changes to the original wording to clarify the action to be taken.

Further details of the specific changes to the recommendations during the 2016 update are available on request.

Recommendations from NICE guideline PH37 that have been amended

Recommendations are labelled **[2012, amended 2016]** if:

- The evidence has not been reviewed, but a change has been made to clarify roles or actions in the original recommendation, extrapolate to the whole population, or where system changes such as establishment of TB control boards have been reflected
- NICE has made editorial changes to the wording to clarify the action to be taken, but where there is no change of meaning to the original recommendation.

Further details of the specific changes to the recommendations during the 2016 update are available on request.

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Accreditation

From: Currie, Brian [redacted]
Sent: 03 December 2019 09:17
To: MCLAUGHLAN, Edward (NHS NATIONAL SERVICES SCOTLAND); STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND); Gillies, Tracey; george.curley@[redacted] 'John Rayner'; Guthrie Lindsay (NHS LOTHIAN); Inverarity Donald (NHS LOTHIAN); Reilly Laura (NHS LOTHIAN); McGill, Julie; Greer, Graeme; Henderson Ronnie (NHS LOTHIAN); IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND)
Cc: MORGAN, Mary (NHS NATIONAL SERVICES SCOTLAND); Susan.Goldsmith[redacted] iain.graham[redacted] alex.mcmahon@[redacted] sorrel.cosens[redacted]
Subject: RHCYP + DCN - Little France - HIgh Value Change 107 - Ventilation Works to Paediatric Critical Care and Haematology / Oncology
Attachments: HVC 107 - Paediatric Critical Care and Haemonc Ventilation_FOR APPROVAL_05_12_19.pdf

Importance: High

Following recent requirements communicated by the Board's Chief Executive and as endorsed by the Executive Steering Board, the attached High Value Change Notice is required to be approved by the parties listed below.

I would be grateful for your response by midday tomorrow, 4th December, 2019, to allow consideration and hopefully final approval by the Oversight Board on Thursday morning of this week.

	Approval Required
Project Manager	*Ronnie Henderson*
Project Technical Adviser	*Mott MacDonald*
Service leads	*Laura Reilly and Julie McGill*
Infection Control	*Lyndsay Guthrie and Donald Inverarity*
Authorising Engineer	*John Rayner*
Project Director	*Brian Currie*
Director of Facilities	*George Curley*
Executive Director	*Tracey Gillies*
HFS	*Eddie McLaughlan and/or Ian Storrar*
HPS	*Laura Imrie*

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

High Value Change Notice

Project:	RHCYP + DCN – Little France Edinburgh

1 – Issue of Change Notice to Project Co			
Title:	**Paediatric Critical Care and Haematology / Oncology Ventilation**		
Reference No: 0107		**Date: 5th December, 2019**	
Target Cost Capital:	**£4.6m**	**Target Cost Revenue:**	**TBA**

High Value Change Requirements (Schedule Part 16, Section 4, Clause 2.1.3)

Single bedrooms and Multi-bedrooms in Paediatric Critical Care

In accordance with Schedule Part 16 (Change Protocol), Project Co is required to design, manufacture, supply, construct, test, commission and complete, and thereafter throughout the Operational Term, provide Services to, maintain, repair, renew and replace, a ventilation system or systems which will deliver **10 air changes/hour at +10pa** as per SHTM 03-01, Appendix 1, Table A1 to the following rooms at the Facilities:

Room Number	Room Type
1-B1-065	*Neo Natal 3 cot area* including 1-B1-022 – *Corridor*, 1-B1-069 – *Staff Base*, 1-B1-066 – *Clean Utility* and 1- B1-071 – *Resus Bay* which are all open to 1-B1-065
1-B1-075	*Single cot cubicle neo natal* including *1-B1-074 en-suite*
1-B1-063	*Open plan bay 4 bed*
1-B1-037	*Single bed cubicle*
1-B1-031	*Open plan bay 4 bed*
1-B1-021	*Single bed cubicle*
1-B1-020	*Single bed cubicle*
1-B1-019	*Single bed cubicle*
1-B1-009	*Open plan bay 4 bed*

Isolation Rooms in Paediatric Critical Care

In accordance with Schedule Part 16 (Change Protocol), Project Co is required to design, manufacture, supply, construct, test, commission and complete, and thereafter throughout the Operational Term, provide Services to, maintain, repair, renew and replace, a ventilation system or systems for a positive pressure ventilated lobby PPVL Single Bedroom Isolation Suite with a lobby air supply terminal with a HEPA filter, as per SHTM 03-01, SHPN 04-01, Supplement 1: Isolation Facilities in Acute Settings (Version 1.0 September 2008) Table 1, to the following rooms at the Facilities.

Project Co may utilise the supply and extract ventilation system description in SHPN 04-01, Supplement 1, Clause 4.5 for a dedicated ventilation system per Suite or SHPN 04-01, Supplement 1, Clause 4.8 for a common ventilation system to multiple Suites as the basis of their design. If Clause 4.8 is selected as the basis of design, a duplicate supply unit is considered necessary. A combination of both methods may be used provided Project Co, as far as is reasonably practical, reuse the existing ventilation installations. Regardless of option chosen, all aspects of the design and installation must be technically compliant with all relevant guidance.

NHSL require to remove or significantly reduce the risk of losing all isolations rooms due to a single point of failure. Ideally each isolation room would benefit from its own supply and extract, however, NHSL appreciate this may not be possible or practical due to other constraints e.g. space. Therefore, Project Co are requested to provide their best practical solution to reduce the risk as low as possible but maintaining guidance criteria as per SHTM 03-01, SHPN 04-01, Supplement 1: Isolation Facilities in Acute Settings (Version 1.0 September 2008) Table 1.

Room Number	Room Type
1-B1-016	Isolation Bedroom
1-B1-017	Isolation Bedroom
1-B1-026	Isolation Bedroom

1-B1-036	Isolation Bedroom

Single bedrooms and Multi-bedrooms in Haematology and Oncology

In accordance with Schedule Part 16 (Change Protocol), Project Co is required to design, manufacture, supply, construct, test, commission and complete, and thereafter throughout the Operational Term, provide Services to, maintain, repair, renew and replace, a ventilation system or systems which will deliver **10 air changes/hour at +10pa** as per SHTM 03-01, Appendix 1, Table A1 and fit Hepa filters (H12 grade) to the air inlets to the following rooms at the Facilities:

Room Number	Room Type
3-C1.4-059	Single Bedroom
3-C1.4-057	Single Bedroom
3-C1.4-055	Single Bedroom
3-C1.4-046	Single Bedroom
3-C1.4-032	Single Bedroom
3-C1.4-018	Single Bedroom
3-C1.4-016	Single Bedroom
3-C1.4-013	Single Bedroom
3-C1.4-010	Single Bedroom
3-C1.4-074	Single Bedroom
3-C1.4-076	Single Bedroom
3-C1.4-078	Single Bedroom
3-C1.4-084	Multi-Bed (3) Day Care
3-C1.4-061	Multi-Bed (6) Day Care

Isolation Rooms in Haematology and Oncology

In accordance with Schedule Part 16 (Change Protocol), Project Co is required to design, manufacture, supply, construct, test, commission and complete, and thereafter throughout the Operational Term, provide Services to, maintain, repair, renew and replace, a ventilation system or systems for a positive pressure ventilated lobby PPVL Single Bedroom Isolation Suite with a lobby air supply terminal with a HEPA filter, as per SHTM 03-01, SHPN 04-01, Supplement 1: Isolation Facilities in Acute Settings (Version 1.0 September 2008) Table 1, to the following rooms at the Facilities.

Project Co may utilise the supply and extract ventilation system description in SHPN 04-01, Supplement 1, Clause 4.5 for a dedicated ventilation system per Suite or SHPN 04-01, Supplement 1, Clause 4.8 for a common ventilation system to multiple Suites as the basis of their design. If Clause 4.8 is selected as the basis of design, a duplicate supply unit is considered necessary. A combination of both methods may be used provided Project Co, as far as is reasonably practical, reuse the existing ventilation installations. Regardless of option chosen, all aspects of the design and installation must be technically compliant with all relevant guidance.

NHSL require to remove or significantly reduce the risk of losing all isolations rooms due to a single point of failure. Ideally each isolation room would benefit from its own supply and extract, however, NHSL appreciate this may not be possible or practical due to other constraints e.g. space. Therefore, Project Co are requested to provide their best practical solution to reduce the risk as low as possible but maintaining guidance criteria as per SHTM 03-01, SHPN 04-01, Supplement 1: Isolation Facilities in Acute Settings (Version 1.0 September 2008) Table 1.

Room Number	Room Type
3-C1.4-040	Isolation Bedroom
3-C1.4-043	Isolation Bedroom
3-C1.4-049	Isolation Bedroom

3-C1.4-052	Isolation Bedroom
3-C1.4-072	Isolation Bedroom

(the "**Ventilation Works and Services**").

All environmental requirements for all spaces in the Facilities served by or affected by the Ventilation Works and Services systems shall be met and maintained – including but not limited to, temperature and control, lighting levels, noise, and humidity. These should be consistent to the agreed parameters throughout the Facilities to meet the specific clinical and operational needs for each space in the Facilities.

The Ventilation Works and Services shall fully comply with SHTM 03-01 requirements which includes, without limitation, implementation of the Ventilation Works and Services so that the system installation, finishes and maintenance regime shall be in accordance with SHTM 03-01 requirements, together with the clinical and operational constraints identified below:

1. All Ventilation Works and Services shall be carried out and monitored after and with reference to a collaborative full Stage 3 HAI SCRIBE assessment being approved by the Board.
2. The fire strategy and systems agreed for the Facilities will be maintained throughout the Ventilation Works and Services and the Operational Term and such that the ventilation systems will integrate with the fire strategy and systems and all other building management systems comprised in the Facilities.
3. The location of the installation within the rooms, external areas, route across such spaces and the take out of any windows, etc, will enable the current operational functionality and safety policies and procedures to be maintained.
4. The design, layouts, finishes and other details etc for the Ventilation Works and Services, at all stages (including during the design development stages), will require to be agreed with the Board's Representative (and in turn the clinical service and related stakeholders and Project Co recognises that in order to achieve agreement from the Board's Representative's the Board's Representative will seek input from the Board and all appropriate stakeholders.
5. Design must provide resilience in compliance with SHTM 03-01 to ensure performance of ventilation to rooms during maintenance downtime.

The Board will, in consultation with Project Co, continue to review costs as the design develops and at other stages. In order for the Board to assess whether the High Value Change Stage 2 Submission offers it value for money the submission shall include as a minimum the following information:

- A detailed and fully quantified pricing schedule for the construction works
- A detailed breakdown of all Preliminaries and general cost items
- Construction issue drawings and specification
- Proposed, construction and commissioning/testing programme
- Construction phase method statement

Date by which parties are required to meet to review the High Value Change Notice and agree the content for the High Value Change Proposal (Schedule Part 16, Section 4, Clause 2.3.1)	**13th December, 2019**

To: **IHS Lothian**

We require the Change described above.
Please advise when Project Co will submit a High Value Change Proposal for the above.

Signed on behalf of NHS Lothian: ……..

Name of Signatory (type or print): ……Brian Currie – Board Rep – NHS Lothian……

Date: 5th December, 2019 ……..

SBAR assessment: Outpatient and therapy areas: Ventilation Room Review RHCYP DCN

Lindsay Guthrie, Lead IPCN

Dr Donald Inverarity, Consultant Microbiologist and Lead ICD

1. **Situation:**

NHS Lothian are required by the Oversight Board "*to consider its clinical service model in light of the ventilation arrangements in place for general wards and other non critical areas (incorporating literature review and design information not yet available)*".

A clinical risk assessment of ventilation installed has been provided in relation to in patient (ward) areas.

A separate review of all outpatient and therapies areas was undertaken in September 2019 by a clinical lead from the project team (Dorothy Hanley); lead infection prevention and control nurse (Lindsay Guthrie) and lead infection control doctor & consultant microbiologist (Dr Donald Inverarity) with project management support from Kelly Bain & Ross Southwell (Mott McDonald).

2. **Background:**

No specific provision is made within SHTM 03-01 Part A Appendix 1 for the ventilation requirements for outpatient consultation rooms, therefore requirements are calculated using other building standards, which take into account the size of the room, availability of natural ventilation (opening window) and maximum number of people intended to use the space at any given time.

This means that rooms which appear on the matrix or hospital plan to have the same named function may have been designed with different ventilation requirements.

The environmental matrix was reviewed to assess the ventilation design specification for all rooms designated as:

- Treatment rooms
- Consultation rooms
- Clinical rooms
- Therapy rooms
- Investigation rooms

Consideration was then given to the risk profile of patients who would use these rooms, and the type of activity regularly undertaken on an outpatient basis.

The outcome of the preliminary independent verification of commissioning testing by IOM was reviewed to confirm that the system is functioning to the design parameters.

3. **Assessment**

3.1 Overall, there were no significant concerns or issues identified in relation to any impact on factors that would compromise delivery of infection prevention and control procedures and ventilation delivered based on the stated intended clinical use of the space and patient population.

3.2 Where treatment rooms were provided, particularly in areas which will see or treat high susceptibility patients (such as paediatric haematology/oncology) these were confirmed to have been designed and performing to deliver 10 air changes per hour at positive pressure in line with the requirements of SHTM 03-01 Part A Appendix 1.

3.3 It was noted that where some consulting rooms were designed to provide 6 air changes, not all such rooms included an opening window, sometime due to the location of the room within the building.

3.4 A multi bed bay in the clinical research facility was designed as contingency to be 'flexed' up to provide additional inpatient accommodation if required for overnight research studies in the future. The environmental matrix for this area showed the ventilation was designed to provide 3 air changes. Based on SHTM 03-01 Part A Appendix 1 this room should achieve 6 air changes if it is intended to be used for in patient accommodation, and is therefore not compliant with current guidance. Further risk assessment is required if the area is used for in patient use [*Recommendation 4.1*].

3.5 OPD 7 will provide Neurosciences outpatient services. No compliance issues were identified, and a treatment room compliant with SHTM 03-01 is provided in this area for any procedure or intervention common to this specialty.

3.6 OPD 8-11 - General paediatric services and specialist OPD including haematology/oncology. All consultation rooms are designed to provide 3 air changes, with exception of room D1-016 which provides 6 air changes. The treatment room in OPD 8-11 is compliant with SHTM 03-01 Part A Appendix 1 and this room should be used for any invasive or high risk intervention or procedure (as appropriate to an outpatient setting) in children or young people considered in a high susceptibility group (e.g. haematology/oncology) [*Recommendation 4.2*]

3.7 OPD 9- Cardio-Respiratory OPD Rooms GD2005/006/009/014were considered in earlier discussion with clinicians who provide care to children and young people with Cystic Fibrosis. [*Recommendation 4.3*]

3.8 In Crichton ward, 2 consulting rooms are provided (labelled as "treatment rooms" on the plans) which have been designed to provide 4 air changes. These are not suitable for any invasive procedures or interventions. [*Recommendation 4.4*]

3. 9 OPD 10 Dental Services: The dental unit was confirmed as providing 10 air changes (supply and extract) which is compliant with guidance for this type of service.

3. 10 OPD 12 (Dressings Clinic) all treatment rooms provide 10 air changes with positive pressure. These are appropriate for dressing changes and other clinical interventions appropriate to an outpatient setting.

3. 11 The rooms in the 'Acorn suite' (forensic services) are designed to deliver 3 air changes per hour, and we have confirmed that no invasive procedures would be performed in this area.

3.12 No significant issues were identified in the therapies treatment area [*Recommendation 4.5*]

4. Recommendations

4.1 We advise further risk assessment of compliance with ventilation standards is carried out by clinical research teams to ensure appropriate control measures to protect staff and young people are in place to minimise any risk from exposure to aerosolised or airborne pathogens as this requires local knowledge regarding which micro-organisms may be encountered depending on the nature of the research study, as at least one current research project relates to children with respiratory viruses.

4.2 The treatment room in OPD 8-11 should be used for any invasive or high risk intervention or procedure (as appropriate to an outpatient setting) in children or young people considered in a high susceptibility group (e.g. haematology/oncology

4.3 We advise that a clear standard operating procedure is developed to inform the use of these OPD 9outpatient rooms for outpatient review and care of children with CF, and in particular, where a diagnosis with *Mycobacterium abscessus* has been made. This should include consideration of leaving the room 'fallow' after any treatment to allow the full volume of room air to be changed.

4.4 A local SOP should be developed to ensure that no invasive treatment or procedures are carried out in the consultation rooms in Crichton ward.

4.5 In therapies, we advise that in treatment rooms 6, 7 & 16 (identified as physiotherapy rooms) that no cough generating procedures (such as induced sputum, NIPPV) are carried out in these rooms as these provide 10 air changes on supply only – this means room air is extracted to corridor, meaning that other patients and staff could potentially be exposed to respiratory pathogens aerosolised during such procedures.

Dental RHCYP

Walk round on 18/02/2021 of Dental surgeries and Atrium/Pod

Advised that all works are reported to be on schedule.

Dental rooms -

Flooring now completed

Ceiling in the process of completion

Power back on and being tested

Week of 22nd Feb

Dental units being put back in place

Week 1st March

Planned for snagging. Dental to check chairs and renew the water and air lines.

Week 8th March

Planned handover

Atrium

Atrium plasterboard taken back to approximately 1400cm in height

Plaster board and insultation replaced – sanding was in progress area being cleaned prior to painting.

Cabinets and water fountain to be reinstalled – planned date for this area to be handed back is the 01/03/2021.

JMH 19/02/2021

From: Henderson, Ronnie
Sent: 21 February 2019 10:55
To: Inverarity, Donald
Cc: Currie, Brian; Douglas, Brian; 'alanhambidge@[redacted] Curley, George; 'Greer, Graeme'
Subject: RE: RHCYP & DCN EDINBURGH - WATER QUALITY
Attachments: Laboratory Results.zip; RHCYP & DCN EDINBURGH - WATER QUALITY; Letter to IHSL - Water System 190213.pdf

Importance: High
Sensitivity: Confidential

Hi Donald,

Thank you for this comprehensive response. I have commented below in red at each of the relevant points. I note from today's press that there is a negative news story relating to S. Aureus and although testing for this is mentioned in SHTM 04-01 part G I think the context is that it should only be done if there are high TVC results from sampling, I cannot find explicit requirement for testing for this as part of handover commissioning or routine maintenance, would appreciate input from yourself, Alan, George & Brian.

Alan, would appreciate your views on the below and attached, unfortunately this is very urgent so hope you can help. Please treat as confidential.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Inverarity, Donald
Sent: 20 February 2019 17:00
To: Henderson, Ronnie
Cc: Currie, Brian
Subject: RE: RHCYP & DCN EDINBURGH - WATER QUALITY
Importance: High
Sensitivity: Confidential

Dear Ronnie,
Thanks for bringing this to my attention. There are a number of things to consider I think with regards to this. Firstly is Brian Douglas as the NHS Lothian Responsible Person for Water and co-chair of the NHS Lothian Water Safety Group aware of the issue? Yes he is I may not have the correct titles but I believe Alan Hambridge is contracted by NHS Lothian to be the Authorising Engineer for Water and I very much think we should be seeking

both Brian and Alan's views on this (particularly as Alan is a UK expert in this area). I think it's also useful to have their views as we had similar issues at the new buildings on the Royal Edinburgh site that required rectifying before hand over that were being discussed at the Water Safety Group. I have copied Alan into this response along with the original attachments

My own views are:

Water testing in an unoccupied building may not necessarily represent what you would see in an occupied building where there is much more flow through storage tanks and pipes/taps/toilets etc. When there is more water flowing through pipes there is less chance for biofilm to develop or bacterial counts to be raised. Agree, issue is should we have any concerns given the results and that the building will not be fully functional until July

Do we have assurance that the correct methodology was used for water sampling? Yes The methodology is different if you are looking for Pseudomonas aeruginosa compared to when you are looking for Legionella species. Pseudomonas aeruginosa testing methodology is very clearly explained in HTM 04-01 Part C but SHTM 04-01 Part C is not explicit about the testing methodology for Pseduomonas aeruginosa and really only deals with the testing method for Legionella slightly confused about this sentence, I think on reading part C that the results and actions are defined for Legionella but not pseudomonas aeruginosa. The preflush and post flush sampling at a time when the pipe has not been used much is crucial for getting representative samples. All agree that the sampling carried out on 15/2 was done correctly, no way of verifying if the sampling on 6/2 & 11/2 was.

Although it is correct that any species of Pseudomonas or Legionella could cause infection, the risk of this happening is not uniform. It depends very much on whether the patient is in an "at risk" category and whether the area sampled is in a "high risk" area. Within the new building there will definitely be "at risk" patients i.e. paediatric immunocompromised cancer patients but there are also high and low risk areas i.e. a public toilet tap would likely be lower risk that a tap in an ensuite isolation room. Its difficult to interpret the overall significance of the lab results without knowing where in the building was sampled and what the intended purpose of that area will be. Think the test results give description of location, none of which were in augmented care areas. **Main issue is do high TVC and P. species counts directly link to an increased risk of the presence of Pseudomonas Aeuriginosa.**

However I would be extremely uncomfortable knowing there is any Legionella species in the water pre-handover as generally it will form biofilm and will come back over time despite corrective measures like flushing and chemical/thermal disnifection and would need continual monitoring in order to know that it stays low and doesn't cause disease.Legionella counts were well below action levels, however I agree this is a concern in a system so young, action has already been taken on this and re-sampling took place yesterday. As you know, the legal consequences to NHS Lothian and its employees from non compliance with L8 are enormous. Agree Inevitably I suspect the pipework in such areas would end up needing replaced. Cause and extent of contamination yet to be established although as I say well below normal action levels.

With regards to Pseudomonas aeurginosa it was my understanding that "augmented care areas" e.g. intensive care or high dependency etc must have water that is free of Pseudomonas aeruginosa and this may be achieved once the throughput of regular flushing has begun. But I really would value the views and knowledge of Alan Hambridge for his informed opinion if that was possible to be arranged within the need for confidentiality etc. It looks like you have evidence of there being no P aeuginosa in the repeat sampling waters so it looks like you have achieved that although I don't know the intended clinical purpose of the areas that have been sampled and thats quite important to put them in context. As previous none are in augmented care areas.

Please see the recent documents from Health Protection Scotland that are relevant to this problem. We have these documents already and we will ask the FM provider to adopt them fully in the operational phase.

I hope that helps.

All the best

Donald

From: Henderson, Ronnie
Sent: 19 February 2019 17:00
To: Inverarity, Donald
Cc: Currie, Brian
Subject: FW: RHCYP & DCN EDINBURGH - WATER QUALITY
Importance: High
Sensitivity: Confidential

Hi Donald,

In light of significant issues elsewhere in the NHS Scotland Estate I thought I would bring the attached to your attention.

To give you a bit of background the FM provider (Bouygues) decided to carry out some water sampling ahead of handover, this took place on the 6th of February. Preliminary results indicated high CFU counts and there were positives for Pseudomonas species and Legionella. The main contractor disputed the method of test and the need to test for Pseudomonas species. As a result all 'fails' from the sampling on the 6th were re-sampled on 15th Feb specifically for Pseudomonas Aeruginosa and these are the first attached results shown in the Zip file, the remaining results are confirmation of the results from the 6th Feb.

To give the issue proper context there are two letters attached from Bouygues to IHSL explaining their concerns, please treat these as confidential for the time being.

I would appreciate it if you could give us your opinion on the infection control and microbiology implications of these results.

If you need to discuss please feel free to call or equally happy to meet.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: GORDON, David [mailto:David.GORDON[redacted]
Sent: 19 February 2019 15:52
To: GRIFFITHS, Mark; weir[redacted] Currie, Brian; matthew.templeton[redacted]
darren.pike[redacted] john.edwards[redacted]
Cc: HALL, Alan; GRAHAM, Eleanor
Subject: RE: RHCYP & DCN EDINBURGH - WATER QUALITY

Wallace,

Further to the correspondence earlier from Mark Griffiths, please find attached the Laboratory final results for all of the sample tests that were performed on site by the BYES contractor Hydro-X.
So that both Arcadis and the NHSL board have all of the correspondence from Bouygues I have also attached our initial letter on this matter.

In the meantime, should you require any further information or to discuss further then please advise.

Kind Regards

David,

David GORDON BSc(Hons), MSc
Regional Manager
Bouygues E&S FM UK Limited
[redacted]
Excel House - Europoint Office Park - Holytown, Motherwell - ML1 4UF
www.bouygues-es.co.uk

Play your part in saving the environment. Please do not print this email unless you really need to!

From: FOX, Nicole **On Behalf Of** GRIFFITHS, Mark
Sent: 19 February 2019 13:52
To: weir[redacted] Currie, Brian ; matthew.templeton[redacted] darren.pike[redacted] john.edwards[redacted]
Cc: GORDON, David ; HALL, Alan ; GRAHAM, Eleanor ; GRIFFITHS, Mark
Subject: RHCYP & DCN EDINBURGH - WATER QUALITY

Dear Mr Weir,

Please see the attached letter.

NB: The laboratory results will follow and will be issued by the Operational team.

Kind regards

Nicole FOX
Personal Assistant
Bouygues E&S FM UK Limited
[redacted]
1 Lambeth Palace Road - Waterloo - London - SE1 7EU
www.bouygues-es.co.uk

Play your part in saving the environment. Please do not print this email unless you really need to!

From: FOX, Nicole on behalf of GRIFFITHS, Mark
To: wei[redacted] Currie, Brian; matthew.templeton@[redacted] darren.pike[redacted] john.edwards[redacted]
Cc: GORDON, David; HALL, Alan; GRAHAM, Eleanor; GRIFFITHS, Mark
Subject: RHCYP & DCN EDINBURGH - WATER QUALITY
Date: 19 February 2019 13:52:07
Attachments: Letter to IHSL - 19.02.19.pdf

Dear Mr Weir,

Please see the attached letter.

NB: The laboratory results will follow and will be issued by the Operational team.

Kind regards

Nicole FOX

Personal Assistant

Bouygues E&S FM UK Limited

[redacted]

1 Lambeth Palace Road - Waterloo - London - SE1 7EU

www.bouygues-es.co.uk

ALS Environmental Ltd
Unit L
Dundyvan Enterprise Park
Coatbridge
North Lanarkshire
ML5 4FR

T:
F:
www.alsenvironmental.co.uk

Ms Hirrst
Hydro - X
Hydro-X Water Treatment Ltd
Unit 3a Eden Place
Outgang Lane
Dinnington S25 3QT

18 February 2019

Test Report: CTD/1674256/2019

Dear Ms Hirrst

Analysis of your sample(s) submitted on 15 February 2019 is now complete and we have pleasure in enclosing the appropriate test report(s).

An invoice for the analysis carried out will be sent under separate cover.

Should you have any queries regarding this report(s) or any part of our service, please contact Customer Services on who will be happy to discuss your requirements.

If you would like to arrange any further analysis, please contact Customer Services. To arrange container delivery or sample collection, please call the Couriers Department directly on [redacted]

Thank you for using ALS Environmental Ltd and we look forward to receiving your next samples.

Yours Sincerely,

Signed: [redacted]

Name: M. Howard

Title: Quality Manager

Report Summary

ANALYSED BY

UKAS TESTING
1314
0897
4409

ALS

Ms Jacky Hirrst
Hydro - X
Hydro-X Water Treatment Ltd
Unit 3a Eden Place
Outgang Lane
Dinnington
S25 3QT

ON BEHALF OF

Hydro-X

Date of Issue: **18 February 2019**

Report Number: **CTD/1674256/2019** Issue **1**

This issue replaces all previous issues

Job Description: Microbiology

Job Location: RHCHP EDINBURGH

Number of Samples included in this report **13**

Job Received: **15 February 2019**

Number of Test Results included in this report **26**

Analysis Commenced: **16 February 2019**

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

ALS Environmental Ltd was not responsible for sampling unless otherwise stated.

Information on the methods of analysis and performance characteristics are available on request.
Opinions and interpretations expressed herein are outside the scope of UKAS accreditation. The results relate only to the items tested.
Tests marked 'Not UKAS Accredited' in this Report/Certificate are not included in the UKAS Accreditation Schedule for our laboratory.

Certificate of Analysis

ANALYSED BY

UKAS TESTING
1314
0897
4409

ALS

ON BEHALF OF

Hydro-X

Report Number:	**CTD/1674256/2019**	Issue	**1**
Laboratory Number:	**17955772**	Sample	**1** of **13**
Sample Source:	**Hydro - X**		
Sample Point Description:	**Drinking water suite**		
Sample Description:	**19-03277 TANK 1 PRE**		
Sample Matrix:	**Drinking Water**		
Sample Date/Time:	**15 February 2019** **12:44**		
Sample Received:	**15 February 2019**		
Analysis Complete:	**18 February 2019**		

Test Description	Result	Units	Analysis Date	Accreditation	Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y Cov	W11

Analyst Comments for 17955772: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

Certificate of Analysis

ANALYSED BY

UKAS TESTING
1314
0897
4409

ALS

ON BEHALF OF

Hydro-X

Report Number:	**CTD/1674256/2019**	Issue	**1**
Laboratory Number:	**17955773**	Sample	**2** of **13**

Sample Source:	**Hydro - X**	
Sample Point Description:	**Drinking water suite**	
Sample Description:	**19-03278 TANK 1 POST**	
Sample Matrix:	**Drinking Water**	
Sample Date/Time:	**15 February 2019**	**12:50**
Sample Received:	**15 February 2019**	
Analysis Complete:	**18 February 2019**	

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955773: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

Certificate of Analysis

ANALYSED BY

UKAS TESTING
1314
0897
4409

ALS

ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955774**

Issue **1**
Sample **3** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03279 TANK 2 PRE CAT 5**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:20**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955774: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955775**

Issue **1**
Sample **4** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03280 TANK 2 POST CAT 5**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:25**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955775: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955776**

Issue **1**
Sample **5** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03281 TANK 4 PRE**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:37**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955776: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955777**

Issue **1**
Sample **6** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03282 TANK 4 POST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:42**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955777: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955778**

Issue **1**
Sample **7** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03283 NEAREST LABWATER PRE**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:14**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955778: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955779**

Issue **1**
Sample **8** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03284 NEAREST LABWATER POST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:20**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955779: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955780**

Issue **1**
Sample **9** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03285 FURTHEST LABWATER PRE**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **12:39**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955780: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955781**

Issue **1**
Sample **10** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03286 FURTHEST LABWATER POST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **13:04**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955781: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955782**

Issue **1**
Sample **11** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03287 KITCHEN PRE FURTHEST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **12:15**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955782: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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ON BEHALF OF

Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955783**

Issue **1**
Sample **12** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03288 KITCHEN POST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **12:22**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955783: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

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Hydro-X

Report Number: **CTD/1674256/2019**
Laboratory Number: **17955784**

Issue **1**
Sample **13** of **13**

Sample Source: **Hydro - X**
Sample Point Description: **Drinking water suite**
Sample Description: **19-03369 NO STRAINER KITCHEN POST**
Sample Matrix: **Drinking Water**
Sample Date/Time: **15 February 2019** **12:30**
Sample Received: **15 February 2019**
Analysis Complete: **18 February 2019**

Test Description	Result	Units	Analysis Date	Accreditation		Method
Pseudomonas Aeruginosa Pres	0	cfu/100ml	18/02/2019	Y	Cov	W11
Pseudomonas aeruginosa, conf.	0	cfu/100ml	18/02/2019	Y	Cov	W11

Analyst Comments for 17955784: No Analyst Comment

This issue replaces all previous issues
Accreditation Codes: Y = UKAS / ISO17025 Accredited, N = Not UKAS / ISO17025 Accredited, M = MCERTS.
Analysed at: CHE = Chester(CH5 3US), CTD = Coatbridge(ML5 4FR), COV = Coventry(CV4 9GU), OTT = Otterbourne(SO21 2SW), S = Subcontracted, TRB = Subcontracted to Trowbridge(BA14 0XD), WAK = Wakefield(WF5 9TG).
For Microbiological determinands 0 or ND=Not Detected, For Legionella ND=Not Detected in volume of sample filtered.
I/S=Insufficient sample For soil/sludge samples: AR=As received, DW=Dry weight.

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

ANALYST COMMENTS FOR REPORT CTD/1674256/2019 Issue 1

This issue replaces all previous issues

Date of Issue: **18 February 2019**

Sample No	Analysis Comments
17955772	
17955773	
17955774	
17955775	
17955776	
17955777	
17955778	
17955779	
17955780	
17955781	
17955782	
17955783	
17955784	

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

DETERMINAND COMMENTS FOR REPORT CTD/1674256/2019

ISSUE 1

This issue replaces all previous issues

Date of Issue: 18 February 2019

Sample No	Description	Determinand	Comments

Signed: [redacted]

Name: **M. Howard** Date: **18 February 2019**

Title: **Quality Manager**

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15297
Sample Point Tank 1 RHS
Sample No: 19-02543
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15298
Sample Point Tank 1 LHS
Sample No: 19-02544
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

Results presented above are a measure of the quality of the water sample received (as is) by Eurofins. These results may not be a true measure of the quality of the sample at point of origin if prescribed sampling and transportation protocols have not been adhered to.
The lower limit of detection (LOD) for legionella is 25cfu per volume or swab tested, apart from the centrifuge method for which there is an LOD of 3cfu/150ml.

All tests are carried out according to our schedule of accreditation unless marked.
Tests marked * are not accredited. Tests marked ‡ were sub contracted and are not accredited. Tests marked † were sub contracted and are accredited according to their schedule.

Comments, opinions, grades and interpretations expressed herein are outside this current scope of UKAS accreditation.

Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15299
Sample Point Tank 2 (Cat 5)
Sample No: 19-02545
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019
Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15300
Sample Point Tank 3 (Cat 5)
Sample No: 19-02546
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019
Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

Results presented above are a measure of the quality of the water sample received (as is) by Eurofins. These results may not be a true measure of the quality of the sample at point of origin if prescribed sampling and transportation protocols have not been adhered to.
The lower limit of detection (LOD) for legionella is 25cfu per volume or swab tested, apart from the centrifuge method for which there is an LOD of 3cfu/150ml.

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15301
Sample Point Tank 4 (Lab Water)
Sample No: 19-02547
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15302
Sample Point Mains Cold Water (Kitchen) Nearest
Sample No: 19-02548
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	R	Legionella species Detected - 25	cfu/1000ml	

Grade Key: 'R' = out of specification.

FAIL

Results presented above are a measure of the quality of the water sample received (as is) by Eurofins. These results may not be a true measure of the quality of the sample at point of origin if prescribed sampling and transportation protocols have not been adhered to.
The lower limit of detection (LOD) for legionella is 25cfu per volume or swab tested, apart from the centrifuge method for which there is an LOD of 3cfu/150ml.

All tests are carried out according to our schedule of accreditation unless marked.
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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15303
Sample Point Mains Cold Water (Kitchen restaurant) Furthest
Sample No: 19-02549
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019
Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15304
Sample Point Domestic Hot (Staffroom) Nearest
Sample No: 19-02550
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019
Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15305
Sample Point Domestic Hot (Restaurant kitchen) Futhest
Sample No: 19-02551
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15306
Sample Point Laboratory Water Nearest
Sample No: 19-02552
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2955058
Job Ref: 19B04253
Number Of Samples: 12
Date Reported: 18/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/15307
Sample Point Laboratory Water Furthest
Sample No: 19-02553
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/15308
Sample Point Cat 5 Nearest
Sample No: 19-02554
Site Name/Number: RHCYP Edinburgh
Engineers Name: Callum Allen / Eleanor Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: N/A
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Legionella	MW28	G	Not Detected	cfu/1000ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

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[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956170
Job Ref: 19B04669
Number Of Samples: 2
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17587
Sample Point LTHW
Sample No: 7
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02573
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/17588
Sample Point CHW
Sample No: 8
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02574
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

This report amends and supersedes Certificate No 2948957 of 10/02/2019 which is now withdrawn

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956173
Job Ref: 19B04658
Number Of Samples: 4
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17443
Sample Point Lab Water Furthest
Sample No: 1
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02567
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	R	6.3×10^4	cfu/ml	E
Total Aerobic Colony Count 22°C 3 Days	MW3	R	>15000	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

E = Estimated Count.

FAIL

LSN: 2S/17444
Sample Point Cat 5 Nearest
Sample No: 2
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02568
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	6	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	47	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	1	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

This report amends and supersedes Certificate No 2948960 of 11/02/2019 which is now withdrawn

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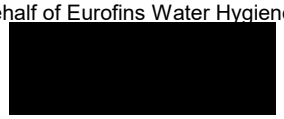
Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited



Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956173
Job Ref: 19B04658
Number Of Samples: 4
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17445
Sample Point Cat 5 Furthest
Sample No: 3
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02569
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	Method	Grade	Result	Unit	Est.
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	6	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/17446
Sample Point Helipad
Sample No: 4
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02570
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	Method	Grade	Result	Unit	Est.
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	2.3×10^{3}	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	2.4×10^{3}	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	>1000	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

This report amends and supersedes Certificate No 2948960 of 11/02/2019 which is now withdrawn

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

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i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956174
Job Ref: 19B04656
Number Of Samples: 10
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17425
Sample Point Tank 1 RHS
Sample No: 3
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02557
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37°C 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	9	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	64	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

LSN: 2S/17426
Sample Point Tank 1 RHS
Sample No: 4
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02558
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37°C 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	2	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	73	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

This report amends and supersedes Certificate No 2948959 of 11/02/2019 which is now withdrawn

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Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

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Wolverhampton,
WV9 5GB,
UK.

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eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956174
Job Ref: 19B04656
Number Of Samples: 10
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17427
Sample Point Tank 2
Sample No: 5
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02559
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	6	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

LSN: 2S/17428
Sample Point Tank 3
Sample No: 6
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02560
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

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[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

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WV9 5GB,
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T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956174
Job Ref: 19B04656
Number Of Samples: 10
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17429
Sample Point Tank 4
Sample No: 7
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02561
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	210	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

LSN: 2S/17430
Sample Point Mains cold (kitchen) nearest
Sample No: 8
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02562
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	5	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	110	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	>1000	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

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[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

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i54 Business Park,
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Wolverhampton,
WV9 5GB,
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eurofins

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EH54 7DE
United Kingdom

Certificate No.: 2956174
Job Ref: 19B04656
Number Of Samples: 10
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17431
Sample Point Mains cold Furthest
Sample No: 9
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02563
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	None Detected	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	170	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	210	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

LSN: 2S/17432
Sample Point Domestic Hot Water (staffroom) Nearest
Sample No: 10
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02564
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	*Method*	*Grade*	*Result*	*Unit*	*Est.*
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	89	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	None Detected	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

This report amends and supersedes Certificate No 2948959 of 11/02/2019 which is now withdrawn

Results presented above are a measure of the quality of the water sample received (as is) by Eurofins. These results may not be a true measure of the quality of the sample at point of origin if prescribed sampling and transportation protocols have not been adhered to.
The lower limit of detection (LOD) for legionella is 25cfu per volume or swab tested, apart from the centrifuge method for which there is an LOD of 3cfu/150ml.

All tests are carried out according to our schedule of accreditation unless marked.
Tests marked * are not accredited. Tests marked ‡ were sub contracted and are not accredited. Tests marked † were sub contracted and are accredited according to their schedule.

Comments, opinions, grades and interpretations expressed herein are outside this current scope of UKAS accreditation.

Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

Eurofins Water Hygiene Testing UK Ltd,
i54 Business Park,
Valiant Way,
Wolverhampton,
WV9 5GB,
UK.

T:+44(0)1506 534 317
E:info@eurofins.co.uk
W:www.eurofins.co.uk

eurofins

Client: Hydro-X Water Treatment Ltd
Unit 4, Dryburgh House
Kirkon Campus
Livingston
West Lothian
EH54 7DE
United Kingdom

Certificate No.: 2956174
Job Ref: 19B04656
Number Of Samples: 10
Date Reported: 19/02/2019

CERTIFICATE OF ANALYSIS

LSN: 2S/17433
Sample Point Domestic Hot Water (Restaurant Kitchen) Furthest
Sample No: 11
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02565
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	Method	Grade	Result	Unit	Est.
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	65	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	G	11	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	G	<1	cfu/100ml	

Grade Key: 'G' = within specification.

Microbiologically Acceptable - PASS

LSN: 2S/17434
Sample Point Lab Water Nearest
Sample No: 12
Site Name/Number: RHCYP Edinburgh
Engineers Name: C.Allen / E.Murphy
Additional Info: N/A
Testing Commenced: 07/02/2019

Date of Sampling: 06/02/2019
Time: N/A
Client Sample Ref: 19-02566
Temperature: N/A
Date Received: 07/02/2019
Work/Job Number: MH136148
Account Manager: N/A

Test Description	Method	Grade	Result	Unit	Est.
Total Aerobic Colony Count 37ºC 2 Days	MW3	G	1.1×10^{3}	cfu/ml	
Total Aerobic Colony Count 22°C 3 Days	MW3	R	>15000	cfu/ml	
Presumptive Pseudomonas spp at 30°C	MW4	R	>1000	cfu/100ml	

Grade Key: 'R' = out of specification. 'G' = within specification.

FAIL

This report amends and supersedes Certificate No 2948959 of 11/02/2019 which is now withdrawn

Results presented above are a measure of the quality of the water sample received (as is) by Eurofins. These results may not be a true measure of the quality of the sample at point of origin if prescribed sampling and transportation protocols have not been adhered to.
The lower limit of detection (LOD) for legionella is 25cfu per volume or swab tested, apart from the centrifuge method for which there is an LOD of 3cfu/150ml.

All tests are carried out according to our schedule of accreditation unless marked.
Tests marked * are not accredited. Tests marked ‡ were sub contracted and are not accredited. Tests marked † were sub contracted and are accredited according to their schedule.

Comments, opinions, grades and interpretations expressed herein are outside this current scope of UKAS accreditation.

Signed for and on behalf of Eurofins Water Hygiene Testing UK Limited

[redacted]

Jennifer Trainer

Water Microbiology Laboratory Manager

UKAS TESTING
9658

BOUYGUES ENERGIES & SERVICES

Our energies for a **Better Life**

F.A.O: Mr. Wallace Weir
IHS Lothian Limited
RHCYP & DCN
50 Little France Crescent
Edinburgh

19 February 2019

By-Hand & e-mail

Dear Wallace,

RHCYP & DCN EDINBURGH - WATER QUALITY

Further to the recent communications from David Wilson of Multiplex and subsequent correspondence from Darren Pike, we do not agree with the Multiplex assessment in their letter of 15th February 2019 and can confirm that all of the samples taken on site on 06th February 2019 were indeed in accordance with the guidance laid out in SHTM-04-01.

Multiplex did not have a representative available for the sampling and instead requested that a Mercury representative attend to witness and assist. Bouygues E&S FM (BYES) supply chain member Hydro-X were therefore joined in the sampling by both the BYES & Mercury Supervisors where all were satisfied with the manner in which the readings were taken and that correct hand hygiene was in place at all times. It is surprising that no response or concerns were received from Mutiplex or their supply chain until after the preliminary results had identified concerns of contaminants within the building water systems.

BYES have already issued the presumptive readings for Pseudomonas Spp, TVC and Legionella to IHSL between 12th February 2019 and 13th February 2019 and have now issued the final results for all readings on 19th February 2019 (including additional sampling for Pseudomonas Aeruginosa which were taken on 15th February 2019).

These results represent a selection of locations that were sampled for a range of pathogens, to provide BYES confidence in the systems in advance of the completion of sampling by Multiplex in keeping with *'Scottish Health Technical Memorandum 04-01: Water safety for healthcare premises Part G: Operational procedures and Exemplar Written Scheme' Section 23.8.* However, these samples have identified some concerns which we have communicated to Multiplex.

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Pseudomonas Spp has been found at the nearest (Sample No. 19-02562) and furthest (Sample No. 19-02563) MCW outlets. Whereas these are not a defined check within SHTM04, they do represent concern for potential system contamination, and a potential established biofilm risk. It is strongly recommended that these are investigated further and retested to determine local or systemic colonisation, and system risk.

A low reading for Legionella (25 CFU/L) has also been detected at the nearest (Sample No. 19-02548) MCW outlet; this does not require to be retested in keeping with Scottish Health Technical Memorandum 04-01 Water safety for healthcare premises Part B: Operational management but is of concern when considered in conjunction with the Pseudomonas Spp Sample No. 19-02562.

TVC samples were recorded to be high at a variety of locations. TVC samples do not specify the bacteria / particles, they represent the total content which may represent a risk to the system. These locations should be retested to determine the breakdown of the high results and the risk to the system or outlets as applicable.

With consideration to 'Scottish Health Technical Memorandum 04-01: Water safety for healthcare premises Part G: Operational procedures and Exemplar Written Scheme', Section this denotes the circumstances under which samples are taken, which includes specific reference to 'as part of commissioning process, prior to handover of a new building or introduction of a (altered, refurbished or new) water system into use;'.

These samples are defined within the document and refer to SHTM 04-01 Section C, and detail the types and locations to be tested. Bacteria to be sampled includes:

- Coliforms
- Legionella
- Escherichia coli
- Salmonella
- Pseudomonas aeruginosa
- Campylobacter
- Aerobic Colony Counts
- E.coli O157
- Environmental Mycobacteria
- Staphylococcus aureus

The locations are detailed within 23.13 as '....initial water system sampling take a Post-Flush sample (as defined in BS 7592: 2008) at sentinel points without disinfection.....'. And we await these results to provide us with the assurance the system is safe and in control.
It is also of note, these samples are not limited to drinking water, they are applicable to 'hot & cold water systems' which include the Cat 5 supplies which have been disputed as being applicable by Multiplex. This requirement is also supported in a related British Standard BS 8554:2015 Code of practice for the sampling and monitoring of hot and cold water services in buildings; as a commissioning requirement.

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BYES would also like to note that we also requested on 23rd November 2018 detailed evidence on the water system maintenance being carried out by Multiplex, and in particular the following which has yet to be provided.

Recorded Temperature recordings of the outlets during testing and flushing
TMV commissioning certificates

We would therefore re-iterate the concerns outlined within our recent communications and request that Multiplex address these urgently and would welcome any input / feedback from the NHS Lothian (Board) Head of Infection Control. We therefore once again give notice in accordance with Clause 30 of the PA that we will be seeking full relief until the above concerns have been addressed.

Kind Regards.

[redacted]

Mark Griffiths
OPERATIONS DIRECTOR
BOUYGUES ENERGIES & SERVICES FM UK LTD

Cc: Alan Hall – Bouygues E&S
David Gordon - Bouygues E&S
Eleanor Graham - Bouygues E&S
Darren Pike - Multiplex
Matthew Templeton – Dalmore
Brian Currie – NHS Lothian
John Edwards - Arcadis

BOUYGUES ENERGIES & SERVICES

Shared innovation

IHS Lothian Limited
RHCYP & DCN
50 Little France Crescent
Edinburgh
EH16 4TJ

13th February 2019

By-Hand & e-mail

For the attention of Mr. Wallace Weir

RE: RHCYP & DCN Edinburgh - Water Quality

Dear Wallace,

We refer to our previous email correspondence from our David Gordon in relation to water quality sampling prior to the RHCYP going live on Thursday 7th February 2019. The Go-Live subsequently did not happen however the planned water sampling did go ahead.

We now have had a presumptive report from our specialist advising that the sampling for water quality at RHCYP & DCN Edinburgh, is indicating counts of Pseudomonas spp and Legionella have been identified in varying concentrations at defined locations. In addition to this, the total aerobic count samples have been found to exceed industry expectations at a small number of other locations.

There have been some suggestion from the Principal Contractor / Principal Designer Multiplex that Pseudomonas Aeruginosa is the only pseudomonas bacteria that requires action as a clinical risk, and whilst it is most certainly the most well studied, the presence of all Pseudomonas bacteria species require action in a healthcare environment. SHTM 04-01 part A Design, Installation and testing identifies that not only Pseudomonas Aeruginosa is of interest, but also specifically makes reference to Pseudomonas spp; and, where practicable, it should be managed/designed out of a system.

Bouygues E&S FM (BYES) are concerned with the presumptive presence of Pseudomonas spp and Legionella at this stage in the process of construction hand over, as all Pseudomonas bacteria species have the ability to create biofilms and establish themselves in such a way that they can be very difficult to eradicate thus causing major infection control concerns.

The presence of biofilm and Legionella in a system is extremely undesirable, as they will create an environment that promotes the proliferation of other potentially pathogenic bacteria, protecting them from excessive temperature, and to a certain extent, chemical disinfection.

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Bouygues E&S FM (BYES) are recording their concern that the Water Systems at RHCYP & DCN Edinburgh are “Out of Control” on the basis of these presumptive reports along with the fact that there has been no management of the water systems in accordance with SHTM 04.

Should the presumptive reporting be followed with firm laboratory reports confirming this position we will therefore not be in a position to accept the building with existing issues with Pseudomonas; and/or Legionella; and/or high TVC which would compromise our ability to operate the system within safe parameters using “normal maintenance activities” thus increasing our risk profile and increased management costs. Furthermore we give notice in accordance with Clause 30 of the PA that we will be seeking full Relief should the laboratory reporting confirm the above concerns.

Kind Regards.

[redacted]

Alan Hall
Contracts Director
Bouygues Energies & Services

Cc:	David Gordon	Bouygues
	Mark Griffiths	Bouygues
	Eleanor Graham	Bouygues
	Darren Pike	Multiplex
	Matthew Templeton	Dalmore

Bouygues E&S FM UK Limited
Registered Office: Becket House • 1 Lambeth Palace Road • London • SE1 7EU
Registered in England No. 04243192 • VAT Registration No. GB 792 4173 12

Health Protection Scotland

NHS National Services Scotland

Rapid Review of Healthcare Associated Infection Risks and Outbreaks Associated with Healthcare Water Systems

Version: 0.4

Author: Infection Control Team

Publication Date:

Contents

Abbreviation list:

CVC: Central venous catheter

EPDM: Ethylene propylene diene monomer

HAI: Healthcare Associated Infection

HFS: Health Facilities Scotland

HPC: Heterotrophic Plate Count

HPS: Health Protection Scotland

HTM: Health Technical Memorandum

ICU: Intensive care unit

NIPCM: National Infection Prevention & Control Manual

NNU: Neonatal unit

NTM: Non-tuberculous mycobacteria

POU: Point-of-Use

Background

Water distribution systems and the associated fixtures and fittings can act as reservoirs for waterborne pathogens in healthcare facilities. Microorganisms often identified within water systems include heterotrophic plate count (HPC) bacteria, *Legionella* spp. and nontuberculosis mycobacteria.[1] These organisms are able to persist by forming biofilms which coat structures within water systems, allowing survival, replication and resistance against disinfection.[2] Experimental studies have demonstrated biofilm resistance to biocides such as chlorine, sodium hypochlorite, glutaraldehyde and quaternary ammonium compounds compared to planktonic cells.[3]

Normally these organisms do not infect healthy individuals. However, they do pose a particular risk to susceptible patients, such as those who are severely immunocompromised; have a breach in dermal integrity; or who are cared for within intensive care units.[4] The cumulative effect of direct contact with colonised water, susceptibility of patients, poor water system management, and non-compliance with infection control practices can lead to HAIs and outbreaks.[5]

Aim

To provide a rapid review of the scientific evidence base on HAI risks and outbreaks associated with healthcare water systems.

Objectives

Objectives for the rapid review were as follows:

- To assess the microorganisms associated with outbreaks due to healthcare water delivery systems.
- To assess the clinical settings and patient populations which may be affected by contaminated healthcare water delivery systems.
- To assess the potential sources of outbreaks linked to healthcare water delivery systems.
- To assess the routes of transmission of waterborne outbreaks linked to healthcare water delivery systems.
- To assess the control measures to put in place to minimise risk of waterborne outbreaks within healthcare facilities.

Search Strategy

Academic databases were searched to identify relevant academic and grey literature from 1998-2019 (see Appendix 1).

Results

The literature search identified 871 articles. After screening 104 articles were included and following additional hand searching and expert recommendation a further 34 papers identified, providing 138 articles for the review. Of the 138 articles, the papers included outbreak reports, case-control studies, pseudo-outbreak reports, and intervention studies in both outbreak and endemic situations linked to water systems. Additional guidance documents were retrieved from Health Protection Scotland (HPS),[6, 7] Health Facilities Scotland (HFS),[2, 6, 8] the UK Department of Health[4, 9] and legislative guidance from the UK Health and Safety Executive[10] on water system safety within healthcare facilities. A report produced by HPS was also included.[11]

Research Questions

What organisms are associated with HAI outbreaks due to healthcare water systems?

A broad range of microorganisms are associated with water system contamination which can lead to healthcare outbreaks or endemic situations. Table 1 displays the organisms most frequently isolated from hospital water delivery systems and includes: 53 articles on *Pseudomonas aeruginosa*;[11-62] 24 articles on *Legionella pneumophila*;[61, 63-84] 19 articles on nontuberculosis mycobacteria (NTM);[61, 85-102] 11 articles on *Klebsiella pneumoniae* studies;[11, 60, 103-110] and 6 articles on *Acinetobacter baummannii*.[111-115]

Table 1. Most frequently cited microorganisms, identified during the rapid review, linked to healthcare water delivery system contamination.

Type of Microorganism	Microorganism Identified
Gram negative bacteria	*Pseudomonas aeruginosa* *Legionella pneumophila* *Klebsiella pneumoniae* *Acinetobacter baumannii*
Mycobacteria	Nontuberculosis mycobacteria (NTM)

Other causative organisms (Table 2) included *Achromobacter* spp.,[116] *Acinetobacter junii,*[117] *Acinetobacter ursingii,*[11] *Burkholderia* spp.,[118-120] *Chryseomonas indologenes,*[11] *Citrobacter freundii*,[121] *Cupriavidus pauculus,*[11] *Elizabethkinga meningoseptica*,[122, 123] *Enterobacter cloacae*,[11, 60, 124-126] *Enterobacter hormaachei spp.,*[127] *Klebsiella oxytoca*,[11, 128-130] *Klebsiella pneumoniae carbamenepase* (KPC)- producing *Enterobacteriae,*[131] KPC-producing *Escherichia coli,*[132] *Pantoea agglomerans*[133], *Pseudomonas fluorescens,*[11, 134] *Pseudomonas putida,*[11, 59, 135] *Staphylococcus aureus,*[132] *Serratia marcescens* [11, 110, 136] and *Stenotrophomonas maltophilia.*[11, 137-139] Fungi including *Candida parapsilosis,*[140] *Candida metapsilosis,*[140] *Aspergillus* spp.,[141] *Fusarium* spp., [142, 143] *Exophiala jeanselmei,*[144] *and Rhizomucor* spp.[141] were additionally identified as the cause of HAI outbreaks, as well as viruses such as Norovirus and an unidentified small round structured virus which were isolated in two studies. [145, 146]

Table 2. Other microorganisms, identified during the rapid review, linked to healthcare water delivery system contamination.

Type of Microorganism	Microorganism Identified

Gram negative bacteria	*Achromobacter* spp *Acinetobacter junii* *Burkholderia* spp. *Citrobacter freundii* *Elizabethkinga meningoseptica* *Enterobacter cloacae* *Klebsiella oxytoca* *Pantoea agglomerans* *Pseudomonas fluorescens* *Pseudomonas putida* *Serratia marcescens* *Stenotrophomonas maltophilia*
Gram positive bacteria	*Staphylococcus aureus*
Fungi	*Aspergillus* spp. *Fusarium* spp. *Exophiala jeanselmei* *Rhizomucor* spp. *Candida parapsilosis* *Candida metapsilosis*
Virus	Norovirus Small round structured virus

The fact that *P. aeruginosa* and *L. pneumophila* were the organisms most commonly associated with outbreaks is reflected in the available guidance on healthcare water systems within the UK. The Department of Health HTM 04-01[4] states that there is a risk of *P. aeruginosa* in patients within augmented care settings. These patients are also at risk of other waterborne pathogens such as *S. maltophilia, B. cepacia* and atypical mycobacteria.[4] Current UK guidance also mentions that *Legionella* spp. are also frequently found to cause infection within healthcare settings following water exposure.[4, 9, 10]

What clinical settings and patient populations are affected?

There is no established definition for augmented care areas. However, the Department of Health[4] defines augmented care areas as those in which medical and nursing procedures performed put patients at risk of infection from environmental and opportunistic pathogens. These high-risk patients include the following:[2, 4, 6]

- Those who are severely immunosuppressed because of disease or treatment;
- Those cared for in intensive care units (ICUs);
- Those with breaches in dermal integrity such as those with extensive burn injuries;
- Patients within neonatal units (NNUs);

- Adult and paediatric ICUs;
- Patients with cancer;
- Patients in transplant or renal wards.

Augmented care settings were most frequently affected with waterborne outbreaks - one of the most common being haematology and oncology units,[12, 13, 18, 28, 30, 35, 37, 43, 59, 63, 75, 84, 88, 93-95, 101, 116, 117, 124, 128, 141-144] with additional outbreaks involving patients within bone marrow and stem cell transplant wards.[33, 35, 39, 60, 66, 71, 73, 82, 83, 86, 88, 95, 100, 134, 144] This was followed by outbreaks within adult and paediatric ICUs[17, 20, 21, 23, 27, 29, 38, 42, 45, 52-54, 56, 62, 66, 70, 73, 74, 84, 103, 106, 107, 109, 114, 115, 125, 136, 138] and NNUs.[14, 15, 23, 31, 32, 48, 50, 51, 57, 72, 123, 139]

Haematology-Oncology Units

Colonisation or infection of patients within haematology and oncology wards was frequently demonstrated within the retrieved literature,[11-13, 18, 28-30, 35, 37, 40, 43, 59, 63, 75, 77, 84, 88, 93-95, 101, 116, 117, 124, 128, 141-144] with 9 of these involving paediatric patients.[30, 59, 93-95, 116, 117, 141, 142] The organisms implicated included Gram negative bacteria: *Achromobacter* spp.,[116] *A. junii,*[117] *E. cloacae,*[124] *P. aeruginosa,*[12, 13, 28-30, 37, 40, 43, 59] *P. putida,*[59] *K. oxytoca,*[128] *and L. pneumophila;*[63, 75, 77, 84] nontuberculosis mycobacteria including *M. mucogenicum;*[93, 94, 101] and fungi such as *Aspergillus* spp.,[141] *E. jeanselmei,*[144] *F. oxysporum,*[142] *F. solani,*[142, 143] and *Rhizomucor* spp.[141]

The underlying medical conditions of the immunocompromised patients who became colonised or infected included: bone marrow or blood cancer such as active leukaemia,[63] acute lymphocytic leukaemia,[30, 37, 59, 93, 94, 116, 141, 142] acute myeloid leukaemia,[28, 37, 77, 93, 101, 116, 128, 142, 143] juvenile myelomonocytic leukaemia,[116] myelodysplastic syndrome,[28, 128] and non-hodgkin lymphoma;[101, 128] organ associated cancer such as hepatoblastoma,[59] medulloblastoma,[30, 117] nephroblastoma,[59] retinoblastoma;[59, 117] other cancer including neuroblastoma,[96, 119] and rhabdomyosarcoma;[30, 94] blood or bone marrow disorder and disease such as aplastic anaemia,[94] autoimmune haemolytic anaemia,[116] idiopathic medullary aplasia,[59] neutropenia;[29, 43, 143, 144] and other undisclosed haematological diseases and malignancies.[43, 124, 144]

In two further studies, haematology and oncology outpatients acquired a waterborne HAI. Outpatients with malignant tumours acquired infections with *P. agglomerans*[133] and patients with sickle cell disease developed infection with *M. mucogenicum*[96] following infusions or flushes of implanted ports respectively, using liquids which had come into contact with contaminated with sink water. In one outbreak not only patients, but a visitor with a history of lung transplant and chronic neutropenia, contracted the outbreak strain of Legionella from a haematology-oncology ward.[63]

Several additional cases of nosocomial infection occurred in patients assumed to be undergoing bone marrow or stem cell transplantation or preparatory conditioning procedures.[33, 35, 39, 60, 66, 71, 73, 82, 83, 86, 88, 95, 100, 134, 144] Infection and/or colonisation was associated with *E. cloacae,*[60] *E. jeanselmei,*[144] *F . solani,*[143] *P. fluorescens,*[134] *P. aeruginosa,*[33, 35, 39, 60] *K. pneumoniae,*[60] *L. pneumoniae,*[66, 71, 73, 82, 83] or NTM.[86, 100] The underlying conditions of these immunosuppressed patients included: acute lymphatic leukemia,[76, 102, 136] acute myeloid leukemia,[33 100, 134] adrenoleukodystrophy,[102] anemia,[39, 102] anaplastic lymphoma,[100] chronic myeloid leukaemia,[40, 82, 134, 143] hemophagocytic lymphohistiocytosis,[100] hodgkin lymphoma,[100, 134] leukemia,[71] mantle cell lymphoma,[40] multiple

myeloma,[33, 82, 134] multiple sclerosis,[33] myelodysplastic syndrome,[100, 134] non-hodgkin lymphoma,[33] neuroblastoma,[100] and osteoporosis.[100]

Multivariate analysis identified neutropenia,[144] long duration of hospital stays,[144] and use of corticosteroids[83, 144] as risk factors for patient acquisition of outbreak pathogens within haematology and bone marrow transplant units. Additionally, during an outbreak of *B. cepacia*, patients with cancer were found to be at a significant risk of acquisition.[119]

Importantly, many of the outbreaks of infection within adult and paediatric haematology and oncology wards were associated with central venous catheters (CVCs) becoming contaminated during patient bathing.[12, 30, 59, 93, 94, 101, 116]

Intensive Care Units (ICUs)

The second most common clinical setting in which waterborne outbreaks occurred was the ICU. This included colonisation and/or infection of patients within general ICUs,[29, 62, 66, 70, 73, 74, 84, 131] surgical ICUs,[20, 21, 38, 42, 54, 56, 106, 115, 136, 138] neurosurgical ICUs,[45, 103, 107] burns ICUs,[17, 52, 112] cardiac ICUs,[27, 125] and paediatric ICUs.[70, 109, 114]

Gram negative organisms were implicated including *A. baumannii,*[112, 114, 115] *P. aeruginosa,*[17, 20, 21, 27, 29, 38, 42, 45, 52, 54, 56, 62] *K. pneumoniae,*[103, 106, 107, 109] *K. oxytoca*,[125] *L. pneumophila,*[66, 70, 74] *S. marcescens,*[136] and *S. maltophilia.*[138]

Patients within ICUs had an array of underlying medical conditions prior to colonisation and/or infection, which included: bacterial infections,[19] bacterial meningitis,[104] burns,[17, 19, 52, 112] cancer,[42, 45, 122] cardiac disease or failure,[19, 27, 55, 110] cystic fibrosis,[19, 27] haemorrhagic events,[45, 103] head or spine injury or trauma,[45, 103] idiopathic pulmonary fibrosis,[27] primary pulmonary hypertension,[26] neurological illness,[136] pneumonia,[104, 110] sarcoidosis,[27] sepsis,[110] stroke,[110] or ulcers.[19]

The characteristics of patients at risk of colonisation and/or infection with pathogens associated with waterborne outbreaks within healthcare facilities were analysed in several case-control studies. Significant risks factors ($p \leq 0.05$) for patients included: undergoing dialysis or haemodialysis,[20, 55] longer stays within ICU,[55, 56, 112] surgery prior or during ICU stay,[26, 56] mechanical ventilation,[56, 136] central lines,[136] length of time with a CVC,[26, 56] arterial catheterisation,[56, 138] urinary catheterisation,[56] warming up with warm air blanket,[26] antibiotic use during admission,[26, 55] preceding infection,[55] frequency of bronchial lavage,[26] intracranial pressure cathetarisation,[136] nebulisation therapy,[136] peripheral nutrition solution/number of days receiving solution,[56, 136] medication received orally,[136] and receiving multiple doses of medication.[136]

Neonatal Units (NNUs)

Neonatal units were also regularly host to outbreaks associated with water systems in healthcare facilities.[14, 15, 23, 31, 32, 48, 50, 52, 57, 72, 123, 139, 140] The majority of outbreaks discussed (75%) were caused by *P. aeruginosa*[14, 15, 23, 31, 32, 48, 50, 51, 57] however, there were also cases of infection in neonates due to *E. meningoseptica,*[123] *L. pneumophila*[72], *S. maltophilia*[139], *Candida parapsilosis* and *Candida metapsilosis.*[140]

Clinical conditions in neonates who were colonised and/or infected included; congenital anomalies, hypoplasia, intraventricular haemorrhage, laryngeal anomalies, oesophageal atresisa, patent ductus arteriosis, pulmonary disease, and respiratory stress disorder.[14, 31]

Case-control studies identified the gestational age and mean birth weight as risk factors, with those with a lower birth weight[14, 48] and lower gestational age[14] at a higher risk of colonisation and/or infection. Additionally case patients were more likely to have exposure to a peripherally inserted catheter or invasive ventilation or respiratory support.[14, 48] These clinical risks factors were noted in additional outbreak reports with at least half of neonates colonised/infected with extremely low birth weight (<1000g),[32, 50] pre-term (<37 weeks),[32, 139] and ventilated or requiring respiratory support.[31, 139] Additionally, neonates who had received blood transfusions were found to be at a higher risk of infection, however, this was found ultimately to be due to the use of a contaminated water bath used to heat transfusion products.[51]

Other Clinical Settings

Less frequently, waterborne colonisation and infection of high-risk patients occurred in other clinical settings. This included surgical units: cardiothoracic[88, 89], general,[64] neurosurgical[81] and paediatric,[41] and transplant units (including lung, liver and kidney)[27, 61, 63, 69, 88, 147] as well as a pacemaker implantation unit.[87]

Additional specialised clinical locations implicated in outbreaks were a bronchoscopy suite,[79] burns units,[24, 135] cardiac wards,[64, 74, 75, 77, 83, 132] an ear, nose throat department,[22] a HIV unit,[92] nephrology wards,[36, 58, 76] and respiratory wards.[64, 76] Other clinical care settings included private or military hospitals,[85, 97] long term care facilities,[80, 102] and a re-education facility.[145]

It was also noted that water system contamination could result in outbreaks across different clinical settings[18, 21, 27, 29, 35, 42, 44, 53, 64, 66-68, 70, 73-77, 83, 84, 88, 91, 95, 98, 119, 143, 146, 147] and between two or more geographically distinct hospitals.[57, 65, 105, 106, 108] In one study, an outbreak of *L. pneumophila* not only affected patients within multiple wards such as chest and general surgery wards but also hospital staff such as those within the chest department and laboratory.[64] Furthermore in one study, a contaminated decorative fountain in a hospital lobby, caused legionella infections in visitors who came into contract with it.[78]

What are the potential sources of waterborne outbreaks?

According to the British Department of Health,[9] healthcare water systems the incoming water supply is reported to be the usual source of *Legionella* spp. with problems arising when measures such as water treatment or temperature controls fail. Additional sources described include water supplied from storage and distribution systems and waste water systems, or system components which have been retrogradely contaminated.

Alongside this, *Legionella* spp. can colonise water fittings, pipework and materials within water systems.[2] The presence of sludge, sediment, scale, organic matter and rust can favour growth and water stagnation encourages this colonisation and biofilm formation.[2] Stagnation arises due to poor water flow, areas with dead-legs, and rises and falls in water temperature.[2] The biofilms formed allow bacterial growth and survival within water systems, and provide protection from control measures such as heat and chlorine.[2] This is highlighted within the UK Health and Safety Executive guidance, which states that 'any water system that has the right environmental conditions could potentially be a source for legionella bacteria growth'.[10]

The hospital water delivery system is a potential source of *P. aeruginosa* infection within augmented care settings.[4] Contributing risks include water system features with oversized water storage tanks, flexible hoses, long branch pipes and dead-legs, with stagnant water and poor temperature control also implicated.[4] Infrequently used water outlets with low water throughput, complex internal tap designs, clinical hand wash basins and waste-water drain outlets are also at risk of contamination with *P. aeruginosa*.[4]

HTM 04-01[9] details that taps and tap water, sinks and sink traps, showers, hydrotherapy pools, ice-makers, disinfectant solutions, haemodialysers, nebuliser chambers, humidifier reservoirs, bronchoscopes and ventilator circuits can become colonised with *Stenotrophomonas* spp.. Additionally, water-based heater-cooler units used during cardiothoracic surgery have been linked to outbreaks of *M. chimaera*.

The studies included within the review, demonstrated many different sources of outbreaks linked to healthcare water systems, however, in some cases no single source was identified.[13, 15, 99, 146] It was not always clear how these sources initially became contaminated. This may have been due to low levels of intrinsic microorganisms within the potable water supply or, as several studies suggested, may be due to contamination following contact with initial index case patient, or hands of healthcare workers treating index patient.[16, 32, 34, 37, 80, 106, 128, 130, 135] Fixtures may also become contaminated due to the improper disposal of bodily fluids, such as emptying the contents of dialysis bags into sinks also used for hand hygiene.[20, 46, 62, 106, 107, 110, 120, 121, 128, 129]

Water Distribution Systems

Water distribution systems within healthcare facilities were the most frequently cited source of outbreaks. Colonisation and/or infection of patients was often due to direct contact with contaminated tap water, or through exposure to equipment, fluids and infusates which had been contaminated with non-sterile tap water supplied by the water system.[14, 25, 33, 43, 58-61, 63-68, 70, 73-77, 80-85, 87, 88, 93-95, 97, 98, 100-102, 108, 116, 118, 119, 142, 143, 145, 147, 148] Water tanks and reservoirs were frequently implicated[85, 87, 101, 142] with contamination associated with sediment and stagnation,[85, 101] which likely attributed to biofilm formation.

Several studies detailed environmental risk factors which may have led to the microbial contamination of water systems such as favourable water temperatures for microbial growth (45-50°C);[63, 74, 75, 147] inadequate disinfectant levels (i.e. low residual chlorine, <1 ppm);[63, 67, 75, 87, 88, 94, 101, 102] contamination of the public water supply;[88, 95, 97] reduced water usage;[68, 88, 102] slow delivery or low flow rates water to outlets;[88, 102] and dead-leg pipes.[66, 68, 74] In one study there was no disinfection programme for the hospital water system which led to an outbreak of *L. pneumophila.*[64] Whilst others had used disinfection systems incorporating ultraviolet light[58] or copper-silver ionization[67] but had failed to prevent water system contamination.

The recent construction of a new build hospital, long term care facility, or specialised unit water system was implicated in subsequent outbreaks of *L. pneumophila* and *P. aeruginosa.*[14, 63, 80, 82] This was hypothesised to have occurred due to water stagnation and biofilm formation for several months before the building was completed and opened.[14, 63, 82] Recent interruption or renovation of water systems was also implicated during outbreaks[25, 66, 73] which may have disrupted established biofilms within older sections of pipe work or caused an increase in the number of dead-legs. An

outbreak of *Fusarium* spp. occurred after reintroduction of the maintenance of water reservoirs in one report, which had been neglected for several years prior.[142]

Additionally, waste water systems were implicated in two hospital outbreaks. In the first hospital discussed, a leaking waste pipe was thought to have caused environmental contamination of a haematology unit.[29] Whilst in another facility, slow drainage and blocked drains resulted in backflow of dirty water into toilets and showers which were improperly cleaned, leading to contamination of environment.[29] Additionally, an unsealed floor drain in a cystoscopy suite used to drain fluids from patients was also indentified as a source, which due to its design allowed blood and urine to float back up to floor level.[36]

Taps and Aerators

Taps (faucets) and aerators (flow-straighteners) of water outlets were also cited in 27 studies as the source of waterborne outbreak within healthcare facilities.[12, 16, 17, 23, 26, 31, 34, 38, 41, 45, 47, 49, 53-56, 96, 103, 111, 117, 122, 123, 125, 136, 138, 139] In many reports it was likely that water faucets had acted as long-term environmental reservoirs, and use had resulted in the subsequent transmission to patients, staff and medical infusions.[12, 16, 17, 26, 34, 38, 41, 45, 47, 53-56, 96, 122, 123, 125, 136] Importantly aerators within taps were also implicated,[23, 103, 117, 122, 138, 139] with organic matter and debris collecting on the wire mesh of these components, resulting in water stagnation and contamination via low levels of microorganisms within potable water.[23, 117, 138] In 5 cases automatic sensor taps where linked to outbreaks[31, 49, 57, 94, 111] with microorganisms isolated from the complex internal structures including aerators, filters, metal support collars and tap bodies,[57, 111] with no or significantly less growth on the equivalent hand operated taps.[31, 57, 94]

Sinks (Basins, Drains and Siphons)

Sinks and associated structures were also associated with waterborne HAI. Sink units, siphons (sink traps), and drains were thought to be implicated in 38 studies,[11, 18, 20, 21, 24, 27, 28, 30, 32, 35, 39, 40, 42, 44-46, 48, 53, 62, 103-107, 109, 110, 112-115, 120, 121, 124, 125, 128-133, 139] as well as a soap dispenser in another.[33] These fixtures and fittings were often one of several environmental reservoirs.[21, 24, 27, 39, 40, 104, 105, 112, 113, 125] Positive cultures of outbreak strains were isolated from sinks units, drains and siphons located in: patient rooms or care environments,[18, 20, 27, 30, 32, 35, 39, 42, 44, 46, 53, 103, 104, 106, 107, 114, 115, 120, 121, 125, 131, 139] outside patient rooms,[129] pharmacy clean rooms,[133] a medicine preparation room,[128] a nurses station,[45] staff bathrooms,[39, 133] examination rooms,[133] infusion rooms,[133] and shower rooms.[112]

Poor design, which allowed splashing, aerosol formation and inadequate infection control, was frequently cited as the reason as to why sinks became the source of waterborne outbreaks. These design features included small and/or shallow sinks;[109, 110, 114] short taps;[30] taps directing water over drains;[110, 124] location of sinks close to countertops used for medical preparations or patient care products;[120, 133] sinks located in close proximity to patients;[42] drainage systems which impaired adequate drainage;[129, 130] improperly sealed joints between walls and sinks;[70] grouted tiles surrounding sinks;[48] poor quality sinks with damaged porcelain.[110] The shallow design of a sink and high water pressure in one study led to staff to place towels around the sink to prevent a damp environment, which resulted in the sink and towels becoming an environmental reservoir and preventing adequate hand hygiene.[114] Additionally, in two outbreaks of *P. aeruginosa* reusable hair washing basins were implicated as additional sources of transmission during outbreaks.[21, 26]

Wash Rooms and Hydrotherapy Rooms

Patient wash rooms and hydrotherapy rooms have been implicated in waterborne outbreaks within healthcare facilities. Shower heads used for patient cleansing have been implicated in several studies, colonised with NTM, *A. baumannii*, *P. aeruginosa* and *S. aureus.*[39, 41, 52, 59, 90, 95, 112, 135] Reports within burns units have documented that shower heads are one of several environmental reservoirs within patient washing facilities and hydrotherapy rooms, with other sources including sinks,[112] showering platforms,[112] bathing stretchers,[135] or patient trolleys.[52] Additionally an adult burns hydrotherapy room was found to harbour *P. aeruginosa* in floor traps, shower trolleys and shower drains, which not only resulted in infection in adult burns patients but in a paediatric burns patient who visited the hydrotherapy room.[19] Other fixtures and fittings within shower rooms which have been identified as potential sources during outbreaks includes shower drains,[27, 52] shower traps,[105] and shower fittings.[146] A whirlpool bath was also implicated in one outbreak, with the bath water becoming contaminated when the tub was filled. Contamination of the bath water occurred in the 2.5 cm long space between the strainer and drain, with the patients who bathed in this contaminated water acquiring *P. aeruginosa* infections.[37]

An unusual case of Mucormycosis infection occurred in two paediatric patients within an oncology unit. This was due to a leaking shower, which caused water damage to plaster in the shower room and linen store. This resulted in a source of infectious moulds, such as *Aspergillus* spp. and *Rhizomucor* spp., which infected the severely immunocompromised patients.[141]

Drinking Water and Ice Dispensers

Drinking water and ice dispensing machines have been identified as sources of infection. Contaminated water and ice have been found to cause infections with NTM and *P. fluorescens* in immunocompromised patients within bone marrow and stem cell units.[86, 134] Additionally an undersink drinking water cooling unit, caused *S. maltophilia* infection within an ICU.[137] Although this system had a carbon filter there were multiple biofilms found in the flexible tube from the carbon filter to the chiller, and from the chiller to tap at the kitchen sink, with the carbon filter found to remove chlorine dioxide from water and accumulate organics allowing microbial multiplication.[137]

Additionally three pseudo-outbreaks were associated with ice machines, with two studies detailing patient colonisation with *M. fortuitum* following consumption of contaminated ice.[91, 92] Ice was implicated in the third pseudo-outbreak when it was used to cool syringes of saline solution used during bronchoscopy, and resulted in patient colonisation with *L. pneumophila.*[79]

Decorative drinking water fountains have also been implicated in cases of legionnaires disease, with one case associated with foam material above the fountain trough causing infection in 8 visitors to a hospital.[78] The second case of infection involved two patients within a radiation oncology suite and was due to stagnation of water for 4 months within the pipes that supplied and re-circulated water to the fountain.[71] Another drinking fountain was implicated in an outbreak of *P. aeruginosa* amongst oncology patients in an ear, nose and throat department.[22]

Water-Based Equipment and Other Sources

In several cases the outbreak source was thought to be water-based medical equipment such as: heart-lung machines and associated heater-cooler units used during cardiothoracic surgery contaminated with *Mycobacterium abscessus,*[88] *Mycobacterium chimaera,*[89] *and Mycobacterium*

wolinsky,[99] water baths contaminated with *P. aeruginosa* used to heat feeding bottles[50] and blood transfusion products[50] within NNUs; humidifiers contaminated with *L. pneumophila* used for oxygen therapy and drug delivery in pnuemology and nephrology units;[76] air humidifiers contaminated with *L. pneumophila* used within NNUs[72] and a bone marrow transplant unit.[82] The initial contamination of this equipment is likely due to use of tap water containing microorganisms.

What are the potential transmission routes for waterborne outbreaks?

Available guidance from Health Protection Scotland and Health Facilities Scotland states that transmission of waterborne *P. aeruginosa* can occur via environment to patient through direct contact with contaminated water, splashes from water outlets, or through indirect contact involving contaminated hands, objects and equipment.[6] Additionally, the guidance states that this organism can be transmitted from patient to patient or patient to environment through clinical procedures which produce aerosols.[6] Health Facilities Scotland and the Department of Health also state that transmission of *Legionella* spp. is through inhalation of aerosols into the lungs.[2] Aerosols can be generated from the process of water splashing on to wash-hand basins, sinks, and baths, in shower cubicles and when flushing toilets.[2] Aspiration of contaminated drinking water in the airways is also a possible route and is a particular risk for patients with nasogastric tubes, stroke patients, those taking sedatives and narcotics and those with motor neurone disease.[2]

In the waterborne outbreak reports retrieved, there were often multiple, complex transmission routes identified or hypothesized. Frequently, transmission was thought to be due to patient exposure to water which was contaminated from within the water system or via water outlets.[17, 25, 26, 34, 60, 61, 63-65, 67, 68, 75, 77, 78, 80, 81, 84, 98, 142, 145, 147] Patient exposure to contaminated water may have occurred during: hand washing, oral hygiene or showering;[13, 28, 54, 59, 93-95, 97, 101, 102, 124, 143] consumption of contaminated water and ice;[86, 91, 92, 100, 134, 136] during nursing care practices using tap water, such as grooming and tube feeding;[14, 22, 23, 38, 41, 88, 102, 118, 137-139] or treatment in hydrotherapy rooms.[19, 52]

Water splashing from sinks was another common route of transmission. This was generally due to the poor design of sinks, with water flowing directly into drains. As a result aerosols were generated and splashing occurred, which contaminated not only the sink basin and water outlet, but the surrounding environment, patients and patient care products in close proximity.[21, 29, 30, 42, 43, 74, 76, 103, 107, 113-115, 120, 121, 123, 126, 128, 130, 143] Additionally, aerosols may have been inhaled by patients when generated from hot water taps,[76] during showering[83, 143] and from water fountains.[71]

Often clinical procedures associated with splash risk included intravenous preparations carried on contaminated trays;[12, 116] infusates prepared near sinks;[133] saline bags used for port flushes contaminated with tap water aerosols;[96] and transfusion products heated in contaminated water baths.[51]

Contaminated tap water was used to prepare disinfectants or antiseptics, which were then used at the site of IV catheters or before venous punctures, allowing inoculation in patient blood stream.[59, 116, 119] Additionally, contaminated deionized water was also implicated in an outbreak of *E. jeanselmei* when used to make antiseptic solutions within a hospital pharmacy.[144]

Transmission was also associated with water-based equipment. This included heart-lung machines and associated heater-cooler units used during cardiac surgery,[88, 89, 99] humidifiers within oxygen therapy and drug delivery equipment,[76] as well as air humidifiers,[72, 82] and carpet cleaners.[83] This

equipment produced aerosols containing opportunistic organisms which could then be inhaled by susceptible patients. Other equipment included bronchoscopes which were flushed with saline which had been chilled using contaminated ice[79] and ureteroscopes which were used alongside inadequately disinfected water during patient procedures.[58]

Furthermore, rinsing patient equipment with tap water was implicated in transmission. This included using tap water to rinse a decontaminated surgical device used on multiple patients,[85] nebuliser cups (which were also stored wet),[120] suction apparatus for ventilated patients,[107] and aspiration tubes for neonates.[108] Patient feeding items were linked to transmission due to contamination with tap water, including containers for nutrition solutions,[45] tube feeding bags and bottles,[59, 73, 118] and milk bottles.[23] Other vectors of transmission included reusable hair wash basins[21, 26] and operating tables and equipment which had been cleaned with contaminated water.[87]

In several of the outbreak studies, it was suggested that transmission was also interlinked with healthcare workers. Contaminated hands were thought to have led to transfer of pathogens during patient care.[13, 32, 45, 113, 120, 125, 126, 128, 131, 138, 146] This may have been due to hand washing or splash-back with contaminated water,[14, 16, 39, 41, 103, 109, 124, 125, 139] the use of sinks which had previously been used for bodily fluid disposal or cleaning of medical instruments,[20, 46, 53, 106, 110, 121, 122, 129, 137] or touching contaminated environmental surfaces such as sinks or drains.[14, 125, 131]

Horizontal patient-patient transmission,[20, 46, 53, 108, 112, 123, 124, 133, 139] was also implicated as an additional route of transmission, with staff thought to facilitate this transfer.[26, 40, 55] Further, colonised, asymptomatic patients were frequently thought to have contributed to the persistence of an outbreak.[36, 45, 145] It was noted in several studies that the movement of patients and staff between wards and hospitals likely encouraged further cross transmission between patients and contamination of environmental structures.[18, 40, 105, 108]

What control measures can be implemented to stop waterborne outbreaks?

Water specific controls for Legionella include shutting down any processors capable of generating waterborne droplets and aerosols, until sampling, remedial work and cleaning has been performed.[9] Additional controls during outbreak situations are advocated. These include cleaning and disinfection of part of, or the entire water system.[10]

Control strategies differed between the studies included in this rapid review and were generally composed of several elements including both infection control precautions and specific measures used to target the environmental source of waterborne infection. It was noted that the replacement of fixtures and fittings[11, 31, 49, 60, 105, 114, 121, 132] or installation of point of use filters (POU) filters[11, 15, 17, 43, 88, 102, 142] was commonly required as a final measure to cease outbreaks. Several studies carried out replacements with less complex structures to prevent water stagnation and biofilm formation, which included aerators without wire meshes,[117] easier to clean sinks and plumbing,[121] rimless toilets to prevent splashing,[29] siphons without grooves,[28] strainers with larger holes to prevent spashing,[129] sinks with deeper basins,[109] sinks without overflow drains,[62] automatic taps replaced with simpler manual taps,[31, 49, 57, 94] taps with altered lengths,[16, 30] and self disinfecting sink siphons.[30, 126] The materials used for replacement of water system piping, fixtures and fittings should be carefully considered to prevent microbial colonisation and corrosion.[8]

The control methods used within the included articles highlights the complexity of outbreaks associated with water systems and the requirement multi-faceted approaches to ensure outbreak resolution, with limited evidence to support a particular strategy bundle.

Infection Control Measures

The National Infection Prevention and Control Manual provides clear guidance on standard infection control and transmission based precautions to minimise risk of healthcare associated infection.[7]

Infection control precautions and hygiene practices were reinforced during water system related outbreaks. The transmission based precautions implemented include: cessation of admissions;[15, 77] transfer of patients to other wards;[15, 101, 141] cohorting or isolation of patients colonised or infected;[15, 32, 38, 42, 45, 48, 50, 113-115, 128] contact precautions;[31, 38, 42, 50, 113, 114, 117, 122, 128, 129, 136, 145] reinforcing hand hygiene awareness and compliance;[15, 39, 48, 50, 114, 115, 117, 122, 128, 129, 131, 136, 139, 145] use of alcohol based hand-rub as part of hand hygiene procedures;[16, 23, 31, 49, 63, 123, 139] education of staff;[20, 29, 32, 39, 49, 50, 62, 95, 96, 114, 115, 121, 130, 131, 140] and enhanced cleaning and decontamination of the hospital environmental and environmental reservoirs.[15, 29, 44, 99, 103, 104, 113, 128, 130, 141, 145, 146] Screening of patients[32, 48, 82, 107, 123, 129, 130] and the environment[32, 33, 65, 81, 83, 87, 103, 107, 113] was often implemented as a result of outbreaks and included monthly bacteriologic surveillance of water supplies in the affected clinical areas.[41, 45, 77]

Water Distribution Systems

Water distribution systems were implicated in the colonisation and/or infection of patients due to the provision of microbiologically contaminated water. Control measures related to water systems included the implementation of water restrictions,[63, 82, 83, 86, 114, 136, 145] with showering avoided or limited to prevent patient exposure to tap water.[21, 77, 83] In many cases patients were provided with bottled water for drinking,[11, 22, 63, 83, 86, 100, 134] and this was also used for care procedures.[34, 67, 136] Sterile water was used frequently for high-risk and immunocompromised patients during care activities such as bathing, oral care and nasogastric feeding.[13, 15, 23, 38, 41, 73, 83, 102, 122, 123, 139] Waterless care techniques were also implemented in several reports, with waterless oral care[111] and use of disposable sponges or wash cloths implemented.[20, 38, 143]

POU filters, including 0.2 µm/PALL filters, were regularly fitted to water outlets during outbreaks, including sinks and shower heads, to protect patients from circulating pathogens.[12, 14, 15, 17, 25, 33, 43, 56, 59-61, 63, 67, 101, 102, 142] Four intervention studies using POU filters, found that rates of patient colonisation and infection significantly decreased following implementation.[25, 56, 60, 61] However in one of these studies sampling of filtered water 7 and 14 days after installation recovered HPC bacteria, although none of these were identified as the organisms which had previously caused patient colonisation and infection.[61] The positive samples were thought to be due to retrograde contamination via water splashing from the basin or contamination through hands and clothes.[61] Another study isolated *P. aeruginosa* and HPC bacteria from taps following POU filter use, again linked to retrograde contamination.[110] However, Scottish guidance currently states that POU filters should not be used as a first line control for outbreaks in high-risk settings.[6] Filters do not eradicate the organism but prevent its discharge into the environment from the filtered outlets, and due to this retention within water system it may be able to multiply and contaminate other parts of the water system.[8] The SHTM 04-01[8] states that filters should only be considered as part of control strategy when the most vulnerable patients are to be treated.

Decontamination of the water system and fixtures and fittings usually included superheating (heat-shock) and flushing (≥60°C),[64, 70, 76, 81, 84, 147] hyperchlorination,[14, 33, 34, 41, 54, 66, 73, 98, 102] or both such measures.[14, 63, 67, 75, 77, 82, 145] However, in several studies these techniques were inadequate with further patient infections of positive environmental samples.[64, 69, 73, 102] The subsequent measures were varied: one study repeated superheating and flushing using water at an increased temperature of 70°C; one study installed POU filters after chlorination failed,[102] another disconnected the hot water supply and used electric showers;[69] whilst in two others complete eradication of the outbreak organism failed even after installation of continuous chlorine units[73] or heat shock units.[70]

Other control measures for water distribution systems included: immediate shut down of water systems;[67] cleaning of water tanks and associated fittings;[15, 75, 87, 101] removal or capping of dead-legs;[77, 83, 133] monitoring and/or increasing chlorine to ensure adequate levels;[63, 87, 94, 98, 133] introduction of continuous, in-line, chlorine dioxide dosing of the water systems;[14, 67, 73, 77, 83, 87, 142] increasing chloramine levels;[88] increasing temperature of water heaters;[75, 84] increasing temperature of circulating hot water temperature;[15, 147] testing of temperature and flow;[14] and engineering controls to improve flow rates, water delivery and system pressure and the initiation of regular maintenance and flushing plans.[16, 75, 87, 88, 101, 133] Further control strategies included installation of heat shock units;[70, 81] UV light systems,[64] silver-copper ionization systems,[75, 80] in-line filters,[58, 142] and a water loop producing microbiologically controlled water.[59]

Taps and Aerators

When taps and aerators were identified as the environmental reservoir of outbreaks, several different control measures were put in place including: restricting the use of sinks;[44, 111, 122, 139] removal of mineral deposits on taps and aerators;[14, 45, 83, 125] cleaning, decontamination or sterilization of taps and aerators;[14, 34, 54, 122, 125] flushing of taps;[76, 83] removal of aerators;[14, 96, 120] replacement of aerators[117, 122, 138, 139] and taps;[16, 29-31, 33, 41, 49, 57, 62, 94, 103, 111, 123, 125, 136] and replacement or installation of mixing valves to ensure correct temperatures at water outlets.[111, 123] Additionally, regular flushing[16] and cleaning of taps[34, 38, 111] and detachable aerators;[34, 56, 117] was implemented.

Sinks (Basins, Drains and Siphons)

Similar control measures were enforced when sinks and associated plumbing were found to be the source of waterborne outbreaks. These measures included: decommissioning or removal of sinks, siphons and overflow holes;[49, 106, 129, 133] removal of mineral deposits[14] and biofilms;[124] cleaning, disinfection, decontamination or sterilization of sinks,[14, 44, 104, 105, 128, 133] siphons[19, 46, 105] and drain pipes;[28, 40-42, 44, 46, 106, 115, 125, 131] replacement of sinks,[18, 28, 29, 45, 62, 106, 107, 109, 111, 114, 121, 128] siphons,[20, 30, 103, 105, 106, 121, 126] and drainage pipes;[18, 23, 107, 121, 129] and implementation of regular cleaning and disinfection of sinks,[28, 48, 101, 109, 114] siphons[45, 101, 121] and drains.[18, 29, 124, 130] Several studies improved sink hygiene practices by implementing dedicated clean sinks,[38, 121] ensuring staff did not using patient sinks for bodily fluid disposal,[20, 56, 62, 107, 131] and storing patient care items away from the sink area.[29, 120] Other measures included addition of shut-off valves in drains,[130] closing floor drains,[36] and fixing or replacing splash backs.[48]

Wash Rooms and Hydrotherapy Rooms

To help control outbreaks related to patient wash rooms, measures put in place included: cleaning of shower heads with sodium hypochlorite;[105] replacement of shower heads and hoses;[59, 83, 95, 101] removal of shower curtains and treatment of room as a wet rooms;[101] ensuring hoses hung straight

to prevent stagnation;[95] and ensuring showers were run before use.[39, 100, 101] The lining of shower hoses as well as those which connect pipe work to fixtures and fittings may be composed materials such as ethylene propylene diene monomer (EPDM) rubber which can allow colonisation with organisms such as *Legionella* spp. and *Pseudomonas* spp.[8] New lining materials are available and should be considered for hoses in used in areas housing high risk patients.[8]

The use of hydrotherapy rooms was ceased in one study[135] whilst another revised disinfectant protocol disinfectants and ensured areas were not persistently wet within the hydrotherapy room to control the outbreak.[19] Additionally, in the case of a whirlpool bath in which bath water had become contaminated due to the space between the drain and strainer, the subsequent control measure was to use baths which had drains which sealed at the top preventing water contamination.[37]

Drinking Water and Ice Dispensers

Water dispensers including drinking fountains and cooling units which acted as environmental reservoirs in the included studies were generally removed from use within the healthcare,[71, 78, 134, 137] however in one case the unit was replaced with one which performed terminal UV treatment.[22] In the case of ice machines, consumption of ice and water from the machine was banned and replaced with bottled water,[86] with machines disconnected, cleaned and disinfected[91, 92] and filters installed,[92, 102] or machines completely removed from service.[91] In one study, ice machines were replaced with smaller models, reducing the potential for water stagnation and continuous drains were installed to allow for daily flushing.[86] In the case of ice baths used for medical syringes, immersing syringes of saline into ice was discontinued and replaced by a practice of immersing the bottle of saline in ice and drawing aliquots of saline from the bottle using sterile technique to avoid contact with the ice.[79]

Water-based Equipment

In the case of heart-lung machines and associated heater-cooler units, this equipment was replaced and sterile or filtered water used for these new devices[88, 89, 99] with regular disinfection and drainage implemented.[88, 99] Sterile water was also used for humidified respiratory equipment,[76] whilst air humidifiers were no longer used.[82] In the case of contaminated water baths, these were either replaced with dry heating incubators[51] or refilled using sterilised water.[50]

Other Control Methods

Several other control measures were used during water associated outbreaks in healthcare facilities. Firstly, sterile water was used for cleaning of reusable patient equipment such as surgical[85] and respiratory equipment[73, 76] and to prepare antiseptic solutions.[116]

Control strategies for patient care during outbreaks included the removal of CVCs[101, 116] or covering CVCs when bathing to prevent contact with non-sterile water.[93-95] Antibiotics were also prescribed for prophylaxis or treatment patients during outbreaks.[82, 96, 101, 116, 141]

Often policies and guidance regarding the aforementioned measures, as well as those on hygiene and other medical procedures such as hydrotherapy and respiratory care, were introduced, reviewed or changed in a bid to prevent further outbreaks.[38, 40, 41, 62, 83, 95, 112, 120, 130, 135, 136]

In several cases, major renovation works were undertaken to stop outbreaks, such as renovations of patient rooms[42] and bathrooms,[142] and reconditioning of water systems.[65, 147] Other significant

measures included ward relocation[27] and, in one case, the complete rebuild of the ward due to the age of the water system.[13]

Discussion and Implications for Future Research

This rapid review highlights the range of microorganisms which can be associated with waterborne outbreaks within healthcare facilities. In the studies retrieved, outbreaks were largely due to Gram negative organisms, with the most frequently cited being *P. aeruginosa*, *L. pneumophila, K. pneumoniae* and *A. baumannii*. NTM were also regularly identified as the causative organisms. A small number of outbreaks within healthcare facilities were due to fungi and viruses causing water system contamination.

In respect of the clinical settings and patients affected, it is clear that immunocompromised patients within haematology-oncology wards, ICUs and NNUs are at particular risk, with others at risk within surgical and transplant units. These high-risk patient groups within such high-risk settings are detailed within current guidance from Health Protection Scotland and Health Facilities Scotland and the Department of Health.[2, 4, 6, 9]

The origins of waterborne outbreaks vary, with contaminated water being the most frequently identified source. Contamination generally occurred within water distribution systems or as a result of contaminated fixtures and fittings. Design of water systems, fitting and fixtures was repeatedly associated with water outbreak. It is therefore clear that the design of both the water distribution system and associated fixtures and fittings can impact the likelihood of bacterial contamination and potential biofilm formation.

This review has also highlighted that installation and renovation of water systems can have a substantial impact on the likelihood of HAI outbreaks. This was demonstrated through several outbreaks which occurred due to water stagnation and biofilm formation prior to the occupation of new buildings and clinical areas[14, 63, 82] even when commissioning and testing had been performed prior to patient occupancy.[80] This should be reviewed in further detail to identify relevant guidance and literature regarding the installation of water systems to identify methods to prevent water stagnation and biofilm formation in the period before hospital facilities are in use.

From the studies included it was also clear that there is a lack of a standardised control measures used during outbreak situations, with only two studies stating their control measures were in line with national guidance.[17, 62] In several cases POU filters were used to control outbreaks[11, 15, 17, 43, 88, 102, 142] however Scottish guidance currently states that these should not be used as a primary control measure during an outbreak.[6] Therefore, further analysis is required to determine the current guidance available on suitable control measures for healthcare outbreaks linked to water systems to ensure suitable and effective resolution through standardised implementation.

Finally, it was noted that water system control measures already in place did not prevent outbreaks.[67, 78, 84] Other studies implemented regular maintenance, cleaning and testing procedures following the outbreak.[16, 18, 28, 29, 34, 38, 45, 48, 56, 75, 86-88, 101, 109, 111, 114, 117, 121, 124, 130, 133] However, these operational, cleaning, and maintenance measures differed in technique and frequency between studies. It would therefore be important to perform further scrutiny of control measures within healthcare facilities to identify current guidance and literature to analyse if these measures are

sufficient to prevent or reduce the number of waterborne outbreaks occurring, or if such measures are being applied in line with existing guidance.

The results of our rapid review are similar to those found by other similar literature reviews.[149, 150] Indeed, both studies concluded that design features promote sink-related infections; by promoting biofilm formation and by disruption of biofilm with subsequent aerosolization, splashing and contamination of surfaces.[149, 150]

Recommendations:

- Further analysis of the available guidance and literature is required to: i) understand the best possible design to ensure waterborne outbreaks are prevented, ii) identify the requirements for the installation of water systems, iii) identify effective infection control measures in case of an outbreak and for maintenance of the water system.

Appendix 1

Search Strategy

Ovid MEDLINE, Embase and Maternity and Infant Care (MIDIRS) were searched on 27/06/2018. Results were limited to English language, human subjects, 1998-Current and following deduplication 798 results were retrieved. Papers were then screened and excluded if they were not a study focussing on outbreaks within healthcare facilities due to water systems, resulting in the selection of 98 articles. Additional hand searching and expert recommendation resulted in the inclusion of an extra 34 papers which met the criteria for inclusion. In total 132 articles were included in the final literature review. Additionally using the Google search engine guidance documents were retrieved from relevant websites for Health Protection Scotland, Health Facilities Scotland, the UK Department of Health and the UK Health and Safety Executive.

A new search was carried out on 01/04/2019 in the abovementioned databases. Results were limited to English language, human subjects, 2018-current and following deduplication 73 results were retrieved. Papers were then screened and excluded if they were not a study focussing on outbreaks within healthcare facilities due to water systems, resulting in the selection of seven articles.

The search strategy used was as follows:

1. exp *water/
2. water system*.mp.
3. (tap* or faucet*).mp.
4. (basin* or sink*).mp.
5. drain*.mp.
6. shower*.mp.
7. outbreak*.mp.
8. exp disease outbreaks/
9. nosocomial infection*.mp.
10. waterborne infection*.mp.
11. hospital*.mp.
12. healthcare facility.mp.
13. healthcare setting*.mp.
14. 1 or 2 or 3 or 4 or 5 or 6
15. 7 or 8 or 9 or 10
16. 11 or 12 or 13
17. 14 and 15 and 16
18. limit 17 to English language
19. limit 18 to human
20. limit 19 to yr=”1998-Current”
21. remove duplicates from 20

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Health Protection Scotland

NHS National Services Scotland

Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHSScotland

Date: 20/12/18

Status: Final v2

Contents

Executive summary

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating and managing a contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with probable linked cases of bloodstream infections associated with wards 2A/2B RHC.

Wards 2A/2B RHC is a haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant Unit. In 2016 a patient within ward 2A RHC was identified as having a blood stream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition received by the child was prepared. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017 however no environmental or water sampling was undertaken at this time.

Between the period of 29th January and 26th September 2018, 23 cases of blood stream infections (11 different organisms) with organisms potentially linked to water contamination were identified. As a result further testing of the water supply was undertaken across both hospital sites early in the investigation. This testing identified widespread contamination of the water system. Control measures implemented included sanitisation of the water supply to ward 2A, installation of the use of point of use filters in wash hand basins and showers in ward 2A/B and other areas where patients were considered high risk. Drain decontamination was undertaken and on 26th September 2018 wards 2A/B were closed and patients decanted to ward 6A QEUH and 4B QEUH. There have been no new linked cases identified since the decant of the patients.

NHSGGC requested support from Health Protection Scotland (HPS) with this incident on 16th March 2018 and Scottish Government invoked the national support framework on 20th March 2018 which requires HPS to lead an investigation and provide board support. This report is a summary of the findings from this ongoing investigation for the period of 29th January 2018 – 26th September 2018. Further technical work is being undertaken for NHSGGC by Health Facilities Scotland (HFS).

Background

Health Protection Scotland

HPS plan and deliver effective and specialist national services which co-ordinate, strengthen and support activities aimed at protecting the people of Scotland from infectious and environmental hazards.

They do this by providing advice, support and information to health professionals, national and local government, the general public and a number of other bodies that play a part in protecting health.

HPS is a division of NHS National Services Scotland which works at the very heart of the health service across Scotland, delivering services critical to frontline patient care and supporting the efficient and effective operation of NHS Scotland. The specialist group involved in supporting NHSGGC in this investigation is the antimicrobial resistance and healthcare associated infection (ARHAI) group. The lead from HPS in this investigation and author of this report is a Consultant Nurse in Infection Prevention and Control with a specialist qualification in water and ventilation and is also the national HAI built environment and decontamination lead. HPS have been supporting NHSGGC with this incident since 16th March 2018. This report has been produced with full support from colleagues across NSS.

National Support Framework

The National Support Framework[1] is a structure that sets out the roles and responsibilities of organisations in the event that a healthcare infection outbreak/incident, is deemed to require additional expert support. The National Support Framework may be invoked by the Scottish Government HAI/AMR Policy Unit or by the NHS Board to optimise patient safety during or following any healthcare incident/outbreak(s)/data exceedance or Healthcare Environment Inspectorate (HEI) visit/report. Scottish Government invoked the national support framework[1] on 20th March 2018

NHS Greater Glasgow and Clyde

NHSGGC is the largest health board in Scotland serving a population of approximately 1.2 million people and employ circa 38,000 staff. The main hospital sites covered by this NHS Board are:

- Inverclyde hospitals campus
- Royal Alexandra campus
- Gartnavel campus
- West Glasgow ambulatory care Campus
- Glasgow Royal Campus
- New Victoria Hospital
- Stobhill campus
- Vale of Leven
- Queen Elizabeth University Hospitals Campus

Queen Elizabeth University Hospital (QEUH)/Royal Hospital for Children (RHC)

NHS Greater Glasgow and Clyde's (NHSGGC) Queen Elizabeth University hospital (QEUH) is a 1109 bedded hospital with 100% ensuite single side room. Construction commenced on the £842 million hospital in 2011 which was handed over to the Board on 26th January 2015 with patient migration commencing from 24th April 2015 until 7th June 2015. The adjoining Royal Hospital for Children (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. The QEUH and RHC were both fully occupied from 15th June 2015. There are a number of additional healthcare facilities in the surrounding grounds including the maternity unit, neurosurgical unit, elderly care unit and the national spinal injuries unit. The QEUH/RHC is Scotland's largest hospital and replaced a number of existing hospitals from the NHSGGC area including:

- Southern General Hospital
- Victoria Infirmary
- Mansionhouse Unit
- Western Infirmary
- Royal Hospital for Sick Children (Yorkhill)

Introduction

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating and managing a contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with 23 probable linked cases of bloodstream infections associated with wards 2A /2B RHC. NHSGGC requested support from HPS with this incident on 16th March 2018 and Scottish Government invoked the national support framework[1] on 20th March 2018 which requires HPS to lead an investigation and provide NHS board support. It is recognised that this investigation and remedial action is still underway and may be ongoing for a considerable period, therefore this report is a summary of the findings from this investigation and includes cases and findings for the period 29th January – 26th September 2018.

An initial report was produced by HPS and submitted to Scottish Government (SG) and NHSGGC on 31st May 2018. Due to the ongoing and complex nature of this incident and investigation a further report was requested. This report is a summary overview of this investigation however due to the large volume of data and complexities associated with this incident further technical work is being undertaken by HFS. HPS worked with the support of HFS as the technical engineering experts to support this investigation and report production. In addition the HAI Policy Unit Scottish Government (HAIPU) has requested a separate detailed review of wards 2A/B to be undertaken. This is currently underway and will form a separate report for HAIPU and NHSGGC.

Summary of clinical cases associated with this incident

Case definition

The case definition in place since January 2018 is:

"*any child linked to wards 2A/B RHC with a blood stream infection (BSI) caused by a gram negative bacillus that had been identified from organisms identified within the water system"*

Ward 2A RHC is a haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant Unit and teenage cancer trust. Ward 2B is the day care component of ward 2A. In total there have been 23 cases identified during the period 29th January and 26th September 2018.

2016-2017

In February 2016 a patient within ward 2A RHC was identified as having a bloodstream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition was made that the child had received. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. Typing by Colindale reference laboratory confirmed the isolate from the washhand basin and the patient were the same. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017. NHSGGC reported that a second hand hygiene sink was found to be positive but following assessment was unable to be removed. Silver hydrogen peroxide treatment was undertaken and repeat testing resulted in zero total viable counts from this outlet.

2018

On 29th January 2018 *Cupriavidus pauculus* was again identified from a bloodstream infection (BSI) in a patient in ward 2A. Following identification of this case a series of investigations were undertaken including water sampling from outlets within the ward area. On 21st February *Pseudomonas fluorescens* was identified from a BSI and between 11th and 16th March 2018, 3 cases of *Stenotrophomonas maltophilia* were identified from patients in ward 2A. On 7th April a further case of *Stenotrophomonas maltophilia* was identified. *Cupriavidas*, *pseudomonas* and *stenotrophomonas* (amongst other gram negative bacillus and fungi) were identified from water samples obtained within wards 2A/B and therefore all cases considered to be linked to the water system. No further cases were reported until April, when between April and June, a further 10 cases were reported: 5 *Enterobacter cloacae*, 3 mixed gram negative bacilli, 2 S*tenotrophomonas maltophilia*. This cluster of mixed organisms, which were present from drain samples prompted the investigation in to the drains within ward 2A/B. Following drain sanitisation and environmental decontamination using hydrogen peroxide vapour, no further cases were reported until 2nd August and between the period 2nd August and 20th September 6 further cases were identified: 1 *Chryseomonas indologenes/Stenotrophomonas maltophilia*, 1 *Serratia marsescens*, 1 *Klebsiella oxytoca*, 2 S*tenotrophomonas maltophilia,* 1 *Enterobacter cloacae.* This latest cluster resulted in immediate further drain decontamination and a temporary decant facility for wards 2A/B being identified, with the patients transferred to wards 6A and 4B on 26th September to allow for investigative and remedial works to be undertaken in wards 2A/B.

In total there have been 23 patient cases identified. A number of patients have multiple organisms so the organism total is greater than the case number.

The organisms linked to cases include:

- *Cupriavidus pauculus* (1)
- *Pseudomonas fluorescens (1)*
- *Pseudomonas aeruginosa* (3)
- *Stenotrophomonas maltophilia* (12)
- *Acinetobacter ursingii* (2)
- *Enterobacter cloacae* (7)
- *Klebsiella oxytoca* (1)
- *Serratia marcescens* (1)
- *Pseudomonas putida* (1)
- *Pantoea sp* (1)
- *Klebsiella pneumonia* (1)
- *Chryseomonas indologenes*(1)

In addition to the organisms detailed above there is evidence of fungal growth in the water system however there have been no associated clinical cases reported.

A timeline of cases is detailed in Appendix 1. This incident has resulted in a number of children requiring additional intervention and some delays in chemotherapy treatment, however, there has been no associated mortality. There have been no associated cases since the temporary closure of wards 2A/B and the decant of the patients to ward 6A QEUH on 26th September 2018.

The clinical component of this incident is considered as occurring within two phases:

- Phase one relates to the water contamination and the clinical cases associated at that time relating to the water system. Following installation of point of use filters, the water system was acknowledged as being of suitable quality for use by patients and staff. Whilst work was ongoing to investigate and manage the water contamination incident the clinical component of this phase was considered over with a debrief held on 15th May 2018

- Phase two relates to the environmental contamination and subsequent associated clinical cases occurring as a result of the contaminated drains and the impact caused by the fitting of point of use filters. Phase two is currently ongoing and will remain open until wards 2A/B have re-opened

Summary of initial findings

Following identification of the potentially contaminated water system in wards 2A/B and the resultant possible linked cases in March 2018, NHSGGC considered the decant of these 2 wards to allow for a full investigation of the source of water contamination in wards 2A/B and consider remedial action. At that time ward 4B QEUH was being prepared for the transfer of adult BMT patients from the Beatson oncology unit. Water sampling was undertaken in this ward prior to decant as a precautionary measure. Results identified the presence of *Cupriavidus pauculus* (and other gram negative bacilli) in water outlets within this ward and was the initial suggestion that there may be widespread contamination of the water system that serves both QEUH and RHC. Further testing across the site provided confirmation of this, with positive samples being identified in a number of areas across both sites at both outlet level and within the water system in the basement level (risers). Within the same timeframe staff within wards 2A/B also reported they had witnessed “black effluent” around the rim of the drain in some wash hand basins. Following visual inspection and laboratory testing, this was considered to be biofilm and sampling identified significant contamination of the drains with microorganisms and fungi. Drain contamination is not unexpected however the level of biofilm evident was not in keeping with a water system of less than four years old.

In an attempt to establish the extent of the water system contamination and any causative factor NHSGGC, supported by HFS and HPS initiated a detailed investigation into the contaminated water system within QEUH/RHC. Support was also requested from a number of external companies experienced in water incident management: These included Leegionella, Public Health England (PHE), water solutions group and Makin & Makin. The detailed investigations led by NHSGGC and supported by HFS/HPS included reviewing commission, installation and maintenance records provided by the contractor. This proved to be challenging due to the archiving of data and there were very few members of the initial project team available who are technically qualified to retrieve data and provide verbal clarification. The detailed findings from these records are included within the technical review.

Results from ongoing water testing were reviewed on a weekly basis and highlighted there was evidence of regressional seeding of contamination which supported NHSGGCs view that a whole system remedial approach was required.

Commissioning and design of the hospital water system

As part of the normal water system commissioning water samples were obtained. Initial preliminary findings have identified that prior to handover from the contractor there were a number of water samples taken that produced results with high level of total viable counts (TVCs). TVCs are indicators that there are hygiene issues within the water system and are quantified as a generic indicator for microbial contamination. Specific microorganisms which can be tested for include: Coliforms, *Escherichia coli (*including O157), *Pseudomonas aeruginosa, Salmonella spp*, *Campylobacter spp* and Environmental Mycobacteria. Testing for these is not conducted as standard within current guidance and typically occurs in response to a suspected or confirmed outbreak, or due to identification of a series of sequential cases.

In response to the high levels of TVCs found as part of the pre handover commissioning sanitisation of the water supply was undertaken by the contractor, with some impact and a reduction in TVCs in most areas, however there are a number of reports which indicate that

there may still have been a number of areas with higher than normally acceptable levels of TVCs.

Design and installation of taps and clinical wash hand basins

The design and construct of wash hand basins, showers and taps in these hospitals were agreed with NHSGGC in line with the Scottish Health Technical Memorandum (SHTM) in place at the point the hospitals were designed (commencing 2009), this included the installation of taps with flow regulators. HFS and HPS were involved in this decision making process as were NHSGGC Infection Control team. The SHTM (SHTM 04-01)[2] was revised in 2015 and no longer supports the use of flow regulators in clinical wash hand basins.

Biofilm formation in flow regulators has been identified in a previously published outbreak.[3] The manufacturers of the taps/flow regulators in place across the QEUH/RHC recommend regular removal of the flow regulators for cleaning/decontamination however do not offer more specific guidance on frequency of decontamination of the flow regulators. The flow regulators in use have a number of components and potentially create ideal conditions for the development of biofilm.

NHSGGC provided an external company (Intertek) with some flow regulators to carry out microbiological testing. This confirmed that flow regulators have the ability to harbour a significant number of micro-organisms with the presence of biofilm being detected on all flow regulators tested and 50% showing high levels of contamination. It is also worthy of note that biofilm was present on some flow regulators which was not immediately obvious on visual inspection.

The taps in place across all clinical wash hand basins in both hospitals are also reported to be non compatible with silver hydrogen peroxide, a product which was used during commission stage to sanitise the water system in view of the high TVC results. It is unclear whether this has caused any degradation of the taps. A tap was deconstructed by NHSGGC and examined for the presence of biofilm, in addition to microbiological sampling. Several components of the tap exhibited microbiological contamination.

The presence of high levels of gram negative bacteria and fungus in the water system may indicate that temperature control required has not always been achieved. Temperature control is included as part of the wider technical review being undertaken for NHSGGC by HFS.

Other aspects discussed in the detailed technical review include:

- Flushing
- Contract/project team
- Roles/responsibilities
- Design and construction
- Guidance and specifications
- Specification of water system
- Flexible hoses
- System description

- Pipe work
- Post handover and maintenance

There are a number of local and national recommendations within this review for both NHSGGC and Nationally. The key NHSGGC and National recommendations from the technical review are included within the recommendation section of this report.

Infection Control at design commissioning and handover

HAI-SCRIBE

Healthcare Associated Infection System for Controlling Risk in the Built Environment (HAI-SCRIBE) [4], reference has been designed as an effective tool for the identification and assessment of potential hazards in the built environment and the management of these risks. HAI-SCRIBE (2007) was in place during the construction and handover of both buildings.

Implementation of HAI-SCRIBE should be the responsibility of a multidisciplinary team of specialists with appropriate skills.

Compliance with HAI-SCRIBE requires an accurate record of the process of hazard assessment and risk management which is essential ‘due diligence’ information.

Evidence has been reviewed in relation to the infection control sign-off of results and the system at commissioning/handover. Whilst there is evidence of involvement with initial results and sanitisation there is no evidence of ongoing input or sign off from the Infection Prevention and Control Team (IPCT). It is noted that there is lack of clarity in current national guidance relating to roles and responsibilities of the IPCT in the commissioning, design and handover of new or refurbished builds. Water was first placed on the Infection prevention and control (IPCT) risk register in 2018. The IPC risk register is reviewed on an annual basis with risks considered and prioritised using a risk scoring system. Water safety was added to the risk register in 2018 in response to the emerging evidence of potential issues associated with this incident. Prior to 2018 water safety did not feature in the IPC risk priorities when scored.

NHSGGC employed a robust approach to the design stage of the hospital project by means of a dedicated Infection Prevention and Control Nurse (IPCN) seconded as part of the project team to support the IPCT aspect of the design stage, commissioning and handover stage.

Whilst there was dedicated resource allocated to the project team, there is no documented evidence of NHSGGC Infection Prevention and Control Team involvement in the commissioning or handover process of the project. However NHSGGC has provided a statement from the Lead Infection Control doctor at the time to confirm that they were involved in reviewing some aspects of the initial water testing methodology and the results for QEUH and RHC during commissioning and handover. The Lead ICD has confirmed being involved in:

- Quality assurance of the water testing methodology used by the commissioning engineers.
- Liaising with Facilities Colleagues in reviewing the water testing results supplied by the commissioning engineers.

- Recommending further actions (dosing), for a small number of outlets with TVCs above the acceptable limits.

In addition to a nurse consultant being seconded as a dedicated resource to the project team with involvement in design, commissioning and handover, the project team were supported by the IPCT. This support included regular review of the new builds hospital project at the infection control committee and senior IPC meetings. NHSGGC reported that both the infection control manager and associate director of nursing (infection control) liaised regularly with the project associate nurse director and ensured the numerous commissioning groups established were supported by a member of the IPCT. In addition all wards were reviewed by a member of the IPCT prior to occupation by patients.

Current management of situation/Control measures

In addition to holding regular incident management IMT meetings (IMT) NHSGGC established a multi disciplinary water technical group which is a sub group of the incident management team. This group is supported by HFS, HPS, with monthly representation from water solutions group and Makin & Makin.

A number of control measures have been instigated during this incident and in particular in wards 2A/B. These included parent and staff education sessions, daily visits to the ward from members of the infection prevention and control team (IPCT), increased domestic hours, environmental monitoring by means of audit, including Standard infection control precautions (SICPs) audits.

Limiting access to water

In the initial investigation the use of water within wards 2A/B was limited with portable wash hand basins being supplied for hand washing. Patients were requested not to use wash hand basins or showers and wipes were provide as an alternative. Drinking water was provided by means of bottled water. Access to water was re-established once point of use filters were in place in showers and wash hand basins/sinks. BMT patients continue to receive sterile water.

Point of Use filters.

Following the identification that the water contamination was widespread across both RHC and QEUH an additional control measure of point of use (POU) filters for high risk areas was implemented to ensure a safe water supply at the point of use. In addition if a high risk patient was being nursed in an area deemed to be of low risk, a point of use filter was fitted to water outlets in their room. POU filters require to be changed every 30 days and are a costly approach, however in the interim until the water contamination can be addressed, is considered the only feasible approach to ensure safe delivery of water. A number of studies found that installation of point of use filters reduced either infection rates in associated healthcare settings[5;6] or pathogen counts within tested water samples.[7]

Once the POU filters were in place the restrictions on access to water within wards 2A/B was removed and patients were able to access washhand basins and showers. It was noted that following the fitting of the POU filters there was a greater splash evident from the wash hand basins as the point of entry of the water from the outlet was closer the basin. This splash was noted more from clinical wash hand basins than ensuite wash hand basins and trough sinks.

Drain Sanitisation

Following the identification of the second phase of cases associated with this incident and the hypothesis that the cases may be related to drain contamination, the drains were inspected by the IPCT. Once the drains were identified as being visibly contaminated with what was thought to be biofilm, a programme of drain sanitisation was undertaken across high risk areas commencing with wards 2A/B.

Environmental decontamination

Prior to and following completion of the first drain decontamination process in wards 2A/B, a terminal clean of all areas using hydrogen peroxide vapour was carried out.

Water treatment

It is well recognised that drinking water distribution systems contain a diverse range of microorganisms.[8-10] The presence of microorganisms is affected by various factors including; the disinfection processes employed, the location and age of the system as well as pipe material.[11]

There were a number of options explored for longer term water treatment by NHSGGC. These options included:

Chlorine dioxide

A number of studies were identified which utilised chlorine dioxide systems within hospital settings, and use of these was found to reduce bacterial numbers.[10,12,13] Various advantages and limitations associated with use of chlorine dioxide are known, with the most relevant summarised below.[14,15]

Advantages**:** Known to be effective against a wide range of bacteria, viruses and some protozoa including Giardia.

Limitations: Production of disinfection by-products (DBP's). Although potential production of DBP's always needs to be considered, the efficacy of water disinfection should not be compromised in trying to eliminate these.[16]

UV light

A number of drinking-water treatment technologies are available which employ UV light radiation to inactivate microorganisms.[15] As with chlorine dioxide, various advantages and limitations associated with use UV are known, with the most relevant summarised below.[14-16]

Advantages: Bacteria, fungi and protozoa (considered to be more effective at killing Cryptosporidium than chlorine dioxide) are readily inactivated at low UV doses, with higher doses required for virus inactivation. In addition, UV disinfection does not result in the formation of DBP's like chlorine dioxide.

Limitations: UV disinfection does not leave any residual compound in treated water and therefore does not offer protection against possible microbial re-growth in distribution pipe-work.

Thermal disinfection

Very limited information was identified in the published literature in relation to advantages and limitations of thermal disinfection. One study found that heat shock treatment at 80˚C reduced Gram negative bacteria in a hospital water system but did not lead to complete eradication.[17] Copper silver ionisation was also considered however this was discounted due to pH levels.

Preferred solution

The NHSGGC preferred method of choice for water treatment was continual dosing chlorine dioxide. This was supported by HFS and HPS. Shock dosing of the system was considered and it was agreed that due to safety issues and the potential impact on both hospitals ability to function during the process, this was not the most appropriate approach. It was also recognised that in the absence of initial shock dosing it may take up to two years for the process to be effective from tank to tap level. The procurement process is well underway and installation expected to commence November 2018.

Temporary closure of wards 2A/B

A recommendation was made by the IMT to pursue the temporary decant of wards 2A/B to allow investigative and remedial work to be undertaken. A number of options were explored resulting in the transfer of patients from wards 2A/B to ward 6A of the QEUH. Adult patients within ward 6A QEUH were transferred to Gartnavel General. Three rooms within the adult BMT (4B) were identified and allocated to the paediatric BMT unit. The patients were transferred on 26th September 2018. It is anticipated that the decant facility will remain in place until mid/late December.

Remedial work/Investigations wards 2A/B

The planned investigations/remedial works planned during the decant period include:

- Drain Survey
- Ventilation review
- Replacement of clinical wash hand basins
- Replacement of taps (with no flow regulator)
- Review of any little used water outlets with a view to remove
- Replacement of sections of pipework where biofilm noted
- Review of toilet cisterns and adaptation to reduce potential toilet plume effect.

Hypothesis

There are a number of workable hypotheses being explored; it is currently considered the most likely cause of the widespread contamination is a combination of hypothesis B and C

A: Ingress contamination

A small low level number of micro-organisms may have been present in the water supply at the point of entry. Lack of temperature or chemical control may have enabled biofilm formation. Due to the increasing biofilm throughout the system this may have allowed any subsequent micro-organisms present at point of entry an opportunity to flourish and cause widespread

contamination of the system.

B: Regressional contamination

This may have occurred due to contamination occurring at the taps/outlets or flow straighteners and contamination has regressed backwards throughout the system causing widespread contamination. The widespread positive results and array of bacteria point to contaminated outlets at installation or contamination of high risk components in the tap from ingress as opposed to the patient contact route.

C: Contamination at installation/commissioning

Contamination may have occurred due to presence of contaminated pipework or outlets. Prior to handover the system required to be sanitised due to high TVC counts. It is unclear if a robust flushing regime was in place from installation to handover and from handover to occupancy to prevent contamination.

Secondary Hypothesis

It is recognised that in many situations control measures or actions taken in an attempt to minimise the risk of HAI there can be unintended consequences. In this scenario the secondary hypothesis is linked to the unintended consequence of the point of use filter use:

POU filters.

In an attempt to provide water of a safe microbiological quality NHSGGC applied point of use filters to all clinical and patient wash hand basins in high risk areas and areas where high risk patients were being treated. These filters meant the exit point of the water from the taps was closer to the washhand basin and as a result caused more splash which may also lead to disruption of any drain biofilm as well as potential environmental contamination. (Pictures 1, 2). At the time of fitting the filters, the issue of biofilm within the drains and the associated risk or the resultant splashing that was being caused had not been identified and therefore the subsequent increased risk of environmental contamination and potential exposure of the children was not recognised.

Picture 1

Picture 2

Additional potential considerations to minimise impact

Ensuite single side rooms/hand hygiene practice

Since 2008 it is recommended that all new build hospitals have 100% en suite single side rooms.[18] As a result this has substantially increased the number of wash hand basins and therefore the frequency with which a wash hand basin is used and the water volume in each basin reduced when compared to multi occupancy wards with a single wash hand basin. Since the introduction and widespread use of alcohol gel, the need for hand washing as a first approach has greatly decreased, as alcohol gel may be used on hands that are not visibly soiled. This requires further exploration and consideration and review of flushing regimes and number of wash hand basins required.

Disposal to drain

A number of drain samples were sent to Intertek for analysis. A report has highlighted that in addition to the general presence of biofilm, there was biofilm noted around the aluminium spigots. There was also some occlusion reported as a result of adhesive and pooling noted between the back of the sink and the pipework. All aluminium spigots in wash hand basins in wards 2A/B were replaced with PVC spigots. In addition a number of foreign objects were identified within the drains. It was also reported that there was evidence of a yellow fluid present suggestive of urine being disposed to the drain. The biofilm has a mustard yellow colour and an odour of ammonia was detected. There was a small amount of yellow liquid in the base of the bowl trap which when removed and looked at in isolation also had an ammonia smell. Parents, families and clinicians are advised that hand wash basins are for hand washing only and additional activities such as fluids being disposed of to drain via a handwash basin should not occur. Staff are aware that this is not acceptable practice however the positioning of a wash hand basin in every ensuite single side room may encourage patients or visitors to expel fluids such as contents of a drink bottle. Items such as coffee, sweet drinks encourage the growth of

bio film and microorganisms within a drain. The large open horizontal drain may also encourage the accidental disposal of foreign items.

Summary

There have been no new reported cases since the decant of patients to ward 6A on 26th September 2018. The IMT will continue to meet regularly until the patients have been transferred back to wards 2A/B. The water subgroup will continue to meet until early/mid 2019 and will be supported by HFS/HPS. It has been evident to HPS that since the identification of this widespread incident and clinical impact on wards 2A/B, patient safety has been paramount with NHSGGC clinicians, facilities, IPCT and management team. A significant financial investment has been made to minimise ongoing risks including widespread use of point of use filters in addition to remedial work planned. A number of lessons can be taken from this incident for NHSGGC and NHSScotland as a whole in relation to water safety and commission, handover and maintenance of buildings. The national work and learning for NHSScotland will be driven via the HAI built environment steering group which is widely represented and chaired by the associate director of facilities (NHSGGC) and deputy chair is the lead ICD (NHSGGC).

Recommendations

A number of local and national recommendations have been made based on the investigation to date. This includes recommendations for NHSGGC which have been identified from a detailed HFS technical review. NHSGGC/HPS/HFS will produce an action plan based on the recommendations as follows:

1. NHSGGC

- To produce a detailed action plan addressing ALL points identified within the HFS technical review and should cover as a minimum:
  - Decontamination
  - The management of the water systems
  - All required rectification work
  - Management of recording systems
  - Routine and reactive maintenance schedules

2. All NHS Boards

- All NHS boards should ensure facilities teams are adequately resourced to ensure maintenance of all aspects of the water system are maintained in accordance with policies and guidance.
- All maintenance undertaken should be recorded and maintenance records should be reviewed regularly to ensure all aspects of the water system are maintained in accordance with policies and guidance

3. HPS/HFS

HPS (supported by HFS) to undertake an urgent national water review of all healthcare premises built since 2013 to provide assurance that a similar incident has not and is not likely to occur elsewhere.

HPS (supported by HFS) to establish a national expert group to:

- Review NHSScotland current approach to water safety including as a minimum:
  - Review NHSScotland current approach to water testing in healthcare settings.
  - Review NHSScotland current surveillance and reporting of potentially linked water related HAI cases.
  - Based on findings develop risk based guidance on water testing protocols, results interpretation roles and responsibilities and remedial steps to be considered.
- Give consideration to the development of a best practice built environment manual which will be evidence based and cover as a minimum current and emerging evidence

and the technical requirements from a clinical, patient safety and HAI perspective that will be adopted by all NHS boards. This will include as a minimum:

- Review existing national and international guidance relating to water safety.
- Develop robust requirements/guidance for all aspects of water safety.
- Develop robust handover requirements in relation to water systems.
- Review of the role of the IPCT into the built environment, and produce clear guidance on roles and responsibilities.
- Establish a risk based approach to water testing and any remedial action required, including roles and responsibilities that NHS boards will adopt.
- Review the requirement for 100% ensuite single side rooms the number of clinical wash hand basins per patient/bed.
- Review the use of flow regulators across NHS Scotland and identify and associated risks and recommend any remedial actions required.

- HPS/HFS will continue to provide support to NHSGGC relating to the current water incident and provide input into the weekly meetings until mid 2019 (and reviewed thereafter).
- Further develop the existing Scottish expertise in the built environment programme (mainly water and ventilation) at national level.

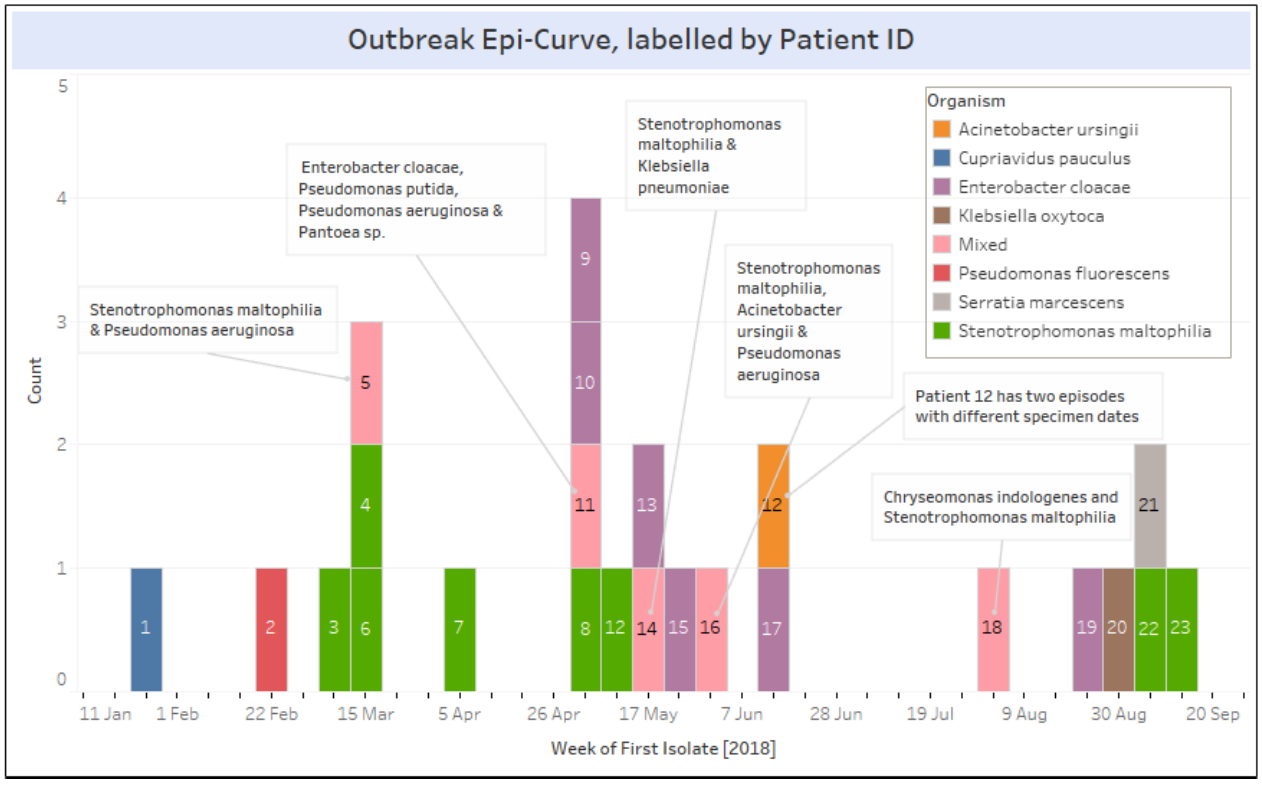
HFS (supported by HPS) to:

- Review all relevant water technical guidance to ensure all aspects are covered within the guidance including as a minimum:
  - Thermal disinfection in sections of water distribution systems
  - Handover checklists
  - Contract management procedures
  - Design guides to eliminate thermal pickup in cold water systems
  - Update advantages and disadvantages of chemical disinfection techniques
  - The organisms Boards should test for and action to take on defined levels
  - Drain cleaning regimes
  - Biofilm growth in drainage systems

.

Appendix : 1 Timeline of cases

The epi-curve demonstrates that only one case of *Cupriavidus pauculus* was reported from 26th January 2018, with the other associated cases being *Stenotrophomonas maltophilia* and/or *Pseudomonas aeruginosa* positive between 21st February 2018 and 5th April 2018.



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Glossary

Alcohol gel	A gel, foam or liquid containing one or more types of alcohol that is rubbed into the hands to inactivate microorganisms and/or temporarily suppress their growth.
Aseptic Suite	An ultra clean environment within a department, (for example pharmacy) where sterile solutions are prepared such as chemotherapy under strict measures.
Bacteria	Microscopic organisms (germs).
Bib taps	A tap or stop cock which has a nozzle bent downwards.
Biofilm	Collective of one or more types of microorganisms, including bacteria, fungi and protists, that stick together and can become embedded on a surface.
Blood stream infection	The presence of bacteria in the bloodstream.
Chemotherapy	A cancer treatment where medication is used to kill cancer cells.
Chlorine dioxide	A chemical compound used for a variety of antimicrobial uses, including the disinfection of drinking water.
Clinical wash hand basins	A sink designated for hand washing in clinical areas
Cluster	A group of similar things located around the same location
Copper silver ionisation	A disinfection process where positively charged copper and silver ions are added into the water system. It is primarily used to control control Legionella, the bacteria responsible for Legionnaires' disease.
Decant	Temporarily transferring people to another location.
Decontamination	Removing, or killing pathogens on an item or surface to make it safe for handling, re-use or disposal, by cleaning, disinfection and/or sterilisation.
Drain	A fixture that provides an exit-point for waste water or water that is to be re-circulated.
Ensuite single side room	A room with space for one patient and containing a bed; locker/wardrobe, clinical wash-hand basin, en-suite shower, WC and wash-hand basin.
Flexible hoses	A flexible hollow tube designed to carry fluids from one location to another and are used to connect taps to the water supply
Flow regulators	Point of use regulators designed to provide constant and maximum flow rates at taps and showers etc. irrespective of changes in demand or water pressure

Flushing	The process of cleaning or "scouring" the interior of water distribution mains (pipes) by sending a rapid flow of water through the mains.
Gram negative bacilli	Gram-negative bacteria are bacteria that do not retain the crystal violet stain used in the gram-staining method of bacterial differentiation; examples include E.coli, and Pseudomonas aeruginosa.
Hydrogen Peroxide Vapour	Vaporized hydrogen peroxide is an airborne disinfectant and infection control measure that can be used for room decontamination after patient use.
Ingress	The act of entering.
Microbiological sampling	Sampling for harmful bacteria, parasites, fungi and viruses including those in water, environment and equipment.
Micro-organism	Any living thing (organism) that is too small to be seen by the naked eye. Bacteria, viruses and some parasites are microorganisms.
Organism:	Any living thing that can grow and reproduce, such as a plant, animal, fungus or bacterium.
Parenteral nutrition:	The giving of special liquid feeding products to a person using an intravenous catheter and bypassing the normal digestion process of the stomach and bowel.
Pathogen:	Any disease-producing infectious agent
Point of use filters:	A device that incorporates an integral filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow therefore protecting the end user from exposure to harmful waterborne pathogens.
Portable wash hand basins	A sink that is not connected to the mains water supply but connects to a water tank which is filled locally.
Regressional seeding	Where micro-organisms from contaminated water outlets/biofilm regress 'back' through the water system and seed other areas (pipes/tanks/outlets). The microorganisms embed themselves and multiply contaminating other areas of the system.
Sanitisation	Use of antimicrobial agent on objects, surfaces or living tissue to reduce the number of disease-causing organisms to non-threatening levels.
Shock dosing	The use of large quantities of chemicals to the water supply to break down organic waste and get rid of bacteria and contamination.
Silver hydrogen peroxide	A solution of stabilised silver in hydrogen peroxide that is used for surface and water decontamination.

Sterile water	Water free of all microorganisms – bacteria, viruses, fungi.
Terminal clean	Cleaning/decontamination of the environment following transfer/discharge of a patient, or when they are no longer considered infectious, to ensure the environment is safe for the next patient or for the same patient on return.
Thermal disinfection	The use of water and heat for the disinfection process for example washer-disinfectors.
Toilet plume effect	The dispersal of microscopic particles as a result of flushing a toilet.
Total viable counts	A quantitative estimate of the concentration of microorganisms such as bacteria, yeast or mould spores in a sample.
Trough sinks	A long, narrow basin designed for communal handwashing with water delivered at hand-washing temperature via mixer taps in conjunction with a thermostatic mixing valve. Usually used for surgical scrubbing.
UV light	A disinfection method that uses short-wavelength ultraviolet (UV-C) light to kill or inactivate microorganisms.
Water outlets	Any hole or opening where water is released for example taps, showerheads.
Water sampling	The analysing of the water supply for harmful bacteria, parasites, and viruses.
Water system	A system of engineered hydrolic and hydraulic components to supply water.
Spigots	A short cylindrical pipe which connects the Clinical Wash Hand basin to the main pipework.
Occlusion	Obstruction or blockage

From: Munro, Anna
Sent: 12 June 2019 12:06
To: Guthrie, Lindsay; Sutherland, SarahJane; Cameron, Fiona; Inverarity, Donald; Kalima, Pota; Horsburgh, Carol
Subject: RE: Important -response required:RE: Confidential: HAI SCRIBE RHCYP Risks and Mitigations

Hi

I don't have anything to add except to stress that we should have the opportunity to comment on the continuity plan for items 4&5. During winter, PARU will be our main RSV cohort area and could present a wider issue for the site if it was to close in the event of a sump issue.

Kind regards

Anna Munro
Geographical Lead South and East Team
NHS Lothian Infection Prevention & Control Services
[redacted]

For more information visit the IPCT Intranet Homepage

From: Guthrie, Lindsay
Sent: 12 June 2019 10:57
To: Sutherland, SarahJane; Cameron, Fiona; Inverarity, Donald; Kalima, Pota; Horsburgh, Carol; Munro, Anna
Subject: Important -response required:RE: Confidential: HAI SCRIBE RHCYP Risks and Mitigations
Importance: High

Hi all
I believe Jim Crombie is looking for a (very) rapid response from IPCT in relation to the meeting held last week.

I agree with the other points Sarah has highlighted, and in general terms of documentation/evidence required – this would include 1) a summary report for both water and ventilation which highlights any fails/exceptions, the clinical location/specialty and remedial actions taken; 2) a clear water plan which is visible to IPCT and clinical management teams – presumably via the Water Safety Group and Ventilation group; and 3) that the 4 proposed strategic groups from George C's governance paper will all hold a topic specific risk register.

As I wasn't able to attend the meeting, and having had limited input into the planning/construction phase, I also have the following questions from the risk register:

Risk 4 & 5: sump issues -states there is a risk of loss of sanitary appliances in clinical areas and flooding in the basement – 'mitigation' has been provided and there is a continuity plan –suggest that the continuity plan is provided so that IPC can comment on this element to ensure that toilet/hand washing/waste water disposal is

appropriately managed. I am not clear why the residual risk is YELLOW for the basement sump AMBER for the garden pump failure with further mitigation in place?

Risk 7: previous leak (water joint failure) – risk of recurrence – do we know which clinical areas were affected by this issue – and are any of them augmented care/high risk areas. Monitoring is noted as a future mitigation – so would want confirmation of this monitoring activity (and outcomes) to be summarised for the RHSC infection control committee and the proposed 'Group 3 Environment' committee proposed in the new Facilities governance structure.

Risk 9: movement joints – noting that these are in clinical areas (including some high risk areas) it would be good to have written confirmation of compatibility for up to 10, 00ppm av chlorine solutions and routine cleaning methods/products – this was discussed at walkround but haven't seen written confirmation

Risk 10: Basement sump – noting adjacency to kitchen/food prep area – highlights odour and pest control as an issue. Would be good to see and agree an HAI scribe for routine access and maintenance. Would be good to see an update/monitoring/exception report provided in relation to this risk – possibly at the 'Group 3 environment' meeting as outlined above? Not being an expert in sumps or plumbing I also have a question in relation to air egress if odour is an issue is there a risk of aerosol/backflow of contaminant which would be relevant to food safety and kitchen hygiene??

Risk 12: don't fully understand the statement about extract ventilation and reduced capacity to a minimum of 10%- or indeed what (if any)impact there would be for IPC – which 4 bed areas are affected by this? I also note that even with mitigation, the residual risk remains AMBER (likely to occur)

Risk 23: location of helipad and 'odour' ingress for RIE/RHSC – would be good to have confirmation of additional filter visualisation/checks affecting theatre air handling units via the quarterly ventilation group (proposed in the Facilities governance paper) - assume this group will have a risk register for ventilation issues across Lothian?

Would appreciate a response ASAP – and no later than end of day Thurs 13th please,
Thanks
Lindsay

From: Sutherland, SarahJane
Sent: 09 June 2019 19:00
To: Cameron, Fiona; Inverarity, Donald; Kalima, Pota; Guthrie, Lindsay; Horsburgh, Carol; Munro, Anna
Cc: Sutherland, SarahJane
Subject: RE: Confidential: HAI SCRIBE RHCYP Risks and Mitigations
Importance: High

Dear All,

As requested, I have reviewed the Risk register circulated from Janice on Wednesday and would be grateful if you could check over the response from an IPCT perspective. Please add/delete or amend as appropriate. Please comment or clarify if suggestions in red should be considered/initiated from an IPC view before I reply to Ronnie, Janice and Jim Crombie et al. Please also identify if you feel any of the 24 residual risks identified are IPC related which I have missed! Jim is looking for a response ASAP.

Following review of the risk register for residual risks, the following evidence is required by the IPCT in order to provide assurance that mitigation measures undertaken result in healthcare system components being fit for purpose and evidence that patient safety issues have been addressed with view to signing off HAI Scribe Stage 4:

Risk 1: Ventilation: Validation of ventilation systems (as per requirements in SHTM 03-01) to include air sampling results from theatres inclusive of particle counts for those that are Laminar flow theatres. The reports should be provided in a format which facilitates easy reading and assessment. (G.Curley (G.C) advised he would like an asset list for critical ventilation systems).

Due to rooms only having 4 air changes per hour opposed to 6, G.C advised that maintenance must be rigorous due to decrease in a/c capacity and IPCT would support this.

Risk 2: Water contamination: Validation of water quality results to be presented on an Excel spreadsheet for ease of reading and assessment. This is currently being undertaken and will be provided by the by project team in due course. IPCT have directly requested with those compiling this information, that the spreadsheet indicates the clinical area/speciality where the water outlet is located in order to assess risk. (G.Curley suggested that a further independent water sampling regime could be undertaken by Westfield Caledonia - ? if required and ? if being taken forward by facilities – Fiona correct me if I misinterpreted this)
G.C has also requested a more specific Water Management Plan from Authorising Engineer as the current plan is 187 pages. Assurance is required that Hard Facilities Management carry out water sampling in line with guidance HTM 04-01.

Risk 6: Mould and Fungus: Mitigation undertaken included the removal of plasterboard, replacement of flooring and fixtures and fittings. A walk round review was carried out by IPCT following flood and damage (Dr Inverarity and Janette Rae). (G.Curley suggested that for further assurance to ascertain that there is no residual damp, particularly as there is often foil coverings within wall cavities - Further review of wall /cavity by removing and visualising area - out with theatre environment ? required).

Risk 14: Access hatches: Where access hatches remain in theatre and these are accessed for maintenance or other, a domestic clean and air sampling/particle counts should be carried out prior to theatre being put back into use. These hatches should feature within the Hard FM maintenance plans.

Risk 20: Entrance matting: Where matting is available/not available at external entrances assurance must be given that an increase in domestic cleaning will be in place as required to ensure that dirt and debris from outdoor footwear is not trailed through the hospital corridors.

Kind regards
Sarah

Sarah Jane Sutherland
Lead HAI Scribe Advisor
Infection Prevention and Control Team
NHS Lothian

[redacted]

<< OLE Object: Picture (Device Independent Bitmap) >>

From: Cameron, Fiona
Sent: 05 June 2019 15:01
To: Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Inverarity, Donald; Kalima, Pota; Munro, Anna
Cc: Fitzpatrick, Ann X
Subject: Confidential: HAI SCRIBE RHCYP Risks and Mitigations

What Jim has asked is can we go through the list and

1. confirm which items are IPC related
2. advise what evidence is required against the items to provide the assurance to progress

They are aware that the ventilation and water evidence needs to be formatted to facilitate the group ease of reading and assessing , they are currently working on this

Fiona

Ms Fiona Cameron
Head of Service
NHS Lothian Infection Prevention & Control Services
[redacted]

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<< OLE Object: Picture (Device Independent Bitmap) >>

From: Mackenzie, Janice
Sent: 05 June 2019 14:52
To: Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Inverarity, Donald; Kalima, Pota
Cc: Currie, Brian; Crombie, Jim; Henderson, Ronnie; Pennykid, Jennifer
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations

Dear All

Further to our meeting today please find attached an electronic version of the Residual Risk Register, please can you treat as confidential.
<< File: 080519 RHCYP DCN Residual Risks.xlsx >>
As agreed at the meeting if you can get back to us if you require any further information/evidence in relation to any of the residual risks

Kind regards

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

[redacted]
<< OLE Object: Picture (Device Independent Bitmap) >>
www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Henderson, Ronnie
Sent: 04 June 2019 17:02
To: Pennykid, Jennifer; Currie, Brian; Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Crombie, Jim; Inverarity, Donald; Mackenzie, Janice
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations
Importance: High

All,

Please find agenda for tomorrow's meeting below:

1. '86' Item List
2. Residual Risk register
3. Water Safety
    - Current Status
    - Sampling & Analysis Results
    - AE's Meeting
4. Ventilation
    - Current Status
    - Independent Validation
5. HAI SCRIBE Stage 4
6. AOCB

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

[redacted]

-----Original Appointment-----
From: Pennykid, Jennifer
Sent: 01 May 2019 10:00
To: Pennykid, Jennifer; Henderson, Ronnie; Currie, Brian; Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Crombie, Jim; Inverarity, Donald; Mackenzie, Janice
Subject: HAI SCRIBE RHCYP Risks and Mitigations
When: 05 June 2019 12:30-14:00 (UTC+00:00) Dublin, Edinburgh, Lisbon, London.
Where: MacKinlay Room RHCYP

<< File: Updated Directions to Site 150398.pdf >>
Dear Jennifer,

I've booked the MacKinlay room for you.

Please go to the "Turnstiles" (shown on map) where the Security team will let you in and then go to the RHCYP Entrance (shown on map) where the Main Reception is. Please sign in at the reception desk.

I'd be grateful if you could send me a list of people attending the meeting so that we can add them to the visitors list to allow them through the security turnstiles.

Many thanks.

With kind regards,

Mashoodha Shah
Project Support Officer

NHS Lothian
RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

HPS Water report

Dated 20/12/18 but only made available to NHS Lothian via Scottish Microbiology and Virology Network on 20/8/19.

Page	Comment	Response	Themes?
3	Water system contamination – are they including drainage as part of the system?		
	Water samples taken for Cupriavidus pauculus from aseptic pharmacy – were these also taken from the ward at this time?	If Cupriavidus pauculus has caused several cases of bloodstream infection at RHC (and is described elsewhere e.g. Ohio, why do none of the recommendations about water testing for Scotland cover testing water for it or other Burkholderiaceae?	Was a microbiologist involved in writing the report?
	Water sampled where patients deemed 'high risk' – what definition are they applying and is it the same as for augmented care areas in the HPS interim guidance?		
	"Drain decontamination was undertaken"	This seems to be through vaporised hydrogen peroxide(p7) but this is known not to be an effective method for sink drain decontamination.	
	Report states 'widespread contamination of the water system' – but unclear what sampling was undertaken in wards 6A and 4B after transfer of haem/onc patients out of ward 2A/B. Control measures outlined are local controls?	Is there a way to determine if a ward (e.g. 6A or 4B) is safe?	
4	The author of this report is a Nurse Consultant in Infection Prevention and Control	Would it not be more helpful to have multidisciplinary involvement e.g. have input from engineering and microbiology and water management background?	
5	QEUH is a 1109 bedded hospital with 100% ensuite single rooms	There are no other facilities in Scotland of this size and likely none with such a demand on plumbing or volume of water outlets so are the	Is this an unintended consequence of 100% single rooms. i.e. are these water quality issues present at Golden Jubilee but not causing

		water findings and issues from QEUH directly transferable to other Scottish hospitals which are smaller with less complex plumbing?	infection because different patient risk or seen at Birmingham QEH where there is a Pseudomonas aeruginosa water quality issue in critical care?
6	'further review of wards 2A/B to be undertaken' – review of what? Environment? Practice?		
7	Case definition is weak. How do you define a patient 'linked' to wards 2A/B? Subsequently lists 23 cases but unclear if some of these are confirmed cases, probable cases of possible cases. It's lacking precision.	Agree on p6 it states there are 23 probable cases of bloodstream infection but there is no definition of "probable "case.	
	23 cases in a period of 8months – would be helpful to have some kind of background incidence rate of Gram negative bloodstream infection from the unit at Yorkhill?		
	A second hand hygiene sink (should be wash hand basin not sink)was found to be positive	Positive from water from the outlet or culture of a drain? Why can you not remove a wash hand basin?	
	Silver H202 treatment of drains – this cannot be in line with the manufacturers stated used and methodology – will not penetrate organic matter?		
	States repeat testing- is this water and drain, or just drain? How did they sample, and how many consecutive samples were obtained?		
	Why were the cases of Stenotrophomonas BSI attributed to water. Was the role of antimicrobial selection considered (exposure to meropenem to which Steno is inherently resistant is common in bone marrow transplant units)?		
	Did the clinical and environmental isolates of Steno and Pseudomonas undergo typing to look		

	for a match with environmental isolates? Were these quantified cultures and if so how much was present in the water?		
	Between April and June there were 10 cases – not clear if these were 10 cases of BSI. If so why were these attributed to being from water? Drains may be positive due to hand decontamination after touching colonised patients rather than drains being the source of infection. Were there any other patients with Gram negative bacteraemia that wasn't attributed to hospital water during this time frame?		
	Drain samples – methodology for sampling unclear		
	Question – do Glasgow domestics routinely use Chlorine for all sanitary items (including sinks...) and have they done so since the building was occupied? Was sink cleaning methodology reviewed as this isn't clear from the report anywhere?		
	When further drain decontamination undertaken, did they also take further water samples, or was the focus only drains??		
	Did they sample the water supply intake to the hospital? What is the background rate of these organisms in the overall supply?		
	Have Glasgow (or another paediatric bone marrow transplant unit) ever audited the range of pathogens that they recovered from blood cultures? How does this list compare ?		

P8	Were all of the organisms associated with cases isolated from water samples? If not, does this not mean that some would be probable cases (likely to be linked to water source in the ward but no micro evidence?) rather than lumping them all as confirmed cases??	Agree it looks like a mix of apples and pears. Enterobacter, Serratia and Klebsiella is more likely coming from a patient source. The high incidence of Stenotrophomonas may be resulting from meropenem exposure and selection not burden in water.	
	What is the total bed base for wards 2A/B?		
	Unclear of the relevance of statement "there is evidence of fungal growth in the water but no associated clinical cases" - also assume they looked at all clinical isolates for the hospital and not just within ward 2A/B	Do they genuinely mean there was fungal "growth" in the water or do they mean that fungi were detected from the water. This does not appear to translate into clinical infection in their experience "no clinical cases" so why is it raised as a risk? Has there been comparison with other Scottish hospital water? Is it accurate to expect that hospital water is free of fungi? Taken to a logical extreme should they not also be looking for water borne parasites to which immunosuppressed patients are susceptible too e.g. cryptosporidium, cyclospora, giardia?	
	No further cases since decant of ward 2A/B – unclear what sampling is in place for 6A – were the outlets here always negative (water and drains) and what control measures did they apply in the decant setting (if any).		
	Unclear about the statement that there is evidence of widespread contamination of the water supply as the report only details contamination in wards 2A/B and the aseptic pharmacy (which is never mentioned again in the report after page 3 despite one case being linked to this location??)		

	Phase 1 – the water system was acknowledged as being of a suitable quality for use	How as this established? By culture? For what purposes was the water being used?	
	Phase 2 – the association is made to contaminated drains and not the water system? Limited information (positive or negative) about impact of POU. Don't really understand what the last bullet point on page 8 actually means?	At any point was there audit of how clinical waste water was being disposed in this unit? Was bathing water being disposed of down clinical wash hand basins? If the aseptic unit was the source do patients outwith 2A/B receive any IV products from the aseptic unit (particularly TPN) and have they had Gram negative BSI? Were such aseptic products ever disposed of down clinical wash hand basins to contaminate them?	
	The report states no further cases between decant (Sept 18) and I assume the report publication in December 18. Have there been any further cases between Jan19 and Aug 19 – and what control measures remain in place? What has further water sampling (any drain sampling??) shown in this period – I think this is a question for HPS as will inform what we do at RHCYP?	Did they use stand alone wash hand basins? If so were they assessed as a possible source?	
9	Narrative describes ' water sampling' – is this supply water as it then goes onto describe/discuss biofilm and drains. Also unclear if the Cuprivadus was only found in water supply or if focus was only on drains based on the descriptions before page 9		
	Now using the term "possible linked case" but there is no case definition for a "possible"		
	Was it established if there was contamination in the water tanks or is it only risers and outlets affected? Would be helpful to know what the pipes are made from – e.g. plastic or copper?		

	Black effluent/mould inside drains is not an unusual finding and would be present in all drains??		
	Leegionella – is this a typo or the company name?	Its a company.	
	Para 2 last sentence – “there were very few members of the initial project team available who are technically qualified to retrieve data and provide verbal clarification” – what does this mean and verbal clarification of what??		
	Results from ongoing water testing were reviewed weekly – what testing, assume weekly frequency? Who was reviewing the results (did this include HPS?)		
	What action is being advised in light of statement –evidence of regression seeding and whole system remedial approach advised – this is not clear to me from the remainder of the report		
	Report suggest testing for coliforms is not standard – but its required for identifying whether the water is of a potable standard.	SHTM 04-01 Part A states: 17.9 After disinfection, microbiological tests for bacteria colony counts at 37°C and coliform bacteria, including *Escherichia coli*, should be carried out under the supervision of the infection prevention control team to establish that the work has been satisfactorily completed. Water samples should be taken from selected areas within the distribution system. The system should not be brought into service until the infection control team certifies that the water is of potable quality.	

	Report suggests pre handover sanitisation was performed because of high TVCs	Wouldn't this have been indicated prior to 30 days of occupation regardless of TVCs. What was it sanitised with?	
P10	There are a number of areas with higher than normally acceptable levels of TVCs	What normal range of TVCs are they using? Where are the areas with residual high TVC counts in the building?	
	Now using terminology clinical wash hand basins rather than sinks		
	Unclear what the action relating to flow regulators is. Was it a recommendation for future builds or expectation of universal removal?		
	50% of flow regulators were "contaminated" at "high levels" but unclear how this was quantified or what they were contaminated with. If the contamination isn't visible what is the method for detecting it?		
	What concentration of silver hydrogen peroxide was used? Was incompatibility established prior to use?		
	Water temperature control is raised as an issue but no indication if records of this from the building management system were scrutinised to establish whether there were deviations in temperature control. What is meant by "high levels" of Gram negative bacteria and fungus in water – what were the organisms present and what were the counts per 100ml water?		
	Unclear whether the focus is on water quality or contamination of drains as a source. Unclear where drains sit in the technical review e.g. part of the water system.		

P 11	In the description of the HAI Scribe process it is unclear if there was anything which would reasonably have been assessed as a hazard or require an action or whether hind sight bias is influencing what would now be considered in a HAI Scribe.		
	There is no evidence of "sign off" from the IPCT. Unclear what this sign off would involve. Water quality assessment is a bigger responsibility than that of the IPCT.	SHTM 04-01 indicates that water quality is only the responsibility of the infection control doctor once it has left the tap.	
	Unclear why water quality should be on IPCT risk register. Should this not be on the corporate risk register or site risk register as a site (or health board) clinical risk?	Presumably prior to 2018 water was not on the IPCT risk register because the outbreak was identified in 2018.	
	In the absence of clinical cases the actions of ICD and IPCT in commissioning, design and handover appears compliant with SHTM 04-01 Part A	17.9 After disinfection, microbiological tests for bacteria colony counts at 37°C and coliform bacteria, including *Escherichia coli*, should be carried out under the supervision of the infection prevention control team to establish that the work has been satisfactorily completed. Water samples should be taken from selected areas within the distribution system. The system should not be brought into service until the infection control team certifies that the water is of potable quality.	
P12	That actions of the IPCT appear to have been consistent with what was required as stated in SHTM 04-01 and HAI Scribe (SHFN 30)		
	The control measures listed are vague and very unclear what specifically was introduced to specifically address a water related hazard or what was being monitored in the environment.		

	We presume the education sessions related to best practice regarding disposal of clinical waste water? Who was reviewing flushing methodlogy or records? Who reviewed tap and WHB cleaning methodology? How was water temp being monitored and deviations acted on? Was correct disposal of clinical waste water enforced?		
	Portable WHB can introduce a risk – how were they filled, was tap or sterile water used, how were they stored and cleaned? Were they a source of micro-organisms?		
	How was the source of contamination in aseptic pharmacy addressed?		
	Unclear what the purpose of the sterile water being given to BMT patients is – was this for drinking or washing?		
	Point of Use Filters – what is meant by high risk areas? Is that patient susceptibility or burden or contamination within the water system? These do not address risk more proximal to water outlet e.g. riser and may not address risk from aseptic product contamination.		
	Splashing from POU filters – was water pressure adjusted. How was the “greater splash” determined		
P13	Why were the drains inspected by IPCT and not estates? What were the IPCT looking for? If a substance was “thought to be biofilm” how as it established what it actually is?		
	The method used for environmental (hydrogen peroxide vapour) decontamination is known not to decontaminate sink drains. Was the terminal		

	clean initially quality assured prior to hydrogen peroxide. What was the terminal clean methodology – was a chlorine based product used?		
	The section on water treatment infers that all hospital water should be of a potable standard. Unclear whether water in QEUH met the quality standard of drinking water or not. The nature of the pipe material is highlighted as important but the report doesn't tell us what the pipes of QEUH and RHC are made from.		
	There should be recognition that the method of water treatment used may have unintended consequences (slightly different to advantages and disadvantages) compatibility with component parts of the plumbing needs to be established first before exposure		
P14	Preferred solution. How was continual dosing chlorine dioxide identified as the preferred option. Does this not create a new patient risk in an occupied building?		
	1. One of the control measures was to move paed BMT patients to ward 4B but the report says there was Gram negative bacilli in water in that area (p9) so how was it risk assessed and considered to be a safe move? 2. What water quality monitoring is being performed in 2A/B while unoccupied? 3. Have patients moved back to 2A and 2B?		

	4. If there is widespread water contamination what is the ongoing testing regimen for water in 4B and 6A? 5. What other local controls are in place e.g. POU filters?		
	It is unclear how the cases, investigation and potential source link to some of the proposed remedial works or the rationale for others (e.g. toilet plume)		
	Hypothesis This section is difficult to follow. Each hypothesis is speculative and unclear what evidence is used to support or discount these.		
P15	There is a statement that splashing risk from POU was not recognised with potential exposure of children. The exposure is not proven .		
P16	The disposal to drain section is very speculative.		
P18	Recommendation 1 We have no access to the action plan described but the bullet point items seems vague e.g. decontamination of what? What aspect of water management system - flushing, temp control?		
	Recommendation 2 Very vague. What policies and what guidance are being referred to? Is water sampling included in the maintenance records? Who in the organisation is responsible – responsible person for water?		
	Recommendation 3 Why is the start date of the urgent water review 2013? Most recommendation seem to be for HFS and HPS.	There are only two points in 2 pages of recommendation relevant to other boards: All NHS boards should ensure facilities teams are adequately resourced to ensure	

		maintenance of all aspects of the water system are maintained in accordance with policies and guidance. ˜ All maintenance undertaken should be recorded and maintenance records should be reviewed regularly to ensure all aspects of the water system are maintained in accordance with policies and guidance	

From: McMahon, Alex <[redacted]
Sent: 13 August 2019 21:24
To: Henderson, Ronnie; Currie, Brian; Graham, Iain; Guthrie, Lindsay; Inverarity, Donald; Curley, George
Cc: Goldsmith, Susan; Gillies, Tracey; Laurenson, Ian; Calder, Carol A
Subject: Fwd: Draft water and ventilation reports
Attachments: 20190809-Vent-RHSC-Report.pdf; ATT00001.htm; 20190809-Vent-RHSC-Report.pdf; ATT00002.htm; Childrens site visit 25 July 2019.docx; ATT00003.htm; Gram Neg RHCYP.xlsx; ATT00004.htm; PI1908010262.pdf; ATT00005.htm; PI1908010263.pdf; ATT00006.htm; PI1908010264.pdf; ATT00007.htm; PI1908010265.pdf; ATT00008.htm; PI1908010266.pdf; ATT00009.htm; PI1908010267.pdf; ATT00010.htm; PI1908010268.pdf; ATT00011.htm; PI1908010269.pdf; ATT00012.htm; PI1908010270.pdf; ATT00013.htm; PI1908010271.pdf; ATT00014.htm; RHCYP v1 Draft Interim Water.pdf; ATT00015.htm

Follow Up Flag: Follow up
Flag Status: Flagged

Dear all

To note the reports as promised from HFS/ HPS.

Ronnie can these be shared with the water quality group for next Wed's meeting.

Ian L and Carol C in Lindsay and Donald's absence can you review with others? Could we have an initial analysis of what the reports say and any actions for Thursdays IMT?

Jacqui is keen that we agree the actions with HFS/ HPS for the Governance Oversight Group so I would hope that the reports, our review than any agreed actions could be taken in a paper to the next meeting of the group on the 22nd Aug.

Alex

Sent from my iPad

Begin forwarded message:

> **From:** "REILLY, Jacqui (NHS NATIONAL SERVICES SCOTLAND)" [redacted]
> **To:** "McMahon, Alex" [redacted]
> **Subject: Fwd: Draft water and ventilation reports**
>
> As promised
>
> Professor Jacqui Reilly
> Sent from my I phone
>
> Begin forwarded message:
>
> > **From:** "MCLAUGHLAN, Edwar [redacted]
> > **To:** "Currie Brian (NHS LOTHIAN)" [redacted]
> > "Susan.Goldsmith@[redacted] "Henderson Ronnie (NHS LOTHIAN)"
> > [redacted]

Cc: "JAMES, Gordon (NHS NATIONAL SERVICES SCOTLAND)" [redacted], "MILLER, James (NHS NATIONAL SERVICES SCOTLAND)" <[redacted] "REILLY, Jacqui (NHS NATIONAL SERVICES SCOTLAND)" [redacted] "STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND)" [redacted] "RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)" [redacted], "Reducing-Risk-Hce (NHS NATIONAL SERVICES SCOTLAND)" [redacted], "IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND)" [redacted] "HARLEY, Kate (NHS NATIONAL SERVICES SCOTLAND)" [redacted]
Subject: Draft water and ventilation reports

Dear colleagues
I understand you have asked for sight of the specialist reports on water and ventilation and I have attached them to this email. They are not yet complete or checked for accuracy and we have not considered, nor taken a view on, any recommendations made therein. They are supplied purely in the interests of openness, so you are sighted on the information we have been given. Further drafts will be produced in due course, and as each issue is considered and added (or not) to our report, we will be in a position to discuss any implications. The next draft of our report will be forwarded when available.
Regards

Eddie
Eddie McLaughlan
Assistant Director
Engineering, Environment and Decontamination
Health Facilities Scotland
Procurement, Commissioning and Facilities
NHS National Services Scotland
3rd Floor, Meridian Court
5 Cadogan Street
Glasgow
G2 6QE
[redacted]
www.hfs.scot.nhs.uk

AUTHORISING ENGINEER (VENTILATION)

REPORT

FOR

NON-CRITICAL VENTILATION SYSTEMS

AT THE

Royal Hospital for Children and Young People, Edinburgh

9 August 2019

Introduction

1. I was asked by Health Facilities Scotland (HFS) to prepare a report on the non-critical Ventilation systems at the new Royal Hospital for Children & Young People, Edinburgh (RHCYP) on 18 Jul 19. The requirement was to produce an initial Red/Amber/Green feedback for specific questions on this situation by 5 Aug, and a more full report by 26 Aug 19. Both of these time frames were subsequently shortened by HFS to 1 & 12 Aug respectively.

2. I agreed to visit the site over the period 1 – 2 Aug 19. I was sent copies of various papers and reports, including the draft Validation Summary from IOM and two schedules of ventilation plant (one for each plant room) dated 25 May 16. I was able to start assembling the data for site wide Air Handling Unit (AHU) Register before arriving on site. This data was later updated with help from Bouygues, and a full list is attached. I concluded that there are a total of 18 non-critical AHUs at the RHCYP.

3. I gave a verbal de-brief on my findings to Ian Storrar on Thu 1 Aug and then submitted an initial Red/Amber/Green (RAG) report by e-mail in the early morning of Fri 2 Aug. This RAG report was later updated that same day in one area following further discussions and on-site visits.

Executive Summary

4. There are a number of design and installation errors in the non-critical ventilation systems which do not generally impede the occupation of the RHCYP Hospital non-critical areas by staff, patients or the general public.

5. However, it is strongly recommended that the issues identified in this report are corrected in a reasonable time frame.

6. Clinicians should be made aware of the physical limits of the suitability of non-critical area use due to the limited ventilation systems provided. The clinicians should include the provision of suitable ventilation in all decisions regarding the temporary and longer term placement of patients, staff and general public.

Investigation Findings

7. Design Information. The final tender for the design for the new RHSC was dated December 2013. It was subsequently updated and incorporated an unknown series of comments and it was republished in August 2014. NHS Lothian assembled an on-site team to liaise with the main contractors. They held a short series of meetings in the summer months of 2016 concerning the Ventilation discipline.

8. It is unclear when and by whom the derogation of ventilation requirements laid down in SHTM 03-01, Appendix 1, Table A1: “Recommended air-change rates.” was agreed. Of particular relevance to this report is that the requirement for General Wards was reportedly reduced from 6 air changes/hour to 4 air changes/hour. The latter figure was used as the design standard for these areas by the organisation carrying out the re-validation tests carried out by IOM.

9. The lack of clarity regarding this derogation process is a major concern. HFS is strongly advised to develop a system for formally agreeing derogations from the standards required by the relevant SHTM or other ruling document. A written proposal by any agency should be screened by an independent Chartered Engineer who has relevant experience in the field of Engineering in question (possibly the Board Authorising Engineer for that discipline). The screening Engineer should then produce a written report to support or deny the request for derogation. This report should be retained by all parties concerned.

10. In addition, the clinicians should be made aware of any ventilation derogations as this factor should be included in their Risk Assessments for positioning vulnerable patients.

11. Commissioning Information. The re-validation of the systems was being undertaken by IOM at the time of my visit. This work included measurements taken from over 2,000 ventilation grilles and the subsequent calculations of the air changes/hour achieved.

12. Initial findings reportedly indicate that some areas failed to achieve the derogated design requirements. The output of the AHUs supplying these areas will probably need to be enhanced to meet these minimum requirements. It is considered preferable to exceed them to approach the standards originally required in SHTM 03-01.

13. I was told that there are no Local Exhaust Ventilation units to be considered for this site. The on-site fume cupboards are subject to an independent inspection and maintenance regime and were not examined.

14. Equipment. I examined several AHUs in both plant rooms and noted that there are some common deficiencies in their design and installation against the requirements of SHTM 03-01.

15. I did not check the operation of the AHUs as this task is included in the current work being undertaken by IOM. It is understood that the detailed control of the ventilation systems is exercised by the BMS system. This was not examined during my site visit.

16. AHU Airtightness. SHTM 03-01, Part A, para 4.13 requires AHUs to have a high degree of air-tightness. The AHU penetrations by water pipes for heating and cooling batteries were often poorly made and left unsealed. AHU 04-03 and 04-07 were noted to be performing poorly against this requirement. All pipe penetrations of AHU surfaces should be checked and leakages sealed.

17. AHU Electrical services. SHTM 03-01, Part A, para 4.17 requires that services are not installed in positions that will reduce or impede access. The AHU major components have been fabricated off-site and installed on-site. The control cabling joints have been made by plug-in units which are then allowed to dangle in the airstream, causing some turbulence as well as unnecessary fatigue on the fittings themselves. These connections should be secured so that they do not impede the airstream.

18. SHTM 03-01, Part A, para 4.17 requires that services are not installed in positions that will reduce or impede access. AHU 04-05 access door is obstructed by an electrical conduit. All access doors in the AHUs should open unimpeded by other installations and fittings.

All AHU doors should be checked for full opening and corrective work instigated where necessary.

19. AHU Internal Lighting. SHTM 03-01, Part A, para 4.18 requires viewing ports to be at a convenient height. This has not been possible with the "double-deck" AHUs used on this site. Pulpit ladders have been provided in each plant room to allow easy access to the top deck of inspection windows. This is considered a reasonable way ahead.

20. SHTM 03-01, Part A, para 4.18 requires that all the lights in a unit should be operated by a single switch. This has been achieved, but these switches are sometimes positioned at about 3m above floor level – i.e., AHU 04-03. It is recommended that such switches are re-positioned to a convenient height from floor level as most inspection hatches are at the lower level.

21. Duct Changes in Section. SHTM 03-01, Part A, paras 5.35 and 5.36 define the allowable changes in duct section. It was noted that several AHU intake duct sections included severe changes in cross-section. All AHU ductwork section changes should be checked to ensure that they are within the allowable limits.

22. AHU Intake Louvres. SHTM 03-01, Part B, para 3.23 requires cleaning access to be provided by hinged louvres or by access doors behind the louvre. The current louvres are not hinged. There is a small hatch in the intake section, but this is not large enough to admit a person to inspect and clean the anti-vermin screen. It is recommended that the louvres are re-configured to include at least a door sized hinged section.

23. SHTM 03-01, Part B, para 3.23 requires the duct behind the louvre to be self-draining, or to be tanked and provided with a drainage system. None of the AHUs that I visited had this facility. This should be provided.

24. AHU Drainage. SHTM 03-01, Part B, paras 3.27 requires drain traps to be the clear (borosilicate) glass type. These were observed to be in use, but several were dirty or contained particulate matter. These traps should all be kept in a "sparkling clean" condition.

25. SHTM 03-01, Part B, para 3.30 requires that AHU drainage systems must have a discharge air gap of at least 15mm above the drainage receptor. The top surface of a grill situated above a floor drain should be taken as the lower reference for this measurement as the grill could support trash that would interrupt the waste water flow. Several air gaps were significantly less than this distance. These systems require critical examination and re-fitting.

26. SHTM 03-01, Part B, para 3.31 requires drainage pipework to have a fall of at least 1 in 60 in the direction of flow. Several drainage lengths were observed to be running parallel to the floor for significant distances. These drains should be carefully checked to ensure that the correct fall is maintained.

27. The drainage system installation for AHU 04-07 was poorly installed. In addition some supports were broken. This system should be replaced.

28. Duct Measurement Points. SHTM 03-01, Part B, para 3.62 requires all air-flow test-points to be clearly identified and size of the duct given. All the test-points found were well capped, but not labelled in any way. This situation should be corrected.

29. Some major branches to the main ducts did not appear to have air-flow test-points inserted. It is recommended that the positioning of all air-flow test-points is re-examined by an independent organisation.

30. In addition to the above, the ventilation system balance appears to be incorrect in places. This was noted particularly on Floor 1 where the corridors seem to be at a higher pressure than the surrounding rooms. This lack of compliance with the SHTM needs to be quantified and corrected. It is strongly recommended that all of the ventilation systems that have been re-balanced should now be re-commissioned.

31. Safe System of Work. I was briefed that Bouygues have started to set up a sound SSoW that utilises an in-house Permit-to-work system for intrusive works and an Authority-for-access system for non-intrusive work on ventilation systems. All plant rooms and AHUs have logbooks. This is considered sound practice.

32. Bouygues have engaged a reputable AE and plan to have at least two APs and two CPs to provide 24/7 cover. A third AP & CP will additionally be trained and appointed to provide cover for the duty personnel when they are on leave or sick. The training of the individuals has been hampered by an unusually high turnover of manpower during the initial months of this contract. Suitable individuals have now been identified to fill all of these requirements. The individuals are currently named as follows:

    a. AE: Paul Crothers.
    b. APs: David Allan, Paul Crothers (until a second AP is trained and appointed), Jonathan Reynolds (requires training and appointment), Bill Whiteman (requires training and appointment).
    c. CPs: Alan Herkes, Garry Ferguson, James Taylor (requires training and appointment).

33. A training and appointment regime should continue to be followed to ensure that adequate skilled manning levels are maintained.

34. Inspection & Maintenance. Bouygues reported that there is a site-wide system for planning downtime for the AHUs to allow for routine inspection and maintenance work. This system requires a 3-month notice period.

35. Bouygues reported that their current PPM system includes daily, weekly and monthly visual checks of the AHUs. They are planning to mark up the differential pressure gauges with green/red sectors to facilitate this process in conjunction with the current work of contractors who are calibrating the ventilation systems.

Recommendations

36. The following actions should be carried out to ensure optimum compliance of the non-critical ventilation systems with SHTM 03-01. They are not in any particular order, but have been SCART prioritised using the following agreed scale.

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

Ser	Rating	Reference	Action Required
1	5	190809/01	A robust and accountable derogation process should be established and used.
2	5	190809/02	Clinicians should include any ventilation derogation levels when they are Risk Assessing the placement of their patients.
3	4	190809/03	All pipe penetrations of AHU surfaces should be checked and sealed to prevent air losses.
4	5	190809/04	Internal AHU control cabling joints should be removed from the airstream in a secure fashion.
5	5	190809/05	All AHU door openings should not be impeded by other service obstructions.
6	2	190809/06	All AHU lighting switches should be positioned to be easily accessible from ground level.
7	3	190809/07	Changes in duct section should be checked to ensure that they are within allowable limits.
8	5	190809/08	AHU intake louvres should be re-configured to allow easy access to the intake section of the plant ductwork.
9	5	190809/09	All AHU intake sections should be provided with drainage.
10	3	190809/10	Borosilicate drainage traps should be kept clean.
11	4	190809/11	AHU drainage pipes should discharge with the correct air-gap clearance from the receptor.
12	5	190809/12	The drainage installation for AHU 04-07 should be replaced.
13	5	190809/13	All air-flow test-points should be clearly labelled with the information required by SHTM 03-01, Part B, para 3.62.
14	4	190809/14	The provision of air-flow test-points should be analysed by an independent organisation. Additional test-points should be inserted where necessary.
15	5	190809/15	All non-critical ventilation systems that have been re-balanced should now be re-commissioned.

Conclusions

37. There are a number of design and installation omissions in the ventilation systems designated for the non-critical areas of the hospital. These are not considered to generally impede the occupation of the RHCYP Hospital non-critical areas by staff, patients or the general public.

38. However, it is strongly recommended that the issues identified above are corrected in a reasonable time frame.

39. Clinicians should be made aware of the physical limits of the suitability of area use due to the limited ventilation systems provided. The clinicians should include the provision of suitable ventilation in all decisions regarding the temporary and longer term placement of patients, staff and general public.

40. Bouygues have set up a sound inspection, maintenance and repair system to support the non-critical ventilation systems.

[redacted]

Eur Ing John M Rayner, BSc (Eng), CEng, FIHEEM, FCMI, MIMechE, MEI, MIET, MSVHSoc, TechIOSH

Authorising Engineer (Ventilation)

TURNER PROFESSIONAL ENGINEERING SERVICES (TPES)

AHU Summary

AHU Number	Zone	Level	Departments served	AHU Status
02-01	2	02	Clinical Management Suite (R1)	Non-critical
02-02	3 & 4	02	Neurophysiology (M4), DCNT Therapies (M2), Equipment library (G2)	Non-critical
02-03	3	00	Radiology / X-ray (Q1)	Mixed purpose
02-04	3	00	Radiology / Gamma Camera (Q1)	Mixed purpose
02-05			Atrium / Main entrance	Non-critical
02-06	4	00	Child & Adolescent Mental Health Services (F1)	Non-critical
02-07	3	00	Staff changing (Q1), Basement level (I2), (S1), (S3), (S4), (S6)	Non-critical
02-08	3	01	Operating theatre support & RHSC Surgical Day Case unit (P1)	Mixed purpose
02-09	3	01	Operating Theatre 1 (RHSC)	Critical
02-10	3	01	Operating Theatre 2 (RHSC) Therapies (M2), Equipment Library (G2)	Critical
02-11	3	01	Operating Theatre 3 (RHSC)	Critical
02-12	3	01	Operating Theatre 4 (RHSC)	Critical
02-13	3	01	Operating Theatre 5 (RHSC)	Critical
02-14	3	01	Operating Theatre 6 (RHSC)	Critical
02-15	3	01	Operating Theatre 1 (DCN)	Critical
02-16	3	01	Operating Theatre 2 (DCN)	Critical
02-17	3	01	Operating Theatre 3 (DCN)	Critical
02-18	3	01	Angiography Procedures	Critical
02-19	3	01	Operating Theatre 4 (DCN)	Critical
02-20	3	01	Operating theatre support & RHSC Surgical Day Case unit (P1) (Intraoperative MRI Department)	Mixed purpose
02-21	4	02	DCN Implants (L2), Programme Investigations Unit (M3), DCN Wards / Health Records Support (N2), Isolation Lobby 2-L2-038, 2-L2-134	Non-critical
02-22	3	00	Radiology / MRI scanners (Q1)	Critical
02-23	4	01	Pediatric Acute Receiving Unit (A2), Spirit & Pastoral Care (J2), Isolation Lobby G-A2-074	Non-critical
02-24	4	01	DCN Acute Care (L1), On-Call Suite (G3), Isolation Lobby 1-L1-104	Non-critical
02-25	3	00	DCN Outpatients (M1), Radiology / CT Scan (Q1)	Mixed purpose

02-26	4	00	Emergency (A1), PARV/Emergency/Radiology shared (A3)	Non-critical
02-27	3	02	Central staff changing (S5), Basement Level – Domestic (S3), Materials Management (S4), Store (S7)	Non-critical
04-01	2	00	RHSC Main Outpatients (D1), Cardiology & Respiration (D2), Family Support Services (K1), Pediatric Dentistry (D5), Social Work (D8), Pod (E1)	Non-critical
04-02	2	03	Family Hotel (K2)	Non-critical
04-03	2	04	RHSC Main Outpatients (D1), RHSC Therapies (D6), Plastics Dressing Clinic (D7), Orthoptics (D4), Audiology (D4)	Non-critical
04-04	2	04	Clinical Education Suite (H3)	Non-critical
04-05	3 & 4	04	Health Records ((R2), Child Life & Health (H1)	Non-critical
04-06	4	01	PICU HDB (B1), Bereavement Suites (J1), Clinical Research Facility (H2)	Mixed purpose
04-07	3	03	Neuroscience (C1.3), Haematology/Oncology Inpatients & Day Care (C1.4), Med/Neuro/Surg/Haemo support (C1.5), Pediatric neurophysiology (C1.7), Special Feeds Unit (C3), Shelled Space (U1)	Non-critical
04-08	3	03	Medical inpatients (C1.1), Surgical Long stay Inpatients (C1.2), Adolescent Shared Accommodation (C1.6), Surgical Short stay Inpatients (C1.8), Wards support areas (C2), Sleep Lab (C4), Medical Day-care Unit (D9)	Non-critical
04-09	2	04	Classroom (C5), Clinical/Management Suite (R1), Restaurant (S7)	Non-critical

Malcolm Thomas

Consulting Engineer

[redacted]

Mr. Ian Storrar
Head of Engineering
Health Facilities Scotland
NHS Nation Services Scotland
3rd floor Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

27 July 2019

Dear Ian,

Children's Hospital, Edinburgh
Site Visit 25 July 2019

I visited site on 25 July to gain an appreciation of the ventilation system as installed. The Hospital is new and yet to be taken into use.

General

Overall first impressions were that the ventilation plant installation overall was average but that there were many minor air leaks, faults and niggles. Most of these will be straightforward to rectify but what was alarming was that even though the Hospital opening had been delayed they still remained to be resolved. The report from IOM highlighted similar issues and it was evident that the system when offered for validation was not ready.

I was concerned to read about the length and configuration of flexible ductwork above the ceilings. The HTM is quite clear that flexible ductwork should be as straight and short as possible, not exceed 1m in length and never be used in lieu of a bend.

Air Handling Units

A major non compliance arises with the ability to change the supply and extract fans in the major Air Handling Units (AHU). They are buried within the AHU with no obvious way to access or remove them. HTM03-03 requires that all elements of an AHU be accessible for maintenance and that over the life of the unit they may need to be removed or replaced. This will not be possible without major disruption with the units as installed. Given the large areas that the individual AHU's serve, changing fans will take a significant amount of time and render the section of the hospital that they serve unavailable.

It was also noted that there is a large amount of loose wiring and plug connectors inside the units and the IOM report also highlighted this issue.

Helicopter Landing Pad

I am unhappy with the location of the helicopter landing pad. There are open courtyards below and various air supply intakes and extract discharges in the vicinity. The downdraft from the helicopter when using the pad will have an adverse effect on the performance of these systems and may result in reverse air flows into the hospital.

I note that there is a ground level helicopter pad adjacent to the neighboring building and within easy reach of the children's hospital and wonder why this facility is not considered adequate. I understand the desire to have a short transfer route for a patient arriving by helicopter but there are also the needs of all the patients in the hospital to consider.

Operating Theatres

UCV Theatres

The "Clean zone" under the Ultra Clean Ventilation terminal is only delineated by a thin line on the floor. Good practice in a new installation such as this is to delineate the entire floor zone in a contracting colour to that of the surrounding floor area. In that way it is immediately obvious when personnel or instrument trolleys stray or get nudged out of the zone. From the comments in the IOM report the line is a late addition so the contractor evidently did not intend to meet the HTM requirement when the flooring was originally laid.

Conventional Theatres - Preparation room

Noted that all the preparation rooms are designed as "Sterile Pack Store" (SPS) rooms. This is normal for Ultra Clean Ventilated (UCV) theatres where good practice recommends that lay up of instruments takes place under the UCV terminal. In Conventional Operating suites instrument packs are normally opened and prepared in "Lay up" preparation room as this cuts down the time between cases. The Preparation room in the conventional theatre in this development is a SPS Prep. It is important that staff using the facility are made aware of this.

Scrub areas

The scrub rooms are effectively an open corridor off the operating room so their volume does not need to be included in the total volume of the operating room. The scrub areas do however need a good air flow from the operating room, down the length of the scrub and out at the far end. The existing ceiling level extract terminal is only designed to extract 100L/s which given that the approximate average volume of the scrub is $33m^3$ only gives 11 air changes per hour to this area. I recommend providing an additional low level extract terminal in the corner adjacent to the far end of the scrub trough. This terminal to extract 100L/s which together with the existing ceiling terminal will result in approximately 20 air changes per hour from the scrub area. Corner duct to be formed with plaster board and fitted with a pull off face extract terminal for ease of cleaning.

Anaesthetic rooms

Supply and extract in Anaesthetic rooms should provide a clean air flow path for the staff to reduce the possibility of them being casually exposed to leaking and /or exhaled Anaesthetic agents. Most rooms are satisfactory but Anaesthetic rooms 31 and 34 need the ceiling supply terminal moving to the opposite side of the room and in Anaesthetic room 30 the ceiling supply terminal is too close to the door and should be relocated towards the middle or further end of the room. (See attached information)

Shared Utility rooms

The extract for the utility rooms is shared between two air handling units. If one AHU is shut down or put into "set back" then there will not be sufficient air extract in the utility. Rather than installing complicated constant volume boxes it would be simpler to fit a small auxiliary extract fan that is controlled by room pressure.

Recovery areas

Satisfactory as these are ventilated with high level supply down the center of the room and low level extract at the head end of the beds.

Isolation rooms

There is an obvious problem of resilience and routine maintenance as up to five isolation rooms are fed from a single AHU which, to make matters worse also serves the critical care unit and some general areas. All the eggs are in one basket! There is an emergency bypass that will allow the load to be taken by another AHU during routine maintenance or breakdown but the operation of this has yet to be proved.

I understand that there is an intention to split the load in two, an approach that I endorse. I have left information about cabinet AHU's with Ian Brodie of Mott Macdonald as these may offer a simpler solution to splitting the load than just adding a single conventional AHU.

Conclusions

Taken overall the design and provision of ventilation in this development has I consider made insufficient allowance for the routine operation and maintenance of the systems. As a consequence resilience is very poor. Breakdowns and unforeseen stoppages will result in significant portions of the hospital without active ventilation. It should be remembered that ventilation is provide in critical areas such as theatres, isolation rooms and critical care in order to reduce the possibility of infection by the airborne route.

The ventilation installation itself is below the standard that would be expected with many outstanding issues that are yet to be resolved. I recommend a full snagging inspection of each systems from its supply intake right through to the discharge position. This should be followed by "cause and effect" testing to prove the control and indication functions.

The fire dampers also need to have their operation proved. Note that in many locations inspection access panels have not been installed so the action of the fire dampers cannot be directly observed. This needs to be rectified.

It is evident that much remains to be done before the hospital can accept patients.

[redacted]

Consulting Engineer
Lead Author HTM 03-01 – Specialised Ventilation for Healthcare Premises

Sample Number	Sample Name	Details 1	Details 2	M043 Aerobic Colony Count @ 37oC 44h cfu/ml	GRAM STAIN	OXIDASE	discription	M042 Aerobic Colony Count @ 22°C 68hrs cfu/ml	GRAM STAIN	OXIDASE	discription
WS10638362	The Royal Hospital for Children and Young People Edingurgh Neonatal	Sample 3	Trough Sink Cold Tap Pre	80	dominant positive (80/20)	positive	short bacilli	20	dominant positive (60/40)	positive	short bacilli
WS10638364	The Royal Hospital for Children and Young People Edingurgh Neonatal	Sample 5	WHB opp Nurses Station Mixer Pre	268	dominant positive (80/20)	positive	short bacilli	400	dominant positive (60/40)	positive	short bacilli
WS10638368	The Royal Hospital for Children and Young People Edingurgh Neonatal	Sample 9	Relative Room en-suite Shower 1-B3-083 Pre	210	dominant positive (80/20)	positive	short bacilli	0	dominant negaitve 70/30	positive	short bacilli
WS10638370	The Royal Hospital for Children and Young People Edingurgh Critical Care	Sample 11	018-021 Beds WHB Mixer (window) 1-B1-063 Pre	230	dominant positive (80/20)	positive	short bacilli	0	dominant negative (70/30)	positive	short bacilli
WS10638382	The Royal Hospital for Children and Young People Edingurgh	Sample 23	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Pre	67	dominant positive (80/20)	positive	short bacilli	100	dominant negative (80/20)	positive	short bacilli
WS10638384	The Royal Hospital for Children and Young People Edingurgh	Sample 25	001 Bed 001 (ES) 1-L1-002 Shower Pre	960	dominant positive (80/20)	positive	short bacilli	30	dominant negative (60/40	positive	short bacilli
WS10638404	The Royal Hospital for Children and Young People Edingurgh	Sample 45	Ward 230/025 WHB Mixer 2L2-087 Pre	220	dominant negative (70/30)	positive	short bacilli	100	dominant negative (70/30)	positive	short bacilli
WS10638408	The Royal Hospital for Children and Young People Edingurgh	Sample 49	Loch Ranza Ward Kitchen SS Hot Pre 3-C1-4-063	770	dominant negative (70/30)	positive	short bacilli	350	dominant negative (70/30)	positive	short bacilli
WS10638419	The Royal Hospital for Children and Young People Edingurgh	Sample 60	3-C1-8-31 Shower Pre Bed 012	74	dominant positive (80/20)	positive	short bacilli	340	dominant negative (70/30)	positive	short bacilli

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ANALYSIS REPORT No. 1908080939 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080939
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010262**		
Product	: Isolates		
Sample description / Batch	: **WS10638414**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Paecilomyces lilacinus
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080940 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080940
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010263**		
Product	: Isolates		
Sample description / Batch	: **WS10638418**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Phoma herbarum

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080941 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080941
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010264**		
Product	: Isolates		
Sample description / Batch	: **WS10638419**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Phoma herbarum
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080942 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080942
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010265**		
Product	: Isolates		
Sample description / Batch	: **WS10638374**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Aspergillus glaucus
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080943 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080943
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010266**		
Product	: Isolates		
Sample description / Batch	: **WS10638393**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	negative	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample the species of mould (growth salmon-pink in colour) could not identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080944 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080944
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010267**		
Product	: Isolates		
Sample description / Batch	: **WS10638368**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Phoma herbarum
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080945 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080945
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010268**		
Product	: Isolates		
Sample description / Batch	: **WS10638366**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	negative	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample the species of mould (growth salmon-pink in colour) could not identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080946 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080946
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010269**		
Product	: Isolates		
Sample description / Batch	: **WS10638415**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Paecilomyces lilacinus
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080947 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080947
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010270**		
Product	: Isolates		
Sample description / Batch	: **WS10638385**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Phoma herbarum

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

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ANALYSIS REPORT No. 1908080948 DATE: 08.08.2019 PAGE 1/1

Client:
ITS Testing Services (UK) Ltd
Intercompany No. 001
The Old Mill, 81 Oxford Road,
Fegg Hayes, Stoke-on-Trent
Staffordshire ST6 6QP
Great Britain

21908080948
PA276651

FAX: +44 (0) 1782 818515
E-Mail: stoke.customerservices@intertek.com

Our reference no.	: **PI1908010271**		
Product	: Isolates		
Sample description / Batch	: **WS10638384**		
Sample received on / transported by	: 01.08.2019 via Parcel service	Seal	: none
Sample temp. when received / stored	: RT	Sampling	: Client
Packaging / Quantity	: Plastic container / 1 agar plate	Start / End of analysis	: 01.08.2019 / 08.08.2019

ANALYSIS REQUESTED: Identification of Microorganisms (510012)

Parameter	Result	Method
Identification	positive	PM DE01.241 (a) [1]

(a) : accredited method. (na) : not accredited method.
(1) after cultivation, MALDI-TOF Bruker Library 6.0.0.0, 6903, version Jan.12th,2017

Interpretation:

In the above mentioned sample following moulds were detected (Species with safe genus identification and probable species are given in brackets):
Phoma herbarum
A further mould (growth salmon-pink in colour) could not be identified.

[redacted]
Dr. Uwe Schröder
Responsible Scientist, Biologist

Water Solutions Group

Specialist Consultant (Water) Audit Report

Water Solutions Group

For

Interim Review of Hot and Cold Water Systems

(DRAFT)

Tim Wafer (FRSPH, MIHEEM, MWMSoc - Authorising Engineer Water and Chlorine Dioxide)

Client: Health Facilities Scotland

The Byre, Haggs Farm Business Park
Haggs Road, Harrogate
HG3 1EQ

Water Solutions Group

Report Title: Review of Hot and Cold Water Systems

Site: Royal Hospital for Children and Young People

Contact: Ian Storrar

Organisation: NHS National Services Scotland

Address: 3rd Floor, Meridian Court, 5 Cadogan Street, Glasgow, G2 6QE

Report Prepared By: The Water Solutions Group

Address: The Byre, Haggs Farm Business Park, Haggs Road, Harrogate, HG3 1EQ

Date of Investigation: 18th July 2019

Date for Review:

Patient Susceptibility: Awaiting feedback. However, have allocated high status.

Caveat: This is an interim report and issued to provide feedback on the investigation to date. Whilst highlighting a number of issues, this report does not represent any recommendations in respect of the occupancy of the building. This will need to be part of a review meeting, as yet to be convened.

Water Solutions Group

Contents

Water Solutions Group

1.0 Assurance Statement

The headings in the following table reflect those from the Health and Safety Executive's Approved Code of Practice L8 (4th edition) published in 2013: Legionnaires Disease; the control of legionella bacteria in water systems. This gives indicators for audit and assurance purposes.

Compliance Actions	Status at audit (S, P/S, U/S)
Appoint a person to be managerially responsible	
Records of appraisal of Responsible Persons & Deputy Responsible Persons by the Authorising Engineer	
Records of appointment of Responsible Persons & Deputy Responsible Persons	
Training records for Responsible Persons & Deputy Responsible Persons	
Identification and assessment of sources of risk	
Risk Assessment programme in place	
Fit for Purpose Risk Assessment reports	
Written scheme of Control	
Risk minimisation scheme, based on outcome of risk assessments	
Policy	
Procedures	
Management, implementation and monitoring of written scheme of control	
Implementation of risk assessment findings	
Monitoring results and suitable remedial actions	
Audit report	
Records	
System of records	

S – Evidence of satisfactory system in place and effective	**P/S** – Partially satisfactory system in place improvement required	**U/S** – system missing or ineffective

Water Solutions Group

2.0 Executive Summary

The Royal Hospital for Children and Young People is a new development in Edinburgh's Bio Quarter Campus adjacent to the Royal Infirmary of Edinburgh.

Questions have been raised at governmental level regarding the suitability of this facility for occupation by patients and staff. The Scottish government have enlisted assistance from Health Facilities Scotland and Health Protection Scotland to determine that the domestic water systems within the building are fit for purpose given the profile of patients undergoing treatment.

A number of specialists have been asked to assist Health Facilities Scotland and H2O Solutions (Europe) LLP, an operating subsidiary of the Water Solutions Group has been enlisted for specialist technical and analytical support, based on their work at the Queen Elizabeth University Hospital, Glasgow.

H2O Solutions (Europe) LLP are supported by the Intertek Group, who are providing in-depth microbiological assistance and specialist analytical services as deemed appropriate (UKAS 4065).

Assessing the results of the sampling undertaken by H2O Solutions (Europe) LLP against the Water Supply Regulations, Private Water Supply Regulations and ACOP L8 (HSG 274 Part 2), the results comply with all of these regulations.

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bacteria in the system to multiply, and is the possible reason for the slightly elevated Total Bacteria Counts observed.

Given this, we would expect the Total Bacteria levels of the water to reduce when the building is fully operational. It should also be noted that reduced movement of water in the system over a prolonged period of time could have a negative impact on the ongoing water quality in the system.

When comparing H2O Solutions (Europe) LLP's set of sample results with the guidance parameters, there is no indication from the microbiological results to suggest that the water system is not fit for use.

However, when we widen the microbiological scope to include other organisms identified at QEUH Glasgow, then currently the results are inconclusive and awaiting further investigation.

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3.0. Audit Summaries & Governance Assurance

Rating	Comment
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	• Poor asset knowledge and management • As yet to be evidenced standard operating procedures • Poor log book keeping and management information • As yet to be evidenced contingency measures • Poor levels of experience of some key personnel
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4.0. Scope

Following an initial discussion with Ian Storrar (HFS) and meeting on site with Ronnie Henderson the following initial scope was agreed:

1) As a result of HPS guidance issued in August 2018, and the belief held by NHS Lothian IPC team that the presence of Pseudomonas aeruginosa at outlets in augmented care areas presents a significant risk of HAIs to undertake random sampling across the facility. This involved retrieving a single, pre-flush sample together with a post flush sample from a variety of outlets and submission for specific analysis for the organism Pseudomonas aeruginosa.

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4) To undertake a review of already compiled documentation from third parties, together with design criteria with a view to making recommendations as to the pathway forward based on current guidance and lessons learned at QEUH Glasgow.

Scope Limitations

This report has to be mindful on the information obtained as part of the investigation, which may include third party reports and practices operated by the current FM provider Bouygues. Many of these aspects should be addressed by the water risk assessment carried out in accordance with BS8580-1:2019.

In respect of microbiological analysis, this is undertaken by the Intertek Group, UKAS accreditation 4065, supported by the Maldi-tof Buker Library.

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5.0. Observations

5.1. The microbiological analysis presents a very different picture to samples so far derived by others:

a) Of the 60 pre/post samples taken for the identification of Pseudomonas aeruginosa - all results have returned negative (all clear).

b) In respect of Legionella, all samples have returned negative (all clear).

c) Some Mould and Fungi positive results have been identified, and these are currently undergoing morphology identification.

d) In respect of gram negatives, there has been some identification and these are currently undergoing investigation.

e) Atypical mycobacteria is a long testing cycle - the results of which will not be known until late August 2019 (estimated 23rd).

f) TVC's at 22 and 37 demonstrated some activity. However, this is not surprising given the under utilisation of the water system.

g) An extension of the sampling (based on Glasgow experience) was an evaluation of the drains at wash hand basins within Neonatal. To this end, the drain outlets were swabbed and sent for culture and analysis. Other than an elevated TVC count, nothing else was identified.

h) In respect of Pseudomonas aeruginosa, there appears to be a degree of variance between the sample results undertaken by various parties over the previous months. Our sampling results did not identify Pseudomonas aeruginosa, whereas sampling by others produced positive results. This has the potential to bring into question the sampling methodology. The actual taking of samples for Pseudomonas aeruginosa is very clearly defined within SHTM and PHE guidance. However, where we have seen variance in results, this has been attributed to a) transportation and b) time at laboratory awaiting processing. The samples (as per the guidance) were taken by ourselves at first water and prior to any flushing. These were then immediately transferred into a temperature

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controlled vehicle by 10am and were being processed in the laboratory by 2pm. This means there was minimal delay in the processing of the samples. It is a well established fact that delay can influence the results.

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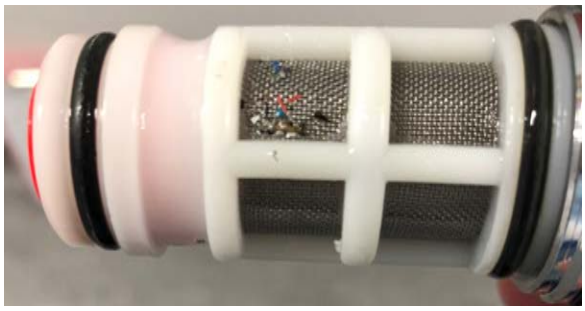
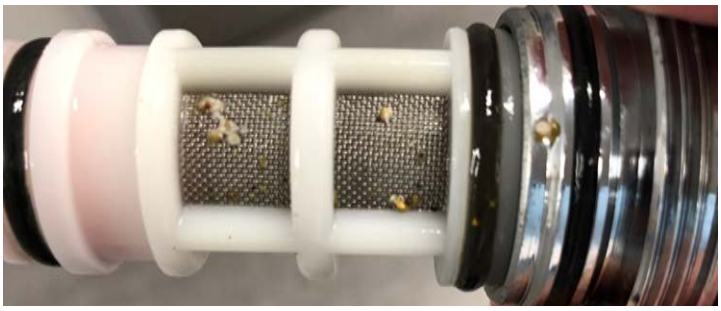

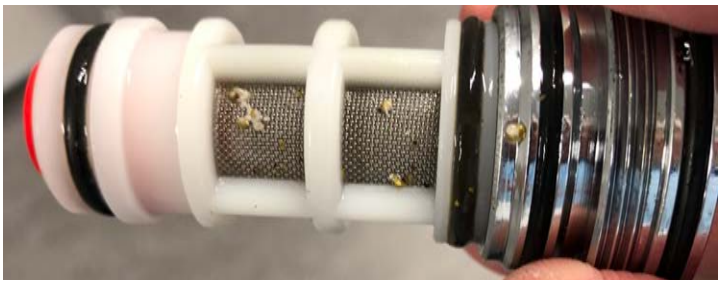

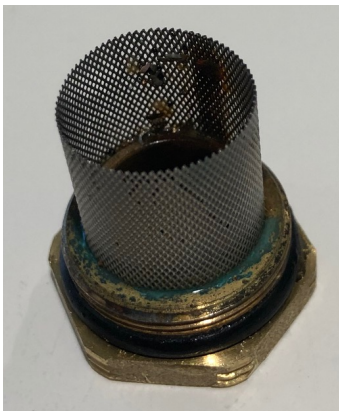
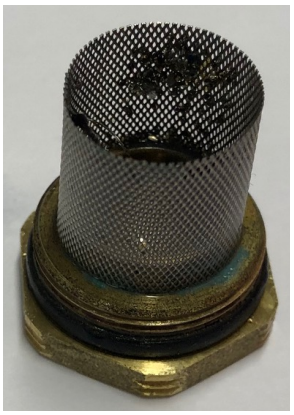


Based on these findings, all strainers on all outlets must be either removed, cleaned and disinfected or replaced with new strainers.

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6.0. Risk Assessments

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A Legionella risk assessment and water hygiene survey report was undertaken on behalf of Bouygues E&S FM UK by Clira water hygiene specialists on 18th-21st February 2019. A further compliance audit was undertaken by Callidus in May 2019. It is disturbing to identify from both of these reports that the risk rating overall for the site was high. Within the risk assessment, there are a large number of identified remedial actions. To date, a large number of them have yet to be completed.

Within this report are some “quick wins”. However, there are more fundamental issues such as the management chain, documentation, training, written scheme, plan - all of which need to be addressed.

We have been advised by Bouygues that much of this has been completed. However, documentary evidence remains outstanding.

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7.0. Recommendations and Actions

Item	Description	Action
1	Tap Strainers and Filters	All filters and strainers to be either removed, cleaned and disinfected or replaced with new. This should be done at the same time as tap cartridge replacement.
2	Flushing	Until occupation of the building has been completed and little used outlets identified, a daily robust flushing regime must be maintained of at least 4 minutes, 3 times a day. All outlets to have temperature measured at start and end of flushing and the information suitably recorded. This action is for all outlets including showers.
3	Zoning	In the event that the hospital is allowed to open, but on a selected area basis, any areas unoccupied should be zoned and if the delay is going to be for some considerable time (e.g. greater than 6 months) then consideration should be given to draining the zone and purging with nitrogen.
4	Training	It was interesting speaking to the Bouygues “Responsible Person” as (at that point in time) they had not been appointed in writing or undertaken an accredited RP course (to the best of his knowledge). Likewise, it was very evident that the support team had very little knowledge or understanding of the water systems within the building and in particular, the Kemper system. More in-depth site training of hot and cold water systems, together with Kemper management system to be undertaken.
5	Risk Assessment Actions	The risk assessment of Feb 2019 needs to be completed and updated by Bouygues and all actions signed off as completed or mitigated.
6	System Disinfection	At this stage, we believe that a shock system disinfection may do more harm than good as it may not completely remove biofilm build up and simply expose further issues that it does not resolve. Our recommendation is to implement a continuous dosing regime based upon Chlorine Dioxide, which can provide both elevated (where applicable) and continuous dosing as an on-going strategy.

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7	Chlorine Dioxide Treatment Regime	Based upon experiences at many healthcare facilties, there is a need for a tried and tested secondary control measure - Chlorine Dioxide. This should be implemented prior to occupation on the cold water storage tanks to treat at 0.5mg/l - Drinking Water Inspectorate Approved Levels. An indicative budgetary figure is £60,000, with a 2-3 week implementation programme.
8	Expansion Vessel Bladder and Component Investigation	Based upon findings at QEUH Glasgow, it is evident that expansion vessel bladders can be high source of biofilm and nutrients to aid microbial growth and can lead to system contamination. There is little evidence in respect of flow through vessels that this is any different and given that the majority of bladders are made from EDPM, a known nutrient source for micro-organisms, further investigation work is essential to determine the current status at Edinburgh.
9	Incoming Water Filtration	As evidenced at QEUH Glasgow, there is a high risk of microbiological contamination build up on the micro filtration plants. It is recommended that Chlorine Dioxide backwash water dosing is implemented without delay. A budgetary figure for both filtration units is £16,000.
10	Tertiary Loop Temperature Measurement	To obtain a better understanding of the temperature profile across the building, particularly at tertiary loops. It is recommended that an automatic measurement and data download system is installed in order that continuous temperature management can be achieved.
11	Drains	Based on the experience at QEUH Glasgow, all wash hand basin drains (or all drains) should be dosed with hysan biocide treatment at intervals to be agreed. However, it would be prudent to implement weekly drain dosing during period prior to occupation.
12	Fire Water Tank	The fire water tank has a large capacity of stagnating water. We would support the Bouygues proposal to install a UV recirculating loop to prevent stagnation and provide a degree of disinfection. The PPM requires review.

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13	Rain Water Harvesting	The words “Rain Water Harvesting” and “Healthcare” do not go together. It is important that a testing regime for the rainwater tank is put in place, which must include organisms related to Ornithological Faecal Matter (e.g. Cryptococcus). A review of disinfection strategy needs to be undertaken.
14	PPM Schedules	The current invisibility of a meaningful water safety plan, SOPs and PPM programme brings into doubt the regime being operated on this site pre and post occupation. It is essential this document is received for review and comment.
15	Shower Heads and Hoses	Currently all shower heads have the capability of reaching the floor drain and toilet. All shower hoses to be replaced to a length preventing the shower head touching the floor. The use of shower head insert replacement (colour coded) should be considered (medi-shower).

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8.0. Disclaimer

This assessment has been based upon information provided by the client. H2O Solutions (Europe) LLP cannot accept any responsibility for any errors or omissions appertaining to the data, records and information provided by the client.

Every reasonable endeavour has been taken by the auditor to ensure the findings and recommendations contained in this report are representative of the issues that require addressing in order to improve current practice.

Water Solutions Group

Specialist Consultant (Water) Audit Report

Water Solutions Group

For

Interim Review of Hot and Cold Water Systems

(DRAFT)

Tim Wafer (FRSPH, MIHEEM, MWMSoc - Authorising Engineer Water and Chlorine Dioxide)

Client: Health Facilities Scotland

The Byre, Haggs Farm Business Park
Haggs Road, Harrogate
HG3 1EQ

Water Solutions Group

Report Title: Review of Hot and Cold Water Systems

Site: Royal Hospital for Children and Young People

Contact: Ian Storrar

Organisation: NHS National Services Scotland

Address: 3rd Floor, Meridian Court, 5 Cadogan Street, Glasgow, G2 6QE

Report Prepared By: The Water Solutions Group

Address: The Byre, Haggs Farm Business Park, Haggs Road, Harrogate, HG3 1EQ

Date of Investigation: 18th July 2019

Date for Review:

Patient Susceptibility: Awaiting feedback. However, have allocated high status.

Caveat: This is an interim report and issued to provide feedback on the investigation to date. Whilst highlighting a number of issues, this report does not represent any recommendations in respect of the occupancy of the building. This will need to be part of a review meeting, as yet to be convened.

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Contents

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1.0 Assurance Statement

The headings in the following table reflect those from the Health and Safety Executive's Approved Code of Practice L8 (4th edition) published in 2013: Legionnaires Disease; the control of legionella bacteria in water systems. This gives indicators for audit and assurance purposes.

Compliance Actions	Status at audit (S, P/S, U/S)
Appoint a person to be managerially responsible	
Records of appraisal of Responsible Persons & Deputy Responsible Persons by the Authorising Engineer	
Records of appointment of Responsible Persons & Deputy Responsible Persons	
Training records for Responsible Persons & Deputy Responsible Persons	
Identification and assessment of sources of risk	
Risk Assessment programme in place	
Fit for Purpose Risk Assessment reports	
Written scheme of Control	
Risk minimisation scheme, based on outcome of risk assessments	
Policy	
Procedures	
Management, implementation and monitoring of written scheme of control	
Implementation of risk assessment findings	
Monitoring results and suitable remedial actions	
Audit report	
Records	
System of records	

S – Evidence of satisfactory system in place and effective	**P/S** – Partially satisfactory system in place improvement required	**U/S** – system missing or ineffective

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2.0 Executive Summary

The Royal Hospital for Children and Young People is a new development in Edinburgh's Bio Quarter Campus adjacent to the Royal Infirmary of Edinburgh.

Questions have been raised at governmental level regarding the suitability of this facility for occupation by patients and staff. The Scottish government have enlisted assistance from Health Facilities Scotland and Health Protection Scotland to determine that the domestic water systems within the building are fit for purpose given the profile of patients undergoing treatment.

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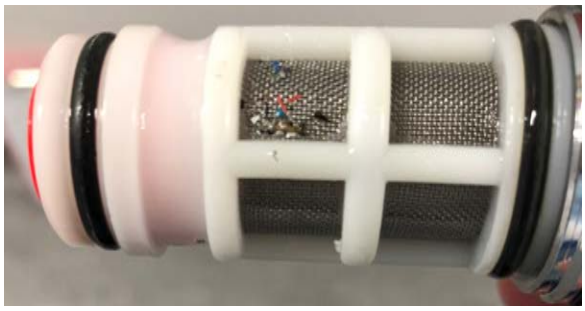
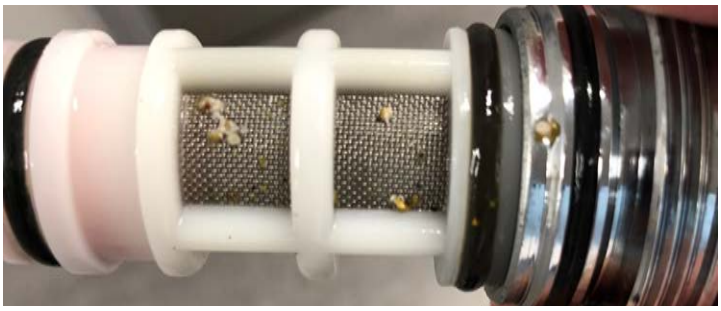

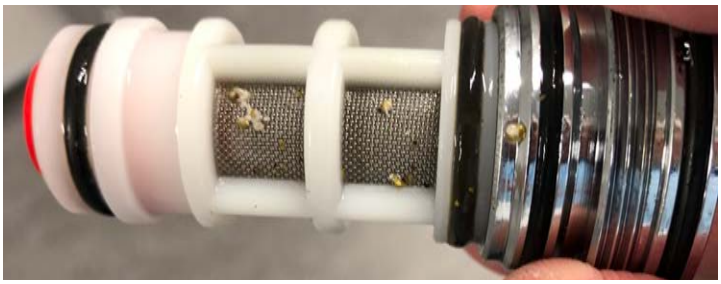

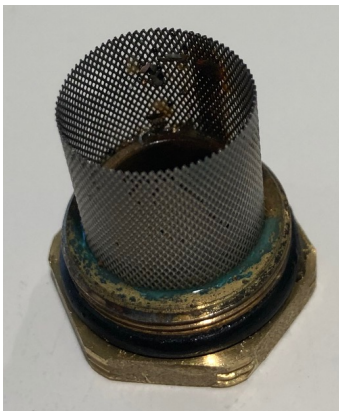
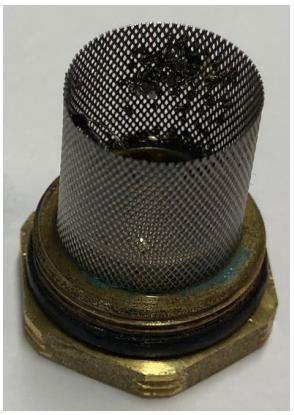


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12	Fire Water Tank	The fire water tank has a large capacity of stagnating water. We would support the Bouygues proposal to install a UV recirculating loop to prevent stagnation and provide a degree of disinfection. The PPM requires review.

Water Solutions Group

13	Rain Water Harvesting	The words “Rain Water Harvesting” and “Healthcare” do not go together. It is important that a testing regime for the rainwater tank is put in place, which must include organisms related to Ornithological Faecal Matter (e.g. Cryptococcus). A review of disinfection strategy needs to be undertaken.
14	PPM Schedules	The current invisibility of a meaningful water safety plan, SOPs and PPM programme brings into doubt the regime being operated on this site pre and post occupation. It is essential this document is received for review and comment.
15	Shower Heads and Hoses	Currently all shower heads have the capability of reaching the floor drain and toilet. All shower hoses to be replaced to a length preventing the shower head touching the floor. The use of shower head insert replacement (colour coded) should be considered (medi-shower).

Water Solutions Group

8.0. Disclaimer

This assessment has been based upon information provided by the client. H2O Solutions (Europe) LLP cannot accept any responsibility for any errors or omissions appertaining to the data, records and information provided by the client.

Every reasonable endeavour has been taken by the auditor to ensure the findings and recommendations contained in this report are representative of the issues that require addressing in order to improve current practice.

Royal Hospital for Children and Young People and Department of Clinical Neurosciences

NHS Lothian response to actions identified in the

NSS National Services Scotland – Review of: Water, Ventilation, Drainage and Plumbing Systems

September 2019
Version 2.0

Introduction

Following the decision to delay moving to the new Royal Hospital for Children and Young People & Department of Clinical Neurosciences in July 2019, NHS National Services Scotland (NSS) were commissioned by Scottish Government to undertake a series of checks to ensure that the relevant technical specifications and guidance applicable to the new hospital had been followed and were being implemented.

Health Facilities Scotland (HFS) and Health Protection Scotland (HPS) have provided their report to Scottish Government on whether the relevant technical specifications and guidance applicable to the RHCYP & DCN are being followed and implemented. The report provides an assessment of actions required where relevant technical specifications and guidance have not been met.

NHS Lothian engaged with NSS throughout the review and addressing follow-up actions. Updates on each action identified in the NSS Review are provided in this response.

Glossary

AHU	Air handling unit
Board	refers to NHS Lothian
HFS	Health Facilities Scotland
HPS	Health Protection Scotland
IHSL	IHS Lothian Limited
IPCT	Infection Prevention and Control Team
NSS	National Services Scotland
SHPN	Scottish Health Planning Note
SHTM	Scottish Health Technical Memorandum
TMT	Thermostatic mixing taps
TMV	Thermostatic mixing valves

Management and Assurance

NSS Review: *Omissions identified in key roles within the management structure, ease of access to information.*

NHS Lothian response: Management roles and responsibilities and will be identified and the responsibility matrix will be reviewed on a regular basis. Archiving of information will be revised in line with guidance and contract requirements

through NHS Lothian's Corporate Management Team.

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
Structures and processes	*Structures and processes are not fully in place to assure the Board that the facility is being operated in compliance with contract requirements. These should be in place from the point where the building services referred to in this report are put into use.*	*NHS Lothian and IHSL should adopt the management and reporting processes as described in SHTM 00 – Best Practice Guidance for Healthcare Engineering and the SHTMs for each critical engineering service.*	**AGREED** Contract management arrangements will follow SHTM 00.
Contract requirements	*Some of the records and documents necessary for the effective and safe operation of the hospital could not be found. The document management system appears to lack a logical structure which will impact on the ability to readily find necessary information. Some of the sections contain none, or only part, of the documentation they should have as required by the Construction (Design and Management) Regulations 2015.*	*The Board should require IHSL to rectify the filing structure of the documentation and verify that the information contained is both complete and accurate as required by the Construction (Design and Management) Regulations 2015.*	**AGREED** A review and demonstration of completeness has been requested from IHSL and additional information has been provided by them.
Alarms	*The alarms for the building are reportedly un-prioritised, resulting in a very large number of alarms potentially masking critical alarms.*	*Prioritise alarms to make most critical failures visible and manageable. Until alarms are prioritised, have procedures and staff in place to ensure critical alarms are not missed as per SHTM 08-05 - Specialist services building management systems.*	**AGREED** NHS Lothian has requested a programme to confirm this in place by the end of September.

Ventilation

NSS Review: *Remedial action is required within both general and theatre ventilation systems. Augmented care redesign was already being considered separately by the Board. Haematology / Oncology is also being reviewed as a result of the review as specific risks were identified. Risk assessments are underway as part of the ward by ward risk assessments being done locally requested as part of the review.*

NHS Lothian response: The required remedial actions are underway with expert input from the engineers. Two Board changes have been progressed for the areas to be redesigned. Discussion with clinical staff and the Infection Prevention and Control Team (IPCT) will guide patient placement in line with documented risk assessments.

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
General ventilation systems 1	*Provision for maintenance or plant failure in the ventilation systems has not been validated in accordance with SHTM 03-01 Ventilation for Healthcare Premises. The bypass arrangements and functioning of ward ventilation in the event of plant failure remains to be demonstrated.*	*Demonstrate efficacy of approach of utilising adjacent air handling unit to supply areas not served by failed plant.* *Commission and validate isolation rooms and general ward spaces in the event of supply by adjacent air handling unit.* *Engage clinical leads and Infection Prevention and Control colleagues in developing service provision strategies in the event of air handling plant failure.* *Confirm damper operation and compliance with fire requirements in bypass mode.*	The date for the demonstration of bypass arrangements is to be confirmed by 13 September 2019. **AGREED** Patient safety in the event of a reduction of air exchange, for any reason, will be managed through infection prevention and control guidance and clinical risk assessment. Work is ongoing with contractors to ensure damper operation is compliant. The programme of works is to be provided by IHSL by 13 September 2019

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
General ventilation systems 2	*Air handling units and ductwork contain numerous deviations from contract requirements (SHTM 03-01) and were found not to be clean despite having been presented for validation. Deviations include: loose internal cabling in the airflow, cable routes allowing air to bypass filters, air leakage at penetrations and possible fan replacement difficulties which need to be corrected.*	*The ventilation systems throughout the hospital should be subject to a full snagging exercise and all defects rectified following which air handling units and ventilation systems are cleaned. All deficiencies identified in validation and specialist Consultant Engineer reports should be addressed as part of this.*	We are working closely with IHSL to ensure all the issues identified in the reports have been rectified. A specimen AHU with all the deficiencies rectified will be made available to NHS Lothian for inspection by HFS and our engineers in September 2019.
General ventilation systems 3	*The general ward ventilation design is based on four air changes per hour mechanical ventilation plus a component of natural ventilation. With a few exceptions, the mechanical component has been validated. However, design and validation information for the natural component has not been proven.*	*Confirm that all areas served by this arrangement are suitable for categorisation as general ward areas or single rooms as listed in SHTM 03-01 Part a, Appendix 1.* *Undertake an IPCT risk assessment ward by ward/ speciality specific in relation to the guidance.*	A risk assessment undertaken by IPCT and clinical teams will be completed by 13 September to ensure that patient placement recognises the general ward ventilation provision.
General ventilation systems 4	*The pressure regimen detailed in the design, and reflecting the environmental matrix, will be affected by opening windows and the pressure between the room and the corridor, and therefore direction of air flow, cannot be relied upon when windows are open.*	*A full assessment of the services and patient population should be carried out and mechanisms for monitoring established.*	**AGREED** Ward level risk assessments will recognise the contribution of open windows to the ventilation provided mechanically.
General ventilation systems 5	*External doors to plant rooms*	*Ensure that excessive gaps are removed and appropriate anti vermin measures are applied to all the doors and screens as per SHTM 03-01 and HFS Interim Guidance - Managing the Risk of Contamination of Ventilation Systems by Fungi from Bird Droppings – February 2019.*	**AGREED** This will be addressed by the end of September. All doors will then comply with the guidance.
General ventilation	*Fire dampers in some locations cannot be adequately tested as duct access has not been*	*Provide access so all fire dampers can be readily visually inspected to verify operation.*	**AGREED** Access to fire dampers will be

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
systems 6	*provided. Also, locations of fire dampers and fire rated ductwork has been questioned in relation to the requirements of SHTM 03-01 and confirmation of compliant provision is awaited.*	*Review fire damper provision and fire rated ductwork and confirm appropriate provision*	corrected as part of the work to air handling units.
General ventilation systems 7	*Air intake location - Air intakes and opening windows are sited in the courtyard below the helipad and at the adjacent RIE. Information has not been provided on the impact of downdraft on air flows and pressures or entrainment of contaminants as per SHTM 03- 01.*	*Demonstrate the effect of helicopter landing on air flows in ventilation systems with intakes below through measurement when test flights take place or through modelling. This should include the air intakes of the RIE adjacent.*	Modelling information has been shared with NSS. The effects of test flights on air flows will be measured in September/ October 2019.
Theatre ventilation systems 1	*Scrub areas which are narrow and deep are unlikely to be scavenged effectively by theatre air changes and require e alternative means of achieving removal of contaminants as per SHTM 03-01. The efficacy of the high level extract to achieve sufficient dilution of contaminants or entrainment of heavier than air water droplets is not in accordance with the requirements of SHTM 03-01and has not demonstrated as equivalent.*	*The ability of the single high level extract provided in deep plan scrub areas to effectively prevent contaminants being dispersed into theatres should be demonstrated and/or additional low level ventilation provided.*	**AGREED** Evidence to confirm the adequate dispersal of contaminants has been requested. If this not satisfactory then a Board change will be instructed to provide low level ventilation.
Theatre ventilation systems 2	*Anaesthetic rooms 31 and 34 do not demonstrate a clean air flow path to reduce exposure of staff to gasses as per SHTM 03-01. Move ceiling supply to opposite side of room from extract. In room 30, move supply away from door.*	*Move ceiling supply to opposite side of room from extract. In room 30, move supply away from door.*	Demonstration of a clean air path has been requested by 13 September 2019; otherwise the supply will be moved.
Theatre ventilation systems 3	*Theatre utility rooms Extract ventilation means theatres have to be used in pairs and taking a theatre out of service may reduce the extract in utility room below the levels as per SHTM 03-01.*	*Add supplementary extract ventilation to allow for one theatre being out of service or plan for service impact following the loss of a pair of theatres.* *NHS Lothian has advised that the appropriate pressure differentials are maintained when only one theatre is operation. Validation*	IHSL have provided evidence that this arrangement meets the standard. Final checks on this are being completed.

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
		evidence is to be provided.	
Isolation room ventilations systems	*Isolation rooms are not served by a single ventilation system for each room as recommended in SHPN4 Supplement 1. The arrangement provided, where ventilation systems serve an area of the building including contained isolation rooms, has not yet been proven in the event of failure of an air handling unit and the implications for service impact are not yet understood.*	*Prove that bypass connections to adjacent ventilation systems will allow safe operation of both areas and / or explain service provision strategy for loss of each area including isolation rooms. Also include assurance on operational effectiveness e.g. the pressure differentials and air flows being maintained.* *Develop clinical service provision strategy to reflect the potential loss of up to 5 of the 19 isolation rooms on the failure of an air handling unit and confirm impact on service continuity.*	The date for the demonstration of bypass arrangements is to be confirmed by 13 September 2019. Detailed advice from the infection control team to allow bespoke risk assessments would be followed in such circumstances.

Water

NSS Review: *Independent testing identified no widespread contamination of the water systems, however, remedial action is required on a number of water system areas as well as system wide disinfection prior to occupation.*

NHS Lothian response: Remedial actions are underway and will be complete prior to occupation. Changes to the regime to maintain water quality have been made to address the findings of this review. System-wide disinfection will take place in the required timeframe prior to occupation.

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
Water services augmented care	*Pseudomonas found in taps, in Paediatric Medical Inpatients and DCN Inpatients . (SHTM 04-01 Part A published in July 2014)*	*All taps (not just TMT/TMV4) to be disinfected and retested. Inspect and replace, as appropriate, taps, tap components and pipework. Replace tap strainers and cartridges in affected TMT taps.*	**AGREED** All taps found positive for pseudomonas prior to occupation will be disinfected and retested using an agreed method statement. To be completed by the end of September 2019.
Water services non-augmented care	*Swarf and biofilm found in tap strainers, contrary to SHTM 04- 01 Water safety for healthcare premises.*	*Replace tap strainers in all areas.*	**AGREED** All tap strainers will be cleaned and replaced if necessary. To be complete by the end of October 2019.
Showers	*Shower hose lengths do not comply with Scottish Water by-laws and guidance in SHTM 04-01 Water safety for healthcare premises.*	*Shorten hose length, or add retaining ring, to ensure that shower head cannot reach WC or drain.* *Disinfect showers, hose and drain after rectification.*	**AGREED** Shower hoses will be rectified by addition of a retaining ring. These have been ordered and will be fitted by end of September.
Water General 1	*Testing has found some fungal / mould contamination and high total viable counts.*	*Given a number of indicators the water system should be disinfected and re-tested.*	**AGREED** The water system will be disinfected and tested prior to occupation.
Water General 2	*Legionella risk assessment actions not recorded as required by HSE Approved Code of Practice and*	*The Legionella Risk assessment Feb 2019 identified a range of actions. The Action Tracker*	**AGREED** Changes to the water

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
	Guidance L8 - Legionnaires' disease. The control of Legionella bacteria in water systems. Legionella risk assessment insufficient to reflect system contamination in general. Those responsible for the system have a responsibility under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) to prevent exposure to microorganisms.	*does not demonstrate that the issues raised have been resolved or a timeline provided for resolution. Record rectification of actions. The risk assessment is heavily focussed on Legionella and not taking into account other organisms in line with patient type that will occupy the building. Broaden to reflect system contamination in general. Develop analysis categorisation of patient type and consideration to susceptibility for each area.*	management plan have been made to reflect this.
Water General 3	*Designated roles and responsibility as per SHTM 00 Best practice guidance for healthcare engineering.*	*The current Responsible Person (RP) has not been appointed in writing and uncertain as to whether received RP training. Additionally, has no previous experience of healthcare.*	**AGREED** The name of the responsible person has been confirmed; their qualifications will be provided.
Water General 4	*Water tanks as per SHTM 04-01 Water safety for healthcare premises.*	*To be inspected. The Raw Water and Filtrate water tanks are interconnected at the drain. These must be separated.*	**AGREED** This work will be complete by the end of September 2019.
Water General 5	*Hot and cold water temperatures / flushing. SHTM 04-01 Water safety for healthcare premises*	*There was an issue with raised cold water temperatures during the boiler outage – this requires investigation.*	**AGREED** Regular monitoring of hot and cold water temperatures is part of the water maintenance plan.
Water General 6	*Filtration Plants*	*From lessons learned by NSS in recent work, microbiological growth potential was identified as part of the Backwash cycle. Consideration should be given to Chlorine dioxide addition to backwash water tank to counter microbiological and biofilms development on filters.*	**CLOSED** NHS Lothian will consider new advice as it is produced and incorporate this into the water management plan as necessary.
Water General 7	*Instant Boil Taps and Rise and Fall Baths*	*These were found to be contaminated and need to be disinfected and tested t demonstrate safe water delivery as per SHTM 04-01 Water safety for healthcare premises.*	**AGREED** This action is underway in conjunction with the manufacturers.

Drainage and Plumbing

NSS Review: *The drainage system has multiple redundancies in place, however, active monitoring is required. Elements of plumbing require disinfection.*

NHS Lothian Response: Monitoring arrangements for drainage are incorporated into the building maintenance schedule. All necessary disinfection of plumbing will be incorporated into the maintenance schedules.

Issue	*NSS Review*	*NSS Action Assessment*	NHS Lothian action
Drainage and plumbing 1	Sinks drains	*Initial testing indicates that these are not significantly contaminated, however the horizontal drain and protruding seal means they retain stagnant water and they need to be disinfected periodically prior to and post occupancy to maintain their condition. From lessons learned, there should be a system of inspection and appropriate remedial action taken.*	**CLOSED** This will be incorporated into the water management plan prior to occupation of the building.
Drainage and plumbing	Bottle traps	*There would appear to be an inconsistency of installation and potential of back-feed from trap to drain. This requires review and rectification.*	**CLOSED** Disinfection of the bottle traps will be incorporated into the regular maintenance regime.
Drainage and plumbing 3	Pumped drainage	*The internal pumped sewage drainage system presents the potential for sewage to back up through basement drains on pump failure and will require active monitoring.*	**CLOSED** The monitoring of pumped drainage is in place and is on the critical alarm list.

NHS National Services Scotland

NHS Lothian - Royal Hospital for Children and Young People & Department of Clinical Neurosciences

NHS National Services Scotland – Review of: Water, Ventilation, Drainage and Plumbing Systems

September 2019
Version D0.20

Contents

1. Executive Summary

1.1 Overview

A decision was taken on 2 July 2019 to delay moving to the new Royal Hospital for Children and Young People & Department of Clinical Neurosciences (RHCYP & DCN) on 9 July. This followed an inspection of the facility which raised concerns regarding the ventilation arrangements for critical care beds and other areas of the hospital. NHS National Services Scotland (NSS) received a commission from Scottish Government to undertake an external series of checks, led by Health Facilities Scotland (HFS) and Health Protection Scotland (HPS), to ensure that the relevant technical specifications and guidance applicable to the new hospital have been followed and are being implemented.

The objectives of the review in relation to RHCYP & DCN were:

- To provide a report by September 2019 to Scottish Government on whether the relevant technical specifications and guidance applicable to the RHCYP & DCN are being followed and implemented.
- Where relevant technical specifications and guidance have not been followed, identify necessary remedial actions.

Given the specific focus on the control of Healthcare Associated Infections (HAI), the review concentrated on a system wide approach for ventilation, water and drainage systems. The process involved site visits, sample inspections and a targeted review of available documentation.

From an early stage of the review process, it was apparent that elements of the Critical Care Unit (CCU) ventilation system required redesign and modification to ensure compliance with guidance. Additionally, Haematology / Oncology is also being reviewed as a result of the review as specific risks were identified. NSS provided advice relating to the design instruction for elements of the CCU ventilation system and similar advice will be provided in relation to Haematology / Oncology.

The review commenced on the 9th July 2019 with this final report published in September 2019 for consideration by the established RHCYP & DCN Oversight Board.

1.2 Summary of findings

The findings have been collated based on information provided by NHS Lothian and on-site reviews of the RHCYP & DCN. Expert advice was sought within the key focus areas of ventilation, water and drainage systems and their overarching management and assurance processes. The following table outlines the status of key findings:

Review	Summary Assessment	No. of Issues per priority				
		1 (H)	2	3	4	5 (L)
Management & Assurance	Omissions identified in key roles within the management structure, ease of access to information and prioritisation of building system alarms.	-	-	1	2	-
Ventilation Systems	Remedial action is required within both general and theatre ventilation systems. Critical Care redesign was already being considered separately by the Board. Haematology / Oncology is also being reviewed as a result of the review as specific risks were identified. Risk assessments are underway as part of the general ward risk assessments being done locally requested as part of the review.	-	1	2	1	-
Water Systems	Independent testing identified no widespread contamination of the water systems, however, remedial action is required on a number of water system areas as well as system wide disinfection prior to occupation.	-	1	2	-	-
Drainage & Plumbing	The drainage system has multiple redundancies in place; active monitoring is required. Elements of plumbing require monitoring and routine disinfection.	-	-	-	1	-

The following definitions were used to categorise the findings:

Priority	Definition
1	Significant – Concerns requiring immediate attention, no adherence with guidance
2	Major – Absence of key controls, major deviations from guidance
3	Moderate – Not all control procedures working effectively, elements of noncompliance with guidance
4	Minor – Minor control procedures lacking or improvement identified based on emerging practice
5	Observation and improvement activity

Overall remedial action is required to be undertaken within the ventilation and water systems prior to the occupation. Following acceptance of this report, the review team are ready to assist the NHS Lothian team in developing a programme of activity and remedial actions to allow a timeline to be constructed which could inform the decision to migrate towards occupancy on a phased basis.

2. Review methodology

2.1 Review process

2.1.1 The review process initially took place between 9th July and 30th August 2019. For this report no further information has been considered after 30th August 2019.

2.1.2 The approach taken was to gather information relating to the services detailed in section 1.2 in drawing, specification, report and oral form and to compare these to the standards and guidance appropriate for the building type, drawing conclusions on whether what is provided matches the requirements. In addition to existing standards and guidance, learning generated from recent experience and national and international guidance and expertise was also used to inform the review. This learning will also inform future guidance development in Scotland.

2.1.3 The review has included

- Establishing a brief.
- Establishing the baseline data to allow the brief to be met.
- Preparation of several question sets to get a greater understanding of the project.
- Preparation and management of detailed question sets and information requests.
- Commissioning UK topic experts to review certain aspects of the project.
- Several site visits.
- Several meetings.
- Analysis of data.
- Analysis of microbiology results related to the hot and cold water systems.
- A rapid review of the literature and international guidance on ventilation systems.

2.2 Standards and Guidance

2.2.1 HFS currently provides a range of advisory and delivery services across a wide variety of topics from a portfolio which covers the built estate, engineering and environment and facilities management. With some exceptions these services are largely advisory in nature, identifying best practice and developing national guidance and standards.

2.2.2 HPS currently provides advice and guidance on all aspects of health protection nationally in Scotland, inclusive of expert advice and guidance on the topic of Healthcare Associated Infections (HAI) and antimicrobial resistance. It maintains and continues to develop a practice guide (National Infection Prevention and Control Manual – NIPCM) as well as a HAI Compendium of all extant guidance and policy appropriate for use in NHSScotland. Like HFS, these services are largely advisory in nature, identifying best practice and developing national guidance and standards. The NHSScotland NIPCM was first published on 13 January 2012 as mandatory guidance, by the Chief Nursing Officer (CNO (2012)1), and updated on 17 May 2012

(CNO(2012)01-update). The NIPCM provides guidance for all those involved in care provision and should be adopted for infection, prevention and control practices and procedures. The NIPCM is mandatory policy for NHSScotland.

The authority of guidance produced by NSS and other national organisations e.g. Healthcare Improvement Scotland is best described by the definitions outlined below (SHMT 00 – Best practice guidelines for healthcare engineering):

Regulations are law, approved by Parliament. These are usually made under the Health and Safety at Work etc Act following proposals from the Health & Safety Commission. Regulations identify certain risks and set out specific actions which must be taken.

Approved Codes of Practice give advice on how to comply with the law by offering practical examples of best practice. If employers follow the advice, they will be doing enough to comply with the law.

Approved Codes of Practice have a special legal status. If employers are prosecuted for a breach of health and safety law, and it is proved that they did not follow the relevant provisions of an Approved Code of Practice, they will need to show that they have complied with the law in some other way, or a court will find them at fault.

Standards (British or European), institutional guides and industry best practice play a large part in how things should be done. They have no direct legal status (unless specified by Regulations). However, should there be an accident; the applied safety practices at the place of work would be examined against existing British or European Standards. It would be difficult to argue in favour of an organisation where safety was not to the described level.

Guidance is issued in some cases to indicate the best way to comply with Regulations, but the guidance has no legal enforcement status.

2.2.3 Whilst guidance is deemed not compulsory by HSE (not legally enforceable), where compliance with guidance is specified in a contract, it becomes a contractual requirement. Therefore, any permitted deviation from it would be expected to follow a formal process with input from all relevant parties with clarity around how the outcome was reached, including risk assessments where appropriate and sign off by all those authorised to approve it.

2.2.4 The terms of standards and guidance are used in the report to refer to the publications setting out the expectations about the level of service to be provided, including legislation, approved codes of practice and guidance. Compliance with guidance is reported on, regardless of whether this implies a contractual requirement, as contract compliance is out with the scope of this report. For the avoidance of doubt we have not considered the project agreement and contractual compliance in accordance with its terms as this is subject to a separate review commissioned by Scottish Government.

2.2.5 The contract model for this project is known as a Non Profit Distribution (NPD) model, which amongst other things is intended to deliver benefits such as:

- Single delivery mechanism.
- Whole life costing.
- Design efficiencies.
- Lifecycle maintenance.
- Improved service provision.

Based on the Board's Construction Requirements (BCRs), including which guidance is to be followed and other parameters, the Special Purpose Vehicle (SPV) develops the design and agrees operational (clinical) functionality with the Board before construction commences and during the Reviewable Design Data process (RDD). It is usual to have an Independent Tester (IT) involved in the project. The IT is a joint appointment to the SPV and the Board. The IT role is to certify the completion of the building as referenced in the project agreement and completion criteria of the contract.

2.3 Reporting methodology

2.3.1 For clarity this report organises issues with each of the systems considered into a priority rating, identifying the importance of deviations from what would be expected based on the standards and guidance. The distinction between the categories is based on NSS judgement of the degree of non-compliance and the implications of that non-compliance. The criteria used are described below.

Priority	Definition
1	Significant – Concerns requiring immediate attention, no adherence with guidance
2	Major – Absence of key controls, major deviations from guidance
3	Moderate – Not all control procedures working effectively, elements of noncompliance with guidance
4	Minor – Minor control procedures lacking or improvement identified based on emerging practice
5	Observation and improvement activity

3. Analysis of information provided

3.1 Information provided

3.1.1 The support of the NHS Lothian project team in responding to questions and accessing data is gratefully acknowledged.

3.1.2 At the time of writing the majority of the information required had been received and whilst the timescale for the review means a selective targeted review of documentation was necessary, the main themes appear clear. However, some information remains outstanding, particularly information requested from Integrated Health Solutions Lothian (IHSL)[1], and NHS Lothian colleagues continue to pursue a response.

3.1.3 The Special Purpose Vehicle (SPV), Contractor, sub-contractors, Facilities Management Contractor and Independent Tester were not directly involved in the production of this report, nor were they requested to verify its contents and they may have additional information not considered here. It is acknowledged that some of the information provided by NHS Lothian came directly from these sources.

Ventilation systems

3.1.4 Prior to this review NHS Lothian commissioned a specialist contractor to validate the performance of ventilation systems within the facility and their report identified that elements of the ventilation system in CCU was not in accordance with current guidance (SHTM 03-01). Whilst this report notes that finding and NSS has been asked to support NHS Lothian in achieving a solution in compliance with guidance, this report focuses primarily on other ventilation issues.

3.1.5 Awaited is the explanation and validation of the ventilation strategy whereby areas with air handling units out of service for whatever reason are served by an adjacent air handling unit, which also continues to serve its own area.

3.1.6 The theatre ventilation appears not to have been installed in accordance with current guidance in respect to required pressure cascades in corridors and removal of contaminants from scrub areas. The Board has sought demonstration of compliance from IHSL in relation to issues identified.

Water systems

3.1.7 Whilst elements of the water testing carried out as part of this review are not detailed in current guidance, and NHS Lothian could not have been expected to be aware, lessons learned recently across health systems suggest that any potential pathogenic contamination found should be eradicated before patients and staff move in. Water test results in RHCYP & DCN indicate some fungi in the water, mainly at taps, as well as higher than anticipated total viable counts (TVC). The latter may be related to the fact that the building is unoccupied with only maintenance processes in place to ensure water turnover. In augmented care areas there is evidence of *Pseudomonas aeruginosa* found in some taps. There would appear to be no systemic contamination of the hot and cold water systems, rather, contamination has

[1] IHSL are the Special Purpose Vehicle (SPV)

been found at outlets, and particularly outlets with complex interstices and organic components which can make them more susceptible to persistent contamination.

Drainage and plumbing systems

3.1.8 The drainage for the hospital utilises one gravity system and two pumped systems. The pumped systems are used to overcome gravity as they are installed below the local water table and level of the external drains. The main concern is the pumped system in the basement in the location of the kitchen. This system has multiple pump backups as well as alternative power supplies. The risk is that if these fail the kitchen drains will back up requiring the kitchen to close, which would have an impact on the services to the hospital. At this stage in the process there appears to be no alternative to locating the drainage system sump in the basement, at least without major structural alterations to the basement and courtyard. It appears that extensive use of standby equipment and power supplies is in place, such that multiple failures would need to occur to cause sewage to back up into the basement. Procedures for maintenance and repair have been extensively considered but will need to be tested in operation.

4. Findings

4.1 Management and assurance

Summary

Review	Summary Assessment	No. of Issues per priority				
		1 (H)	2	3	4	5 (L)
Management & Assurance	Omissions identified in key roles within the management structure, ease of access to information and prioritisation of building system alarms.	-	-	1	2	-

Main Findings

Priority	Review	Action Assessment
4	Structures and processes are not fully in place to assure the Board that the facility is being operated in compliance with contract requirements. These should be in place from the point where the building services referred to in this report are put into use.	NHS Lothian and IHSL should adopt the management and reporting processes as described in SHTM 00 - Best Practice Guidance for Healthcare Engineering and the SHTMs for each critical engineering service.
3	Some of the records and documents necessary for the effective and safe operation of the hospital could not be found. The document management system appears to lack a logical structure which will impact on the ability to readily find necessary information. Some of the sections contain none, or only part, of the documentation they should have as required by the Construction (Design and Management) Regulations 2015.	The Board should require IHSL to rectify the filing structure of the documentation and verify that the information contained is both complete and accurate as required by the Construction (Design and Management) Regulations 2015.
4	The alarms for the building are reportedly un-prioritised, resulting in a very large number of alarms potentially masking critical alarms.	Prioritise alarms to make most critical failures visible and manageable. Until alarms are prioritised, have procedures and staff in place to ensure critical alarms are not missed as per SHTM08-05 - Specialist services building management systems.

Detailed Narrative

4.1.1 Healthcare organisations have a duty of care to patients, their workforce and the general public to ensure a safe and appropriate environment. This requirement is identified in a wide range of legislation. At the most senior level within an organisation, the appointed responsible person should have access to a robust structure which delivers governance, assurance and compliance through a formal reporting mechanism.

4.1.2 The review identified that for both IHSL and NHS Lothian, there were omissions in the identification, appointment and definition of key roles in an effective management structure. Additionally, some records which are necessary to demonstrate compliance with appropriate standards and guidance remain outstanding.

4.1.3 The Board cannot pass its responsibilities under health and safety law to a third party. It can pass duties, but the responsibility for ensuring the safety of those accessing its premises remains with the Board. To discharge its duties, the Board should ensure appropriate structures, processes and personnel are in place to ensure that those responsible for operating the facility are doing so in compliance. The structures and processes set out in the Scottish Health Technical Memorandum (SHTM) suite of guidance, Statutory Compliance Audit and Risk Tool (SCART)[2] and Healthcare Associated Infection-System for Controlling Risk in the Built Environment (HAI_SCRIBE) [3] produced by Health Facilities Scotland, should form the core of this. These arrangements should be in place as soon as practicable and prior to occupation of the RHYCP & DCN.

4.2 Ventilation

Summary

Review	Summary Assessment	No. of Issues per priority				
		1 (H)	2	3	4	5 (L)
Ventilation Systems	Remedial action is required within both general and theatre ventilation systems. Critical Care redesign was already being considered separately by the Board. Haematology / Oncology is also being reviewed as a result of the review as specific risks were identified. Risk assessments are underway as part of the general ward risk assessments being done locally requested as part of the review.	-	1	2	-	-

[2] SCART is a risk based tool used by Boards in NHS Scotland to measure their compliance against statutory and non-statutory position.
[3] HAI_SCRIBE provides Built Environment Infection Prevention and Control information for Design Teams, Construction Teams, Infection Prevention and Control Teams and Estates & Facilities Teams, as well as an assessment process allowing the identification and management of infection control risks in the built environment.

Main Findings

Priority	Review	Action Assessment
2	**General Ventilation Systems -** Provision for maintenance or plant failure in the ventilation systems has not been validated in accordance with SHTM 03-01 Ventilation for Healthcare Premises. The bypass arrangements and functioning of ward ventilation in the event of plant failure remains to be demonstrated.	Demonstrate efficacy of approach of utilising adjacent air handling unit to supply areas not served by failed plant. Commission and validate isolation rooms and general ward spaces in the event of supply by adjacent air handling unit. Engage clinical leads and Infection Prevention and Control colleagues in developing service provision strategies in the event of air handling plant failure. Confirm damper operation and compliance with fire requirements in bypass mode.
	Air handling units and ductwork contain numerous deviations from contract requirements (SHTM 03-01) and were found not to be clean despite having been presented for validation. Deviations include: loose internal cabling in the airflow, cable routes allowing air to bypass filters, air leakage at penetrations and possible fan replacement difficulties which need to be corrected	The ventilation systems throughout the hospital should be subject to a full snagging exercise and all defects rectified following which air handling units and ventilation systems are cleaned. All deficiencies identified in validation and specialist Consultant Engineer reports should be addressed as part of this.
	The general ward ventilation design is based on four air changes per hour mechanical ventilation plus a component of natural ventilation. With a few exceptions, the mechanical component has been validated. However, design and validation information for the natural component has not been proven.	Confirm that all areas served by this arrangement are suitable for categorisation as general ward areas or single rooms as listed in SHTM03-01a Appendix 1. Undertake an IPCT risk assessment ward by ward/ speciality specific in relation to the guidance.
	The pressure regimen detailed in the design, and reflecting the environmental matrix, will be affected by opening windows and the pressure between the room and the corridor, and therefore direction of air flow, cannot be relied upon when windows are open.	A full assessment of the services and patient population should be carried out and mechanisms for monitoring established.

	External doors to plant rooms	Ensure that excessive gaps are removed and appropriate anti vermin measures are applied to all the doors and screens as per SHTM 03-01 and HFS Interim Guidance - Managing the Risk of Contamination of Ventilation Systems by Fungi from Bird Droppings – February 2019.
	Fire dampers in some locations cannot be adequately tested as duct access has not been provided. Also, locations of fire dampers and fire rated ductwork has been questioned in relation to the requirements of SHTM 03-01.	Provide access so all fire dampers can be readily visually inspected to verify operation. Review fire damper provision and fire rated ductwork and confirm appropriate provision
	Air intake location - Air intakes and opening windows are sited in the courtyard below the helipad and at the adjacent RIE. Information has not been provided on the impact of downdraft on air flows and pressures or entrainment of contaminants as per SHTM 03-01.	Demonstrate the effect of helicopter landing on air flows in ventilation systems with intakes below through measurement or modelling. This should include the air intakes of the RIE adjacent.
3	**Theatre Ventilation Systems** - Scrub areas which are narrow and deep are unlikely to be scavenged effectively by theatre air changes and require alternative means of achieving removal of contaminants as per SHTM 03-01. The efficacy of the high level extract to achieve sufficient dilution of contaminants or entrainment of heavier than air water droplets is not demonstrated.	The ability of the single high level extract provided in deep plan scrub areas to effectively prevent contaminants being dispersed into theatres should be demonstrated and/or additional low level ventilation provided.
	Anaesthetic rooms 31 and 34 do not demonstrate a clean air flow path to reduce exposure of staff to gasses as per SHTM 03-01.	Move ceiling supply to opposite side of room from extract. In room 30, move supply away from door.
	Theatre utility rooms Extract ventilation means theatres have to be used in pairs and taking a theatre out of service may reduce the extract in utility room below the levels as per SHTM 03-01.	Add supplementary extract ventilation to allow for one theatre being out of service or plan for service impact following the loss of a pair of theatres. *NHS Lothian has advised that the appropriate pressure differentials*

		are maintained when only one theatre is operation. Validation evidence is to be provided.
3	**Isolation Room Ventilation Systems -** are not served by a single ventilation system for each room as recommended in SHPN4 Supplement 1. The arrangement provided, where ventilation systems serve an area of the building including contained isolation rooms, has not yet been proven in the event of failure of an air handling unit and the implications for service impact are not yet understood.	Prove that bypass connections to adjacent ventilation systems will allow safe operation of both areas and / or explain service provision strategy for loss of each area including isolation rooms. Also include assurance on operational effectiveness e.g. the pressure differentials and air flows being maintained. Develop clinical service provision strategy to reflect the potential loss of up to 5 of the 19 isolation rooms on the failure of an air handling unit and confirm impact on service continuity.

Detailed Narrative

4.2.1 The ventilation systems at RHCYP & DCN were considered in relation to legislation, guidance and the lessons learned from other recent similar projects which may have an impact on the patient group.

4.2.2 The principal legislation which is relevant to the ventilation systems is The Control of Substances Hazardous to Health Regulations 2002 (COSHH).

4.2.3 The principal guidance which is relevant to the ventilation systems is: Scottish Health Technical Memorandum (SHTM) 03-01: Ventilation for healthcare premises; and Scottish Health Planning Note 04 Inpatient Accommodation, Supplement 1 Isolation Facilities in Acute Settings.

4.2.4 Elements of the ventilation within Critical Care were identified by NHS Lothian's validation contractor, and verified in this review, to be not in accordance with the requirements of SHTM 03-01. NHS Lothian is working with IHSL to design a suitable solution to provide the conditions required within CCU. NSS has been asked by Scottish Government to support NHS Lothian to ensure that the system delivered is compliant with requirements.

4.2.5 The general ventilation for non-specialist applications, such as single/shared rooms in general wards, was identified by the Board's validation contractor as having lower air change rates than specified in SHTM 03-01, i.e. 4 air changes per hour as opposed to 6. During the review, NHS Lothian supplied information about a natural ventilation component, with some documents referring to a mixed mode ventilation system. However, IHSL advised that natural ventilation is not part of their design. NSS visited the site with specialist ventilation consultants who produced a report on the general ventilation systems and noted non-compliances with air handling unit provision and installation and pressure regimens, including several identified by the Board's validation contractor.

From an infection prevention and control perspective, there is low-quality to no evidence from outbreak reports and current guidance, respectively, to support minimum ventilation requirements. Therefore, it is not possible to make conclusive statements regarding the individual minimum ventilation parameters for inpatient care areas. A rapid review of the literature found limited clinical evidence to directly implicate air change rates alone in having a direct impact on the development of an outbreak or incidence of infection. Therefore, it is reasonable that, in the absence of evidence, healthcare design teams should continue to adhere to current national guidance. In the event of a deviation from the current recommended ventilation parameters, design teams should ensure that air changes per hour are maintained as close as possible to the recommended air changes per hour without compromising other aspects of the ventilation system requirements. In addition a full assessment of the services and patient population should be carried out and mechanisms for monitoring established. Caution is advised in relying on air change rates alone to provide adequate protection from infection; this is only one part of a multifactorial process involved in creating the appropriate airflow patterns with appropriate mixing and dilution of contaminants. Further research is required to look beyond air change rates to examine the effects that other factors such as supply and exhaust location, door position and motion, spatial orientation, surface composition, temperature, humidity, and air distribution patterns have on particle migration in clinical areas.

4.2.6 Theatre ventilation was identified by NHS Lothian's validation contractor as having some deficiencies. NSS visited the site with a specialist Consultant Engineer, who was lead author on the last three iterations of the ventilation HTM guidance. This identified and confirmed several deficiencies, including lack of evidence about the efficacy of the ventilation in the scrub rooms; deviating from the standard models recommended in SHTM 03-01. The current design of the theatre ventilation system is such that maintenance might entail loss of two theatres rather than one. Additionally, there is an overuse of flexible ductwork, potentially causing problems with balancing theatre ventilation. All issues identified are rectifiable, and as such should not prevent the theatres being put into use following remedial action.

4.2.7 The building contains a number of Positive Pressure Ventilated Lobby (PPVL) isolation rooms for which the guidance, SHPN4 supplement 1, recommends that each isolation room should ideally have its own air handling unit, such that if an air handling unit fails, or is offline for maintenance, only one isolation room is out of commission.

The building, as built, has an air handling unit serving each area of the building, including any contained isolation rooms. This means that up to five out of 19 isolation rooms may be out of action in the event of an air handling unit failure. NHS Lothian have advised that the strategy for maintenance is that a bypass duct will be used to feed an area from an adjacent air handling unit. This mode has not yet been proven and the successful operation of isolation rooms and other spaces in the event of use of this bypass strategy has not been demonstrated. NHS Lothian needs to consider in its clinical service model how each isolation room and ward will function in the event of loss of an air handling unit. This will require full design and validation of air change rates, pressure differentials and direction of air flow for each area in this mode, as well as predicted times to rectify any plant failure.

4.2.8 IHSL has advised that the design of the isolation rooms is as per Scottish Health Planning Note (SHPN) 04-01 Supplement 1: In-patient Accommodation: Options for

Choice Supplement 1: Isolation Facilities in Acute Settings. This guidance notes that isolation rooms ideally should have its own air handling unit (AHU) and the ventilation systems should be as robust as possible so that standby fans are not required. The guidance acknowledges that in high rise buildings a common supply and extract may be the only feasible solution with duct branches fitted with spring close gas tight dampers in the event of failure. The height of this building is less than that defined in the Scottish Building Standards Technical Handbook - Non-Domestic, for high rise (18m). The solution at RHCYP & DCN does not include the gas tight dampers at ward level as required by the validated design parameters detailed in SHPN 04-01 Supplement 1.

4.2.9 Additional observations during a site visit by NSS have highlighted potential concerns linked to the location of some high risk wards, including Haematology / Oncology in relation to the helipad. A demonstration of the effect of helicopter landing/take-off on airflows needs to be completed by NHS Lothian.

4.3 Water

Summary

Review	Summary Assessment	No. of Issues per priority				
		1	2	3	4	5
Water Systems	Independent testing identified no widespread contamination of the water systems, however, remedial action is required on a number of water system areas as well as system wide disinfection prior to occupation.	-	1	2	1	-

Main Findings

Priority	Review	Action Assessment
4	**Water Services Critical Care -** Pseudomonas found in taps, in critical care areas. (SHTM 04-01 Part A published in July 2014)	All taps (not just TMT/TMV[4]) to be disinfected and retested. Inspect and replace, as appropriate, taps, tap components and pipework. Replace tap strainers and cartridges in CCU TMT taps.
3	**Water Services Non Critical Care** - Swarf and biofilm found in tap strainers, contrary to SHTM 04-01 Water safety for healthcare premises.	Replace tap strainers in all areas.

[4] TMT – Thermostatic Mixing Taps, TMV – Thermostatic Mixing Values

2	**Showers -** Shower hose lengths do not comply with Scottish Water bye laws and guidance in SHTM 04-01 Water safety for healthcare premises.	Shorten hose length, or add retaining ring, to ensure that shower head cannot reach WC or drain Disinfect showers, hose and drain after rectification.
3	**Water General** - Testing has found some fungal / mould contamination.	The water system should be disinfected and re-tested.
	Legionella risk assessment actions not recorded as required by HSE Approved Code of Practice and Guidance L8 - Legionnaires' disease. The control of *Legionella* bacteria in water systems. *Legionella* risk assessment insufficient to reflect system contamination in general. Those responsible for the system have a responsibility under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) to prevent exposure to microorganisms.	The *Legionella* Risk assessment Feb 2019 identified a range of actions. The Action Tracker does not demonstrate that the issues raised have been resolved or a timeline provided for resolution. Record rectification of actions. The risk assessment is heavily focussed on *Legionella* and not taking into account other organisms in line with patient type that will occupy the building. Broaden to reflect system contamination in general. Develop analysis categorisation of patient type and consideration to susceptibility for each area.
	Designated roles and responsibility as per SHTM 00 Best practice guidance for healthcare engineering.	The current Responsible Person (RP) has not been appointed in writing and uncertain as to whether received RP training. Additionally, has no previous experience of healthcare.
	Water tanks as per SHTM 04-01 Water safety for healthcare premises.	To be inspected. The Raw Water and Filtrate water tanks are interconnected at the drain. These must be separated.
	Hot and cold water temperatures / flushing. SHTM 04-01 Water safety for healthcare premises	There was an issue with raised cold water temperatures during the boiler outage – this requires investigation.
	Filtration Plants	From lessons learned by NSS in recent work, microbiological growth potential was identified as part of the Backwash cycle. Consideration should be given to Chlorine dioxide addition to backwash water tank to counter microbiological and biofilm development on filters.

	Instant Boil Taps and Rise and Fall Baths	These were found to be contaminated and need to be disinfected and tested to demonstrate safe water delivery as per SHTM 04-01 Water safety for healthcare premises.

Detailed Narrative

4.3.1 The domestic hot and cold water services (DHCWS) at RHCYP & DCN were considered in relation to legislation, guidance and the lessons learned from other recent similar projects which may have an impact on the patient group.

4.3.2 The legislation which is relevant to the water system are Public Water Supplies (Scotland) Regulations SSI 2014/364 and The Control of Substances Hazardous to Health Regulations 2002 (COSHH). In relation to COSHH, the Health and Safety Executive (HSE) note that "*Micro-organisms are covered in COSHH by the term biological agents. These are defined as any micro-organism, cell culture, prion or human endoparasite whether or not genetically modified which may cause infection, allergy, toxicity or otherwise create a hazard to human health*."

4.3.3 The guidance which is relevant to the water system are HSE Approved Code of Practice L8: Legionnaires' disease. The control of *Legionella* bacteria in water systems; HSE 274: Legionnaires' disease: Technical guidance; Scottish Healthcare Technical Memorandum (SHTM) 04-01: Water safety for healthcare premises and HPS document: *Pseudomonas aeruginosa* routine water sampling in augmented care areas for NHS Scotland (*published in draft September 2018*).

4.3.4 From initial inspection of the Independent Tester's reports, there is evidence that areas of the pipe work systems were installed without end protection. This may have allowed dust and organic material to enter the pipe system and this may not have been eradicated by the disinfection process.

4.3.5 From the construction commissioning records contained within the electronic operating and maintenance document repository, it is noted that there is no record of leachate flushing of the system.

4.3.6 The Facilities Management (FM) contractor Bouygues FM (BFM) commissioned a *Legionella* risk assessment when they took possession of the site from the construction contractor. This report has yet to be provided and will be reviewed and assessed when presented.

4.3.7 NHS Lothian commissioned a specialist safety consultant in May 2019 to conduct an overall safety audit of the RHCYP & DCN. Contained within their report is a section on the water system. They assessed the risk condition of the system as "high" mainly as a result of BFM's *Legionella* risk assessment, the lack of evidence of flushing across the system, the lack of maintenance on shower heads and outstanding information on the water management responsibilities by BFM.

4.3.8 NHS Lothian separately commissioned water testing from a specialist water safety consultant, on 12th July 2019, which indicated that certain tap outlets within the augmented care areas were positive for *Pseudomonas aeruginosa*. This report also

noted high Total Viable Counts (TVC). In addition, *Pseudomonas aeruginosa* was recorded in the Instant Boil Taps and the rise and fall baths. The consultant concluded that there was no evidence of wide spread contamination of the water system.

4.3.9 As part of the NSS review, a specialist water consultant carried out water tests around the facility on 18th July 2019 to determine if there were any significant issues.

4.3.10 In summary the NSS specialist contractor concluded from their investigations and as a result of the microbiological samples taken by them and others that: -

- There was no indication that the water system (as a whole) was cause for concern referenced to existing guidance.
- There was no atypical mycobacteria found in the 60 samples taken (mainly from neonatal and intensive care areas); however, there was some Gram-negative activity and mould present.
- Concern was expressed regarding the management of the water system given the lack of occupancy and turnover of the water system.
- The management aspects of the water system by IHSL's FM contractor were not satisfactorily demonstrated.
- The system showed signs of biofilm and swarf contamination, particularly at the taps.
- Shower heads and hoses do not meet the required standards with respect to length.
- During the site investigation it was noted that the cold water temperatures were rising and the hot water temperatures decreasing. In discussions with BFM it was discovered that a boiler had tripped, together with the circulating pumps, and the other boilers did not come on as they should have. The result of this was that the temperature of the water for both hot and cold domestic water systems fell into the *Legionella* growth band for approximately a 12 hour period.
- The NSS commissioned consultant engaged noted that at commissioning only 5% sampling of the number of taps across the whole hospital was completed.
- The management strategy for the Kemper system (water temperature regulation system) requires close control to ensure that water is not "dumped" unnecessarily in an effort to control cold water temperatures.

4.3.11 The tests for atypical mycobacteria proved negative. However fungi were identified in 22% of the samples taken in the water system based on a sample size of 60 taps from a population of c2000. These are not required to be tested as part of the current guidance. However, based on NSS experiences at other hospital sites it was considered prudent to have these tests done.

4.3.12 As a direct result of lessons learned by NSS from work undertaken after the construction of RHCYP & DCN, it is recommended that components parts of the water system are replaced and the originals tested, particularly those which have proven to be problematic.

4.4 Drainage and Plumbing

Summary

Review	Summary Assessment	No. of Issues per priority				
		1 (H)	2	3	4	5 (L)
Drainage & Plumbing	The drainage system has multiple redundancies in place, however, active monitoring is required. Elements of plumbing require disinfection.	-	-	-	1	-

Main Findings

Priority	Review	Action Assessment
4	Sinks drains	Initial testing indicates that these are not significantly contaminated, however the horizontal drain and protruding seal means they retain stagnant water and they need to be disinfected periodically prior to and post occupancy to maintain their condition. From lessons learned, there should be a system of periodic testing and disinfection for wash hand basins with particular focus on augmented care areas.
	Bottle traps	There would appear to be an inconsistency of installation and potential of back-feed from trap to drain. This requires review and rectification.
	Trough Sinks	From previous projects, the drains in trough sinks have been identified as high risk potential due to high microbiological activity. This requires review and treatment strategy considered.
	Pumped Drainage	The internal pumped sewage drainage system presents the potential for sewage to back up through basement drains on pump failure and will require active monitoring.

Detailed Narrative

4.4.1 The range of clinical and non-clinical wash hand basins chosen by the SPV are from a recognised manufacturer of healthcare drainage products. There is no facility to

connect the tap on the sink as the taps are panel mounted. The drain connection is at the rear of the sink bowl and there is no overflow, all as per guidance.

4.4.2 The connection on to the wash hand basin from the drain has proven to be an area where water does not drain freely as the connection reduces the diameter of the drainage outlet and creates a dam effect. Lessons learned by NSS from other projects, after commencement of the construction of RHCYP & DCN, have shown that various organisms were grown from this area in some circumstances.

4.4.3 The waste connection from the sink to the main above ground drainage system is via “bottle trap” rather than a conventional “U-bend”. Lessons learned by NSS from other projects, after commencement of the construction of RHCYP & DCN, identify this arrangement as a risk for bacterial growth.

4.4.4 The plumbing system is connected to the main sewage system via three drainage systems. The first is a gravity fed system. The second is a sump pump arrangement in the external courtyard. The third is a sump in the basement area of the hospital. The rationale behind the use of the sumps is that the basement areas are below the water table and any waste material has to be pumped up and out to the sewer.

4.4.5 The Independent Tester has noted in their report of 30th June 2017 that an issue had been raised regarding the capacity of the basement sump. In further investigation this appears to be related to the fact that more areas/floors were connected to this system than NHS Lothian had originally been made aware of.

4.4.6 The main drainage risk lies with the basement sump. It has a resilience system of back-up power supplies, multiple pumps and alarm systems to three different locations. There are two discharge pipes to sewer, reducing the risk of blockage and the consequent risk of sewage backing up into the basement in the proximity of the kitchen. In addition, if a failure occurred or a maintenance activity was to take place, the location of this sump chamber would mean that all traffic flow through the basement corridor would have to be halted to permit a safe operating procedure to be implemented.

4.4.7 The external courtyard sump has a duty/standby pump as well as a spare submersible pump and also has similar alarm arrangements to the basement pumps. In the event of a catastrophic blockage and spillage the court yard would be impacted.

End of Report

From: McMahon, Alex
Sent: 06 August 2019 14:06
To: Guthrie, Lindsay; Inverarity, Donald
Subject: Fw: Draft RAG Report of the NSS review of the NHSL RHCYP and DCN
Attachments: 2019-08-05 Letter to C McLaughlin - RHCYP DCN RAG Report.pdf; 2019-08-05 NSS RAG Report for RHCYP and DCN v0.7.pdf

Both, in complete confidence can you review this report and read it in line with the paper that Tracey sent around earlier.

If you could give comment on the RAG report with any evidence to support that would be very helpful for Thursdays oversight group.

Help appreciated.

Alex
Sent from my BlackBerry 10 smartphone on the EE network.
From: Gillies, Tracey [redacted]
Sent: Tuesday, 6 August 2019 2:03 PM
To: McMahon, Alex
Subject: FW: Draft RAG Report of the NSS review of the NHSL RHCYP and DCN

From: Goldsmith, Susan
Sent: 06 August 2019 09:38
To: McMahon, Alex; Gillies, Tracey
Subject: FW: Draft RAG Report of the NSS review of the NHSL RHCYP and DCN

Alex/Tracey

Here is first draft – can you please review. Clearly issue of circulation so can you please not circulate until we discuss

Thanks Susan

From: MILLER, James (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Sent: 06 August 2019 08:23
To: Goldsmith, Susan [redacted]
Cc: JAMES, Gordon (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: Draft RAG Report of the NSS review of the NHSL RHCYP and DCN

Dear Susan.
Please find a copy of the draft report issued to SG yesterday, Christine has asked that this is a restricted circulation and that any comments on factual accuracy should be fed back to the review team [redacted]).

Regards

Jim Miller
Director
Procurement, Commissioning & Facilities

NHS National Services Scotland
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE
[redacted]

From: Reducing-Risk-Hce (NHS NATIONAL SERVICES SCOTLAND)
Sent: 05 August 2019 15:34
To: Christine.mclaughlin[redacted]
Cc: MILLER, James (NHS NATIONAL SERVICES SCOTLAND)
<j.miller[redacted] JAMES, Gordon (NHS NATIONAL SERVICES SCOTLAND)[redacted]
Subject: Draft RAG Report of the NSS review of the NHSL RHCYP and DCN

Dear Christine,

Please see the attached letter and RAG Report on the NSS review of the RHYCP and DNC from Jim Miller.

Kind regards,
Kelly

Kelly McGrogan
Programme Manager
Programme Management Services (PgMS)
Business Services

NHS National Services Scotland
[redacted]
http://www.nhsnss.org/

Health Facilities Scotland
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE
Telephone 0141 207 1600
www.nhsnss.org

Christine McLaughlin
Director of Health Finance
Scottish Government
St Andrews House
Edinburgh
EH1 3DG

Date 05/08/2019
Your Ref
Our Ref

Enquiries to [redacted]

Dear Christine,

NSS (HFS & HPS) review of the NHS Lothian Royal Hospital for Children and Young People and Department of Neurosciences

As per our project plan, please find enclosed a draft RAG report. This reflects findings to date on the Water, Ventilation and Drainage systems as these relate to the main HAI Built Environment Risks.

We have flagged in our regular updates that information is incomplete at this stage and this is reflected by gaps in the report. We have just concluded a very positive gap analysis meeting with NHS Lothian colleagues today to clarify and seek further information. On receipt and assessment of this it should enable submission of the completed RAG report by 19 August as per the project plan.

The initial RAG report concentrates on those areas where work is required, and therefore only Red and Amber issues are recorded. It is also acknowledged that some of these issues may well be planned, scheduled or confirmed by NHSL, but that this provides the picture as at the date of the report.

The work to assess the determination and impact of the air changes in the general ward areas is progressing well, and I would hope that this can be added to the RAG report within a week, along with updates as these are received.

Additionally, we are working closely with NHSL colleagues on the description and specification of the remedial works in relation to critical care areas.

We met with Susan Goldsmith today and appraised her of the progress. I believe it would be very useful, and could shorten out timelines for NHSL to have sight of this draft report prior to the first oversight group, and would welcome your views if you feel this is appropriate.

Please do not hesitate to contact me if you have any questions.

Yours sincerely,

JIM MILLER
Director, Procurement, Commissioning & Facilities, NSS
Senior Responsible Officer RHCYP review group, NSS

Attachment: Appendix 1 – Draft RAG Report

cc: Gordon James HFS

NSS (HPS & HFS) Technical Review of the Royal Hospital for Children and Young People (RHCYP) and Department of Clinical Neurosciences

Draft & In Confidence – RAG Status Report

05th August 2019

Version Draft 0.7

NSS (HFS & HPS) RAG Table for Royal Hospital for Children and Young People and Department of Clinical Neurosciences

Date 5th August 2019, Version Draft.07

The attached initial draft RAG report has been collated based on information provided, on-site reviews of the RHCYP and expert advice sought within the key focus areas of Ventilation, Water and Drainage systems. NSS would like to thank the NHS Lothian project team for their corporation, input and access to the required information.

This report uses a high level RAG status to review each of the components. The following table describes the RAG and Status:

RAG	Description
Red	Unacceptable condition for patients and staff
Amber	Remedial work required
Green	No comment

Summary:

- Work is still progressing on all issues covered in this draft report and views and RAG status may change.
- There are numerous issues not necessarily impacting significantly on the ability to occupy the building but nonetheless requiring rectification for the building to function the way a new building should. These are not included in this report.
- The report focusses on areas where potential problems have been identified and these are rated red or amber and changed to green following verification of remedial work.
- Issues which would have been rated green initially are not included.

Water Systems:

Service	Comment	Remedial work	RAG
Water services (critical care)			**R**
	Pseudomonas found in taps, in critical care areas.	All taps (not just TMT/TMV) to be disinfected and retested. Follow guidance.	**R**
		Replace tap strainers and cartridges in CCU TMT taps.	**R**
		Showers require to be disinfected.	**R**
		Implementation plan required.	**A**
Water services (non- critical care)			**A**
	Swarf and biofilm found in tap strainers.	Replace tap strainers in all areas.	**A**
Showers (all areas)			**R**
	Shower hose lengths do not comply with Scottish Water bye laws and guidance.	Shorted hose length or retaining ring to ensure that head cannot reach WC or drain	**R**
		Disinfect hose and drain after rectification.	**R**
Water (general)			**R**
	Testing has found widespread fungal contamination.	The water system should be disinfected and re-tested.	**R**

Service	Comment	Remedial work	RAG
	Legionella risk assessment.	The Legionella Risk assessment Feb 2019 identified a range of actions. The Action Tracker does not demonstrate that the issued raised have been resolved or a timeline provided for resolution. The risk assessment is too heavily focussed on Legionella and not taking into account other organisms in line with patient type. There is no categorisation of patient type anywhere in what we have been provided and consideration to susceptibility.	R
	Designated roles and responsibility.	It has not been demonstrated that there are authorised persons or competent persons for the water services as defined in SHTM 00 and SHTM 04-01. In addition, a responsibility matrix and interface to NHSL water management group is required. The current Responsible Person has not been appointed in writing and uncertain as to whether received RP training. Additionally, has no previous experience of healthcare.	Information awaited

Service	Comment	Remedial work	RAG
	Water tanks	To be inspected. The Raw Water and Filtrate water tanks are interconnected at the drain. These MUST be separated.	**A**
	Expansion vessels should be checked for susceptibility to bacterial growth.	Bladder from expansion vessels to be inspected.	**A**
	Hot and cold water temperatures / Flushing.	There was an issue with raised cold water temperatures during the boiler outage – this requires investigation.	**A**
	Filtration Plants	From work done at Glasgow micro-biological growth potential was identified as part of the Backwash cycle. Suggest Chlorine dioxide addition to backwash water tank to aid microbiological and biofilm development on filters.	**R**
	ZIP & HYDRO Units	These were found to be contaminated and are required to be disinfected and tested to demonstrate safe water delivery.	**R**

Service	Comment	Remedial Work	RAG
General (no specific topic)			Items individually rated.
	Information missing	Provide missing information as per information request sheet(s). (1) Water Safety Policy (2) Water Safety plan (3) System of Control (4) PPM Schedule (5) Hydro-X sample results with dated timeline (6) Flushing Records (7) Temperature Records (8) Sentinel Temperature Results (9) Kemper System Maintenance schedule and records (10) Flushing records for taps pre June 2019 (11) Expansion Vessel management protocol (12) Arjo bath commissioning records and results	Status may change depending on information provided and review.
	Callidus compliance report, May 2019	This audit has returned a RED status. A schedule, program of completion for each identified item and demonstration mechanism is required.	**R**
	Roof plant room	Water leaks should be traced and appropriate remedial action taken.	A

Drainage:

Service	Comment	Remedial Work	RAG
Drainage			**A**
	Sinks drains	Initial testing indicates that these are not significantly contaminated, however they need to be disinfected periodically prior to and post occupancy to maintain their condition. Suggest utilising the Hysan methodology being employed at QEUH and RCH Glasgow.	**A**
	Bottle traps	There would appear to be an inconsistency of installation and potential of back-feed from trap to drain. This requires review.	**A**
	Trough Sinks	The drains in trough sinks have been identified as high risk potential. This requires review and treatment strategy considered.	**A**
	Pumped Drainage	The Rainwater drainage system presents the potential for flooding on pump failure and requires review.	Information awaited

Ventilation:

Service	Comment	Remedial Work	RAG
Ventilation (general)			Items individually rated.
	Air Handling Units (AHU)	Confirm AHU comply with the requirements of SHTM 03-01, including fan change, filter bypass, air leakage etc.	Information awaited
	External doors to plant rooms	Ensure that excessive gaps are removed and appropriate anti vermin measures are applied to all the doors and screens.	**A**
	Air intake location - Air intakes are sited in the well below the helipad but information has not been provided on the impact of downdraft on air flows and pressures or entrainment of contaminants.	Demonstrate the effect of helicopter landing on air flows through measurement or modelling.	**R**
Ventilation (Isolation rooms and the areas containing them)	Isolation rooms are not served by a single ventilation system for each room as recommended in SHPN4 Supplement 1. The arrangement provided where ventilation systems serve an area of the building including contained isolation rooms has not yet been proven in the event of failure of an air handling unit and the implications for service impact are not yet understood.	Prove that bypass connections to adjacent ventilation systems will allow safe operation of both areas and / or explain service provision strategy for loss of each area including isolation rooms.	**R**

Service	Comment	Remedial Action	RAG
Ventilation Theatres	The ability of the single high level extract of linear scrub rooms should be demonstrated or additional low level ventilation provided.	Show that mixing and extract in scrub rooms effectively prevents contaminants being dispersed into theatres or provide additional extract.	R
	Anaesthetic rooms 31 and 34 do not demonstrate a clean air flow path to reduce exposure of staff to gasses.	Move ceiling supply to opposite side of room from extract. In room 30, move supply away from door.	A
	Theatre utility rooms Extract ventilation means theatres have to be used in pairs and taking a theatre out of service reduces extract in utility room too low.	Add supplementary extract ventilation to allow for one theatre being out of service or demonstrate resilience following the loss of a pair of theatres.	A
	Theatre corridor extract and pressure differentials do not comply with requirements.	Modify theatre corridor ventilation to comply and test and commission.	R
	Provision for maintenance without unnecessarily affecting service appears poor.	For each area, the Board should have the maintenance and failure contingencies mapped and agreement of clinical colleagues for the expected impact on room availability.	A
	Fire dampers in some locations cannot be adequately tested as duct access has not been provided. Also, locations of fire dampers and fire rated ductwork has been questioned.	Provide access so all fire dampers can be readily visually inspected to verify operation. Review fire damper provision and fire rated ductwork and confirm appropriate provision.	A

Service	Comment	Remedial Action	RAG
	On inspection the ventilation systems throughout the building had clearly not been snagged and were not ready for validation or operation.	A full snagging of the ventilation systems should be undertaken and rectification put in place. E.G. air handling unit leaks, filter bypass, dust in AHUs and ductwork, missing duct access, firestopping, fire dampers.	R

Systems not yet tested:

Service	Comment	Remedial Action	RAG
Electrical	Not inspected yet due to priority put on water, ventilation and drainage.		
Fire	Not inspected yet due to priority put on water, ventilation and drainage.		
Medical Gasses	Not inspected yet due to priority put on water, ventilation and drainage.		

END.

From: Curley, George
Sent: 17 July 2019 17:52
To: Goldsmith, Susan; Guthrie, Lindsay; Inverarity, Donald; McMahon, Alex
Cc: Calder, Marion
Subject: FW: RHCYP & DCN Water Safety Assessment - July 2019
Attachments: RHCYP & DCN Water Condition Assessment July 2019.pdf; RHCYP & DCN Water Sampling - July 2019.xls

Hi all please find attached water quality check.

Regards George

From: John Bryson
Sent: 17 July 2019 17:23
To: Curley, George
Cc: Henderson, Ronnie
Subject: RHCYP & DCN Water Safety Assessment - July 2019

George/Ronnie
Please see attached report and supporting attachment.
I have issued this without the peer checking which would be our normal procedure, so would be grateful for your and Ronnie's and Brian's feedback.
Regards
John

NHS Lothian

Royal Hospital for Children and Young People
&
Department of Clinical Neurosciences

Little France Crescent
Edinburgh

Water Safety Assessment

July 2019

CONTENTS

Prepared By	Verified By	Authorised By
John A Bryson	Colin Mitchell	John A Bryson

The Authors may he be contacted regarding the report content as follows;
Email : [redacted]

Tel : [redacted]

The Royal Hospital for Children and Young People and Department of Clinical Neurosciences (RHCYP & DCN) is a new development in Edinburgh's BioQuarter Campus adjacent to the Royal Infirmary of Edinburgh. Construction, commissioning and formal handover to NHS Lothian is complete, but prior to occupancy and commencement of clinical operations, NHS Lothian were keen to confirm the bacteriological safety of the water supplied from the domestic systems within the building. Westfield Caledonian were commissioned therefore to carry out a series of tests, to both quantify the risk of infection specifically from *Pseudomonas aeruginosa* in augmented care areas, and to assess the bacteriological load within the domestic systems generally. These works were carried out between 1st and 12th July 2019, by Westfield Caledonian's John Bryson and Ross Findlay.

From initial discussions with NHS Lothian Director of Estates, Mr George Curley, and subsequent discussions with the NHS Lothian Commissioning Manager and Infection Prevention and Control Team representatives, the following three scopes were agreed;

1. As a result of revised HPS Guidance issued in August 2018, and the belief held by the NHS Lothian IPC Team that the presence of *Pseudomonas aeruginosa* at outlets in augmented care areas presents a significant risk of HAIs, we undertook to carry out the routine sampling described in the HPS Guidance. Specifically, this involved retrieving a single, Pre-flush sample from each outlet in the augmented care areas identified by the IPCT, for subsequent analysis specifically for the organism *Pseudomonas aeruginosa*.

2. To assess the overall bacteriological load on the water within the distribution systems, a schedule of sample locations was derived for sampling and subsequent analyses. The schedule was to be concentrated on un-tempered hot and cold outlets, although a number of thermostatically mixed outlets were to be sampled from to ascertain the impact these components were having on the bacteriological safety of the discharged water.

3. The final component of the scopes was initially open ended, as it was to carry out further investigative sampling and inspection, the extent of which would be dependent on the results deriving from the initial two components.

Scope Limitations

Although any deficiencies or omissions observed are reported in this document, it should be noted that the agreed scopes did not involve the inspection or assessment of any plant items, the assessment of applied operating practices or control strategies, or a review of the currently applied water safety control measures. All these aspects should be addressed by a suitable and sufficient risk assessment carried out in accordance with BS 8580-1:2019 “Water quality. Risk assessments for Legionella control. Code of practice”.

The Scopes were applicable to the domestic systems serving patient care areas. No cognisance of supplementary systems (Laboratory and Irrigation systems) was made.

3.1 Pseudomonas Aeruginosa

A total of 580 outlets were sampled from within the designated augmented care areas, and subsequently analysed specifically for the organism *Pseudomonas aeruginosa*. A total of 56 samples returned positive results for the organism, around 10% of those sampled. However, the vast majority of the positives were returned from two specific locations, namely the Paediatric Medical Inpatients (3-C1.1) and the DCN Inpatients (2-L2) areas. The schedule overleaf summarises the analyses results by sampled location, together with an overview of the type of outlets which returned the positives.

A review of these results, in conjunction with the water distribution drawings, indicated that these two areas were in fact supplied from the same riser (M2) with very little contamination being evident in the outlets supplied from the other risers in the building (which supply the augmented care areas). Whilst this observation may suggest that the riser is a common factor for the areas of contamination, the subsequent "System Condition" testing carried out throughout the building and discussed elsewhere in this report, do not suggest that this riser displays any less satisfactory hygienic characteristics than other parts of the distribution systems.

Whilst a number of shower outlets, and most of the Zip drinking water dispensers and Arjo baths sampled from returned positive *Pseudomonas aeruginosa* results, it was noted that the majority of positives derived from Markwik 21 thermostatic mixing taps. Interestingly, not a single one of the many Contour thermostatic taps sampled from returned positive results. It is clear therefore that where the *Pseudomonas aeruginosa* contamination was present, the Markwik taps seemed to be particularly prone to colonisation.

It was also noted that all the Arjo baths tested, and most of the Zip Hydrotap outlets, returned unsatisfactory results. Both these types of machines are known to be particularly prone to internal bacteriological colonisation, and as such require the implementation of specific and rigorous internal hygienic maintenance activities. It is our experience that Zip Hydrotaps are particularly prone to colonisation by *Pseudomonas aeruginosa.*

Paediatric Medical Inpatients (3-C1.1)
No. of Outlets sampled – 84
Outlets Ps.ae. Positive – 20 (24%), of which,
Showers; 4
Hot via TMV (push-button); 1
Cold (push-button); 1
Markwick 21 taps; 11
Zip Hydrotaps; 1
Arjo Bath; 2 (both outlets same bath)

Neuroscience Outpatients (3-C1.3)
No. of Outlets sampled – 45
Outlets Ps.ae. Positive – 1 of which,
Arjo Bath; 1

Haematology Oncology (3-C1.4)
No. of Outlets sampled – 100
Outlets Ps.ae. Positive – 1 of which,
Arjo Bath; 1

DCN Inpatients (2-L2)
No. of Outlets sampled – 170
Outlets Ps.ae. Positive – 31 (18%), of which,
Showers; 4
Hot via TMV (push-button); 3
Markwick 21 taps; 21
Untempered Hot; 1
Arjo Bath; 2 (both outlets same bath)

Paediatric Intensive Care Unit HDU (1-B1)
No. of Outlets sampled – 72
Outlets Ps.ae. Positive – 0

DCN Acute Care (1-L1)
No. of Outlets sampled – 90
Outlets Ps.ae. Positive – 2 of which,
Pantry Sink Mixer; 1
Zip Hydrotap; 1

Clinical Research – Isolation room(s) (1-H2 rooms 18,21,22,23 &24)
No. of Outlets sampled – 7
Outlets Ps.ae. Positive – 0

Plastic Dressings Clinic (1-D7)
No. of Outlets sampled – 8
Outlets Ps.ae. Positive – 0

CAMHS – Isolation room (G-A2 rooms 72,73.74)
No. of Outlets sampled – 4
Outlets Ps.ae. Positive – 1 of which,
Markwick21 tap; 1

3.2 System Condition Testing

To form a view on the overall microbiological loading within the domestic systems, an outlet sampling schedule was implemented. The cold water distribution systems within these premises is of the venturi flow-splitter circulating type, whose design intent is to ensure cold water flow to as-close-as-practical to the supplied outlet, regardless of outlet usage. To facilitate flow during periods of low usage, or elevated system temperatures, each subordinate distribution component is terminated at a dump valve, whose operation will artificially induce flow through all system pipework sections. Each of these subordinate distribution systems were identified and samples retrieved from as close as possible to the end-of-line dump point. To establish the microbiological load on the distribution systems, without the results being compromised by the thermostatic mixing process, where possible samples were retrieved from un-tempered hot outlets and cold taps. The predominance of thermostatic mixing taps on the site means that un-tempered hot and cold outlets were typically only found in the Dirty Utility Rooms and DSRs, which were not always located near the end of the distribution line. However, it is considered the implemented sampling schedule provided a good indication in respect of the microbiological safety of the water within the distribution systems. Samples were also retrieved from mixed outlets at the end of lines.

A total of 198 samples were retrieved for this purpose, and subsequently analysed for the 2 Day (37°C) and 3 Day (22°C) TVC, coliforms, *E.coli* and *Pseudomonas aeruginosa*. Samples were also retrieved from 33 outlets and specifically analysed for the presence of Legionella. Typically, these were retrieved from end-of-line showers. The observations arising from a review of these results, are summarised overleaf.

- Neither coliforms or *E.coli* were isolated in any of the samples retrieved.

- At the time of writing, none of the Legionella samples returned positive results. (Full results not available until 22nd July 2019).

- All un-tempered hot outlets returned very low TVC results, particularly where Post-flush samples were taken. Given that the vast majority of hot outlets almost immediately discharged water in excess of 60°C, this is unsurprising, and confirms the effectiveness of the thermal control regime applied to the hot water distribution system. Where this observation was not the case, was where unsatisfactorily low hot water supply temperatures were noted, and this is further discussed in Section 3.4 of this report.

- Generally, un-tempered cold outlets returned satisfactory TVC analysis results on Post-flush samples (typically after one minute of flushing), although a notable number of outlets returned very high TVC results where Pre-flush samples were retrieved. This tends to confirm the general bacteriological safety of the water in the distribution systems (including from Riser M2), but suggests there may be elements of system deterioration between the tertiary return point and the outlets themselves.

- All Pre-flush samples from thermostatically mixed outlets returned elevated TVC results, although it should be noted that Pre-flush samples were only retrieved in the augmented care areas. Post-flush TVC levels were generally found to be satisfactory, although a number did return elevated TVC results. Again, this tends to suggest that there is no systemic contamination in the hot and cold supplies to these outlets, but that local contamination, including between the tertiary return points and the outlets themselves, is present.

- TVC analysis results from all tested Zip Hydrotap machines and Arjo baths were very unsatisfactory.

3.1 Investigative Sampling

Given the high number of positives for *Pseudomonas aeruginosa* recovered from the DCN Inpatients and Paediatric Medical Inpatients areas, and the apparent absence of the contamination in the hot and cold distribution systems, further investigative sampling was carried out to confirm this latter assertion and identify consistent possible sources of the contamination. The strategy applied was to select four of the outlets which returned high concentrations of the organism and sequentially sample from the outlet supply, and subsequent locations to the point of discharge.

All tests were carried out with no flushing of the outlet. Firstly, the tertiary return temperatures were measured on both the hot and cold supplies to each outlet. Secondly, the interconnecting pipework between the hot and cold supply service valves and outlets themselves was removed, and samples retrieved from each of the hot and cold supplies, taking care to sanitise "non-system" components of the sample point which the discharged water may come into contact with. The supplying pipework was then reinstated, and the filter/NRV assemblies were removed from each of the hot and cold sides of the Markwik tap. Again, care was taken to sanitise the non-contact components, and samples were retrieved from the hot and cold inlets to the tap. The detachable spout was then removed, and a fifth sample was taken by operating the tap and retrieving the water discharged directly from the thermostatic mixing valve. Finally, the spout was reinstated and an initial discharge sample was retrieved from the outlet.

In respect of the circulating systems, the range of the hot tertiary returns measured was 56.4°C to 60.7°C, and for the cold circulating system, temperatures ranged from 15.9°C to 19.5°C. Although our preference would be to have hot water circulation closer to 60°C, the hot temperatures may be considered satisfactory, and given all cold temperatures were noted to be below 20°C, again, no operational issues were perceived at the four tested outlets.

The sample analysis results for this exercise are given in full in an attachment to this report, but Figure 1 overleaf summarises the results for ease of interpretation. It can be seen that there was no *Pseudomonas aeruginosa* in either the hot or cold water supply systems to the outlet. It can also be seen that the general bacteriological load on the hot water supply was extremely low, which may be expected given the elevated temperatures being circulated to the test points.

However, high TVC results were returned from the samples retrieved from the cold water supply to the outlet, and whilst the temperatures recorded suggest that water circulation was occurring to the test points, a degree of microbiological contamination was evident in the supply system. At the hot inlet barrel to the TMV, no *Pseudomonas* was detected at three of the four tested taps, although a single colony was isolated in the fourth sample. The TVC of bacteria in three of the four samples was slightly elevated, although very low counts were recorded from the first location, which had the hot water return temperature recorded at greater than 60°C. At the cold inlet to the TMV for each tap, high TVCs were returned, which was consistent with the result of the sample taken from the supplying section. There was however evidence of *Pseudomonas aeruginosa* contamination at three of the tested outlets, albeit in fairly low concentrations.

Pseudomonas was detected in all four samples retrieved from the TMV discharge (with spout removed), generally at very high concentrations. Very high TVCs were also recorded confirming a very poor hygienic condition of the components between the inlet to the tap and the TMV outlet. Similarly, *Pseudomonas* was detected in all four samples taken from the Markwik tap once the spout had been reinstated, albeit at slightly lower concentrations. However, this latter observation may purely be a result of the 250ml which had been flushed out to retrieve the previous sample.

These analysis results suggest the following:

- There is no evidence of *Pseudomonas aeruginosa* contamination within the hot or cold distribution system.

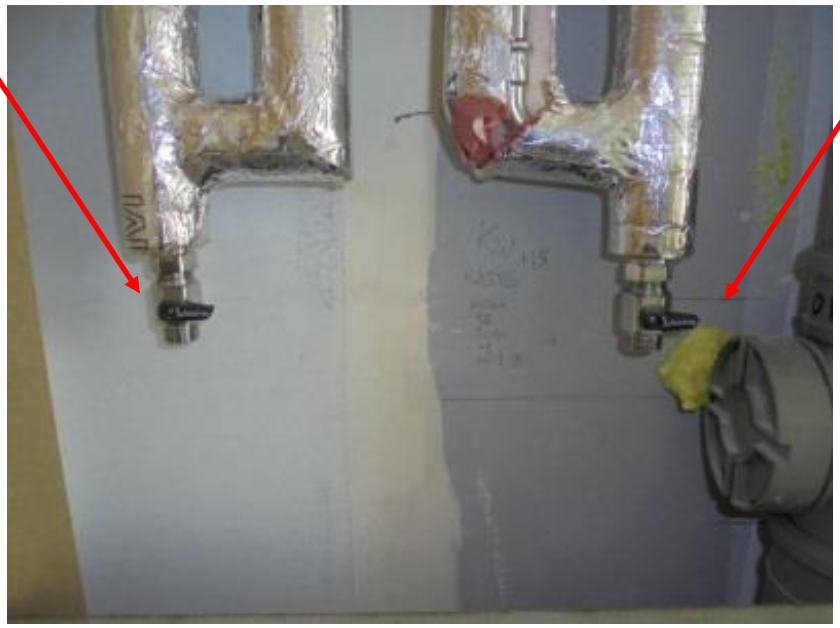
- There is however sufficient evidence to suggest an unsatisfactory high microbiological loading on the cold water supply system (all from the M2 riser).

- The thermostatic mixing components of the tap are clearly the source of the *Pseudomonas aeruginosa* colonisation.

- Contaminant (biofilm) creep is beginning to occur from the thermostatic control components back into the hot and cold water supply lines.

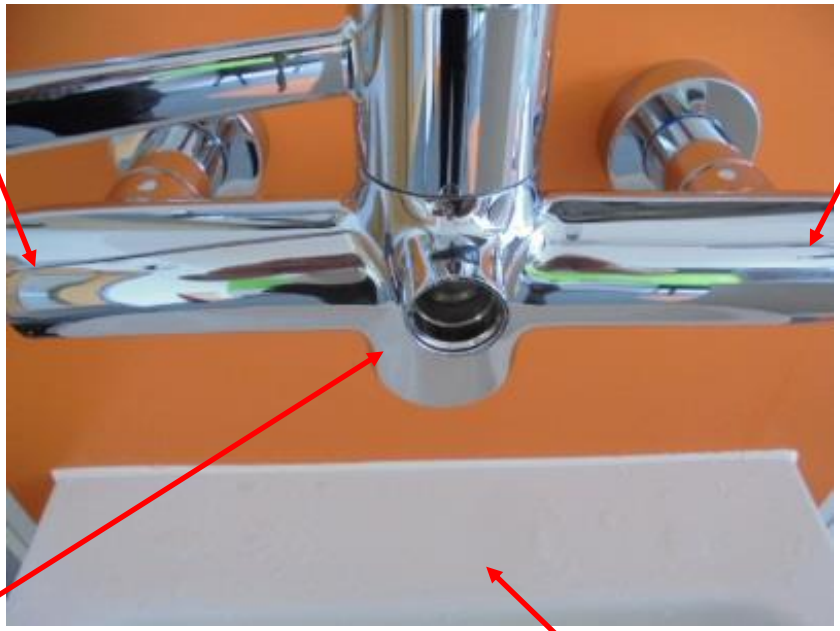
Location	Ps.ae.	2 Day	3 Day	Return °C
1	<1	<1	<1	60.1-60.7
2	<1	1	<1	57.5-57.7
3	<1	<1	<1	57.4-58.1
4	<1	<1	<1	56.4-56.9

Location	Ps.ae.	2 Day	3 Day	Return °C
1	<1	**>1000**	**>1000**	18.7-18.8
2	<1	**>1000**	**>1000**	15.9-16.5
3	<1	**272**	**>1000**	16.7-17.5
4	<1	**400**	**>1000**	18.4-19.5



Location	Ps.ae.	2 Day	3 Day
1	<1	<1	1
2	<1	**432**	240
3	<1	**336**	**448**
4	**1**	**640**	**472**

Location	Ps.ae.	2 Day	3 Day
1	<1	**576**	**528**
2	**50**	**>1000**	**>1000**
3	**1**	**>1000**	**>1000**
4	**4**	**>1000**	**>1000**



Location	Ps.ae.	2 Day	3 Day
1	**24**	**>1000**	**>1000**
2	**>100**	**>1000**	**>1000**
3	**>100**	**>1000**	**>1000**
4	**>100**	**>1000**	**>1000**

Location	Ps.ae.	2 Day	3 Day
1	**3**	**>1000**	**>1000**
2	**>100**	**560**	**392**
3	**80**	**>1000**	**>1000**
4	**>100**	**>1000**	**>1000**

3.4 Other Observations

As has been noted in the Scope Limitations section of this report, these works did not include any inspection or assessment of components, reviews of operational practices or control strategies, or of currently applied control measures. However, as part of the investigative works carried out subsequent to the main sampling exercise, a number of observations arose which it is considered will have an impact on the bacteriological safety of the water supplied to the outlets on these premises.

In-line Strainers

In August 2018 Westfield Caledonian were asked to comment on the proposed methodology for carrying out a system disinfection during commissioning of these systems. One of the observations made was that the methodology should include the removal and cleaning of all in-line strainers which are invariably provided to protect the components of thermostatic mixing devices.

All thermostatic mixing valves and Markwik 21 thermostatic taps are provided with integral strainers at both the hot and cold inlets, whilst the Contour thermostatic taps are provided with in-line strainers on the hot and cold supply lines to the outlets. Whilst no shower thermostatic valves or TMVs (difficult access) were accessed, the integral strainers fitted to the four Markwik taps which were subjected to the investigative sampling, and the in-line strainers supplying a number of Contour taps, were accessed and inspected. Some illustrations of the conditions found are given overleaf, and it can be seen that all strainers were found to be subject to some degree of contaminant retention, ranging from very little to substantial. It is considered very unlikely that the observed contaminants have arisen since the commissioning process, and it would appear that either the necessary cleaning and removal was not carried out at the appropriate point of the commissioning process, or the works were ineffective.

Whilst the observed contamination cannot be identified as the cause of the *Pseudomonas aeruginosa* contamination which was evident at a significant number of outlets, it is clear the conditions are not conducive to maintaining the bacteriological safety of the discharged water, and this will require remediation.

Circulating Temperatures

Each cold outlet (and thermostatic control device cold inlet) is supplied by a flow and return arrangement on the cold water distribution system. Flow through the pipework is induced by flow-splitter valves which utilise the venturi effect to induce flow through the tertiary loop, when flow occurs in the main supply line. When turnover through the cold distribution system section is low, and/or temperatures exceed a pre-set value (usually 20°C or less), automatic controls should activate an end-of-line dump valve, which will simulate flow through the all components of the system and dump the water until end-of-line temperatures below the set point are achieved. During these works, the majority of end-of-line cold tertiary loop return temperatures were recorded, and generally found to be below 20°C. There were a number of occasions however when unsatisfactorily high temperatures were noted, with one end-of-line cold outlet discharging water in excess of 25°C for several minutes.

Similarly, un-tempered hot outlets generally discharged water in excess of 60°C, within a few seconds of operation, and always within one minute of flushing. Again however there were a number of un-tempered extremity outlets, or thermostatic tap inlets, where temperatures below 55°C were noted.

Current guidance suggests that hot water return temperatures should be measured and recorded as an ongoing control measure (at varying frequencies for principal, subordinate and tertiary loops) and it is assumed that the current FM provider on the site has such a programme in place for both the hot and cold systems. However, our observations suggest that the frequency, or tested locations, require to be reviewed, as there are clearly a number of areas where unsatisfactory circulation is occurring.

Hot and Cold Inlet Barrels to Markwik Thermostatic Taps Provided With Filter and NRV Cartridges

Hot and Cold Supplies to Contour Taps Provided With In-line Strainers

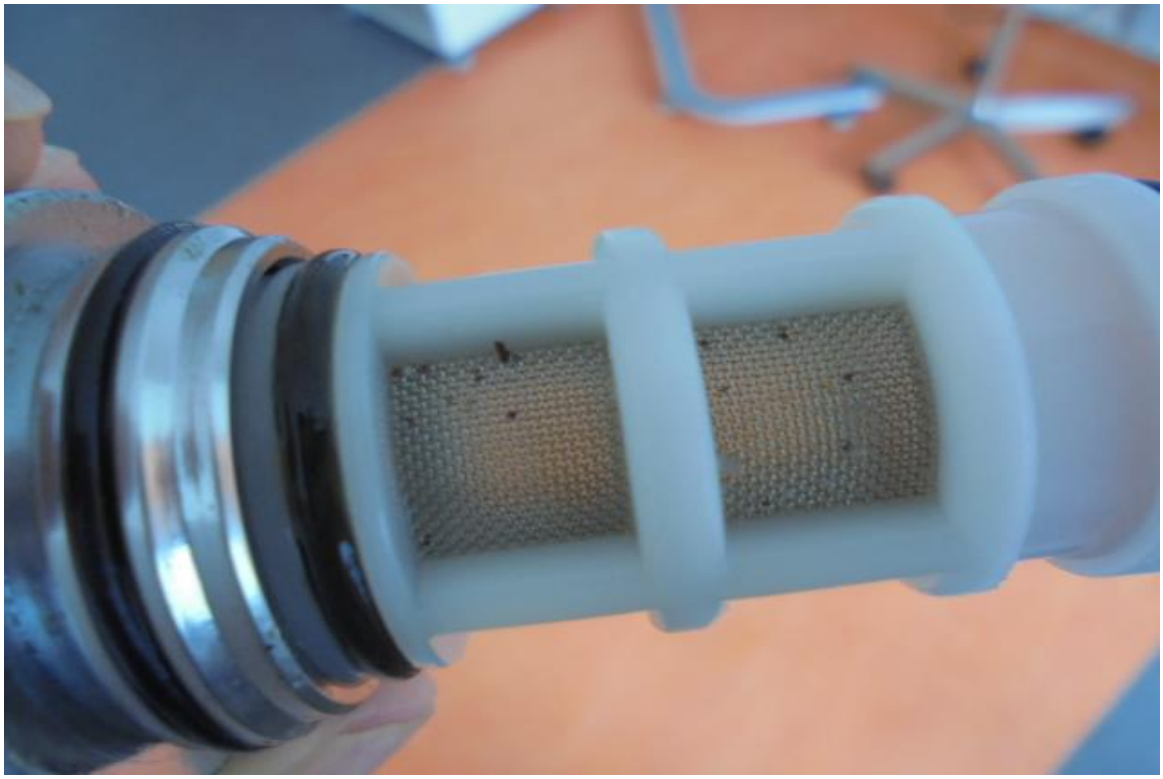


Illustration of Slight Particulate Accumulation on Markwik Inlet Strainer

Further Illustration of Minor Particulate Accumulation on Markwik Inlet Filter

Fairly Extensive Contamination Observed on Markwik Inlet Filter

Installation Debris Accumulation on Markwik Inlet Filter

Minor Accumulation on Contour In-line Strainer

Installation Debris Retained in Contour In-line Strainer

Significant Oxidation Contamination on Contour In-line Strainer

Substantial Debris Accumulation on Contour In-line Strainer

Low Hot Water Supply Temperature to Markwik Inlet

Hot Water Supply from Untempered Outlet Too Low

Elevated Cold Water Supply Temperature Recorded at End-of-Line Outlet

From review of the findings from all three scopes, the following conclusions have been drawn:

1. There is nothing to suggest that *Pseudomonas aeruginosa* contamination is systemic, and that both the hot and cold distribution systems are free from the contamination.

2. General bacteriological contamination of the DHWS distribution system was consistently low, and large sections of the CWS distribution systems also returned satisfactory bacteriological analysis results. However, there is sufficient evidence to suggest that localised general microbiological contamination is present in the CWS distribution system, and that system disinfection would be a prudent pre-occupancy control measure to implement.

3. Where *Pseudomonas aeruginosa* outlet contamination was identified, it was further confirmed that the source of the contamination is specifically the thermostatic mixing components, and that specific remediation activities require to be carried out at all these components. This should include all Markwik 21 taps, all shower thermostatic valves, and all remote thermostatic mixing valves.

4. Appropriate post-commissioning strainer decontamination has not been carried out (effectively) resulting in significant retained contaminants in these components. The above remediation maintenance for all thermostatic outlets should include the removal and cleaning, or replacing where corrosion is evident, of all in-line and integral strainers.

5. End-of-line tertiary return temperature measurements suggest that a number of areas are not achieving satisfactory circulation (both hot and cold).

From the previously described Findings and Conclusions, the following recommendations are made;

5.1 Remedial

- All Markwik 21 taps, shower thermostatic valves, and remote thermostatic mixing valves should be fully serviced and decontaminated. This should include the removal and cleaning of all integral strainers, and decontamination of the Markwik taps by utilisation of the thermal disinfection bypass tappings. The Markwiks can also be autoclaved to kill any microbiological contaminants, but the flushing process has the added benefit of being more effective at dislodging biofilm. In-line strainers on the supplies to all Contour taps should also be removed and cleaned or replaced.

- Although large sections of the CWS distribution system was found to supply bacteriologically safe water, a sufficient number of poor TVC results were returned to suggest that some sections may be hygienically compromised. Furthermore, given it had been in excess of six months since the post-commissioning disinfection of these systems, a pre-occupancy disinfection of all system components would be prudent, and consistent with good practice. It is recommended therefore that, on completion of the above described remediation works, a full system disinfection is carried out, ideally utilising a control agent which is known to be effective against biofilms.

- The Zip Hydrotap and Arjo bath service companies should be advised of the unsatisfactory results, and asked to carry out the appropriate remediation works specific to these machines. The should also be asked provide sanitising procedures and frequencies for approval.

5.2 Control Measures

A review of the currently applied Water Safety Plan should be carried out to ensure the following activities are effectively carried out.

- Six-monthly routine sampling specifically for *Pseudomonas aeruginosa* should be carried out on all outlets within augmented care areas. This testing should be in addition to the return-to-service testing decreed by the current HPS Guidance for outlets where positive results have already occurred.

- A review of return temperature monitoring frequencies and locations should be carried out to ensure that ***all*** hot and cold subordinate and tertiary return loops are tested at the appropriate frequency.

- All thermostatic outlets should be maintained in accordance with the manufacturers' guidance as a minimum, but at least be subjected to annual servicing and decontamination activities. This should include the disinfection (by TMV bypass or autoclaving), of the Markwik taps and the removal of all in-line and integral strainers.

RHCYP & DCN Sampling Locations and Ananlysis Results - 1st July - 11th July 2019

Sample	Date	Area	Location	Type	Ps.ae.	Lp	2-Day TVC	3-Day TVC	Coliforms	E.coli	Remarks
1	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
2	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Post-Flush	28	-	224	256	<1	<1	Markwik Thermostatic Tap
3	01 July 2019	3-C1.1	Room 066 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
4	01 July 2019	3-C1.1	Room 066 Shower	Pre-Flush	<1	-	-	-	-	-	Mixed
5	01 July 2019	3-C1.1	Room 066 Shower	Pre-Flush	-	<40	-	-	-	-	Mixed
6	01 July 2019	3-C1.1	Room 067 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
7	01 July 2019	3-C1.1	Room 068 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
8	01 July 2019	3-C1.1	Room 068 Shower	Pre-flush	<1	-	-	-	-	-	Mixed
9	01 July 2019	3-C1.1	Room 063 Wash Hand Basin	Pre-Flush	9	-	-	-	-	-	Markwik Thermostatic Tap
10	01 July 2019	3-C1.1	Room 064 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
11	01 July 2019	3-C1.1	Room 064 Shower	Pre-Flush	4	-	-	-	-	-	Mixed
12	01 July 2019	3-C1.1	Room 032 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
13	01 July 2019	3-C1.1	Room 033 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
14	01 July 2019	3-C1.1	Room 034 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
15	01 July 2019	3-C1.1	Room 034 Shower	Pre-Flush	<1	-	-	-	-	-	Mixed
16	01 July 2019	3-C1.1	Room 035 Wash Hand Basin	Pre-Flush	47	-	-	-	-	-	Markwik Thermostatic Tap
17	01 July 2019	3-C1.1	Room 036 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
18	01 July 2019	3-C1.1	Room 037 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
19	01 July 2019	3-C1.1	Room 037 Shower	Pre-Flush	<1	-	-	-	-	-	Mixed
20	01 July 2019	3-C1.1	Room 044 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Dirty Utility
21	01 July 2019	3-C1.1	Room 044 Sink Hot	Pre-Flush	<1	-	1	1	<1	<1	Hot - Dirty Utility
22	01 July 2019	3-C1.1	Room 044 Sink Cold	Pre-Flush	<1	-	192	560	<1	<1	Cold - Dirty Utility
23	01 July 2019	3-C1.1	Room 044 Sink Cold	Post-Flush	<1	-	3	<1	<1	<1	Cold - Dirty Utility
24	01 July 2019	3-C1.1	Room 043 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Treatment Room
25	01 July 2019	3-C1.1	Room 042 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap - Clean Utility
26	01 July 2019	3-C1.1	Room 039 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
27	01 July 2019	3-C1.1	Room 040 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
28	01 July 2019	3-C1.1	Room 041 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
29	01 July 2019	3-C1.1	Room 041 Shower	Pre-Flush	1	-	-	-	-	-	Mixed
30	01 July 2019	3-C1.1	Room 027 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
31	01 July 2019	3-C1.1	Room 025 Corridor Wash Hand Basin	Pre-Flush	3	-	-	-	-	-	Markwik Thermostatic Tap
32	01 July 2019	3-C1.1	Room 021 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Hot (Thermostatic Mixing Valve)
33	01 July 2019	3-C1.1	Room 021 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
34	01 July 2019	3-C1.1	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
35	01 July 2019	3-C1.1	Room 023 Sink Hot	Pre-Flush	<1	-	>1000	>1000	<1	<1	Pantry Mixer - Untempered
36	01 July 2019	3-C1.1	Room 023 Sink Cold	Pre-Flush	<1	-	352	>1000	<1	<1	Pantry - Cold
37	01 July 2019	3-C1.1	Room 023 Sink Cold	Post-Flush	<1	-	<1	10	<1	<1	Pantry - Cold
38	01 July 2019	3-C1.1	Room 023 Zip Hydrotap	Pre-Flush	>100	-	>1000	>1000	<1	<1	
39	01 July 2019	3-C1.1	Room 026 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
40	01 July 2019	3-C1.1	Room 018 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
41	01 July 2019	3-C1.1	Room 019 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
42	01 July 2019	3-C1.1	Room 019 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
43	01 July 2019	3-C1.1	Room 020 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
44	01 July 2019	3-C1.1	Room 058 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Mixed (Wall Discharge)
45	01 July 2019	3-C1.1	Room 070 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
46	01 July 2019	3-C1.1	Room 059 Wash Hand Basin Hot	Pre-Flush	>100	-	-	-	-	-	Hot (Mixed) Wall Discharge
47	01 July 2019	3-C1.1	Room 059 Wash Hand Basin Cold	Pre-Flush	8	-	-	-	-	-	Cold (Wall Discharge)
48	01 July 2019	3-C1.1	Room 059 Shower	Pre-Flush	<1	-	-	-	-	-	Mixed (Wall Discharge)
49	01 July 2019	3-C1.1	Room 060 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
50	01 July 2019	3-C1.1	Room 061 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
51	01 July 2019	3-C1.1	Room 061 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
52	01 July 2019	3-C1.1	Room 046 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
53	01 July 2019	3-C1.1	Room 047 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
54	01 July 2019	3-C1.1	Room 048 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
55	01 July 2019	3-C1.1	Room 048 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
56	01 July 2019	3-C1.1	Room 056 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
57	01 July 2019	3-C1.1	Room 057 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
58	01 July 2019	3-C1.1	Room 057 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
59	01 July 2019	3-C1.1	Room 049 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
60	01 July 2019	3-C1.1	Room 049 Arjo Deluge	Pre-Flush	>100	-	-	-	-	-	Mixer - Arjo Bath
61	01 July 2019	3-C1.1	Room 049 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Arjo Bath
62	01 July 2019	3-C1.1	Room 017 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	DSR - Mixed
63	01 July 2019	3-C1.1	Room 017 SS Sink Hot	Pre-Flush	<1	-	1	<1	<1	<1	Hot (Tempered 2)
64	01 July 2019	3-C1.1	Room 017 SS Sink Cold	Pre-Flush	<1	-	13	560	<1	<1	Cold
65	01 July 2019	3-C1.1	Room 017 SS Sink Cold	Post-Flush	<1	-	1	7	<1	<1	Cold
66	01 July 2019	3-C1.1	Room 052 Corridor Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
67	01 July 2019	3-C1.1	Room 052 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
68	01 July 2019	3-C1.1	Room 055 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
69	01 July 2019	3-C1.1	Room 055 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
70	01 July 2019	3-C1.1	Room 054 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
71	01 July 2019	3-C1.1	Room 053 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
72	01 July 2019	3-C1.1	Room 053 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
73	01 July 2019	3-C1.1	Room 006 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
74	01 July 2019	3-C1.1	Room 004 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
75	01 July 2019	3-C1.1	Room 005 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
76	01 July 2019	3-C1.1	Room 005 Shower 1	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
77	01 July 2019	3-C1.1	Room 005 Shower 2	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
78	01 July 2019	3-C1.1	Room 015 Wash Hand Basin	Pre-Flush	1	-	-	-	-	-	Markwik Thermostatic Tap
79	01 July 2019	3-C1.1	Room 016 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
80	01 July 2019	3-C1.1	Room 016 Shower 1	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
81	01 July 2019	3-C1.1	Room 016 Shower 2	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
82	01 July 2019	3-C1.1	Room 013 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
83	01 July 2019	3-C1.1	Room 014 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
84	01 July 2019	3-C1.1	Room 014 Shower 1	Pre-Flush	7	-	-	-	-	-	Thermostatic Mixer
85	01 July 2019	3-C1.1	Room 014 Shower 2	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
86	01 July 2019	3-C1.1	Room 009 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
87	01 July 2019	3-C1.1	Room 009 Wash hand basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
88	01 July 2019	3-C1.1	Room 010 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
89	01 July 2019	3-C1.1	Room 010 Shower 1	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
90	01 July 2019	3-C1.1	Room 010 Shower 2	Pre-Flush	>100	-	-	-	-	-	Thermostatic Mixer
91	01 July 2019	3-C1.1	Room 010 Shower 2	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
92	02 July 2019	3-C1.3	Room 040 Sink Cold	Pre-Flush	<1	-	24	440	<1	<1	DSR - Cold
93	02 July 2019	3-C1.3	Room 040 Sink Cold	Post-Flush	<1	-	<1	2	<1	<1	DSR - Cold
94	02 July 2019	3-C1.3	Room 039 Wash Hand Basin Mixed	Pre-Flush	<1	-	-	-	-	-	Mixed
95	02 July 2019	3-C1.3	Room 039 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve
96	02 July 2019	3-C1.3	Room 039 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
97	02 July 2019	3-C1.3	Room 004 Wash Hand Basin Mixed	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
98	02 July 2019	3-C1.3	Room 038 Wash Hand Basin Mixed	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Clean Utility
99	02 July 2019	3-C1.3	Room 037 Wash Hand Basin Mixed	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Treatment Room
100	02 July 2019	3-C1.3	Room 036 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Dirty Utility
101	02 July 2019	3-C1.3	Room 036 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixing Valve? - Dirty Utility
102	02 July 2019	3-C1.3	Room 036 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Dirty Utility
103	02 July 2019	3-C1.3	Room 035 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
104	02 July 2019	3-C1.3	Room 035 Arjo Deluge	Pre-Flush	<1	-	-	-	-	-	Mixed
105	02 July 2019	3-C1.3	Room 035 Arjo Spray	Pre-Flush	21	-	-	-	-	-	Mixed
106	02 July 2019	3-C1.3	Room 007 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
107	02 July 2019	3-C1.3	Room 008 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
108	02 July 2019	3-C1.3	Room 009 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
109	02 July 2019	3-C1.3	Room 009 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
110	02 July 2019	3-C1.3	Room 034 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixing Valve?
111	02 July 2019	3-C1.3	Room 034 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	
112	02 July 2019	3-C1.3	Room 034 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered
113	02 July 2019	3-C1.3	Room 034 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
114	02 July 2019	3-C1.3	Room 034 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	
115	02 July 2019	3-C1.3	Room 011 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
116	02 July 2019	3-C1.3	Room 010 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
117	02 July 2019	3-C1.3	Room 012 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
118	02 July 2019	3-C1.3	Room 012 Shower 1	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
119	02 July 2019	3-C1.3	Room 012 Shower 2	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
120	02 July 2019	3-C1.3	Room 013 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
121	02 July 2019	3-C1.3	Room 014 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap

122	02 July 2019	3-C1.3	Room 032 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
123	02 July 2019	3-C1.3	Room 033 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
124	02 July 2019	3-C1.3	Room 033 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
125	02 July 2019	3-C1.3	Room 030 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
126	02 July 2019	3-C1.3	Room 031 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
127	02 July 2019	3-C1.3	Room 031 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
128	02 July 2019	3-C1.3	Room 028 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - After Flushing by Bouygues
129	02 July 2019	3-C1.3	Room 029 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - After Flushing by Bouygues
130	02 July 2019	3-C1.3	Room 029 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - After Flushing by Bouygues
131	02 July 2019	3-C1.3	Room 025/028 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - After Flushing by Bouygues
132	02 July 2019	3-C1.3	Room 025 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered - After Flushing by Bouygues
133	02 July 2019	3-C1.3	Room 025 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered - After Flushing by Bouygues
134	02 July 2019	3-C1.3	Room 025 Sink Cold	Pre-Flush	<1	-	62	>1000	<1	<1	Cold - After Flushing by Bouygues
135	02 July 2019	3-C1.3	Room 025 Sink Cold	Post-Flush	<1	-	1	7	<1	<1	Cold - After Flushing by Bouygues
136	02 July 2019	3-C1.3	Room 025 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - After Flushing by Bouygues
137	02 July 2019	3-C1.3	Room 025 Wash Hand Basin	Post-Flush	<1	-	63	92	<1	<1	Markwik Thermostatic Tap - After Flushing by Bouygues
138	02 July 2019	3-C1.3	Room 029 Shower	Pre-Flush	<1	<40	-	-	-	-	Thermostatic Mixer - After Flushing by Bouygues
139	02 July 2019	3-C1.3	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - After Flushing by Bouygues
140	02 July 2019	3-C1.3	Room 022 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - After Flushing by Bouygues
141	02 July 2019	3-C1.3	Room 023 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - After Flushing by Bouygues
142	02 July 2019	3-C1.4	Room 078 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
143	02 July 2019	3-C1.4	Room 078 Wash Hand Basin	Post-Flush	<1	-	103	108	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
144	02 July 2019	3-C1.4	Room 079 Wash Hand Basin	Pre-Flush	<1	-	336	224	<1	<1	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
145	02 July 2019	3-C1.4	Room 078 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
146	02 July 2019	3-C1.4	Room 079 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
147	02 July 2019	3-C1.4	Room 064 Corridor	Pre-Flush	<1	-	-	-	-	-	Mixer - Flushed by Bouygues <2 Hours
148	02 July 2019	3-C1.4	Room 064 Sink Hot	Pre-Flush	<1	-	240	156	<1	<1	Untempered - Flushed by Bouygues <2 Hours
149	02 July 2019	3-C1.4	Room 064 Sink Cold	Pre-Flush	<1	-	22	47	<1	<1	Cold - Flushed by Bouygues <2 Hours
150	02 July 2019	3-C1.4	Room 064 Sink Cold	Post-Flush	<1	-	2	2	<1	<1	Cold - Flushed by Bouygues <2 Hours
151	02 July 2019	3-C1.4	Room 064 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	Flushed by Bouygues <2 Hours
152	02 July 2019	3-C1.4	Room 064 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixing Valve - Flushed by Bouygues <2 Hours
153	02 July 2019	3-C1.4	Room 064 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Cold - Flushed by Bouygues <2 Hours
154	02 July 2019	3-C1.4	Room 063 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
155	02 July 2019	3-C1.4	Room 063 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve - Flushed by Bouygues <2 Hours
156	02 July 2019	3-C1.4	Room 063 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Flushed by Bouygues <2 Hours
157	02 July 2019	3-C1.4	Room 076 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
158	02 July 2019	3-C1.4	Room 077 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
159	02 July 2019	3-C1.4	Room 077 Shower	Pre-Flush	<1	-	-	-	-	-	
160	02 July 2019	3-C1.4	Room 059 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
161	02 July 2019	3-C1.4	Room 060 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
162	02 July 2019	3-C1.4	Room 060 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
163	02 July 2019	3-C1.4	Room 074 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
164	02 July 2019	3-C1.4	Room 075 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
165	02 July 2019	3-C1.4	Room 075 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
166	02 July 2019	3-C1.4	Room 057 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
167	02 July 2019	3-C1.4	Room 058 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
168	02 July 2019	3-C1.4	Room 058 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
169	02 July 2019	3-C1.4	Room 071 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
170	02 July 2019	3-C1.4	Room 072 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
171	02 July 2019	3-C1.4	Room 073 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
172	02 July 2019	3-C1.4	Room 073 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
173	02 July 2019	3-C1.4	Room 053 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
174	02 July 2019	3-C1.4	Room 052 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
175	02 July 2019	3-C1.4	Room 051 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
176	02 July 2019	3-C1.4	Room 051 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
177	02 July 2019	3-C1.4	Room 055 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
178	02 July 2019	3-C1.4	Room 056 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
179	02 July 2019	3-C1.4	Room 056 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
180	02 July 2019	3-C1.4	Room 048 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
181	02 July 2019	3-C1.4	Room 049 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
182	02 July 2019	3-C1.4	Room 050 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
183	02 July 2019	3-C1.4	Room 050 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
184	02 July 2019	3-C1.4	Room 046 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
185	02 July 2019	3-C1.4	Room 047 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
186	02 July 2019	3-C1.4	Room 047 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
187	02 July 2019	3-C1.4	Room 044 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
188	02 July 2019	3-C1.4	Room 043 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
189	02 July 2019	3-C1.4	Room 042 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
190	02 July 2019	3-C1.4	Room 042 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
191	02 July 2019	3-C1.4	Room 038 Wash hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
192	02 July 2019	3-C1.4	Room 039 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
193	02 July 2019	3-C1.4	Room 040 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
194	02 July 2019	3-C1.4	Room 041 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
195	02 July 2019	3-C1.4	Room 041 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
196	02 July 2019	3-C1.4	Room 032 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
197	02 July 2019	3-C1.4	Room 033 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
198	02 July 2019	3-C1.4	Room 033 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
199	02 July 2019	3-C1.4	Room 022 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
200	02 July 2019	3-C1.4	Room 022 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered - Flushed by Bouygues <2 Hours
201	02 July 2019	3-C1.4	Room 022 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold - Flushed by Bouygues <2 Hours
202	02 July 2019	3-C1.4	Room 037 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
203	02 July 2019	3-C1.4	Room 036 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
204	02 July 2019	3-C1.4	Room 018 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
205	02 July 2019	3-C1.4	Room 019 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
206	02 July 2019	3-C1.4	Room 019 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
207	02 July 2019	3-C1.4	Room 016 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
208	02 July 2019	3-C1.4	Room 017 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
209	02 July 2019	3-C1.4	Room 017 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
210	02 July 2019	3-C1.4	Room 015 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
211	02 July 2019	3-C1.4	Room 015 Sink	Pre-Flush	<1	-	-	-	-	-	Mixer (Not Thermostatic) - Flushed by Bouygues <2 Hours
212	02 July 2019	3-C1.4	Room 013 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
213	02 July 2019	3-C1.4	Room 014 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
214	02 July 2019	3-C1.4	Room 014 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
215	02 July 2019	3-C1.4	Room 011 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
216	02 July 2019	3-C1.4	Room 011 Arjo Deluge	Pre-Flush	<1	-	-	-	-	-	Mixed - Flushed by Bouygues <2 Hours
217	02 July 2019	3-C1.4	Room 011 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Mixed - Flushed by Bouygues <2 Hours
218	02 July 2019	3-C1.4	Room 010 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Mixed - Flushed by Bouygues <2 Hours
219	02 July 2019	3-C1.4	Room 009 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
220	02 July 2019	3-C1.4	Room 009 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
221	02 July 2019	3-C1.4	Room 002 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
222	02 July 2019	3-C1.4	Room 008 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
223	02 July 2019	3-C1.4	Room 005 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
224	02 July 2019	3-C1.4	Room 005 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered - Flushed by Bouygues <2 Hours
225	02 July 2019	3-C1.4	Room 005 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold - Flushed by Bouygues <2 Hours
226	02 July 2019	3-C1.4	Room 082 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered - Flushed by Bouygues <2 Hours
227	02 July 2019	3-C1.4	Room 082 Sink Cold	Pre-Flush	<1	-	>1000	>1000	<1	<1	Cold - Flushed by Bouygues <2 Hours
228	02 July 2019	3-C1.4	Room 082 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	Flushed by Bouygues <2 Hours
229	02 July 2019	3-C1.4	Room 084 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
230	02 July 2019	3-C1.4	Room 085 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
231	02 July 2019	3-C1.4	Room 085 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
232	02 July 2019	3-C1.4	Room 061 Door Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
233	02 July 2019	3-C1.4	Room 061 Wash Hand Basin 2	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
234	02 July 2019	3-C1.4	Room 062 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
235	02 July 2019	3-C1.4	Room 062 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
236	02 July 2019	3-C1.4	Room 087 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
237	02 July 2019	3-C1.4	Room 083 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
238	02 July 2019	3-C1.4	Room 083 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered - Flushed by Bouygues <2 Hours
239	02 July 2019	3-C1.4	Room 083 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold - Flushed by Bouygues <2 Hours
240	02 July 2019	3-C1.4	Room 082 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Ref Sample 227. Flushed by Bouygues <2 Hours
241	02 July 2019	3-C1.4	Room 066 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
242	02 July 2019	3-C1.4	Room 065 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
243	02 July 2019	3-C1.4	Reception Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
244	02 July 2019	3-C1.4	Reception Wash Hand Basin	Post-Flush	<1	-	320	612	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
245	02 July 2019	3-C1.4	Room 067 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
246	03 July 2019	2-L2	Room 015 Corridor Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
247	03 July 2019	2-L2	Room 015 Corridor Wash Hand Basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap

248	03 July 2019	2-L2	Room 015 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
249	03 July 2019	2-L2	Room 016 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
250	03 July 2019	2-L2	Room 016 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
251	03 July 2019	2-L2	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
252	03 July 2019	2-L2	Room 022 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
253	03 July 2019	2-L2	Room 022 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
254	03 July 2019	2-L2	Room 061 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
255	03 July 2019	2-L2	Room 013 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
256	03 July 2019	2-L2	Room 014 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
257	03 July 2019	2-L2	Room 014 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
258	03 July 2019	2-L2	Room 026 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
259	03 July 2019	2-L2	Room 027 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
260	03 July 2019	2-L2	Room 002 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
261	03 July 2019	2-L2	Room 031 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
262	03 July 2019	2-L2	Room 031 Sink Hot	Pre-Flush	<1	-	1	<1	<1	<1	Untempered
263	03 July 2019	2-L2	Room 031 Sink Hot	Post-Flush	<1	-	2	<1	<1	<1	Untempered
264	03 July 2019	2-L2	Room 031 Sink Cold	Pre-Flush	<1	-	97	816	<1	<1	Cold
265	03 July 2019	2-L2	Room 031 Sink Cold	Post-Flush	<1	-	2	2	<1	<1	Cold
266	03 July 2019	2-L2	Room 010 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed (Wall Discharge)
267	03 July 2019	2-L2	Room 011 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve (Wall Discharge)
268	03 July 2019	2-L2	Room 011 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Wall Discharge
269	03 July 2019	2-L2	Room 011 Shower	Pre-Flush	>100	-	-	-	-	-	Thermostatic Mixer
270	03 July 2019	2-L2	Room 032 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
271	03 July 2019	2-L2	Room 033 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
272	03 July 2019	2-L2	Room 033 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
273	03 July 2019	2-L2	Room 072 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
274	03 July 2019	2-L2	Room 006 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
275	03 July 2019	2-L2	Room 007 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
276	03 July 2019	2-L2	Room 007 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
277	03 July 2019	2-L2	Room 015 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
278	03 July 2019	2-L2	Room 004 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
279	03 July 2019	2-L2	Room 005 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
280	03 July 2019	2-L2	Room 005 Wash Hand Basin	Pre-Flush	25	-	-	-	-	-	Markwik Thermostatic Tap
281	03 July 2019	2-L2	Room 018 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
282	03 July 2019	2-L2	Room 019 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
283	03 July 2019	2-L2	Room 019 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
284	03 July 2019	2-L2	Room 030 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
285	03 July 2019	2-L2	Room 030 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered
286	03 July 2019	2-L2	Room 030 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
287	03 July 2019	2-L2	Room 034 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
288	03 July 2019	2-L2	Room 035 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
289	03 July 2019	2-L2	Room 035 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
290	03 July 2019	2-L2	Room 023 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
291	03 July 2019	2-L2	Room 024 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
292	03 July 2019	2-L2	Room 024 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
293	03 July 2019	2-L2	Room 036 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
294	03 July 2019	2-L2	Room 037 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
295	03 July 2019	2-L2	Room 037 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
296	03 July 2019	2-L2	Room 028 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
297	03 July 2019	2-L2	Room 029 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
298	03 July 2019	2-L2	Room 029 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
299	03 July 2019	2-L2	Room 050 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
300	03 July 2019	2-L2	Room 051 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
301	03 July 2019	2-L2	Room 051 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
302	03 July 2019	2-L2	Room 046 Wash Hand Basin	Pre-Flush	32	-	-	-	-	-	Markwik Thermostatic Tap
303	03 July 2019	2-L2	Room 047 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
304	03 July 2019	2-L2	Room 047 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
305	03 July 2019	2-L2	Room 048 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
306	03 July 2019	2-L2	Room 049 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
307	03 July 2019	2-L2	Room 049 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
308	03 July 2019	2-L2	Room 041 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
309	03 July 2019	2-L2	Room 042 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
310	03 July 2019	2-L2	Room 042 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
311	03 July 2019	2-L2	Room 052 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
312	03 July 2019	2-L2	Room 043 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
313	03 July 2019	2-L2	Room 044 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
314	03 July 2019	2-L2	Room 044 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
315	03 July 2019	2-L2	Room 038 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
316	03 July 2019	2-L2	Room 039 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
317	03 July 2019	2-L2	Room 040 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
318	03 July 2019	2-L2	Room 040 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
319	03 July 2019	2-L2	Room 002 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
320	03 July 2019	2-L2	Room 068 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
321	03 July 2019	2-L2	Room 071 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
322	03 July 2019	2-L2	Room 054 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
323	03 July 2019	2-L2	Room 054 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered
324	03 July 2019	2-L2	Room 054 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered
325	03 July 2019	2-L2	Room 054 Sink Cold	Pre-Flush	<1	-	>1000	>1000	<1	<1	Cold
326	03 July 2019	2-L2	Room 054 Sink Cold	Post-Flush	<1	-	8	17	<1	<1	Cold
327	03 July 2019	2-L2	Room 060 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
328	03 July 2019	2-L2	Room 062 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered - Single Spout Mixer
329	03 July 2019	2-L2	Room 062 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold - Single Spout Mixer
330	03 July 2019	2-L2	Room 062 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve
331	03 July 2019	2-L2	Room 062 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Cold
332	03 July 2019	2-L2	Room 062 Zip Hydrotap	Pre-Flush	<1	-	-	-	-	-	
333	03 July 2019	2-L2	Room 080 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
334	03 July 2019	2-L2	Room 080 Arjo Deluge	Pre-Flush	>100	-	-	-	-	-	Mixed
335	03 July 2019	2-L2	Room 080 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Mixed
336	03 July 2019	2-L2	Room 134 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
337	03 July 2019	2-L2	Room 135 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
338	03 July 2019	2-L2	Room 136 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
339	03 July 2019	2-L2	Room 136 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
340	03 July 2019	2-L2	Room 079 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
341	03 July 2019	2-L2	Room 087 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
342	03 July 2019	2-L2	Room 088 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
343	03 July 2019	2-L2	Room 088 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
344	03 July 2019	2-L2	Room 090 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
345	03 July 2019	2-L2	Room 091 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
346	03 July 2019	2-L2	Room 091 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
347	03 July 2019	2-L2	Room 130 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
348	03 July 2019	2-L2	Room 131 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
349	03 July 2019	2-L2	Room 131 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
350	03 July 2019	2-L2	Room 097 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
351	03 July 2019	2-L2	Room 096 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
352	03 July 2019	2-L2	Room 096 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
353	03 July 2019	2-L2	Room 125 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
354	03 July 2019	2-L2	Room 126 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
355	03 July 2019	2-L2	Room 126 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
356	03 July 2019	2-L2	Room 102 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
357	03 July 2019	2-L2	Room 103 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
358	03 July 2019	2-L2	Room 103 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
359	03 July 2019	2-L2	Room 123 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
360	03 July 2019	2-L2	Room 124 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
361	03 July 2019	2-L2	Room 124 Shower	Pre-Flush	35	-	-	-	-	-	Thermostatic Mixer
362	03 July 2019	2-L2	Room 104 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
363	03 July 2019	2-L2	Room 105 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
364	03 July 2019	2-L2	Room 105 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
365	03 July 2019	2-L2	Room 111 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
366	03 July 2019	2-L2	Room 110 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
367	03 July 2019	2-L2	Room 110 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
368	03 July 2019	2-L2	Room 119 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
369	03 July 2019	2-L2	Room 120 (119 Ensuite) Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
370	03 July 2019	2-L2	Room 120 (119 Ensuite) Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
371	03 July 2019	2-L2	Room 117 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
372	03 July 2019	2-L2	Room 118 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
373	03 July 2019	2-L2	Room 118 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer

374	03 July 2019	2-L2	Room 113 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
375	03 July 2019	2-L2	Room 114 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
376	03 July 2019	2-L2	Room 114 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
377	03 July 2019	2-L2	Room 121 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
378	03 July 2019	2-L2	Room 122 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
379	03 July 2019	2-L2	Room 122 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
380	03 July 2019	2-L2	Room 127 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
381	03 July 2019	2-L2	Room 127 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered
382	03 July 2019	2-L2	Room 127 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
383	03 July 2019	2-L2	Room 108 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
384	03 July 2019	2-L2	Room 109 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
385	03 July 2019	2-L2	Room 109 Shower	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
386	03 July 2019	2-L2	Room 106 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
387	03 July 2019	2-L2	Room 107 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
388	03 July 2019	2-L2	Room 107 Shower	Pre-Flush	<1	-	-	-	-	-	Mixed Wall Outlet
389	03 July 2019	2-L2	Room 142 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Outlet
390	03 July 2019	2-L2	Room 143 Wash Hand Basin Hot	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Outlet
391	03 July 2019	2-L2	Room 143 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Wall Outlet
392	03 July 2019	2-L2	Room 143 Shower	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Shower
393	03 July 2019	2-L2	Room 128 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed
394	03 July 2019	2-L2	Room 128 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
395	03 July 2019	2-L2	Room 128 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
396	03 July 2019	2-L2	Room 128 Sink Cold	Pre-Flush	<1	-	808	>1000	<1	<1	Cold
397	03 July 2019	2-L2	Room 128 Sink Cold	Post-Flush	<1	-	<1	14	<1	<1	Cold
398	03 July 2019	2-L2	Room 094 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
399	03 July 2019	2-L2	Room 095 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
400	03 July 2019	2-L2	Room 095 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
401	03 July 2019	2-L2	Room 139 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
402	03 July 2019	2-L2	Room 138 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
403	03 July 2019	2-L2	Room 138 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
404	03 July 2019	2-L2	Room 140 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
405	03 July 2019	2-L2	Room 141 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
406	03 July 2019	2-L2	Room 141 Shower	Pre-Flush	1	-	-	-	-	-	Thermostatic Mixer
407	03 July 2019	2-L2	Room 082 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
408	03 July 2019	2-L2	Room 083 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
409	03 July 2019	2-L2	Room 083 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
410	03 July 2019	2-L2	Room 084 Wash Hand Basin	Pre-Flush	7	-	-	-	-	-	Markwik Thermostatic Tap
411	03 July 2019	2-L2	Room 085 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
412	03 July 2019	2-L2	Room 085 Shower	Pre-Flush	46	-	-	-	-	-	Thermostatic Mixer
413	03 July 2019	2-L2	Room 092 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
414	03 July 2019	2-L2	Room 093 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
415	03 July 2019	2-L2	Room 093 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
416	03 July 2019	2-L2	Room 093 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
417	03 July 2019	2-L2	Room 088 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
418	03 July 2019	2-L2	Room 078 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve
419	03 July 2019	2-L2	Room 078 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Cold
420	03 July 2019	2-L2	Room 078 Sink Cold	Pre-Flush	>100	-	-	-	-	-	Mixed discharge
421	03 July 2019	2-L2	Room 078 Sink Hot	Pre-Flush	<1	-	>1000	>1000	<1	<1	Mixed discharge
422	03 July 2019	2-L2	Room 078 Zip Hydrotap	Pre-Flush	<1		>1000	>1000	<1	<1	
423	03 July 2019	2-L2	Room 066 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
424	03 July 2019	2-L2	Room 075 Corridor Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
425	03 July 2019	2-L2	Room 065 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
426	04 July 2019	1-B1	Neonatal Unit SS Trough Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
427	04 July 2019	1-B1	Neonatal Unit SS Trough Cold	Pre-Flush	<1	-	-	-	-	-	Cold
428	04 July 2019	1-B1	Neonatal Unit Wash Hand Basin 1	Pre-Flush	<1	-	-	-	-	-	From SS Trough. Markwik Thermostatic Tap
429	04 July 2019	1-B1	Neonatal Unit Wash Hand Basin 2	Pre-Flush	<1	-	-	-	-	-	From SS Trough. Markwik Thermostatic Tap
430	04 July 2019	1-B1	Neonatal Unit Wash Hand Basin 3	Pre-Flush	<1	-	-	-	-	-	From SS Trough. Markwik Thermostatic Tap
431	04 July 2019	1-B1	Neonatal Unit Wash Hand Basin 4	Pre-Flush	<1	-	-	-	-	-	From SS Trough. Markwik Thermostatic Tap
432	04 July 2019	1-B1	Room 075 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
433	04 July 2019	1-B1	Room 074 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
434	04 July 2019	1-B1	Room 074 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
435	04 July 2019	1-B1	Neonatal Unit SS Trough Hot	Post-Flush	<1	-	1	1	<1	<1	Untempered Hot
436	04 July 2019	1-B1	Neonatal Unit SS Trough Cold	Post-Flush	<1	-	3	1	<1	<1	Cold
437	04 July 2019	1-B1	Room 077 Sink Hot	Post-Flush	<1	-	-	-	-	-	Untempered Hot
438	04 July 2019	1-B1	Room 077 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
439	04 July 2019	1-B1	Room 077 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
440	04 July 2019	1-B1	Room 068 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
441	04 July 2019	1-B1	Room 079 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
442	04 July 2019	1-B1	Room 079 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
443	04 July 2019	1-B1	Room 080 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
444	04 July 2019	1-B1	Room 084 Drinking Fountain	Pre-Flush	<1	-	68	216	<1	<1	Cold Setting
445	04 July 2019	1-B1	Room 083 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
446	04 July 2019	1-B1	Room 083 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
447	04 July 2019	1-B1	Room 073 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
448	04 July 2019	1-B1	Room 073 Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
449	04 July 2019	1-B1	Room 073 Cold	Pre-Flush	<1	-	211	312	<1	<1	Cold
450	04 July 2019	1-B1	Room 073 Sink Cold	Post-Flush	<1	-	1	1	<1	<1	Cold
451	04 July 2019	1-B1	Room 045 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
452	04 July 2019	1-B1	Room 045 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
453	04 July 2019	1-B1	Room 045 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
454	04 July 2019	1-B1	Room 063 Wash Hand Basin South	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
455	04 July 2019	1-B1	Room 063 Wash Hand Basin West	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
456	04 July 2019	1-B1	Room 063 Wash Hand Basin North	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
457	04 July 2019	1-B1	Room 063 Wash Hand Basin East	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
458	04 July 2019	1-B1	Room 037 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
459	04 July 2019	1-B1	Room 033 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
460	04 July 2019	1-B1	Room 036 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
461	04 July 2019	1-B1	Room 070 Staff Base Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
462	04 July 2019	1-B1	Room 032 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
463	04 July 2019	1-B1	Room 032 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
464	04 July 2019	1-B1	Room 041 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
465	04 July 2019	1-B1	Room 064 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
466	04 July 2019	1-B1	Room 064 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
467	04 July 2019	1-B1	Room 064 Sink Hot	Post-Flush	<1	-	<1	1	<1	<1	Untempered Hot
468	04 July 2019	1-B1	Room 064 Sink Cold	Pre-Flush	<1	-	848	>1000	<1	<1	Cold
469	04 July 2019	1-B1	Room 064 Sink Cold	Post-Flush	<1	-	<1	2	<1	<1	Cold
470	04 July 2019	1-B1	Room 031 Wash Hand Basin North	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
471	04 July 2019	1-B1	Room 031 Wash Hand Basin East	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
472	04 July 2019	1-B1	Room 031 Wash Hand Basin South	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
473	04 July 2019	1-B1	Room 031 Wash Hand Basin West	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
474	04 July 2019	1-B1	Room 036 Wash Hand Basin	Post-Flush	<1	-	73	65	<1	<1	Markwik Thermostatic Tap. End of line.
475	04 July 2019	1-B1	Room 052 Staff Base Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
476	04 July 2019	1-B1	Room 025 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
477	04 July 2019	1-B1	Room 026 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
478	04 July 2019	1-B1	Room 027 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
479	04 July 2019	1-B1	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
480	04 July 2019	1-B1	Room 020 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
481	04 July 2019	1-B1	Room 019 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
482	04 July 2019	1-B1	Room 018 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
483	04 July 2019	1-B1	Room 017 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
484	04 July 2019	1-B1	Room 015 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
485	04 July 2019	1-B1	Room 016 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
486	04 July 2019	1-B1	Room 040 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
487	04 July 2019	1-B1	Room 040 SS Sink	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
488	04 July 2019	1-B1	Room 017 Wash Hand Basin	Post-Flush	<1	-	22	38	<1	<1	Markwik Thermostatic Tap. End of line.
489	04 July 2019	1-B1	Room 009 Wash Hand Basin West	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
490	04 July 2019	1-B1	Room 009 Wash Hand Basin North	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
491	04 July 2019	1-B1	Room 009 Wash Hand Basin East	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
492	04 July 2019	1-B1	Room 009 Wash Hand Basin South	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
493	04 July 2019	1-B1	Room 007 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of line.
494	04 July 2019	1-B1	Room 007 Wash Hand Basin	Post-Flush	<1	-	71	93	<1	<1	Markwik Thermostatic Tap. End of line.
495	04 July 2019	1-B1	Room 007 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
496	04 July 2019	1-B1	Room 007 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
497	04 July 2019	1-B1	Room 007 Sink Cold	Pre-Flush	<1	-	656	912	<1	<1	Cold. End of line.
498	04 July 2019	1-B1	Room 007 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. End of line.
499	04 July 2019	1-B1	Room 007 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap

500	04 July 2019	1-J.1	Room 004 Sink Mixer	Pre-Flush	<1	-	-	-	-	-	Mid-point Mixer (Single Spout)
501	04 July 2019	1-J.1	Room 002 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
502	04 July 2019	1-J.1	Room 003 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
503	04 July 2019	1-B1	Room 005 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
504	04 July 2019	1-B1	Room 006 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
505	04 July 2019	1-B1	Room 003 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
506	04 July 2019	1-B1	Room 003 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
507	04 July 2019	1-B1	Room 003 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
508	04 July 2019	1-B1	Room 003 Sink Cold	Post-Flush	<1	-	1	<1	<1	<1	Cold
509	04 July 2019	1-B1	Room 003 Zip Hydrotap	Pre-Flush	<1	-	58	>1000	<1	<1	
510	04 July 2019	1-L1	Room 077 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
511	04 July 2019	1-L1	Room 077 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
512	04 July 2019	1-L1	Room 107 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
513	04 July 2019	1-L1	Room 072 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
514	04 July 2019	1-L1	Room 080 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
515	04 July 2019	1-L1	Room 054 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Via Thermostatic Mixing Valve
516	04 July 2019	1-L1	Room 054 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Cold
517	04 July 2019	1-L1	Room 054 Sink Hot	Pre-Flush	30	-	-	-	-	-	Untempered Hot. Monoblock Tap.
518	04 July 2019	1-L1	Room 054 Sink Cold	Pre-Flush	<1	-	-	-	-	-	
519	04 July 2019	1-L1	Room 054 Zip Hydrotap	Pre-Flush	>100	-	-	-	-	-	Cold. Monoblock Tap.
520	04 July 2019	1-L1	Room 093 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
521	04 July 2019	1-L1	Room 094 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
522	04 July 2019	1-L1	Room 094 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
523	04 July 2019	1-L1	Room 100 Door Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
524	04 July 2019	1-L1	Room 100 Window Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
525	04 July 2019	1-L1	Room 101 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
526	04 July 2019	1-L1	Room 101 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
527	04 July 2019	1-L1	Room 091 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
528	04 July 2019	1-L1	Room 092 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
529	04 July 2019	1-L1	Room 092 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
530	04 July 2019	1-L1	Room 103 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
531	04 July 2019	1-L1	Room 088 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
532	04 July 2019	1-L1	Room 087 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
533	04 July 2019	1-L1	Room 087 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
534	04 July 2019	1-L1	Room 097 Door Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
535	04 July 2019	1-L1	Room 097 Window Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
536	04 July 2019	1-L1	Room 099 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
537	04 July 2019	1-L1	Room 099 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
538	04 July 2019	1-L1	Room 083 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
539	04 July 2019	1-L1	Room 084 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
540	04 July 2019	1-L1	Room 084 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
541	04 July 2019	1-L1	Room 047 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
542	04 July 2019	1-L1	Room 068 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
543	04 July 2019	1-L1	Room 069 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
544	04 July 2019	1-L1	Room 069 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
545	04 July 2019	1-L1	Room 104 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
546	04 July 2019	1-L1	Room 061 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
547	04 July 2019	1-L1	Room 061 Sink Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
548	04 July 2019	1-L1	Room 061 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
549	04 July 2019	1-L1	Room 095 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of Line.
550	04 July 2019	1-L1	Room 095 Wash Hand Basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of Line.
551	04 July 2019	1-L1	Room 095 Sink Hot	Pre-Flush	<1	-	118	192	<1	<1	Untempered Hot. End of Line.
552	04 July 2019	1-L1	Room 095 Sink Hot	Post-Flush	<1	-	27	23	<1	<1	Untempered Hot. End of Line.
553	04 July 2019	1-L1	Room 095 Sink Cold	Pre-Flush	<1	-	40	232	<1	<1	Cold. End of Line.
554	04 July 2019	1-L1	Room 095 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. End of Line.
555	04 July 2019	1-L1	Room 066 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
556	04 July 2019	1-L1	Room 067 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
557	04 July 2019	1-L1	Room 067 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
558	04 July 2019	1-L1	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
559	04 July 2019	1-L1	Room 022 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
560	04 July 2019	1-L1	Room 022 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer. Shower Fault - No Hot.
561	04 July 2019	1-L1	Room 024 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
562	04 July 2019	1-L1	Room 025 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
563	04 July 2019	1-L1	Room 025 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
564	04 July 2019	1-L1	Room 017 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
565	04 July 2019	1-L1	Room 018 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
566	04 July 2019	1-L1	Room 018 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
567	04 July 2019	1-L1	Room 034 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
568	04 July 2019	1-L1	Room 035 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
569	04 July 2019	1-L1	Room 035 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
570	04 July 2019	1-L1	Room 015 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Wall Tap - Via Thermostatix Mixing Valve
571	04 July 2019	1-L1	Room 016 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Wall Tap - Via Thermostatix Mixing Valve
572	04 July 2019	1-L1	Room 016 Wash Hand Basin Cold	Pre-Flush	<1	-	-	-	-	-	Wall Tap - Cold
573	04 July 2019	1-L1	Room 016 Shower	Pre-Flush	<1	-	-	-	-	-	Fixed Head Via Thermostatic Mixing Valve
574	04 July 2019	1-L1	Room 038 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
575	04 July 2019	1-L1	Room 039 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
576	04 July 2019	1-L1	Room 039 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
577	04 July 2019	1-L1	Room 010 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
578	04 July 2019	1-L1	Room 011 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
579	04 July 2019	1-L1	Room 011 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer. Shower Fault - No Hot.
580	04 July 2019	1-L1	Room 044 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
581	04 July 2019	1-L1	Room 040 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
582	04 July 2019	1-L1	Room 040 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
583	04 July 2019	1-L1	Room 006 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
584	04 July 2019	1-L1	Room 007 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
585	04 July 2019	1-L1	Room 007 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
586	04 July 2019	1-L1	Room 014 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
587	04 July 2019	1-L1	Room 079 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
588	04 July 2019	1-L1	Room 014 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
589	04 July 2019	1-L1	Room 026 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
590	04 July 2019	1-L1	Room 033 Sink Hot	Pre-Flush	<1	-	<1	1	<1	<1	Untempered Hot. Start of Line.
591	04 July 2019	1-L1	Room 033 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot. Start of Line.
592	04 July 2019	1-L1	Room 033 Sink Cold	Pre-Flush	<1	-	552	608	<1	<1	Cold. Start of Line.
593	04 July 2019	1-L1	Room 033 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. Start of Line.
594	04 July 2019	1-L1	Room 033 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
595	04 July 2019	1-L1	Room 002 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
596	04 July 2019	1-L1	Room 003 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
597	04 July 2019	1-L1	Room 003 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
598	04 July 2019	1-L1	Room 073 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
599	04 July 2019	1-L1	Room 032 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
600	04 July 2019	1-L1	Room 031 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
601	04 July 2019	1-L1	Room 030 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
602	04 July 2019	1-L1	Room 029 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
603	04 July 2019	1-L1	Room 028 Corridor Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
604	04 July 2019	1-L1	Room 002 Wash Hand Basin Mixed	Post-Flush	<1	-	12	4	<1	<1	End of Line
605	04 July 2019	1-L1	Room 002 Wash Hand Basin Cold	Post-Flush	<1	-	2	7	<1	<1	End of Line: Cold Setting, but Mixed Spout.
606	04 July 2019	1-L1	Room 005 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
607	04 July 2019	1-L1	Room 003 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
608	04 July 2019	1-L1	Room 022 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer. Shower Fault - No Hot.
609	04 July 2019	1-L1	Room 069 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
610	04 July 2019	1-L1	Room 092 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
611	04 July 2019	1-L1	Room 098 Wash Hand Basin	Pre-Flush	-	<40	-	-	-	-	Markwik Thermostatic Tap
612	04 July 2019	1-L1	Room 032 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
613	04 July 2019	1-L1	Room 074 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
614	04 July 2019	1.H2	Room 021 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
615	04 July 2019	1.H2	Room 018 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
616	04 July 2019	1.H2	Room 018 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
617	04 July 2019	1.H2	Room 023 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
618	04 July 2019	1.H2	Room 024 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
619	04 July 2019	1.H2	Room 022 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
620	04 July 2019	1.H2	Room 022 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer
621	04 July 2019	1.H2	Room 018 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
622	04 July 2019	G.A2	Room 074 Wash Hand Basin	Pre-Flush	5	-	-	-	-	-	Markwik Thermostatic Tap
623	04 July 2019	G.A2	Room 072 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
624	04 July 2019	G.A2	Room 073 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Contour Thermostatic Tap
625	04 July 2019	G.A2	Room 073 Shower	Pre-Flush	<1	-	-	-	-	-	Thermostatic Mixer

626	04 July 2019	G.A2	Room 073 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
627	04 July 2019	1.D7	Room 006 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
628	04 July 2019	1.D7	Room 004 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
629	04 July 2019	1.D7	Room 004 Wash Hand Basin Hot	Pre-Flush	<1	-	-	-	-	-	Untempered Hot
630	04 July 2019	1.D7	Room 004 Sink Cold	Pre-Flush	<1	-	-	-	-	-	Cold
631	04 July 2019	1.D7	Room 003 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
632	04 July 2019	1.D7	Room 001 Wash Hand Basin	Pre-Flush	<1	-	-	-	-	-	Markwik Thermostatic Tap
633	04 July 2019	1.D7	Room 001 Arjo Deluge	Pre-Flush	<1	-	-	-	-	-	Arjo Bath - Mixed
634	04 July 2019	1.D7	Room 001 Arjo Spray	Pre-Flush	<1	-	-	-	-	-	Arjo Bath - Mixed
635	04 July 2019	1.D7	Room 001 Arjo Spray	Pre-Flush	-	<40	-	-	-	-	Arjo Bath - Mixed
636	05 July 2019	3-C1.8	Room 005 Corridor Wash Hand Basin Mixed	1 minute flush	<1	-	32	49	<1	<1	34°C. At End of Line.
637	05 July 2019	3.C1.8	Room 006 Shower	Pre-Flush	-	<40	-	-	-	-	37°C. At End of Line.
638	05 July 2019	3.C1.8	Room 012 Hot	1 minute flush	<1	-	<1	<1	<1	<1	64°C. DSR. Nearest to Riser.
639	05 July 2019	3.C1.8	Room 012 Cold	1 minute flush	<1	-	1	1	<1	<1	14°C. DSR. Nearest to Riser.
640	05 July 2019	3.C1.2	Room 010 Wash Hand Basin Mixed	1 minute flush	<1	-	60	45	<1	<1	37°C. At End of Line.
641	05 July 2019	3.C1.2	Room 003 Shower	Pre-Flush	-	<40	-	-	-	-	38°C. At End of Line.
642	05 July 2019	3.C1.2	Room 013 Hot	1 minute flush	<1	-	<1	<1	<1	<1	63°C. DSR. At End of Line.
643	05 July 2019	3.C1.2	Room 013 Cold	1 minute flush	<1	-	<1	7	<1	<1	17°C. DSR. At End of Line.
644	05 July 2019	3.D9	Room 024 Wash Hand Basin Mixed	1 minute flush	<1	-	70	51	<1	<1	36°C. At End of Line.
645	05 July 2019	3.D9	Room 025 Shower	Pre-Flush	-	<40	-	-	-	-	36°C. At End of Line.
646	05 July 2019	3.D9	Room 017 Hot	1 minute flush	<1	-	<1	<1	<1	<1	53°C. Close to End of Line. Dirty Utility.
647	05 July 2019	3.D9	Room 017 Cold	1 minute flush	<1	-	1	1	<1	<1	15°C. Close to End of Line. Dirty Utility.
648	05 July 2019	3.K2	Room 024 Wash Hand Basin	1 minute flush	<1	-	43	26	<1	<1	30°C. End of Line. Mid-point Sample.
649	05 July 2019	3.K2	Room 024 Shower	Pre-Flush	-	<40	-	-	-	-	28°C. End of Line. Manual Mixer.
650	05 July 2019	3.K2	Room 047 Hot	1 minute flush	<1	-	21	<1	<1	<1	64°C. DSR. Hot System. Mid-point.
651	05 July 2019	3.K2	Room 047 Cold	1 minute flush	<1	-	<1	<1	<1	<1	16°C DSR. Cold System. Mid-point.
652	05 July 2019	3.K2	Room 050 Hot	1 minute flush	<1	-	12	10	<1	<1	40°C. Single Spout Kitchen Tap - Flushed at 1 Minute of Hottest via Thermostatic Mixing Valve
653	05 July 2019	3.K2	Room 050 Cold	1 minute flush	<1	-	7	10	<1	<1	18°C. Single Spout Kitchen Tap - Flushed at 1 Minute of Coldest.
654	05 July 2019	3.K2	Room 066 Wash Hand Basin	1 minute flush	<1	-	80	41	<1	<1	32°C. Thermostatic Mixer Tap. End of Line.
655	05 July 2019	3.K2	Room 066 Shower	Pre-Flush	-	<40	-	-	-	-	33°C. Manual Mixer. End of Line.
656	05 July 2019	3.H3	Room 012 Hot	1 minute flush	<1	-	8	<1	<1	<1	62°C. DSR. End of Line.
657	05 July 2019	3.H3	Room 012 Cold	1 minute flush	<1	-	5	<1	<1	<1	18°C. DSR. End of Line.
658	09 July 2019	2.S5	005 Female Change WHB	1 minute flush	<1	-	10	13	<1	<1	38°C. Contour. End of line.
659	09 July 2019	2.S5	005 Female Change Shower	Pre-Flush	-		-	-	-	-	29°C. Composite of 1&5. End of line.
660	09 July 2019	2.S5	004 Male Change WHB	1 minute flush	<1	-	15	14	<1	<1	41°C. Contour. End of line.
661	09 July 2019	2.S5	004 Male Change Shower	Pre-Flush	-		-	-	-	-	31°C. Composite of 1&3. End of line.
662	09 July 2019	2.S5	003 DSR Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	51°C. Untempered Hot. End of line. Too cool.
663	09 July 2019	2.S5	003 DSR Sink Cold	1 minute flush	<1	-	4	<1	<1	<1	16°C. Cold. End of line.
664	09 July 2019	2.S5	003 DSR whb Mixed	1 minute flush	<1	-	61	53	<1	<1	37°C. Markwick - End of line.
665	09 July 2019	2.M2	009 Pantry Sink Hot	1 minute flush	<1	-	21	<1	<1	<1	43°C. Via TMV. End of line.
666	09 July 2019	2.M2	009 Pantry Sink Cold	1 minute flush	<1	-	3	<1	<1	<1	17°C. Cold. End of line.
667	09 July 2019	2.M2	009 Pantry WHB Mixer	1 minute flush	<1	-	19	7	<1	<1	38°C. Marwick - end of line.
668	09 July 2019	2.M2	007 Shower	Pre-Flush	-		-	-	-	-	31°C. Thermostatic Mixer. End of line.
669	10 July 2019	2.M2	007 Bath Hot	1 minute flush	<1	-	<1	<1	<1	<1	60°C. Untempered hot. End of line.
670	09 July 2019	2.M4	018 whb Mixer	1 minute flush	<1	-	76	57	<1	<1	41°C. Marwick - end of line.
671	09 July 2019	2.M4	006 WHB Mixer	1 minute flush	<1	-	5	7	<1	<1	41°C. Contour. Near end of line.
672	09 July 2019	2.G2	002 Sink Hot	1 minute flush	<1	-	3	<1	<1	<1	63°C. Untempered hot. Near riser. DSR.
673	10 July 2019	2.G2	002 Sink Cold	1 minute flush	<1	-	<1	5	<1	<1	17°C. Cold. Near riser. DSR.
674	09 July 2019	2.R1	057 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	65°C. Untempered hot. Near riser. BOA.
675	09 July 2019	2.R1	057 Sink Cold	1 minute flush	<1	-	2	<1	<1	<1	17°C. Cold. Near riser. BOA.
676	09 July 2019	2.R1	016 WHB Mixer	1 minute flush	<1	-	38	<1	<1	<1	45°C. Contour. Mid line. Disabled
677	09 July 2019	2.R1	060 Sink Hot	1 minute flush	<1	-	9	14	<1	<1	62°C. Untempered hot. End of line. BOA.
678	09 July 2019	2.R1	060 Sink Cold	1 minute flush	<1	-	<1	1	<1	<1	19°C. Cold. End of line. BOA.
679	09 July 2019	2.R1	032 whb Mixer	1 minute flush	<1	-	12	3	<1	<1	44°C. Contour. End of line. Disabled.
680	09 July 2019	2.R1	034 Sink Cold	1 minute flush	<1	-	<1	2	<1	<1	16°C. Cold. End of line. DSR.
681	09 July 2019	2.R1	034 Sink Hot	1 minute flush	<1	-	3	1	<1	<1	64°C. Untempered hot. End of line. DSR.
682	09 July 2019	2.R1	034 WHB Mixer	1 minute flush	<1	-	132	85	<1	<1	44°C. Marwick - end of line.
683	10 July 2019	1.D4	010 Sink Hot	1 minute flush	<1	-	2	<1	<1	<1	64°C. Untempered hot. Mid point.
684	10 July 2019	1.D4	010 Sink Cold	1 minute flush	<1	-	<1	1	<1	<1	17°C. Cold. Mid point.
685	10 July 2019	1.D1	048 WHB Mixer	1 minute flush	<1	-	55	29	<1	<1	42°C. Marwick - end of line.
686	10 July 2019	1.D6	006 WHB Mixer	1 minute flush	<1	-	3	6	<1	<1	41°C. Contour. End of line.
687	10 July 2019	1.D6	019 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	62°C. Untempered hot. Near end line.
688	10 July 2019	1.D6	019 Sink Cold	1 minute flush	<1	-	5	<1	<1	<1	18°C. Cold. Near end line.
689	10 July 2019	1.D6	019 WHB Mixer	1 minute flush	<1	-	93	28	<1	<1	42°C. Marwick - near end of line.
690	10 July 2019	1.D1	010 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	64°C. Dirty unit. Untempered hot. Near riser.
691	10 July 2019	1.D1	010 Sink Cold	1 minute flush	<1	-	<1	3	<1	<1	16°C. Dirty unit. Cold. Near riser.
692	10 July 2019	1.D6	019 Shower	Pre-Flush	-		-	-	-	-	31°C. Thermostatic mixer.
693	10 July 2019	1.P1	163 Sink Hot	1 minute flush	<1	-	<1	3	<1	<1	63°C. Untempered hot. DSR. Mid point.
694	10 July 2019	1.P1	163 Sink Cold	1 minute flush	<1	-	1	<1	<1	<1	16°C. Cold. DSR. Mid point.
695	10 July 2019	1.P1	010 WHB Mixer	1 minute flush	<1	-	296	184	<1	<1	41°C. Marwick. End of line
696	10 July 2019	1.P1	011 whb Mixer	1 minute flush	<1	-	14	5	<1	<1	42°C. Contour. End of line.
697	10 July 2019	1.P1	006 Shower	Pre-Flush	-		-	-	-	-	30°C. Thermostatic mixer.
698	10 July 2019	1.P1	012 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	58°C. Untempered hot. End of line.
699	10 July 2019	1.P1	012 Sink Cold	1 minute flush	<1	-	13	9	<1	<1	23°C. Cold. End of line. Too warm.
700	10 July 2019	1.P1	012 whb Mixer	1 minute flush	<1	-	208	132	<1	<1	42°C. Marwick. End of line.
701	10 July 2019	1.P1	012 whb Mixer	Pre-Flush	-		-	-	-	-	38°C. Marwick. End of line.
702	10 July 2019	1.P1	183 Sink Mixer Pre-flush	1 minute flush	<1	-	>1000	>1000	<1	<1	Pre-flush. Marwick. Mid point.
703	10 July 2019	1.P1	183 Sink Mixer Post Flush	1 minute flush	<1	-	208	256	<1	<1	Post flush. Marwick. Mid point.
704	10 July 2019	1.P1	090 Sink Hot	1 minute flush	<1	-	128	75	<1	<1	42°C. Untempered hot. Too cold at 1 minute. 48°C at 3 minutes. 50°C at 5 minutes.
705	10 July 2019	1.P1	090 Sink Cold	1 minute flush	<1	-	<1	<1	<1	<1	Cold. End of line.
706	10 July 2019	1.P1	Recovery LHS WHB Mixer	1 minute flush	<1	-	>1000	>1000	<1	<1	40°C. Marwick. End of line.
707	10 July 2019	1.P1	100 LHS WHB Mixe	1 minute flush	<1	-	5	3	<1	<1	42°C. Contour. End of line.
708	10 July 2019	1.P1	100 Showers	Pre-Flush	-		-	-	-	-	29°C. Thermostatic mixer. Composite of 1&3. Female change. End of line.
709	10 July 2019	1.P1	102 RHS WHB Mixer	1 minute flush	<1	-	6	2	<1	<1	40°C. Contour. End of line.
710	10 July 2019	1.P1	102 Showers	Pre-Flush	-		-	-	-	-	30°C. Thermostatic mixer. Composite of 2&3. Male changine. End of line.
711	10 July 2019	1.H2	012 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	62°C. Untempered hot. End of line.
712	10 July 2019	1.H2	012 Sink Cold	1 minute flush	<1	-	35	43	<1	<1	18°C. Cold. End of line.
713	10 July 2019	1.H2	012 whb Mixer	1 minute flush	<1	-	24	22	<1	<1	44°C. Contour. End of line.
714	10 July 2019	1.H2	020 WHB Mixer	1 minute flush	<1	-	42	19	<1	<1	41°C. Marwick. End of line.
715	11 July 2019	G.K1	017 Sink Hot	1 minute flush	<1	-	16	10	<1	<1	63°C. Untempered hot. End of line.
716	11 July 2019	G.K1	017 Sink Cold	1 minute flush	<1	-	<1	7	<1	<1	18°C. Cold. End of line.
717	11 July 2019	G.K1	017 WHB Mixer	1 minute flush	<1	-	34	14	<1	<1	41°C. Contour. End of line.
718	11 July 2019	G.K1	026 WHB Mixer	1 minute flush	<1	-	240	172	<1	<1	41°C. Marwick. End of line.
719	11 July 2019	G.D2	013 Sink Hot	1 minute flush	<1	-	224	39	<1	<1	57°C. Untempered hot. End of line.
720	11 July 2019	G.D2	013 Sink Cold	1 minute flush	<1	-	2	10	<1	<1	18°C. Cold. End of line.
721	11 July 2019	G.D2	013 WHB Mixer	1 minute flush	<1	-	125	49	<1	<1	42°C. Marwick. End of line.
722	11 July 2019	G.D2	004 WHB Mixer	1 minute flush	<1	-	9	16	<1	<1	41°C. Contour. End of line.
723	11 July 2019	G.Q1	017 Sink Hot	1 minute flush	<1	-	12	8	<1	<1	63.1°C. Untempered hot. End of line.
724	11 July 2019	G.Q1	017 Sink Cold	1 minute flush	<1	-	1	2	<1	<1	17°C. Cold. End of line.
725	11 July 2019	G.Q1	017 WHB Mixer	1 minute flush	<1	-	28	48	<1	<1	42°C. Marwick. End of line.
726	11 July 2019	G.Q1	019 WHB Mixer	1 minute flush	<1	-	1	<1	<1	<1	47°C. Contour. End of line. Too hot.
727	11 July 2019	G.Q1	052 Sink Hot	1 minute flush	<1	-	4	8	<1	<1	63°C. Untempered hot. End of line.
728	11 July 2019	G.Q1	052 Sink Cold	1 minute flush	<1	-	1	2	<1	<1	17°C. Cold. End of line.
729	11 July 2019	G.Q1	052 WHB Mixer	1 minute flush	<1	-	107	39	<1	<1	40°C. Marwick. End of line.
730	11 July 2019	G.Q1	048 WHB Mixer	1 minute flush	<1	-	4	4	<1	<1	45°C. Contour. End of line.
731	11 July 2019	G.Q1	102 Sink Hot	1 minute flush	<1	-	2	<1	<1	<1	61°C. Untempered hot. End of line.
732	11 July 2019	G.Q1	102 Sink Cold	1 minute flush	<1	-	<1	2	<1	<1	17°C. Cold. End of line.
733	11 July 2019	G.Q1	102 WHB Mixer	1 minute flush	<1	-	40	21	<1	<1	40°C. Marwick. End of line.
734	11 July 2019	G.Q1	097 WHB Mixer	1 minute flush	<1	-	16	3	<1	<1	42°C. Contour. End of line.
735	11 July 2019	G.N1	003 WHB Mixer	1 minute flush	<1	-	<1	1	<1	<1	42°. Contour. End of line.
736	11 July 2019	G.N1	004 WHB Mixer	Pre-Flush	-		-	-	-	-	36°C. Contour. End of line.
737	11 July 2019	G.Q1	081 WHB Mixer	1 minute flush	<1	-	208	188	<1	<1	41°C. Marwick. Near end of line.
738	11 July 2019	G.M1	005 Sink Hot	1 minute flush	<1	-	640	584	<1	<1	49°C. Untempered hot. End of line. Too cool after 1 minute.
739	11 July 2019	G.M1	005 Sink Cold	1 minute flush	<1	-	1	<1	<1	<1	18°C. Cold. End of line.
740	11 July 2019	G.M1	005 WHB Mixer	1 minute flush	<1	-	288	384	<1	<1	42°C. Marwick. End of line.
741	11 July 2019	G.M1	045 WHB Mixer	1 minute flush	<1	-	>1000	>1000	<1	<1	39°C. Contour. End of line.
742	11 July 2019	G.A1	031 Sink Hot	1 minute flush	<1	-	272	160	<1	<1	53°C. Untempered hot. Too cool after 1 minute. End of line.
743	11 July 2019	G.A1	031 Sink Cold	1 minute flush	<1	-	22	29	<1	<1	18°C. End of line.
744	11 July 2019	G.A1	033 WHB Mixer	1 minute flush	<1	-	>1000	>1000	<1	<1	42°C. Contour. End of line.
745	11 July 2019	G.A1	031 WHB Mixer	1 minute flush	<1	-	32	212	<1	<1	40°C. Marwick. End of line.
746	11 July 2019	G.A1	035 WHB Mixer	1 minute flush	<1	-	304	152	<1	<1	41°C. Marwick. End of line.
747	11 July 2019	G.A1	042 WHB Mixer	1 minute flush	<1	-	15	18	<1	<1	39°C. Contour. End of line.
748	11 July 2019	G.A1	047 WHB Mixer	1 minute flush	<1	-	18	16	<1	<1	43°C. Contour. End of line.
749	11 July 2019	G.A1	056 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	51°C. Untempered hot. Too cool. Near end of line.
750	11 July 2019	G.A1	056 Sink Cold	1 minute flush	<1	-	<1	1	<1	<1	18°C. Cold. Near end of line.
751	11 July 2019	G.A2	031 WHB Mixer	1 minute flush	<1	-	52	37	<1	<1	41°C. Marwick. End of line.

752	11 July 2019	G.A2	032 Shower	Pre-Flush	-		-	-	-	-	31°C. Thermostatic mixer. End of line.
753	11 July 2019	G.A2	040 Sink Hot	1 minute flush	<1	-	11	14	<1	<1	40°C. Via TMV. Near riser.
754	11 July 2019	G.A2	040 Sink Cold	1 minute flush	<1	-	1	<1	<1	<1	21°C. Cold. Near riser. Too warm.
755	11 July 2019	G.A2	080 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	62°C. Untempered hot. End of line.
756	11 July 2019	G.A2	080 Sink Cold	1 minute flush	<1	-	2	5	<1	<1	26°C. Cold. End of line. Too Warm.
757	11 July 2019	G.A2	080 WHB Mixer	1 minute flush	<1	-	1	<1	<1	<1	44°C. Marwick. End of line.
758	11 July 2019	G.A2	076 WHB Mixer	1 minute flush	<1	-	5	4	<1	<1	42°C. Contour. Near end of line.
759	11 July 2019	G.A2	076 Arjo Spray	Pre-Flush	-		-	-	-	-	31°C. Arjo-pre-mixed discharge.
760	11 July 2019	G.F1	088 Wall Spout Hot	1 minute flush	<1	-	80	71	<1	<1	42°C. Button operated.
761	11 July 2019	G.F1	088 Wall Spout Cold	1 minute flush	<1	-	65	92	<1	<1	41°C. Button operated.
762	11 July 2019	G.F1	088 Shower	Pre-Flush	-		-	-	-	-	18°C. Button operated.
763	11 July 2019	G.F1	057 Sink Hot	1 minute flush	<1	-	<1	<1	<1	<1	63°C. Untempered hot. Near end of line.
764	11 July 2019	G.F1	057 Sink Cold	1 minute flush	<1	-	7	6	<1	<1	17°C. Cold. Near end of line.
765	11 July 2019	Basement	Main Kitchen MWS	2 minute flush	<1	-	<1	<1	<1	<1	15.0°C.
766	11 July 2019	Basement	Main Kitchen CWS	2 minute flush	<1	-	2	1	<1	<1	15.5°C.

Augmented Care Pseudomonas aeruginosa Sample Positive Locations

Sample	Date	Area	Location	Type	Ps.ae.	Lp	2-Day TVC	3-Day TVC	Coliforms	E.coli	Remarks
1	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
2	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Post-Flush	28	-	224	256	<1	<1	Markwik Thermostatic Tap
9	01 July 2019	3-C1.1	Room 063 Wash Hand Basin	Pre-Flush	9	-	-	-	-	-	Markwik Thermostatic Tap
11	01 July 2019	3-C1.1	Room 064 Shower	Pre-Flush	4	-	-	-	-	-	Mixed
13	01 July 2019	3-C1.1	Room 033 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
16	01 July 2019	3-C1.1	Room 035 Wash Hand Basin	Pre-Flush	47	-	-	-	-	-	Markwik Thermostatic Tap
25	01 July 2019	3-C1.1	Room 042 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap - Clean Utility
29	01 July 2019	3-C1.1	Room 041 Shower	Pre-Flush	1	-	-	-	-	-	Mixed
31	01 July 2019	3-C1.1	Room 025 Corridor Wash Hand Basin	Pre-Flush	3	-	-	-	-	-	Markwik Thermostatic Tap
38	01 July 2019	3-C1.1	Room 023 Zip Hydrotap	Pre-Flush	>100	-	>1000	>1000	<1	<1	
46	01 July 2019	3-C1.1	Room 059 Wash Hand Basin Hot	Pre-Flush	>100	-	-	-	-	-	Hot (Mixed) Wall Discharge
47	01 July 2019	3-C1.1	Room 059 Wash Hand Basin Cold	Pre-Flush	8	-	-	-	-	-	Cold (Wall Discharge)
52	01 July 2019	3-C1.1	Room 046 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
60	01 July 2019	3-C1.1	Room 049 Arjo Deluge	Pre-Flush	>100	-	-	-	-	-	Mixer - Arjo Bath
61	01 July 2019	3-C1.1	Room 049 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Arjo Bath
62	01 July 2019	3-C1.1	Room 017 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	DSR - Markwik Thermostatic Tap
66	01 July 2019	3-C1.1	Room 052 Corridor Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
78	01 July 2019	3-C1.1	Room 015 Wash Hand Basin	Pre-Flush	1	-	-	-	-	-	Markwik Thermostatic Tap
84	01 July 2019	3-C1.1	Room 014 Shower 1	Pre-Flush	7	-	-	-	-	-	Thermostatic Mixer
86	01 July 2019	3-C1.1	Room 009 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
90	01 July 2019	3-C1.1	Room 010 Shower 2	Pre-Flush	>100	-	-	-	-	-	Thermostatic Mixer
105	02 July 2019	3-C1.3	Room 035 Arjo Spray	Pre-Flush	21	-	-	-	-	-	Mixed
217	02 July 2019	3-C1.4	Room 011 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Mixed - Flushed by Bouygues <2 Hours
261	03 July 2019	2-L2	Room 031 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
266	03 July 2019	2-L2	Room 010 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed (Wall Discharge)
269	03 July 2019	2-L2	Room 011 Shower	Pre-Flush	>100	-	-	-	-	-	Thermostatic Mixer
270	03 July 2019	2-L2	Room 032 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
280	03 July 2019	2-L2	Room 005 Wash Hand Basin	Pre-Flush	25	-	-	-	-	-	Markwik Thermostatic Tap
281	03 July 2019	2-L2	Room 018 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
284	03 July 2019	2-L2	Room 030 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
287	03 July 2019	2-L2	Room 034 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
293	03 July 2019	2-L2	Room 036 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
302	03 July 2019	2-L2	Room 046 Wash Hand Basin	Pre-Flush	32	-	-	-	-	-	Markwik Thermostatic Tap
334	03 July 2019	2-L2	Room 080 Arjo Deluge	Pre-Flush	>100	-	-	-	-	-	Mixed
335	03 July 2019	2-L2	Room 080 Arjo Spray	Pre-Flush	>100	-	-	-	-	-	Mixed
353	03 July 2019	2-L2	Room 125 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
356	03 July 2019	2-L2	Room 102 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
359	03 July 2019	2-L2	Room 123 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
361	03 July 2019	2-L2	Room 124 Shower	Pre-Flush	35	-	-	-	-	-	Thermostatic Mixer
362	03 July 2019	2-L2	Room 104 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
368	03 July 2019	2-L2	Room 119 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
371	03 July 2019	2-L2	Room 117 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
374	03 July 2019	2-L2	Room 113 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
380	03 July 2019	2-L2	Room 127 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
386	03 July 2019	2-L2	Room 106 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
389	03 July 2019	2-L2	Room 142 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Outlet
390	03 July 2019	2-L2	Room 143 Wash Hand Basin Hot	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Outlet
392	03 July 2019	2-L2	Room 143 Shower	Pre-Flush	>100	-	-	-	-	-	Mixed Wall Shower
393	03 July 2019	2-L2	Room 128 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Mixed
404	03 July 2019	2-L2	Room 140 Wash Hand Basin	Pre-Flush	>100	-	-	-	-	-	Markwik Thermostatic Tap
406	03 July 2019	2-L2	Room 141 Shower	Pre-Flush	1	-	-	-	-	-	Thermostatic Mixer
410	03 July 2019	2-L2	Room 084 Wash Hand Basin	Pre-Flush	7	-	-	-	-	-	Markwik Thermostatic Tap
412	03 July 2019	2-L2	Room 085 Shower	Pre-Flush	46	-	-	-	-	-	Thermostatic Mixer
420	03 July 2019	2-L2	Room 078 Sink Cold	Pre-Flush	>100	-	-	-	-	-	Mixed discharge
517	04 July 2019	1-L1	Room 054 Sink Hot	Pre-Flush	30	-	-	-	-	-	Untempered Hot. Monoblock Tap.
519	04 July 2019	1-L1	Room 054 Zip Hydrotap	Pre-Flush	>100	-	-	-	-	-	Cold. Monoblock Tap.
622	04 July 2019	G.A2	Room 074 Wash Hand Basin	Pre-Flush	5	-	-	-	-	-	Markwik Thermostatic Tap

System Condition Sampling Analysis Results

Sample	Date	Area	Location	Type	Ps.ae.	Lp	2-Day TVC	3-Day TVC	Coliforms	E.coli	Remarks
1	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
2	01 July 2019	3-C1.1	Room 065 Wash Hand Basin	Post-Flush	28	-	224	256	<1	<1	Markwik Thermostatic Tap
21	01 July 2019	3-C1.1	Room 044 Sink Hot	Pre-Flush	<1	-	1	1	<1	<1	Hot - Dirty Utility
22	01 July 2019	3-C1.1	Room 044 Sink Cold	Pre-Flush	<1	-	192	560	<1	<1	Cold - Dirty Utility
23	01 July 2019	3-C1.1	Room 044 Sink Cold	Post-Flush	<1	-	3	<1	<1	<1	Cold - Dirty Utility
35	01 July 2019	3-C1.1	Room 023 Sink Hot	Pre-Flush	<1	-	>1000	>1000	<1	<1	Pantry Mixer - Untempered
36	01 July 2019	3-C1.1	Room 023 Sink Cold	Pre-Flush	<1	-	352	>1000	<1	<1	Pantry - Cold
37	01 July 2019	3-C1.1	Room 023 Sink Cold	Post-Flush	<1	-	<1	10	<1	<1	Pantry - Cold
38	01 July 2019	3-C1.1	Room 023 Zip Hydrotap	Pre-Flush	>100	-	>1000	>1000	<1	<1	
39	01 July 2019	3-C1.1	Room 026 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
63	01 July 2019	3-C1.1	Room 017 SS Sink Hot	Pre-Flush	<1	-	1	<1	<1	<1	Hot (Tempered 2)
64	01 July 2019	3-C1.1	Room 017 SS Sink Cold	Pre-Flush	<1	-	13	560	<1	<1	Cold
65	01 July 2019	3-C1.1	Room 017 SS Sink Cold	Post-Flush	<1	-	1	7	<1	<1	Cold
86	01 July 2019	3-C1.1	Room 009 Wash Hand Basin	Pre-Flush	1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
87	01 July 2019	3-C1.1	Room 009 Wash hand basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
92	02 July 2019	3-C1.3	Room 040 Sink Cold	Pre-Flush	<1	-	24	440	<1	<1	DSR - Cold
93	02 July 2019	3-C1.3	Room 040 Sink Cold	Post-Flush	<1	-	<1	2	<1	<1	DSR - Cold
114	02 July 2019	3-C1.3	Room 034 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	Drinking Water Outlet
132	02 July 2019	3-C1.3	Room 025 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered - After Flushing by Bouygues
133	02 July 2019	3-C1.3	Room 025 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered - After Flushing by Bouygues
134	02 July 2019	3-C1.3	Room 025 Sink Cold	Pre-Flush	<1	-	62	>1000	<1	<1	Cold - After Flushing by Bouygues
135	02 July 2019	3-C1.3	Room 025 Sink Cold	Post-Flush	<1	-	1	7	<1	<1	Cold - After Flushing by Bouygues
136	02 July 2019	3-C1.3	Room 025 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - After Flushing by Bouygues
137	02 July 2019	3-C1.3	Room 025 Wash Hand Basin	Post-Flush	<1	-	63	92	<1	<1	Markwik Thermostatic Tap - After Flushing by Bouygues
142	02 July 2019	3-C1.4	Room 078 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
143	02 July 2019	3-C1.4	Room 078 Wash Hand Basin	Post-Flush	<1	-	103	108	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
144	02 July 2019	3-C1.4	Room 079 Wash Hand Basin	Pre-Flush	<1	-	336	224	<1	<1	Contour Thermostatic Tap - Flushed by Bouygues <2 Hours
148	02 July 2019	3-C1.4	Room 064 Sink Hot	Pre-Flush	<1	-	240	156	<1	<1	Untempered - Flushed by Bouygues <2 Hours
149	02 July 2019	3-C1.4	Room 064 Sink Cold	Pre-Flush	<1	-	22	47	<1	<1	Cold - Flushed by Bouygues <2 Hours
150	02 July 2019	3-C1.4	Room 064 Sink Cold	Post-Flush	<1	-	2	2	<1	<1	Cold - Flushed by Bouygues <2 Hours
151	02 July 2019	3-C1.4	Room 064 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	Flushed by Bouygues <2 Hours
227	02 July 2019	3-C1.4	Room 082 Sink Cold	Pre-Flush	<1	-	>1000	>1000	<1	<1	Cold - Flushed by Bouygues <2 Hours
228	02 July 2019	3-C1.4	Room 082 Zip Hydrotap	Pre-Flush	<1	-	>1000	>1000	<1	<1	
240	02 July 2019	3-C1.4	Room 082 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Ref Sample 227. Flushed by Bouygues <2 Hours
243	02 July 2019	3-C1.4	Reception Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
244	02 July 2019	3-C1.4	Reception Wash Hand Basin	Post-Flush	<1	-	320	612	<1	<1	Markwik Thermostatic Tap - Flushed by Bouygues <2 Hours
246	03 July 2019	2-L2	Room 015 Corridor Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
247	03 July 2019	2-L2	Room 015 Corridor Wash Hand Basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
262	03 July 2019	2-L2	Room 031 Sink Hot	Pre-Flush	<1	-	1	<1	<1	<1	Untempered
263	03 July 2019	2-L2	Room 031 Sink Hot	Post-Flush	<1	-	2	<1	<1	<1	Untempered
264	03 July 2019	2-L2	Room 031 Sink Cold	Pre-Flush	<1	-	97	816	<1	<1	Cold
265	03 July 2019	2-L2	Room 031 Sink Cold	Post-Flush	<1	-	2	2	<1	<1	Cold
323	03 July 2019	2-L2	Room 054 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered
324	03 July 2019	2-L2	Room 054 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered
325	03 July 2019	2-L2	Room 054 Sink Cold	Pre-Flush	<1	-	>1000	>1000	<1	<1	Cold
326	03 July 2019	2-L2	Room 054 Sink Cold	Post-Flush	<1	-	8	17	<1	<1	Cold
394	03 July 2019	2-L2	Room 128 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
395	03 July 2019	2-L2	Room 128 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
396	03 July 2019	2-L2	Room 128 Sink Cold	Pre-Flush	<1	-	808	>1000	<1	<1	Cold
397	03 July 2019	2-L2	Room 128 Sink Cold	Post-Flush	<1	-	<1	14	<1	<1	Cold
421	03 July 2019	2-L2	Room 078 Sink Hot	Pre-Flush	<1	-	>1000	>1000	<1	<1	Mixed discharge
422	03 July 2019	2-L2	Room 078 Zip Hydrotap	Pre-Flush	<1		>1000	>1000	<1	<1	
424	03 July 2019	2-L2	Room 075 Corridor Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap
435	04 July 2019	1-B1	Neonatal Unit SS Trough Hot	Post-Flush	<1	-	1	1	<1	<1	Untempered Hot
436	04 July 2019	1-B1	Neonatal Unit SS Trough Cold	Post-Flush	<1	-	3	1	<1	<1	Cold
444	04 July 2019	1-B1	Room 084 Drinking Fountain	Pre-Flush	<1	-	68	216	<1	<1	Cold Setting
449	04 July 2019	1-B1	Room 073 Cold	Pre-Flush	<1	-	211	312	<1	<1	Cold
450	04 July 2019	1-B1	Room 073 Sink Cold	Post-Flush	<1	-	1	1	<1	<1	Cold
466	04 July 2019	1-B1	Room 064 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
467	04 July 2019	1-B1	Room 064 Sink Hot	Post-Flush	<1	-	<1	1	<1	<1	Untempered Hot
468	04 July 2019	1-B1	Room 064 Sink Cold	Pre-Flush	<1	-	848	>1000	<1	<1	Cold
469	04 July 2019	1-B1	Room 064 Sink Cold	Post-Flush	<1	-	<1	2	<1	<1	Cold
474	04 July 2019	1-B1	Room 036 Wash Hand Basin	Post-Flush	<1	-	73	65	<1	<1	Markwik Thermostatic Tap. End of line.
488	04 July 2019	1-B1	Room 017 Wash Hand Basin	Post-Flush	<1	-	22	38	<1	<1	Markwik Thermostatic Tap. End of line.
493	04 July 2019	1-B1	Room 007 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of line.
494	04 July 2019	1-B1	Room 007 Wash Hand Basin	Post-Flush	<1	-	71	93	<1	<1	Markwik Thermostatic Tap. End of line.
495	04 July 2019	1-B1	Room 007 Sink Hot	Pre-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
496	04 July 2019	1-B1	Room 007 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot
497	04 July 2019	1-B1	Room 007 Sink Cold	Pre-Flush	<1	-	656	912	<1	<1	Cold. End of line.
498	04 July 2019	1-B1	Room 007 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. End of line.
508	04 July 2019	1-B1	Room 003 Sink Cold	Post-Flush	<1	-	1	<1	<1	<1	Cold
509	04 July 2019	1-B1	Room 003 Zip Hydrotap	Pre-Flush	<1	-	58	>1000	<1	<1	
549	04 July 2019	1-L1	Room 095 Wash Hand Basin	Pre-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of Line.
550	04 July 2019	1-L1	Room 095 Wash Hand Basin	Post-Flush	<1	-	>1000	>1000	<1	<1	Markwik Thermostatic Tap. End of Line.
551	04 July 2019	1-L1	Room 095 Sink Hot	Pre-Flush	<1	-	118	192	<1	<1	Untempered Hot. End of Line.
552	04 July 2019	1-L1	Room 095 Sink Hot	Post-Flush	<1	-	27	23	<1	<1	Untempered Hot. End of Line.
553	04 July 2019	1-L1	Room 095 Sink Cold	Pre-Flush	<1	-	40	232	<1	<1	Cold. End of Line.
554	04 July 2019	1-L1	Room 095 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. End of Line.
590	04 July 2019	1-L1	Room 033 Sink Hot	Pre-Flush	<1	-	<1	1	<1	<1	Untempered Hot. Start of Line.
591	04 July 2019	1-L1	Room 033 Sink Hot	Post-Flush	<1	-	<1	<1	<1	<1	Untempered Hot. Start of Line.
592	04 July 2019	1-L1	Room 033 Sink Cold	Pre-Flush	<1	-	552	608	<1	<1	Cold. Start of Line.
593	04 July 2019	1-L1	Room 033 Sink Cold	Post-Flush	<1	-	<1	1	<1	<1	Cold. Start of Line.
604	04 July 2019	1-L1	Room 002 Wash Hand Basin	Post-Flush	<1	-	12	4	<1	<1	End of Line
605	04 July 2019	1-L1	Room 002 Wash Hand Basin Cold	Post-Flush	<1	-	2	7	<1	<1	End of Line: Cold Setting, but Mixed Spout.
636	05 July 2019	3-C1.8	Room 005 Corridor Wash Hand Basin Mixed	1 minute flush	<1	-	32	49	<1	<1	34°C. At End of Line.
638	05 July 2019	3.C1.8	Room 012 Hot	1 minute flush	<1	-	<1	<1	<1	<1	64°C. DSR. Nearest to Riser.
639	05 July 2019	3.C1.8	Room 012 Cold	1 minute flush	<1	-	1	1	<1	<1	14°C. DSR. Nearest to Riser.
640	05 July 2019	3.C1.2	Room 010 Wash Hand Basin Mixed	1 minute flush	<1	-	60	45	<1	<1	37°C. At End of Line.
642	05 July 2019	3.C1.2	Room 013 Hot	1 minute flush	<1	-	<1	<1	<1	<1	63°C. DSR. At End of Line.
643	05 July 2019	3.C1.2	Room 013 Cold	1 minute flush	<1	-	<1	7	<1	<1	17°C. DSR. At End of Line.
644	05 July 2019	3.D9	Room 024 Wash Hand Basin Mixed	1 minute flush	<1	-	70	51	<1	<1	36°C. At End of Line.
646	05 July 2019	3.D9	Room 017 Hot	1 minute flush	<1	-	<1	<1	<1	<1	53°C. Close to End of Line. Dirty Utility.
647	05 July 2019	3.D9	Room 017 Cold	1 minute flush	<1	-	1	1	<1	<1	15°C. Close to End of Line. Dirty Utility.
648	05 July 2019	3.K2	Room 024 Wash Hand Basin	1 minute flush	<1	-	43	26	<1	<1	30°C. End of Line. Mid-point Sample.
650	05 July 2019	3.K2	Room 047 Hot	1 minute flush	<1	-	21	<1	<1	<1	64°C. DSR. Hot System. Mid-point.
651	05 July 2019	3.K2	Room 047 Cold	1 minute flush	<1	-	<1	<1	<1	<1	16°C DSR. Cold System. Mid-point.
652	05 July 2019	3.K2	Room 050 Hot	1 minute flush	<1	-	12	10	<1	<1	40°C. Single Spout Kitchen Tap - Flushed at 1 Minute of Hottest via Thermostatic Mixing Valve
653	05 July 2019	3.K2	Room 050 Cold	1 minute flush	<1	-	7	10	<1	<1	18°C. Single Spout Kitchen Tap - Flushed at 1 Minute of Coldest.
654	05 July 2019	3.K2	Room 066 Wash Hand Basin	1 minute flush	<1	-	80	41	<1	<1	32°C. Thermostatic Mixer Tap. End of Line.
656	05 July 2019	3.H3	Room 012 Hot	1 minute flush	<1	-	8	<1	<1	<1	62°C. DSR. End of Line.
657	05 July 2019	3.H3	Room 012 Cold	1 minute flush	<1	-	5	<1	<1	<1	18°C. DSR. End of Line.
658	09 July 2019	2.S5	005 Female Change WHB	1 minute flush	<1		10	13	<1	<1	38°C. Contour. End of line.
660	09 July 2019	2.S5	004 Male Change WHB	1 minute flush	<1		15	14	<1	<1	41°C. Contour. End of line.
662	09 July 2019	2.S5	003 DSR Sink Hot	1 minute flush	<1		<1	<1	<1	<1	51°C. Untempered Hot. End of line. Too cool.
663	09 July 2019	2.S5	003 DSR Sink Cold	1 minute flush	<1		4	<1	<1	<1	16°C. Cold. End of line.
664	09 July 2019	2.S5	003 DSR whb Mixed	1 minute flush	<1		61	53	<1	<1	37°C. Markwick - End of line.
665	09 July 2019	2.M2	009 Pantry Sink Hot	1 minute flush	<1		21	<1	<1	<1	43°C. Via TMV. End of line.
666	09 July 2019	2.M2	009 Pantry Sink Cold	1 minute flush	<1		3	<1	<1	<1	17°C. Cold. End of line.
667	09 July 2019	2.M2	009 Pantry WHB Mixer	1 minute flush	<1		19	7	<1	<1	38°C. Marwick - end of line.
669	10 July 2019	2.M2	007 Bath Hot	1 minute flush	<1		<1	<1	<1	<1	60°C. Untempered hot. End of line.
670	09 July 2019	2.M4	018 whb Mixer	1 minute flush	<1		76	57	<1	<1	41°C. Marwick - end of line.
671	09 July 2019	2.M4	006 WHB Mixer	1 minute flush	<1		5	7	<1	<1	41°C. Contour. Near end of line.
672	09 July 2019	2.G2	002 Sink Hot	1 minute flush	<1		3	<1	<1	<1	63°C. Untempered hot. Near riser. DSR.
673	10 July 2019	2.G2	002 Sink Cold	1 minute flush	<1		<1	5	<1	<1	17°C. Cold. Near riser. DSR.
674	09 July 2019	2.R1	057 Sink Hot	1 minute flush	<1		<1	<1	<1	<1	65°C. Untempered hot. Near riser. BOA.
675	09 July 2019	2.R1	057 Sink Cold	1 minute flush	<1		2	<1	<1	<1	17°C. Cold. Near riser. BOA.
676	09 July 2019	2.R1	016 WHB Mixer	1 minute flush	<1		38	<1	<1	<1	45°C. Contour. Mid line. Disabled
677	09 July 2019	2.R1	060 Sink Hot	1 minute flush	<1		9	14	<1	<1	62°C. Untempered hot. End of line. BOA.
678	09 July 2019	2.R1	060 Sink Cold	1 minute flush	<1		<1	1	<1	<1	19°C. Cold. End of line. BOA.
679	09 July 2019	2.R1	032 whb Mixer	1 minute flush	<1		12	3	<1	<1	44°C. Contour. End of line. Disabled.
680	09 July 2019	2.R1	034 Sink Cold	1 minute flush	<1		<1	2	<1	<1	16°C. Cold. End of line. DSR.
681	09 July 2019	2.R1	034 Sink Hot	1 minute flush	<1		3	1	<1	<1	64°C. Untempered hot. End of line. DSR.
682	09 July 2019	2.R1	034 WHB Mixer	1 minute flush	<1		132	85	<1	<1	44°C. Marwick - end of line.
683	10 July 2019	1.D4	010 Sink Hot	1 minute flush	<1		2	<1	<1	<1	64°C. Untempered hot. Mid point.
684	10 July 2019	1.D4	010 Sink Cold	1 minute flush	<1		<1	1	<1	<1	17°C. Cold. Mid point.
685	10 July 2019	1.D1	048 WHB Mixer	1 minute flush	<1		55	29	<1	<1	42°C. Marwick - end of line.
686	10 July 2019	1.D6	006 WHB Mixer	1 minute flush	<1		3	6	<1	<1	41°C. Contour. End of line.
687	10 July 2019	1.D6	019 Sink Hot	1 minute flush	<1		<1	<1	<1	<1	62°C. Untempered hot. Near end line.

688	10 July 2019	1.D6	019 Sink Cold	1 minute flush	<1	5	<1	<1	<1	18°C. Cold. Near end line.
689	10 July 2019	1.D6	019 WHB Mixer	1 minute flush	<1	93	28	<1	<1	42°C. Marwick - near end of line.
690	10 July 2019	1.D1	010 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	64°C. Dirty unit. Untempered hot. Near riser.
691	10 July 2019	1.D1	010 Sink Cold	1 minute flush	<1	<1	3	<1	<1	16°C. Dirty unit. Cold. Near riser.
693	10 July 2019	1.P1	163 Sink Hot	1 minute flush	<1	<1	3	<1	<1	63°C. Untempered hot. DSR. Mid point.
694	10 July 2019	1.P1	163 Sink Cold	1 minute flush	<1	1	<1	<1	<1	16°C. Cold. DSR. Mid point.
695	10 July 2019	1.P1	010 WHB Mixer	1 minute flush	<1	296	184	<1	<1	41°C. Marwick. End of line
696	10 July 2019	1.P1	011 whb Mixer	1 minute flush	<1	14	5	<1	<1	42°C. Contour. End of line.
698	10 July 2019	1.P1	012 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	58°C. Untempered hot. End of line.
699	10 July 2019	1.P1	012 Sink Cold	1 minute flush	<1	13	9	<1	<1	23°C. Cold. End of line. Too warm.
700	10 July 2019	1.P1	012 whb Mixer	1 minute flush	<1	208	132	<1	<1	42°C. Marwick. End of line.
702	10 July 2019	1.P1	183 Sink Mixer Pre-flush	1 minute flush	<1	>1000	>1000	<1	<1	Pre-flush. Marwick. Mid point.
703	10 July 2019	1.P1	183 Sink Mixer Post Flush	1 minute flush	<1	208	256	<1	<1	Post flush. Marwick. Mid point.
704	10 July 2019	1.P1	090 Sink Hot	1 minute flush	<1	128	75	<1	<1	42°C. Untempered hot. Too cold at 1 minute. 48°C at 3 minutes. 50°C at 5 minutes.
705	10 July 2019	1.P1	090 Sink Cold	1 minute flush	<1	<1	<1	<1	<1	Cold. End of line.
706	10 July 2019	1.P1	Recovery LHS WHB Mixer	1 minute flush	<1	>1000	>1000	<1	<1	40°C. Marwick. End of line.
707	10 July 2019	1.P1	100 LHS WHB Mixe	1 minute flush	<1	5	3	<1	<1	42°C. Contour. End of line.
709	10 July 2019	1.P1	102 RHS WHB Mixer	1 minute flush	<1	6	2	<1	<1	40°C. Contour. End of line.
711	10 July 2019	1.H2	012 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	62°C. Untempered hot. End of line.
712	10 July 2019	1.H2	012 Sink Cold	1 minute flush	<1	35	43	<1	<1	18°C. Cold. End of line.
713	10 July 2019	1.H2	012 whb Mixer	1 minute flush	<1	24	22	<1	<1	44°C. Contour. End of line.
714	10 July 2019	1.H2	020 WHB Mixer	1 minute flush	<1	42	19	<1	<1	41°C. Marwick. End of line.
715	11 July 2019	G.K1	017 Sink Hot	1 minute flush	<1	16	10	<1	<1	63°C. Untempered hot. End of line.
716	11 July 2019	G.K1	017 Sink Cold	1 minute flush	<1	<1	7	<1	<1	18°C. Cold. End of line.
717	11 July 2019	G.K1	017 WHB Mixer	1 minute flush	<1	34	14	<1	<1	41°C. Contour. End of line.
718	11 July 2019	G.K1	026 WHB Mixer	1 minute flush	<1	240	172	<1	<1	41°C. Marwick. End of line.
719	11 July 2019	G.D2	013 Sink Hot	1 minute flush	<1	224	39	<1	<1	57°C. Untempered hot. End of line.
720	11 July 2019	G.D2	013 Sink Cold	1 minute flush	<1	2	10	<1	<1	18°C. Cold. End of line.
721	11 July 2019	G.D2	013 WHB Mixer	1 minute flush	<1	125	49	<1	<1	42°C. Marwick. End of line.
722	11 July 2019	G.D2	004 WHB Mixer	1 minute flush	<1	9	16	<1	<1	41°C. Contour. End of line.
723	11 July 2019	G.Q1	017 Sink Hot	1 minute flush	<1	12	8	<1	<1	63.1°C. Untempered hot. End of line.
724	11 July 2019	G.Q1	017 Sink Cold	1 minute flush	<1	1	2	<1	<1	17°C. Cold. End of line.
725	11 July 2019	G.Q1	017 WHB Mixer	1 minute flush	<1	28	48	<1	<1	42°C. Marwick. End of line.
726	11 July 2019	G.Q1	019 WHB Mixer	1 minute flush	<1	1	<1	<1	<1	47°C. Contour. End of line. Too hot.
727	11 July 2019	G.Q1	052 Sink Hot	1 minute flush	<1	4	8	<1	<1	63°C. Untempered hot. End of line.
728	11 July 2019	G.Q1	052 Sink Cold	1 minute flush	<1	1	2	<1	<1	17°C. Cold. End of line.
729	11 July 2019	G.Q1	052 WHB Mixer	1 minute flush	<1	107	39	<1	<1	40°C. Marwick. End of line.
730	11 July 2019	G.Q1	048 WHB Mixer	1 minute flush	<1	4	4	<1	<1	45°C. Contour. End of line.
731	11 July 2019	G.Q1	102 Sink Hot	1 minute flush	<1	2	<1	<1	<1	61°C. Untempered hot. End of line.
732	11 July 2019	G.Q1	102 Sink Cold	1 minute flush	<1	<1	2	<1	<1	17°C. Cold. End of line.
733	11 July 2019	G.Q1	102 WHB Mixer	1 minute flush	<1	40	21	<1	<1	40°C. Marwick. End of line.
734	11 July 2019	G.Q1	097 WHB Mixer	1 minute flush	<1	16	3	<1	<1	42°C. Contour. End of line.
735	11 July 2019	G.N1	003 WHB Mixer	1 minute flush	<1	<1	1	<1	<1	42°. Contour. End of line.
737	11 July 2019	G.Q1	081 WHB Mixer	1 minute flush	<1	208	188	<1	<1	41°C. Marwick. Near end of line.
738	11 July 2019	G.M1	005 Sink Hot	1 minute flush	<1	640	584	<1	<1	49°C. Untempered hot. End of line. Too cool after 1 minute.
739	11 July 2019	G.M1	005 Sink Cold	1 minute flush	<1	1	<1	<1	<1	18°C. Cold. End of line.
740	11 July 2019	G.M1	005 WHB Mixer	1 minute flush	<1	288	384	<1	<1	42°C. Marwick. End of line.
741	11 July 2019	G.M1	045 WHB Mixer	1 minute flush	<1	>1000	>1000	<1	<1	39°C. Contour. End of line.
742	11 July 2019	G.A1	031 Sink Hot	1 minute flush	<1	272	160	<1	<1	53°C. Untempered hot. Too cool after 1 minute. End of line.
743	11 July 2019	G.A1	031 Sink Cold	1 minute flush	<1	22	29	<1	<1	18°C. End of line.
744	11 July 2019	G.A1	033 WHB Mixer	1 minute flush	<1	>1000	>1000	<1	<1	42°C. Contour. End of line.
745	11 July 2019	G.A1	031 WHB Mixer	1 minute flush	<1	32	212	<1	<1	40°C. Marwick. End of line.
746	11 July 2019	G.A1	035 WHB Mixer	1 minute flush	<1	304	152	<1	<1	41°C. Marwick. End of line.
747	11 July 2019	G.A1	042 WHB Mixer	1 minute flush	<1	15	18	<1	<1	39°C. Contour. End of line.
748	11 July 2019	G.A1	047 WHB Mixer	1 minute flush	<1	18	16	<1	<1	43°C. Contour. End of line.
749	11 July 2019	G.A1	056 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	51°C. Untempered hot. Too cool. Near end of line.
750	11 July 2019	G.A1	056 Sink Cold	1 minute flush	<1	<1	1	<1	<1	18°C. Cold. Near end of line.
751	11 July 2019	G.A2	031 WHB Mixer	1 minute flush	<1	52	37	<1	<1	41°C. Marwick. End of line.
753	11 July 2019	G.A2	040 Sink Hot	1 minute flush	<1	11	14	<1	<1	40°C. Via TMV. Near riser.
754	11 July 2019	G.A2	040 Sink Cold	1 minute flush	<1	1	<1	<1	<1	21°C. Cold. Near riser. Too warm.
755	11 July 2019	G.A2	080 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	62°C. Untempered hot. End of line.
756	11 July 2019	G.A2	080 Sink Cold	1 minute flush	<1	2	5	<1	<1	26°C. Cold. End of line. Too Warm.
757	11 July 2019	G.A2	080 WHB Mixer	1 minute flush	<1	1	<1	<1	<1	44°C. Marwick. End of line.
758	11 July 2019	G.A2	076 WHB Mixer	1 minute flush	<1	5	4	<1	<1	42°C. Contour. Near end of line.
760	11 July 2019	G.F1	088 Wall Spout Hot	1 minute flush	<1	80	71	<1	<1	42°C. Button operated.
761	11 July 2019	G.F1	088 Wall Spout Cold	1 minute flush	<1	65	92	<1	<1	41°C. Button operated.
763	11 July 2019	G.F1	057 Sink Hot	1 minute flush	<1	<1	<1	<1	<1	63°C. Untempered hot. Near end of line.
764	11 July 2019	G.F1	057 Sink Cold	1 minute flush	<1	7	6	<1	<1	17°C. Cold. Near end of line.
765	11 July 2019		Main Kitchen MWS	2 minute flush	<1	<1	<1	<1	<1	15.0°C.
766	11 July 2019		Main Kitchen CWS	2 minute flush	<1	2	1	<1	<1	15.5°C.

Legionella Sample Locations (Note; not all analyses complete at 17th July)

Sample	Date	Area	Location	Type	Ps.ae.	Lp	2-Day TVC	3 Day TVC	Coliforms	E.coli	Remarks
5	01/07/2019	3-C1.1	Room 066 Shower	Pre-Flush	-	<40	-	-	-	-	Mixed
91	01/07/2019	3-C1.1	Room 010 Shower 2	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
145	02/07/2019	3-C1.4	Room 078 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer - Flushed by Bouygues <2 Hours
277	03/07/2019	2-L2	Room 015 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
416	03/07/2019	2-L2	Room 093 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
417	03/07/2019	2-L2	Room 088 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
607	04/07/2019	1-L1	Room 003 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
608	04/07/2019	1-L1	Room 022 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer. Shower Fault - No Hot.
609	04/07/2019	1-L1	Room 069 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
610	04/07/2019	1-L1	Room 092 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
611	04/07/2019	1-L1	Room 098 Wash Hand Basin	Pre-Flush	-	<40	-	-	-	-	Markwik Thermostatic Tap
612	04/07/2019	1-L1	Room 032 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
613	04/07/2019	1-L1	Room 074 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
621	04/07/2019	1.H2	Room 018 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
626	04/07/2019	G.A2	Room 073 Shower	Pre-Flush	-	<40	-	-	-	-	Thermostatic Mixer
635	04/07/2019	1.D7	Room 001 Arjo Spray	Pre-Flush	-	<40	-	-	-	-	Arjo Bath - Mixed
637	05/07/2019	3.C1.8	Room 006 Shower	Pre-Flush	-	<40	-	-	-	-	37°C. At End of Line.
641	05/07/2019	3.C1.2	Room 003 Shower	Pre-Flush	-	<40	-	-	-	-	38°C. At End of Line.
645	05/07/2019	3.D9	Room 025 Shower	Pre-Flush	-	<40	-	-	-	-	36°C. At End of Line.
649	05/07/2019	3.K2	Room 024 Shower	Pre-Flush	-	<40	-	-	-	-	28°C. End of Line. Manual Mixer.
655	05/07/2019	3.K2	Room 066 Shower	Pre-Flush	-	<40	-	-	-	-	33°C. Manual Mixer. End of Line.
659	09/07/2019	2.S5	005 Female Change Shower	Pre-Flush	-		-	-	-	-	Composite of 1&5. End of line.
661	09/07/2019	2.S5	004 Male Change Shower	Pre-Flush	-		-	-	-	-	Composite of 1&3. End of line.
668	09/07/2019	2.M2	007 Shower	Pre-Flush	-		-	-	-	-	Thermostatic Mixer. End of line.
692	10/07/2019	1.D6	019 Shower	Pre-Flush	-		-	-	-	-	Thermostatic mixer.
697	10/07/2019	1.P1	006 Shower	Pre-Flush	-		-	-	-	-	Thermostatic mixer.
701	10/07/2019	1.P1	012 whb Mixer	Pre-Flush	-		-	-	-	-	Marwick. End of line.
708	10/07/2019	1.P1	100 Showers	Pre-Flush	-		-	-	-	-	Thermostatic mixer. Composite of 1&3. Female change. End of line.
710	10/07/2019	1.P1	102 Showers	Pre-Flush	-		-	-	-	-	Thermostatic mixer. Composite of 2&3. Male changine. End of line.
736	11/07/2019	G.N1	004 WHB Mixer	Pre-Flush	-		-	-	-	-	Contour. End of line.
752	11/07/2019	G.A2	032 Shower	Pre-Flush	-		-	-	-	-	Thermostatic mixer. End of line.
759	11/07/2019	G.A2	076 Arjo Spray	Pre-Flush	-		-	-	-	-	Arjo-pre-mixed discharge.
762	11/07/2019	G.F1	088 Shower	Pre-Flush	-		-	-	-	-	Button operated.

Pseudomonas aeruginosa Positive Markwik Taps - Investigative Sampling Results - 12th July 2019

Sample	Date	Area	Location	Type	Ps.ae.	Lp	2-Day TVC	3 Day TVC	Coliforms	E.coli	Remarks
1	12/07/2019	3-C1.1 033	Hot After Service Valve		<1		<1	<1	<1	<1	Hot tertiary return range 60.1°C - 60.7°C.
2	12/07/2019	3-C1.1 033	Cold After Service Valve		<1		>1000	>1000	<1	<1	Cold tertiary return range 18.7°C - 18.8°C.
3	12/07/2019	3-C1.1 033	Hot TMV Inlet		<1		<1	1	<1	<1	
4	12/07/2019	3-C1.1 033	Cold TMV Inlet		<1		576	528	<1	<1	
5	12/07/2019	3-C1.1 033	TMV Outlet Spout Removed		24		>1000	>1000	<1	<1	
6	12/07/2019	3-C1.1 033	Spout Discharge		3		>1000	>1000	<1	<1	
7	12/07/2019	3.C1.1 046	Hot After Service Valve		<1		1	<1	<1	<1	Hot tertiary return range 57.5°C - 57.7°C.
8	12/07/2019	3.C1.1 046	Cold After Service Valve		<1		>1000	>1000	<1	<1	Cold tertiary return range 15.9°C - 16.5°C.
9	12/07/2019	3.C1.1 046	Hot TMV Inlet		<1		432	240	<1	<1	
10	12/07/2019	3.C1.1 046	Cold TMV Inlet		50		>1000	>1000	<1	<1	
11	12/07/2019	3.C1.1 046	TMV Outlet Spout Removed		>100		>1000	>1000	<1	<1	
12	12/07/2019	3.C1.1 046	Spout Discharge		>100		560	392	<1	<1	
13	12/07/2019	2.L2 018	Hot After Service Valve		<1		<1	<1	<1	<1	Hot tertiary return range 57.4°C - 58.1°C.
14	12/07/2019	2.L2 018	Cold After Service Valve		<1		272	>1000	<1	<1	Cold tertiary return range 16.7°C - 17.5°C.
15	12/07/2019	2.L2 018	Hot TMV Inlet		<1		336	448	<1	<1	
16	12/07/2019	2.L2 018	Cold TMV Inlet		1		>1000	>1000	<1	<1	
17	12/07/2019	2.L2 018	TMV Outlet Spout Removed		>100		>1000	>1000	<1	<1	
18	12/07/2019	2.L2 018	Spout Discharge		80		>1000	>1000	<1	<1	
19	12/07/2019	2.L2 119	Hot After Service Valve		<1		<1	<1	<1	<1	Hot tertiary return range 56.4°C - 56.9°C.
20	12/07/2019	2.L2 119	Cold After Service Valve		<1		400	>1000	<1	<1	Cold tertiary return range 18.4°C - 19.5°C.
21	12/07/2019	2.L2 119	Hot TMV Inlet		1		640	472	<1	<1	
22	12/07/2019	2.L2 119	Cold TMV Inlet		4		>1000	>1000	<1	<1	
23	12/07/2019	2.L2 119	TMV Outlet Spout Removed		>100		>1000	>1000	<1	<1	
24	12/07/2019	2.L2 119	Spout Discharge		>100		>1000	>1000	<1	<1	
25	12/07/2019	2.L2 078	Hot	Pre-flush	2		21	18	<1	<1	Single spout tap (hot & cold). Resample.

IPCT response to Westfield Caledonian Water Safety Report: 19th July 2019

Lindsay Guthrie (Lead IPCN) Dr Donald Inverarity (Consultant Microbiologist & Lead ICD)

General comment

- NHS Lothian water safety group should be provided with a copy of the Hard FM water management plan for RHCYP as a matter of priority – this will provide further detail and assurance regarding control measures for Legionella.
- The provider should also confirm in this plan their approach to water management in relation to Pseudomonas aeruginosa in augmented care areas – as per HPS interim guidance (2018).
- The scope of the external review is limited only to augmented care areas – which includes Critical care, neonatal unit, haematology oncology, medical ward (Cystic Fibrosis and immunocompromised patients), plastics dressing clinic, and Neurosurgery (local definition adopted by NHS Lothian)
- The recommendations made in the report are specific to augmented care and protecting vulnerable patients. Based on experience from other NHS Boards, it would be prudent to adopt the recommendations to protect the plumbing system from ongoing seeding and compromise future water quality across the site
- It is reassuring that paediatric intensive care, haematology oncology are relatively unaffected by water quality issues
- Some anti-ligature taps are affected by Pseudomonas – need to confirm if these outlets will support use of PAL point of use filters (one of the key control measures going forwards) and explore other options if required
- Shower hose length needs to be reviewed – direct contact between the shower head and floor drain is currently possible (risk of contamination) (identified by HPS on site visit)
- Drainage was not considered within the scope of this review – at this stage, the impact of any drainage issues on the site on water delivery or quality is unknown

Table 1: Water quality issues

Page	Issue identified in report	Infection risk	Other clinical risk	Other organisational risk	NHS Lothian AE(Water) comment
1	The augmented care areas which test positive for Pseudomonas aeruginosa , these are predominantly within Dalhousie Ward (Medical Paediatric In patients) and Ward 231 (Adult Medical Neurology) Positive outlets are linked to the same riser (M2). Issues identified are localised to the outlets, and not the wider water distribution system	Risk of Pseudomonas infection (patients) through exposure to contaminated water if corrective action not taken. **Higher risk associated with Dalhousie ward – Cystic fibrosis patients will be cared for in this area – there is a risk of lung infection with recognised mortality** Risk of recurrent positive water results from these locations.	Whilst outlets test positive, there is an impact on service delivery – these outlets will be taken out of use to complete remedial work and further testing	Clarity required in relation to costs associated with water testing and remedial actions – and who will cover cost. Ongoing costs associated with regular water testing (external provider) and remedial actions to address issues If autoclaving of taps considered – costs associated with external sterilisation service and costs to increase stock of taps to facilitate turnaround time	
1	ARJO baths – all baths tested were positive for Pseudomonas and overall TVC counts were high. This includes the bath in Haematology-Oncology unit	These baths are known to be a Pseudomonas risk. Even with a cleaning and maintenance schedule, our view is these pose an unacceptable risk of invasive Pseudomonas infection to vulnerable patients from this equipment.	Pseudomonas aeruginosa readily becomes resistant to antimicrobials and a persisting environmental source of this organism in a clinical area with high antimicrobial consumption may adversely impact on	Cost pressure associated with replacement or removal of ARJO baths from some/all areas Financial and human cost of an outbreak of Pseudomonas infection	

Page	Issue identified in report	Infection risk	Other clinical risk	Other organisational risk	NHS Lothian AE(Water) comment
		It should be considered that ARJO baths in non augmented care areas (e.g. surgical wards) would pose a similar risk of infection to all patients with wounds or invasive devices	antimicrobial stewardship and treatment efficacy.	Reputational damage and potential for litigation	
1 4	The majority of Zip hydro taps (water for consumption) tested positive for Pseudomonas. This tap is known to be prone to colonisation ZIP taps demonstrated unacceptably high total viable counts (TVC) – i.e. poor drinking water quality	Whilst this does not pose a risk to patients through clinical exposure, there is a risk of retrograde seeding of Pseudomonas to other pipe work and water supply within the building			
4	System condition testing demonstrated that overall the bacteriological quality of water was satisfactory – need clarity from the AE on the statement that there may be system deterioration between	Infection risk from water supply at present is localised to specific areas (Dalhousie, Ward 231, ARJO baths) - in the absence of effective control there is a risk of retrograde seeding of		Impact on service delivery if water outlets removed from use to facilitate decontamination/disinfection	

Page	Issue identified in report	Infection risk	Other clinical risk	Other organisational risk	NHS Lothian AE(Water) comment
	tertiary return point and outlets The overall point being made is contamination is occurring local to the water outlets, not from the wider water system	Pseudomonas to other pipe work and water supply within the building			
6	Unsatisfactory microbiological load on the cold water supply (M2 riser) – this is associated with the presence of Pseudomonas in multiple outlets provided off this riser. There is evidence of biofilm creep back into hot and cold water supply	There is a risk of seeding of bacteria affecting other floors fed by this riser. This may translate into clinical infection through exposure to water as part of clinical care in areas outwith Dalhousie or Ward 231		Impact on service delivery if water outlets removed from use to facilitate decontamination/disinfection	
8	Evidence of particulate contamination in tap strainers	*"Current conditions are not conducive to maintaining the bacteriological safety of the discharged water, and this will require remediation"* Particulate matter will support growth of biofilm within water systems		"*it is considered very unlikely that the observed contamination have arisen since the commissioning process, and* ***it would appear that either the necessary cleaning and removal was not carried out at the appropriate point of the commissioning process****, or the works were ineffective*"	

Page	Issue identified in report	Infection risk	Other clinical risk	Other organisational risk	NHS Lothian AE(Water) comment
9	Issues with water temperature control Cold water temperatures were identified in excess of 20° C Hot water was identified below 55°C	Inadequate temperature control of hot and cold water will facilitate growth of Legionella – this is a risk to patients, staff and the wider public		Non compliance with Risk of litigation from non compliance with HSE (2013) 'The control of Legionella bacteria in water systems approved code of practice ' if a hospital associated case identified	

Compliance Audit

Royal Hospital for Children and Young People, Edinburgh

With Findings and Recommendations

Date: May 2019

Contents

1. Executive Summary

On a project of this size there will always be teething problems and issues that arise, so it is important that stakeholders work in partnership to address any issues that may come to the fore, and it was great to see the close relationship between NHSL site team and the FM provider team. I wish to express my thanks for the cooperation and hospitality shown during my visit by Ronnie Henderson (NHSL), Richard Hair and David Gordon (Bouygues); this was extremely helpful in allowing me to conduct the audit in an effective manner. It is important to note that each of the Bouygues staff the author encountered and interacted with during this site visits were professional and helpful.

This report was compiled following site visits to the Royal Hospital for Children and Young People (RHCYP), Edinburgh on 21st, 22nd March and 25th, 26th April and many of the items identified in the Simple Compliance audit will be repeated here but many wont, and this report is designed to give the client a high-level view of findings on site.

Observations were made during the assessment and walk about in areas of the Hospital and Energy Centre with several comments being made under each relevant section within the report, to ensure that the health and safety responsibilities of Bouygues, as Hard FM Provider and IHSL, as SPV are being discharged adequately and the significant key areas identified which should be addressed. We also carried out an audit whilst on site using our online portal "Simple Compliance" (SC) which records findings against pre-set questions and automatically provides actions to the providers for noncompliance items. The SC audit was published on 27th March. In addition, a summary of recommendations and corrective actions is included at Section 6 of this report.

IHS Lothian Ltd (IHSL) the SPV were invited to attend the initial introductory meeting, site walk round and requested to demonstrate compliance and monitoring information however, whilst they attended the introductory meeting and walk round, they have suggested the interface agreement between Bouygues and Multiplex should be utilised for the provision of information requested from the SPV. The SPV provided access to an online portal to view Multiplex documentation however, this information was a library of PDF files that were numbered and not named so it was difficult to navigate when looking for specific documents and not useful. On publishing the Simple Compliance audit IHSL contacted Callidus and requested face to face meetings to discuss the online audit and the information requested for this report. On several occasions IHSL raised concerns regards the timing of this audit as there were still a large amount of construction works being completed under the "Settlement Agreement". The author felt it was prevalent to discuss the partnership and innovative approach commissioned by NHSL however, the SPV did not agree with the authors view and stated that partnership is always practiced on this Contract.

The FM provider, Bouygues, embraced the audit and whilst supporting requests for information they demonstrated excellent compliance knowledge and as previous, have a very good relationships with the Client, NHSL.

In summary, we found the management arrangements on the contract required development to such a degree to categorise the assessment as RED (as defined below). The contract has

only been live now for a short period of just over two months. It is reported that the site was handed over to NHS Lothian under a “Settlement Agreement” where there are still construction works going on and ownership of areas under health & safety, compliance and maintenance are split between the Hard FM Provider and Construction Co, so not all areas have been passed over to Bouygues. Bouygues demonstrated they are managing the areas handed over to them with a mix of in-house engineers and contractors carrying out maintenance on the site.

	Unsatisfactory, Significant Improvements Needed	Health and safety control measures are not functioning as designed and/or will have a material impact on both statutory compliance and/or contractual obligations. Health and safety control measures are lacking or have degraded since the last audit and is a contributing factor to non-compliance. Immediate management actions need to be taken to address the deficiencies noted, (Project Co & NHSL is currently considered to be at risk).

2. Introduction

The purpose of the assessment visit was to focus on the positive elements of the health and safety management arrangements of the organisation. There was an element of compliance evidence checking however, the main objective was to identify evidence of arrangements underpinning the safety management system and how individuals at all levels within the organisations integrate safety into the day to day operations of the project.

The purpose of the report is to concisely present an overview of the findings of the assessment visit for areas where access was permitted, and evidence demonstrated.

During our visits we reviewed a few examples of management system arrangements and contract documentation. No commercially sensitive (project related) information was taken, although the report may refer to specifics as evidence of industry best practice.

The contents of this report should not be construed as acceptance that the organisation is fully compliant with all existing legislation, as only a representative sample of areas available and evidence was examined.

The following indicates some of the applicable, legislation, standards, guidance and contract documentation which have relevance to the subject areas assessed:

		Applicable areas to NHSL							
		H&S Management	Contractor Management	Statutory Compliance	Fire and Emergency Planning	Legionella	Asbestos	Performance Monitoring	Training
Reference	Project Agreement	●	●	●	●	●		●	●
	Management of Health and Safety at Work Regulations 1999	●	●	●	●			●	●
	COSHH Regulations 2002			●					●
	Electricity at Work Regulations 1989			●					
	Regulatory Reform (Fire Safety) Order 2005				●				●
	LOLER Regulations 1998			●					
	PUWER Regulations 1998			●					
	Work at Height Regulations 2005	●	●	●					
	ACOP (L8) – Control of Legionella in Water Systems			●		●			
	Control of Asbestos Regulations						●		

Note: This is not an exhaustive list of all applicable legislation, guidance etc on the project.

3. Project Details

3.1 Client

NHS Lothian

3.2 SPV

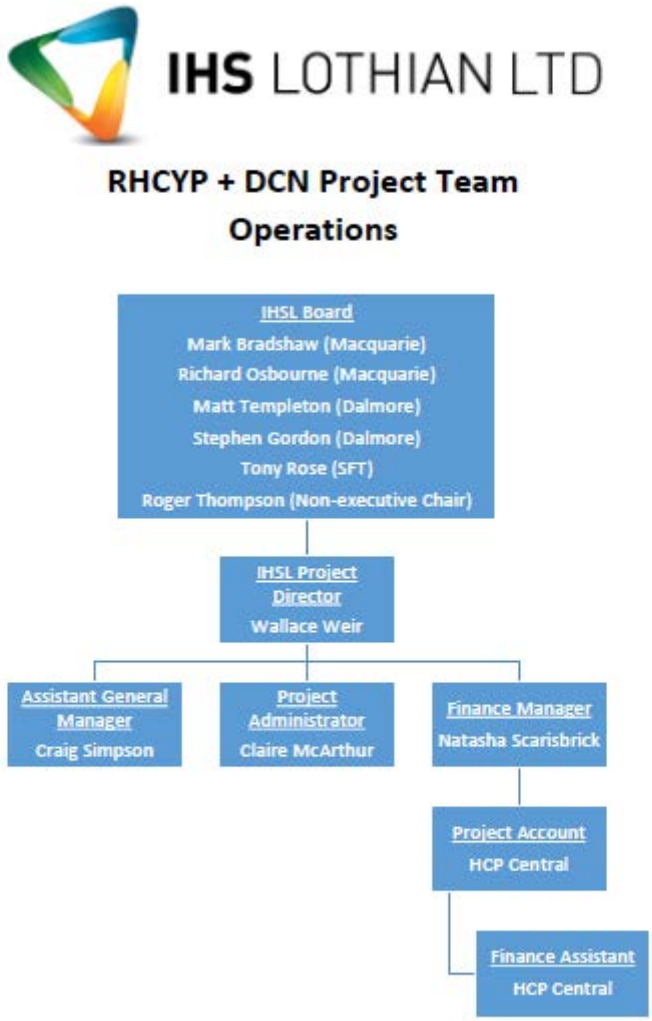
IHS Lothian LTD

3.3 Hard FM Service Provider

Bouygues FM

3.4 SPV Organisation – IHS Lothian Limited

NOTE - This organisation chart was supplied by the IHSL Project Director however, the Assistant General Manager introduced to the audit was Bob Brown who will be replaced by Craig Simpson.



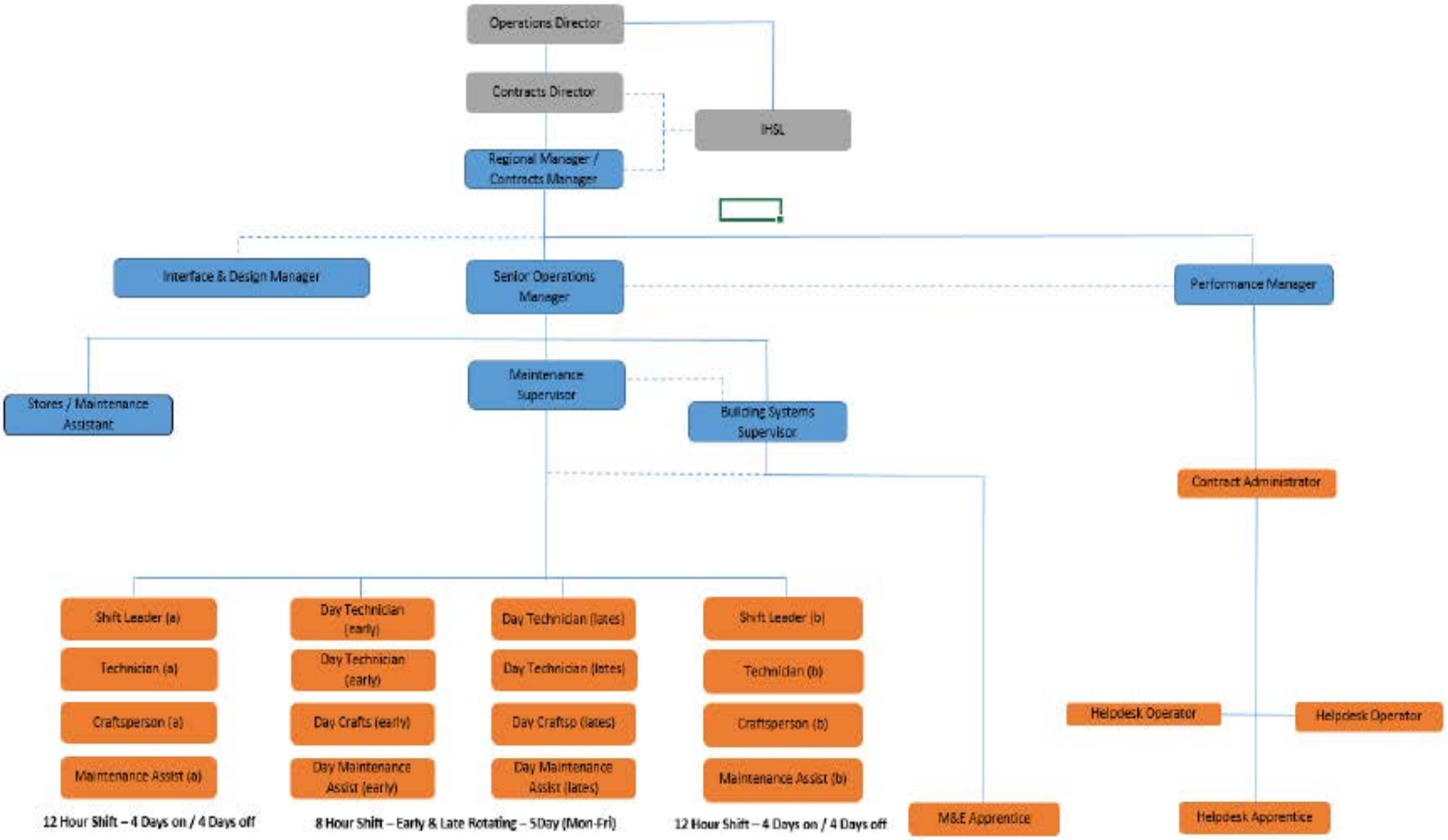
FM Structure – Bouygues FM

BOUYGUES ENERGIES & SERVICES

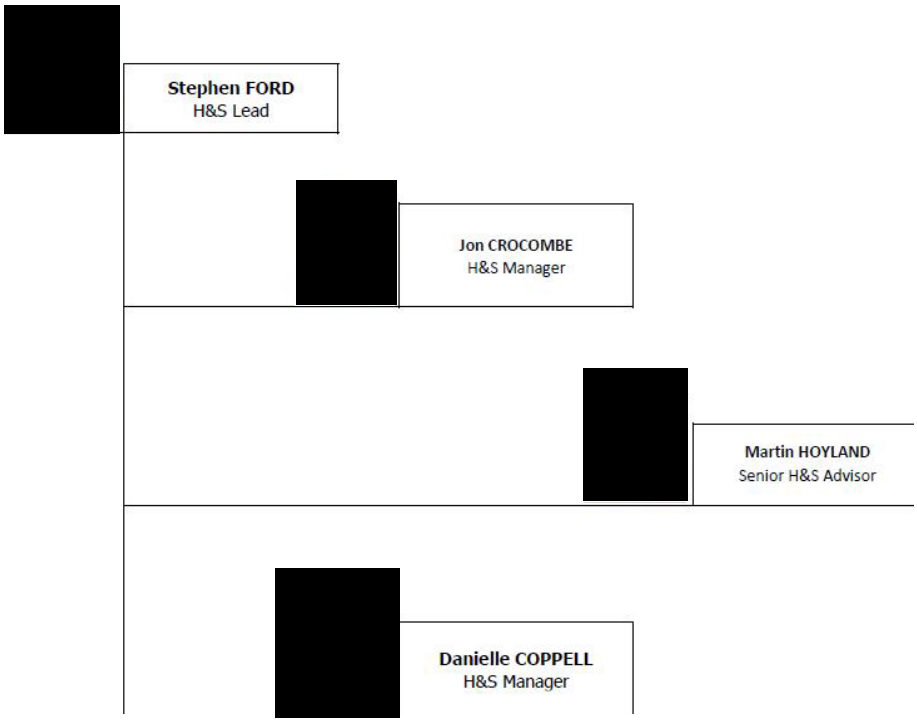
IHS LOTHIAN LTD

NHS Lothian

RHCYP & DCN Edinburgh - Bouygues E&S FM – Organisational Chart



Bouygues FM: Health and Safety (Site Support)



Bouygues: Health and Safety Organogram – Appendix B

4. Review of previous SHE Assessment

This site only handed over to NHSL, under a Settlement Agreement to allow IHSL to complete construction works, in Feb 2019 so there were no previous SHE Assessment's to review.

5. Assessment findings

5.1 Health and Safety Management

Observations:

Health and Safety Management System

The *Royal Hospital for Children and Young People, Edinburgh (RHCYP),* NHSL was handed over on 22nd February 2019 under a Settlement Agreement between *NHS Lothian* and *IHS Lothian Ltd* (SPV), an agreement that allows NHSL take handover of the building whilst construction works and remedials have still to be completed. As a result of ongoing construction works there are areas of building maintenance responsibilities that have not yet been signed off and handed over to the FM provider Bouygues; so much of the Health & Safety information for maintenance visits and first year's defects has still to be done, and for this report information was requested from IHSL and remains outstanding.

We would advise that IHSL have failed to support this audit as we normally expect from an SPV company. Initial requests for information from IHSL were put in writing and IHSL responded asking for face to face meetings. This was discussed at the first available face to face meeting on 25th April where the SPV Deputy General Manager articulated that information should be provided by Multiplex or Bouygues (through their interface agreement) and not through IHSL. Some of the evidence requested was monitoring information however, the SPV representative told the meeting that IHSL do not monitor records. This was discussed during a request that the SPV was monitoring the construction contractor to ensure water flushing was being discharged appropriately but the SPV responded that this would be "duplicating work if they were to monitor". A request was made to IHSL for the following information but to date the SPV has not provided any evidence;

- Assessment of management system documentation
- Review of management structure roles and responsibilities
- Demonstrate how IHSL will ensure SPV Management under the project agreement
- Arrangements identify and address key requirements of the contract
- Assessment of communication and performance monitoring

The Hard FM provider, Bouygues, are still collating their asset list, as packages of work are handed over, and they were able to demonstrate their PPM program covers areas that have been handed over and maintenance works are now in progress. Bouygues report that they will continue to use a number of the construction sub-contractors as specialist maintenance contractors for the first year which will support manufacturers maintenance guidance, awareness and identification of any defects.

Bouygues FM demonstrated excellent evidence of project-specific health and safety management arrangements relating to the activities on site (as required by the Project Agreement). During the audit, we consulted with Bouygues Senior Design Interface & Asset Manager, Richard Hair, who discussed and demonstrated FM health and safety project specific documentation, processes and policy. This was required to be in place upon commencement of the concession period. It is imperative that the health and safety management system is established to provide both the client and FM that on-site arrangements are adequately planned, managed and resourced.

A site walk round with IHSL and Bouygues FM, for familiarisation and visual inspection, highlighted areas for comment and recommendation within this report. These areas were discussed with stakeholders during the walk round.

Areas that were demonstrated included Roles & Responsibilities, Risk Register, General arrangements for managing H&S on the Contract, Competency Matrix for Key Personnel, Control of Contractors, Access to competent H&S advice and arrangements for monitoring and reporting performance and Duty Holder Structure for key activities (Electrical, Water, Fire, Medical Gas, etc), and FM demonstrated compliance for Duty Holder Competence and a very good structure for controlling High Risk Activities (Permit to Work system, AE, AP, CP appointments). Due to the ongoing areas of construction some information e.g. Legionella, was not available, but FM will complete the documentation to meet the compliance structure organogram once the remaining construction areas are completed and signed off.

Once the Compliance Structure is in place, Bouygues FM will have an excellent Management system that will;

- Demonstrate how FM comply with the key requirements of their FM Agreement
- Allow the SPV to monitor performance and provide meaningful reporting to NHSL based on agreed standards
- Allow NHSL to obtain demonstrable evidence of compliance against the Project Agreement
- Provide all parties with reassurance that there is a structure in place which is adequately resourced to manage the risks on site.

Guidance and Documentation

The Bouygues Contract management team demonstrated both H&S qualifications and a very good knowledge of H&S roles and responsibilities on site. They are supported by a central H&S team and Stephen Ford – Health, Safety and Environmental Lead for Bouygues E&S UK Limited, who visits the site monthly and is contactable outside of these planned visits at any time. The FM site team have access to the Bouygues Health and Safety documents on line and have a very good H&S notice board in the main corridor of the FM suite.

The HS&E Team carry out site visits to support staff performance and understanding of H&S documentation and requirements. The Bouygues HS&E team are in regular

contact with site teams to add or improve the H&S information relating to Hard FM activities. Whilst on site we recommend that Bouygues FM refer to specific health sector guidance contained within Scottish Health Technical Memoranda (SHTM) and utilise this guidance when providing FM activities.

Bouygues FM also demonstrated reporting of near misses and use this information to improve processes and information.

It is good to see a process of constant improvement, and whilst the health and safety guidance documentation on site is suitably developed to manage the specific activities undertaken. Guidance had failed to observe there was no provision of rubber matting to the floors at electrical switchgear. (See Appendix E)

Risk Management and Risk Assessment

Bouygues FM demonstrated an excellent library of H&S documentation including Risk Assessments and COSHH Assessments, all relevant to their responsibilities on site.

Bouygues FM demonstrated a proactive approach and documentation to show a good understanding of Risk Assessments and Risk Management. However, due to the Settlement Agreement and the different stakeholders on site there was some confusion regards the quality and risks in the Plant Rooms, who was responsible and the escalation process to drive remedials.

Bouygues FM advised that Plant issues have been raised to IHSL but did not appear to have any progress or completion dates, e.g. requests for Legionella information, Heat Station Plant rooms high temperatures and Heat Station Plant room flooding and humidity.

When discussed IHSL articulated the items identified did not offer any serious risk and reported that Multiplex was working on remedials and reminded that areas of the building were still under construction however, we would recommend that the areas identified do offer a number of risks and the information requested should be made available and shared with NHSL.

We have requested that IHSL support the audit and provide information to demonstrate how IHSL will ensure SPV Management under the project agreement, arrangements to identify and address key requirements of the contract, and assessment of communication and performance monitoring however, IHSL have not provided this information.

Provision of competent advice

Bouygues FM have access to the Bouygues Health, Safety & Environmental Team, a group of competent Advisors, Manager and Director. They are available to the site team by email or phone call and the HS&E Manager visits the site monthly. Through regular communication and programmed site visits they provide a good support structure across the NHS Lothian, (RHCYP) Contract and are delighted to work closely with NHSL and their advisors.

The H&S and compliance information support and feedback from the Bouygues FM site team throughout this audit was very good.

Bouygues FM demonstrated they are supported by external provider's through and were appointed through the procurement process for work tendered by FM.

Corrective Actions Required:

Ref	Findings / Recommendations
5.1.a	HV/LV AE to comment on the lack of rubber matting in electrical Plant areas and offer remedials.
5.1.b	Bouygues FM should report all building issues and self-identified maintenance through the Helpdesk including heat station issues. This provides an excellent tool to demonstrate reporting and provides the client with sight of repairs and issues.
5.1.c	We recommend that IHSL to provide evidence as requested in our Health & Safety Management System paragraphs.
5.1.d	Not used

5.2 Contractor Management

Observations:

Contractor Procurement

Hard FM sub-contractors are Bouygues approved through a strict approval process. A list of sub-contractors is available to the site team and is maintained by the Hard FM procurement team. The site team can request new contractors are added to the list through following the questionnaire process. Any contractors who do not meet the requirements of this process are not taken forward to work for Hard FM.

The contractor's questionnaire is robust with a strict question set that must be met. Contractors are approved through this approval process but also checked by the SHEQ team. The sub-contractor list is with the Hard FM procurement team.

Contractor Control on Site

Hard FM sub-contractors are required to submit RAMS online prior to any works commencing. The RAMS are reviewed by Hard FM staff and sent back to the contractor if not suitable and sufficient, once approved works commence. For PPM works, Bouygues FM informs the client of the works in advance to request access. Bouygues FM reported the client is made aware of who will be completing the works and Bouygues FM control site access, RAMS and any Permits.

Bouygues FM induct all sub-contractor staff before work commences and records are kept in the Hard FM office on site. Contractors are only allowed access to site as controlled by Bouygues FM however, this is complicated by the ongoing construction works.

Under the *Settlement Agreement* IHSL have an agreement where Multiplex are still on-site completing construction works. Although Bouygues FM control Permits for site

areas Multiplex and their contractors were seen to be moving freely around the site. NHSL also have management, Admin and Soft FM staff on site. Requests were made to IHSL for evidence of construction RAMS, Legionella information and how IHSL are performance monitoring but to date no suitable information has been provided.

Permits to Work

Bouygues FM have a Permit office in the FM suite and an excellent library of records to show that Permits are controlled and issued in line with RAMS following a site induction.

Permits are issued to control high risk activities as follows:

- Emergency Light Checks in 2nd floor Plant Room
- Hot Works – Ground floor – floor repairs
- Various others

During the assessment we examined the following Permits to Work.

Ref	Date	Area Covered	Organisation	Comments
006	21/03/19	2nd floor Plant Room	Mercury	Emergency Light Checks
HW005	13/03/19	Hot works - Ground Floor	Xtreme Flooring	Floor repairs

During the assessment, we witnessed the following Contractor Induction Records:

Date	Name	Organisation	Comments
15/03/19	Various	GSS	
11/03/19	Fran Rizzo	Musbury Fabrics	
11/03/19	Gary Ridgewell	RMCH	

Corrective Actions Required:

Ref	Findings / Recommendations
5.2.a	Although areas are controlled through the access control system, we would recommend the site access and control of contractors is tightened up on a daily basis to understand who is on site, where they should be working, what they are doing and timescales for completion, clean work area and checks/signoff.

Ref	Findings / Recommendations
5.2.b	Not used

5.3 Statutory Compliance

Observations:

PPM Systems and Management Arrangements

At present the asset information and PPM process is still being collated as there are areas under the Hard FM Contract that have still to be handed over to the Bouygues FM. This does not yet allow the Hard FM provider to have a complete plan that captures all Statutory, Mandatory, Function Critical and Discretionary assets at the appropriate frequencies however, Bouygues FM were able to demonstrate a good PPM planner that covers the areas they are currently maintaining. This planner is shared with the SPV and client prior to the programme of works commencing. As work packages are agreed, signed off and handed over Bouygues FM will add these to the planner.

Bouygues FM confirmed the PPM planner is still being complied using the asset register following SHTMs and guidance. Bouygues FM acknowledge this is still in progress and is being updated.

The site has only been handed over for a short period so many of the maintenance tasks are planned. During the assessment, the following commissioning records were inspected.

Item	Date	Inspected By	Comments
Gas Booster	15/04/19	Utile	
Passenger Lifts	19/04/19	Zurich	
Damper Control system	31/10/18	Safegard Systems	
Anchor point test	13/06/17	Arjo	
Lightning Protection	19/04/19	PTSG	
Boilers	16/08/18	Bosch	
Generators	26/03/19	Dieselec Thistle	

Corrective Actions Required:

Ref	Findings / Recommendations
5.3.a	We recommend that Bouygues keep NHSL updated as they receive handover of packages and areas of the building regards information, quality and any issues.
5.3.b	Not used

Ref	Findings / Recommendations
5.3.c	Not used

5.4 Fire and Emergency Planning

Observations:

Fire maintenance is part of the Hard FM Contract however, there are areas of ongoing construction works where, its reported, that void detection above bedroom areas was an addition so the Fire maintenance has not yet been fully handed over. Further information was requested from IHSL then again on 25/03/19 from Multiplex but this has still to be provided.

It was observed that the construction contractor is using Energy Centre space to store construction materials. The housekeeping of the construction materials in the boiler house highlighted poor management and several risks including blocking a fire exit, risks from slips trips and falls. (See appendix F)

Fire Risk Strategy and Fire Risk Assessments

*This is a NHS Lothian action and at the time of the audits the Fire Officer (Jim Gardiner) had completed a FRA on 16/07/18 that covered the fit out stage and joint occupancy (commissioning) period. This will be superseded when to Settlement Agreement works are complete and the full building and systems has been handed over ready for patient access.

During the assessment we examined the maintenance records for fire equipment as follows:

Item	Date	Inspected By	Comments
Fire Alarm Quarterly	24/01/19	Boston Networks	
Emergency Lighting	PPM	Bouygues	
Fire Damper (Commissioning)	31/10/18	Safegard Systems	Maintenance by Swegon – to start
Emergency Lighting (Routine)	Monthly PPM	Bouygues	
Fire Extinguisher	Sep 18	Walker Fire	
Fire Door Inspection	PPM	Scotdor	
Fire Strategy	03/09/18	WSP	
Emergency Lighting (Periodic)		NR	

Corrective Actions Required:

Ref	Findings / Recommendations
5.4.a	We recommend that Bouygues keep NHSL updated as they receive handover of the fire detection infrastructure regards information, quality and any issues.

Ref	Findings / Recommendations
5.4.b	NHSL Fire Officer to complete FRA and make available to the SPV and FM provider prior to patient occupation.
5.4.c	Not used
5.4.d	Not used

5.5 Legionella

Observations:

Due to the Settlement Agreement the Legionella completions were still underway and remained with the construction company, Multiplex. A request for information was submitted to IHSL however, no information was provided by IHSL although they did confirm its existence and that Multiplex would supply this information.

Various areas of legionella risk were identified during the site walk round and details recorded later in this report.

In the Simple Compliance audit, all Legionella actions were assigned to the IHSL Project Director, as discussed with the Project Director prior to the audit taking place.

Although water systems have still to be handed over to the Hard FM provider, Bouygues commissioned their specialist contractor, Clira Water Hygiene Specialists, to deliver a Legionella Risk Assessment and Water Hygiene Survey Report which was completed on 21st Feb 19. The survey at that time identifies the overall risk rating for the site as high.

Observations: Main Building

4th Floor Labs

The audit was guided around areas including fourth floor rooms and looked at a section of the Laboratory area. These rooms have flushing sheets present that identify outlets in the room with dates and signatures for flushing however, it was noted that outlets for clinical equipment were not identified on the flushing sheets and were not being flushed. This was discussed with IHSL who advised that as one outlet was on a return loop, the area of "dead leg" was under 100mm and small enough that it did not require being flushed. The author did not agree with this as it was still an outlet and suggested this should be added. In the following room another area of pipework for clinical equipment was identified, this time is was considerably over the 100mm but still was not identified on the flushing sheet. The author suggested this highlighted a risk across this area, and also where outlets for clinical equipment were not being flushed. (See Appendix D)

There are various areas designed as roof courtyards/garden areas where a water supply has been added, during the audit the author requested flushing information for these areas as there was no flushing sheets available in these areas as per the rooms. The author was informed these areas are being flushed and following the meeting on Friday

26th April Multiplex provided evidence of the flushing however, we can report the evidence provided does not follow the same process as the rooms by identifying individual flushing points and we have still not witnessed suitable flushing evidence is available. As Multiplex are unable to provide suitable evidence of flushing to these areas, we recommend this is a non-compliance. We recommend these documents should have been monitored by the IHSL in their role as SPV to ensure compliance.

The author discussed Plant room areas where stand pipes are present and flushing information was not available at the time of the audit. Bouygues FM reported that the construction company have confirmed these areas are being flushed however, evidence has still to be witnessed.

The audit identified that L8 maintenance to shower heads is not currently in practice. IHSL recommend that maintenance of these areas is not required as the "site has been live since 22nd Feb 19 and the maintenance is every six months". We would recommend NHSL request sight of the Multiplex risk assessment we feel the SPV must be referring to as recommended maintenance for showerheads is quarterly. Multiplex articulated that they had disinfected the water system in Sep and Dec 18, then again in Feb 19 so this would negate the need for shower descale, and the SPV agreed with this presumption however, that author does not concur with this as flushing disinfectant through a water system does not meet the required maintenance for descaling showerheads nor does it meet the timescales, but as previous we feel the SPV must be referring to a risk assessment when stating it is a six monthly maintenance and this should be tabled by Multiplex or corrected prior to handover of the water system to the FM provider.

At the time of the audit no access was provided to inspect the internals of water tanks.

IHSL demonstrated multiple copies of testing documentation which they recommend identifies there is currently no water risk. However, we would suggest the flushing regime is not as robust as was first reported and flushing records are not duplicated across all outlets. (See Appendix D)

Scheme of Control

No scheme of control was demonstrated by IHSL.

Bouygues FM demonstrated the named individuals with Legionella Duty Holder responsibilities were: Ian Clark (AE), Alan Herkes (RP), Alan Herkes (CP), David Murphy (CP).

Name	Date Appointed	Duty Holder Role	Letter Issued Y/N
Ian Clark	18/05/18	TA	Certificate
Alan Herkes	04/02/19	AP	Yes
David Murphy	TBC	CP	TBC

During the assessment we requested the following records through IHSL but no documentation has been shared:

Record	Inspected By	Date	Comments
Calorifier Temp Checks			Requested
Water Sampling			Various provided through online portal.
Outlet Flushing		Twice weekly	Rooms have flushing sheets present. Note: some areas were missed e.g. clinical equipment outlets, courtyards, stand pipes.
Shower Descale			Requested, SPV report this is not required.
Outlet Temps			Requested
Quarterly TVC Sampling			Various provided through online portal.
Coliforms Sampling Escherichia coli Sampling			Various provided through online portal.

Corrective Actions Required:

Ref	Findings / Recommendations
5.5.a	IHSL (monitoring Multiplex) to ensure a robust flushing regime that has identified all outlets is in place and reported accurately and reported back to NHSL.
5.5.b	IHSL (managing Construction Co) to demonstrate a safe water system is in place prior to handover of water system maintenance.
5.5.c	IHSL to confirm their duty holder responsibilities for water.
5.5.d	Not used
5.5.e	Not used
5.5.f	Not used

5.6 Building Observations

Observations: Basement Plant Rooms

Heat Station 4

The temperature when entering Heat Station 4 was excessive and we would recommend this is investigated and reported back to NHSL. It was confirmed that air handling to the Plant areas was in operation, so it is unusual to feel the Plant area so hot. The Plant all looked to be insulated and at that time of the audit it was difficult to

identify why the space remained so hot. IHSL were present but did not identify the heat loss as an issue. The heat loss will impact on utility costs.

Heat Station 3

On entering Heat Station 3 we witnessed very hot water discharging from calorifier plant with about 10mm-20mm standing water in the Plant room. There is no mechanical drainage in this Plant room and there has been 100mm holes cored through the block wall to allow water to flow out of the Heat Station Plant room and into the Pneumatic Plant room next door.

We would recommend the design of this Plant room is addressed to identify if a drainage source is required as allowing water to run through a block wall into another Plant area is unacceptable in a new building.
The block wall with the holes cored through it should be investigated to confirm any fire rating has not been compromised. (See Appendix C2)
The Plant room design has the Plant raised off the concrete floor on, what looks like, steel RSJs covered with steel chequered plate. This metal work is showing signs of rusting that would indicate the water has been discharging for considerable time. (See Appendix C1)
During the audit the author was informed by IHSL that Multiplex was “trying to identify” the cause of the water discharging onto the floor and IHSL believe it was because the full building was not in full use however, the author does not agree with this diagnosis and reports it is unacceptable to have this level of flooding in a new building, in an area that has been commissioned.
Due to the heat in this Plant room and the very hot water discharging, the air is humid, and we would recommend that this is a risk as the humid air is drawn through the ducting and Air Handling Plant. We would recommend that IHSL confirm the controls in the Plant room are designed to operate in these conditions for any length of time. We would recommend that these areas are investigated to ascertain what the impact of the humidity is having and what the risks are. (See Appendix C1)

Pneumatic Plant Room

Water was draining through 100mm holes from Heat Station 3 and was ponding on the floor of the Pneumatic Plant room. There is a drainage outlet in this Plant room, but the floor is not raked towards the outlet so the water running from the Heat station must accumulate and pond to a level before water meets the outlet. We would advise that cutting holes through a block wall in a new Plant room to allow water to flow through is unacceptable and we would recommend this is investigated to ascertain why this has happened and what damage the water in the Plant room is causing/has caused. (See Appendix C2)
A computer was sitting to one end of the Plant room on a small desk, the desk was saturated and there was a risk of the moisture meeting the computer. There were also electrical cables behind the desk sitting in water. This was witnessed by all

stakeholders during the walk round. The following day this area was revisited, and as it had not been addressed the author articulated the risks, as there are tradesmen and staff standing in water which is very close to electrical equipment, and the FM Provider moved the PC. (See Appendix C3)

HV/LV Plant Rooms

On inspecting the LV Plant area, it was evident that one of the Transformers in the HV side was generating "load noise" and that it was considerably louder than the other transformers. The author understands that Bouygues AP for HV is monitoring this transformer. We would recommend the manufacturer and installer are asked to advise on the cause and any risk as it is unusual that one of four Transformers is generating such "loud noise".

Rain Water Tank Plant Room

On viewing the rain water tank room is was identified that a waste pipe through the slab from the area above did not appear to have a Fire Collar. Fire Collars were clearly visible to other areas where pipe work was entering through the slab. (See Appendix C4)

Basement Plant Rooms

Many of the basement plant rooms have a small bund wall inside the doorways, prior to accessing plant areas, which also impacts on escape. These walls are not marked up as a hazard to support safe evacuation. As these are the escape routes, we would recommend some form of visual marking is practiced. (See Appendix C5)

Observations: Roof Plant Rooms

Only a small section of roof area plant rooms was inspected with no issues highlighted.

Lifts

It was identified that the condition of the Lifts did not reflect a brand-new building and at the time of the audit the commissioning information was not available for witnessing however, this information was shared at the meeting on Thu 25th April. The SPV articulated that the Lifts were identified for latent defects and were programmed for repair although no completion date for these repairs could be provided.

Observations: Energy Centre

Energy Centre - Boiler Plant Room

The author, with Bouygues FM staff present, identified a strong smell of Gas near the Gas inlet in the Boiler Plant room. Bouygues FM articulated they would follow this up as any smell of Gas is a risk. Bouygues FM later reported that this area was checked with

a Gas sniffer and no leaks were identified. There is Gas Detection is above the boilers (See Appendix G). At the meeting on Fri 26th April we were informed a maintenance visit had identified Gas leaks at each of the boilers which was now being addressed. At that time it was unclear how commissioning and later checks had not identified the Gas leak.

Asbestos

There is a statement by Multiplex to say that there were no materials containing asbestos used in the construction of the site.

Corrective Actions Required:

Ref	Findings / Recommendations
5.6.a	Heat Station 4, recommend heat loss is investigated and reported back to NHSL, by Multiplex
5.6.b	Heat Station 3, recommend discharging water is investigated and rectified with investigation to determine the impact on Plant, gauges and electrical equipment with findings shared with NHSL, by Multiplex
5.6.c	Heat Station 3, recommend the humid air entering the ventilation is investigated and risk assessed and reported back to NHSL by IHSL
5.6.d	Heat Station 3, recommend the Plant Room design and lack of drainage is assessed by Multiplex
5.6.e	IHSL to confirm - Heat Station 3 recommend the cutting of “drainage holes” through the block wall has not impacted on the Fire Rating or integrity of wall.
5.6.f	Heat Station 3, recommend the condition of the Plant base plates is addressed to suit a new Plant Room by Multiplex
5.6.g	Multiplex - recommend HV Plant Room, transformer “load noise” is investigated and report provided to NHSL
5.6.h	Rainwater Tank Plant Room, Fire Collar to be fitted around the white plastic waste pipe by Multiplex
5.6.i	Basement Plant Rooms, Bund Wall to be marked for identification on the escape route by Multiplex
5.6.j	Multiplex - Energy Centre, smell of gas to be investigated and remedials reported back to NHSL.
5.6.k	IHSL to confirm latent defect list and remedial dates for the Lifts
5.6.l	Not used

5.7 Training

Observations:

Training Analysis and Planning

Bouygues FM demonstrated an excellent training matrix and hard copies of certificates. Each member of staff has a training matrix and the level of training and planning is good.

Training Provision, Recording and Relevance of Training Provision

Training can be identified by company policy, line management, SHEQ, at the request of the engineers or as dictated by guidance and it is added to training matrix records.

Roles and responsibilities are clearly defined with support between shift patterns. Ongoing training provision is good, and records are available on site in hard copy and electronically.

Bouygues FM were able to demonstrate that they have a contingency in place to support the site team from engineers in other areas and contractors should support staff ever be required for this contract.

Corrective Actions Required:

Ref	Findings / Recommendations
5.7.a	We would recommend Bouygues share the positive training and contingency information with the Client as it is very positive

5.8 Performance Monitoring

Observations:

Project Level Performance Monitoring

The CAFM System and Helpdesk record performance and this is demonstrated in the client monthly report. Performance monitoring is carried out by the SPV through monthly reporting and monthly meetings but at the time of audit there had been no site audits carried out carried out by the SPV.

Health and Safety Audits

SHEQ have regular visits programmed and are in regular contact with site teams.

At the time of audit there was no SPV audits carried out or programmed.

Director H&S Tours

As these are new sites there has not been a Directors H&S Tour, but this should be programmed and shared with the site.

Ongoing Support from Competent Person

The site teams have ongoing support from the Technical Manager and Line Management above that position.

Other forms of Performance Monitoring

Liaison meetings, Contract Meetings and adhoc meetings take place. The site team are in regular contact with an NHS Lothian point of contact to allow discussions to take place out of programmed dates.

Corrective Actions Required:

Ref	Findings / Recommendations
5.8.a	IHSL should demonstrate that they are discharging their duties as per the Project Agreement
5.8.b	Not used

6. Summary Report

Summary Points

The table below summarises the assessments remedial actions, it is essential that [Service Provider] take these findings and address their legal and contractual obligations in establishing, implementing and maintaining its safety management systems, when identifying hazards, assessing risks and determining controls measures.

Ref	Award	Findings/Recommendations	Target Date	Owner	Closed Date
	Health and Safety Management				
6.1.a		HV/LV AE to comment on the lack of rubber matting in electrical Plant areas and offer remedials.	19/07/ 19	Bouygues	
6.1.b		Bouygues should report all building issues and self-identified maintenance through the Helpdesk including heat station issues. This provides an excellent tool to demonstrate reporting and provides the client with sight of repairs and issues.	31/07/ 19	Bouygues	
6.1.c		We recommend that IHSL to provide evidence as requested in our Health & Safety Management System paragraphs.	31/07/ 19	IHSL	
6.1.d		Not used			
	Contractor Management				
6.2.a		Although areas are controlled through the access control system, we would recommend the site access and control of contractors is	19/07/ 19	Bouygues	

		tightened up on a daily basis to understand who is on site, where they should be working, what they are doing and timescales for completion, clean work area and checks/signoff.			
6.2.b		Not used			

	Statutory Compliance				
6.3.a		We recommend that Bouygues keep NHSL updated as they receive handover of packages and areas of the building regards information, quality and any issues.	Ongoing	Bouygues	
6.3.b		Not used			
6.3.c		Not used			

	Fire and Emergency Planning				
6.4.a		We recommend that Bouygues keep NHSL updated as they receive handover of the fire detection infrastructure regards information, quality and any issues.	Ongoing	Bouygues	
6.4.b		NHSL Fire Officer to complete FRA and make available to the SPV and FM provider prior to patient occupation.	31/07/ 19	NHSL	
6.4.c		Not used			
6.4.d		Not used			

	Legionella				
6.5.a		IHSL (monitoring Multiplex) to ensure a robust flushing regime that has identified all outlets is in place and reported accurately and reported back to NHSL.	July 19	IHSL	
6.5.b		IHSL (monitoring Multiplex) to demonstrate a safe water system is in place prior to handover of water system maintenance and reported back to NHSL.	TBA	IHSL	
6.5.c		IHSL to confirm their duty holder responsibilities for water.	31/07/ 19	IHSL	
6.5.d		Not used			

	Building Observations				
6.6.a		Multiplex - Heat Station 4, recommend heat loss is investigated and reported back to NHSL.	19/07/ 19	Multiplex	
6.6.b		Multiplex - Heat Station 3, recommend discharging water is investigated and rectified with investigation on any damage or impact and findings shared with NHSL.	19/07/ 19	Multiplex	
6.6.c		Multiplex - Heat Station 3, recommend the humid air entering the ventilation is investigated and reported back to NHSL.	19/07/ 19	Multiplex	
6.6.d		Multiplex - Heat Station 3, recommend the Plant Room design and lack of drainage is assessed and reported back to NHSL.	31/07/ 19	Multiplex	
6.6.e		Multiplex to confirm - Heat Station 3 recommend the cutting of “drainage holes” through the block wall has not impacted on the Fire Rating or integrity of wall.	31/07/ 19	Multiplex	
6.6.f		Multiplex - Heat Station 3, recommend the condition of the Plant base plates is addressed to suit a new Plant Room.	31/07/ 19	Multiplex	
6.6.g		Multiplex - recommend HV Plant Room, transformer “load noise” is investigated and report provided to NHSL.	31/07/ 19	Multiplex	
6.6.h		Multiplex - Rainwater Tank Plant Room, investigation why a Fire Collar has not been fitted to waste pipe entering through ceiling slab and any remedials required are completed.	31/07/ 19	Multiplex	
6.6.i		Multiplex - Basement Plant Rooms, Bund Wall is marked up and identified as affecting fire escape route.	31/07/ 19	Multiplex	
6.6.j		Multiplex - Energy Centre, smell of gas to be investigated and remedials reported back to NHSL.	19/07/ 19	Multiplex	
6.6.k		IHSL to confirm latent defect list and remedial dates for the Lifts	31/07/ 19	IHSL	
6.6.l		Not used			

	Training			
6.7.a		We would recommend Bouygues share the positive training and contingency information with the Client as it is very positive	TBA	Bouygues

	Performance Monitoring				
6.8.a		IHSL should demonstrate that they are discharging their duties as per the Project Agreement	31/07/ 19	IHSL	
6.8.b		Not used			
6.8.c		Not used			

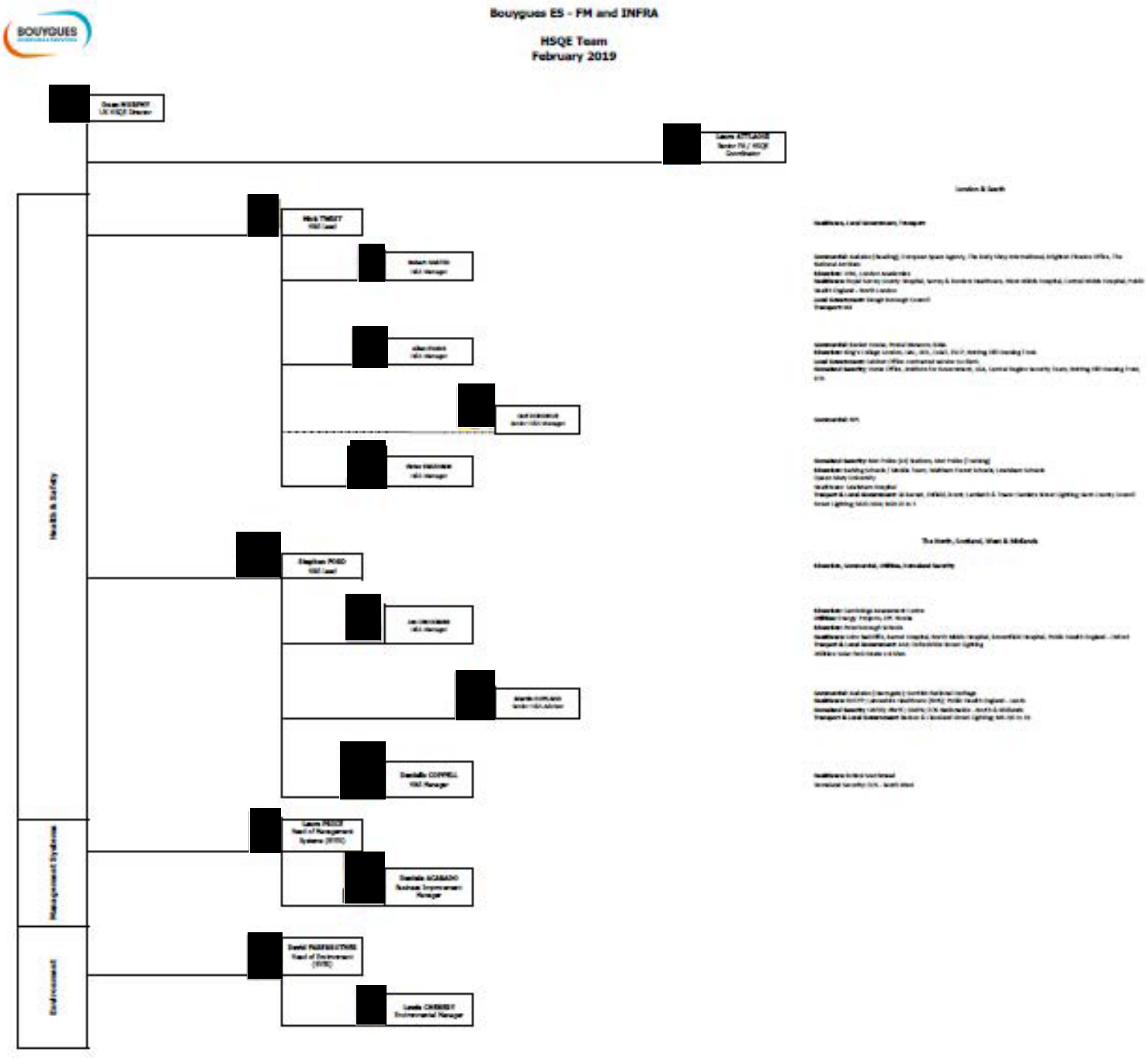
Key to Colour Coding and Timescales for Action	
	A major gap in management arrangements, which directly breaches the requirements of legislation. Project Co is at risk. IMMEDIATE ACTION REQUIRED
	A gap in management arrangements resulting from not fully complying with legislation. Project Co is not considered to be at imminent risk, but corrective action should be implemented within an agreed timescale to remedy the issue. WITHIN 3 MONTHS.
	Opportunity for Improvement. There is no direct breach of compliance, but the existing management arrangements could be improved to provide a more suitable or robust solution. ACTION PLAN TO BE AGREED.

Appendix A – Summary of Assessment Grading Scale

Award	*Audit Rating*	*Definition*
	Controlled, Minor Improvements Needed	All or many of the health and safety control measures are functioning as intended; however, some minor changes may be necessary to make the controlled environment more effective and efficient. Some minor actions may be necessary at this time (Project Co is not considered to be at risk).

	Moderate Improvements Needed	Some of the health and safety control measures are in place and functioning; however, several major issues were noted that could jeopardize statutory compliance or contractual obligations. Actions will be necessary to address the deficiencies noted, (Project Co may be considered at risk in the short to medium term were corrective action not implemented).
	Unsatisfactory, Significant Improvements Needed	Health and safety control measures are not functioning as designed and/or will have a material impact on both statutory compliance and/or contractual obligations. Health and safety control measures are lacking or have degraded since the last audit and is a contributing factor to non-compliance. Immediate management actions need to be taken to address the deficiencies noted, (Project Co is currently considered to be at risk).

Appendix B – Bouygues H&S Organogram

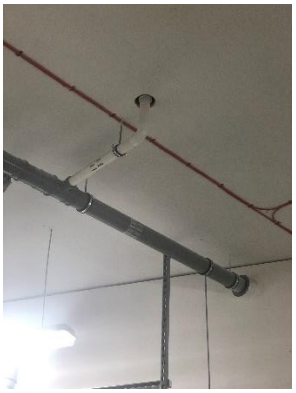


Appendix C – 1 (Heat station 3 – Flooding)

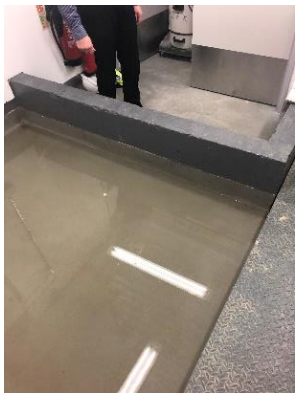
Appendix C – 2 (Pneumatic Plant Room – Flooding, holes through wall and outlet)

Appendix C – 3 (Pneumatic Plant Room – PC risk)

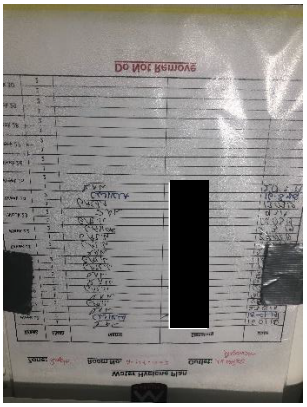
Appendix C – 4 (Fire collar and fire collar missing)

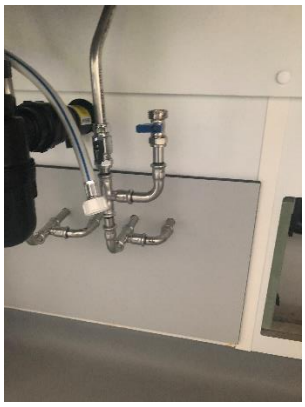


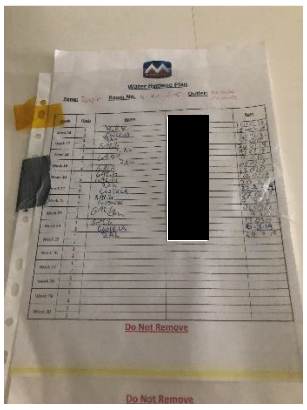
Appendix C – 5 (Bund Walls not marked for fire exit)



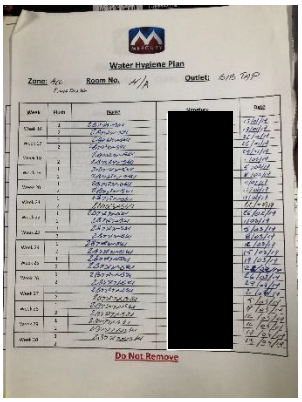
Appendix D – Legionella – (Lab Flushing Points and information)

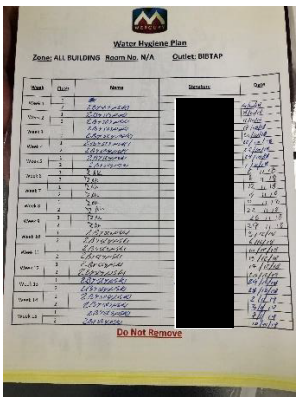






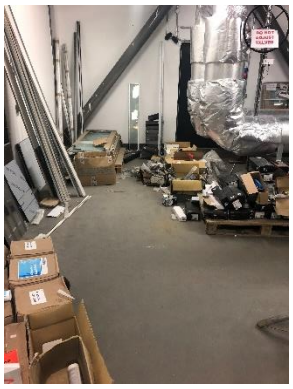
(Courtyard Flushing information)





Appendix E – Missing Electrical Matting

Appendix F – Blocked Fire Exit (Poor storage of construction materials in Energy Centre).



Guidelines for Drinking-water Quality

FOURTH EDITION
INCORPORATING
THE FIRST ADDENDUM

World Health Organization

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Preface

Access to safe drinking-water is essential to health, a basic human right and a component of effective policy for health protection.

The importance of water, sanitation and hygiene for health and development has been reflected in the outcomes of a series of international policy forums. This includes, most recently, the adoption of the Sustainable Development Goals by countries, in 2015, which include a target and indicator on safe drinking-water. Further, the United Nations (UN) General Assembly declared in 2010 that safe and clean drinking-water and sanitation is a human right, essential to the full enjoyment of life and all other human rights. These commitments build on a long history of support including the UN Generaly Assembly adopting the Millennium Development Goals in 2000 and declaring the period 2005–2015 as the International Decade for Action, "Water for Life".

Access to safe drinking-water is important as a health and development issue at national, regional and local levels. In some regions, it has been shown that investments in water supply and sanitation can yield a net economic benefit, because the reductions in adverse health effects and health-care costs outweigh the costs of undertaking the interventions. This is true for investments ranging from major water supply infrastructure through to water treatment in the home. Experience has also shown that interventions in improving access to safe water favour the poor in particular, whether in rural or urban areas, and can be an effective part of poverty alleviation strategies.

The World Health Organization (WHO) published four editions of the *Guidelines for drinking-water quality* (in 1983–1984, 1993–1997, 2004, and 2011), as successors to the previous WHO *International standards for drinking water*, which were published in 1958, 1963 and 1971. Since 1995, the Guidelines have been kept up to date through a process of rolling revision, which leads to the regular publication of addenda that may add to or supersede information in previous volumes, as well as expert reviews on key issues in preparation for the revision of the Guidelines.

Leading the process of the development of the fourth edition was the Water, Sanitation, Hygiene and Health Unit within WHO Headquarters. The Chemical Safety Unit and the Risk Assessment and Management Unit provided input on chemical hazards, and the Radiation Programme provided input on radiological hazards. All six WHO regional offices participated in the process, in consultation with Member States.

This version of the Guidelines integrates the fourth edition, which was published in 2011, with the first addendum to the fourth edition published in 2016. It supersedes previous editions of the Guidelines and previous International Standards.

The primary goal of the Guidelines is to protect public health associated with drinking-water quality. The overall objectives of the Guidelines are to:

- provide an authoritative basis for the effective consideration of public health in setting national or regional drinking-water policies and actions;
- provide a comprehensive preventive risk management framework for health protection, from catchment to consumer, that covers policy formulation and standard setting, risk-based management approaches and surveillance;
- emphasize achievable practices and the formulation of sound regulations that are applicable to low-income, middle-income and industrialized countries alike;
- summarize the health implications associated with contaminants in drinking-water, and the role of risk assessment and risk management in disease prevention and control;
- summarize effective options for drinking-water management; and
- provide guidance on hazard identification and risk assessment.

This edition of the Guidelines, incorporating the first addendum, further develops concepts, approaches and information introduced in previous editions, including the comprehensive preventive risk management approach for ensuring drinking-water quality that was introduced in the third edition. This edition considers:

- drinking-water safety, including minimum procedures and specific guideline values, and how these are intended to be used;
- approaches used in deriving the Guidelines, including guideline values;
- microbial hazards, which continue to be the primary concern in both developing and developed countries. Experience has shown the value of a systematic approach to securing microbial safety. This edition builds on the preventive principles introduced in the third edition on ensuring the microbial safety of drinking-water through a multiple-barrier approach, highlighting the importance of source water protection;
- climate change, which results in changing water temperature and rainfall patterns, severe and prolonged drought or increased flooding, and its implications for water quality and water scarcity, recognizing the importance of managing these impacts as part of water management strategies;
- chemical contaminants in drinking-water, including information on chemicals not considered previously (e.g. pesticides used for vector control in drinking-water); revisions of existing chemical fact sheets, taking into account new scientific information; and reduced coverage in the Guidelines in cases where new information suggests a lesser priority;
- key chemicals responsible for large-scale health effects through drinking-water exposure (e.g. arsenic, fluoride, lead, nitrate, selenium and uranium), with the Guidelines providing guidance on identifying local priorities and on management;

- the important roles of many different stakeholders in ensuring drinking-water safety; this edition furthers the discussion introduced in the third edition of the roles and responsibilities of key stakeholders in ensuring drinking-water safety; and
- guidance in situations other than traditional community supplies or managed utilities, such as rainwater harvesting and other non-piped supplies or dual-piped systems.

The Guidelines are accompanied by a series of supporting publications. These include internationally peer-reviewed risk assessments for specific chemicals (see list of chapter 12 background documents in Annex 2) and other publications explaining the scientific basis of the development of the Guidelines and providing guidance on good practice in their implementation (see Annex 1). The publication *Guidelines for drinking-water quality Volume 3—Surveillance and control of community supplies* (1997, revision forthcoming) provides guidance on good practice in surveillance, monitoring and assessment of drinking-water quality in community supplies.

The Guidelines are addressed primarily to water and health regulators, policy-makers and their advisors, to assist in the development of national policies and regulations. The Guidelines and associated documents are also used by many others as a source of information on water quality and health, and on effective management approaches.

The Guidelines are recognized as representing the position of the UN system on issues of drinking-water quality and health by "UN-Water", the body that coordinates among the 24 UN agencies and programmes concerned with water issues.

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The preparation of the fourth edition of the *Guidelines for drinking-water quality*, the first addendum to the fourth edition and supporting documentation covered a period of more than 10 years. It involved the participation of hundreds of experts from a wide range of developing and developed countries. The contributions of all who participated in the preparation and finalization of the fourth edition and the first addendum to the fourth edition, including those individuals listed in Annex 7, are gratefully acknowledged.

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Dr F. Ahmed, Bangladesh University of Engineering and Technology, Bangladesh (*Small systems*)

Dr I. Chorus, Federal Environment Agency, Germany (*Resource and source protection*)

Dr J. Cotruvo, Joseph Cotruvo & Associates/NSF International Collaborating Centre, USA (*Materials and chemicals used in the production and distribution of drinking-water*)

Dr D. Cunliffe, Department of Health, Australia (*Public health*)

Dr A.M. de Roda Husman, National Institute for Public Health and the Environment (RIVM), the Netherlands (*Viruses and risk assessment*)

Dr T. Endo, Ministry of Health, Labour and Welfare, Japan (*Parasites*)

Mr J.K. Fawell, Independent Consultant, United Kingdom (*Naturally occurring and industrial contaminants* and *Pesticides*)

Ms M. Giddings, Health Canada, Canada (*Disinfectants and disinfection by-products*)

Dr G. Howard, British High Commission, India (*Monitoring and assessment*)

Mr P. Jackson, WRc-NSF Ltd, United Kingdom (*Chemicals – Practical aspects*)

Dr S. Kumar, University of Malaya, Malaysia (*Protozoa and risk management*)

Dr S. Kunikane, Institute for Environmental Sciences, Japan (*Operations and Maintenance Network*)

Professor Y. Magara, Hokkaido University, Japan (*Analytical aspects*)

Dr A.V.F. Ngowi, Muhimbili University of Health and Allied Sciences, United Republic of Tanzania (*Pesticides*)

Dr E. Ohanian, Environmental Protection Agency, USA (*Disinfectants and disinfection by-products*)

Dr C.N. Ong, National University of Singapore, Singapore (*Emerging chemical hazards*)

Mr O. Schmoll, Federal Environment Agency, Germany (*Water safety plan capacity building and monitoring*)

Professor M. Sobsey, University of North Carolina, USA (*Risk management*)

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Abbreviations used in text

2,4-D	2,4-dichlorophenoxyacetic acid
2,4-DB	2,4-dichlorophenoxybutyric acid
2,4-DP	dichlorprop
2,4,5-T	2,4,5-trichlorophenoxyacetic acid
2,4,5-TP	2,4,5-trichlorophenoxy propionic acid; fenoprop
AAS	atomic absorption spectrometry
Absor	absorptiometry
ADI	acceptable daily intake
AES	atomic emission spectrometry
AIDS	acquired immunodeficiency syndrome
AMPA	aminomethylphosphonic acid
ARfD	acute reference dose
BDCM	bromodichloromethane
BMD	benchmark dose
BMDL	lower confidence limit on the benchmark dose
BMDLx	lower 95% confidence limit on the benchmark dose for an x% response
BTEX	benzene, toluene, ethylbenzene and xylenes
Bti	*Bacillus thuringiensis israelensis*
bw	body weight
CAS	Chemical Abstracts Service
Col	colorimetry
CSAF	chemical-specific adjustment factor
Ct	product of disinfectant concentration and contact time
DAEC	diffusely adherent *E. coli*
DALY	disability-adjusted life year

DBCM	dibromochloromethane
DBCP	1,2-dibromo-3-chloropropane
DBP	disinfection by-product
DCA	dichloroacetic acid
DCB	dichlorobenzene
DCP	dichloropropane
DDT	dichlorodiphenyltrichloroethane
DEHA	di(2-ethylhexyl)adipate
DEHP	di(2-ethylhexyl)phthalate
DNA	deoxyribonucleic acid
DPD	*N*,*N*-diethyl-1,4-phenylenediamine sulfate
EAAS	electrothermal atomic absorption spectrometry
EAEC	enteroaggregative *E. coli*
ECD	electron capture detector
EDTA	ethylenediaminetetraacetic acid; edetic acid
EHEC	enterohaemorrhagic *E. coli*
EIEC	enteroinvasive *E. coli*
ELISA	enzyme-linked immunosorbent assay
EPEC	enteropathogenic *E. coli*
ETEC	enterotoxigenic *E. coli*
F_0	parental generation
F_1	first filial generation
FAAS	flame atomic absorption spectrometry
FAO	Food and Agriculture Organization of the United Nations
FD	fluorescence detector
FID	flame ionization detector
FPD	flame photodiode detector
GAC	granular activated carbon
GC	gas chromatography
GL	guidance level (used for radionuclides in drinking-water)
GV	guideline value
HAA	haloacetic acid
HAV	hepatitis A virus
HCB	hexachlorobenzene
HCBD	hexachlorobutadiene
HCH	hexachlorocyclohexane
HEV	hepatitis E virus
HIV	human immunodeficiency virus

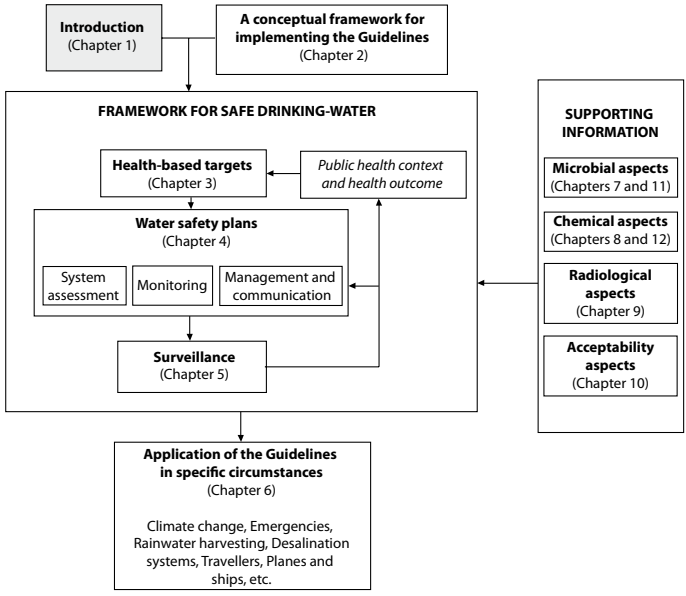
HPC	heterotrophic plate count
HPLC	high-performance liquid chromatography

IARC	International Agency for Research on Cancer
IC	ion chromatography
ICP	inductively coupled plasma
ICRP	International Commission on Radiological Protection
IDC	individual dose criterion
IPCS	International Programme on Chemical Safety
IQ	intelligence quotient
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOAEL	lowest-observed-adverse-effect level
LRV	$\log_{10}$ reduction value
MCB	monochlorobenzene
MCPA	4-(2-methyl-4-chlorophenoxy)acetic acid
MCPB	2,4-MCPB; 4-(4-chloro-o-tolyloxy)butyric acid; 4-(4-chloro-2-methylphenoxy)butanoic acid
MCPP	2(2-methyl-chlorophenoxy) propionic acid; mecoprop
MDL	method detection limit
MMT	methylcyclopentadienyl manganese tricarbonyl
MS	mass spectrometry
MS/MS	tandem mass spectrometry
MTBE	methyl *tertiary*-butyl ether
MX	3-chloro-4-dichloromethyl-5-hydroxy-2(5H)-furanone
NDMA	*N*-nitrosodimethylamine
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NTA	nitrilotriacetic acid
NTP	National Toxicology Program (USA)
NTU	nephelometric turbidity unit
PAC	powdered activated carbon
PAH	polynuclear aromatic hydrocarbon
PCP	pentachlorophenol
PCR	polymerase chain reaction
PD	photoionization detector
PMTDI	provisional maximum tolerable daily intake
PPA	protein phosphatase assay

PT	purge and trap
PTDI	provisional tolerable daily intake

PTMI	provisional tolerable monthly intake
PTWI	provisional tolerable weekly intake
PVC	polyvinyl chloride
QMRA	quantitative microbial risk assessment
RNA	ribonucleic acid
SI	Système international d'unités (International System of Units)
SODIS	solar water disinfection
sp.	species (singular)
spp.	species (plural)
subsp.	subspecies (singular)
TBA	terbuthylazine
TCB	trichlorobenzene
TCU	true colour unit
TD_{05}	tumorigenic dose$_{05}$, the dose associated with a 5% excess incidence of tumours in experimental animal studies
TDI	tolerable daily intake
TDS	total dissolved solids
THM	trihalomethane
TID	thermal ionization detector; total indicative dose
UF	uncertainty factor
UN	United Nations
UNICEF	United Nations Children's Fund
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
USA	United States of America
UV	ultraviolet
UVPAD	ultraviolet photodiode array detector
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme
WSP	water safety plan
YLD	years of healthy life lost in states of less than full health (i.e. years lived with a disability)
YLL	years of life lost by premature mortality

1 Introduction



The primary purpose of the *Guidelines for drinking-water quality* is the protection of public health. The Guidelines provide the recommendations of the World Health Organization (WHO) for managing the risk from hazards that may compromise the safety of drinking-water. The recommendations should be considered in the context of managing the risk from other sources of exposure to these hazards, such as waste, air, food and consumer products.

1.1 General considerations and principles

Water is essential to sustain life, and a satisfactory (adequate, safe and accessible) supply must be available to all. Improving access to safe drinking-water can result in tangible benefits to health. Every effort should be made to achieve drinking-water that is as safe as practicable.

Safe drinking-water, as defined by the Guidelines, does not represent any significant risk to health over a lifetime of consumption, including different sensitivities that may occur between life stages. Those at greatest risk of waterborne disease are infants and young children, people who are debilitated and the elderly, especially when living

Diseases related to contamination of drinking-water constitute a major burden on human health. Interventions to improve the quality of drinking-water provide significant benefits to health.

under unsanitary conditions. Those who are generally at risk of waterborne illness may need to take additional steps to protect themselves against exposure to waterborne pathogens, such as boiling their drinking-water. Safe drinking-water is required for all usual domestic purposes, including drinking, food preparation and personal hygiene. The Guidelines are applicable to packaged water and ice intended for human consumption. However, water of higher quality may be required for some special purposes, such as renal dialysis and cleaning of contact lenses, or for certain purposes in food production and pharmaceutical use. The Guidelines may not be suitable for the protection of aquatic life or for some industries.

The Guidelines are intended to support the development and implementation of risk management strategies that will ensure the safety of drinking-water supplies through the control of hazardous constituents of water. These strategies may include national or regional standards developed from the scientific basis provided in the Guidelines. The Guidelines describe reasonable minimum requirements of safe practice to protect the health of consumers and derive numerical "guideline values" for constituents of water or indicators of water quality. When defining mandatory limits, it is preferable to consider the Guidelines in the context of local or national environmental, social, economic and cultural conditions. The Guidelines should also be part of an overall health protection strategy that includes sanitation and other strategies, such as managing food contamination. This strategy would also normally be incorporated into a legislative and regulatory framework that adapts the Guidelines to address local requirements and circumstances (see also section 2.6).

The main reason for not promoting the adoption of international standards for drinking-water quality is the advantage provided by the use of a risk–benefit approach (qualitative or quantitative) in the establishment of national standards and regulations. Further, the Guidelines are best used to promote an integrated preventive management framework for safety applied from catchment to consumer. The Guidelines provide a scientific point of departure for national authorities to develop drinking-water regulations and standards appropriate for the national situation. In developing standards and regulations, care should be taken to ensure that scarce resources are not unnecessarily diverted to the development of standards and the monitoring of substances of relatively minor importance to public health. The approach followed in these Guidelines is intended to lead to national standards and regulations that can be readily implemented and enforced and are protective of public health.

The nature and form of drinking-water standards may vary among countries and regions. There is no single approach that is universally applicable. It is essential in the development and implementation of standards that the current or planned legislation relating to water, health and local government is taken into account and that the capacity of regulators in the country is assessed. Approaches that may work in one country or region will not necessarily transfer to other countries or regions. It is essential that each country review its needs and capacities in developing a regulatory framework.

The judgement of safety—or what is an acceptable level of risk in particular circumstances—is a matter in which society as a whole has a role to play. The final judgement as to whether the benefit resulting from the adoption of any of the Guidelines or guideline values as national or local standards justifies the cost is for each country to decide.

Although the Guidelines describe a quality of water that is acceptable for lifelong consumption, the establishment of these Guidelines, including guideline values, should not be regarded as implying that the quality of drinking-water may be degraded to the recommended level. Indeed, a continuous effort should be made to maintain drinking-water quality at the highest possible level.

An important concept in the allocation of resources to improving drinking-water safety is that of incremental improvement towards long-term health-based targets. Priorities set to remedy the most urgent problems (e.g. protection from pathogens; see section 1.1.2) may be linked to long-term targets of further water quality improvements (e.g. improvements in the acceptability of drinking-water in terms of its taste, odour and appearance; see section 1.1.6).

An important concept in the allocation of resources to improving drinking-water safety is that of incremental improvement towards long-term water quality targets.

1.1.1 Framework for safe drinking-water

The basic and essential requirements to ensure the safety of drinking-water are a "framework" for safe drinking-water, comprising health-based targets established by a competent health authority, adequate and properly managed systems (adequate infrastructure, proper monitoring and effective planning and management) and a system of independent surveillance.

A holistic approach to the risk assessment and risk management of a drinking-water supply increases confidence in the safety of the drinking-water. This approach entails systematic assessment of risks throughout a drinking-water supply—from the catchment and its source water through to the consumer—and identification of the ways in which these risks can be managed, including methods to ensure that control measures are working effectively. It incorporates strategies to deal with day-to-day management of water quality, including upsets and failures. In this respect, climate change—in the form of increased and more severe periods of drought or more intense rainfall events leading to flooding—can have an impact on both the quality and the quantity of water and will require planning and management to minimize adverse

In Stockholm, in 1999, it was agreed that future guidelines for drinking-water, wastewater and recreational water should integrate assessment of risk, risk management options and exposure control elements within a single framework with embedded quality targets (see the supporting document *Water quality—Guidelines, standards and health*; Annex 1). Following this approach, the assessment of risk is not a goal in its own right, but rather a basis for decision-making. The framework for safe drinking-water and the recommended approach for regulations, policies and programmes are based on this overall framework, known as the Stockholm Framework (see chapter 2).

impacts on drinking-water supplies. Climate change also needs to be considered in the light of demographic change, such as the continuing growth of cities, which itself brings significant challenges for drinking-water supply.

In support of the framework for safe drinking-water, the Guidelines provide a range of supporting information, including microbial aspects (chapters 7 and 11), chemical aspects (chapters 8 and 12), radiological aspects (chapter 9) and acceptability aspects (chapter 10). Figure 1.1 provides an overview of the interrelationships among the individual chapters of the Guidelines in ensuring drinking-water safety.

The Guidelines are applicable to large metropolitan and small community piped drinking-water systems and to non-piped drinking-water systems in communities and in individual dwellings. The Guidelines are also applicable to a range of specific circumstances (chapter 6), including buildings, travellers and conveyances.

1.1.2 Microbial aspects

Securing the microbial safety of drinking-water supplies is based on the use of multiple barriers, from catchment to consumer, to prevent the contamination of drinking-water or to reduce contamination to levels not injurious to health. Safety is increased if multiple barriers are in place, including protection of water resources, proper selection and operation of a series of treatment steps and management of distribution systems (piped or otherwise) to maintain and protect treated water quality. The preferred strategy is a management approach that places the primary emphasis on preventing or reducing the entry of pathogens into water sources and reducing reliance on treatment processes for removal of pathogens.

In general terms, the greatest microbial risks are associated with ingestion of water that is contaminated with faeces from humans or animals (including birds). Faeces can be a source of pathogenic bacteria, viruses, protozoa and helminths.

Faecally derived pathogens are the principal concerns in setting health-based targets for microbial safety. Microbial water quality often varies rapidly and over a wide range. Short-term peaks in pathogen concentration may increase disease risks considerably and may trigger outbreaks of waterborne disease. Furthermore, by the time microbial contamination is detected, many people may have been exposed. For these reasons, reliance cannot be placed solely on end-product testing, even when frequent, to determine the microbial safety of drinking-water.

> The potential health consequences of microbial contamination are such that its control must always be of paramount importance and must never be compromised.

Particular attention should be directed to a water safety framework and implementing comprehensive water safety plans to consistently ensure drinking-water safety and thereby protect public health (see chapter 4). Failure to ensure drinking-water safety may expose the community to the risk of outbreaks of intestinal and other infectious diseases. Outbreaks of waterborne disease are particularly to be avoided because of their capacity to result in the simultaneous infection of a large number of persons and potentially a high proportion of the community.

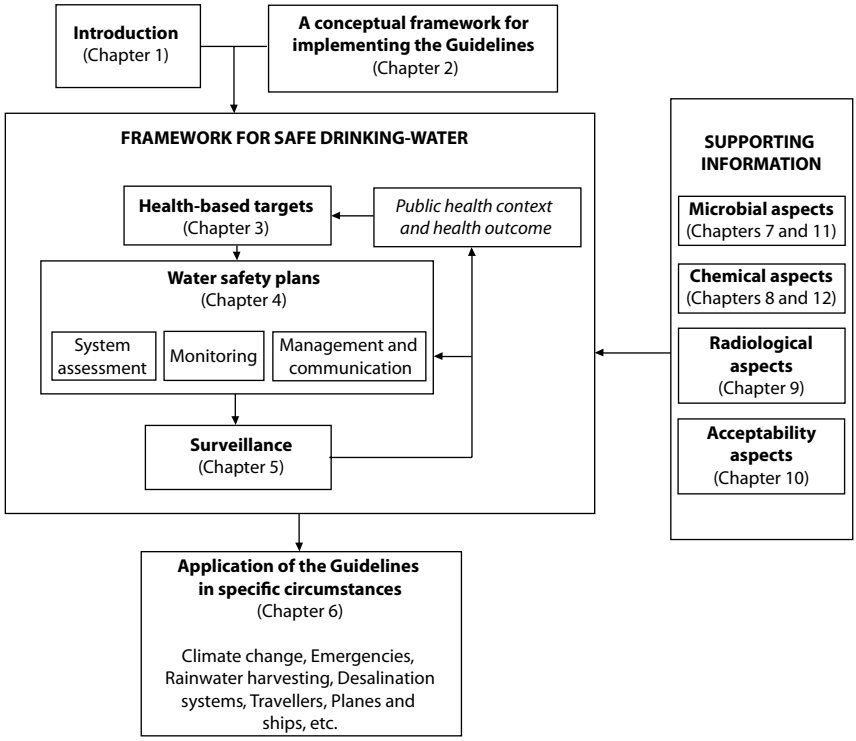


Figure 1.1 Interrelationships among the individual chapters of the *Guidelines for drinking-water quality* in ensuring drinking-water safety

In addition to faecally borne pathogens, other microbial hazards, such as guinea worm (*Dracunculus medinensis*), toxic cyanobacteria and *Legionella*, may be of public health importance under specific circumstances.

Although water can be a very significant source of infectious organisms, many of the diseases that may be waterborne may also be transmitted by other routes, including person-to-person contact, food intake and droplets and aerosols. Depending on the circumstances and in the absence of waterborne outbreaks, these routes may be more important than waterborne transmission.

Microbial aspects of water quality are considered in more detail in chapter 7, with fact sheets on specific microorganisms provided in chapter 11.

1.1.3 Disinfection

Disinfection is of unquestionable importance in the supply of safe drinking-water. The destruction of pathogenic microorganisms is essential and very commonly involves the use of reactive chemical agents such as chlorine.

Disinfection is an effective barrier to many pathogens (especially bacteria) during drinking-water treatment and should be used for surface waters and for groundwater subject to faecal contamination. Residual disinfection is used to provide a partial safeguard against low-level contamination and growth within the distribution system.

Chemical disinfection of a drinking-water supply that is faecally contaminated will reduce the overall risk of disease but may not necessarily render the supply safe. For example, chlorine disinfection of drinking-water has limitations against the protozoan pathogens—in particular *Cryptosporidium*—and some viruses. Disinfection efficacy may also be unsatisfactory against pathogens within flocs or particles, which protect them from the action of disinfectants. High levels of turbidity can protect microorganisms from the effects of disinfection, stimulate the growth of bacteria and give rise to a significant chlorine demand. It is essential that an overall management strategy is implemented in which multiple barriers, including source water protection and appropriate treatment processes, as well as protection during storage and distribution, are used in conjunction with disinfection to prevent or remove microbial contamination.

The use of chemical disinfectants in water treatment usually results in the formation of chemical by-products. However, the risks to health from these by-products are extremely small in comparison with the risks associated with inadequate disinfection, and it is important that disinfection efficacy not be compromised in attempting to control such by-products.

Disinfection should not be compromised in attempting to control disinfection by-products.

Some disinfectants, such as chlorine, can be easily monitored and controlled as a drinking-water disinfectant, and frequent monitoring is recommended wherever chlorination is practised.

Disinfection of drinking-water is considered in more detail in chapter 7 and Annex 5, with fact sheets on specific disinfectants and disinfection by-products provided in chapter 12.

1.1.4 Chemical aspects

The health concerns associated with chemical constituents of drinking-water differ from those associated with microbial contamination and arise primarily from the ability of chemical constituents to cause adverse health effects after prolonged periods of exposure. There are few chemical constituents of water that can lead to health problems resulting from a single exposure, except through massive accidental contamination of a drinking-water supply. Moreover, experience shows that in many, but not all, such incidents, the water becomes undrinkable owing to unacceptable taste, odour and appearance.

The great majority of evident water-related health problems are the result of microbial (bacterial, viral, protozoan or other biological) contamination. Nevertheless, an appreciable number of serious health concerns may occur as a result of the chemical contamination of drinking-water.

In situations where short-term exposure is not likely to lead to health impairment, it is often most effective to concentrate the available resources for remedial action on finding and eliminating the source of contamination, rather than on installing expensive drinking-water treatment for the removal of the chemical constituent.

There are many chemicals that may occur in drinking-water; however, only a few are of immediate health concern in any given circumstance. The priority given to both monitoring and remedial action for chemical contaminants in drinking-water should be managed to ensure that scarce resources are not unnecessarily directed towards those of little or no health concern (see the supporting document *Chemical safety of drinking-water*; Annex 1).

There are few chemicals for which the contribution from drinking-water to overall intake is an important factor in preventing disease. One example is the effect of fluoride in drinking-water in protecting against dental caries. The Guidelines do not attempt to define minimum desirable concentrations for chemicals in drinking-water.

Guideline values are derived for many chemical constituents of drinking-water. A guideline value normally represents the concentration of a constituent that does not result in any significant risk to health over a lifetime of consumption. A number of provisional guideline values have been established based on the practical level of treatment performance or analytical achievability. In these cases, the guideline value is higher than the calculated health-based value.

The chemical aspects of drinking-water quality are considered in more detail in chapter 8, with fact sheets on specific chemical contaminants provided in chapter 12.

1.1.5 Radiological aspects

The health risks associated with the presence of naturally occurring radionuclides in drinking-water should also be taken into consideration, although the contribution of drinking-water to total exposure to radionuclides is very small under normal circumstances.

Formal guideline values are not set for individual radionuclides in drinking-water. Rather, the approach used is based on screening drinking-water for gross alpha and gross beta radiation activity. Although finding levels of activity above screening values does not indicate any immediate risk to health, it should trigger further investigation to determine the radionuclides responsible and the possible risks, taking local circumstances into account.

The guidance levels for radionuclides recommended in these Guidelines do not apply to drinking-water supplies contaminated during emergencies arising from accidental releases of radioactive substances to the environment.

Radiological aspects of drinking-water quality are considered in more detail in chapter 9.

1.1.6 Acceptability aspects: taste, odour and appearance

Water should be free of tastes and odours that would be objectionable to the majority of consumers.

In assessing the quality of drinking-water, consumers rely principally upon their senses. Microbial, chemical and physical constituents of water may affect the appearance, odour or taste of the water, and the consumer will evaluate the quality and acceptability of the water on the basis of these criteria. Although these constituents may have no direct health effects, water that is highly turbid, is highly coloured or has an

objectionable taste or odour may be regarded by consumers as unsafe and rejected. In extreme cases, consumers may avoid aesthetically unacceptable but otherwise safe drinking-water in favour of more pleasant but potentially unsafe sources. It is therefore wise to be aware of consumer perceptions and to take into account both health-related guideline values and aesthetic criteria when assessing drinking-water supplies and developing regulations and standards.

Changes in the normal appearance, taste or odour of a drinking-water supply may signal changes in the quality of the raw water source or deficiencies in the treatment process and should be investigated.

Acceptability aspects of drinking-water quality are considered in more detail in chapter 10.

1.2 Roles and responsibilities in drinking-water safety management

Preventive management is the preferred approach to ensuring drinking-water safety and should take account of the characteristics of the drinking-water supply from catchment and source to its use by consumers. As many aspects of drinking-water quality management are often outside the direct responsibility of the water supplier, it is essential that a collaborative multiagency approach be adopted to ensure that agencies with responsibility for specific areas within the water cycle are involved in the management of water quality. One example is where catchments and source waters are beyond the drinking-water supplier's jurisdiction. Consultation with other authorities will generally be necessary for other elements of drinking-water quality management, such as monitoring and reporting requirements, emergency response plans and communication strategies.

> A preventive integrated management approach with collaboration from all relevant agencies is the preferred approach to ensuring drinking-water safety

Major stakeholders that could affect or be affected by decisions or activities of the drinking-water supplier should be encouraged to coordinate their planning and management activities where appropriate. These could include, for example, health and resource management agencies, consumers, industry and plumbers. Appropriate mechanisms and documentation should be established for stakeholder commitment and involvement.

1.2.1 Surveillance and quality control

In order to protect public health, a dual-role approach, differentiating the roles and responsibilities of service providers from those of an authority responsible for independent oversight protective of public health ("drinking-water supply surveillance"), has proven to be effective.

Organizational arrangements for the maintenance and improvement of drinking-water supply services should therefore take into account the vital and complementary roles of the agency respon-

> Drinking-water suppliers are responsible at all times for the quality and safety of the water that they produce

sible for surveillance and of the water supplier. The two functions of surveillance and quality control are best performed by separate and independent entities because of the conflict of interest that arises when the two are combined. In this:

- national agencies provide a framework of targets, standards and legislation to enable and require suppliers to meet defined obligations;
- agencies involved in supplying water for consumption by any means should be required to ensure and verify that the systems they administer are capable of delivering safe water and that they routinely achieve this;
- a surveillance agency is responsible for independent (external) surveillance through periodic audit of all aspects of safety and/or verification testing.

In practice, there may not always be a clear division of responsibilities between the surveillance and drinking-water supply agencies. In some cases, the range of professional, governmental, nongovernmental and private institutions may be wider and more complex than that discussed above. Whatever the existing framework, it is important that clear strategies and structures be developed for implementing water safety plans, quality control and surveillance, collating and summarizing data, reporting and disseminating the findings and taking remedial action. Clear lines of accountability and communication are essential.

Surveillance is an investigative activity undertaken to identify and evaluate potential health risks associated with drinking-water. Surveillance contributes to the protection of public health by promoting improvement of the quality, quantity, accessibility, coverage (i.e. populations with reliable access), affordability and continuity of drinking-water supplies (termed "service indicators"). The surveillance authority must have the authority to determine whether a water supplier is fulfilling its obligations.

> Surveillance of drinking-water quality can be defined as "the continuous and vigilant public health assessment and review of the safety and acceptability of drinking-water supplies" (WHO, 1976).

In most countries, the agency responsible for the surveillance of drinking-water supply services is the ministry of health (or public health) and its regional or departmental offices. In some countries, it may be an environmental protection agency; in others, the environmental health departments of local government may have some responsibility.

Surveillance requires a systematic programme of surveys, which may include auditing, analysis, sanitary inspection and institutional and community aspects. It should cover the whole of the drinking-water system, including sources and activities in the catchment, transmission infrastructure, treatment plants, storage reservoirs and distribution systems (whether piped or unpiped).

Ensuring timely action to prevent problems and ensure the correction of faults should be one aim of a surveillance programme. There may at times be a need for penalties to encourage and ensure compliance. The surveillance agency must therefore be supported by strong and enforceable legislation. However, it is important that the agency develops a positive and supportive relationship with suppliers, with the application of penalties used as a last resort.

The surveillance agency should be empowered by law to compel water suppliers to recommend the boiling of water or other measures when microbial contamination that could threaten public health is detected.

1.2.2 Public health authorities

In order to effectively support the protection of public health, a national entity with responsibility for public health will normally act in four areas:

1) *surveillance of health status and trends*, including outbreak detection and investigation, generally directly but in some instances through a decentralized body;
2) directly establishing drinking-water *norms and standards*. National public health authorities often have the primary responsibility for setting norms on drinking-water supply, which may include the setting of water quality targets, performance and safety targets and directly specified requirements (e.g. treatment). Normative activity is not restricted to water quality but also includes, for example, regulation and approval of materials and chemicals used in the production and distribution of drinking-water (see section 8.5.4) and establishing minimum standards in areas such as domestic plumbing (see section 1.2.10). Nor is it a static activity, because as changes occur in drinking-water supply practice, in technologies and in materials available (e.g. in plumbing materials and treatment processes), so health priorities and responses to them will also change;
3) representing health concerns in *wider policy development*, especially health policy and integrated water resource management (see section 1.2.4). Health concerns will often suggest a supportive role towards resource allocation to those concerned with drinking-water supply extension and improvement, will often involve lobbying for the primary requirement to satisfy drinking-water needs above other priorities and may imply involvement in conflict resolution;
4) *direct action*, generally through subsidiary bodies (e.g. regional and local environmental health administrations) or by providing guidance to other local entities (e.g. local government) in surveillance of drinking-water supplies. These roles vary widely according to national and local structures and responsibilities and frequently include a supportive role to community suppliers, where local authorities often intervene directly.

Public health surveillance (i.e. surveillance of health status and trends) contributes to verifying drinking-water safety. It takes into consideration disease in the entire population, which may be exposed to pathogenic microorganisms from a range of sources, not only drinking-water. National public health authorities may also undertake or direct research to evaluate the role of water as a risk factor in disease, through case–control, cohort or intervention studies, for example. Public health surveillance teams typically operate at national, regional and local levels, as well as in cities and rural health centres. Routine surveillance includes:

- ongoing monitoring of reportable diseases, many of which can be caused by waterborne pathogens;
- outbreak detection;

- long-term trend analysis;
- geographic and demographic analysis;
- feedback to water authorities.

Public health surveillance can be enhanced in a variety of ways to identify possible waterborne outbreaks in response to suspicion about unusual disease incidence or following deterioration of water quality. Epidemiological investigations include:

- outbreak investigations;
- intervention studies to evaluate intervention options;
- case–control or cohort studies to evaluate the role of water as a risk factor in disease.

However, public health surveillance cannot be relied upon to provide information in a timely manner to enable short-term operational response to control waterborne disease. Limitations include:

- outbreaks of non-reportable disease;
- time delay between exposure and illness;
- time delay between illness and reporting;
- low level of reporting;
- difficulties in identifying causative pathogens and sources.

The public health authority operates reactively, as well as proactively, against the background of overall public health policy and in interaction with all stakeholders. In accounting for public health context, priority will normally be afforded to disadvantaged groups. This will generally entail balancing drinking-water safety management and improvement with the need to ensure access to reliable supplies of safe drinking-water in adequate quantities.

In order to develop an understanding of the national drinking-water situation, the national public health authority should periodically produce reports outlining the state of national water quality and highlighting public health concerns and priorities in the context of overall public health priorities. This implies the need for effective exchange of information between local, regional and national agencies.

National health authorities should lead or participate in the formulation and implementation of policy to ensure access to some form of reliable, safe drinking-water supply. Where this has not been achieved, appropriate tools and education should be made available to implement individual or household-level treatment and safe storage.

1.2.3 Local authorities

Local environmental health authorities often play an important role in managing water resources and drinking-water supplies. This may include catchment inspection and authorization of activities in the catchment that may have an impact on source water quality. It can also include verifying and auditing (surveillance) of the management of formal drinking-water systems. Local environmental health authorities will also give specific guidance to communities or individuals in designing and implementing community and household drinking-water systems and correcting deficiencies, and they may also be responsible for surveillance of community and household

drinking-water supplies. They have an important role to play in educating consumers where household water treatment is necessary.

Management of household and small community drinking-water supplies generally requires education programmes about drinking-water supply and water quality. Such programmes should normally include:

- water hygiene awareness raising;
- basic technical training and technology transfer in drinking-water supply and management;
- consideration of and approaches to overcoming sociocultural barriers to acceptance of water quality interventions;
- motivation, mobilization and social marketing activities;
- a system of continued support, follow-up and dissemination of the water quality programme to achieve and maintain sustainability.

These programmes can be administered at the community level by local health authorities or other entities, such as nongovernmental organizations and the private sector. If the programme arises from other entities, the involvement of the local health authority in the development and implementation of the water quality education and training programme is strongly encouraged.

Approaches to participatory hygiene and sanitation education and training programmes are described in other WHO documents (see Simpson-Hébert, Sawyer & Clarke, 1996; Sawyer, Simpson-Hébert & Wood, 1998; Brikké, 2000).

1.2.4 Water resource management

Water resource management is an integral aspect of the preventive management of drinking-water quality. Prevention of microbial and chemical contamination of source water is the first barrier against drinking-water contamination of public health concern.

Water resource management and potentially polluting human activity in the catchment will influence water quality downstream and in aquifers. This will have an impact on the treatment steps required to ensure safe water, and preventive action may be preferable to upgrading treatment.

The influence of land use on water quality should be assessed as part of water resource management. This assessment is not normally undertaken by health authorities or drinking-water supply agencies alone and should take into consideration:

- land cover modification;
- extraction activities;
- construction/modification of waterways;
- application of fertilizers, herbicides, pesticides and other chemicals;
- livestock density and application of manure;
- road construction, maintenance and use;
- various forms of recreation;
- urban or rural residential development, with particular attention to excreta disposal, sanitation, landfill and waste disposal;

- other potentially polluting human activities, such as industry, mining and military sites.

Water resource management may be the responsibility of catchment management agencies and/or other entities controlling or affecting water resources, such as industrial, agricultural, navigation and flood control entities.

The extent to which the responsibilities of health or drinking-water supply agencies include water resource management varies greatly between countries and communities. Regardless of government structures and sector responsibilities, it is important that health authorities liaise and collaborate with sectors managing the water resource and regulating land use in the catchment.

Establishing close collaboration between the public health authority, water supplier and resource management agency assists recognition of the health hazards potentially occurring in the system. It is also important for ensuring that the protection of drinking-water resources is considered in decisions for land use or regulations to control contamination of water resources. Depending on the setting, this may include involvement of further sectors, such as agriculture, traffic, tourism or urban development.

To ensure the adequate protection of drinking-water sources, national authorities will normally interact with other sectors in formulating national policy for integrated water resource management. Regional and local structures for implementing the policy will be set up, and national authorities will guide regional and local authorities by providing tools.

Regional environmental or public health authorities have an important task in participating in the preparation of integrated water resource management plans to ensure the best available drinking-water source quality. For further information, see the supporting document *Protecting groundwater for health* and *Protecting surface water for health* (see Annex 1).

1.2.5 Drinking-water supply agencies

Drinking-water supplies vary from very large urban systems servicing large populations with tens of millions of people to small community systems providing water to very small populations. In most countries, they include community sources as well as piped means of supply.

Drinking-water supply agencies are responsible for quality assurance and quality control (see section 1.2.1). Their key responsibilities are to prepare and implement water safety plans (for more information, see chapter 4).

In many cases, the water supplier is not responsible for the management of the catchment feeding the sources of its supplies. The roles of the water supplier with respect to catchments are to participate in interagency water resource management activities, to understand the risks arising from potentially contaminating activities and incidents and to use this information in assessing risks to the drinking-water supply and developing and applying appropriate management. Although drinking-water suppliers may not undertake catchment surveys and pollution risk assessment alone, their role is to recognize the need for them and to initiate multiagency collaboration—for example, with health and environmental authorities.

Experience has shown that an association of stakeholders in drinking-water supply (e.g. operators, managers and specialist groups such as small suppliers, scientists, sociologists, legislators and politicians) can provide a valuable non-threatening forum for the interchange of ideas.

For further information, see the supporting document *Water safety plans* (see Annex 1).

1.2.6 Community management

Community-managed drinking-water systems, with both piped and non-piped distribution, are common worldwide in both developed and developing countries. The precise definition of a community drinking-water system will vary. Although a definition based on population size or the type of supply may be appropriate under many conditions, approaches to administration and management provide a distinction between the drinking-water systems of small communities and those of larger towns and cities. This includes the increased reliance on often untrained and sometimes unpaid community members in the administration and operation of community drinking-water systems. Drinking-water systems in periurban areas—the communities surrounding major towns and cities—in developing countries may also have the characteristics of community systems.

Effective and sustainable programmes for the management of community drinking-water quality require the active support and involvement of local communities. These communities should be involved at all stages of such programmes, including initial surveys; decisions on siting of wells, siting of intakes or establishing protection zones; monitoring and surveillance of drinking-water supplies; reporting faults, carrying out maintenance and taking remedial action; and supportive actions, including sanitation and hygiene practices.

A community may already be highly organized and taking action on health or drinking-water supply issues. Alternatively, it may lack a well-developed drinking-water system; some sectors of the community, such as women, may be poorly represented; and there may be disagreements or factional conflicts. In these situations, achieving community participation will take more time and effort to bring people together, resolve differences, agree on common aims and take action. Visits, possibly over several years, will often be needed to provide support and encouragement and to ensure that the structures created for safe drinking-water supply continue to operate. This may involve setting up hygiene and health educational programmes to ensure that the community:

- is aware of the importance of drinking-water quality and its relationship with health and of the need for safe drinking-water in sufficient quantities for domestic use for drinking, cooking and hygiene;
- recognizes the importance of surveillance and the need for a community response;
- understands and is prepared to play its role in the surveillance process;
- has the necessary skills to perform that role;
- is aware of requirements for the protection of drinking-water supplies from pollution.

For further information, see the 1997 volume entitled *Surveillance and control of community supplies* (WHO, 1997); the supporting document *Water safety plans* (Annex 1); Simpson-Hébert, Sawyer & Clarke (1996); Sawyer, Simpson-Hébert & Wood (1998); and Brikké (2000).

1.2.7 Water vendors

Vendors selling water to households or at collection points are common in many parts of the world where scarcity of water or faults in or lack of infrastructure limits access to suitable quantities of drinking-water. Water vendors use a range of modes of transport to carry drinking-water for sale directly to the consumer, including tanker trucks and wheelbarrows or trolleys. In the context of these Guidelines, water vending does not include bottled or packaged water (which is considered in section 6.14) or water sold through vending machines.

There are a number of health concerns associated with water supplied to consumers by water vendors. These include access to adequate volumes and concern regarding inadequate treatment or transport in inappropriate containers, which can result in contamination.

More detailed information on treatment of vended water, undertaking a risk assessment of vended water supplies, operational monitoring of control measures, management plans and independent surveillance is included in section 6.3.

1.2.8 Individual consumers

Everyone consumes water from one source or another, and consumers often play important roles in the collection, treatment and storage of water. Consumer actions may help to ensure the safety of the water they consume and may also contribute to improvement or contamination of the water consumed by others. Consumers have the responsibility for ensuring that their actions do not have an adverse impact on water quality. Installation and maintenance of household plumbing systems should be undertaken preferably by qualified and authorized plumbers (see section 1.2.10) or other persons with appropriate expertise to ensure that cross-connections or backflow events do not result in contamination of local water supplies.

In most countries, there are populations whose water is derived from household sources, such as private wells and rainwater. In households using non-piped water supplies, appropriate efforts are needed to ensure safe collection, storage and perhaps treatment of their drinking-water. In some circumstances, households and individuals may wish to treat water in the home to increase their confidence in its safety. This would be relevant where community supplies are absent or where community supplies are known to be contaminated or causing waterborne disease (see chapter 7). Public health surveillance or other local authorities may provide guidance to support households and individual consumers in ensuring the safety of their drinking-water. Such guidance is best provided in the context of a community education and training programme.

1.2.9 Certification agencies

Certification is used to verify that devices and materials used in the drinking-water supply meet a given level of quality and safety. Certification is a process in which

an independent organization validates the claims of the manufacturers against a formal standard or criterion or provides an independent assessment of possible risks of contamination from a material or process. The certification agency may be responsible for seeking data from manufacturers, generating test results, conducting inspections and audits and possibly making recommendations on product performance.

Certification has been applied to technologies used at household and community levels, such as hand pumps; materials used by water supplies, such as treatment chemicals; and devices used in the household for collection, treatment and storage.

Certification of products or processes involved in the collection, treatment, storage and distribution of water can be overseen by government agencies or private organizations. Certification procedures will depend on the standards against which the products are certified, certification criteria and the party that performs the certification.

Certification can also be applied to the implementation of water safety plans. This can take the form of an independent organization or party undertaking audits to verify that plans have been properly designed, are being implemented correctly and are effective.

National, local government or private (third-party auditing) certification programmes have a number of possible objectives:

- certification of products to ensure that their use does not threaten the safety of the user or the general public, such as by causing contamination of drinking-water with toxic substances, substances that could affect consumer acceptability or substances that support the growth of microorganisms;
- product testing, to avoid retesting at local levels or prior to each procurement;
- ensuring uniform quality and condition of products;
- certification and accreditation of analytical and other testing laboratories;
- control of materials and chemicals used for the treatment of drinking-water, including the performance of devices for household use;
- ensuring that water safety plans are effective.

An important step in any certification procedure is the establishment of standards, which must form the basis of assessment of the products. These standards should also—as far as possible—contain the criteria for approval. In procedures for certification on technical aspects, these standards are generally developed in cooperation with the manufacturers, the certifying agency and the consumers. The national public health authorities should have responsibility for developing the parts of the approval process or criteria relating directly to public health. For further information on the control of materials and chemicals used for the treatment of drinking-water, see section 8.5.4.

1.2.10 Plumbing

Significant adverse health effects have been associated with inadequate plumbing systems within public and private buildings arising from poor design, incorrect installation, alterations and inadequate maintenance.

Numerous factors influence the quality of water within a building's piped distribution system and may result in microbial or chemical contamination of drinking-water. Outbreaks of gastrointestinal disease can occur through faecal contamination of drinking-water within buildings arising from deficiencies in roof storage tanks and cross-connections with wastewater pipes, for example. Poorly designed plumbing systems can cause stagnation of water and provide a suitable environment for the proliferation of *Legionella*. Plumbing materials, pipes, fittings and coatings can result in elevated heavy metal (e.g. lead) concentrations in drinking-water, and inappropriate materials can be conducive to bacterial growth. Potential adverse health effects may not be confined to the individual building. Exposure of other consumers to contaminants is possible through contamination of the local public distribution system, beyond the particular building, through cross-contamination of drinking-water and backflow.

The delivery of water that complies with relevant standards within buildings generally relies on a plumbing system that is not directly managed by the water supplier. Reliance is therefore placed on proper installation of plumbing and, for larger buildings, on building-specific water safety plans (see section 6.9).

To ensure the safety of drinking-water supplies within the building system, plumbing practices must prevent the introduction of hazards to health. This can be achieved by ensuring that:

- pipes carrying either water or wastes are watertight, durable, of smooth and unobstructed interior and protected against anticipated stresses;
- cross-connections between the drinking-water supply and the wastewater removal systems do not occur;
- roof storage systems are intact and not subject to intrusion of microbial or chemical contaminants;
- hot and cold water systems are designed to minimize the proliferation of *Legionella* (see also sections 6.10 and 11.1);
- appropriate protection is in place to prevent backflow;
- the system design of multistorey buildings minimizes pressure fluctuations;
- waste is discharged without contaminating drinking-water;
- plumbing systems function efficiently.

It is important that plumbers are appropriately qualified, have the competence to undertake necessary servicing of plumbing systems to ensure compliance with local regulations and use only materials approved as safe for use with drinking-water.

Design of the plumbing systems of new buildings should normally be approved prior to construction and be inspected by an appropriate regulatory body during construction and prior to commissioning of the buildings.

For more information on the essential roles of proper drinking-water system and waste system plumbing in public health, see the supporting document *Health aspects of plumbing* (Annex 1).

1.3 Supporting resources to the Guidelines

1.3.1 Published documents

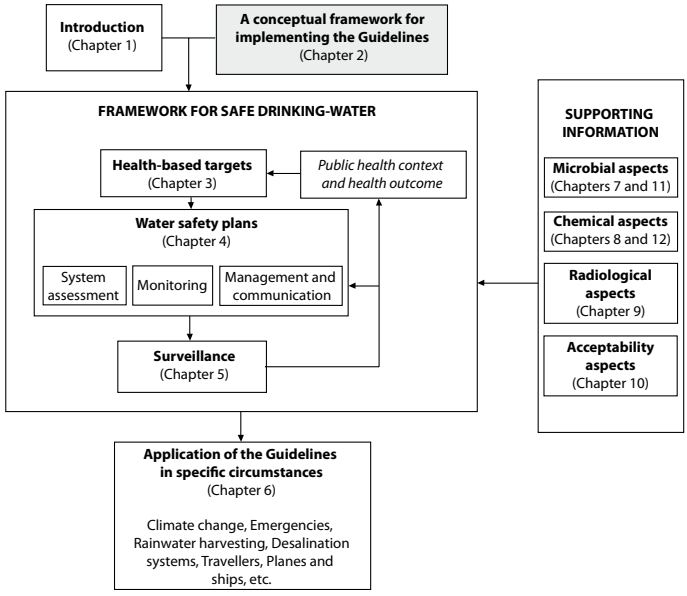
These Guidelines are accompanied by separate texts that provide background information substantiating the derivation of the Guidelines and providing guidance on good practice towards their effective implementation. These are available as published texts, for download from the WHO web site and on CD-ROM. Reference details are provided in Annex 1.

1.3.2 Capacity-building networks

To promote the rapid dissemination of information, improve knowledge exchange, translate evidence and advice into public health policy and practice and facilitate implementation of these Guidelines, a number of international networks have been established. These international networks bring together drinking-water quality specialists, drinking-water supply managers, health regulators, community managers and other stakeholders. The focus areas for these networks are water safety planning for larger systems, including effective operations and maintenance, safe management of small community water supplies, household water treatment and safe storage and optimizing drinking-water regulations to protect public health.

Further information on these networks is available at http://www.who.int/water_sanitation_health/water-quality/en/.

2
A conceptual framework for implementing the Guidelines



The basic and essential requirement to ensure the safety of drinking-water is the implementation of a "framework for safe drinking-water" based on the Guidelines. This framework provides a preventive, risk-based approach to managing water quality. It would be composed of health-based targets established by a competent health authority using the Guidelines as a starting point, adequate and properly managed systems (adequate infrastructure, proper monitoring and effective planning and management) and a system of independent surveillance. Such a framework would normally be enshrined in national standards, regulations, or guidelines, in conjunction with relevant policies and programmes (see sections 2.6 and 2.7). Resultant regulations and policies should be appropriate to local circumstances, taking into consideration environmental, social, economic and cultural issues and priority setting.

The framework for safe drinking-water is a preventive management approach comprising three key components:

1) health-based targets based on an evaluation of health risks (section 2.1 and chapter 3);
2) water safety plans (WSPs), comprising (section 2.2 and chapter 4):
   - a system assessment to determine whether the drinking-water supply (from source through treatment to the point of consumption) as a whole can deliver water of a quality that meets the health-based targets (section 4.1);
   - operational monitoring of the control measures in the drinking-water supply that are of particular importance in securing drinking-water safety (section 4.2);
   - management plans documenting the system assessment and monitoring plans and describing actions to be taken in normal operation and incident conditions, including upgrade and improvement, documentation and communication (sections 4.4–4.6);
3) a system of independent surveillance that verifies that the above are operating properly (section 2.3 and chapter 5).

Verification to determine whether the performance of the drinking-water supply is in compliance with the health-based targets and whether the WSP itself is effective may be undertaken by the supplier, surveillance agencies or a combination of the two (see section 4.3).

2.1 Health-based targets

Health-based targets are an essential component of the drinking-water safety framework. They should be established by a high-level authority responsible for health in consultation with others, including water suppliers and affected communities. They should take account of the overall public health situation and contribution of drinking-water quality to disease due to waterborne microbes and chemicals, as a part of overall water and health policy. They must also take account of the importance of ensuring access to water for all consumers.

Health-based targets provide the basis for the application of the Guidelines to all types of drinking-water suppliers. Some constituents of drinking-water may cause adverse health effects from single exposures (e.g. pathogenic microorganisms) or long-term exposures (e.g. many chemicals). Because of the range of constituents in water, their mode of action and the nature of fluctuations in their concentrations, there are four principal types of health-based targets used as a basis for identifying safety requirements:

1) *Health outcome targets:* Where waterborne disease contributes to a measurable and significant burden, reducing exposure through drinking-water has the potential to appreciably reduce the risks and incidence of disease. In such circumstances, it is possible to establish a health-based target in terms of a quantifiable reduction in the overall level of disease. This is most applicable where adverse effects follow shortly after exposure, where such effects are readily and reliably monitored and where changes in exposure can also be readily and reliably monitored. This type of health outcome target is primarily applicable to some microbial hazards in developing countries and chemical hazards with clearly defined health effects

largely attributable to water (e.g. fluoride, nitrate/nitrite and arsenic). In other circumstances, health outcome targets may be the basis for evaluation of results through quantitative risk assessment models. In these cases, health outcomes are estimated based on information concerning high-dose exposure and dose–response relationships. The results may be employed directly as a basis for the specification of water quality targets or provide the basis for development of the other types of health-based targets. Health outcome targets based on information on the impact of tested interventions on the health of real populations are ideal, but rarely available. More common are health outcome targets based on defined levels of tolerable risk, either absolute or fractions of total disease burden, usually based on toxicological studies in experimental animals and occasionally based on epidemiological evidence.

2) *Water quality targets:* Water quality targets are established for individual drinking-water constituents that represent a health risk from long-term exposure and where fluctuations in concentration are small. They are typically expressed as guideline values (concentrations) of the substances or chemicals of concern.
3) *Performance targets:* Performance targets are employed for constituents where short-term exposure represents a public health risk or where large fluctuations in numbers or concentration can occur over short periods with significant health implications. These are typically technology based and expressed in terms of required reductions of the substance of concern or effectiveness in preventing contamination.
4) *Specified technology targets:* National regulatory agencies may establish other recommendations for specific actions for smaller municipal, community and household drinking-water supplies. Such targets may identify specific permissible devices or processes for given situations and/or for generic drinking-water system types.

It is important that health-based targets are realistic under local operating conditions and are set to protect and improve public health. Health-based targets underpin the development of WSPs, provide information with which to evaluate the adequacy of existing installations and assist in identifying the level and type of inspection and analytical verifications that are appropriate.

Most countries apply several types of targets for different types of supplies and different contaminants. In order to ensure that they are relevant and supportive, representative scenarios should be developed, including description of assumptions, management options, control measures and indicator systems for performance tracking and verification, where appropriate. These should be supported by general guidance addressing the identification of national, regional or local priorities and progressive implementation, thereby helping to ensure that best use is made of limited resources.

Health-based targets are considered in more detail in chapter 3.

For guidance on how to prioritize constituents based on greatest risk to public health, the reader should refer to section 2.5 and the supporting document *Chemical safety of drinking-water* (Annex 1).

2.2 Water safety plans

Overall control of the microbial and chemical quality of drinking-water requires the development of management plans that, when implemented, provide the basis for system protection and process control to ensure that numbers of pathogens and concentrations of chemicals present a negligible risk to public health and that water is acceptable to consumers. The management plans developed by water suppliers are WSPs. A WSP comprises system assessment and design, operational monitoring and management plans, including documentation and communication. The elements of a WSP build on the multiple-barrier principle, the principles of hazard analysis and critical control points and other systematic management approaches. The plans should address all aspects of the drinking-water supply and focus on the control of abstraction, treatment and delivery of drinking-water.

Many drinking-water supplies provide adequate safe drinking-water in the absence of formalized WSPs. Major benefits of developing and implementing a WSP for these supplies include the systematic and detailed assessment and prioritization of hazards, the operational monitoring of barriers or control measures and improved documentation. In addition, a WSP provides for an organized and structured system to minimize the chance of failure through oversight or lapse of management and for contingency plans to respond to system failures or unforeseen events that may have an impact on water quality, such as increasing severe droughts, heavy rainfall or flood events.

2.2.1 System assessment and design

Assessment of the drinking-water system is applicable, with suitable modifications, to large utilities with piped distribution systems, piped and non-piped community supplies, including hand pumps, and individual domestic supplies, including rainwater. The complexity of a WSP varies with the circumstances. Assessment can be of existing infrastructure or of plans for new supplies or for upgrading existing supplies. As drinking-water quality varies throughout the system, the assessment should aim to determine whether the final quality of water delivered to the consumer will routinely meet established health-based targets. Understanding source quality and changes throughout the system requires expert input. The assessment of systems should be reviewed periodically.

The system assessment needs to take into consideration the behaviour of selected constituents or groups of constituents that may influence water quality. After actual and potential hazards, including events and scenarios that may affect water quality, have been identified and documented, the level of risk for each hazard can be estimated and ranked, based on the likelihood and severity of the consequences.

Validation is an element of system assessment. It is undertaken to ensure that the information supporting the plan is correct and is concerned with the assessment of the scientific and technical inputs into the WSP. Evidence to support the WSP can come from a wide variety of sources, including scientific literature, regulation and legislation departments, historical data, professional bodies and supplier knowledge.

The WSP is the management tool that should be used to assist in actually meeting the health-based targets, and it should be developed following the steps outlined in

chapter 4. If the system is unlikely to be capable of meeting the health-based targets, a programme of upgrading (which may include capital investment or training) should be initiated to ensure that the drinking-water supply would meet the targets. The WSP is an important tool in identifying deficiencies and where improvements are most needed. In the interim, the WSP should be used to assist in making every effort to supply water of the highest achievable quality. Where a significant risk to public health exists, additional measures may be appropriate, including notification, information on compensatory options (e.g. boiling or disinfection at the point of use) and availability of alternative and emergency supplies when necessary.

System assessment and design are considered in more detail in section 4.1 (see also the supporting document *Upgrading water treatment plants*; Annex 1).

2.2.2 Operational monitoring

Operational monitoring is the conduct of planned observations or measurements to assess whether the control measures in a drinking-water system are operating properly. It is possible to set limits for control measures, monitor those limits and take corrective action in response to a detected deviation before the water becomes unsafe. Operational monitoring would include actions, for example, to rapidly and regularly assess whether the structure around a hand pump is complete and undamaged, the turbidity of water following filtration is below a certain value or the chlorine residual after disinfection plants or at the far point of the distribution system is above an agreed value.

Operational monitoring is usually carried out through simple observations and tests, in order to rapidly confirm that control measures are continuing to work. Control measures are actions implemented in the drinking-water system that prevent, reduce or eliminate contamination and are identified in system assessment. They include, for example, management actions related to the catchment, the immediate area around a well, filters and disinfection infrastructure and piped distribution systems. If collectively operating properly, they would ensure that health-based targets are met.

The frequency of operational monitoring varies with the nature of the control measure—for example, checking structural integrity monthly to yearly, monitoring turbidity online or very frequently and monitoring disinfectant residual at multiple points daily or continuously online. If monitoring shows that a limit does not meet specifications, then there is the potential for water to be, or to become, unsafe. The objective is timely monitoring of control measures, with a logically based sampling plan, to prevent the delivery of potentially unsafe water.

Operational monitoring includes observing or testing parameters such as turbidity, chlorine residual or structural integrity. More complex or costly microbial or chemical tests are generally applied as part of validation and verification activities (discussed in sections 4.1.7 and 4.3, respectively) rather than as part of operational monitoring.

In order not only to have confidence that the chain of supply is operating properly, but to confirm that safe water quality is being achieved and maintained, it is necessary to carry out verification, as outlined in section 4.3.

The use of indicator organisms (see section 11.6) in the monitoring of water quality is discussed in the supporting document *Assessing microbial safety of drinking water* (see Annex 1), and operational monitoring is considered in more detail in section 4.2.

2.2.3 Management plans, documentation and communication

A management plan documents system assessment and operational monitoring and verification plans and describes actions in both normal operation and during "incidents" where a loss of control of the system may occur. The management plan should also outline procedures and other supporting programmes required to ensure optimal operation of the drinking-water system.

As the management of some aspects of the drinking-water system often falls outside the responsibility of a single agency, it is essential that the roles, accountabilities and responsibilities of the various agencies involved be defined in order to coordinate their planning and management. Appropriate mechanisms and documentation should therefore be established for ensuring stakeholder involvement and commitment. This may include establishing working groups, committees or task forces, with appropriate representatives, and developing partnership agreements, including, for example, signed memoranda of understanding (see also section 1.2).

Documentation of all aspects of drinking-water quality management is essential. Documents should describe activities that are undertaken and how procedures are performed. They should also include detailed information on:

- assessment of the drinking-water system (including flow diagrams and potential hazards);
- control measures and operational monitoring and verification plans and performance consistency;
- routine operation and management procedures;
- incident and emergency response plans;
- supporting measures, including:
  - training programmes;
  - research and development;
  - procedures for evaluating results and reporting;
  - performance evaluations, audits and reviews;
  - communication protocols;
- community consultation.

Documentation and record systems should be kept as simple and focused as possible. The level of detail in the documentation of procedures should be sufficient to provide assurance of operational control when coupled with suitably qualified and competent operators.

Mechanisms should be established to periodically review and, where necessary, revise documents to reflect changing circumstances. Documents should be assembled in a manner that will enable any necessary modifications to be made easily. A document control system should be developed to ensure that current versions are in use and obsolete documents are discarded.

Appropriate documentation and reporting of incidents or emergencies should also be established. The organization should learn as much as possible from an incident to improve preparedness and planning for future events. Review of an incident may indicate necessary amendments to existing protocols.

Effective communication to increase community awareness and knowledge of drinking-water quality issues and the various areas of responsibility helps consumers to understand and contribute to decisions about the service provided by a drinking-water supplier or land use constraints imposed in catchment areas. It can encourage the willingness of consumers to generate funds to finance needed improvements. A thorough understanding of the diversity of views held by individuals or groups in the community is necessary to satisfy community expectations.

Management, documentation and communication are considered in more detail in sections 4.4, 4.5 and 4.6.

2.3 Surveillance

Surveillance agencies are responsible for an independent (external) and periodic review of all aspects of quality and public health safety and should have the power to investigate and to compel action to respond to and rectify incidents of contamination-caused outbreaks of waterborne disease or other threats to public health. The act of surveillance includes identifying potential drinking-water contamination and waterborne illness events and, more proactively, assessing compliance with WSPs and promoting improvement of the quality, quantity, accessibility, coverage, affordability and continuity of drinking-water supplies.

Surveillance of drinking-water requires a systematic programme of data collection and surveys that may include auditing of WSPs, analysis, sanitary inspection and institutional and community aspects. It should cover the whole of the drinking-water system, including sources and activities in the catchment, transmission infrastructure, whether piped or unpiped, treatment plants, storage reservoirs and distribution systems.

As incremental improvement and prioritizing action in systems presenting greatest overall risk to public health are important, there are advantages to adopting a grading scheme for the relative safety of drinking-water supplies (see chapter 4). More sophisticated grading schemes may be of particular use in community supplies where the frequency of testing is low and exclusive reliance on analytical results is particularly inappropriate. Such schemes will typically take account of both analytical findings and sanitary inspection through approaches such as those presented in section 4.1.2.

The role of surveillance is discussed in section 1.2.1 and chapter 5.

2.4 Verification of drinking-water quality

Drinking-water safety is secured by application of a WSP, which includes monitoring the efficiency of control measures using appropriately selected determinants. In addition to this operational monitoring, a final verification of quality is required.

Verification is the use of methods, procedures or tests in addition to those used in operational monitoring to determine whether the performance of the drinking-water

supply is in compliance with the stated objectives outlined by the health-based targets and whether the WSP needs modification or revalidation.

Verification of drinking-water may be undertaken by the supplier, surveillance agencies or a combination of the two (see section 4.3). Although verification is most commonly carried out by the surveillance agency, a utility-led verification programme can provide an additional level of confidence, supplementing regulations that specify monitoring parameters and frequencies.

2.4.1 Microbial water quality

For microbial water quality, verification is likely to be based on the analysis of faecal indicator microorganisms, with the organism of choice being *Escherichia coli* or, alternatively, thermotolerant coliforms (see sections 4.3.1, 7.4 and 11.6). Monitoring of specific pathogens may be included on very limited occasions to verify that an outbreak was waterborne or that a WSP has been effective. *Escherichia coli* provides conclusive evidence of recent faecal pollution and should not be present in drinking-water. Under certain circumstances, additional indicators, such as bacteriophages or bacterial spores, may be used.

However, water quality can vary rapidly, and all systems are at risk of occasional failure. For example, rainfall can greatly increase the levels of microbial contamination in source waters, and waterborne outbreaks often occur following rainfall. Results of analytical testing must be interpreted taking this into account.

2.4.2 Chemical water quality

Assessment of the adequacy of the chemical quality of drinking-water relies on comparison of the results of water quality analysis with guideline values. These Guidelines provide guideline values for many more chemical contaminants than will actually affect any particular water supply, so judicious choices for monitoring and surveillance should be made prior to initiating an analytical chemical assessment.

For additives (i.e. chemicals deriving primarily from materials and chemicals used in the production and distribution of drinking-water), emphasis is placed on the direct control of the quality of these commercial products. In controlling drinking-water additives, testing procedures typically assess whether the product meets the specifications (see section 8.5.4).

As indicated in chapter 1, most chemicals are of concern only following long-term exposure; however, some hazardous chemicals that occur in drinking-water are of concern because of effects arising from sequences of exposures over a short period. Where the concentration of the chemical of interest (e.g. nitrate/nitrite, which is associated with methaemoglobinaemia in bottle-fed infants) varies widely, even a series of analytical results may fail to fully identify and describe the public health risk. In controlling such hazards, attention must be given to both knowledge of causal factors such as fertilizer use in agriculture and trends in detected concentrations, as these will indicate whether a significant problem may arise in the future. Other hazards may arise intermittently, often associated with seasonal activity or seasonal conditions. One example is the occurrence of blooms of toxic cyanobacteria in surface water.

A *guideline value* represents the concentration of a constituent that does not exceed tolerable risk to the health of the consumer over a lifetime of consumption. Guideline values for some chemical contaminants (e.g. lead, nitrate) are set to be protective for susceptible subpopulations. These guideline values are also protective of the general population over a lifetime.

It is important that recommended guideline values are scientifically justified, practical and feasible to implement as well as protective of public health. Guideline values are not normally set at concentrations lower than the detection limits achievable under routine laboratory operating conditions. Moreover, some guideline values are established taking into account available techniques for controlling, removing or reducing the concentration of the contaminant to the desired level. In some instances, therefore, provisional guideline values have been set for contaminants for which calculated health-based values are not practically achievable.

2.5 Identifying priority concerns

These Guidelines cover a large number of potential constituents in drinking-water in order to meet the varied needs of countries worldwide. Generally, however, only a few constituents will be of public health concern under any given circumstances. It is essential that the national regulatory agency and local water authorities identify and respond to the constituents of relevance to the local circumstances. This will ensure that efforts and investments can be directed to those constituents that have the greatest risk or public health significance.

Health-based targets are established for potentially hazardous water constituents and provide a basis for assessing drinking-water quality. Different parameters may require different priorities for management to improve and protect public health. In general, the priorities, in decreasing order, are to:

- ensure an adequate supply of microbially safe water and maintain acceptability to discourage consumers from using potentially less microbially safe water;
- manage key chemical hazards known to cause adverse health effects;
- address other chemical hazards, particularly those that affect the acceptability of drinking-water in terms of its taste, odour and appearance;
- apply appropriate technologies to reduce contaminant concentrations in the source to below the guideline or regulated values.

The two key features in choosing hazards for which setting a standard is desirable on health grounds are the health impacts (severity) associated with the substance and the probability of significant occurrence (exposure). Combined, these elements determine the risk associated with a particular hazard. For

Many microbial and chemical constituents of drinking-water can potentially cause adverse human health effects. The detection of these constituents in both raw water and water delivered to consumers is often slow, complex and costly, which limits early warning capability and affordability. Reliance on water quality determination alone is insufficient to protect public health. As it is neither physically nor economically feasible to test for all drinking-water quality parameters, the use of monitoring effort and resources should be carefully planned and directed at significant or key characteristics.

microbial hazards, the setting of targets will be influenced by occurrence and concentrations in source waters and the relative contribution of waterborne organisms to disease. For chemical hazards, the factors to be considered are the severity of health effects and the frequency of exposure of the population in combination with the concentration to which they will be exposed. The probability of health effects clearly depends on the toxicity and the concentration, but it also depends on the period of exposure. For most chemicals, health impacts are associated with long-term exposure. Hence, in the event that exposure is occasional, the risk of an adverse health effect is likely to be low, unless the concentration is extremely high. The substances of highest priority will therefore be those that occur widely, are present in drinking-water sources or drinking-water all or most of the time and are present at concentrations that are of health concern.

Guidance on determining which chemicals are of importance in a particular situation is given in the supporting document *Chemical safety of drinking-water* (Annex 1).

Although WHO does not set formal guideline values for substances on the basis of consumer acceptability (i.e. substances that affect the appearance, taste or odour of drinking-water), it is not uncommon for standards to be set for substances and parameters that relate to consumer acceptability. Although exceeding such a standard is not a direct issue for health, it may be of great significance for consumer confidence and may lead consumers to obtain their water from an alternative, less safe source. Such standards are usually based on local considerations of acceptability.

Priority setting should be undertaken on the basis of a systematic assessment based on collaborative effort among all relevant agencies and may be applied at national and system-specific levels. At the national level, priorities need to be set in order to identify the relevant hazards, based on an assessment of risk—i.e. severity and exposure. At the level of individual water supplies, it may be necessary to also prioritize constituents for effective system management. These processes may require the input of a broad range of stakeholders, including health, water resources, drinking-water supply, environment, agriculture and geological services/mining authorities, to establish a mechanism for sharing information and reaching consensus on drinking-water quality issues.

2.5.1 Undertaking a drinking-water quality assessment

In order to determine which constituents are, indeed, of concern, it will be necessary to undertake a drinking-water quality assessment. It is important to identify what types of drinking-water systems are in place in the country (e.g. piped water supplies, non-piped water supplies, vended water) and the quality of drinking-water sources and supplies.

Additional information that should be considered in the assessment includes catchment type (protected, unprotected), wastewater discharges, geology, topography, agricultural land use, industrial activities, sanitary surveys, records of previous monitoring, inspections and local and community knowledge. The wider the range of data sources used, the more useful the results of the process will be.

In many situations, authorities or consumers may have already identified a number of drinking-water quality problems, particularly where they cause obvious health effects or acceptability problems. These existing problems would normally be assigned a high priority.

Drinking-water supplies that represent the greatest risks to public health should be identified, with resources allocated accordingly.

2.5.2 Assessing microbial priorities

The most common and widespread health risk associated with drinking-water is microbial contamination, the consequences of which mean that its control must always be of paramount importance. Priority needs to be given to improving and developing the drinking-water supplies that represent the greatest public health risk.

The most common and widespread health risk associated with drinking-water is microbial contamination, the consequences of which mean that its control must always be of paramount importance.

Health-based targets for microbial contaminants are discussed in section 3.2, and a comprehensive consideration of microbial aspects of drinking-water quality is contained in chapter 7.

2.5.3 Assessing chemical priorities

Not all of the chemicals with guideline values will be present in all water supplies or, indeed, all countries. If they do exist, they may not be found at levels of concern. Conversely, some chemicals without guideline values or not addressed in the Guidelines may nevertheless be of legitimate local concern under special circumstances.

Risk management strategies (as reflected in national standards and monitoring activities) and commitment of resources should give priority to those chemicals that pose a risk to human health or to those with significant impacts on the acceptability of water.

Only a few chemicals have been shown to cause widespread health effects in humans as a consequence of exposure through drinking-water when they are present in excessive quantities. These include fluoride, arsenic and nitrate. Human health effects associated with lead (from domestic plumbing) have also been demonstrated in some areas, and there is concern because of the potential extent of exposure to selenium and uranium in some areas at concentrations of human health significance. Iron and manganese are of widespread significance because of their effects on acceptability. These constituents should be taken into consideration as part of any priority-setting process. In some cases, assessment will indicate that no risk of significant exposure exists at the national, regional or system level.

Drinking-water may be only a minor contributor to the overall exposure to a particular chemical, and in some circumstances controlling the levels in drinking-water, at potentially considerable expense, may have little impact on overall exposure. Drinking-water risk management strategies should therefore be considered in conjunction with other potential sources of human exposure.

The process of "short-listing" chemicals of concern may initially be a simple classification of high and low risk to identify broad issues. This may be refined using data from more detailed assessments and analysis and may take into consideration rare events, variability and uncertainty.

Guidance on how to undertake prioritization of chemicals in drinking-water is provided in the supporting document *Chemical safety of drinking-water* (Annex 1). This deals with issues including:

- the probability of exposure (including the period of exposure) of the consumer to the chemical;
- the concentration of the chemical that is likely to give rise to health effects (see also section 8.5);
- the evidence of health effects or exposure arising through drinking-water, as opposed to other sources, and relative ease of control of the different sources of exposure.

Additional information on the hazards and risks of many chemicals not included in these Guidelines is available from several sources, including WHO Environmental Health Criteria monographs and Concise International Chemical Assessment Documents, reports by the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Meeting on Pesticide Residues and the Joint FAO/WHO Expert Committee on Food Additives and information from competent national authorities. These information sources have been peer reviewed and provide readily accessible information on toxicology, hazards and risks of many less common contaminants. They can help water suppliers and health officials to decide upon the significance (if any) of a detected chemical and on the response that might be appropriate.

2.6 Developing drinking-water quality standards

Health-based targets, including numeric guideline values and other targets described in the *Guidelines for drinking-water quality*, are not intended to be mandatory limits, but are provided as the scientific point of departure for development of national or regional numerical drinking-water quality standards. No single approach is universally applicable, and the nature and form of drinking-water standards may vary among countries and regions.

In developing national drinking-water standards based on these Guidelines, it will be necessary to take account of a variety of environmental, social, cultural, economic, dietary and other conditions affecting potential exposure. This may lead to national standards that differ appreciably from these Guidelines, both in scope as well as in risk targets. A programme based on modest but realistic goals—including fewer water quality parameters of priority health concern at attainable levels consistent with providing a reasonable degree of public health protection in terms of reduction of disease or disease risk within the population—may achieve more than an overambitious one, especially if targets are upgraded periodically.

To ensure that standards are acceptable to consumers, communities served, together with the major water users, should be involved in the standards-setting pro-

cess. Public health agencies may be closer to the community than those responsible for its drinking-water supply. At a local level, they also interact with other sectors (e.g. education), and their combined action is essential to ensure active community involvement.

2.6.1 Adapting guideline values to locally relevant standards

In order to account for variations in exposure from different sources (e.g. water, food) in different parts of the world, the proportion of the tolerable daily intake allocated to drinking-water in setting guideline values for many chemicals will vary. Where relevant exposure data are available, authorities are encouraged to develop context-specific guideline values that are tailored to local circumstances and conditions. For example, in areas where the intake of a particular contaminant in drinking-water is known to be much greater than that from other sources (e.g. air and food), it may be appropriate to allocate a greater proportion of the tolerable daily intake to drinking-water to derive a guideline value more suited to the local conditions.

Daily water intake can vary significantly in different parts of the world, seasonally and particularly where consumers are involved in manual labour in hot climates. Local adjustments to the daily water consumption value may be needed in setting local standards, as in the case of fluoride, for example.

Volatile substances in water may be released into the air during showering and through a range of other household activities. Under such circumstances, inhalation may become a significant route of exposure. Where such exposure is shown to be important for a particular substance (i.e. high volatility, low ventilation rates and high rates of showering/bathing), it may be appropriate to adjust the guideline value. For those substances that are particularly volatile, such as chloroform, the correction factor would be approximately equivalent to a doubling of exposure. For further details, the reader should refer to section 8.2.9.

2.6.2 Periodic review and revision of standards

As knowledge increases, there may be changes to specific guideline values or consideration of new hazards for the safety of drinking-water. There will also be changes in the technology of drinking-water treatment and analytical methods for contaminants. National or subnational standards must therefore be subjected to periodic review and should be structured in such a way that changes can be made readily. Changes may need to be made to modify standards, remove parameters or add new parameters, but no changes should be made without proper justification through risk assessment and prioritization of resources for protecting public health. Where changes are justified, it is important that they are communicated to all stakeholders.

2.7 Drinking-water regulations and supporting policies and programmes

The incorporation of a preventive risk management and prioritization approach to drinking-water quality regulations, policies and programmes will:

- ensure that regulations support the prioritization of drinking-water quality parameters to be tested, instead of making mandatory the testing of every parameter in these Guidelines;
- ensure implementation of appropriate sanitation measures at community and household levels and encourage action to prevent or mitigate contamination at source;
- identify drinking-water supplies that represent the greatest risks to public health and thus determine the appropriate allocation of resources.

2.7.1 Regulations

The alignment of national drinking-water quality regulations with the principles outlined in these Guidelines will ensure that:

- there is an explicit link between drinking-water quality regulations and the protection of public health;
- regulations are designed to ensure safe drinking-water from source to consumer, using multiple barriers;
- regulations are based on good practices that have been proven to be appropriate and effective over time;
- a variety of tools are in place to build and ensure compliance with regulations, including education and training programmes, incentives to encourage good practices and penalties, if enforcement is required;
- regulations are appropriate and realistic within national, subnational and local contexts, including specific provisions or approaches for certain contexts or types of supplies, such as small community water supplies;
- stakeholder roles and responsibilities, including how they should work together, are clearly defined;
- "what, when and how" information is shared between stakeholders—including consumers—and required action is clearly defined for normal operations and in response to incidents or emergencies;
- regulations are adaptable to reflect changes in contexts, understanding and technological innovation and are periodically reviewed and updated;
- regulations are supported by appropriate policies and programmes.

The aim of drinking-water quality regulations should be to ensure that the consumer has access to sustainable, sufficient and safe drinking-water. Enabling legislation should provide broad powers and scope to related regulations and include public health protection objectives, such as the prevention of waterborne disease and the provision of an adequate supply of drinking-water. Drinking-water regulations should focus on improvements to the provision and safety of drinking-water through a variety of requirements, tools and compliance strategies. Although sanctions are needed within regulations, the principal aim is not to shut down deficient water supplies.

Drinking-water quality regulations are not the only mechanism by which public health can be protected. Other regulatory mechanisms include those related to source water protection, infrastructure, water treatment and delivery, surveillance and response to potential contamination and waterborne illness events.

Drinking-water quality regulations may also provide for interim standards, permitted deviations and exemptions as part of a national or regional policy, rather than as a result of local initiatives. This may take the form of temporary exemptions for certain communities or areas for defined periods of time. Short-term and medium-term targets should be set so that the most significant risks to human health are managed first. Regulatory frameworks should support long-term progressive improvements.

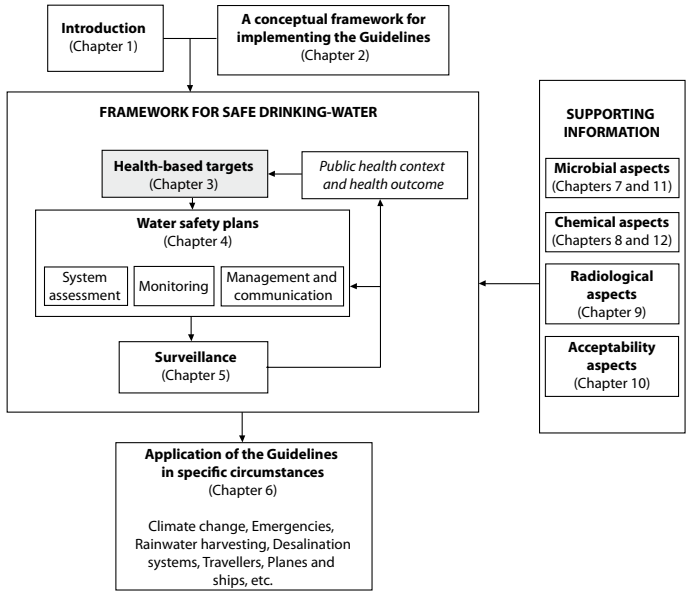
2.7.2 Supporting policies and programmes

Developing and promulgating regulations alone will not ensure that public health is protected. Regulations must be supported by adequate policies and programmes. This includes ensuring that regulatory authorities, such as enforcement agencies, have sufficient resources to fulfil their responsibilities and that the appropriate policy and programme supports are in place to assist those required to comply with regulations. In other words, the appropriate supports need to be in place so that those being regulated and those who are responsible for regulating are not destined to fail.

Implementation or modification of policies and programmes to provide safe drinking-water should not be delayed because of a lack of appropriate regulation. Even where drinking-water regulations do not yet exist, it may be possible to encourage, and even enforce, the supply of safe drinking-water through, for example, educational efforts or commercial, contractual arrangements between consumer and supplier (e.g. based on civil law).

In countries where universal access to safe drinking-water at an acceptable level of service has not been achieved, policies should refer to expressed targets for increases in sustainable access to safe drinking-water. Such policy statements should be consistent with achievement of the Millennium Development Goals (http://www.un.org/millenniumgoals/) of the United Nations Millennium Declaration and should take account of levels of acceptable access outlined in General Comment 15 on the Right to Water of the United Nations Committee on Economic, Social and Cultural Rights (http://umn.edu/humanrts/gencomm/escgencom15.htm) and associated documents.

3
Health-based targets



Health-based targets are measurable health, water quality or performance objectives that are established based on a judgement of safety and on risk assessments of waterborne hazards. These Guidelines describe four distinct types of health-based targets, applicable to all types of hazards and water supplies:

1) health outcome targets (e.g. tolerable burdens of disease);
2) water quality targets (e.g. guideline values for chemical hazards);
3) performance targets (e.g. log reductions of specific pathogens);
4) specified technology targets (e.g. application of defined treatment processes).

These targets are common components of existing drinking-water guidelines or standards that are used to protect and improve drinking-water quality and, consequently, human health. They provide benchmarks for water suppliers and regulators to confirm the adequacy of existing systems or the need for improvement. They underpin the development of water safety plans and verification of successful implementation. Where

Health-based targets can be used to support incremental improvement by marking out milestones to guide progress towards water safety and public health goals.

required, health-based targets can be used to support incremental improvement by marking out milestones to guide progress towards water safety and public health goals. This normally requires periodic review and updating of priorities and targets. In turn, norms and standards should also be periodically updated (see section 2.6.2).

Health-based targets should assist in determining specific interventions appropriate to delivering safe drinking-water, including control measures such as source protection and treatment processes.

3.1 Setting health-based targets

The use of health-based targets is applicable in countries at all levels of development. To ensure effective health protection and improvement, targets need to be realistic, measurable, based on scientific data and relevant to local conditions (including economic, environmental, social and cultural conditions) and financial, technical and institutional resources. Health-based targets should be part of an overall public health policy, taking into account public health status and trends and the contribution of drinking-water to the transmission of infectious disease and to overall exposure to hazardous chemicals both in individual settings and within overall health management.

Although water can be a source of microbial, chemical or radiological hazards, it is by no means the only source. In setting targets, consideration needs to be given to other sources, including food, air, person-to-person contact and consumer products, as well as poor sanitation and personal hygiene. Where the overall burden of disease from multiple exposure routes is very high, there is limited value in setting strict targets for drinking-water. For example, there is limited value in establishing a strict target for a chemical hazard if drinking-water provides only a small proportion of the total exposure to that chemical. The cost of meeting such targets could unnecessarily divert funding from other, more pressing health interventions and is not consistent with the public health objective of reducing overall levels of risk from all sources of exposure to environmental hazards (Prüss et al., 2002; Prüss & Corvalan, 2006).

It is also important to take account of the impact of the proposed intervention on overall rates of disease. For some pathogens and their associated diseases, interventions in water quality may be ineffective and may therefore not be justified. This may be the case where other routes of exposure dominate. For others, long experience has shown the effectiveness of improving drinking-water supply and quality management in the control of waterborne diseases such as typhoid and dysentery.

Meeting health-based targets should be viewed in the context of broader public health policy, including initiatives to improve sanitation, waste disposal, personal hygiene and public education on ways to reduce both personal exposure to hazards and impacts of personal activity on water resources. Improved public health, reduced carriage of pathogens and reduced human impacts on water

> The judgement of safety—or what is a tolerable burden of disease in particular circumstances—is a matter in which society as a whole has a role to play. The final judgement as to whether the benefit resulting from the adoption of any of the health-based targets justifies the cost is for each country to decide.

Table 3.1 Benefits of health-based targets

Target development stage	Benefit
Formulation	Provides insight into the health of the population
	Reveals gaps in knowledge
	Supports priority setting
	Increases the transparency of health policy
	Promotes consistency among national health programmes
	Stimulates debate
Implementation	Inspires and motivates collaborating authorities to take action
	Improves commitment
	Fosters accountability
	Guides the rational allocation of resources
Evaluation	Supplies established milestones for incremental improvements
	Provides opportunity to take action to correct deficiencies and/or deviations
	Identifies data needs and discrepancies

resources all contribute to drinking-water safety (Howard et al., 2002). Public health prioritization would normally indicate that the major contributors to disease should be dealt with preferentially, taking account of the costs and impacts of potential interventions. However, this does not mean ignoring lesser targets if they can be easily achieved for little cost, as long as this does not divert attention from major targets.

An important concept in the allocation of resources to improving drinking-water safety is the possibility of establishing less stringent transitional targets supported by sound risk management systems in order to encourage incremental improvements of the quality of drinking-water. In this regard, health-based targets can be used as the basis for supporting and measuring incremental progress in water quality improvement. Improvements can relate to progression through increasingly tighter targets or evolution through target types that more precisely reflect the health protection goals (e.g. from specified technology targets to performance targets).

The processes of formulating, implementing, communicating and evaluating health-based targets provide benefits to the overall preventive management of drinking-water quality. These benefits are outlined in Table 3.1.

3.2 Disability-adjusted life years, tolerable disease burden and reference level of risk

At a national level, decisions about risk acceptance and tolerable burdens of disease are complex and need to take account of the probability and severity of impact in addition to the environmental, social, cultural, economic and political dimensions that play important roles in decision-making. Negotiations are an important part of these processes, and the outcome may very well be unique in each situation. Notwithstanding the complexity of these decisions, definitions of tolerable burdens of disease and reference levels of risk are required to provide a baseline for the development of health-based targets and as a point of departure for decisions in specific situations.

Descriptions of tolerable burdens of disease relating to water are typically expressed in terms of specific health outcomes such as maximum frequencies of diarrhoeal disease or cancer incidence. However, these descriptions do not consider the severity of the outcomes. The various hazards that may be present in water are associated with very diverse health outcomes with different impacts ranging from mild diarrhoea to potentially severe outcomes such as typhoid, cancer or skeletal fluorosis.

A common "metric" is needed that can be used to quantify and compare the burden of disease associated with different water-related hazards, taking into account varying probabilities, severities and duration of effects. Such a metric should be applicable regardless of the type of hazard (microbial, chemical or radiological) to enable the use of a consistent approach for each hazard. The metric used in these Guidelines is the disability-adjusted life year, or DALY (Box 3.1). The World Health Organization has used DALYs quite extensively to evaluate public health priorities and to assess the disease burden associated with environmental exposures, particularly for microbial hazards.

A key advantage of using the DALY is its aggregation of different impacts on the quality and quantity of life and its focus on actual outcomes rather than potential risks; hence, it supports rational public health priority setting. DALYs can be used to define tolerable burden of disease and the related reference level of risk.

"Tolerable burden of disease" represents an upper limit of the burden of health effects associated with waterborne disease that is established by national policy-makers. "Reference level of risk" is an equivalent term used in the context of quantitative risk assessments.

In these Guidelines, the tolerable burden of disease is defined as an upper limit of 10^{-6} DALY per person per year. This upper-limit DALY is approximately equivalent to a 10^{-5} excess lifetime risk of cancer (i.e. 1 excess case of cancer per 100 000 people ingesting drinking-water at the water quality target daily over a 70-year period), which is the risk level used in these Guidelines to determine guideline values for genotoxic carcinogens.

Expressing health-based targets for chemical hazards in DALYs has the advantage of enabling comparisons with microbial risks. However, use of the DALY approach for chemicals has been limited in practice due to gaps in knowledge.

The 10^{-6} DALY tolerable burden of disease target may not be achievable or realistic in some locations and circumstances in the near term. Where the overall burden of disease by multiple exposure routes (water, food, air, direct personal contact, etc.) is very high, setting a 10^{-6} DALY per person per year level of disease burden from waterborne exposure alone will have little impact on the overall disease burden. Setting a less stringent level of acceptable risk, such as 10^{-5} or 10^{-4} DALY per person per year, from waterborne exposure may be more realistic, yet still consistent with the goals of providing high-quality, safer water.

3.3 Types of health-based targets

The nature and typical application of health-based targets are presented in Table 3.2. Health-based targets differ considerably with respect to the amount of resources

Box 3.1 Disability-adjusted life years

The various hazards that can be present in water can have very different health outcomes. Some outcomes are mild (e.g. diarrhoea), whereas others can be severe (e.g. cholera, haemolytic uraemic syndrome associated with *Escherichia coli* O157 or cancer). Some are acute (e.g. diarrhoea), whereas others are delayed (e.g. infectious hepatitis or cancer). Some especially relate to certain age ranges and groups (e.g. skeletal fluorosis in older adults often arises from long-term exposure to high levels of fluoride in childhood; infection with hepatitis E virus has a very high mortality rate among pregnant women). In addition, any one hazard may cause multiple effects (e.g. gastroenteritis, Gullain-Barré syndrome, reactive arthritis and mortality associated with *Campylobacter*).

In order to support public health priority setting, a common metric is required that can be applied to all types of hazard and takes into account different health outcomes, including probabilities, severities and duration of effects. The disability-adjusted life year (DALY) provides this metric.

The basic principle of the DALY is to weight each health impact in terms of severity within the range of 0 for good health to 1 for death. The weighting is then multiplied by duration of the effect and the number of people affected. In the case of death, duration is regarded as the years lost in relation to normal life expectancy. Using this approach, a mild diarrhoea with a severity weighting of 0.1 and lasting for 7 days results in a DALY of 0.002, whereas death resulting in a loss of 30 years of life equates to a DALY of 30.

Hence, DALY = YLL (years of life lost) + YLD (years lived with a disability or illness). In this context, *disability* refers to a condition that detracts from good health.
For example, infection with rotavirus (in developed countries) causes:

- mild diarrhoea (severity rating of 0.1) lasting 7 days in 97.5% of cases;
- severe diarrhoea (severity rating of 0.23) lasting 7 days in 2.5% of cases;
- rare deaths of very young children in 0.015% of cases.

The DALY per case can then be calculated as follows:

$$\begin{aligned} \text{DALY} &= (0.1 \times 7/365 \times 0.975) + (0.23 \times 7/365 \times 0.025) + (1 \times 70 \times 0.00015) \\ &= 0.0019 + 0.0001 + 0.0105 \\ &= 0.0125 \end{aligned}$$

Infection with *Cryptosporidium* can cause watery diarrhoea (severity weighting of 0.067) lasting for 7 days with extremely rare deaths in 0.0001% of cases. This equates to a DALY per case of 0.0015.

Further information on the use of DALYs in establishing health-based targets is included in the supporting document *Quantifying public health risk in the WHO Guidelines for drinking-water quality* (Annex 1).

needed for their development and implementation and in relation to the precision with which the public health benefits of risk management actions can be defined. The most precise are health outcome targets, which underpin the derivation of the remaining targets, as shown in Figure 3.1. Each target type is based on those above it in Table 3.2, and assumptions with default values are introduced in moving down between target types. The targets towards the top of the table require greater scientific and technical inputs and are therefore more precisely related to the level of health protection. Target types at the bottom of Table 3.2 require the least interpretation by practitioners in implementation, but depend on a number of assumptions (e.g. establishing specified technology targets in the absence of sufficient source water quality data to apply performance targets for microbial pathogens). Efforts should be made to collect additional information when critical data for applying the next stage of target setting may not be available. This incremental improvement will ensure that the health-based targets will be as pertinent as possible to local circumstances.

Table 3.2 Nature and application of health-based targets

Type of target	Nature of target	Typical applications	Notes
Health outcome	Defined tolerable burden of disease	High-level policy target set at national level, used to inform derivation of performance, water quality and specified technology targets	These Guidelines define a tolerable burden of disease of 10^{-6} DALY per person per year
	No adverse effect or negligible risk	Chemical or radiological hazards	Derived from international chemical or radionuclide risk assessments
Water quality	Guideline values	Chemical hazards	Based on individual chemical risk assessments
		Microbial water quality targets are not normally applied	*Escherichia coli* is used as an indicator of faecal contamination and to verify water quality
		Radiological water quality targets are not normally applied	Radiological screening levels are applied
Performance	Specified removal of hazards	Microbial hazards (expressed as log reductions)	Specific targets set by water supplier based on quantitative microbial risk assessment and health outcome targets or generic targets set at national level
		Chemical hazards (expressed as percentage removal)	Specific targets set by water supplier based on chemical guideline values or generic targets set at national level
Specified technology	Defined technologies	Control of microbial and chemical hazards	Set at national level; based on assessments of source water quality, frequently underpinned by established or validated performance of the specified technology (e.g. requirement of filtration for surface water)

When establishing health-based targets, care should be taken to account for short-term events and fluctuations in water quality along with "steady-state" conditions. This is particularly important when developing performance and specified technology targets. Short-term water quality can significantly deteriorate, for example, following heavy rain and during maintenance. Catastrophic events can result in periods of very degraded source water quality and greatly decreased efficiency in many processes, or even system failure, greatly increasing the likelihood of a disease outbreak, Events like these provide additional justification for the long-established "multiple-barrier principle" in water safety.

For chemical hazards, health-based targets most commonly take the form of water quality targets, using the guideline values outlined in section 8.5. Performance targets expressed as percentage removals or specified technology targets can also be applied to chemical hazards.

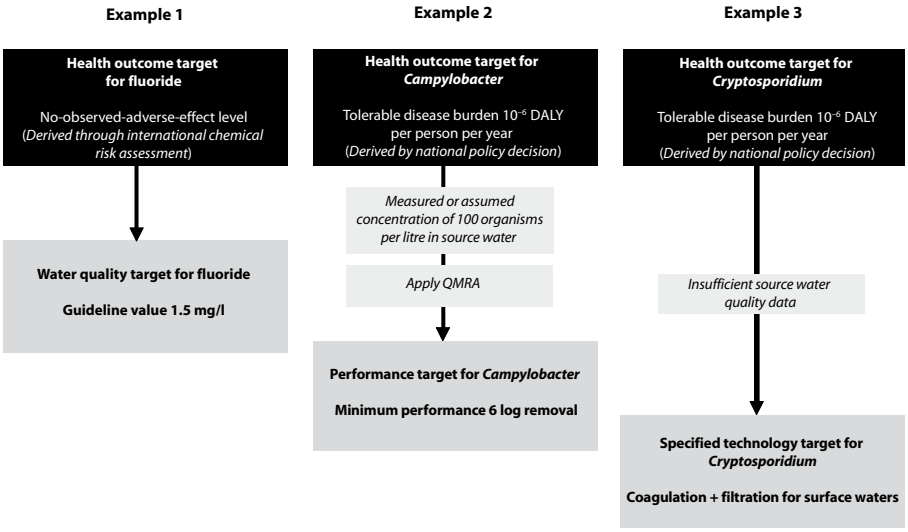


Figure 3.1 Examples of how to set health-based targets for various hazards

For microbial hazards, health-based targets usually take the form of performance or specified technology targets. The choice of target will be influenced by the number of data available on source water quality, with performance targets requiring more information. Water quality targets are typically not developed for pathogens, because monitoring finished drinking-water for pathogens is not considered a feasible or cost-effective option. Concentrations of pathogens equivalent to a health outcome target of 10^{-6} DALY per person per year are typically less than 1 organism per 10^4–10^5 litres. Therefore, it is more feasible and cost-effective to monitor for indicator organisms such as *E. coli*.

In practice, risks to public health from drinking-water are often attributable to a single hazard at a time; therefore, in deriving targets, the reference level of risk is applied independently to each hazard.

3.3.1 Health outcome targets

The most direct descriptions of drinking-water safety are health outcome targets, such as upper limits on frequencies of diarrhoeal disease or cancer incidence. These upper limits represent tolerable burdens of disease and are typically set at the national level. They underpin the derivation of water quality, performance and specified technology targets (Figure 3.1). These Guidelines define a tolerable burden of disease of 10^{-6} DALY per person per year. For threshold chemicals, the health outcome target is based on no-observed-adverse-effect levels (see section 8.2).

Health outcome targets must be translated into water quality, performance or specified technology targets in order to be actioned by the water supplier as part of the water safety plan.

3.3.2 Water quality targets

Water quality targets are the most common form of health-based target applied to chemicals that may be found in drinking-water. The guideline values for individual chemicals described in section 8.5 provide water quality targets that can be used to verify that water safety plans have been effective in managing risks from chemicals in drinking-water.

Guideline values are established on the basis of international risk assessments of the health effects associated with exposure to the chemical in water. In developing national drinking-water standards (or health-based targets) based on these guideline values, it will be necessary to take into consideration a variety of environmental, social, cultural, economic, dietary and other conditions affecting potential exposure, as well as the default assumptions that are used to derive the guideline values. Exposure from chemicals in drinking-water is typically minor in comparison with that from other sources (e.g. food, consumer products and air), with a few important exceptions (e.g. arsenic and fluoride). This may lead to national targets that differ appreciably from the guideline values. In some cases, it may be appropriate to take action to prevent exposure to a chemical from sources other than drinking-water (e.g. lead from soldered cans and from petrol).

One example is that of the health-based target for fluoride in drinking-water. A guideline value of 1.5 mg/l is recommended in Table A3.3 of Annex 3, with a comment that "Volume of water consumed and intake from other sources should be considered when setting national standards." Thus, in a country with a warm climate year-round and where piped water is the preferred source of drinking-water, authorities may select a health-based target for fluoride that is lower than this guideline value, as water consumption is expected to be higher. On a similar note, the health-based target should be reviewed in terms of its impact on the most vulnerable section of the population.

Where water treatment processes have been put in place to remove or reduce specific chemicals (see section 8.4 and Annex 5), water quality targets should be used to determine appropriate treatment requirements.

It is important that water quality targets are established only for those chemicals that, following rigorous assessment, have been determined to be of health concern or of concern for the acceptability of the drinking-water to consumers. There is little value in undertaking measurements for chemicals that are unlikely to be in the system, that will be present only at concentrations much lower than the guideline value or that have no human health effects or effects on drinking-water acceptability. One example is that of radionuclides in drinking-water, which may be present in such minute quantities that their contribution to the overall health risks from drinking-water will be negligible. Analysis of individual radionuclides requires sophisticated and expensive procedures; hence, in such cases, measurements of gross alpha and gross beta activities may be adopted as the screening tests for the presence of radionuclides in drinking-water, as discussed in section 9.3.

Water quality targets are also used in the certification process for chemicals that occur in water as a result of treatment processes or from materials in contact with water. In such applications, assumptions are made in order to derive standards for materials and chemicals that can be employed in their certification. Generally, allow-

ance must be made for the incremental increase over levels found in water sources. For some materials (e.g. domestic plumbing), assumptions must also account for the relatively high release of some substances for a short period following installation.

Escherichia coli remains an important indicator of faecal contamination for verification of water quality, but measurements of *E. coli* do not represent a risk-based water quality target. The use of *E. coli* as an indicator organism is discussed in more detail in chapter 7.

3.3.3 Performance targets

Although performance targets can be applied to chemical hazards, the most common application is for control of microbial hazards in piped supplies. Performance targets assist in the selection and use of control measures that are capable of preventing pathogens from breaching the barriers of source protection, treatment and distribution systems or preventing growth within the distribution system.

Performance targets define requirements in relation to source water quality. Ideally, this should be based on system-specific data; more commonly, however, targets will be specified in relation to broad categories of source water quality and type (see section 7.2). The derivation of performance targets requires the integration of factors such as tolerable disease burden (acceptable risk), including severity of disease outcomes, and, for pathogens, quantitative microbial risk assessment (see section 7.2). There are insufficient data, and it is not realistic, to derive performance targets for all potentially waterborne pathogens. The practical approach is to derive targets for reference pathogens representing groups of pathogens (e.g. bacteria, viruses and protozoa). Selection of reference pathogens should take into account variations in susceptibility to treatment as well as local conditions, including prevalence of waterborne transmission and source water characteristics.

The most common application of performance targets is in identifying appropriate combinations of treatment processes to reduce pathogen concentrations in source water to a level that will meet health outcome targets and hence be safe. This is normally expressed in terms of log reductions. Selection of processes requires evidence that they will meet required performance targets (i.e. validation; see sections 2.2.2 and 4.1.7). Examples of treatment processes and pathogen reductions are given in section 7.3.

Performance targets can be applied to catchment controls that are aimed at reducing pathogen concentrations through preventive measures and to measures to prevent ingress of contamination through distribution systems. Performance targets are also important in certification of point-of-use devices and specified technologies used for drinking-water treatment. Certification of devices is discussed elsewhere (see section 1.2.9).

Performance targets can be applied to chemical hazards. In comparison with targets for microbial hazards, they are typically applied to specific chemicals, with performance measured in terms of percentage reduction (see section 8.4).

3.3.4 Specified technology targets

Specified technology targets typically take the form of recommendations concerning technologies applicable in certain circumstances (e.g. filtration and disinfection of

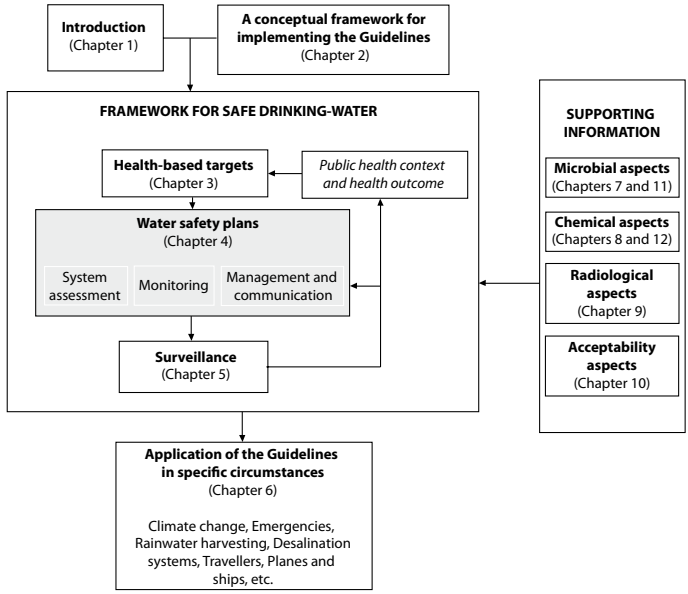
surface water). Selection of technologies is usually based on qualitative assessments of source water type and quality (e.g. impacted surface water, protected groundwater). Specified technology targets are most frequently applied to small community supplies and to devices used at the household level. They can be applied to both microbial and chemical hazards.

Smaller municipal and community drinking-water suppliers often have limited resources and ability to develop individual system assessments and health-based targets. National regulatory agencies may therefore directly specify technology requirements or approved options. These may include, for example:

- specific and approved treatment processes in relation to source types and characteristics;
- providing guidance on requirements for protection of well heads;
- requirements for protection of drinking-water quality in distribution systems.

It is important to review specified targets on a regular basis to ensure that they are kept up to date in terms of the prevailing scientific knowledge about the technology and its application.

4
Water safety plans



The most effective means of consistently ensuring the safety of a drinking-water supply is through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in the water supply from catchment to consumer. In these Guidelines, such approaches are termed water safety plans (WSPs). The WSP approach has been developed to organize and systematize a long history of management practices applied to drinking-water and to ensure the applicability of these practices to the management of drinking-water quality. WSPs represent an evolution of the concept of sanitary surveys and vulnerability assessments that include and encompass the whole of the water supply system and its operation. The WSP approach draws on many of the principles and concepts from other risk management approaches, in particular the multiple-barrier approach and hazard assessment and critical control points (as used in the food industry).

This chapter focuses on the key principles of WSPs and is not a comprehensive guide to their application in practice. Practical information on how to develop and implement a WSP is available in the supporting documents *Water safety plan manual* and *Water safety planning for small community water supplies* (Annex 1).

WSPs vary in complexity, as appropriate for the situation. In many cases, they will be quite simple, focusing on the key hazards identified for the specific drinking-water supply system. The wide range of examples of control measures given in the following text does not imply that all of these are appropriate in all cases.

WSPs should, by preference, be developed for individual drinking-water systems. For smaller systems, it may be possible to develop generic WSPs by a statutory body or accredited third-party organization. In these settings, guidance on household water storage, handling and use may also be required. Plans dealing with household water should be linked to a hygiene education programme and advice to households in maintaining water safety.

A WSP has three key components, which are guided by health-based targets (see chapter 3) and overseen through drinking-water supply surveillance (see chapter 5). They are:

A WSP comprises, as a minimum, the three key components that are the responsibility of the drinking-water supplier in order to ensure that drinking-water is safe. These are:

- a system assessment;
- effective operational monitoring;
- management and communication.

1) a *system assessment* to determine whether the drinking-water supply chain (up to the point of consumption) as a whole can deliver water of a quality that meets identified targets. This also includes the assessment of design criteria of new systems;
2) identifying control measures in a drinking-water system that will collectively control identified risks and ensure that the health-based targets are met. For each control measure identified, an appropriate means of *operational monitoring* should be defined that will ensure that any deviation from required performance is rapidly detected in a timely manner;
3) *management and communication plans* describing actions to be taken during normal operation or incident conditions and documenting the system assessment, including upgrade and improvement planning, monitoring and communication plans and supporting programmes.

The primary objectives of a WSP in ensuring good drinking-water supply practice are the prevention or minimization of contamination of source waters, the reduction or removal of contamination through treatment processes and the prevention of contamination during storage, distribution and handling of drinking-water. These objectives are equally applicable to large piped drinking-water supplies, small community supplies (see section 1.2.6) and household systems and are achieved through:

- development of an understanding of the specific system and its capability to supply water that meets water quality targets;
- identification of potential sources of contamination and how they can be controlled;
- validation of control measures employed to control hazards;
- implementation of a system for operational monitoring of the control measures within the water system;
- timely corrective actions to ensure that safe water is consistently supplied;

- undertaking verification of drinking-water quality to ensure that the WSP is being implemented correctly and is achieving the performance required to meet relevant national, regional and local water quality standards or objectives.

WSPs are a powerful tool for the drinking-water supplier to manage the supply safely. They also assist surveillance by public health authorities. Key benefits for water suppliers implementing WSPs include:

- demonstration of "due diligence";
- improved compliance;
- rationalizing and documenting existing operational procedures, leading to gains in efficiency, improvement of performance and quicker response to incidents;
- better targeted and justification for long-term capital investments based on risk assessment;
- improved management of existing staff knowledge and identification of critical gaps in skills for staff;
- improved stakeholder relationships.

One of the challenges and responsibilities of water suppliers and regulators is to anticipate, plan for and provide for climate variations and weather extremes. WSPs are an effective tool to manage such variations and extremes (see also section 6.1).

Where a defined entity is responsible for a drinking-water supply, its responsibility should include the preparation and implementation of a WSP. This plan should normally be reviewed and agreed upon with the authority responsible for protection of public health to ensure that it will deliver water of a quality consistent with the defined targets.

Where there is no formal service provider, the competent national or regional authority should act as a source of information and guidance on the adequacy of appropriate management of community and individual drinking-water supplies. This will include defining requirements for operational monitoring and management. Approaches to verification in these circumstances will depend on the capacity of local authorities and communities and should be defined in national policy.

Many water suppliers may face practical challenges in initiating, developing and implementing a WSP. These include mistaken perceptions that one prescribed methodology must be followed; that WSP steps must be undertaken with risks managed from source to tap in a defined order; that developing a WSP always requires external expertise; that WSPs supersede, rather than build on, existing good practices; and that WSPs are necessarily complicated and are not appropriate for small supplies.

Although WSP implementation demands a certain minimum standard in terms of the steps involved (Figure 4.1), it is a flexible approach that should rely on the water supplier's existing practices and fit the way that a supplier is organized.

The WSP is a vital step in identifying the hazards and risks associated with the source water catchment, particularly where the water supplier does not manage the catchment, or with established treatment and distribution systems. Starting with existing treatment to ensure that it is operating at its optimum at all times is a vital component, as this is often the key barrier that prevents hazards from reaching

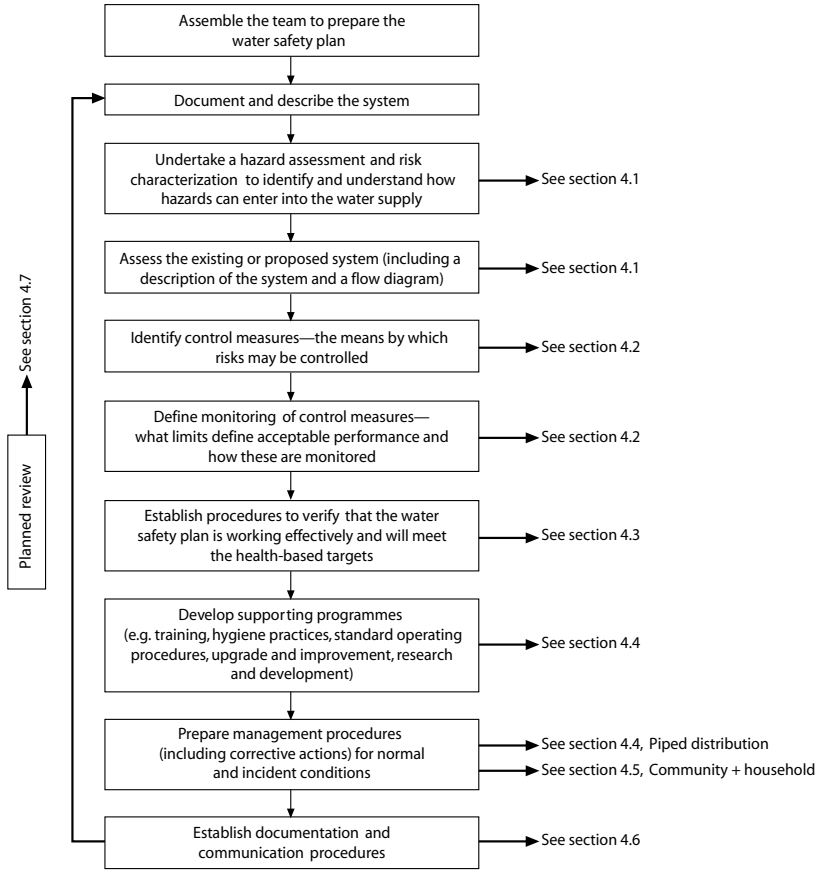


Figure 4.1 Overview of the steps in developing a water safety plan

drinking-water. It must be recognized that even if other hazards are identified in the catchment, remediation may take time, and this should not be a reason for delaying the start of WSP preparation and implementation. Similarly, initiating the process of ensuring that the distribution system is intact and managed appropriately is a vital step that is under the control of the water supplier.

Many of the procedures inherent in the WSP, such as documenting the system and ensuring that standard operating procedures are established for each of the treatment processes and the operation of the distribution system, are simply normal good practice in drinking-water supply. The WSP should therefore build on and improve existing practice.

WSPs should also not be seen as a competing initiative to existing programmes already being undertaken. For example, a programme that addresses non-revenue water (e.g. leakage), although primarily addressing a water quantity issue, is also part of a WSP. A non-revenue water programme would address issues such as intermittent supply and low water pressure, both of which are contributing factors to contamination of drinking-water in the distribution system.

It is recognized that it will not be possible to fully establish a WSP all at once, but the mapping of the system, the identification of the hazards and the assessment of the risks will provide a framework for prioritizing actions and will identify the requirements for continuing improvement as resources become available. They will also identify and help make the case for resource allocation and investment so that they can be targeted to provide the greatest benefit, thus optimizing resources and investment.

In some countries, the regulatory system is relatively complex. A vital component of WSPs and the delivery of safe drinking-water is proper communication and exchange of information between regulators, including environmental authorities, and between regulators or authorities and water suppliers. This is particularly important if resources are to be optimized, and shared information can lead to savings on all sides, while ensuring that drinking-water supplies are improved.

Small supplies remain a significant challenge for many countries, partly because human, technical and financial resources are limited. The introduction of WSPs helps to identify simple and cost-effective steps that can be taken to protect and improve such supplies. It is important that health authorities emphasize the importance of safe drinking-water to the local community and raise the status of the operator's role in the community. It would also be helpful for the relevant authorities to provide a resource or point of contact where operators can obtain advice on and help for WSP implementation.

4.1 System assessment and design

The first stage in developing a WSP is to form a multidisciplinary team of experts with a thorough understanding of the drinking-water system involved. The team should be led by the drinking-water supplier and have sufficient expertise in abstraction, treatment and distribution of drinking-water. Typically, such a team would include individuals involved in each stage of the supply of drinking-water and in many cases representatives from a wider group of stakeholders with collective responsibility for the water supply system from catchment to consumer. Teams could include engineers, catchment and water managers, water quality specialists, environmental or public health or hygienist professionals, operational staff and representatives of consumers or from the community. In most settings, the team will include members from external agencies, including the relevant regulatory agency. For small water supplies, additional external expertise may be useful in addition to operational personnel.

Effective management of the drinking-water system requires a comprehensive understanding of the system, the range and magnitude of hazards and hazardous events that may affect the system and the ability of existing processes and infrastructure to manage actual or potential risks (otherwise known as a *sanitary survey*). It also requires an assessment of capabilities to meet targets. When a new system or an upgrade of an existing system is being planned, the first step in developing a WSP is the collection and evaluation of all available relevant information and consideration of what risks may arise during delivery of water to the consumer.

Assessment of the drinking-water system supports subsequent steps in the WSP in which effective strategies for control of hazards are planned and implemented.

The assessment and evaluation of a drinking-water system are enhanced through an accurate system description, including a flow diagram. The system description should provide an overview of the drinking-water system, including characterization of the source, identification of potential pollution sources in the catchment, measures for resource and source protection, treatment processes, storage and mechanisms for distribution (including piped and non-piped systems). It is essential that the description and the flow diagram of the drinking-water system are conceptually accurate. If the description is not correct, it is possible to overlook potential hazards that may be significant. To ensure accuracy, the system description should be validated by visually checking against features observed on the ground.

Effective risk management requires the identification of potential hazards and hazardous events and an assessment of the level of risk presented by each. In this context:

- a *hazard* is a biological, chemical, physical or radiological agent that has the potential to cause harm;
- a *hazardous* event is an incident or situation that can lead to the presence of a hazard (what can happen and how);
- *risk* is the likelihood of identified hazards causing harm in exposed populations in a specified time frame, including the magnitude of that harm and/or the consequences.

Data on the occurrence of pathogens and chemicals in source waters and in drinking-water combined with information concerning the effectiveness of existing controls enable an assessment of whether health-based targets can be achieved with the existing infrastructure. They also assist in identifying catchment management measures, treatment processes and distribution system operating conditions that would reasonably be expected to achieve those health-based targets if improvements are required.

It may often be more efficient to invest in preventive processes within the catchment than to invest in major treatment infrastructure to manage a hazard.

To ensure the accuracy of the assessment, including an overall estimate of risk, it is essential that all elements of the drinking-water system (catchment, treatment and distribution) are considered concurrently and that interactions among these elements are taken into consideration.

4.1.1 New systems

When drinking-water supply sources are being investigated or developed, it is prudent to undertake a wide range of analyses in order to establish overall safety and to determine potential sources of contamination of the drinking-water supply source. These analyses would normally include hydrological analysis, geological assessment and land use inventories to determine potential chemical and radiological contaminants.

When designing new systems, all water quality factors should be taken into account in selecting technologies for abstraction and treatment of new resources. Variations in the turbidity and other parameters of raw surface waters can be considerable, and allowance must be made for this. Treatment plants should be designed to take account of variations known or expected to occur with significant frequency rather than for average water quality; otherwise, for example, filters may rapidly become blocked or sedimentation tanks overloaded. The chemical aggressiveness of some

groundwaters may affect the integrity of borehole casings and pumps, leading to unacceptably high levels of iron in the supply, eventual breakdown and expensive repair work. Both the quality and availability of drinking-water may be reduced and public health endangered.

4.1.2 Collecting and evaluating available data

Areas that should be taken into consideration as part of the assessment of the drinking-water system include all real or potential hazards and hazardous events associated with each step in the drinking-water system that could result in contamination or interruption of supply. In most cases, consultation with public health and other sectors, including land and water users and all those who regulate activities in the catchment, will be required for the analysis of catchments. A structured approach is important to ensure that significant issues are not overlooked and that areas of greatest risk are identified.

The overall assessment of the drinking-water system should take into consideration any historical water quality data that may assist in understanding source water characteristics and drinking-water system performance both over time and following specific events (e.g. heavy rainfall). For examples of information to consider in assessing components of the drinking-water system, see Module 3 in the supporting document *Water safety plan manual* (Annex 1).

Prioritizing hazards for control

Once potential hazards and their sources have been identified, the risk associated with each hazard or hazardous event should be compared so that priorities for risk management can be established and documented. Although there are numerous contaminants that can compromise drinking-water quality, not every hazard or hazardous event will require the same degree of attention.

The risk associated with each hazard or hazardous event may be described by identifying the likelihood of occurrence (e.g. certain, possible, rare) and evaluating the severity of consequences if the hazard occurred (e.g. insignificant, major, catastrophic). The aim should be to distinguish between important and less important hazards or hazardous events. The approach used typically involves a semiquantitative matrix.

Simple scoring matrices often apply technical information from guidelines, scientific literature and industry practice with well-informed "expert" judgement based on knowledge and experience of WSP team members, supported by peer review or benchmarking. Scoring is specific for each drinking-water system, as each system is unique. Where generic WSPs are developed for technologies used by small drinking-water systems, the scoring will be specific to the technology rather than the individual drinking-water system.

By using risk ranking, control measures can be prioritized in relation to their significance. A variety of semiquantitative and qualitative approaches to ranking risk can be applied, and Module 3 of the supporting document *Water safety plan manual* (Annex 1) provides a series of practice-based examples. An example of a semiquantitative approach is given in Table 4.1. Application of this matrix relies to a significant extent on expert opinion to make judgements on the public health risk posed by hazards or hazardous events.

Table 4.1 Example of a simple scoring matrix for ranking risks

Likelihood	Severity of consequences				
	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain	5	10	15	20	25
Likely	4	8	12	16	20
Moderately likely	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare	1	2	3	4	5

Risk score	< 6	6–9	10–15	> 15
Risk rating	Low	Medium	High	Very high

An example of descriptors that can be used to rate the likelihood of occurrence and severity of consequences is given in Table 4.2. A "cut-off" point must be determined, above which all risks will require immediate attention. There is little value in expending large amounts of effort to consider very low risks.

Control measures

The assessment and planning of control measures should ensure that health-based targets will be met and should be based on hazard identification and risk assessment. The level of control applied to a hazard should be proportional to the associated risk ranking. Assessment of control measures involves:

- identifying existing control measures for each significant hazard or hazardous event from catchment to consumer;
- evaluating whether the control measures, when considered together, are effective in reducing risk to acceptable levels;
- if improvement is required, evaluating alternative and additional control measures that could be applied.

Identification and implementation of control measures should be based on the multiple-barrier principle. The strength of this approach is that a failure of one barrier may be compensated by effective operation of the remaining barriers, thus minimizing the likelihood of contaminants passing through the entire system and being present in sufficient amounts to cause harm to consumers. Many control measures may contribute to control more than one hazard, whereas some hazards may require more than one control measure for effective control. Examples of control measures are provided in the following sections.

> Control measures are activities or processes within the drinking-water supply used to eliminate or significantly reduce the occurrence of a water safety hazard. These measures are applied collectively to ensure that drinking-water consistently meets health-based targets.

All control measures are important and should be afforded ongoing attention. They should be subject to operational monitoring and control, with the means of

Table 4.2 Examples of definitions of likelihood and severity categories that can be used in risk scoring

Item	Rating	Definition
Likelihood categories		
Almost certain	5	Once per day
Likely	4	Once per week
Moderately likely	3	Once per month
Unlikely	2	Once per year
Rare	1	Once every 5 years
Severity categories		
Catastrophic	5	Public health impact
Major	4	Regulatory impact
Moderate	3	Aesthetic impact
Minor	2	Compliance impact
Insignificant	1	No impact or not detectable

monitoring and frequency of data collection based on the nature of the control measure and the rapidity with which change may occur (see section 4.2).

4.1.3 Resource and source protection

Effective catchment management has many benefits. By decreasing the contamination of the source water, the amount of treatment required is reduced. This may reduce the production of treatment by-products and minimize operational costs.

Hazard identification

Understanding the reasons for variations in raw water quality is important, as it will influence the requirements for treatment, treatment efficiency and the resulting health risk associated with the finished drinking-water. In general, raw water quality is influenced by both natural and human use factors. Important natural factors include wildlife, climate, topography, geology and vegetation. Human use factors include point sources (e.g. wastewater discharges) and non-point sources (e.g. surface runoff). For example, discharges of municipal wastewater can be a major source of pathogens; urban runoff and livestock can contribute substantial microbial load; body contact recreation can be a source of faecal contamination; and agricultural runoff, including agrochemicals and manure, can lead to increased challenges to treatment.

Whether water is drawn from surface or underground sources, it is important that the characteristics of the local catchment or aquifer are understood and that the scenarios that could lead to water pollution are identified and managed. The extent to which potentially polluting activities in the catchment can be reduced may appear to be limited by competition for water and pressure for increased development in the catchment. However, introducing good practices in land use and in containment of hazards is often possible without substantially restricting activities, and collaboration between stakeholders may be a powerful tool to reduce pollution without reducing beneficial development.

Resource and source protection provides the first barrier in protection of drinking-water quality. Where catchment management is beyond the jurisdiction of the drinking-water supplier, the planning and implementation of control measures will require coordination with other agencies. These may include planning authorities, catchment boards, environmental and water resource regulators, road authorities, emergency services and agricultural, industrial and other commercial entities whose activities have an impact on water quality. It may not be possible to apply all aspects of resource and source protection initially; nevertheless, priority should be given to catchment management. This will contribute to a sense of ownership and joint responsibility for drinking-water resources through multistakeholder bodies that assess pollution risks and develop plans for improving management practices for reducing these risks.

Groundwater from deep and confined aquifers is usually microbially safe and chemically stable in the absence of direct contamination; however, shallow or unconfined aquifers can be subject to contamination from discharges or seepages associated with agricultural practices (e.g. pathogens, nitrates and pesticides), on-site sanitation and sewerage (e.g. pathogens and nitrates) and industrial wastes. For examples of hazards and hazardous situations that should be taken into consideration as part of a hazard analysis and risk assessment, see Module 4 in the supporting document *Water safety plan manual* and the supporting documents *Protecting groundwater for health* and *Protecting surface water for health* (Annex 1).

Control measures

Effective resource and source protection includes the following elements:

- developing and implementing a catchment management plan, which includes control measures to protect surface water and groundwater sources;
- ensuring that planning regulations include the protection of water resources (land use planning and watershed management) from potentially polluting activities and are enforced;
- promoting awareness in the community of the impact of human activity on water quality.

Where a number of water sources are available, there may be flexibility in the selection of water for treatment and supply. It may be possible to avoid taking water from rivers and streams when water quality is poor (e.g. following heavy rainfall) in order to reduce risk and prevent potential problems in subsequent treatment processes.

Retention of water in reservoirs can reduce the number of faecal microorganisms through settling and inactivation, including solar (ultraviolet) disinfection, but also provides opportunities for the introduction of contamination. Most pathogenic microorganisms of faecal origin (enteric pathogens) do not survive indefinitely in the environment. Substantial die-off of enteric bacteria will occur over a period of weeks. Enteric viruses and protozoa will often survive for longer periods (weeks to months) but are often removed by settling and antagonism from indigenous microbes. Retention also allows suspended material to settle, which makes subsequent disinfection more effective and reduces the formation of disinfection by-products (DBPs).

Control measures for groundwater sources should include protecting the aquifer and the local area around the borehead from contamination and ensuring the physical

integrity of the bore (surface sealed, casing intact, etc.); further information can be found in the supporting document *Protecting groundwater for health* (Annex 1).

For examples of control measures for effective protection of source water and catchments and of water extraction and storage systems, see Module 4 in the supporting document *Water safety plan manual* and the supporting document *Protecting surface water for health* (Annex 1). Further information on the use of indicator organisms in catchment characterization is also available in chapter 4 of the supporting document *Assessing microbial safety of drinking water* (Annex 1).

4.1.4 Treatment

After source water protection, the next barriers to contamination of the drinking-water system are those of water treatment processes, including disinfection and physical removal of contaminants.

Hazard identification

Hazards may be introduced during treatment, or hazardous events may allow contaminants to pass through treatment in significant concentrations. Constituents of drinking-water can be introduced through the treatment process, including chemical additives used in the treatment process or products in contact with drinking-water. Sporadic high turbidity in source water can overwhelm treatment processes, allowing enteric pathogens into treated water and the distribution system. Similarly, suboptimal filtration following filter backwashing can lead to the introduction of pathogens into the distribution system.

For examples of potential hazards and hazardous events that can have an impact on the performance of drinking-water treatment, see Module 3 in the supporting document *Water safety plan manual* (Annex 1).

Control measures

Control measures may include pretreatment, coagulation, flocculation, sedimentation, filtration and disinfection.

Pretreatment includes processes such as roughing filters, microstrainers, off-stream storage and bankside filtration. Pretreatment options may be compatible with a variety of treatment processes ranging in complexity from simple disinfection to membrane processes. Pretreatment can reduce or stabilize the microbial, natural organic matter and particulate load.

Coagulation, flocculation, sedimentation (or flotation) and filtration remove particles, including microorganisms (bacteria, viruses and protozoa). It is important that processes are optimized and controlled to achieve consistent and reliable performance. Chemical coagulation is the most important step in determining the removal efficiency of coagulation, flocculation and clarification processes. It also directly affects the removal efficiency of granular media filtration units and has indirect impacts on the efficiency of the disinfection process. While it is unlikely that the coagulation process itself introduces any new microbial hazards to finished water, a failure or inefficiency in the coagulation process could result in an increased microbial load entering drinking-water distribution.

Various filtration processes are used in drinking-water treatment, including granular, slow sand, precoat and membrane (microfiltration, ultrafiltration, nanofiltration

and reverse osmosis) filtration. With proper design and operation, filtration can act as a consistent and effective barrier for pathogenic microorganisms and may in some cases be the only treatment barrier (e.g. for removing *Cryptosporidium* oocysts by direct filtration when chlorine is used as the sole disinfectant).

Application of an adequate concentration of disinfectant is an essential element for most treatment systems to achieve the necessary level of microbial risk reduction. Taking account of the level of microbial inactivation required for the more resistant microbial pathogens through the application of the *Ct* concept (product of disinfectant concentration and contact time) for a particular pH and temperature ensures that other, more sensitive microbes are also effectively controlled. Where disinfection is used, measures to minimize DBP formation should be taken into consideration.

The most commonly used disinfection process is chlorination. Ozonation, ultraviolet irradiation, chloramination and application of chlorine dioxide are also used. These methods are very effective in killing bacteria and can be reasonably effective in inactivating viruses (depending on type), and some may inactivate many protozoa, including *Giardia* and *Cryptosporidium*. For effective removal or inactivation of protozoal cysts and oocysts, filtration with the aid of coagulation and flocculation (to reduce particles and turbidity) followed by disinfection (by one or a combination of disinfectants) is the most practical method.

Storage of water after disinfection and before supply to consumers can improve disinfection by increasing disinfectant contact times. This can be particularly important for more resistant microorganisms, such as *Giardia* and some viruses.

For examples of treatment control measures, see Module 4 in the supporting document *Water safety plan manual* (Annex 1). Further information can also be found in the supporting document *Water treatment and pathogen control* (Annex 1).

4.1.5 Piped distribution systems

Water treatment should be optimized to prevent microbial growth, corrosion of pipe materials and the formation of deposits.

Maintaining good water quality in the distribution system will depend on the design and operation of the system and on maintenance and survey procedures to prevent contamination and to prevent and remove the accumulation of internal deposits.

Hazard identification

The protection of the distribution system is essential for providing safe drinking-water. Because of the nature of the distribution system, which may include many kilometres of pipe, storage tanks, interconnections with industrial users and the potential for tampering and vandalism, opportunities for microbial and chemical contamination exist. For examples of hazards and hazardous events in piped distribution systems, see Module 3 in the supporting document *Water safety plan manual* (Annex 1).

When contamination by enteric pathogens or hazardous chemicals occurs within the distribution system, it is likely that consumers will be exposed. to the pathogens or chemicals. In the case of pathogen ingress, even where disinfectant residuals are employed to limit microbial occurrence, they may be inadequate to overcome the contamination or may be ineffective against some or all of the pathogen types introduced.

As a result, pathogens may occur in concentrations that could lead to infection and illness.

Where water is supplied intermittently, the resulting low water pressure will allow the ingress of contaminated water into the system through breaks, cracks, joints and pinholes. Intermittent supplies are not desirable but are very common in many countries and are frequently associated with contamination. The control of water quality in intermittent supplies represents a significant challenge, as the risks of infiltration and backflow increase significantly. The risks may be elevated seasonally as soil moisture conditions increase the likelihood of a pressure gradient developing from the soil to the pipe. Where contaminants enter the pipes in an intermittent supply, the charging of the system when supply is restored may increase risks to consumers, as a concentrated "slug" of contaminated water can be expected to flow through the system. Where household storage is used to overcome intermittent supply, localized use of disinfectants to reduce microbial proliferation may be warranted.

Drinking-water entering the distribution system may contain free-living amoebae and environmental strains of various heterotrophic bacterial and fungal species. Under favourable conditions, amoebae and heterotrophs, including strains of *Citrobacter*, *Enterobacter* and *Klebsiella*, may colonize distribution systems and form biofilms. There is no evidence to implicate the occurrence of most microorganisms from biofilms (one exception is *Legionella*, which can colonize water systems in buildings) with adverse health effects in the general population through drinking-water, with the possible exception of severely immunocompromised people (see the supporting document *Heterotrophic plate counts and drinking-water safety*; Annex 1).

Water temperatures and nutrient concentrations are not generally elevated enough within the distribution system to support the growth of *E. coli* (or enteric pathogenic bacteria) in biofilms. Thus, the presence of *E. coli* should be considered as evidence of recent faecal contamination.

Natural disasters, including flood, drought and earth tremors, may significantly affect piped water distribution systems.

Control measures

Water entering the distribution system must be microbially safe and ideally should also be biologically stable. The distribution system itself must provide a secure barrier to contamination as the water is transported to the user. Maintaining a disinfectant residual throughout the distribution system can provide some protection against recontamination and limit microbial growth problems. Chloramination has proved successful in controlling *Naegleria fowleri* in water and sediments in long pipelines and may reduce the regrowth of *Legionella* within buildings.

Residual disinfectant will provide partial protection against microbial contamination, but it may also mask the detection of contamination through the use of conventional faecal indicator bacteria such as *E. coli*, particularly by resistant organisms. Where a disinfectant residual is used within a distribution system, measures to minimize DBP production should be taken into consideration.

Water distribution systems should be fully enclosed, and storage reservoirs and tanks should be securely roofed with external drainage to prevent contamination.

Control of short-circuiting and prevention of stagnation in both storage and distribution contribute to prevention of microbial growth. A number of strategies can be adopted to maintain the quality of water within the distribution system, including use of backflow prevention devices, maintaining positive pressure throughout the system and implementation of efficient maintenance procedures. It is also important that appropriate security measures be put in place to prevent unauthorized access to or interference with the drinking-water system infrastructure.

Control measures may include using a more stable secondary disinfecting chemical (e.g. chloramines instead of free chlorine), undertaking a programme of pipe replacement, flushing and relining and maintaining positive pressure in the distribution system. Reducing the time that water is in the system by avoiding stagnation in storage tanks, loops and dead-end sections will also contribute to maintaining drinking-water quality. For other examples of distribution system control measures, see Module 4 in the supporting document *Water safety plan manual* (Annex 1). Further information is also available in the supporting document *Safe piped water* (Annex 1).

4.1.6 Non-piped, community and household systems

Hazard identification

For non-piped, community and household drinking-water systems, hazard identification would ideally be performed on a case-by-case basis. In practice, however, reliance is typically placed on general assumptions of hazardous conditions that are relevant for technologies or system types and that may be defined at a national or regional level.

For examples of hazards and hazardous situations potentially associated with various non-piped sources of water, see Module 3 in the supporting documents *Water safety plan manual* and *Water safety planning for small community water supplies* (Annex 1). Further guidance is also provided in the supporting document *Water safety plans* (Annex 1) and in the 1997 volume entitled *Surveillance and control of community supplies* (WHO, 1997).

Control measures

The control measures required ideally depend on the characteristics of the source water and the associated catchment; in practice, standard approaches may be applied for each of these, rather than customized assessment of each system.

For examples of control measures for various non-piped sources, see Module 4 in the supporting documents *Water safety plan manual* and *Water safety planning for small community water supplies* (Annex 1) and the 1997 report entitled *Surveillance and control of community supplies* (WHO, 1997).

In most cases, contamination of groundwater supplies can be controlled by a combination of simple measures. In the absence of fractures or fissures, which may allow rapid transport of contaminants to the source, groundwater in confined or deep aquifers will generally be free of pathogenic microorganisms. Bores should be encased to a reasonable depth, and boreheads should be sealed to prevent ingress of surface water or shallow groundwater.

Rainwater harvesting systems, particularly those involving storage in aboveground tanks, can be a relatively safe supply of water (see section 6.2). The principal sources of contamination are birds, small mammals and debris collected on roofs. The impact

of these sources can be minimized by simple measures: guttering should be cleared regularly, overhanging branches should be kept to a minimum (because they can be a source of debris and can increase access to roof catchment areas by birds and small mammals) and inlet pipes to tanks should include leaf litter strainers. First-flush diverters, which prevent the initial roof-cleaning wash of water (20–25 litres) from entering tanks, are recommended. If first-flush diverters are not available, a detachable downpipe can be used manually to provide the same result.

In general, surface waters will require at least disinfection, and usually also filtration, to ensure microbial safety. The first barrier is based on minimizing contamination from human waste, livestock and other hazards at the source.

The greater the protection of the water source, the less the reliance on treatment or disinfection. Water should be protected during storage and delivery to consumers by ensuring that the distribution and storage systems are enclosed. This applies to both community piped systems and vendor-supplied water (section 6.3). For water stored in the home, protection from contamination can be achieved by use of enclosed or otherwise safely designed storage containers that prevent the introduction of hands, dippers or other extraneous sources of contamination.

For control of chemical hazards, reliance may be placed primarily on initial screening of sources and on ensuring the quality and performance of treatment chemicals, materials and devices available for this use, including water storage systems.

Model WSPs may be developed generically for the following types of water supply:

- groundwater from protected boreholes or wells with mechanized pumping;
- conventional treatment of water;
- multistage filtration;
- storage and distribution through supplier-managed piped systems;
- storage and distribution through community-managed piped systems;
- water vendors;
- water on conveyances (planes, ships and trains);
- tubewells from which water is collected by hand;
- springs from which water is collected by hand;
- simple protected dug wells;
- rainwater catchments.

Guidance is available regarding how water safety may be ensured for household water collection, transport and storage (see the supporting document *Managing water in the home*; Annex 1). This should be used in conjunction with hygiene education programmes to support health promotion in order to reduce water-related disease.

4.1.7 Validation

For the WSP to be relied on for anticipating and managing the hazards and hazardous events for which it was set in place, it needs to be supported by accurate and reliable technical information. Validation is concerned with obtaining evidence on the performance of control measures. Depending on the type of control, validation can be done by site inspection, using existing data and literature or targeted

monitoring programmes to demonstrate performance under normal and exceptional circumstances.

Validation is an investigative activity to identify the effectiveness of a control measure. It is typically an intensive activity when a system is initially constructed or rehabilitated. It provides information on reliably achievable water quality in preference to assumed values and also to define the operational criteria required to ensure that the control measure contributes to effective control of hazards.

Validation of treatment processes is required to show that the treatment processes can operate as required and achieve required levels of hazard reduction. In the case of microbial hazards, these required levels commonly take the form of performance targets based on the use of reference pathogens (see section 7.2). Validation can be undertaken during pilot stage studies or during initial implementation of a new or modified water treatment system. It is also a useful tool in the optimization of existing treatment processes.

The first stage of validation is to consider data and information that already exist. Sources include the scientific literature, relevant industry bodies, partnering and benchmarking with larger authorities, manufacturers' specifications and historical data. This stage will inform the testing requirements. It is important that data used in validation are relevant for system-specific conditions, as variations in water composition and quality, for example, may have a large impact on the efficacy of control measures.

Validation is not used for day-to-day management of drinking-water supplies; as a result, microbial parameters that may be inappropriate for operational monitoring can be used, and the lag time for return of results and additional costs from pathogen measurements can often be tolerated. Parameters should be chosen to reflect the microorganisms being targeted by treatment (see section 7.2). Increasingly, indicator parameters are being used in validation. For example, coliphage can be used to assess the effectiveness of virus removal by filtration processes or to measure the effectiveness of disinfection processes, whereas *Clostridium perfringens* can be used to measure the effectiveness of the removal of protozoa by filtration processes.

Validation should not be confused with routine operational monitoring, which is designed to show that validated control measures continue to work effectively (see section 4.2). The validation process often leads to improvements in operating performance through the identification of the most effective and robust operating modes. Additional benefits of the validation process may include identification of more suitable operational monitoring parameters for unit performance.

4.1.8 Upgrade and improvement

The assessment of the drinking-water system may indicate that existing practices and control measures may not ensure drinking-water safety. In some instances, all that may be needed is to review, document and formalize these practices and address any areas where improvements are required; in others, major infrastructure changes may

be needed. The assessment of the system should be used as a basis to develop a plan to address identified needs for full implementation of a WSP.

Improvement of the drinking-water system may encompass a wide range of issues, such as:

- capital works;
- training;
- enhanced operational procedures;
- community consultation programmes;
- research and development;
- developing incident protocols;
- communication and reporting.

Upgrade and improvement plans can include short-term (e.g. 1 year) or long-term programmes. Short-term improvements might include, for example, improvements to community consultation and the development of community awareness programmes. Long-term capital works projects could include covering of water storages or enhanced coagulation and filtration.

Implementation of improvement plans may have significant budgetary implications and therefore may require detailed analysis and careful prioritization in accord with the outcomes of risk assessment. Implementation of plans should be monitored to confirm that improvements have been made and are effective. Control measures often require considerable expenditure, and decisions about water quality improvements cannot be made in isolation from other aspects of drinking-water supply that compete for limited financial resources. Priorities will need to be established, and improvements may need to be phased in over a period of time.

4.2 Operational monitoring and maintaining control

Operational monitoring is a planned and routine set of activities used to determine that control measures continue to work effectively. In operational monitoring, the drinking-water supplier monitors each control measure in a timely manner with the objectives to enable effective system management and to ensure that health-based targets are achieved.

4.2.1 Determining system control measures

The identity and number of control measures are system specific and will be determined by the number and nature of hazards and hazardous events as well as the magnitude of associated risks.

Control measures should reflect the likelihood and consequences of loss of control. Control measures have a number of operational requirements, including the following:

- operational monitoring parameters that can be measured and for which limits can be set to define the operational effectiveness of the activity;
- operational monitoring parameters that can be monitored with sufficient frequency to reveal failures in a timely fashion;

- procedures for corrective action that can be implemented in response to deviation from limits.

4.2.2 Selecting operational monitoring parameters

Operational monitoring can include measurement of parameters or observational activities. The parameters selected for operational monitoring should reflect the effectiveness of each control measure, provide a timely indication of performance, be readily measured and provide the opportunity for an appropriate response. Examples include measurable variables, such as chlorine residuals, pH and turbidity, or observable factors, such as the integrity of vermin-proof screens.

Operational monitoring assesses the performance of control measures at appropriate time intervals. The intervals may vary widely—for example, from online control of residual chlorine to quarterly verification of the integrity of the plinth surrounding a well.

Enteric pathogens or indicator organisms are often of limited use for operational monitoring, because the time taken to process and analyse water samples does not allow operational adjustments to be made prior to supply.

A range of parameters can be used in operational monitoring:

- For source waters, these include turbidity, ultraviolet absorbency, algal growth, flow and retention time, colour, conductivity, local meteorological events and integrity of protective (e.g. fences) or abstraction infrastructures (e.g. well seals) (see the supporting documents *Protecting groundwater for health* and *Protecting surface water for health*; Annex 1).
- For treatment, parameters may include disinfectant concentration and contact time, ultraviolet intensity, pH, light absorbency, membrane integrity, turbidity and colour (see the supporting document *Water treatment and pathogen control*; Annex 1).
- In piped distribution systems, operational monitoring parameters may include the following:
  - *Chlorine residual monitoring* provides a rapid indication of problems that will direct measurement of microbial parameters. A sudden disappearance of an otherwise stable residual can indicate ingress of contamination. Alternatively, difficulties in maintaining residuals at points in a distribution system or a gradual disappearance of residual may indicate that the water or pipework has a high oxidant demand due to growth of bacteria.
  - *Oxidation–reduction potential* (or redox potential) measurement can also be used in the operational monitoring of disinfection efficacy. It is possible to define a minimum level of oxidation–reduction potential necessary to ensure effective disinfection. This value has to be determined on a case-by-case basis; universal values cannot be recommended. Further research and evaluation of oxidation–reduction potential as an operational monitoring technique are highly desirable.
  - *Heterotrophic bacteria* present in a supply can be a useful indicator of changes, such as increased microbial growth potential, increased biofilm

activity, extended retention times or stagnation and a breakdown of integrity of the system. The numbers of heterotrophic bacteria present in a supply may

reflect the presence of large contact surfaces within the treatment system, such as in-line filters, and may not be a direct indicator of the condition within the distribution system (see the supporting document *Heterotrophic plate counts and drinking-water safety*; Annex 1).

— *Pressure measurement and turbidity* are also useful operational monitoring parameters in piped distribution systems (see the supporting document *Turbidity: information for regulators and operators of water supplies*; Annex 1).

Guidance for management of distribution system operation and maintenance is available (see the supporting document *Safe piped water*; Annex 1) and includes the development of a monitoring programme for water quality and other parameters such as pressure.

Examples of operational monitoring parameters are provided in Table 4.3.

4.2.3 Establishing operational and critical limits

Control measures need to have defined limits for operational acceptability—termed operational limits—that can be applied to operational monitoring parameters. Operational limits should be defined for parameters applying to each control measure. If monitoring shows that an operational limit has been exceeded, then predetermined corrective actions (see section 4.4) need to be applied. The detection of the deviation and implementation of corrective action should be possible in a time frame adequate to maintain performance and water safety.

For some control measures, a second series of "critical limits" may also be defined, outside of which confidence in water safety would be lost. Deviations from critical limits will usually require urgent action, including immediate notification of the appropriate health authority.

Operational and critical limits can be upper limits, lower limits, a range or an "envelope" of performance measures.

4.2.4 Non-piped, community and household systems

Generally, surface water or shallow groundwater should not be used as a source of drinking-water without sanitary protection or treatment.

Monitoring of water sources (including rainwater tanks) by community operators or households will typically involve periodic sanitary inspection (for details, see the 1997 volume entitled *Surveillance and control of community supplies*; WHO, 1997). The sanitary inspection forms used should be comprehensible and easy to use; for instance, the forms may be pictorial. The risk factors included should be preferably related to activities that are under the control of the operator and that may affect water quality. The links to action from the results of operational monitoring should be clear, and training will be required.

Operators should also undertake regular physical assessments of the water, especially after heavy rains, to monitor whether any obvious changes in water quality have occurred (e.g. changes in colour, odour, taste or turbidity).

Maintaining the quality of water during collection and manual transport is the responsibility of the household. Good hygiene practices are required and should be sup-

ported through hygiene education. Hygiene education programmes should provide households and communities with skills to monitor and manage their water hygiene.

Table 4.3 Examples of operational monitoring parameters that can be used to monitor control measures

Operational parameter	Raw water	Coagulation	Sedimentation	Filtration	Disinfection	Distribution system
pH		✓	✓		✓	✓
Turbidity (or particle count)	✓	✓	✓	✓	✓	✓
Dissolved oxygen	✓					
Stream/river flow	✓					
Rainfall	✓					
Colour	✓					
Conductivity (total dissolved solids)	✓					
Organic carbon	✓		✓			
Algae, algal toxins and metabolites	✓					✓
Chemical dosage		✓			✓	
Flow rate		✓	✓	✓	✓	
Net charge		✓				
Streaming current value		✓				
Headloss				✓		
Ct (disinfectant concentration × contact time)					✓	
Disinfectant residual					✓	✓
Oxidation–reduction potential					✓	
DBPs					✓	✓
Heterotrophic bacteria					✓	✓
Hydraulic pressure						✓

If treatment is applied to water from community sources (such as boreholes, wells and springs) as well as household rainwater collection, then operational monitoring is advisable. When household treatment is introduced, it is essential that information (and, where appropriate, training) be provided to users to ensure that they understand basic operational monitoring requirements.

4.3 Verification

Verification provides a final check on the overall performance of the drinking-water supply chain and the safety of drinking-water being supplied to consumers. Verification should be undertaken by the surveillance agency; water suppliers may also undertake internal verification programmes.

For microbial verification, testing is typically for faecal indicator bacteria in treated water and water in distribution. For verification of chemical safety, testing for chemicals of concern may be at the end of treatment, in distribution or at the point of consumption (depending on whether the concentrations are likely to change in distribution). Trihalomethanes and haloacetic acids are the most common DBPs and occur at among the highest concentrations in drinking-water. Under many circumstances, they can serve as a suitable measure that will reflect the concentration of a wide range of related chlorinated DBPs.

In addition to operational monitoring of the performance of the individual components of a drinking-water system, it is necessary to undertake final *verification* for reassurance that the system as a whole is operating safely. Verification may be undertaken by the supplier, by an independent authority or by a combination of these, depending on the administrative regime in a given country. It typically includes testing for faecal indicator organisms and hazardous chemicals, as well as auditing that WSPs are being implemented as intended and are working effectively.

Frequencies of sampling should reflect the need to balance the benefits and costs of obtaining more information. Sampling frequencies are usually based on the population served or on the volume of water supplied, to reflect the increased population risk. Frequency of testing for individual characteristics will also depend on variability. Sampling and analysis are required most frequently for microbial and less often for chemical constituents. This is because even brief episodes of microbial contamination can lead directly to illness in consumers, whereas episodes of chemical contamination that would constitute an acute health concern, in the absence of a specific event (e.g. chemical overdosing at a treatment plant), are rare. Sampling frequencies for water leaving treatment depend on the quality of the water source and the type of treatment.

Plans should be developed to respond to results that do not meet water quality targets. These should include investigation of the cause of non-compliance and, where necessary, corrective action, such as boil water advisories. Repeated failure to meet targets should lead to review of the WSP and development of improvement plans.

4.3.1 Microbial water quality

Verification of the microbial quality of drinking-water typically includes testing for *Escherichia coli* as an indicator of faecal pollution. In practice, testing for thermotolerant coliform bacteria can be an acceptable alternative in many circumstances. Although *E. coli* is useful, it has limitations. Enteric viruses and protozoa are more resistant to disinfection; consequently, the absence of *E. coli* will not necessarily indicate freedom from these organisms. Under certain circumstances, the inclusion of more resistant indicators, such as bacteriophages and/or bacterial spores, should be considered (see section 7.4).

Verification of the microbial quality of water in supply must be designed to ensure the best possible chance of detecting contamination. Sampling should therefore account for potential variations of water quality in distribution. This will normally mean taking account of locations and of times of increased likelihood of contamination.

Faecal contamination will not be distributed evenly throughout a piped distribution system. In systems where water quality is good, this significantly reduces the probability of detecting faecal indicator bacteria in the relatively few samples collected.

The chances of detecting contamination in systems reporting predominantly negative results for faecal indicator bacteria can be increased by using more frequent presence/absence testing. Presence/absence testing can be simpler, faster and less expensive than quantitative methods. Comparative studies of the presence/absence and quantitative methods demonstrate that the presence/absence methods can maximize the detection of faecal indicator bacteria. However, presence/absence testing is appropriate only in a system where the majority of tests for indicator organisms provide negative results.

The more frequently the water is examined for faecal indicator organisms, the more likely it is that contamination will be detected. Frequent examination by a simple method is more valuable than less frequent examination by a complex test or series of tests.

The nature and likelihood of contamination can vary seasonally, with rainfall and with other local conditions. Sampling should normally be random but should be increased at times of epidemics, flooding or emergency operations or following interruptions of supply or repair work.

Recommended minimum sample numbers for verification of the microbial quality of drinking-water are shown in Table 4.4.

4.3.2 Chemical water quality

Issues that need to be addressed in developing chemical verification include the availability of appropriate analytical facilities, the cost of analyses, the possible deterioration of samples, the stability of the contaminant, the likely occurrence of the contaminant in various supplies, the most suitable point for monitoring and the frequency of sampling.

For a given chemical, the location and frequency of sampling will be determined by its principal sources (see chapter 8) and variability in its concentration. Substances that do not change significantly in concentration over time require less frequent sampling than those that might vary significantly.

In many cases, analysis of source water quality once per year, or even less, may be adequate, particularly in stable groundwaters, where the concentrations of naturally occurring substances of concern will vary very slowly over time. Concentrations of naturally occurring substances are likely to be more variable in surface waters, and surface waters therefore may require a greater number of samples, depending on the contaminant and its importance.

Sampling locations will depend on the water quality characteristic being examined. Sampling at the treatment plant or at the head of the distribution system may be sufficient for constituents whose concentrations do not change during delivery. However, for those constituents whose concentrations can change during distribution, sampling should be undertaken following consideration of the behaviour or source of the specific substance. Samples should include points near the extremities of the distribution system and taps connected directly to the mains in houses and large

Table 4.4 Recommended minimum sample numbers for faecal indicator testing in distribution systems[a]

Type of water supply and population	Total number of samples per year
Point sources	Progressive sampling of all sources over 3- to 5-year cycles (maximum)
Piped supplies	
< 5000	12
5000–100 000	12 per 5000 population
> 100 000–500 000	12 per 10 000 population plus an additional 120 samples
> 500 000	12 per 50 000 population plus an additional 600 samples

[a] Parameters such as chlorine, turbidity and pH should be tested more frequently as part of operational and verification monitoring.

multioccupancy buildings. Lead, for example, should be sampled at consumers' taps, as the source of lead is usually service connections or plumbing in buildings.

For further information, see the supporting document *Chemical safety of drinking-water* (Annex 1).

4.3.3 Source waters

Verification testing of source waters is particularly important where there is no water treatment. It will also be useful following failure of the treatment process or as part of an investigation of a waterborne disease outbreak. The frequency of testing will depend on the reason for carrying out the sampling. Testing frequency may be:

- on a regular basis (the frequency of verification testing will depend on several factors, including the size of the community supplied, the reliability of the quality of the drinking-water or degree of treatment and the presence of local risk factors);
- on an occasional basis (e.g. random or during visits to community-managed drinking-water supplies);
- increased following degradation of source water quality resulting from predictable incidents, emergencies or unplanned events considered likely to increase the potential for a breakthrough in contamination (e.g. following a flood, upstream spills).

Prior to commissioning a new drinking-water supply, a wider range of analyses should be carried out, including parameters identified as potentially being present from a review of data from similar supplies or from a risk assessment of the source.

4.3.4 Piped distribution systems

The choice of sampling points will be dependent on the individual water supply. The nature of the public health risk posed by pathogens and the contamination potential throughout distribution systems mean that collection of samples for microbial analysis (and associated parameters, such as chlorine residual, pH and turbidity) will typically be done frequently and from dispersed sampling sites. Careful consideration of sampling points and frequency is required for chemical constituents that arise

from piping and plumbing materials and that are not controlled through their direct regulation and for constituents whose concentrations change in distribution, such as trihalomethanes. The use of stratified random sampling in distribution systems has proven to be effective.

4.3.5 Community-managed supplies

If the performance of a community drinking-water system is to be properly evaluated, a number of factors must be considered. Some countries that have developed national strategies for the surveillance and quality control of drinking-water systems have adopted *quantitative service indicators* (i.e. quality, quantity, accessibility, coverage, affordability and continuity) for application at community, regional and national levels. Usual practice would be to include the critical parameters for microbial quality (normally *E. coli*, chlorine, turbidity and pH) and for a sanitary inspection to be carried out. Methods for these tests must be standardized and approved. It is recommended that field test kits be validated for performance against reference or standard methods and approved for use in verification testing.

Together, service indicators provide a basis for setting targets for community drinking-water supplies. They serve as a quantitative guide to the adequacy of drinking-water supplies and provide consumers with an objective measure of the quality of the overall service and thus the degree of public health protection afforded.

Periodic testing and sanitary inspection of community drinking-water supplies should typically be undertaken by the surveillance agency and should assess microbial hazards and known problem chemicals (see also chapter 5). Frequent sampling is unlikely to be possible, and one approach is therefore a rolling programme of visits to ensure that each supply is visited once every 3–5 years. The primary purpose is to inform strategic planning and policy rather than to assess compliance of individual drinking-water supplies. Comprehensive analysis of the chemical quality of all sources is recommended prior to commissioning as a minimum and preferably every 3–5 years thereafter.

Advice on the design of sampling programmes and on the frequency of sampling for community supplies is given in the 1997 volume, *Surveillance and control of community supplies* (WHO, 1997).

4.3.6 Quality assurance and quality control

Appropriate quality assurance and analytical quality control procedures should be implemented for all activities linked to the production of drinking-water quality data. These procedures will ensure that the data are fit for purpose—in other words, that the results produced are of adequate accuracy. Fit for purpose, or adequate accuracy, will be defined in the water quality monitoring programme, which will include a statement about accuracy and precision of the data. Because of the wide range of substances, methods, equipment and accuracy requirements likely to be involved in the monitoring of drinking-water, many detailed, practical aspects of analytical quality control are concerned. These are beyond the scope of this publication.

The design and implementation of a quality assurance programme for analytical laboratories are described in detail in *Water quality monitoring: A practical guide to the*

design and implementation of freshwater quality studies and monitoring programmes (Bartram & Ballance, 1996). The relevant chapter relates to standard ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, which provides a framework for the management of quality in analytical laboratories.

Guidance on sampling is given in the International Organization for Standardization (ISO) standards listed in Table 4.5.

4.3.7 Water safety plans

In addition to testing of water quality, verification should include audits of WSPs to demonstrate that the plans have been properly designed, are being implemented correctly and are effective. Factors to consider include the following:

- all significant hazards and hazardous events have been identified;
- appropriate control measures have been included;
- appropriate operational monitoring procedures have been established;
- appropriate operational limits have been defined;
- corrective actions have been identified;
- appropriate verification monitoring procedures have been established.

Audits can be undertaken as part of internal or external reviews and may form part of surveillance by independent authorities. Auditing can have both an assessment and a compliance-checking function. Further information can be found in the supporting document *A practical guide to auditing water safety plans* (Annex 1).

4.4 Management procedures for piped distribution systems

Much of a management plan will describe actions to be taken to maintain optimal operation under normal operating conditions. These will include both responses to normal variations in operational monitoring parameters and responses when operational monitoring parameters reach critical limits. All activities, including standard operating procedures applied during normal conditions and planned responses to incidents and emergencies, should be documented.

> Effective management implies definition of actions to be taken during normal operational conditions, of actions to be taken in specific "incident" situations where a loss of control of the system may occur and of procedures to be followed in unforeseen (emergency) situations. Management procedures should be documented alongside system assessment, monitoring plans, supporting programmes and communication required to ensure safe operation of the system.

A significant deviation in operational monitoring where a critical limit is exceeded (or in verification) is often referred to as an "incident". An incident is any situation in which there is reason to suspect that water being supplied for drinking may be, or may become, unsafe (i.e. confidence in water safety is lost). As part of a WSP, management procedures should be defined for response to predictable incidents as well as unpredictable incidents and emergencies.

Incident response plans can have a range of alert levels. These can be minor early warning, necessitating no more than additional investigation, through to emergency.

Emergencies are likely to require the resources of organizations beyond the drinking-water supplier, particularly the public health authorities.

Table 4.5 International Organization for Standardization (ISO) standards for water quality giving guidance on sampling[a]

ISO standard no.	Title (water quality)
5667-1:2006	Sampling—Part 1: Guidance on the design of sampling programmes and sampling techniques
5667-3:2003	Sampling—Part 3: Guidance on the preservation and handling of water samples
5667-4:1987	Sampling—Part 4: Guidance on sampling from lakes, natural and man-made
5667-5:2006	Sampling—Part 5: Guidance on sampling of drinking water and water from treatment works and piped distribution systems
5667-6:2005	Sampling—Part 6: Guidance on sampling of rivers and streams
5667-11:2009	Sampling—Part 11: Guidance on sampling of groundwaters
5667-13:1997	Sampling—Part 13: Guidance on sampling of sludges from sewage and water treatment works
5667-14:1998	Sampling—Part 14: Guidance on quality assurance of environmental water sampling and handling
5667-16:1998	Sampling—Part 16: Guidance on biotesting of samples
5667-20:2008	Sampling—Part 20: Guidance on the use of sampling data for decision making—Compliance with thresholds and classification systems
5667-21:2010	Sampling—Part 21: Guidance on sampling of drinking water distributed by tankers or means other than distribution pipes
5667-23:2011	Sampling—Part 23: Guidance on passive sampling in surface waters
5668-17:2008	Sampling—Part 17: Guidance on sampling of bulk suspended sediments
13530:2009	Guidance on analytical quality control for chemical and physicochemical water analysis
17381:2003	Selection and application of ready-to-use test kit methods in water analysis

[a] ISO has also established quality management standards relating to drinking-water supply, including ISO 24510:2007, Activities relating to drinking water and wastewater services—Guidelines for the assessment and for the improvement of the service to users; and ISO 24512:2007, Activities relating to drinking water and wastewater services—Guidelines for the management of drinking water utilities and for the assessment of drinking water services.

Incident response plans typically comprise:

- accountabilities and contact details for key personnel, often including several organizations and individuals;
- lists of measurable indicators and limit values/conditions that would trigger incidents, along with a scale of alert levels;
- clear description of the actions required in response to alerts;
- location and identity of the standard operating procedures and required equipment;
- location of backup equipment;
- relevant logistical and technical information;
- checklists and quick reference guides.

The plan may need to be followed at very short notice, so standby rosters, effective communication systems and up-to-date training and documentation are required.

Staff should be trained in response procedures to ensure that they can manage incidents or emergencies effectively. Incident and emergency response plans should be periodically reviewed and practised. This improves preparedness and provides opportunities to improve the effectiveness of plans before an emergency occurs.

Following any incident or emergency, an investigation should be undertaken involving all concerned staff. The investigation should consider factors such as:

- the cause of the problem;
- how the problem was first identified or recognized;
- the most essential actions required;
- any communication problems that arose, and how they were addressed;
- the immediate and longer-term consequences;
- how well the emergency response plan functioned.

Appropriate documentation and reporting of the incident or emergency should also be established. The organization should learn as much as possible from the incident or emergency to improve preparedness and planning for future incidents. Review of the incident or emergency may indicate necessary amendments to the WSP and existing protocols.

The preparation of clear procedures, definition of accountability and provision of equipment for the sampling and storing of water in the event of an incident can be valuable for follow-up epidemiological or other investigations, and the sampling and storage of water from early on during a suspected incident should be part of the response plan.

4.4.1 Predictable incidents ("deviations")

Many incidents (e.g. exceedance of a critical limit) can be foreseen, and management plans can specify resulting actions. Actions may include, for example, temporary change of water sources (if possible), increasing coagulation dose, use of backup disinfection or increasing disinfectant concentrations in distribution systems.

4.4.2 Unplanned events

Some scenarios that lead to water being considered potentially unsafe might not be specifically identified within incident response plans. This may be either because the events were unforeseen or because they were considered too unlikely to justify preparing detailed corrective action plans. To allow for such events, a general incident response plan should be developed. The plan would be used to provide general guidance on identifying and handling of incidents along with specific guidance on responses that would be applied to many different types of incident.

A protocol for situation assessment and declaring incidents would be provided in a general incident response plan that includes personal accountabilities and categorical selection criteria. The selection criteria may include time to effect, population affected and nature of the suspected hazard.

The success of general incident responses depends on the experience, judgement and skill of the personnel operating and managing the drinking-water supply. However, generic activities that are common in response to many incidents can be incorporated within general incident response plans. For example, for piped systems, emergency flushing standard operating procedures can be prepared and tested for use in the event that contaminated water needs to be flushed from a piped system. Similarly, standard operating procedures for rapidly changing or bypassing reservoirs can be prepared, tested and incorporated. The development of such a "toolkit" of supporting material limits the likelihood of error and speeds up responses during incidents.

4.4.3 Emergencies

Water suppliers should develop plans to be invoked in the event of an emergency. These plans should consider potential natural disasters (e.g. earthquakes, floods, damage to electrical equipment by lightning strikes), accidents (e.g. spills in the watershed, interruptions in electricity supply), damage to treatment plant and distribution system and human actions (e.g. strikes, sabotage). Emergency plans should clearly specify responsibilities for coordinating measures to be taken, a communication plan to alert and inform users of the drinking-water supply and plans for providing and distributing emergency supplies of drinking-water.

Plans should be developed in consultation with relevant regulatory authorities and other key agencies and should be consistent with national and local emergency response arrangements. Key areas to be addressed in emergency response plans include:

- response actions, including increased monitoring;
- responsibilities of authorities internal and external to the organization;
- plans for emergency drinking-water supplies;
- communication protocols and strategies, including notification procedures (internal, regulatory body, media and public);
- mechanisms for increased public health surveillance.

Response plans for emergencies and unforeseen events involving microorganisms or chemicals should also include the basis for issuing boil water advisories (see section 7.6.1) and water avoidance advisories (see section 8.7.10). The objective of the advisory should be taken in the public interest.. Therefore, the advisory should be issued after rapid, but careful, consideration of available information and conclusion that there is an ongoing risk to public health that outweighs any risk from the advice to boil or avoid water. The advisory will typically be managed by public health authorities. A decision to close a drinking-water supply carries an obligation to provide an alternative safe supply and is very rarely justifiable because of the adverse effects, especially to health, of restricting access to water. Specific actions in the event of a guideline exceedance or an emergency are discussed in section 7.6 (microbial hazards) and section 8.7 (chemical hazards); more general considerations are discussed in section 6.7. "Practice" emergencies are an important part of the maintenance of readiness for emergencies. They help to determine the potential actions that can be taken in different circumstances for a specific water supply.

4.4.4 Preparing a monitoring plan

Programmes should be developed for operational and verification monitoring and documented as part of a WSP, detailing the strategies and procedures to follow for monitoring the various aspects of the drinking-water system. The monitoring plans should be fully documented and should include the following information:

- parameters to be monitored;
- sampling location and frequency;
- sampling methods and equipment;
- schedules for sampling;
- references to corrective action procedures, including responsibilities;
- qualifications and certification requirements for testing laboratories;
- methods for quality assurance and validation of sampling results;
- requirements for checking and interpreting results;
- responsibilities and necessary qualifications of staff;
- requirements for documentation and management of records, including how monitoring results will be recorded and stored;
- requirements for reporting and communication of results.

4.4.5 Supporting programmes

Many actions are important in ensuring drinking-water safety but do not directly affect drinking-water quality and are therefore not control measures. These are referred to as "supporting programmes" and should also be documented in a WSP. Supporting programmes could involve:

- controlling access to treatment plants, catchments and reservoirs and implementing the appropriate security measures to prevent transfer of hazards from people when they do enter source water;
- developing verification protocols for the use of chemicals and materials in the drinking-water supply—for instance, to ensure the use of suppliers that participate in quality assurance programmes;
- using designated equipment for attending to incidents such as mains bursts (e.g. equipment should be designated for potable water work only and not for sewage work);
- training and educational programmes for personnel involved in activities that could influence drinking-water safety; training should be implemented as part of induction programmes and frequently updated;
- research and development to improve understanding of water quality, including the quality of source waters, and treatment.

Actions that are important in ensuring drinking-water safety but do not directly affect drinking-water quality are referred to as supporting programmes.

Supporting programmes will consist almost entirely of items that drinking-water suppliers and handlers will ordinarily have in place as part of their normal operation. For most, the implementation of supporting programmes will involve:

- collation of existing operational and management practices;
- initial and, thereafter, periodic review and updating to continually improve practices;
- promotion of good practices to encourage their use;
- audit of practices to check that they are being used, including taking corrective actions in case of non-conformance.

Codes of good operating and management practice and hygienic working practice are essential elements of supporting programmes. These are often captured within standard operating procedures. They include, but are not limited to:

- hygienic working practices in maintenance;
- attention to personal hygiene;
- training and competence of personnel involved in drinking-water supply;
- tools for managing the actions of staff, such as quality assurance systems;
- securing stakeholder commitment, at all levels, to the provision of safe drinking-water;
- education of communities whose activities may influence drinking-water quality;
- calibration of monitoring equipment;
- record keeping.

Comparison of one set of supporting programmes with the supporting programmes of other suppliers, through peer review, benchmarking and personnel or document exchange, can stimulate ideas for improved practice.

Supporting programmes can be extensive, be varied and involve multiple organizations and individuals. Many supporting programmes involve water resource protection measures and typically include aspects of land use control. Some water resource protection measures are engineered, such as effluent treatment processes and stormwater management practices that may be used as control measures.

4.5 Management of community and household water supplies

Community-managed drinking-water supplies worldwide are more frequently contaminated than larger drinking-water supplies, may be more prone to operating discontinuously (or intermittently) and break down or fail more frequently.

To ensure safe drinking-water, the focus in small supplies should be on:

- informing the public;
- assessing the water supply to determine whether it is able to meet identified health-based targets (see section 4.1);
- monitoring identified control measures and training operators to ensure that all likely hazards can be controlled and that risks are maintained at a tolerable level (see section 4.2);
- operational monitoring of the drinking-water system (see section 4.2);
- implementing systematic water quality management procedures (see section 4.4), including documentation and communication (see section 4.6);
- establishing appropriate incident response protocols (usually encompassing actions at the individual supply, backed by training of operators, and actions required by local or national authorities) (see sections 4.4.2 and 4.4.3); and

- developing programmes to upgrade and improve existing water delivery (usually defined at a national or regional level rather than at the level of individual supplies) (see section 4.1.8).

For small point sources serving communities or individual households, the emphasis should be on selecting source water of the best available quality and on protecting its quality by the use of multiple barriers (usually within source protection) and maintenance programmes. Whatever the source (groundwater, surface water or rainwater tanks), communities and householders should assure themselves that the water is safe to drink. Generally, surface water and shallow groundwater under the direct influence of surface water (which includes shallow groundwater with preferential flow paths) should receive treatment.

The parameters recommended for the minimum monitoring of community supplies are those that best establish the hygienic state of the water and thus the risk of waterborne disease. The essential parameters of water quality are *E. coli*—thermotolerant (faecal) coliforms are accepted as suitable substitutes—and chlorine residual (if chlorination is practised). These should be supplemented, where appropriate, by pH adjustment (if chlorination is practised) and measurement of turbidity.

These parameters may be measured on site using relatively unsophisticated testing equipment, and improved and relatively low cost systems continue to be developed. On-site testing is essential for the determination of turbidity and chlorine residual, which change rapidly during transport and storage; it is also important for the other parameters where laboratory support is lacking or where transportation problems would render conventional sampling and analysis impractical.

Other health-related parameters of local significance should also be measured. The overall approach to control of chemical contamination is outlined in chapter 8.

4.6 Documentation and communication

Documentation of a WSP should include:

- description and assessment of the drinking-water system (see section 4.1), including programmes to upgrade and improve existing water delivery (see section 4.1.8);
- the plan for operational monitoring and verification of the drinking-water system (see sections 4.2 and 4.3);
- water safety management procedures for normal operation, incidents (specific and general) and emergency situations (see sections 4.4.1, 4.4.2 and 4.4.3), including communication plans; and
- description of supporting programmes (see section 4.4.5).

Records are essential to review the adequacy of the WSP and to demonstrate the adherence of the drinking-water system to the WSP. Several types of records are generally kept:

- supporting documentation for developing the WSP, including validation;
- records and results generated through operational monitoring and verification;
- outcomes of incident investigations;

- documentation of methods and procedures used;
- records of employee training programmes.

By tracking records generated through operational monitoring and verification, an operator or manager can detect that a process is approaching its operational or critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Periodic review of WSP records is recommended so that trends can be noted and appropriate actions decided upon and implemented. Records are also essential when surveillance is implemented through auditing-based approaches.

Communication strategies should include:

- procedures for promptly advising of any significant incidents within the drinking-water supply, including notification of the public health authority;
- summary information to be made available to consumers—for example, through annual reports and on the Internet;
- establishment of mechanisms to receive and actively address community complaints in a timely fashion.

The right of consumers to health-related information on the water supplied to them for domestic purposes is fundamental. However, in many communities, the simple right of access to information will not ensure that individuals are aware of the quality of the water supplied to them; furthermore, the probability of consuming unsafe water may be relatively high. The agencies responsible for monitoring should therefore develop strategies for disseminating and explaining the significance of health-related information. Further information on communication is provided in section 5.5.

4.7 Planned review

4.7.1 Periodic review

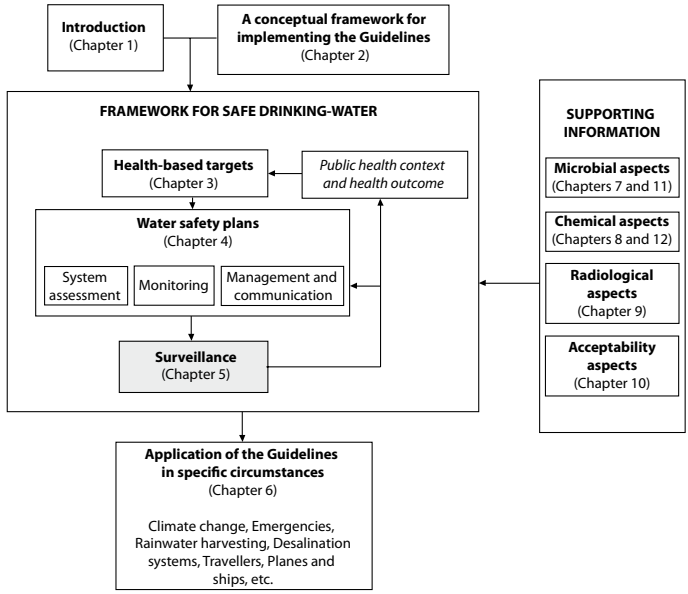
WSPs should not be regarded as static documents. They need to be regularly reviewed and revised to ensure that they are functioning correctly and that they are kept up to date in light of changes in water systems or new developments. Reviews should consider:

- data collected as part of monitoring processes;
- changes to water sources and catchments;
- changes to treatment, demand and distribution;
- implementation of improvement and upgrade programmes;
- revised procedures;
- emerging hazards and risks.

4.7.2 Post-incident review

WSPs should also be reviewed following incidents and emergencies to ensure that, where possible, incidents do not recur and, where this is not possible (e.g. floods), to reduce impacts. Post-incident reviews may identify areas for improvement and the need for revision of WSPs.

5
Surveillance



Drinking-water supply surveillance is "the continuous and vigilant public health assessment and review of the safety and acceptability of drinking-water supplies" (WHO, 1976). This surveillance contributes to the protection of public health by promoting improvement of the quality, quantity, accessibility, coverage, affordability and continuity of water supplies (known as service indicators) and is complementary to the quality control function of the drinking-water supplier. Drinking-water supply surveillance does not remove or replace the responsibility of the drinking-water supplier to ensure that a drinking-water supply is of acceptable quality and meets predetermined health-based targets.

All members of the population receive drinking-water by some means—including the use of piped supplies with or without treatment and with or without pumping (supplied via domestic connection or public standpipe), delivery by tanker truck or carriage by beasts of burden or collection from groundwater sources (springs or wells) or surface sources (lakes, rivers and streams). It is important for the surveillance agency to build up a picture of the frequency of use of the different types of supply, especially as a preliminary step in the planning of a surveillance programme. There

is little to be gained from surveillance of piped water supplies alone if these are available to only a small proportion of the population or if they represent a minority of supplies.

Information alone does not lead to improvement. Instead, the effective management and use of the information generated by surveillance make possible the rational improvement of water supplies—where "rational" implies that available resources are used for maximum public health benefit.

Surveillance is an important element in the development of strategies for incremental improvement of the quality of drinking-water supply services. It is important that strategies be developed for implementing surveillance, collating, analysing and summarizing data and reporting and disseminating the findings and that the strategies are accompanied by recommendations for remedial action. Follow-up will be required to ensure that remedial action is taken.

Surveillance extends beyond drinking-water supplies operated by a discrete drinking-water supplier to include drinking-water supplies that are managed by communities and includes assurance of good hygiene in the collection and storage of household water.

The surveillance agency must have, or have access to, legal expertise in addition to expertise on drinking-water and water quality. Drinking-water supply surveillance is also used to ensure that any transgressions that may occur are appropriately investigated and resolved. In many cases, it will be more appropriate to use surveillance as a mechanism for collaboration between public health agencies and drinking-water suppliers to improve drinking-water supply than to resort to enforcement, particularly where the problem lies mainly with community-managed drinking-water supplies.

The authorities responsible for drinking-water supply surveillance may be the public health ministry or other agency (see section 1.2.1), and their roles encompass four areas of activity:

1) public health oversight of organized drinking-water supplies;
2) public health oversight and information support to populations without access to organized drinking-water supplies, including communities and households;
3) consolidation of information from diverse sources to enable understanding of the overall drinking-water supply situation for a country or region as a whole as an input to the development of coherent public health–centred policies and practices;
4) participation in the investigation, reporting and compilation of outbreaks of waterborne disease.

A drinking-water supply surveillance programme should normally include processes for approval of water safety plans (WSPs). This approval will normally involve review of the system assessment, of the identification of appropriate control measures and supporting programmes and of operational monitoring and management plans. It should ensure that the WSP covers normal operating conditions and predictable incidents (deviations) and has contingency plans in case of an emergency or unplanned event.

The surveillance agency may also support or undertake the development of WSPs for community-managed drinking-water supplies and household water treatment and storage. Such plans may be generic for particular technologies rather than specific for individual systems.

5.1 Types of approaches

There are two types of approaches to surveillance of drinking-water quality: audit-based approaches and approaches relying on direct assessment. Implementation of surveillance will generally include a mixture of these approaches according to supply type and may involve using rolling programmes whereby systems are addressed progressively. Often it is not possible to undertake extensive surveillance of all community or household supplies. In these cases, well-designed surveys should be undertaken in order to understand the situation at the national or regional level.

5.1.1 Audit

In the audit approach to surveillance, assessment activities, including verification testing, are undertaken largely by the supplier, with third-party auditing to verify compliance. It is increasingly common that analytical services are procured from accredited external laboratories. Some authorities are also experimenting with the use of such arrangements for services such as sanitary inspection, sampling and audit reviews.

An audit approach requires the existence of a stable source of expertise and capacity within the surveillance agency in order to:

- review and approve new WSPs;
- undertake or oversee auditing of the implementation of individual WSPs as a programmed routine activity;
- respond to, investigate and provide advice on receipt of reports on significant incidents.

Periodic audit of the implementation of WSPs is required:

- at intervals (the frequency of routine audits will be dependent on factors such as the size of the population served and the nature and quality of source water and treatment facilities);
- following substantial changes to the source, the distribution or storage system or treatment processes;
- following significant incidents.

Periodic audit would normally include the following elements:

- examination of records to ensure that system management is being carried out as described in the WSP;
- ensuring that operational monitoring parameters are kept within operational limits and that compliance is being maintained;
- ensuring that verification programmes are operated by the water supplier (either through in-house expertise or through a third-party arrangement);

- assessment of supporting programmes and of strategies for improving and updating the WSP;
- in some circumstances, sanitary inspection, which may cover the whole of the drinking-water system, including sources, transmission infrastructure, treatment plants, storage reservoirs and distribution systems.

In response to reports of significant incidents, it is necessary to ensure that:

- the event is investigated promptly and appropriately;
- the cause of the event is determined and corrected;
- the incident and corrective action are documented and reported to appropriate authorities;
- the WSP is reassessed to avoid the occurrence of a similar situation.

The implementation of an audit-based approach places responsibility on the drinking-water supplier to provide the surveillance agency with information regarding system performance against agreed indicators. In addition, a programme of announced and unannounced visits by auditors to drinking-water suppliers should be implemented to review documentation and records of operational practice in order to ensure that data submitted are reliable. Such an approach does not necessarily imply that water suppliers are likely to falsify records, but it does provide an important means of reassuring consumers that there is true independent verification of the activities of the water supplier. The surveillance agency will normally retain the authority to undertake some analysis of drinking-water quality to verify performance or enter into a third-party arrangement for such analysis.

5.1.2 Direct assessment

It may be appropriate for the drinking-water supply surveillance agency to carry out independent testing of water supplies. Such an approach often implies that the agency has access to analytical facilities with staff trained to carry out sampling, analysis and sanitary inspection.

Direct assessment also implies that surveillance agencies have the capacity to assess findings and to report to and advise suppliers and communities. A surveillance programme based on direct assessment would normally include:

- specified approaches to large municipality/small municipality/community supplies and individual household supplies;
- sanitary inspections to be carried out by qualified personnel;
- sampling to be carried out by qualified personnel;
- tests to be conducted using suitable methods by accredited laboratories or using approved field testing equipment and qualified personnel;
- procedures on reporting findings and follow-up to ensure that they have been acted on.

For community-managed drinking-water supplies and where the development of in-house verification or third-party arrangements is limited, direct assessment may be used as the principal system of surveillance. This may apply to drinking-water supplies

in small towns by small-scale private sector operators or local government. Direct assessment may lead to the identification of requirements to amend or update the WSP, and the process to be followed when undertaking such amendments should be clearly identified.

Where direct assessment is carried out by the surveillance agency, it complements other verification testing of the water supplier. General guidance on verification testing, which is also applicable to surveillance through direct assessment, is provided in section 4.3.

5.2 Adapting approaches to specific circumstances

5.2.1 Urban areas in developing countries

Drinking-water supply arrangements in urban areas of developing countries are typically complex. There can often be one or more large piped supplies with household and public connections, in combination with a range of alternative drinking-water supplies, including point sources and vended water. In these situations, the surveillance programme should take account of the different sources of drinking-water and the potential for deterioration in quality during collection, storage and use. Furthermore, the population will vary in terms of socioeconomic status and vulnerability to water-related disease.

In many situations, zoning the urban area on the basis of vulnerability and drinking-water supply arrangements is required. The zoning system should include all populations within the urban area, including informal and periurban settlements, regardless of their legal status, in order to direct resources to where greatest improvements (or benefits) to public health will be achieved. This provides a mechanism to ensure that non-piped drinking-water sources are also included within drinking-water supply surveillance activities.

Experience has shown that zoning can be developed using qualitative and quantitative methods and is useful in identifying vulnerable groups and priority communities where drinking-water supply improvements are required.

5.2.2 Community drinking-water supplies

Small community-managed drinking-water supplies are found in most countries and may be the predominant form of drinking-water supply for large sections of the population. The precise definition of a "community drinking-water supply" will vary, but administration and management arrangements are often what set community supplies apart, especially in developing countries. Community-managed supplies may include simple piped water systems or a range of point sources, such as boreholes with hand pumps, dug wells and protected springs.

The control of water quality and implementation of surveillance programmes for such supplies often face significant constraints. These typically include:

- limited capacity and skills within the community to undertake process control and verification; this may increase the need both for surveillance to assess the state of drinking-water supplies and for surveillance staff to provide training and support to community members;

- the very large number of widely dispersed supplies, which significantly increases overall costs in undertaking surveillance activities.

Furthermore, it is often small community-managed water supplies that present the greatest water quality problems.

Experience from both developing and developed countries has shown that surveillance of community-managed drinking-water supplies can be effective when well designed and when the objectives are geared more towards a supportive role to enhance community management than towards enforcement of compliance.

Surveillance of community drinking-water supplies requires a systematic programme of surveys that encompass all aspects of the drinking-water supply to the population as a whole, including sanitary inspection (including catchment inspections) and institutional and community aspects. Surveillance should address variability in source water quality, treatment process efficacy and the quality of distributed or household-treated and household-stored water.

Experience has also shown that the role of surveillance may include health education and health promotion activities to improve healthy behaviour towards management of drinking-water supply and sanitation. Participatory activities can include sanitary inspection by communities and, where appropriate, community-based testing of drinking-water quality using affordable field test kits and other accessible testing resources.

In the evaluation of overall strategies, the principal aim should be to derive overall lessons for improving water safety for all community supplies, rather than relying on monitoring the performance of individual supplies.

Frequent visits to every individual supply may be impractical because of the very large numbers of such supplies and the limitations of resources for such visits. However, surveillance of large numbers of community supplies can be achieved through a rolling programme of visits. Commonly, the aim will be to visit each supply periodically (once every 3–5 years at a minimum) using either stratified random sampling or cluster sampling to select specific supplies to be visited. During each visit, sanitary inspection and water quality analysis will normally be done to provide insight to contamination and its causes.

During each visit, testing of water stored in the home may be undertaken in a sample of households. The objective for such testing is to determine whether contamination occurs primarily at the source or within the home. This will allow evaluation of the need for investment in supply improvement or education on good hygiene practices for household treatment and safe storage. Household testing may also be used to evaluate the impact of a specific hygiene education programme.

5.2.3 Household treatment and storage systems

Where water is handled during storage in households, it may be vulnerable to contamination, and sampling of household-stored water is of interest in independent surveillance. It is often undertaken on a "survey" basis to develop insights into the extent and nature of prevailing problems. Surveillance systems managed by public health author-

ities for drinking-water supplies using household treatment and household storage containers are therefore recommended.

The principal focus of surveillance of household-based interventions will be assessment of their acceptance and impact through sample surveys so as to evaluate and inform overall strategy development and refinement. Systematic determination of continued, correct and effective use and management is recommended so that deficiencies in use and management can be identified and corrected by those responsible.

5.3 Adequacy of supply

As the drinking-water supply surveillance agency has an interest in the population at large, its interest extends beyond water quality in isolation to include all aspects of the adequacy of drinking-water supply for the protection of public health.

In undertaking an assessment of the adequacy of the drinking-water supply, the following basic service parameters of a drinking-water supply should normally be taken into consideration:

- *Quality:* whether the supply has regularly verified water quality and an approved WSP (see chapter 4) that has been validated and is subject to periodic audit to demonstrate compliance with relevant regulations (see chapters 3 and 4);
- *Quantity (service level):* the proportion of the population with access to different levels of drinking-water supply (e.g. no access, basic access, intermediate access and optimal access) as a surrogate for health impacts in relation to quantity of water used;
- *Accessibility:* the percentage of the population that has reasonable access to an improved drinking-water supply;
- *Affordability:* the tariff paid by domestic consumers;
- *Continuity:* the percentage of the time during which drinking-water is available (daily, weekly and seasonally).

5.3.1 Quantity (service level)

The quantity of water collected and used by households has an important influence on health. There is a basic human physiological requirement for water to maintain adequate hydration and an additional requirement for food preparation. There is a further requirement for water to support hygiene, which is necessary for health.

Estimates of the volume of water needed for health purposes vary widely. In deriving World Health Organization (WHO) guideline values, it is assumed that the daily per capita consumption of drinking-water is approximately 2 litres for adults, although actual consumption varies according to climate, activity level and diet. Based on currently available data, a minimum volume of 7.5 litres per capita per day will provide sufficient water for hydration and incorporation into food for most people under most conditions. In addition, adequate domestic water is needed for food preparation, laundry and personal and domestic hygiene, which are also important for health. Water may also be important in income generation and amenity uses.

Table 5.1 Service level and quantity of water collected

Service level	Distance/time	Likely volumes of water collected	Public health risk from poor hygiene	Intervention priority and actions
No access	More than 1 km / more than 30 min round-trip	Very low: 5 litres per capita per day	**Very high** Hygiene practice compromised Basic consumption may be compromised	**Very high** Provision of basic level of service Hygiene education Household water treatment and safe storage as interim measure
Basic access	Within 1 km / within 30 min round-trip	Approximately 20 litres per capita per day on average	**High** Hygiene may be compromised Laundry may occur off-plot	**High** Provision of improved level of service Hygiene education Household water treatment and safe storage as interim measure
Intermediate access	Water provided on-plot through at least one tap (yard level)	Approximately 50 litres per capita per day on average	**Low** Hygiene should not be compromised Laundry likely to occur on-plot	**Low** Hygiene promotion still yields health gains Encourage optimal access
Optimal access	Supply of water through multiple taps within the house	100–200 litres per capita per day on average	**Very low** Hygiene should not be compromised Laundry will occur on-plot	**Very low** Hygiene promotion still yields health gains

Source: *Domestic water quantity, service level and health (supporting document in Annex 1)*

The quantities of water collected and used by households are primarily a function of the distance to the water supply or total collection time required. This broadly equates to the level of service. Four levels of service can be defined, as shown in Table 5.1.

Service level is a useful and easily measured indicator that provides a valid surrogate for the quantity of water collected by households and is the preferred indicator for surveillance. Available evidence indicates that health gains accrue from improving service level in two key stages: the delivery of water within 1 km or 30 minutes of total collection time; and when supplied to a yard level of service. Further health gains are likely to occur once water is supplied through multiple taps, as this will increase water availability for diverse hygiene practices. The volume of water collected may also depend on the reliability and cost of the water. Therefore, collection of data on these indicators is important.

5.3.2 Accessibility

From the public health standpoint, the proportion of the population with reliable access to safe drinking-water is the most important single indicator of the overall success of a drinking-water supply programme.

There are a number of definitions of access (or coverage), many with qualifications regarding safety or adequacy. Access to safe drinking-water for the Millennium Development Goals is currently measured by the WHO/ United Nations Children's Fund (UNICEF) Joint Monitoring Programme for Water Supply and Sanitation through a proxy that assesses the use of improved drinking-water sources by households. An improved drinking-water source is one that by the nature of its construction and design adequately protects the source from outside contamination, in particular by faecal matter. The underlying assumption is that improved sources are more likely to supply safe drinking-water than unimproved sources. Improved and unimproved water supply technologies are summarized below:

- *Improved drinking-water sources:*
  - piped water into dwelling, yard or plot
  - public tap or standpipe
  - tubewell or borehole
  - protected dug well
  - protected spring
  - rainwater collection.
- *Unimproved drinking-water sources:*
  - unprotected dug well
  - unprotected spring
  - cart with small tank or drum provided by water vendor
  - tanker truck provision of water
  - surface water (river, dam, lake, pond, stream, canal, irrigation channel)
  - bottled water.[1]

Determining the proportion of a population with reliable access to drinking-water is an important function of a drinking-water surveillance agency. This task can be facilitated by establishing a common defi nition for reasonable access, appropriate to a local context, which may describe a minimum quantity of water supplies per person per day together with a maximum tolerable distance/time to a source (e.g. 20 litres, and within 1 km/30 minutes, respectively, for basic access).

5.3.3 Affordability

The affordability of water has a significant influence on the use of water and selection of water sources. Households with the lowest levels of access to safe water supply frequently pay more for their water than do households connected to a piped water system. The high cost of water may force households to use alternative sources of water of poorer quality that represent a greater risk to health. Furthermore, high costs

[1] Bottled water is considered to be improved only when the household uses drinking-water from an improved source for cooking and personal hygiene.

of water may reduce the volumes of water used by households, which in turn may influence hygiene practices and increase risks of disease transmission.

When assessing affordability, it is important to collect data on the price at the point of purchase. Where households are connected to the drinking-water supplier, this will be the tariff applied. Where water is purchased from public standpipes or from neighbours, the price at the point of purchase may be very different from the drinking-water supplier tariff. Many alternative water sources (notably vendors) also involve costs, and these costs should be included in evaluations of affordability. In addition to recurrent costs, the costs for initial acquisition of a connection should also be considered when evaluating affordability.

5.3.4 Continuity

Interruptions to drinking-water supply, either because of intermittent sources or resulting from engineering inefficiencies, are a major determinant of the access to and quality of drinking-water. Analysis of data on continuity of supply requires the consideration of several components. Continuity can be classified as follows:

- year-round service from a reliable source with no interruption of flow at the tap or source;
- year-round service with frequent (daily or weekly) interruptions, of which the most common causes are:
  - restricted pumping regimes in pumped systems, whether planned or due to power failure or sporadic failure;
  - peak demand exceeding the flow capacity of the transmission mains or the capacity of the reservoir;
  - excessive leakage within the distribution system;
  - excessive demands on community-managed point sources;
- seasonal service variation resulting from source fluctuation, which typically has three causes:
  - natural variation in source volume during the year;
  - volume limitation because of competition with other uses, such as irrigation;
  - periods of high turbidity when the source water may be untreatable;
- compounded frequent and seasonal discontinuity.

These classifications reflect broad categories of continuity, which are likely to affect hygiene in different ways. Any interruption of service is likely to result in degradation of water quality, increased risk of exposure to contaminated water and therefore increased risk of waterborne disease. Daily or weekly discontinuity results in low supply pressure and a consequent risk of in-pipe recontamination. Other consequences include reduced availability and lower volume use, which adversely affect hygiene. Household water storage may be necessary, and this may lead to an increase in the risk of contamination during such storage and associated handling. Seasonal discontinuity often forces users to obtain water from inferior and distant sources. As a consequence, in addition to the obvious reduction in quality and quantity, time is lost in water collection.

5.4 Planning and implementation

For drinking-water supply surveillance to lead to improvements in drinking-water supply, it is vital that the mechanisms for promoting improvement are recognized and used.

The focus of drinking-water supply-related improvement activities (whether these are establishment of regional or national priorities, hygiene education programmes or enforcement compliance) will depend on the nature of the drinking-water supplies and the types of problems identified. A list of mechanisms for drinking-water supply improvement based on the output of surveillance is given below:

- *Establishing national priorities:* When the most common problems and shortcomings in the drinking-water system have been identified, national strategies can be formulated for improvements and remedial measures; these might include changes in training (of managers, administrators, engineers or field staff), rolling programmes for rehabilitation or improvement or changes in funding strategies to target specific needs.
- *Establishing subnational/regional priorities:* Regional offices of drinking-water supply agencies can decide in which communities to work and which remedial activities are priorities; public health criteria should be considered when priorities are set.
- *Establishing hygiene education programmes:* Not all of the problems revealed by surveillance are technical in nature, and not all are solved by drinking-water suppliers; surveillance also looks at problems involving community and household supplies, water collection and transport and household treatment and storage. The solutions to many of these problems are likely to require educational and promotional activities.
- *Auditing of WSPs and upgrading:* The information generated by surveillance can be used to audit WSPs and to assess whether these are in compliance. Drinking-water systems and their associated WSPs should be upgraded where they are found to be deficient, although feasibility must be considered, and enforcement of upgrading should be linked to strategies for progressive improvement.
- *Ensuring community operation and maintenance:* Support should be provided by a designated authority to enable community members to be trained so that they are able to assume responsibility for the operation and maintenance of community drinking-water supplies.
- *Establishing public awareness and information channels:* Publication of information on public health aspects of drinking-water supplies, water quality and the performance of suppliers can encourage suppliers to follow good practices, mobilize public opinion and response and reduce the need for regulatory enforcement, which should be an option of last resort.
- *Implementing programmes for household water treatment and safe storage:* If information from surveillance reveals no or only basic access to water service, as defined in Table 5.1, or unsafe supplied water, the implementation of programmes to promote household water treatment and safe storage may be advised to improve water quality and promote hygienic water management at the household level. These may be effective interim measures for provision of safer water supported by appropriate outreach, education and training activities and creating supply

chains for appropriate household water treatment and safe storage technologies. Further information is available in section 7.3.2 and the 1997 volume, *Surveillance and control of community supplies* (WHO, 1997).

In order to make best use of limited resources where surveillance is not yet practised, it is advisable to start with a basic programme that develops in a planned manner. Activities in the early stages should generate enough useful data to demonstrate the value of surveillance. Thereafter, the objective should be to progress to more advanced surveillance as resources and conditions permit.

The activities normally undertaken in the initial, intermediate and advanced stages of development of drinking-water supply surveillance are summarized as follows:

- *Initial phase:*
  - Establish requirements for institutional development.
  - Provide training for staff involved in the programme.
  - Define the role of participants (e.g. quality assurance/quality control by supplier, surveillance by public health authority).
  - Develop methodologies suitable for the area.
  - Commence routine surveillance in priority areas (including inventories).
  - Limit verification to essential parameters and known problem substances.
  - Establish reporting, filing and communication systems.
  - Advocate improvements according to identified priorities.
  - Establish reporting to local suppliers, communities, media and regional authorities.
  - Establish liaison with communities; identify community roles in surveillance and means of promoting community participation.
- *Intermediate phase:*
  - Train staff involved in the programme.
  - Establish and expand systematic routine surveillance.
  - Expand access to analytical capability (often by means of regional laboratories, national laboratories being largely responsible for analytical quality control and training of regional laboratory staff).
  - Undertake surveys for chemical contaminants using wider range of analytical methods.
  - Evaluate all methodologies (sampling, analysis, etc.).
  - Use appropriate standard methods (e.g. analytical methods, fieldwork procedures).
  - Develop capacity for statistical analysis of data.
  - Establish national database.
  - Identify common problems and improve activities to address them at regional and national levels.
  - Expand reporting to include interpretation at the national level.
  - Draft or revise health-based targets as part of a framework for safe drinking-water.
  - Use legal enforcement where necessary.
  - Involve communities routinely in surveillance implementation.

- *Advanced phase:*
  - Provide further or advanced training for staff involved in the programme.
  - Establish routine surveillance for all health and acceptability parameters at defined frequencies.
  - Use a full network of national, regional and local laboratories (including analytical quality control).
  - Use national framework for drinking-water quality.
  - Improve water services on the basis of national and local priorities, hygiene education and enforcement of standards.
  - Establish regional database archives compatible with national database.
  - Disseminate data at all levels (local, regional and national).
  - Involve communities routinely in surveillance implementation.

5.5 Reporting and communicating

An essential element of a successful surveillance programme is the reporting of results to stakeholders. It is important to establish appropriate systems of reporting to all relevant bodies. Proper reporting and feedback will support the development of effective remedial strategies. The ability of the surveillance programme to identify and advocate interventions to improve water supply is highly dependent on the ability to analyse and present information in a meaningful way to different target audiences. The target audiences for surveillance information will typically include:

- public health officials at local, regional and national levels;
- water suppliers;
- local administrations;
- communities and water users;
- local, regional and national authorities responsible for development planning and investment.

5.5.1 Interaction with community and consumers

Community participation is a desirable component of surveillance, particularly for community and household drinking-water supplies. As primary beneficiaries of improved drinking-water supplies, community members have a right to take part in decision-making. The community represents a resource that can be drawn upon for local knowledge and experience. They are the people who are likely to first notice problems in the drinking-water supply and therefore can provide an indication of when immediate remedial action is required. Communication strategies should include:

> The right of consumers to information on the safety of the water supplied to them for domestic purposes is fundamental.

- provision of summary information to consumers (e.g. through annual reports or the Internet);
- establishment and involvement of consumer associations at local, regional and national levels.

In many communities, however, the simple right of access to information will not ensure that individuals are aware of the quality or safety of the water supplied to them. The agencies responsible for surveillance should develop strategies for disseminating and explaining the significance of results obtained.

It may not be feasible for the surveillance agency to provide feedback information directly to the entire community. Thus, it may be appropriate to use community organizations, where these exist, to provide an effective channel for providing feedback information to users. Some local organizations (e.g. local councils and community-based organizations, such as women's groups, religious groups and schools) have regular meetings in the communities that they serve and can therefore provide a mechanism of relaying important information to a large number of people within the community. Furthermore, by using local organizations, it is often easier to initiate a process of discussion and decision-making within the community concerning water quality. The most important element in working with local organizations is to ensure that the organization selected can access the whole community and can initiate discussion on the results of surveillance (see sections 7.6.1 and 8.7).

5.5.2 Regional use of data

Strategies for regional prioritization are typically of a medium-term nature and have specific data requirements. While the management of information at a national level is aimed at highlighting common or recurrent problems, the objective at a regional level is to assign a degree of priority to individual interventions. It is therefore important to derive a relative measure of health risk. Although this information cannot be used on its own to determine which systems should be given immediate attention (which would also require the analysis of economic, social, environmental and cultural factors), it provides an extremely important tool for determining regional priorities. It should be a declared objective to ensure that remedial action is carried out each year on a predetermined proportion of the systems classified as high risk.

At the regional level, it is also important to monitor the improvement in (or deterioration of) both individual drinking-water supplies and the supplies as a whole. In this context, simple measures, such as the mean sanitary inspection score of all systems, the proportion of systems with given degrees of faecal contamination, the population with different levels of service and the mean cost of domestic consumption, should be calculated yearly and changes monitored.

As shown in Table 7.10 in section 7.4, the aim should be to provide drinking-water that contains no faecal indicator organisms, such as *Escherichia coli*. However, in many developing and developed countries, a high proportion of household and small community drinking-water systems, in particular, fail to meet requirements for water safety, including the absence of *E. coli*. In such circumstances, it is important that realistic goals for progressive improvement are agreed upon and implemented. It is practical to classify water quality results in terms of an overall grading for water safety linked to priority for action, as illustrated in Table 5.2.

Grading schemes may be of particular use in community supplies where the frequency of testing is low and reliance on analytical results alone is especially inappropriate. Such schemes will typically take account of both analytical findings

Table 5.2 Example of categorization of drinking-water systems on the basis of population size and quality rating in order to prioritize actions (see also Table 7.10)

Quality of drinking-water system[a]	Proportion (%) of samples negative for *E. coli*		
	< 5000 population	5000–100 000 population	> 100 000 population
A	90	95	99
B	80	90	95
C	70	85	90
D	60	80	85

[a] Quality decreases from A to D.

Table 5.3 Example of assessment of priority of remedial actions of community drinking-water supplies based on a grading system of microbial quality and sanitary inspection rating or score[a]

		Sanitary inspection risk score (susceptibility of supply to contamination from human and animal faeces)			
		0–2	3–5	6–8	9–10
E.coli classification[b]	A				
	B				
	C				
	D				

Low risk: no action required	Intermediate risk: low action priority	High risk: higher action priority	Very high risk: urgent action required

[a] Where there is a potential discrepancy between the results of the microbial water quality assessment and the sanitary inspection, further follow-up or investigation is required.
[b] Classifications based on those shown in Table 5.2. Quality decreases from A to D.
Source: Adapted from Lloyd & Bartram (1991). See also the supporting document *Rapid assessment of drinking-water quality* (Annex 1).

and results of the sanitary inspection through matrices such as the one illustrated in Table 5.3.

Combined analysis of sanitary inspection and water quality data can be used to identify the most important causes of and control measures for contamination. This is important to support effective and rational decision-making. For instance, it will be important to know whether on-site or off-site sanitation could be associated with contamination of drinking-water, as the remedial actions required to address either source of contamination will be very different. This analysis may also identify other factors associated with contamination, such as heavy rainfall. As the data will be non-parametric, suitable methods for analysis include chi-square, odds ratios and logistic regression models.

Combined analysis of sanitary inspection and water quality data is especially useful in assessing household water management systems. Microbial water quality data

Table 5.4 Example of assessment of priority of remedial action for household drinking-water systems based on a grading system of microbial quality and sanitary inspection rating or scores[a]

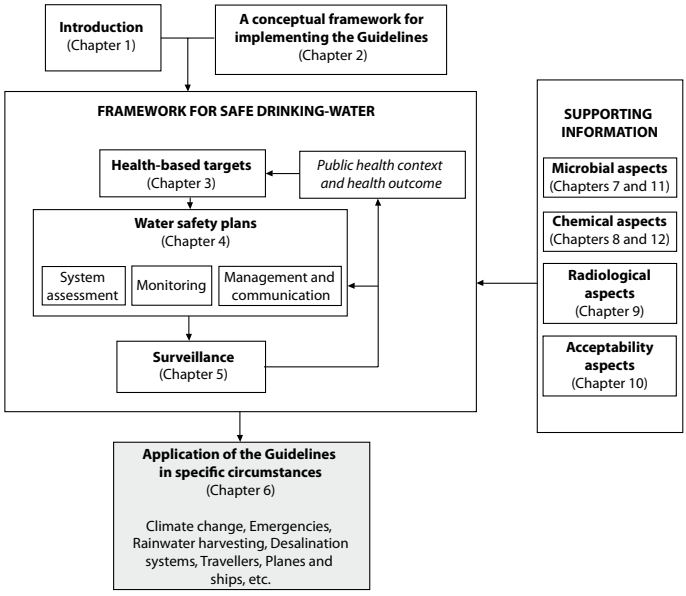
		Sanitary inspection risk score (susceptibility of supply to contamination from human and animal faeces)			
		0–2	3–5	6–8	9–10
***E.coli* classification (as decimal concentration/100)**	< 1				
	1–10				
	11–100				
	> 100				

Low risk: no action required	Intermediate risk: low action priority	High risk: higher action priority	Very high risk: urgent action required

[a] Where there is a potential discrepancy between the results of the microbial water quality assessment and the sanitary inspection, further follow-up or investigation is required.

are often limited, and sanitary inspection risk scoring therefore becomes an important consideration in assessing household water systems, their management and priority for remedial actions. An example of a combined system to assess risk and prioritize remedial actions for household water systems is shown in Table 5.4.

6
Application of the Guidelines in specific circumstances



These Guidelines provide a generally applicable approach to ensuring the safety of drinking-water supplied through piped distribution and community supplies. This chapter describes the application of the Guidelines in some commonly encountered circumstances and specific issues that should be taken into account in each. The sections are not intended to stand alone, and reference is made to more comprehensive supporting documents that provide detailed guidance. In all the specific circumstances described below, the principles enshrined in water safety plans (WSPs) apply. However, the WSP should be tailored to the type of supply in each circumstance; for example, routine chemical and microbiological monitoring of rainwater may not be feasible at a household level, but preventive barriers are both applicable and achievable.

As indicated in chapter 4, WSPs require careful consideration of possible hazards, and forward planning is one of the important requirements in ensuring that both the quantity and quality of water supplies are maintained. One of the significant concerns for the future is climate change, but there remains considerable uncertainty as to its

impact on a local or even subregional level. Nevertheless, it is expected that all types of supply will be affected, including the specific circumstances discussed below.

6.1 Climate change, water scarcity and heavy rainfall

Regional or localized droughts and heavy precipitation events and floods have always occurred, but they appear to be increasing in frequency, and greater extremes of climate should be expected. Anticipating and planning for these events, such that sufficient quantities of safe water can be delivered to consumers without disruptions, are not only key responsibilities of water suppliers, but a growing challenge. The effects of these climate extremes on water quality and quantity will be especially acute in areas with growing populations. In such areas, existing water supplies typically are already stressed, and there is little, if any, water supply margin available to them in the event of a major or extended duration weather event. This is especially true in regions with desert-like climates, such as parts of the Mediterranean, the Middle East, Australia and the south-western United States of America.

Over an extended period of time, climate change may foster greater extremes in weather, including more frequent and longer spells with much higher peak temperatures, droughts, greater frequency of heavy precipitation and violent storms. Changes in sea level from melting ice can affect coastal groundwater, causing salination, which may also occur as a result of over-abstraction. With changes in water quantity come changes in water quality: greater or lesser runoff affects the sediment loading, chemical composition, total organic carbon content and microbial quality. These changes require modifications in water storage capacity and water treatment to ensure safe drinking-water. Changes in groundwater levels may also lead to altered mineral composition, and moves to deeper groundwater may tap into aquifers with high mineral content or high levels of specific constituents of concern for health.

To provide for adequate water quantity and quality in the event of these changes and extremes, natural supplies may need to be augmented in some areas, together with use of more climate-resilient technologies and processes. Water treatment systems may need to be upgraded and obtain greater storage capacity to be able to cope with greater microbial, turbidity and chemical loadings. New sources of water may need to be developed, such as recycled wastewater or desalinated brackish water or seawater, and new strategies may need to be implemented, such as aquifer storage and recovery.

6.2 Rainwater harvesting

Rainwater harvesting is widely practised at a household level but is increasingly being used on a larger community scale. Rainwater can provide an important source of drinking-water in some circumstances as well as a useful source of water for blending with other sources to reduce the levels of contaminants of health concern, such as arsenic and fluoride.

The development of formal WSPs at the household level may not always be practical, but promotion of sanitary inspection with simple good practice is important. Well-designed rainwater harvesting systems with clean catchments, covered cisterns

and storage tanks, and treatment, as appropriate, supported by good hygiene at point of use, can offer drinking-water with very low health risk.

Rainwater is initially relatively free from impurities, except those picked up by the rain from the atmosphere. However, the quality of rainwater may subsequently deteriorate during harvesting, storage and household use. Wind-blown dirt, leaves, faecal droppings from birds and other animals, insects and litter on the catchment areas, such as roofs and in cisterns, can contaminate rainwater, as can particles from the atmosphere, such as soot from burning materials such as old tyres. Regular cleaning of catchment surfaces and gutters should be undertaken to minimize the accumulation of debris. Wire meshes or inlet filters should be placed over the top of downpipes to prevent leaves and other debris from entering storage containers and cleaned regularly to prevent clogging.

Materials used in the catchment and storage tank should be approved for use in contact with drinking-water and should not leach contaminants or cause taste, odour or discoloration. As rainwater is slightly acidic and very low in dissolved minerals, it can dissolve metals and other impurities from materials of the catchment and storage tank, resulting in unacceptably high concentrations of contaminants in the water. Most solid roof materials are suitable for collecting rainwater, but roofs with bitumen-based coatings are generally not recommended, as they may leach hazardous substances or cause taste problems. Care should be taken to ensure that lead-based paints are not used on roof catchments. Thatched roofs can cause discoloration or deposition of particles in collected water.

Poor hygiene in water storage and abstraction from storage containers or at the point of use can also represent a health concern, but risks can be minimized by good design and practice. Faecal contamination is quite common, particularly in samples collected shortly after rainfall, but can be minimized by good practice. Higher microbial concentrations are generally found in the first flush of rainwater, decreasing as the rain continues; therefore, microbial contamination is less in rainy seasons when catchments are frequently washed with fresh rainwater. A system to divert the contaminated first flow of rainwater from roof surfaces is necessary, and automatic devices that prevent the first flush of runoff from being collected in storage are recommended. If diverters are not available, a detachable downpipe can be used manually to provide the same result.

Storage tanks can present breeding sites for mosquitoes, including species that transmit dengue virus (see section 8.6). Covers discourage mosquito breeding and help to prevent faecal contaminants and sunlight, which will promote algal growth, from reaching the water. Covers should be fitted, and openings need to be protected by mosquito-proof mesh. Cracks in the tank can result in contamination of stored water, whereas water withdrawal using contaminated containers is a potential cause of both faecal and chemical contamination. Storage containers should preferably be fitted with a mechanism such as a tap or outlet pipe that enables hygienic abstraction of water.

Further treatment at the point of consumption may be applied to ensure better quality of drinking-water and reduce health risk. Solar water disinfection and point-of-use chlorination are examples of low-cost disinfection options for the treatment

of stored rainwater. These and other household water treatment technologies are discussed in more detail in sections 7.3.2 (microbial) and 8.4.4 (chemical).

6.3 Vended water

Vended water is common in many parts of the world where scarcity of supplies or lack of infrastructure limits access to suitable quantities of safe drinking-water. Although water vending is more common in developing countries, it also occurs in developed countries.

In the context of these Guidelines, water vending implies private vending of drinking-water, but does not include bottled or packaged water (which is considered in section 6.14) or water sold in bottles through vending machines.

Water vending may be undertaken by formal bodies, such as water utilities or registered associations, by contracted suppliers or by informal and independent suppliers. Where formal vending is practised, the water typically comes from treated utility supplies or registered sources and is supplied in tankers or from standpipes and water kiosks. Informal suppliers tend to use a range of sources, including untreated surface water, dug wells and boreholes, and deliver small volumes for domestic use, often in containers loaded onto small carts or tanker trucks.

Both the quality and adequacy of vended supplies can vary significantly, and vended water has been associated with outbreaks of diarrhoeal disease (Hutin, Luby & Paquet, 2003). Water supplied to users should be suitable for drinking and comply with national or regional guidelines and regulatory requirements. The chemical and microbial quality of untreated or private sources of water should be tested to determine their suitability for use and to identify appropriate control measures, including treatment requirements. Surface water and some dug well and borehole waters are not suitable for drinking without treatment; disinfection is the minimum requirement, and filtration is often required when surface water is used.

In many developing countries, consumers purchase water from kiosks and then carry the water home in a variety of containers of varying size. Measures should be taken to protect vended water from contamination during transport as well as storage in the home, including transporting and storing water in containers that are clean, free from both faecal and chemical contamination and either enclosed or with narrow openings, ideally fitted with a dispensing device such as a spigot that prevents hand access and other sources of extraneous contamination. Good hygiene is required and should be supported by educational programmes.

In other cases, particularly in developed countries, vendors transport and deliver the water to users in tanker trucks. If large volumes are being transported, the addition of chlorine to provide a free residual concentration of at least 0.5 mg/l at the point of delivery to users is desirable. Tankers should also be used solely for water or, if this is not possible, should be thoroughly cleaned prior to use.

All components of systems associated with supplying and delivering vended water need to be designed and operated in a manner that protects water quality. Water storage containers, pipework and fittings should not include defects such as structural faults that allow leakage and permit the entry of contaminants. Cleanliness of storage containers, standpipes, taps and hoses needs to be maintained. Hoses used to transfer

water at kiosks or used on carts and tanker trucks should be protected from contamination (e.g. by preventing contact of the ends with the ground) and drained when not in use. The area around standpipes should include drainage or be constructed in a manner to prevent pooling of water. Materials used in all components, including pipework, containers and hoses, need to be suitable for use in contact with drinking-water and should not result in contamination of the water with hazardous chemicals or with substances that could adversely affect its taste.

All components of water vending, including sources, methods of abstraction and transport, should be incorporated into a WSP. Where vendors are registered or have a contract with a water utility, implementation and operation of the WSP should be regularly checked by the utility. WSPs and the operation of water vendors should also be subject to independent surveillance.

6.4 Bulk water supply

Bulk water supplies can be either untreated or treated water, but usually there is limited or no choice in the provision of such supplies. They may be provided where one agency or company controls a large raw water source, usually surface water, and provides water to one or several other water suppliers. Bulk water supplies can be delivered by pipeline or tanker or using ships or fleets of road or rail tankers.

In all cases, it is important that the bulk supply is incorporated into the WSP of the receiving supply and treated as another source. Where bulk supplies of treated water have been used to provide support during a drought or emergency, it is vital that the receiving supplier takes steps to ensure that the water is safe before it is introduced into the receiving distribution system. At all stages, it is important that there is close communication between all parties involved and that the procedures and requirements are documented, understood and carried out with appropriate monitoring and verification.

The potential hazards from bulk water are similar to those from any water supply, but there are additional sources of contamination, such as inappropriate containers and materials and lack of sanitation and hygiene at bulk water filling connections or transfer points. Pipelines may be vulnerable to contamination along the transmission route, particularly if there is the potential for unapproved connections into the system.

Many of the requirements for bulk supply are the same as for any piped supply, such as using approved materials that will not adversely affect water quality. Where tankers are used, these should be of a suitable material and be clean and free from microbial and chemical contamination. To minimize contamination during filling of bulk water containers or water tankers and charging of water transmission pipelines, sanitary inspections and maintenance of sanitary conditions for water filling stations are necessary. These sites should have proper drainage to avoid standing water and flooding, should not be exposed to sources of contamination and should be secure, with access restricted to authorized personnel. At water filling and delivery points, nozzles and couplings should be protected from sources of contamination, including animals. Installation of protective coverings for filling and receiving connectors would help in this respect. Some plastic pipe materials are permeable to organic chemicals,

and transfer of substances such as petroleum hydrocarbons could diminish the structural integrity of the pipe materials or render the water unpalatable to consumers. Such piping is most likely to be found in transfer hoses, so the cleanliness of the transfer points where tankers are used is vital, as is protection of the transfer area from spills of petroleum fuels.

Implementation of security measures to guard against intentional contamination and theft may also be warranted.

6.5 Desalination systems

Desalination is used to remove salts from brackish or saline surface water and groundwater in order to render it acceptable for human consumption or other uses. It is increasing employed to provide drinking-water because of a growing scarcity of fresh water driven by population growth, overexploitation of water resources and climate change. Desalination facilities exist all over the world, particularly in the eastern Mediterranean region, with use increasing on all continents. Small-scale desalination is used to supply fresh water on ships and to provide additional fresh water in some hot and arid regions.

These Guidelines are fully applicable to desalinated water supply systems; however, desalination presents certain differences in emphasis, as summarized below.

Desalinated water has a very low total organic carbon content and low disinfectant demand, so disinfection by-products are generally of little concern, although brominated organics may occur owing to the presence of bromide in seawater. Membrane and distillation desalination processes are very efficient at removing higher molecular weight organic chemicals and virtually all inorganic chemicals, and volatile organic compounds are vented during thermal desalination processes. Where membranes are used, boron and some smaller molecular weight organic substances may not be excluded, so it is important to establish the membrane capability. Because of the apparently high effectiveness of some of the processes used (especially distillation and reverse osmosis) in removing both microorganisms and chemical constituents, these processes may be employed as single-stage treatments or combined with only a low level of residual disinfectant. For further information, see the supporting document *Water treatment and pathogen control* (Annex 1). Pretreatment is largely in place to protect the desalination process, but it will also remove certain hazards present in brackish or saline waters.

Water produced by desalination is low in minerals and usually aggressive towards materials with which it comes into contact, such as materials used for distribution pipes, storage and plumbing. During post-treatment, the water must be stabilized or remineralized prior to distribution to reduce its corrosive nature. Stabilization is commonly achieved by adding chemical constituents such as calcium and magnesium carbonate along with pH adjustment or through blending with small volumes of mineral-rich waters. Seawater and spent seawater that has undergone electrolysis to form hypochlorite have been used for this purpose, but the latter practice has essentially ended because of the formation of bromate in the distributed water. Blending waters should be pretreated to ensure their microbial safety, because the post-desalination residual disinfectant level may be insufficient to control pathogens present in the blending water.

Desalinated water contains lower than usual concentrations of dissolved solids and essential elements such as calcium and magnesium, which are commonly found in water (see the supporting document *Calcium and magnesium in drinking-water*; Annex 1). Drinking-water typically contributes a small proportion to the recommended daily intake of essential elements, with most of the intake occurring through food. Fluoride would also be missing from desalinated water unless it were added prior to distribution, which may be considered by countries in which sugar consumption is high (WHO, 2005b).

High temperatures of distributed water in warm climate areas and difficulty in maintaining disinfectant residuals during transport over long distances may lead to microbial aftergrowth, depending on nutrient availability. Although such growth is likely to be without health significance (see the supporting document *Heterotrophic plate counts and drinking-water safety*; Annex 1), it can contribute to problems of acceptability. The use of chloramines constitutes an advantageous alternative to free chlorine in distribution systems with long residence times and elevated temperatures, although nitrite formation by organisms in biofilms needs to be considered where chloramination is practised and excess ammonia is present.

Extensive information on desalination for safe drinking-water supply is available in the book *Desalination technology: Health and environmental impacts* (Cotruvo et al., 2010) and the supporting document *Safe drinking-water from desalination* (Annex 1).

6.6 Dual piped water supply systems

In some locations, households and buildings served with a piped drinking-water supply may also receive piped water from an alternative source for non-potable purposes, creating a dual piped water supply system. The alternative water source is usually provided to reduce the use of high-quality water resources for non-potable uses (e.g. toilets, washing clothes, irrigation) or simply to conserve scarce water resources.

Non-potable piped supplies can potentially introduce health hazards, commonly through accidental cross-connections between potable and non-potable piped supplies. Measures to control health risks from dual piped supply systems include:

- use of good design practices that prevent cross-connections;
- unambiguous labelling of both systems to ensure that the non-potable supply is not mistaken for the potable supply;
- installation of the non-potable piped system only by qualified plumbers;
- regulation of non-potable piped systems by the authority responsible for drinking-water surveillance;
- public communication about the potential health risks from exposure to non-potable water through cross-connections and the dangers of modifying systems by inexperienced and non-certified individuals.

Increasingly in developed countries, dual systems are being installed at a household level or in public buildings. Guidance should be provided on installation, particularly where this is by non-certified individuals. Potable water supplied into the building should be fitted with a non-return valve in order to prevent backflow into the public water supply.

6.7 Emergencies and disasters

Safe drinking-water is one of the most important public health requirements in most emergencies and disasters, along with adequate sanitation. The greatest waterborne risk to health comes from the transmission of faecal pathogens as a result of inadequate sanitation, hygiene and protection of drinking-water sources. Some disasters, including those caused by or involving damage to chemical or nuclear industrial installations, spillage in transport or volcanic activity, may result in contamination by chemical or radiological hazards of concern. The circumstances of most large-scale emergencies will vary, and each will present its own peculiar problems and challenges.

Where a number of agencies are involved in disaster relief or overseeing an emergency, it is vital that there is good communication between the agencies and coordination of their activities. It is also important that the overall coordinators take advice from the experts in a particular field, such as water supply and sanitation. This section considers primarily large-scale disasters and emergencies, although much of the information will apply to smaller-scale emergencies as well. For microbiological and chemical emergencies on a smaller scale in piped supplies, the relevant sections in chapters 7 and 8 should be consulted.

When people are displaced by conflict and natural disaster, they may move to an area where unprotected water sources are contaminated. When population density is high and sanitation is inadequate, unprotected water sources in and around the temporary settlement are highly likely to become contaminated. A displaced population with low immunity due to malnutrition as a consequence of food shortages or the burden of other diseases is at an increased risk of an outbreak of waterborne disease.

Emergency planning initiatives should include three phases:

1) vulnerability assessments (which should be part of a WSP for any large supply) to identify the critical elements of the existing systems that, if compromised, would result in major disruption of basic services;
2) mitigation plans to identify feasible actions to prevent or reduce the disruptive effects related to the loss of the vulnerable elements or facilities;
3) emergency preparedness plans to facilitate managing the crisis and the restoration of service should disruptions occur.

The key is to anticipate probable events, have plans in place, prepare to respond when needed, have backup materials and facilities and have conducted simulations so that the organization and its staff will be effective in the event of an emergency.

Available sources of water are limited in most emergency situations, and providing a sufficient quantity of water for personal and domestic hygiene as well as for drinking and cooking is important. National drinking-water quality standards should therefore be flexible, taking into consideration the risks and benefits to health in the short and long term, and should not excessively restrict water availability for hygiene, as this would often result in an increased overall risk of disease transmission.

There are a number of factors to take into consideration when providing drinking-water for a population affected by a disaster, including the following:

- *The quantity of water available and the reliability of supply:* These are likely to be the overriding concerns in most emergency situations, as it is usually easier to improve water quality than to increase its availability or to move the affected population closer to another water source.
- *The equitability of access to water:* Even if sufficient water is available to meet minimum needs, additional measures may be needed to ensure that access is equitable. Unless water points are sufficiently close to their dwellings, people will not be able to collect enough water for their needs. Water may need to be rationed to ensure that everyone's basic needs are met.
- *Protecting the water source against contamination:* This should always be a priority in emergencies, whether or not disinfection of the water supply is considered necessary.
- *The need for disinfection:* Disinfection, maintaining an adequate disinfectant residual and, where necessary, pretreatment to reduce turbidity to as low as feasible in order to ensure the efficiency of disinfection are essential components in ensuring a safe drinking-water supply. The information in Table 6.1 in section 6.11, on drinking-water disinfection methods that can be used by travellers, may be applied to temporary uses in emergency situations.
- *Longer-term planning for continuing emergency situations:* When the first phase of an emergency or disaster is over and the cleanup is in progress, consideration needs to be given to the longer-term provision of safe water and sanitation. In this case, pre-planning can be invaluable.
- *Acceptability:* It is important to ensure that drinking-water provided in emergencies is acceptable to the consumers in terms of taste, odour and appearance, or the consumers may resort to water from unprotected or untreated supplies.
- *The need for containers to collect and store water:* Containers that are hygienic and appropriate to local needs and habits are needed for the collection and storage of water to be used for washing, cooking and bathing.
- *The availability of bottled or packaged water:* Provision of bottled or packaged water from a reliable source is often an effective way to quickly provide safe, potable water in emergencies and disasters. Brewers and soft drink producers, if they are part of the emergency response plan, are often capable of converting their processes to produce bottled or packaged water in emergencies. This is particularly valuable if they have water treatment plants for ensuring the quality of water used as an ingredient in their processes.

In many emergency situations, water is collected from central water collection points, stored in containers and then transferred to cooking and drinking vessels by the affected people. It is important that people be aware of the risks to health from contamination of water from the point of collection to the moment of consumption and have the means to reduce or eliminate these risks. Detailed information may be found in Wisner & Adams (2003).

Water quality should be monitored during emergencies, including sanitary inspection and microbial water sampling and analysis; monitoring of water treatment processes, including disinfection; monitoring of water quality at all water collection

points and in a sample of homes; and water quality assessment in the investigation of disease outbreaks or the evaluation of hygiene promotion activities, as required.

Monitoring and reporting systems should be designed and managed to ensure that action is swiftly taken to protect health. Health information should also be monitored to ensure that water quality can be rapidly investigated when it is suspected of contributing to a health problem and treatment processes, particularly disinfection, can be modified as required.

Where large numbers of water samples need testing or analysis of a broad range of parameters is of interest, laboratory analysis is usually most appropriate. If the drinking-water supplier's laboratories or laboratories at environmental health offices and universities no longer function because of the disaster, a temporary laboratory may need to be set up. Where samples are transported to laboratories, appropriate handling is important to ensure meaningful results. Portable testing kits allow the determination in the field of key water quality parameters, such as thermotolerant coliform count, free residual chlorine, pH, turbidity and filterability.

Workers should be trained in the correct procedures for collecting, labelling, packing and transporting samples and in supplying supporting information from the sanitary survey to help interpret laboratory results. For guidance on methods of water sampling and testing, see Bartram & Ballance (1996), WHO (1997) and APHA, AWWA & WEF (2005).

6.8 Temporary water supplies

A number of waterborne disease outbreaks have occurred as a result of poor management and design of temporary water supplies, which are distributed water supplies for planned seasonal or time-limited events (e.g. festivals, markets and summer camps). Water supplies for holiday towns are not covered, because they are permanent supplies, although substantial seasonal variations in demand bring specific problems.

A systematic approach to drinking-water safety, including adequate quantity and quality, is needed for temporary water supplies. A WSP is an essential requirement in identifying the hazards and risks and developing good management procedures to deal with them. Chapter 4 and other sections in chapter 6 provide additional useful information. Where water is supplied through tankers, the requirements are the same as for vended water (section 6.3) and bulk water supplies (section 6.4).

A temporary water supply may be independent (i.e. not connected to any other water supply system and with its own facilities from source to tap) or dependent (i.e. receiving treated water from an existing water supply system but with independent distribution facilities). The risk of drinking-water contamination is usually lower in dependent systems, provided there is access to the technologies, expertise and management of the permanent system. A contract is often made between the organizer of an event (e.g. a festival) and a water supply entity, which should include the water quantity and quality supplied by the entity, the roles and responsibilities of each party in water quality management, the locations and frequency of water quality monitoring, sanitary inspection and surveillance by a health authority and the provision of adequate and properly sited sanitation. Coordination between an event organizer, a water supply entity and the relevant health authority is very important for ensuring drinking-water safety.

Temporary water supply systems can vary substantially in terms of their scale, period of operation, water use and fluctuations in demand, and these variations should be taken into consideration during the planning and design stages. In the case of an independent system, adequate consideration should also be given to the selection of a water source in terms of quantity, quality and treatment processes, and care should be taken not to adversely affect any other supply or water source. Where a temporary system is directly connected to a mains water supply, it is important to prevent the accidental contamination of the mains water supply through backflow during construction and operation of the temporary system. Water consumption for firefighting, hand washing and toilet flushing should be taken into account in estimating total and predictable variations in water demand where there are no other water sources available for such purposes.

Water quality targets for temporary supplies should be the same as those for permanent water supplies. Disinfection should be considered indispensable in a temporary supply, and it is preferable to maintain a certain level of disinfectant (e.g. chlorine) residual at service taps. If the supply is not for potable uses, appropriate action should be taken to ensure that it is not used for drinking.

If a temporary water supply is used recurrently, it is essential to fully flush the entire system with water containing a higher than normal disinfectant residual before restarting. When planning installation on site, positioning of pipes, hoses and connections should take risks of contamination into account—for example, by avoiding the placement of hosing and fittings on the ground near sites of potential faecal contamination or storage tanks in direct sunlight where rising temperatures support microbial growth. It is also important to ensure that the facility has no defects, including leakage, that could cause the deterioration of water quality and that water quality at every service tap satisfies the required quality target. Important control measures during dismantling and transport of installations include emptying hoses, preferably drying them and storing them so that ingress of contamination is avoided. In all cases, the materials should be approved for use in contact with potable water.

Care should be taken in planning and designing wastewater management and disposal facilities, particularly to ensure that lavatories and disposal facilities are located so as to avoid any risk of adversely affecting source water quality or stored water. It is also important to prevent runoff from other areas, such as livestock pens, from entering the source. The source, treatment facilities and distribution reservoirs should be well protected from access by animals (e.g. bird faeces) and humans by covers or roofs.

A temporary system is usually more vulnerable to accidental and deliberate contamination than an existing permanent water supply system, and attention needs to be paid to security. All water treatment facilities should be thoroughly inspected at least every day. All of these procedures and requirements should be included in the operational management documents that are at the core of the WSP.

Signs are an important part of ensuring that water from taps is used appropriately and the protection of water sources and drinking-water infrastructure. The signs should be easily understood and used in conjunction with other barriers, such as fences.

Water quality and appearance should be routinely monitored at the service taps of a temporary water supply system. At the very least, water temperature and disinfectant residual should be monitored every day as simple rapid tests that act as indicators of possible problems. Other basic parameters that should be regularly monitored, if possible, include pH, conductivity, turbidity, colour and *Escherichia coli* (or, alternatively, thermotolerant coliforms). Routine sanitary inspection of a temporary water supply by the appropriate health authority is very important. If any problem related to water quality arises, remedial actions that are included in the management documents supporting the WSP should be taken promptly. If a temporary water supply system is to be used for a period of more than a few weeks, regular surveillance by the appropriate health authority should be implemented.

6.9 Buildings[1]

Drinking-water systems in buildings can be a significant source of contamination, and poor management of these systems has contributed to outbreaks of disease and illness. One of the challenges in ensuring water safety is that responsibility for many actions essential to the control of drinking-water quality in buildings is often outside the mandate of the drinking-water supplier. Roles and responsibilities of different stakeholders relating to the safe management of drinking-water systems within buildings can be influenced by a number of factors, including ownership of assets and rights of access. WSPs established for management of public water supplies are not typically extended to buildings, although the water supplier WSP may include a number of initiatives to ensure that backflow prevention is in place or to provide information to consumers on protecting their own water quality. In many cases, owners, managers or maintenance personnel are responsible for managing building water supplies, but awareness and application of drinking-water guidelines are often limited, and so educational supporting programmes may be required.

The design of water networks in buildings is variable, as influenced by the diversity of building types (e.g. schools, child-care facilities, residential buildings, hotels, sports facilities, factories, office blocks, museums, transport terminals), designs and water uses. Drinking-water systems in buildings are typically divided into hot and cold water networks and may be connected to water-based devices (e.g. cooling towers, boilers, swimming pools) or point-of-use equipment (e.g. washing machines).

General drinking-water safety is ensured by good management practices, including sound design, routine maintenance protocols, regular cleaning, temperature management and flow management (avoidance of stagnation). These practices should be incorporated in WSPs developed by building owners or managers. WSPs for buildings should address cold and hot drinking-water networks and consider water-based devices and point-of-use equipment. Regulatory or other appropriate authorities may provide guidance on the development and application of WSPs for drinking-water systems in buildings.

[1] Hospitals, nursing care homes and other health-care facilities are discussed in section 6.10.

The regulator can specify compliance requirements for buildings in general or for specific types of buildings based on the level of risk. Schools, hotels and some other large buildings are high-risk environments because of both the complex nature of their drinking-water systems and the vulnerability of some users, occupants and visitors, and heightened vigilance in terms of operational monitoring, validation of control measures and verification is generally justified. Compliance may require that maintenance and monitoring programmes be carried out through a building-specific WSP. It may be appropriate to display maintenance and monitoring programmes and certification of compliance at a conspicuous location within the building. Compliance could be verified and certified by an independent auditor.

The principal hazard that may threaten drinking-water systems of buildings is ingress of contamination from external water supplies or through faults in the distribution system (including storage tanks). Unapproved and inappropriate fittings and materials can lead to the release of chemical substances from tanks, piping, jointing and plumbing materials. The release may vary with the age of the material and the contact period; for example, first-draw water contains higher concentrations of lead or copper. Cross-connections with chemical storage containers, backflow from point-of-use equipment and cross-connections with non-potable supplies can lead to a range of contaminants entering drinking-water.

Where water is supplied directly to equipment in buildings, the potential for backflow into the mains network exists. This may be driven by high pressures generated in equipment connected to mains water supplies or by low pressures in the mains, but it can be prevented by fitting appropriate backflow prevention devices.

An additional problem not directly related to drinking-water is microbial growth (e.g. *Legionella*) on surfaces and in water-based devices that may lead to an inhalation hazard from spray droplets. Growth of such bacteria can be controlled through basic measures (e.g. maintaining water outside the range at which *Legionella* proliferate, i.e. > 50 °C for hot water and < 25 °C for cold water, or maintaining a suitable disinfectant residual). Poor temperature control can occur in cold water systems through inadequate insulation and separation from hot water systems and in hot water systems in heating devices and storage containers, inappropriate location of tempering devices, long branch mains and dead ends (i.e. lengths of pipe, closed at one end, through which no water passes). In large buildings, there is increased potential for growth of *Legionella* in long water distribution systems, and maintenance of these systems needs particular attention. For further information on *Legionella* in drinking-water, see section 11.1 and the supporting document *Legionella and the prevention of legionellosis* (Annex 1).

Effective assessment of potential health hazards and risks requires documentation of the physical structure of water systems in buildings. This should be kept up to date and include hot and cold water networks, including materials used; point-of-entry treatment; point-of-use treatment, equipment and systems (e.g. for firefighting) connected to the drinking-water supply; and water-based devices supplied by the drinking-water system.

In undertaking an assessment of the building's distribution system, a range of specific issues must be taken into consideration that relate to ingress, introduction and proliferation of contaminants, including:

- the quality and management of external supplies;
- use of independent water supplies;
- intermittent supplies;
- pressure of water within the system;
- temperature of water (in both cold and hot water systems);
- integrity of storage tanks;
- areas subject to intermittent or seasonal use (e.g. hotels with seasonal occupancy, schools);
- cross-connections, especially in mixed systems;
- backflow prevention;
- system design to minimize dead/blind ends and other areas of potential stagnation;
- the use of materials and coatings approved for use with drinking-water.

The aim of a distribution system within a large building is to supply safe drinking-water at adequate pressure and flow. The quality of water entering building supplies will be ensured by a water utility or by the installation of point-of-entry devices typically managed by the building owner or operator. To maintain drinking-water quality, it is important to minimize transit times, low flows and low pressures.

Procedures should be established for repairs, renovations or extensions of systems to ensure that water safety is maintained, and all work, including changes to water systems, should be documented. Following work on the system, it would be appropriate to disinfect and flush.

Monitoring should focus on ensuring that control measures are working effectively. Where possible, this should include monitoring by maintenance personnel using field kits for parameters such as temperature, pH and disinfectant residuals. The frequency will vary depending on the size and use of the building, but it should be weekly in large buildings. Monitoring of drinking-water quality will be more frequent when the building is new or recently commissioned.

Independent surveillance is a desirable element in ensuring continued water safety within buildings and should be undertaken by the relevant health agency or other independent authority.

To ensure the safety of drinking-water within buildings, supportive activities of national regulatory agencies include:

- specific attention to application of codes of good practice (e.g. at commissioning and in contracting construction and rehabilitation);
- suitable education and training programmes for building owners and managers, engineers, plumbers and operators of water-based devices (e.g. cooling towers and evaporative condensers);
- regulation of the plumbing community and use of certified professionals;
- effective certification and use of materials and devices in the marketplace;
- codes of practice for design and operation of water-based devices;

For further guidance, see the supporting document *Water safety in buildings* (Annex 1).

6.10 Health-care facilities

Health-care facilities include hospitals, health centres and hospices, residential care, dental surgeries and dialysis units. Drinking-water in such facilities should be suitable for human consumption and for all usual domestic purposes, including personal hygiene. However, it may not be suitable for all uses or for some patients, and further processing or treatment or other safeguards may be required.

Although microorganisms such as *Pseudomonas aeruginosa* and mycobacteria, *Acinetobacter*, *Aeromonas* and *Aspergillus* species do not appear to represent a health concern through water consumption by the general population, including most patients in health-care facilities, they may be of concern for severely immunosuppressed persons, such as those with neutrophil counts below 500 per microlitre (see the supporting document *Heterotrophic plate counts and drinking-water safety*; Annex 1). Some of these microorganisms also have the potential to cause infections if drinking-water is used to wash burns or medical devices such as endoscopes and catheters. Water used for such purposes may require additional processing, such as microfiltration or sterilization, depending on use.

Health-care facilities may include environments that support the proliferation and dissemination of *Legionella* (see section 11.1 and the supporting document *Legionella and the prevention of legionellosis*; Annex 1). Some equipment, such as water-cooled high-speed drills in dental surgeries, is of particular concern for both inhalation of droplets and infection of wounds.

Renal dialysis requires large volumes of water that is of higher quality than drinking-water. Water used for dialysis requires special processing to minimize the presence of microorganisms, endotoxins, toxins and chemical contaminants. There are special requirements regarding aluminium, which, in the past, has caused dialysis dementia, and dialysis patients are also sensitive to chloramines, which needs to be considered when chloramination is used to disinfect drinking-water supplies, particularly in areas where there are home dialysis patients.

All health-care facilities should have specific WSPs as part of their infection control programme. These plans should address issues such as water quality and treatment requirements, cleaning of specialized equipment and control of microbial growth in water systems and ancillary equipment.

6.11 Safe drinking-water for travellers

The most common sources of exposure to disease-causing organisms for travellers are contaminated drinking-water and food that has been washed with contaminated water. Diarrhoea is the most common symptom of waterborne infection, affecting 20–50% of all travellers or about 10 million people per year. Cases can occur even among people staying in high-quality resorts and hotels. In some parts of the world, tap or bottled water that has not been produced under proper conditions may not be safe, even if it is clear and colourless.

No vaccine is capable of conferring general protection against infectious diarrhoea, which is caused by many different pathogens. It is important that travellers be aware of the possibility of illness and take appropriate steps to minimize the risks. Preventive measures while living or travelling in areas with questionable drinking-water quality include the following:

- Drink only bottled water or other beverages (carbonated beverages, pasteurized juices and milk) provided in sealed tamper-proof containers and bottled/canned by known manufacturers (preferably certified by responsible authorities). Hotel personnel or local hosts are often good sources of information about which local brands are safe.
- Drink water that has been treated effectively at point of use (e.g. through boiling, filtration or chemical disinfection) and stored in clean containers.
- Drink hot beverages such as coffee and tea that are made with boiled water and are kept hot and stored in clean containers.
- Avoid brushing teeth with unsafe water.
- Do not use ice unless it has been made from safe water.
- Avoid salads or other uncooked foods that may have been washed or prepared with unsafe water.

Water can be treated in small quantities by travellers to significantly improve its safety. Numerous simple treatment approaches and commercially available technologies are available to travellers to disinfect drinking-water for single-person or family use. Travellers should select a water treatment approach that removes or inactivates all classes of pathogens. Technologies should be certified by a credible organization, and manufacturers' instructions should be followed carefully.

Bringing water to a rolling boil is the simplest and most effective way to kill all disease-causing pathogens, even in turbid water and at high altitudes. The hot water should be allowed to cool without the addition of ice. If the water is turbid and needs to be clarified for aesthetic reasons, this should be done before boiling.

If it is not possible to boil water, chemical disinfection of clear, non-turbid water is effective for killing bacteria and most viruses and some protozoa (but not, for example, *Cryptosporidium* oocysts). Certain chlorine-based or iodine-based compounds are most widely used for disinfection of drinking-water by travellers. Following chlorination or iodination, an activated carbon (charcoal) filter may be used to remove excess taste and odour from the water. The use of iodine is not recommended for long-term use by infants, pregnant women, those with a history of thyroid disease and those with known hypersensitivity to iodine unless treatment includes an effective post-disinfection iodine removal device (e.g. activated carbon). Travellers intending to use iodine treatment daily for all water consumed for more than 3–4 weeks should consult a physician beforehand and not use it in excessive amounts. Silver is sometimes promoted as a disinfectant, but it is not recommended, as its efficacy is uncertain and it requires lengthy contact periods.

Suspended particles in water can reduce the effectiveness of disinfectants, and turbid water should be clarified or filtered before disinfection. Chemical products that

combine clarification (coagulation and flocculation to remove particles) with chlorine disinfection are available.

Portable point-of-use filtration devices tested and rated to remove protozoa and some bacteria, such as ceramic, membrane (mainly reverse osmosis) and activated carbon block filters, are also available. A pore size rating of 1 μm or less is recommended to ensure the removal of *Cryptosporidium* oocysts. These filters may require a pre-filter to remove suspended particles in order to avoid clogging the final filter.

Unless water is boiled, a combination of techniques (e.g. clarification and/or filtration followed by chemical disinfection) is recommended. This combination provides a multiple treatment barrier that removes significant numbers of protozoa in addition to killing bacteria and viruses.

For people with weakened immune systems, pregnant women and infants, extra precautions are recommended to reduce the risk of infection from water contaminated with *Cryptosporidium*, for example. Boiling and storing water in a protected container are recommended, although internationally or nationally certified bottled or mineral water may also be acceptable.

The treatment methods described here, with the exception of carbon filtration and reverse osmosis, will generally not reduce levels of most chemical contaminants in drinking-water. However, these are not usually of health concern in the short term.

Further information on household water treatment of microbial and chemical contaminants of water can be found in sections 7.3.2 and 8.4.4, respectively. Table 6.1 provides a summary of drinking-water disinfection methods that can be used by travellers.

6.12 Aircraft and airports

The importance of water as a potential vehicle for infectious disease transmission on aircraft has been well documented. In general terms, the greatest microbial risks are those associated with ingestion of water that is contaminated with human and animal excreta. If the source of water used to replenish aircraft supplies is contaminated and adequate precautions are not taken, disease can be spread through the aircraft water if it used for drinking or tooth cleaning. It is thus imperative that airports comply with the International Health Regulations (2005) and be provided with potable drinking-water from a source approved by the appropriate regulatory agency (WHO, 2005a). Airports usually have special arrangements for managing water after it has entered the airport.

A potable water source is not a safeguard if the water is subsequently contaminated during transfer, storage or distribution in aircraft. A WSP covering water management within airports from receipt of the water through to its transfer to the aircraft (e.g. by water servicing vehicles or water bowsers), complemented by measures to ensure that water quality is maintained on the aircraft (e.g. safe materials and good practices in design, construction, operation and maintenance of aircraft systems), provides a framework for water safety in aviation.

In undertaking an assessment of the general airport/aircraft water distribution system, a range of specific issues must be taken into consideration, including:

Table 6.1 Drinking-water disinfection methods for use by travellers

Method	Recommendation	What it does	What it does *not* do
Boiling	Bring water to a rolling boil and allow to cool	Kills all pathogens	Does not remove turbidity/cloudiness Does not provide residual chemical disinfectant, such as chlorine, to protect against contamination
Chlorine compounds: 1. Unscented household bleach (sodium hypochlorite) 2. Sodium dichloroisocyanurate tablet 3. Calcium hypochlorite	For typical room temperature and water temperature of 25 °C, minimum contact time should be 30 min; increase contact time for colder water—e.g. double time for each 10 °C less than 25 °C Prepare according to instructions Should be added to clear water or after settling or clarification to be most effective Type and typical dosage: 1. Household bleach (5%)—4 drops per litre 2. Sodium dichloroisocyanurate—1 tablet (per package directions) 3. Calcium hypochlorite (1% stock solution)[a]—4 drops per litre	Effective for killing most bacteria and viruses Longer contact time required to kill *Giardia* cysts, especially when water is cold	Not effective against *Cryptosporidium*; not as effective as iodine when using turbid water
Flocculant-chlorine tablet or sachet	Dose per package directions	Effective for killing or removing most waterborne pathogens (coagulant-flocculants partially remove *Cryptosporidium*)	Flocculated water must be decanted into a clean container, preferably through a clean fabric filter

Table 6.1 (continued)

Method	Recommendation	What it does	What it does *not* do
Iodine: 1. Tincture of iodine (2% solution) 2. Iodine (10% solution) 3. Iodine tablet 4. Iodinated (triiodide or pentaiodide) resin	25 °C—minimum contact for 30 min; increase contact time for colder water Prepare according to package instructions Type and typical dosage: 1. Tincture of iodine (2% solution)—5 drops per litre 2. Iodine (10% solution)—8 drops per litre 3. Iodine tablet—1 or 2 tablets per litre 4. Iodinated (triiodide or pentaiodide) resin—room temperature according to directions and stay within rated capacity *Caution*: Not recommended for pregnant women, for people with thyroid problems or for more than a few months' time. Excess iodine may be removed after iodine treatment through use of a carbon filter or other effective process.	Kills most pathogens Longer contact time is required to kill *Giardia* cysts, especially when water is cold Carbon filtration after an iodine resin will remove excess iodine from the water; replace the carbon filter regularly	Not effective against *Cryptosporidium*
Portable filtering devices: 1. Ceramic filters 2. Carbon filters; some carbon block filters will remove *Cryptosporidium*—only if tested and certified for oocyst removal 3. Membrane filter (microfilter, ultrafilter, nanofilter and reverse osmosis) type devices	Check pore size rating and reported removal efficiencies for different pathogens (viruses, bacteria and protozoa) provided by manufacturer and certified by a national or international certification agency. Filter media pore size must be rated at 1 µm (absolute) or less. Note that water must be clear to prevent clogging of pores. Filtration or settling of turbid water to clarify it is recommended before disinfection with chlorine or iodine if water is not boiled	1 µm or less filter pore size will remove *Giardia*, *Cryptosporidium* and other protozoa Approved reverse osmosis device can remove almost all pathogens Some filters include a chemical disinfectant such as iodine or chlorine to kill microbes; check for manufacturer's claim and documentation from an independent national or international certification agency	Most bacteria and viruses will not be removed by filters with a pore size larger than 1 µm Microfilters may not remove viruses, especially from clear waters; additional treatment such as chemical disinfection or boiling/pasteurization may be needed to reduce viruses Most carbon block filters do not remove pathogens, other than possibly protozoa, even if carbon is impregnated with silver, because pore size is too large (> 1 µm)

[a] To make a 1% stock solution of calcium hypochlorite, add (to 1 litre of water) 28 g if chlorine content is 35%, 15.4 g if chlorine content is 65% or 14.3 g if chlorine content is 70%.

- quality of source water and the need for additional treatment;
- design and construction of airport storage tanks and pipes;
- design and construction of water servicing vehicles;
- use of materials and fittings approved for contact with drinking-water at all stages;
- water loading techniques;
- any treatment systems on aircraft (e.g. ultraviolet disinfection);
- maintenance of on-board plumbing;
- prevention of cross-connections, including backflow prevention.

The airport authority has responsibility for safe drinking-water supply, including operational monitoring, until water is transferred to the aircraft operator. The primary emphasis of monitoring is to ensure that management processes are operating efficiently—for example, the source water quality is not compromised; all parts of the system, including hydrants, hoses and bowsers, are clean and in good repair; backflow prevention is in place; and any filters are clean. In addition, the system should be disinfected and flushed after maintenance or repairs, and the microbiological quality of the water should be checked, preferably before the system is returned to service.

Transfer of water into the aircraft and the aircraft drinking-water system also has the potential to introduce hazards, even if the water is of good quality up to this point. It is therefore important that staff involved be properly trained and understand the reasons for the precautions to be taken and the care required in preventing contamination. The precautions described in previous sections regarding transfer of drinking-water from a piped supply or from bowsers and tankers are essential, including maintaining the cleanliness of vehicles and transfer points. There is a significant potential for aviation fuel to contaminate the system, and only small quantities of low molecular weight hydrocarbons can cause the water to be unacceptable. In addition, staff employed in drinking-water supply must not be engaged in activities related to aircraft toilet servicing without first taking all necessary precautions (e.g. thorough hand washing, change of outer garments). All of these requirements and procedures should be properly documented as part of the WSP for the airport water transfer system and should be made clear to airlines using the airport to ensure that they play their part as key stakeholders.

Independent surveillance is an important part of the WSP, because circumstances and equipment or staff may change, and the weakening of barriers or the introduction of new risks may not be noticed. This would include initial review and approval of the WSP, periodic review and direct assessment of the provisions and operation of the WSP, paying specific attention to the aircraft industry's codes of practice, the supporting document *Guide to hygiene and sanitation in aviation* (Annex 1) and airport health or airline regulations. It is also important that the response to any incident is recorded and reviewed and any lessons learnt incorporated into the WSP.

6.13 Ships

The importance of water as a vehicle for infectious disease transmission on ships has been clearly documented. In general terms, the greatest microbial risks are associated with ingestion of water that is contaminated with human and animal excreta. However,

chemical contamination could also occur on ships as a result of contaminated bulk water being brought aboard in port, cross-connections on board or improper on-board treatment. The supporting document *Guide to ship sanitation* (Annex 1) describes the factors that can be encountered during water treatment, transfer, production, storage or distribution in ships and specific features of the organization of the supply and the regulatory framework. To this end, it is vital that all staff responsible for working with the potable water system are properly trained.

The organization of water supply systems covering shore facilities and ships differs considerably from conventional water transfer on land but is similar to that for airports. The port authority has responsibility for providing safe potable water for loading onto vessels. If water is suspected to have come from an unsafe source, the ship's master may have to decide if any additional treatment (e.g. hyperchlorination or filtration) is necessary. When treatment on board or prior to boarding is necessary, the treatment selected should be that which is best suited to the water and which is most easily operated and maintained by the ship's officers and crew.

Water is delivered to ships by hoses or transferred to the ship via water boats or barges. The transfer from shore to ship is a potential source of microbial or chemical contamination. In addition to shore-to-ship transfer of water and bulk storage on board ship, many ships use desalination (see section 6.4) to produce their own drinking-water.

In contrast to a shore facility, plumbing aboard ships consists of numerous piping systems carrying potable water, seawater, sewage and fuel and fitted into a relatively confined space. Piping systems are normally extensive and complex, making them difficult to inspect, repair and maintain. A number of waterborne outbreaks on ships have been caused by contamination of potable water after it had been loaded onto the ship—for example, by sewage or bilge water when the water storage systems were not adequately designed and constructed. Potable water should be stored in one or more tanks that are constructed, located and protected so as to be safe against contamination. Potable water lines should be protected and located so that they will not be submerged in bilge water or pass through tanks storing non-potable liquids. It is important to design the system to prevent deterioration of water quality during distribution by minimizing stagnation and dead ends and to take into account ship movement, which increases the possibility of surge and backflow.

An overall assessment of the operation of the ship's water supply should be made, for which the final responsibility lies with the ship's master, who must ensure that all of the management processes in place are functioning efficiently. An important part of this process is ensuring that those crew who are responsible for the fresh drinking-water supply are properly trained and receive refresher training as appropriate. In developing a WSP and ensuring that the system is capable of supplying safe water, the following need to be considered:

- quality of source water if this is from a shore-based source along with the equipment and method of transfer from shore to ship;
- desalination equipment and processes where these are used, taking into consideration the points raised in section 6.5;

- design and construction of storage tanks and pipework, including the use of approved materials and chemicals and clear colour coding of pipes for different purposes;
- minimization of dead ends and areas of stagnation, which may be managed by periodic flushing;
- filtration systems and other treatment systems on board the ship, including disinfection and delivery of residual disinfection;
- prevention of cross-connections and presence of working backflow prevention devices;
- maintenance of adequate water pressure within the system;
- presence of a disinfectant residual throughout the system.

The system needs to be checked regularly for cleanliness and repair, and parameters such as pH and disinfectant residual need to be checked daily. Where possible, checks on microbiological quality such as plate counts and faecal coliforms, even if only in port, help to ensure that the supply continues to deliver safe water. There also need to be suitable procedures in place to ensure safety after maintenance or repair, including specific disinfection of the system or the affected zone. Any indication of a problem, such as illness or taste or odour problems, should be immediately investigated and the system corrected if it is shown to be the source. In confined communities such as on ships, person-to-person spread of infectious disease is a major issue. Someone who has been working on the latrines and sanitation system on ships should not transfer to work on the drinking-water system without thorough hand washing and a change of outer clothing.

Independent surveillance is a desirable element in ensuring drinking-water safety on ships. This implies that there will be periodic audit and direct assessment and the review and approval of the WSP. Specific attention should be given to the shipping industry's codes of practice, the supporting document *Guide to ship sanitation* (Annex 1) and port health and shipping regulations. Independent surveillance should also include ensuring that any specific incidents that affect or might have affected water quality have been properly investigated and the lessons to be learnt are incorporated in the WSP.

6.14 Packaged drinking-water

Bottled water and water in containers are widely available in both industrialized and developing countries. Consumers purchase packaged drinking-water for reasons such as taste, convenience or fashion, but safety and potential health benefits are also important considerations.

Water is packaged for consumption in a range of vessels, including cans, laminated boxes and plastic bags, but it is most commonly supplied in glass or plastic bottles. Bottled water also comes in various sizes, from single servings to large carbuoys holding up to 80 litres. Control of the quality of materials, containers and closures for bottled water is of special concern. Ozone is sometimes used for final disinfection prior to bottling because it does not impart a taste to the water. If the water contains naturally occurring bromide, this can lead to the formation of bromate unless care is taken to minimize its formation.

The Guidelines provide a basis for derivation of standards for all packaged waters. As with other sources of drinking-water, safety is pursued through a combination of safety management and end product quality standards and testing and is more readily achievable because batches can be held until results are available. The international framework for packaged water regulation is provided by the Codex Alimentarius Commission of the World Health Organization and the Food and Agriculture Organization of the United Nations.

The Codex Alimentarius Commission has developed a *Standard for natural mineral waters*—which describes the product and its compositional and quality factors, including prescribed treatments, limits for certain chemicals, hygiene, packaging and labelling—and an associated Code of Practice. It has also developed a *Standard for bottled/packaged waters* to cover packaged drinking-water other than natural mineral waters. Both relevant Codex standards refer directly to these Guidelines; the Codex standards for bottled/packaged water are directly equivalent to the guideline values established in these Guidelines. Under the Codex *Standard for natural mineral waters* and associated Code of Practice, natural mineral waters must conform to strict requirements, including collection and bottling without further treatment from a natural source, such as a spring or well. In comparison, the Codex *Standard for bottled/packaged waters includes waters* from other sources, in addition to springs and wells, and treatment to improve their safety and quality. The distinctions between these standards are especially relevant in regions where natural mineral waters have a long cultural history. For further information on the Codex *Standard for natural mineral waters* and its companion Code of Practice and the Codex *Standard for bottled/packaged waters*, readers are referred to the Codex web site (http://www.codexalimentarius.net/).

The Codex Alimentarius Commission's *Code of practice for collecting, processing and marketing of natural mineral waters* provides guidance on a range of good manufacturing practices and provides a generic WSP applied to packaged drinking-water.

Some consumers believe that certain natural mineral waters have medicinal properties or offer other health benefits. Some such waters have higher mineral content, sometimes significantly higher than concentrations normally accepted in drinking-water. They often have a long tradition of use and are often accepted on the basis that they are considered foods rather than drinking-water per se. Although certain mineral waters may be useful in providing essential micronutrients, such as calcium and magnesium, these Guidelines do not make recommendations regarding minimum concentrations of essential elements because of the uncertainties surrounding mineral nutrition from drinking-water. Packaged waters with very low mineral content, such as distilled or demineralized waters, are also consumed. There is insufficient scientific information on the benefits or hazards of long-term consumption of very low mineral waters to allow any recommendations to be made (WHO, 2005b; see also the supporting document *Calcium and magnesium in drinking-water*; Annex 1).

Another form of packaged water is ice that is intended for adding to drinks and which may come into contact with food to be eaten without cooking. Ice prepared and sold in this manner should be treated the same as any packaged water for potable use.

6.15 Food production and processing

The quality of water defined by the Guidelines is such that it is suitable for all normal uses in the food industry. Some processes have special water quality requirements in order to secure the desired characteristics of the product, and the Guidelines do not necessarily guarantee that such special requirements are met.

Poor quality drinking-water may have a severe impact in food processing and potentially on public health. The consequences of a failure to use water of suitable quality in food processing will depend on the use of the water and the subsequent processing of potentially contaminated materials. Variations in water quality that may be tolerated occasionally in drinking-water supply may be unacceptable for some uses in the food industry. These variations may result in a significant financial impact on food production—for example, through product recalls.

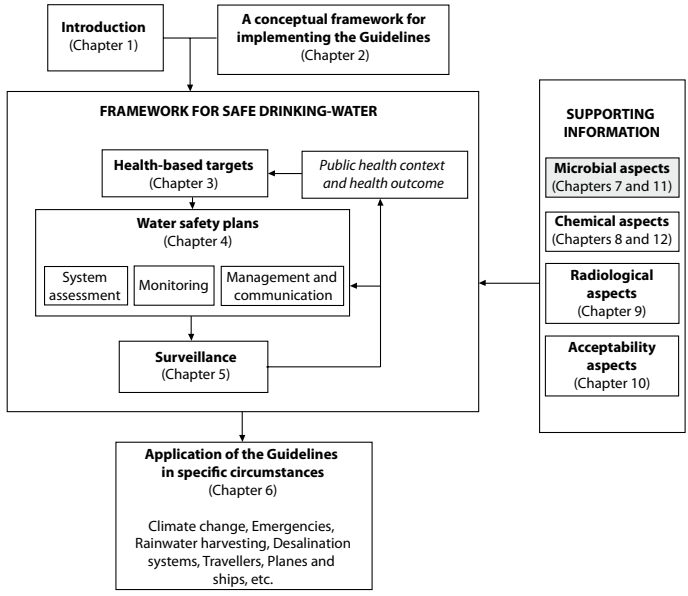
The diverse uses of water in food production and processing have different water quality requirements. Uses include irrigation and livestock watering; as an ingredient or where used in washing or "refreshing" of foods, such as misting of salad vegetables in grocery stores; and those in which contact between the water and foodstuff should be minimal (as in heating or cooling and cleaning water).

To reduce microbial contamination, specific treatments (e.g. heat) capable of removing a range of pathogenic organisms of public health concern may be used in food processing. The effect of these treatments should be taken into account when assessing the impacts of deterioration in drinking-water quality on a food production or processing facility. For example, water that is used in canning will usually be heated to a temperature that is at least equivalent to pasteurization.

Information on deterioration of the microbial or chemical quality of a drinking-water supply should be promptly communicated to food and beverage production facilities.

For further information on disinfection of water for use in food production and processing, see FAO/WHO (2009).

7
Microbial aspects



The greatest risk to public health from microbes in water is associated with consumption of drinking-water that is contaminated with human and animal excreta, although other sources and routes of exposure may also be significant.

Waterborne outbreaks have been associated with inadequate treatment of water supplies and unsatisfactory management of drinking-water distribution. For example, in distribution systems, such outbreaks have been linked to cross-connections, contamination during storage, low water pressure and intermittent supply. Waterborne outbreaks are preventable if an integrated risk management framework based on a multiple-barrier approach from catchment to consumer is applied. Implementing an integrated risk management framework to keep the water safe from contamination in distribution systems includes the protection of water sources, the proper selection and operation of drinking-water treatment processes, and the correct management of risks within the distribution systems (for further information, see the supporting document *Water safety in distribution systems*; Annex 1).

This chapter focuses on organisms for which there is evidence, from outbreak studies or from prospective studies in non-outbreak situations, of diseases being caused by ingestion of drinking-water, inhalation of water droplets or dermal contact

with drinking-water and their prevention and control. For the purpose of the Guidelines, these routes are considered waterborne.

Chapter 11 (Microbial fact sheets) provides additional detailed information on individual waterborne pathogens, as well as on indicator microorganisms.

7.1 Microbial hazards associated with drinking-water

Infectious diseases caused by pathogenic bacteria, viruses and parasites (e.g. protozoa and helminths) are the most common and widespread health risk associated with drinking-water. The public health burden is determined by the severity and incidence of the illnesses associated with pathogens, their infectivity and the population exposed. In vulnerable subpopulations, disease outcome may be more severe.

Breakdown in water supply safety (source, treatment and distribution) may lead to large-scale contamination and potentially to detectable disease outbreaks. In some cases, low-level, potentially repeated contamination may lead to significant sporadic disease, but public health surveillance is unlikely to identify contaminated drinking-water as the source.

Infectious diseases caused by pathogenic bacteria, viruses, protozoa and helminths are the most common and widespread health risk associated with drinking-water.

Waterborne pathogens have several properties that distinguish them from other drinking-water contaminants:

- Pathogens can cause acute and also chronic health effects.
- Some pathogens can grow in the environment.
- Pathogens are discrete.
- Pathogens are often aggregated or adherent to suspended solids in water, and pathogen concentrations vary in time, so that the likelihood of acquiring an infective dose cannot be predicted from their average concentration in water.
- Exposure to a pathogen resulting in disease depends upon the dose, invasiveness and virulence of the pathogen, as well as the immune status of the individual.
- If infection is established, pathogens multiply in their host.
- Certain waterborne pathogens are also able to multiply in food, beverages or warm water systems, perpetuating or even increasing the likelihood of infection.
- Unlike many chemical agents, pathogens do not exhibit a cumulative effect.

Quantitative microbial risk assessment (QMRA), a mathematical framework for evaluating infectious risks from human pathogens, can assist in understanding and managing waterborne microbial hazards, especially those associated with sporadic disease.

7.1.1 Waterborne infections

The pathogens that may be transmitted through contaminated drinking-water are diverse in characteristics, behaviour and resistance. Table 7.1 provides general information on pathogens that are of relevance for drinking-water supply management. Waterborne transmission of the pathogens listed has been confirmed by epidemiological studies and case histories. Part of the demonstration of pathogenicity involves reproducing the disease in suitable hosts. Experimental studies in which healthy adult volunteers are exposed to known numbers of pathogens provide information, but these data are applicable to only a part of the exposed population; extrapolation to more vulnerable subpopulations is an issue that remains to be studied in more detail. Table 7.2 provides information on organisms that have been suggested as possible causes of waterborne disease but where evidence is inconclusive or lacking. The spectrum of pathogens may change as a result of host, pathogen and environmental changes such as fluctuations in human and animal populations, reuse of wastewater, changes in lifestyles and medical interventions, population movement and travel, selective pressures for new pathogens and mutants or recombinations of existing pathogens. The immunity of individuals also varies considerably, whether acquired

Table 7.1 Pathogens transmitted through drinking-water[a]

Pathogen	Type species/ genus/group[b]	Health significance[c]	Persistence in water supplies[d]	Resistance to chlorine[e]	Relative infectivity[f]	Important animal source
Bacteria						
Burkholderia	*B. pseudomallei*	High	May multiply	Low	Low	No
Campylobacter	*C. coli* *C. jejuni*	High	Moderate	Low	Moderate	Yes
Escherichia coli – Diarrhoeagenic[g]		High	Moderate	Low	Low	Yes
E. coli – Enterohaemorrhagic	*E. coli* O157	High	Moderate	Low	High	Yes
Francisella	*F. tularensis*	High	Long	Moderate	High	Yes
Legionella	*L. pneumophila*	High	May multiply	Low	Moderate	No
Mycobacteria (non-tuberculous)	*Mycobacterium avium* complex	Low	May multiply	High	Low	No
Salmonella typhi		High	Moderate	Low	Low	No
Other salmonellae	*S. enterica* *S. bongori*	High	May multiply	Low	Low	Yes
Shigella	*S. dysenteriae*	High	Short	Low	High	No
Vibrio	*V. cholerae* O1 and O139	High	Short to long[h]	Low	Low	No
Viruses						
Adenoviridae	Adenoviruses	Moderate	Long	Moderate	High	No
Astroviridae	Astroviruses	Moderate	Long	Moderate	High	No
Caliciviridae	Noroviruses, Sapoviruses	High	Long	Moderate	High	Potentially
Hepeviridae	Hepatitis E virus	High	Long	Moderate	High	Potentially
Picornaviridae	Enteroviruses, Parechoviruses, Hepatitis A virus	High	Long	Moderate	High	No
Reoviridae	Rotaviruses	High	Long	Moderate	High	No

Table 7.1 (continued)

Pathogen	Type species/ genus/group[b]	Health significance[c]	Persistence in water supplies[d]	Resistance to chlorine[e]	Relative infectivity[f]	Important animal source
Protozoa						
Acanthamoeba	*A. culbertsoni*	High	May multiply	High	High	No
Cryptosporidium	*C. hominis/parvum*	High	Long	High	High	Yes
Cyclospora	*C. cayetanensis*	High	Long	High	High	No
Entamoeba	*E. histolytica*	High	Moderate	High	High	No
Giardia	*G. intestinalis*	High	Moderate	High	High	Yes
Naegleria	*N. fowleri*	High	May multiply	Low	Moderate	No
Helminths						
Dracunculus	*D. medinensis*	High	Moderate	Moderate	High	No

[a] This table contains pathogens for which there is some evidence of health significance related to their occurrence in drinking-water supplies. More information on these and other pathogens is presented in chapter 11.

[b] The type species listed (e.g. *L. pneumophila*) are those most commonly linked to waterborne transmission but other species may also cause disease.

[c] Health significance relates to the incidence and severity of disease, including association with outbreaks.

[d] Detection period for infective stage in water at 20 °C: short, up to 1 week; moderate, 1 week to 1 month; long, over 1 month.

[e] Within pathogen species and groups, there are likely to be variations in resistance, which could be further impacted by characteristics of the water supply and operating conditions. Resistance is based on 99% inactivation at 20 °C where, generally, low represents a Ct_{99} of < 1 min.mg/L, moderate 1–30 min.mg/L and high > 30 min.mg/L (where C = the concentration of free chlorine in mg/L and t = contact time in minutes) under the following conditions: the infective stage is freely suspended in water treated at conventional doses and contact times, and the pH is between 7 and 8. It should be noted that organisms that survive and grow in biofilms, such as *Legionella* and mycobacteria, will be protected from chlorination.

[f] From experiments with human volunteers, from epidemiological evidence and from experimental animal studies. High means infective doses can be 1–10^2 organisms or particles, moderate 10^2–10^4 and low > 10^4.

[g] Includes enteropathogenic, enterotoxigenic, enteroinvasive, diffusely adherent and enteroaggregative.

[h] *Vibrio cholerae* may persist for long periods in association with copepods and other aquatic organisms.

by contact with a pathogen or influenced by such factors as age, sex, state of health and living conditions.

For pathogens transmitted by the faecal–oral route, drinking-water is only one vehicle of transmission. Contamination of food, hands, utensils and clothing can also play a role, particularly when domestic sanitation and hygiene are poor. Improvements in the quality and availability of water, excreta disposal and general hygiene are all important in reducing faecal–oral disease transmission.

Microbial drinking-water safety is not related only to faecal contamination. Some organisms grow in piped water distribution systems (e.g. *Legionella*), whereas others occur in source waters (e.g. guinea worm [*Dracunculus medinensis*]) and may cause outbreaks and individual cases. Some other microbes (e.g. toxic cyanobacteria) require specific management approaches, which are covered elsewhere in these Guidelines (see section 11.5).

Although consumption of contaminated drinking-water represents the greatest risk, other routes of transmission can also lead to disease, with some pathogens transmitted by multiple routes (e.g. adenovirus) (Figure 7.1). Certain serious illnesses result from inhalation of water droplets (aerosols) in which the causative organisms have multiplied because of warm waters and the presence of nutrients. These include legionellosis, caused by *Legionella* spp., and illnesses caused by the amoebae *Naegleria fowleri* (primary amoebic meningoencephalitis) and *Acanthamoeba* spp. (amoebic meningitis, pulmonary infections).

Schistosomiasis (bilharziasis) is a major parasitic disease of tropical and subtropical regions that is transmitted when the larval stage (cercariae), which is released by infected aquatic snails, penetrates the skin. It is primarily spread by contact with water. Ready availability of safe drinking-water contributes to disease prevention by reducing the need for contact with contaminated water resources—for example, when collecting water to carry to the home or when using water for bathing or laundry.

It is conceivable that unsafe drinking-water contaminated with soil or faeces could act as a carrier of other infectious parasites, such as *Balantidium coli* (balantidiasis) and certain helminths (species of *Fasciola*, *Fasciolopsis*, *Echinococcus*, *Spirometra*, *Ascaris*, *Trichuris*, *Toxocara*, *Necator*, *Ancylostoma*, *Strongyloides* and *Taenia solium*). However, in most of these, the normal mode of transmission is ingestion of the eggs in food contaminated with faeces or faecally contaminated soil (in the case of *Taenia solium*, ingestion of the larval cysticercus stage in uncooked pork) rather than ingestion of contaminated drinking-water.

Other pathogens that may be naturally present in the environment may be able to cause disease in vulnerable subpopulations: the elderly or the very young, patients with burns or extensive wounds, those undergoing immunosuppressive therapy or those with acquired immunodeficiency syndrome (AIDS). If water used by such persons for drinking or bathing contains sufficient numbers of these organisms, they can produce various infections of the skin and the mucous membranes of the eye, ear, nose and throat. Examples of such agents are *Pseudomonas aeruginosa* and species of *Flavobacterium*, *Acinetobacter*, *Klebsiella*, *Serratia*, *Aeromonas* and certain "slow-growing" (non-tuberculous) mycobacteria (see the supporting document *Pathogenic*

Table 7.2 Microorganisms for which transmission through drinking-water has been proposed but for which evidence is inconclusive or lacking[a]

Microorganism	Type species/ genus/group[b]	Waterborne transmission evidence (or epidemiological features)	Presence and behaviour in water supplies	Resistance to chlorine[c]
Bacteria				
Acinetobacter	*A. calcoaceticus baumannii complex*	Possible issue in health-care facilities (non-gastrointestinal)	Common and can multiply	Low
Aeromonas	*A. hydrophila*	Clinical isolates do not match environmental isolates	Common and can multiply	Low
Enterobacter	*E. sakazakii*	Infection associated with infant formula; no evidence of waterborne transmission	Unlikely	Low
Helicobacter	*H. pylori*	Suggested, but no direct evidence; familial transmission primary route	Detected, survives for limited time	Low
Klebsiella	*K. pneumoniae*	Possible issue in health-care facilities (non-gastrointestinal)	Can multiply	Low
Leptospira	*L. interrogans*	No evidence of transmission through drinking-water ingestion. Primarily spread by contact with contaminated surface water; outbreaks associated with flooding	Can survive for months in water	Low
Pseudomonas	*P. aeruginosa*	Possible issue in health-care facilities (non-gastrointestinal)	Common and can multiply	Moderate
Staphylococcus	*S. aureus*	No evidence of transmission through drinking-water; hands are the most important source	Common and can multiply	Moderate
Tsukamurella	*T. paurometabola*	Possible issue in health-care facilities (non-gastrointestinal)	Common and can multiply	Unknown
Yersinia	*Y. enterocolitica*	Species detected in water probably non-pathogenic; food is the primary source	Common and can multiply	Low

Table 7.2 (continued)

Microorganism	Type species/ genus/group[b]	Waterborne transmission evidence (or epidemiological features)	Presence and behaviour in water supplies	Resistance to chlorine[c]
Viruses				
Filoviridae	Ebola virus	No evidence of transmission through drinking-water	Unlikely	Low
Orthomyxoviridae	Influenza viruses	No evidence for waterborne transmission	Unlikely	Low
Coronaviridae	Severe acute respiratory syndrome (SARS) coronaviruses	Some evidence for transmission via inhalation of droplets	Unlikely	Unknown
Picornaviridae/ Kobuvirus	Aichivirus	Present in fecal wastes, wastewater and sometimes contaminated drinking water	Likely present in faecally contamined water	Moderate
Protozoa				
Balantidium	*B. coli*	One outbreak reported in 1971	Detected	High
Blastocystis	*B. hominis*	Plausible, but limited evidence	Unknown, persistence[d] likely	High
Isospora	*I. belli*	Plausible, but no evidence	Unknown	High
Microsporidia	–	Plausible, but limited evidence; infections predominantly in persons with acquired immunodeficiency syndrome (AIDS)	Detected, persistence likely	Moderate
Toxoplasma	*T. gondii*	One outbreak reported in 1995	Long	High

Table 7.2 (continued)

Microorganism	Type species/ genus/group[b]	Waterborne transmission evidence (or epidemiological features)	Presence and behaviour in water supplies	Resistance to chlorine[c]
Helminths				
Fasciola	*F. hepatica* *F. gigantica*	Plausible, detected in water in hyperendemic regions	Detected	High
Free-living nematodes (other than *Dracunculus medinensis*)	–	Plausible, but transmission primarily associated with food or soil	Detected and can multiply	High
Schistosoma	*S. mansoni* *S. japonicum* *S. mekongi* *S. intercalatum* *S. haematobium*	No evidence of transmission through drinking-water ingestion. Primarily spread by contact with contaminated surface water in communities with inadequate access to safe drinking-water	Life cycle involves animal and snail hosts; can be released into water following reproduction in freshwater snails	Moderate

[a] More information on these and other pathogens is presented in Chapter 11.
[b] The type species listed (e.g. *H. pylori*) are those most commonly linked to waterborne transmission but other species may also cause disease.
[c] Resistance is based on 99% inactivation at 20 °C where, generally, low represents a Ct_{99} of < 1 min.mg/L, moderate 1–30 min.mg/L and high > 30 min.mg/L (where C = the concentration of free chlorine in mg/L and t = contact time in minutes) under the following conditions: the infective stage is freely suspended in water treated at conventional doses and contact times, and the pH is between 7 and 8. It should be noted that organisms that survive and grow in biofilms, such as *Pseudomonas aeruginosa*, will be protected from chlorination.
[d] Persistence means survival for 1 month or more.

mycobacteria in water; Annex 1). A number of these organisms are listed in Table 7.2 (and described in more detail in chapter 11).

Most of the human pathogens listed in Table 7.1 (which are also described in more detail in chapter 11) are distributed worldwide; some, however, such as those causing outbreaks of cholera or guinea worm disease, are regional. Eradication of *Dracunculus medinensis* is a recognized target of the World Health Assembly (1991).

It is likely that there are pathogens not shown in Table 7.1 that are also transmitted by water. This is because the number of known pathogens for which water is a transmission route continues to increase as new or previously unrecognized pathogens continue to be discovered (WHO, 2003).

7.1.2 Emerging issues

A number of developments are subsumed under the concept of "emerging issues" in drinking-water. Global changes, such as human development, population growth and movement and climate change (see section 6.1), exert pressures on the quality and quantity of water resources that may influence waterborne disease risks. Between 1972 and 1999, 35 new agents of disease were discovered, and many more have re-emerged

after long periods of inactivity or are expanding into areas where they have not previously been reported (WHO, 2003). In 2003, a coronavirus was identified as the causative agent of severe acute respiratory syndrome, causing a multinational outbreak. Even more recently, influenza viruses originating from animal reservoirs have been transmitted to humans on several occasions, causing flu pandemics and seasonal epidemic influenza episodes (see the supporting document *Review of latest available evidence on potential transmission of avian influenza (H5N1) through water and sewage and ways to reduce the risks to human health*; Annex 1). Zoonotic pathogens make up 75% of the emerging pathogens and are of increasing concern for human health, along with pathogens with strictly human-to-human transmission. Zoonotic pathogens pose the greatest challenges to ensuring the safety of drinking-water and ambient water, now and in the future (see the supporting document Waterborne zoonoses; Annex 1). For each emerging pathogen, whether zoonotic or not, it should be considered whether it

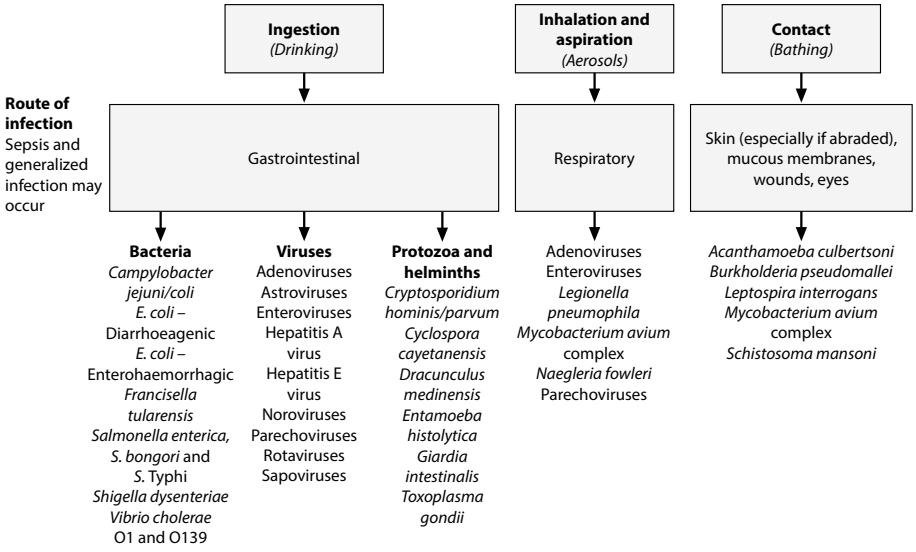


Figure 7.1 Transmission pathways for and examples of water-related pathogens

can be transmitted through water and, if so, which prevention and control measures can be suggested to minimize this risk.

7.1.3 Persistence and growth in water

Waterborne pathogens, such as *Legionella*, may grow in water, whereas other host-dependent waterborne pathogens, such as noroviruses and *Cryptosporidium*, cannot grow in water, but are able to persist.

Host-dependent waterborne pathogens, after leaving the body of their host, gradually lose viability and the ability to infect. The rate of decay is usually exponential, and a pathogen will become undetectable after a certain period. Pathogens with low persistence must rapidly find new hosts and are more likely to be spread by person-to-person contact or poor personal hygiene than by drinking-water. Persistence is affected by several factors, of which temperature is the most important. Decay is usually faster at higher temperatures and may be mediated by the lethal effects of ultraviolet (UV) radiation in sunlight acting near the water surface.

Relatively high amounts of biodegradable organic carbon, together with warm waters and low residual concentrations of chlorine, can permit growth of *Legionella*, *Vibrio cholerae*, *Naegleria fowleri*, *Acanthamoeba* and nuisance organisms in some surface waters and during water distribution (see also the supporting documents *Heterotrophic plate counts and drinking-water safety and Legionella and the prevention of legionellosis*; Annex 1).

Microbial water quality may vary rapidly and widely. Short-term peaks in pathogen concentration may increase disease risks considerably and may also trigger outbreaks of waterborne disease. Microorganisms can accumulate in sediments and are mobilized when water flow increases. Results of water quality testing for microbes are not normally available in time to inform management action and prevent the supply of unsafe water.

7.1.4 Public health aspects

Outbreaks of waterborne disease may affect large numbers of persons, and the first priority in developing and applying controls on drinking-water quality should be the control of such outbreaks. Available evidence also suggests that drinking-water can contribute to background rates of disease in non-outbreak situations, and control of drinking-water quality should therefore also address waterborne disease in the general community.

Experience has shown that systems for the detection of waterborne disease outbreaks are typically inefficient in countries at all levels of socioeconomic development, and failure to detect outbreaks is not a guarantee that they do not occur; nor does it suggest that drinking-water should necessarily be considered safe.

Some of the pathogens that are known to be transmitted through contaminated drinking-water lead to severe and sometimes life-threatening disease. Examples include typhoid, cholera, infectious hepatitis (caused by hepatitis A virus or hepatitis E virus) and disease caused by *Shigella* spp. and *E. coli* O157. Others are typically associated with less severe outcomes, such as self-limiting diarrhoeal disease (e.g. noroviruses, *Cryptosporidium*).

The effects of exposure to pathogens are not the same for all individuals or, as a consequence, for all populations. Repeated exposure to a pathogen may be associated with a lower probability or severity of illness because of the effects of acquired immunity. For some pathogens (e.g. hepatitis A virus), immunity is lifelong, whereas for others (e.g. *Campylobacter*), the protective effects may be restricted to a few months to years. In contrast, vulnerable subpopulations (e.g. the young, the elderly, pregnant women, the immunocompromised) may have a greater probability of illness or the illness may be more severe, including mortality. Not all pathogens have greater effects in all vulnerable subpopulations.

Not all infected individuals will develop symptomatic disease. The proportion of the infected population that is asymptomatic (including carriers) differs between pathogens and also depends on population characteristics, such as prevalence of immunity. Those with asymptomatic infections as well as patients during and after illness may all contribute to secondary spread of pathogens.

7.2 Health-based target setting

7.2.1 Health-based targets applied to microbial hazards

General approaches to health-based target setting are described in section 2.1 and chapter 3.

Sources of information on health risks may be from both epidemiology and QMRA, and typically both are employed as complementary sources. Development of health-based targets for many pathogens may be constrained by limitations in the data. Additional data, derived from both epidemiology and QMRA, are becoming progressively more available. Locally generated data will always be of great value in setting national targets.

Health-based targets may be set using a direct health outcome approach, where the waterborne disease burden is believed to be sufficiently high to allow measurement

of the impact of interventions—that is, epidemiological measurement of reductions in disease that can be attributed to improvements in drinking-water quality.

Interpreting and applying information from analytical epidemiological studies to derive health-based targets for application at a national or local level require consideration of a number of factors, including the following questions:

- Are specific estimates of disease reduction or indicative ranges of expected reductions to be provided?
- How representative of the target population was the study sample in order to assure confidence in the reliability of the results across a wider group?
- To what extent will minor differences in demographic or socioeconomic conditions affect expected outcomes?

More commonly, QMRA is used as the basis for setting microbial health-based targets, particularly where the fraction of disease that can be attributed to drinking-water is low or difficult to measure directly through public health surveillance or analytical epidemiological studies.

For the control of microbial hazards, the most frequent form of health-based target applied is performance targets (see section 3.3.3), which are anchored to a predetermined tolerable burden of disease and established by applying QMRA taking into account raw water quality. Water quality targets (see section 3.3.2) are typically not developed for pathogens; monitoring finished water for pathogens is not considered a feasible or cost-effective option because pathogen concentrations equivalent to tolerable levels of risk are typically less than 1 organism per 10^4–10^5 litres.

7.2.2 Reference pathogens

It is not practical, and there are insufficient data, to set performance targets for all potentially waterborne pathogens, including bacteria, viruses, protozoa and helminths. A more practical approach is to identify reference pathogens that represent groups of pathogens, taking into account variations in characteristics, behaviours and susceptibilities of each group to different treatment processes. Typically, different reference pathogens will be identified to represent bacteria, viruses, protozoa and helminths.

Selection criteria for reference pathogens include all of the following elements:

- waterborne transmission established as a route of infection;
- sufficient data available to enable a QMRA to be performed, including data on dose–response relationships in humans and disease burden;
- occurrence in source waters;
- persistence in the environment;
- sensitivity to removal or inactivation by treatment processes;
- infectivity, incidence and severity of disease.

Some of the criteria, such as environmental persistence and sensitivity to treatment processes, relate to the specific characteristics of the reference pathogens. Other criteria can be subject to local circumstances and conditions. These can include waterborne disease

burden, which can be influenced by the prevalence of the organism from other sources, levels of immunity and nutrition (e.g. rotavirus infections have different outcomes in high- and low-income regions); and occurrence of the organism in source waters (e.g. presence of toxigenic *Vibrio cholerae* and *Entamoeba histolytica* is more common in defined geographical regions, whereas *Naegleria fowleri* is associated with warmer waters).

Selection of reference pathogens

The selection of reference pathogens may vary between different countries and regions and should take account of local conditions, including incidence and severity of waterborne disease and source water characteristics (see section 7.3.1). Evidence of disease prevalence and significance should be used in selecting reference pathogens. However, the range of potential reference pathogens is limited by data availability, particularly in regard to human dose–response models for QMRA.

Decision-making regarding selection of reference pathogens should be informed by all available data sources, including infectious disease surveillance and targeted studies, outbreak investigations and registries of laboratory-confirmed clinical cases. Such data can help identify the pathogens that are likely to be the biggest contributors to the burden of waterborne disease. It is these pathogens that may be suitable choices as reference pathogens and to consider when establishing health-based targets.

Viruses

Viruses are the smallest pathogens and hence are more difficult to remove by physical processes such as filtration. Specific viruses may be less sensitive to disinfection than bacteria and parasites (e.g. adenovirus is less sensitive to UV light). Viruses can persist for long periods in water. Infective doses are typically low. Viruses typically have a limited host range, and many are species specific. Most human enteric viruses are not carried by animals, although there are some exceptions, including specific strains of hepatitis E virus (Table 7.1).

Rotaviruses, enteroviruses and noroviruses have been identified as potential reference pathogens. Rotaviruses are the most important cause of gastrointestinal infection in children and can have severe consequences, including hospitalization and death, with the latter being far more frequent in low-income regions. There is a dose–response model for rotaviruses, but there is no routine culture-based method for quantifying infectious units. Typically, rotaviruses are excreted in very large numbers by infected patients, and waters contaminated by human waste could contain high concentrations. Occasional outbreaks of waterborne disease have been recorded. In low-income countries, sources other than water are likely to dominate.

Enteroviruses, including polioviruses and the more recently recognized parechoviruses, can cause mild febrile illness, but are also important causative agents of severe diseases, such as paralysis, meningitis and encephalitis, in children. There is a dose–response model for enteroviruses, and there is a routine culture-based analysis for measuring infective particles. Enteroviruses are excreted in very large numbers by infected patients, and waters contaminated by human waste could contain high concentrations.

Noroviruses are a major cause of acute gastroenteritis in all age groups. Symptoms of illness are generally mild and rarely last longer than 3 days; however, infection does not yield lasting protective immunity. Hence, the burden of disease per case is lower than for rotaviruses. Numerous outbreaks have been attributed to drinking-water. A dose–response model has been developed to estimate infectivity for several norovirus strains, but no culture-based method is available.

Bacteria

Bacteria are generally the group of pathogens that is most sensitive to inactivation by disinfection. Some free-living pathogens, such as *Legionella* and non-tuberculous mycobacteria, can grow in water environments, but enteric bacteria typically do not grow in water and survive for shorter periods than viruses or protozoa. Many bacterial species that are infective to humans are carried by animals.

There are a number of potentially waterborne bacterial pathogens with known dose–response models, including *Vibrio*, *Campylobacter*, *E. coli* O157, *Salmonella* and *Shigella*.

Toxigenic *Vibrio cholerae* can cause watery diarrhoea. When it is left untreated, as may be the case when people are displaced by conflict and natural disaster, case fatality rates are very high. The infective dose is relatively high. Large waterborne outbreaks have been described and keep occurring.

Campylobacter is an important cause of diarrhoea worldwide. Illness can produce a wide range of symptoms, but mortality is low. Compared with other bacterial pathogens, the infective dose is relatively low and can be below 1000 organisms. It is relatively common in the environment, and waterborne outbreaks have been recorded.

Waterborne infection by *E. coli* O157 and other enterohaemorrhagic strains of *E. coli* is far less common than infection by *Campylobacter*, but the symptoms of infection are more severe, including haemolytic uraemic syndrome and death. The infective dose can be very low (fewer than 100 organisms).

Shigella causes over 2 million infections each year, including about 60 000 deaths, mainly in developing countries. The infective dose is low and can be as few as 10–100 organisms. Waterborne outbreaks have been recorded.

Although non-typhoidal *Salmonella* rarely causes waterborne outbreaks, *S. Typhi* causes large and devastating outbreaks of waterborne typhoid.

Protozoa

Protozoa are the group of pathogens that is least sensitive to inactivation by chemical disinfection. UV light irradiation is effective against *Cryptosporidium*, but *Cryptosporidium* is highly resistant to oxidizing disinfectants such as chlorine. Protozoa are of a moderate size (> 2 μm) and can be removed by physical processes. They can survive for long periods in water. They are moderately species specific. Livestock and humans can be sources of protozoa such as *Cryptosporidium* and *Balantidium*, whereas humans are the sole reservoirs of pathogenic *Cyclospora* and *Entamoeba*. Infective doses are typically low.

There are dose–response models available for *Giardia* and *Cryptosporidium*. *Giardia* infections are generally more common than *Cryptosporidium* infections, and

symptoms can be longer lasting. However, *Cryptosporidium* is smaller than *Giardia* and hence more difficult to remove by physical processes; it is also more resistant to oxidizing disinfectants, and there is some evidence that it survives longer in water environments.

7.2.3 Quantitative microbial risk assessment

QMRA systematically combines available information on exposure (i.e. the number of pathogens ingested) and dose–response models to produce estimates of the probability of infection associated with exposure to pathogens in drinking-water. Epidemiological data on frequency of asymptomatic infections, duration and severity of illness can then be used to estimate disease burdens.

QMRA can be used to determine performance targets and as the basis for assessing the effects of improved water quality on health in the population and subpopulations. Mathematical modelling can be used to estimate the effects of low doses of pathogens in drinking-water on health.

Risk assessment, including QMRA, commences with problem formulation to identify all possible hazards and their pathways from sources to recipients. Human exposure to the pathogens (environmental concentrations and volumes ingested) and dose–response relationships for selected (or reference) organisms are then combined to characterize the risks. With the use of additional information (social, cultural, political, economic, environmental, etc.), management options can be prioritized. To encourage stakeholder support and participation, a transparent procedure and active risk communication at each stage of the process are important. An example of a risk assessment approach is outlined in Table 7.3 and described below. For more detailed information on QMRA in the context of drinking-water safety, see the supporting document *Quantitative microbial risk assessment: application for water safety management*; Annex 1).

Problem formulation and hazard identification

All potential hazards, sources and events that can lead to the presence of microbial pathogens (i.e. what can happen and how) should be identified and documented for each component of the drinking-water system, regardless of whether or not the component is under the direct control of the drinking-water supplier. This includes point sources of pollution (e.g. human and industrial waste discharges) as well as diffuse sources (e.g. those arising from agricultural and animal husbandry activities). Continuous, intermittent or seasonal pollution patterns should also be considered, as well as extreme and infrequent events, such as droughts and floods.

The broader sense of hazards includes hazardous scenarios, which are events that may lead to exposure of consumers to specific pathogenic microorganisms. In this, the hazardous event (e.g. peak contamination of source water with domestic wastewater) may be referred to as the hazard.

As a QMRA cannot be performed for each of the hazards identified, representative (or reference) organisms are selected that, if controlled, would ensure control of all pathogens of concern. Typically, this implies inclusion of at least one bacterium, virus, protozoan or helminth. In this section, *Campylobacter*, rotavirus and *Crypto-*

sporidium have been used as example reference pathogens to illustrate application of risk assessment and calculation of performance targets.

Table 7.3 Risk assessment paradigm for pathogen health risks

Step	Aim
1. Problem formulation and hazard identification	To identify all possible hazards associated with drinking-water that would have an adverse public health consequence, as well as their pathways from source(s) to consumer(s)
2. Exposure assessment	To determine the size and nature of the population exposed and the route, amount and duration of the exposure
3. Dose–response assessment	To characterize the relationship between exposure and the incidence of the health effect
4. Risk characterization	To integrate the information from exposure, dose–response and health interventions in order to estimate the magnitude of the public health problem and to evaluate variability and uncertainty

Source: Adapted from Haas, Rose & Gerba (1999)

Exposure assessment

Exposure assessment in the context of drinking-water consumption involves estimation of the number of pathogens to which an individual is exposed, principally through ingestion. Exposure assessment inevitably contains uncertainty and must account for variability of such factors as concentrations of pathogens over time and volumes ingested.

Exposure can be considered as a single dose of pathogens that a consumer ingests at a certain point in time or the total amount over several exposures (e.g. over a year). Exposure is determined by the concentration of pathogens in drinking-water and the volume of water consumed.

It is rarely possible or appropriate to directly measure pathogens in drinking-water on a regular basis. More often, concentrations in raw waters are assumed or measured, and estimated reductions—for example, through treatment—are applied to estimate the concentration in the water consumed. Pathogen measurement, when performed, is generally best carried out at the location where the pathogens are at highest concentration (generally raw waters). Estimation of their removal by sequential control measures is generally achieved by the use of indicator organisms such as *E. coli* for enteric bacterial pathogens (see Table 7.4; see also the supporting document *Water treatment and pathogen control* in Annex 1).

The other component of exposure assessment, which is common to all pathogens, is the volume of unboiled water consumed by the population, including person-to-person variation in consumption behaviour and especially consumption behaviour of vulnerable subpopulations. For microbial hazards, it is important that the unboiled volume of drinking-water, both consumed directly and used in food preparation, is used in the risk assessment, as heating will rapidly inactivate pathogens. This amount is lower than that used for deriving water quality targets, such as chemical guideline values.

The daily exposure of a consumer to pathogens in drinking-water can be assessed by multiplying the concentration of pathogens in drinking-water by the volume of drinking-water consumed (i.e. dose). For the purposes of the example model calculations, drinking-water consumption was assumed to be 1 litre of unboiled water per day, but location-specific data on drinking-water consumption are preferred.

Dose–response assessment

The probability of an adverse health effect following exposure to one or more pathogenic organisms is derived from a dose–response model. Available dose–response data have been obtained mainly from studies using healthy adult volunteers. However, adequate data are lacking for vulnerable subpopulations, such as children, the elderly and the immunocompromised, who may suffer more severe disease outcomes.

The conceptual basis for the dose–response model is the observation that exposure to the described dose leads to the probability of infection as a conditional event: for infection to occur, one or more viable pathogens must have been ingested. Furthermore, one or more of these ingested pathogens must have survived in the host's body. An important concept is the single-hit principle (i.e. that even a single pathogen may be able to cause infection and disease). This concept supersedes the concept of (minimum) infectious dose that is frequently used in older literature (see the supporting document *Hazard characterization for pathogens in food and water*; Annex 1).

In general, well-dispersed pathogens in water are considered to be Poisson distributed. When the individual probability of any organism surviving and starting infection is the same, the dose–response relationship simplifies to an exponential function. If, however, there is heterogeneity in this individual probability, this leads to the beta-Poisson dose–response relationship, where the "beta" stands for the distribution of the individual probabilities among pathogens (and hosts). At low exposures, such as would typically occur in drinking-water, the dose–response model is approximately linear and can be represented simply as the probability of infection resulting from exposure to a single organism (see the supporting document *Hazard characterization for pathogens in food and water*; Annex 1).

Risk characterization

Risk characterization brings together the data collected on exposure, dose–response and the incidence and severity of disease.

The probability of infection can be estimated as the product of the exposure to drinking-water and the probability that exposure to one organism would result in infection. The probability of infection per day is multiplied by 365 to calculate the probability of infection per year. In doing so, it is assumed that different exposure events are independent, in that no protective immunity is built up. This simplification is justified for low risks only, such as those discussed here.

Not all infected individuals will develop clinical illness; asymptomatic infection is common for most pathogens. The percentage of infected persons who will develop clinical illness depends on the pathogen, but also on other factors, such as the immune status of the host. Risk of illness per year is obtained by multiplying the probability of infection by the probability of illness given infection.

The low numbers in Table 7.4 can be interpreted to represent the probability that a single individual will develop illness in a given year. For example, a risk of illness for *Campylobacter* of 2.2×10^{-4} per year indicates that, on average, 1 out of 4600 consumers would contract campylobacteriosis from consumption of drinking-water.

To translate the risk of developing a specific illness to disease burden per case, the metric disability-adjusted life year, or DALY, is used (see Box 3.1 in chapter 3). This

metric reflects not only the effects of acute end-points (e.g. diarrhoeal illness) but also mortality and the effects of more serious end-points (e.g. Guillain-Barré syndrome associated with *Campylobacter*). The disease burden per case varies widely. For example, the disease burden per 1000 cases of rotavirus diarrhoea is 480 DALYs in low-income regions, where child mortality frequently occurs. However, it is 14 DALYs per 1000 cases in high-income regions, where hospital facilities are accessible to the great majority of the population (see the supporting document *Quantifying public health risk in the WHO Guidelines for drinking-water quality*; Annex 1). This considerable difference in disease burden results in far stricter treatment requirements in low-income regions for the same raw water quality in order to obtain the same risk (expressed as DALYs per person per year). Ideally, the health outcome target of 10^{-6} DALY per person per year in Table 7.4 should be adapted to specific national situations. In Table 7.4, no accounting is made for effects on immunocompromised persons (e.g. cryptosporidiosis in patients with human immunodeficiency virus or AIDS), which is significant in some countries. Section 3.2 gives more information on the DALY metric and how it is applied to derive a reference level of risk.

Only a proportion of the population may be susceptible to some pathogens, because immunity developed after an initial episode of infection or illness may provide lifelong protection. Examples include hepatitis A virus and rotaviruses. It is estimated that in developing countries, all children above the age of 5 years are immune to rotaviruses because of repeated exposure in the first years of life. This translates to an average of 17% of the population being susceptible to rotavirus illness. In developed countries, rotavirus infection is also common in the first years of life, and the illness is diagnosed mainly in young children, but the percentage of young children as part of the total population is lower. This translates to an average of 6% of the population in developed countries being susceptible.

The uncertainty of the risk outcome is the result of the uncertainty and variability of the data collected in the various steps of the risk assessment. Risk assessment models should ideally account for this variability and uncertainty, although here we present only point estimates (see below).

It is important to choose the most appropriate point estimate for each of the variables. Theoretical considerations show that risks are directly proportional to the arithmetic mean of the ingested dose. Hence, arithmetic means of variables such as concentration in raw water, removal by treatment and consumption of drinking-water are recommended. This recommendation is different from the usual practice among microbiologists and engineers of converting concentrations and treatment effects to log values and making calculations or specifications on the log scale. Such calculations result in estimates of the geometric mean rather than the arithmetic mean, and these may significantly underestimate risk. Analysing site-specific data may therefore require going back to the raw data (i.e. counts and tested volumes) rather than relying on reported log-transformed values, as these introduce ambiguity.

Emergencies such as major storms and floods can lead to substantial deteriorations in source water quality, including large short-term increases in pathogen concentrations. These should not be included in calculations of arithmetic means. Inclusion will lead to higher levels of treatment being applied on a continuous basis, with sub-

stantial cost implications. It is more efficient to develop specific plans to deal with the events and emergencies (see section 4.4). Such plans can include enhanced treatment or (if possible) selection of alternative sources of water during an emergency.

7.2.4 Risk-based performance target setting

The process outlined above enables estimation of risk on a population level, taking account of raw water quality and impact of control. This can be compared with the

Table 7.4 Linking tolerable disease burden and raw water quality for reference pathogens: example calculation

River water (human and livestock pollution)	Units	*Cryptosporidium*	*Campylobacter*	Rotavirus[a]
Raw water quality (C_R)	Organisms per litre	10	100	10
Treatment effect needed to reach tolerable risk (PT)	Log_{10} reduction value	5.89	5.98	5.96
Drinking-water quality (C_D)	Organisms per litre	1.3×10^{-5}	1.05×10^{-4}	1.1×10^{-5}
Consumption of unheated drinking-water (V)	Litres per day	1	1	1
Exposure by drinking-water (E)	Organisms per day	1.3×10^{-5}	1.05×10^{-4}	1.1×10^{-5}
Dose–response (r)[b]	Probability of infection per organism	2.0×10^{-1}	1.9×10^{-2}	5.9×10^{-1}
Risk of infection ($P_{inf,d}$)	Per day	2.6×10^{-6}	2.0×10^{-6}	6.5×10^{-6}
Risk of infection ($P_{inf,y}$)	Per year	9.5×10^{-4}	7.3×10^{-4}	2.4×10^{-3}
Risk of (diarrhoeal) illness given infection ($P_{ill\|inf}$)	Probability of illness per infection	0.7	0.3	0.5
Risk of (diarrhoeal) illness (P_{ill})	Per year	6.7×10^{-4}	2.2×10^{-4}	1.2×10^{-3}
Disease burden (db)	DALY per case	1.5×10^{-3}	4.6×10^{-3}	1.4×10^{-2}
Susceptible fraction (f_s)	Percentage of population	100	100	6
Health outcome target (HT)	DALY per year[c]	1×10^{-6}	1×10^{-6}	1 × 10–6
Formulas:	$C_D = C_R \div 10^{PT}$	$P_{inf,d} = E \times r$	$HT = P_{ill} \times db \times f_s \div 100$	
	$E = C_D \times V$	$P_{ill} = P_{inf,y} \times P_{ill\|inf}$		

DALY, disability-adjusted life year

[a] Data from high-income regions. In low-income regions, severity is typically higher (see the supporting document *Quantifying public health risk in the WHO Guidelines for drinking-water quality*; Annex 1).

[b] Dose–response for *Campylobacter* and rotavirus from Haas, Rose & Gerba (1999) and for *Cryptosporidium* from the supporting document *Risk assessment of Cryptosporidium in drinking water* (Annex 1).

[c] For a person drinking 1 litre per day (V).

reference level of risk (see section 3.2) or a locally developed tolerable risk. The calculations enable quantification of the degree of source protection or treatment that is needed to achieve a specified level of tolerable risk and analysis of the estimated impact of changes in control measures.

Performance targets are most frequently applied to treatment performance—that is, to determine the microbial reduction necessary to ensure water safety. A performance target may be applied to a specific system (i.e. formulated in response to local raw water characteristics) or generalized (e.g. formulated in response to raw water quality assumptions based on a certain type of source) (see also the supporting document *Water treatment and pathogen control*; Annex 1).

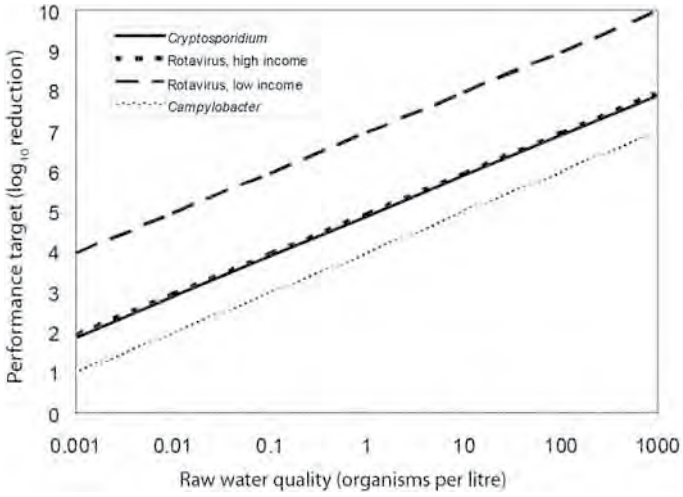


Figure 7.2 Performance targets for example bacterial, viral and protozoan pathogens in relation to raw water quality (to achieve 10–6 DALY per person per year)

Figure 7.2 illustrates the targets for treatment performance for a range of pathogens occurring in raw water. For example, 10 microorganisms per litre of raw water will lead to a performance target of 5.89 logs (or 99.999 87% reduction) for *Cryptosporidium* or of 5.96 logs (99.999 89% reduction) for rotaviruses in high-income regions to achieve 10^{-6} DALY per person per year (see also Table 7.5 below). The difference in performance targets for rotaviruses in high- and low-income countries (5.96 and 7.96 logs; Figure 7.2) is related to the difference in disease severity caused by this organism. In low-income countries, the child case fatality rate is relatively high, and, as a consequence, the disease burden is higher. Also, a larger proportion of the population in low-income countries is under the age of 5 and at risk for rotavirus infection.

The derivation of these performance targets is described in Table 7.5, which provides an example of the data and calculations that would normally be used to construct a risk assessment model for waterborne pathogens. The table presents data for representatives of the three major groups of pathogens (bacteria, viruses and protozoa) from a range of sources. These example calculations aim at achieving the reference level of risk of 10^{-6} DALY per person per year, as described in section 3.2. The data in the table illustrate the calculations needed to arrive at a risk estimate and are not guideline values.

7.2.5 Presenting the outcome of performance target development

Table 7.5 presents some data from Table 7.4 in a format that is more meaningful to risk managers. The average concentration of pathogens in drinking-water is included for information. It is not a water quality target, nor is it intended to encourage pathogen monitoring in finished water. As an example, a concentration of 1.3×10^{-5} *Cryptosporidium* per litre (see Table 7.4) corresponds to 1 oocyst per 79 000 litres (see Table 7.5). The performance target (in the row "Treatment effect" in Table 7.4), expressed as a

Table 7.5 Health-based targets derived from example calculation in Table 7.4

	Cryptosporidium	*Campylobacter*	Rotavirus[a]
Organisms per litre in raw water	10	100	10
Health outcome target	10^{-6} DALY per person per year	10^{-6} DALY per person per year	10^{-6} DALY per person per year
Risk of diarrhoeal illness[b]	1 per 1500 per year	1 per 4600 per year	1 per 14 000 per year
Drinking-water quality	1 per 79 000 litres	1 per 9500 litres	1 per 90 000 litres
Performance target[c]	5.89 $\log_{10}$ units	5.98 $\log_{10}$ units	5.96 $\log_{10}$ units

[a] Data from high-income regions. In low-income regions, severity is typically higher, but drinking-water transmission is unlikely to dominate.
[b] For the susceptible population.
[c] Performance target is a measure of log reduction of pathogens based on raw water quality.

$\log_{10}$ reduction value, is the most important management information in the risk assessment table. It can also be expressed as a per cent reduction. For example, a 5.96 $\log_{10}$ unit reduction for rotaviruses corresponds to a 99.999 89% reduction.

7.2.6 Adapting risk-based performance target setting to local circumstances

The reference pathogens illustrated in the previous sections will not be priority pathogens in all regions of the world. Wherever possible, country- or site-specific information should be used in assessments of this type. If no specific data are available, an approximate risk estimate can be based on default values (see Table 7.6 below).

Table 7.5 accounts only for changes in water quality derived from treatment and not from source protection measures, which are often important contributors to overall safety, affecting pathogen concentration and/or variability. The risk estimates presented in Table 7.4 also assume that there is no degradation of water quality in the distribution network. These may not be realistic assumptions under all circumstances, and it is advisable to take these factors into account wherever possible.

Table 7.5 presents point estimates only and does not account for variability and uncertainty. Full risk assessment models would incorporate such factors by representing the input variables by statistical distributions rather than by point estimates. However, such models are currently beyond the means of many countries, and data to define such distributions are scarce. Producing such data may involve considerable efforts in terms of time and resources, but will lead to much improved insight into the actual raw water quality and treatment performance.

The necessary degree of treatment also depends on the values assumed for variables that can be taken into account in the risk assessment model. One such variable is drinking-water consumption. Figure 7.3 shows the effect of variation in the consumption of unboiled drinking-water on the performance targets for *Cryptosporidium*. If the raw water concentration is 1 oocyst per litre, the performance target varies between 4.3 and 5.2 $\log_{10}$ units if consumption values vary between 0.25 and 2 litres per day. Another variable is the fraction of the population that is susceptible. Some outbreak data suggest that in developed countries, a significant proportion of the population above 5 years of age may not be immune to rotavirus illness. Figure 7.4

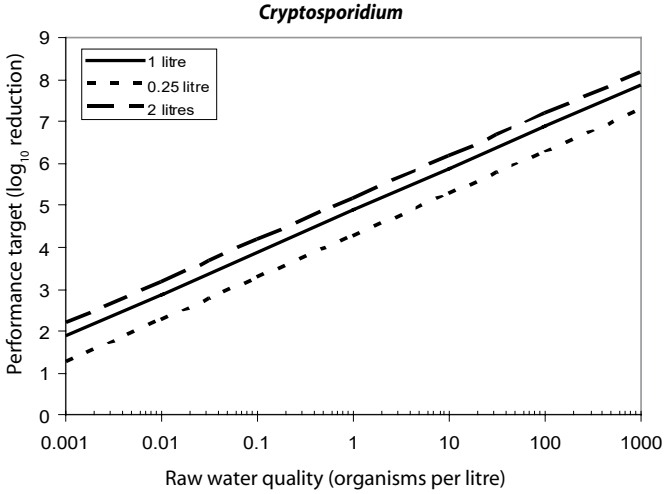


Figure 7.3 Performance targets for *Cryptosporidium* in relation to the daily consumption of unboiled drinking-water (to achieve 10^{-6} DALY per person per year)

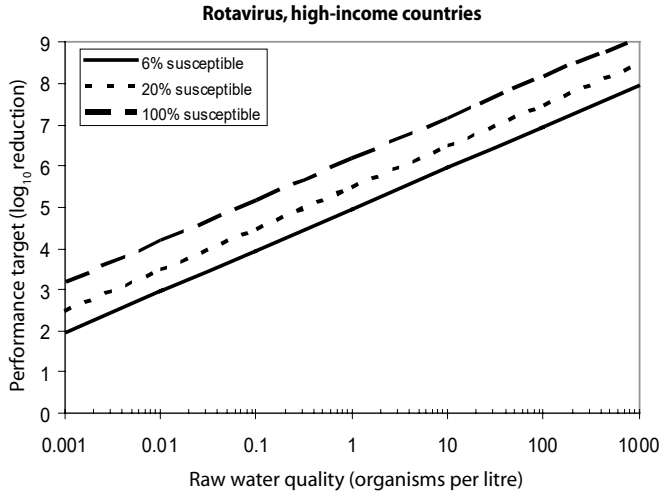


Figure 7.4 Performance targets for rotaviruses in relation to the fraction of the population that is susceptible to illness (to achieve 10^{-6} DALY per person per year)

shows the effect of variation in the susceptible fraction of the population. If the raw water concentration is 10 rotavirus particles per litre, the performance target increases from 5.96 to 7.18 as the susceptible fraction increases from 6% to 100%.

7.2.7 Health outcome targets

Health outcome targets that identify disease reductions in a community should be responded to by the control measures set out in water safety plans and associated

Table 7.6 Example occurrence of selected indicators and pathogens in faeces, wastewater and raw water (local data will vary)

Microbe	Number per gram of faeces	Number per litre in untreated wastewater	Number per litre in raw water
Faecal coliforms (*E. coli* and *Klebsiella*)	10^7 (mostly non-pathogenic)	10^6–10^{10}	100–100 000
Campylobacter spp.	10^6	100–10^6	100–10 000
Vibrio cholerae[a]	10^6	100–10^6	100–10^8
Enteroviruses	10^6	1–1000	0.01–10
Rotaviruses	10^9	50–5000	0.01–100
Cryptosporidium	10^7	1–10 000	0–1000
Giardia intestinalis	10^7	1–10 000	0–1000

[a] *Vibrio* can grow in the aquatic environment.
Sources: Feachem et al. (1983); Stelzer (1988); Jones, Betaieb & Telford (1990); Stampi et al. (1992); Koenraad et al. (1994); Gerba et al. (1996); AWWA (1999); Maier, Pepper & Gerba (2000); Metcalf & Eddy, Inc. (2003); Bitton (2005); Lodder & de Roda Husman (2005); Schijven & de Roda Husman (2006); Masini et al. (2007); Rutjes et al. (2009); Lodder et al. (2010)

water quality interventions at community and household levels. These targets would identify expected disease reductions in communities receiving the interventions.

The prioritization of water quality interventions should focus on those aspects that are estimated to contribute more than, for example, 5% of the burden of a given disease (e.g. 5% of total diarrhoea). In many parts of the world, the implementation of a water quality intervention that results in an estimated health gain of more than 5% would be considered extremely worthwhile. Directly demonstrating the health gains arising from improving water quality—as assessed, for example, by reduced *E. coli* counts at the point of consumption—may be possible where disease burden is high and effective interventions are applied and can be a powerful tool to demonstrate a first step in incremental drinking-water safety improvement.

Where a specified quantified disease reduction is identified as a health outcome target, it is advisable to undertake ongoing proactive public health surveillance among representative communities to measure the effectiveness of water quality interventions.

7.3 Occurrence and treatment of pathogens

As discussed in section 4.1, system assessment involves determining whether the drinking-water supply chain as a whole can deliver drinking-water quality that meets identified targets. This requires an understanding of the quality of source water and the efficacy of control measures, such as treatment.

7.3.1 Occurrence

An understanding of pathogen occurrence in source waters is essential, because it facilitates selection of the highest-quality source for drinking-water supply, determines pathogen concentrations in source waters and provides a basis for establishing treatment requirements to meet health-based targets within a water safety plan.

By far the most accurate way of determining pathogen concentrations in specific catchments and other water sources is by analysing pathogen concentrations in water

over a period of time, taking care to include consideration of seasonal variation and peak events such as storms. Direct measurement of pathogens and indicator organisms in the specific source waters for which a water safety plan and its target pathogens are being established is recommended wherever possible, because this provides the best estimates of microbial concentrations. However, resource limitations in many settings preclude this. In the absence of measured pathogen concentrations, an alternative interim approach is to make estimations based on available data, such as the results of sanitary surveys combined with indicator testing.

In the case of absence of data on the occurrence and distribution of human pathogens in water for the community or area of implementation, concentrations in raw waters can be inferred from observational data on numbers of pathogens per gram of faeces representing direct faecal contamination or from numbers of pathogens per litre of untreated wastewater (Table 7.6). Data from sanitary surveys can be used to estimate the impact of raw or treated wastewater discharged into source waters. In treated wastewater, the concentrations of pathogens may be reduced 10- to 100-fold or more, depending on the efficiency of the treatment process. The concentrations of pathogens in raw waters can be estimated from concentrations of pathogens in wastewater and the fraction of wastewater present in source waters. In addition, some indicative concentrations of pathogens in source waters are given that were measured at specific locations, but these concentrations may differ widely between locations.

From Table 7.6, it may be clear that faecal indicator bacteria, such as *E. coli*, are always present at high concentrations in wastewater. Everybody sheds *E. coli*; nevertheless concentrations vary widely. Only infected persons shed pathogens; therefore, the concentrations of pathogens in wastewater vary even more. Such variations are due to shedding patterns, but they also depend on other factors, such as the size of the population discharging into wastewater and dilution with other types of wastewater, such as industrial wastewater. Conventional wastewater treatment commonly reduces microbial concentrations by one or two orders of magnitude before the wastewater is discharged into surface waters. At other locations, raw wastewater may be discharged directly, or discharges may occur occasionally during combined sewer overflows. Discharged wastewater is diluted in receiving surface waters, leading to reduced pathogen numbers, with the dilution factor being very location specific. Pathogen inactivation, die-off or partitioning to sediments may also play a role in pathogen reduction. These factors differ with the surface water body and climate. This variability suggests that concentrations of faecal indicators and pathogens vary even more in surface water than in wastewater.

Because of differences in survival, the ratio of pathogen to *E. coli* at the point of discharge will not be the same as farther downstream. A comparison of data on *E. coli* with pathogen concentrations in surface waters indicates that, overall, there is a positive relationship between the presence of pathogens in surface water and *E. coli* concentration, but that pathogen concentrations may vary widely from low to high at any *E. coli* concentration. Even the absence of *E. coli* is not a guarantee for the absence of pathogens or for pathogen concentrations to be below those of significance for public health.

The estimates based on field data in Table 7.6 provide a useful guide to the concentrations of enteric pathogens in a variety of sources affected by faecal contamination.

However, there are a number of limitations and sources of uncertainty in these data, including the following:

- Although data on pathogens and *E. coli* were derived from different regions in the world, they are by far mostly from high-income countries.
- There are concerns about the sensitivity and robustness of analytical techniques, particularly for viruses and protozoa, largely associated with the recoveries achieved by techniques used to process and concentrate large sample volumes typically used in testing for these organisms.
- Numbers of pathogens were derived using a variety of methods, including culture-based methods using media or cells, molecular-based tests (such as polymerase chain reaction) and microscopy, and should be interpreted with care.
- The lack of knowledge about the infectivity of the pathogens for humans has implications in risk assessment and should be addressed.

7.3.2 Treatment

Understanding the efficacy of control measures includes validation (see sections 2.2 and 4.1.7). Validation is important both in ensuring that treatment will achieve the desired goals (performance targets) and in assessing areas in which efficacy may be improved (e.g. by comparing performance achieved with that shown to be achievable through well-run processes). Water treatment could be applied in a drinking-water treatment plant (central treatment) to piped systems or in the home or at the point of use in settings other than piped supplies.

Central treatment

Waters of very high quality, such as groundwater from confined aquifers, may rely on protection of the source water and the distribution system as the principal control measures for provision of safe water. More typically, water treatment is required to remove or destroy pathogenic microorganisms. In many cases (e.g. poor quality surface water), multiple treatment stages are required, including, for example, coagulation, flocculation, sedimentation, filtration and disinfection. Table 7.7 provides a summary of treatment processes that are commonly used individually or in combination to achieve microbial reductions (see also Annex 5). The minimum and maximum removals are indicated as $\log_{10}$ reduction values and may occur under failing and optimal treatment conditions, respectively.

The microbial reductions presented in Table 7.7 are for broad groups or categories of microbes: bacteria, viruses and protozoa. This is because it is generally the case that treatment efficacy for microbial reduction differs among these microbial groups as a result of the inherently different properties of the microbes (e.g. size, nature of protective outer layers, physicochemical surface properties). Within these microbial groups, differences in treatment process efficiencies are smaller among the specific species, types or strains of microbes. Such differences do occur, however, and the table presents conservative estimates of microbial reductions based on the more resistant or persistent pathogenic members of that microbial group. Where differences in removal by treatment between specific members of a microbial group are great, the results for the individual microbes are presented separately in the table.

Treatment efficacy for microbial reduction can also differ when aggregating different treatment processes. Applying multiple barriers in treatment, for example in drinking-water treatment plants, may strengthen performance, as failure of one process does not result in failure of the entire treatment. However, both positive and negative interactions can occur between multiple treatment steps, and how these interactions affect the overall water quality and water treatment performance is not yet completely understood. In positive interactions, the inactivation of a contaminant is higher when two steps are occurring together than when each of the steps occurs separately—as happens, for example, when coagulation and sedimentation are operating under optimal conditions, and there is an increase in performance of rapid sand filters. In contrast, negative interactions can occur when failure in the first step of the treatment process could lead to a failure of the next process—for example, if coagulation fails to remove organic material, this could lead to a reduced efficacy of subsequent disinfection and a potential increase in DBPs. An overall assessment of the drinking-water treatment performance, as part of the implementation of the WSP, will assist in understanding the efficacy of the multiple treatment processes to ensure the safety of the drinking-water supply.

Table 7.7 Reductions of bacteria, viruses and protozoa achieved by water treatment technologies at drinking-water treatment plants for large communities

Treatment process	Enteric pathogen group	Minimum removal (LRV)	Maximum removal (LRV)	Notes
Pretreatment				
Roughing filters	Bacteria	0.2	2.3	Depends on filter medium, coagulant
Storage reservoirs	Bacteria	0.7	2.2	Residence time > 40 days
	Protozoa	1.4	2.3	Residence time 160 days
Bank filtration	Viruses	> 2.1	8.3	Depends on travel distance, soil type, pumping rate, pH, ionic strength
	Bacteria	2	> 6	
	Protozoa	> 1	> 2	
Coagulation, flocculation and sedimentation				
Conventional clarification	Viruses	0.1	3.4	Depends on coagulation conditions
	Bacteria	0.2	2	
	Protozoa	1	2	
High-rate clarification	Protozoa	> 2	2.8	Depends on use of appropriate blanket polymer
Dissolved air flotation	Protozoa	0.6	2.6	Depends on coagulant dose
Lime softening	Viruses	2	4	Depends on pH and settling time
	Bacteria	1	4	
	Protozoa	0	2	

Table 7.7 (continued)

Treatment process	Enteric pathogen group	Minimum removal (LRV)	Maximum removal (LRV)	Notes
Filtration				
Granular high-rate filtration	Viruses	0	3.5	Depends on filter media and coagulation pretreatment; filtered water turbidity of ≤ 0.3 NTU in 95% of samples (and none to exceed 1 NTU) associated with 1–2 log reduction of viruses and 3 log reduction of *Cryptosporidium*[a]
	Bacteria	0.2	4.4	
	Protozoa	0.4	3.3	
Slow sand filtration	Viruses	0.25	4	Depends on presence of schmutzdecke, grain size, flow rate, operating conditions (mainly temperature, pH); filtered water turbidity of ≤ 1NTU in 95% of samples (and none to exceed 5 NTU) associated with 1–2 log reduction of viruses and 2.5–3 log reduction of *Cryptosporidium*[a]
	Bacteria	2	6	
	Protozoa	0.3	> 5	
Precoat filtration	Viruses	1	1.7	If filter cake is present
	Bacteria	0.2	2.3	Depends on chemical pretreatment
	Protozoa	3	6.7	Depends on media grade and filtration rate
Membrane filtration: microfiltration, ultrafiltration, nanofiltration, reverse osmosis	Viruses	< 1	> 6.5	Varies with membrane pore size (microfilters, ultrafilters, nanofilters and reverse osmosis filters), integrity of filter medium and filter seals, and resistance to chemical and biological ("grow-through") degradation; maximum reductions associated with filtered water turbidity of < 0.1 NTU[a]
	Bacteria	1	> 7	
	Protozoa	2.3	> 7	

Table 7.7 (continued)

Treatment process	Enteric pathogen group	Reduction	Notes
Primary disinfection[b,c]			
Chlorine	Viruses	2 (Ct_{99} 2–30 min·mg/l; 0–10 °C; pH 7–9)	Free chlorine × contact time predicts efficacy; not effective against *Cryptosporidium* oocysts. Turbidity and chlorine-demanding solutes inhibit this process; hence, turbidity should be kept below 1 NTU to support effective disinfection. Where this is not practical, turbidities should be kept below 5 NTU with higher chlorine doses or contact times.[a] In addition to initial disinfection, the benefits of maintaining free chlorine residuals throughout distribution systems at or above 0.2 mg/l should be considered
	Bacteria	2 (Ct_{99} 0.04–0.08 min·mg/l; 5 °C; pH 6-7)	
	Protozoa	2 (Ct_{99} 25–245 min·mg/l; 0–25 °C; pH 7–8; mainly *Giardia*)	
Chlorine dioxide	Viruses	2 (Ct99 2–30 min·mg/l; 0–10 °C; pH 7–9)	
	Bacteria	2 (Ct_{99} 0.02–0.3 min·mg/l; 15–25 °C; pH 6.5–7)	
	Protozoa	2 (Ct_{99} 100 min·mg/l)	
Ozone	Viruses	2 (Ct_{99} 0.006–0.2 min·mg/l)	Viruses generally more resistant than bacteria
	Bacteria	2 (Ct_{99} 0.02 min·mg/l)	
	Protozoa	2 (Ct_{99} 0.5–40 min·mg/l)	Depends on temperature; *Cryptosporidium* varies widely
UV	Viruses	4 (7–186 mJ/cm^2)	Effectiveness of disinfection depends on delivered fluence (dose), which varies with intensity, exposure time and UV wavelength. Excessive turbidity and certain dissolved species inhibit this process; hence, turbidity should be kept below 1 NTU to support effective disinfection. Where this is not practical, turbidities should be kept below 5 NTU with higher fluences[a]
	Bacteria	4 (0.65–230 mJ/cm^2)	
	Protozoa	4 (< 1–60 mJ/cm^2)	

Ct, product of disinfectant concentration and contact time; LRV, log_{10} reduction value
[a] See *Turbidity: Information for regulators and operators of water supplies* (Annex 1)
[b] Chemical disinfection: Ct values are given that achieve 2 LRV.
[c] UV irradiation: UV dose range is given that achieves 4 LRV.
Sources: Chevrefils et al. (2006); Dullemont et al. (2006); Hijnen, Beerendonk & Medema (2006); see also the supporting document *Water treatment and pathogen control* (Annex 1).

Further information about these water treatment processes, their operations and their performance for pathogen reduction in piped water supplies is provided in more detail in the supporting document *Water treatment and pathogen control* (Annex 1).

Household treatment

Household water treatment technologies are any of a range of devices or methods employed for the purposes of treating water in the home or at the point of use in other settings. These are also known as point-of-use or point-of-entry water treatment technologies (Cotruvo & Sobsey, 2006; Nath, Bloomfield & Jones, 2006; see also the supporting document *Managing water in the home*, Annex 1). Household water treatment technologies comprise a range of options that enable individuals and communities to treat collected water or contaminated piped water to remove or inactivate microbial

pathogens. Many of these methods are coupled with safe storage of the treated water to preclude or minimize contamination after household treatment (Wright, Gundry & Conroy, 2003).

Household water treatment and safe storage have been shown to significantly improve water quality and reduce waterborne infectious disease risks (Fewtrell & Colford, 2004; Clasen et al., 2006). Household water treatment approaches have the potential to have rapid and significant positive health impacts in situations where piped water systems are not possible and where people rely on source water that may be contaminated or where stored water becomes contaminated because of unhygienic handling during transport or in the home. Household water treatment can also be used to overcome the widespread problem of microbially unsafe piped water supplies. Similar small technologies can also be used by travellers in areas where the drinking-water quality is uncertain (see also section 6.11).

Not all household water treatment technologies are highly effective in reducing all classes of waterborne pathogens (bacteria, viruses, protozoa and helminths). For example, chlorine is ineffective for inactivating oocysts of the waterborne protozoan *Cryptosporidium*, whereas some filtration methods, such as ceramic and cloth or fibre filters, are ineffective in removing enteric viruses. Therefore, careful consideration of the health-based target microbes to control in a drinking-water source is needed when choosing among these technologies.

Definitions and descriptions of the various household water treatment technologies for microbial contamination follow:

- *Chemical disinfection:* Chemical disinfection of drinking-water includes any chlorine-based technology, such as chlorine dioxide, as well as ozone, some other oxidants and some strong acids and bases. Except for ozone, proper dosing of chemical disinfectants is intended to maintain a residual concentration in the water to provide some protection from post-treatment contamination during storage. Disinfection of household drinking-water in developing countries is done primarily with free chlorine, either in liquid form as hypochlorous acid (commercial household bleach or more dilute sodium hypochlorite solution between 0.5% and 1% hypochlorite marketed for household water treatment use) or in dry form as calcium hypochlorite or sodium dichloroisocyanurate. This is because these forms of free chlorine are convenient, relatively safe to handle, inexpensive and easy to dose. However, sodium trichloroisocyanurate and chlorine dioxide are also used in some household water treatment technologies. Proper dosing of chlorine for household water treatment is critical in order to provide enough free chlorine to maintain a residual during storage and use. Recommendations are to dose with free chlorine at about 2 mg/l to clear water (< 10 nephelometric turbidity units [NTU]) and twice that (4 mg/l) to turbid water (> 10 NTU). Although these free chlorine doses may lead to chlorine residuals that exceed the recommended chlorine residual for water that is centrally treated at the point of delivery, 0.2–0.5 mg/l, these doses are considered suitable for household water treatment to maintain a free chlorine residual of 0.2 mg/l in stored household water treated by chlorination. Further information on point-of-use chlorination can be found

in the document *Preventing travellers' diarrhoea: How to make drinking water safe* (WHO, 2005).

Disinfection of drinking-water with iodine, which is also a strong oxidant, is generally not recommended for extended use unless the residual concentrations are controlled, because of concerns about adverse effects of excess intake on the thyroid gland; however, this issue is being re-examined, because dietary iodine deficiency is a serious health problem in many parts of the world (see also section 6.11 and Table 6.1). As for central treatment, ozone for household water treatment must be generated on site, typically by corona discharge or electrolytically, both of which require electricity. As a result, ozone is not recommended for household water treatment because of the need for a reliable source of electricity to generate it, its complexity of generation and proper dosing in a small application, and its relatively high cost. Strong acids or bases are not recommended as chemical disinfectants for drinking-water, as they are hazardous chemicals that can alter the pH of the water to dangerously low or high levels. However, as an emergency or short-term intervention, the juices of some citrus fruits, such as limes and lemons, can be added to water to inactivate *Vibrio cholerae*, if enough is added to sufficiently lower the pH of the water (probably to pH less than 4.5).

- *Membrane, porous ceramic or composite filters:* These are filters with defined pore sizes and include carbon block filters, porous ceramics containing colloidal silver, reactive membranes, polymeric membranes and fibre/cloth filters. They rely on physical straining through a single porous surface or multiple surfaces having structured pores to physically remove and retain microbes by size exclusion. Some of these filters may also employ chemical antimicrobial or bacteriostatic surfaces or chemical modifications to cause microbes to become adsorbed to filter media surfaces, to be inactivated or at least to not multiply. Cloth filters, such as those of sari cloth, have been recommended for reducing *Vibrio cholerae* in water. However, these filters reduce only vibrios associated with copepods, other large crustaceans or other large eukaryotes retained by the cloth. These cloths will not retain dispersed vibrios or other bacteria not associated with copepods, other crustaceans, suspended sediment or large eukaryotes, because the pores of the cloth fabric are much larger than the bacteria, allowing them to pass through. Most household filter technologies operate by gravity flow or by water pressure provided from a piped supply. However, some forms of ultrafiltration, nanofiltration and reverse osmosis filtration may require a reliable supply of electricity to operate.
- *Granular media filters:* Granular media filters include those containing sand or diatomaceous earth or others using discrete particles as packed beds or layers of surfaces over or through which water is passed. These filters retain microbes by a combination of physical and chemical processes, including physical straining, sedimentation and adsorption. Some may also employ chemically active antimicrobial or bacteriostatic surfaces or other chemical modifications. Other granular media filters are biologically active because they develop layers of microbes and their associated exopolymers on the surface of or within the granular medium matrix. This biologically active layer, called the *schmutzdecke* in conventional slow sand filters, retains microbes and often leads to their inactivation and

biodegradation. A household-scale filter with a biologically active surface layer that can be dosed intermittently with water has been developed.

- *Solar disinfection:* There are a number of technologies using solar irradiation to disinfect water. Some use solar radiation to inactivate microbes in either dark or opaque containers by relying on heat from sunlight energy. Others, such as the solar water disinfection or SODIS system, use clear plastic containers penetrated by UV radiation from sunlight that rely on the combined action of the UV radiation, oxidative activity associated with dissolved oxygen and heat. Other physical forms of solar radiation exposure systems also employ combinations of these solar radiation effects in other types of containers, such as UV-penetrable plastic bags (e.g. the "solar puddle") and panels.
- *UV light technologies using lamps:* A number of drinking-water treatment technologies employ UV light radiation from UV lamps to inactivate microbes. For household- or small-scale water treatment, most employ low-pressure mercury arc lamps producing monochromatic UV radiation at a germicidal wavelength of 254 nm. Typically, these technologies allow water in a vessel or in flow-through reactors to be exposed to the UV radiation from the UV lamps at sufficient dose (fluence) to inactivate waterborne pathogens. These may have limited application in developing countries because of the need for a reliable supply of electricity, cost and maintenance requirements.
- *Thermal (heat) technologies:* Thermal technologies are those whose primary mechanism for the destruction of microbes in water is heat produced by burning fuel. These include boiling and heating to pasteurization temperatures (typically > 63 °C for 30 minutes when applied to milk). The recommended procedure for water treatment is to raise the temperature so that a rolling boil is achieved, removing the water from the heat and allowing it to cool naturally, and then protecting it from post-treatment contamination during storage (see the supporting document *Boil water*; Annex 1). The above-mentioned solar technologies using solar radiation for heat or for a combination of heat and UV radiation from sunlight are distinguished from this category.
- *Coagulation, precipitation and/or sedimentation:* Coagulation or precipitation is any device or method employing a natural or chemical coagulant or precipitant to coagulate or precipitate suspended particles, including microbes, to enhance their sedimentation. Sedimentation is any method for water treatment using the settling of suspended particles, including microbes, to remove them from the water. These methods may be used along with cloth or fibre media for a straining step to remove the floc (the large coagulated or precipitated particles that form in the water). This category includes simple sedimentation (i.e. that achieved without the use of a chemical coagulant). This method often employs a series of three pots or other water storage vessels in series, in which sedimented (settled) water is carefully transferred by decanting daily; by the third vessel, the water has been sequentially settled and stored a total of at least 2 days to reduce microbes.
- *Combination (multiple-barrier) treatment approaches:* These are any of the above technologies used together, either simultaneously or sequentially, for water treatment. These combination treatments include coagulation plus disinfection, media filtration plus disinfection or media filtration plus membrane filtration. Some are

commercial single-use chemical products in the form of granules, powders or tablets containing a chemical coagulant, such as an iron or aluminium salt, and a disinfectant, such as chlorine. When added to water, these chemicals coagulate and flocculate impurities to promote rapid and efficient sedimentation and also deliver the chemical disinfectant (e.g. free chlorine) to inactivate microbes. Other combined treatment technologies are physical devices that include two or more stages of treatment, such as media or membrane filters or adsorbents to physically remove microbes and either chemical disinfectants or another physical treatment process (e.g. UV radiation) to kill any remaining microbes not physically removed by filtration or adsorption. Many of these combined household water treatment technologies are commercial products that can be purchased for household or other local use. It is important to choose commercial combination devices based on consideration of the treatment technologies that have been included in the device. It is also desirable to require that they meet specific microbial reduction performance criteria and preferably be certified for such performance by a credible national or international authority, such as government or an independent organization representing the private sector that certifies good practice and documented performance.

Estimated reductions of waterborne bacteria, viruses and protozoan parasites by several of the above-mentioned household water treatment technologies are summarized in Table 7.8. These reductions are based on the results of studies reported in the scientific literature. Two categories of effectiveness are reported: baseline removals and maximum removals. Baseline removals are those typically expected in actual field practice when done by relatively unskilled persons who apply the treatment to raw waters of average and varying quality and where there are minimum facilities or supporting instruments to optimize treatment conditions and practices. Maximum removals are those possible when treatment is optimized by skilled operators who are supported with instrumentation and other tools to maintain the highest level of performance in waters of predictable and unchanging quality (e.g. a test water seeded with known concentrations of specific microbes). It should be noted that there are differences in the $\log_{10}$ reduction value performance of certain water treatment processes as specified for household water treatment in Table 7.8 and for central treatment in Table 7.7. These differences in performance by the same treatment technologies are to be expected, because central treatment is often applied to water that is of desirable quality for the treatment process, and treatment is applied by trained operators using properly engineered and operationally controlled processes. In contrast, household water treatment is often applied to waters having a range of water qualities, some of which are suboptimal for best technology performance, and the treatment is often applied without the use of specialized operational controls by people who are relatively untrained and unskilled in treatment operations, compared with people managing central water treatment facilities. Further details on these treatment processes, including the factors that influence their performance and the basis for the $\log_{10}$ reduction value performance levels provided in Table 7.8, can be found in the supporting documents *Managing water in the home* and *Evaluating household water treatment options* (Annex 1).

Table 7.8 Reductions of bacteria, viruses and protozoa achieved by household water treatment technologies

Treatment process	Enteric pathogen group	Baseline removal (LRV)	Maximum removal (LRV)	Notes
Chemical disinfection				
Free chlorine disinfection	Bacteria	3	6	Free chlorine × contact time predicts efficacy; not effective against *Cryptosporidium* oocysts. Turbidity and chlorine-demanding solutes inhibit this process; hence, turbidity should be kept below 1 NTU to support effective disinfection. Where this is not practical, the aim should be to keep turbidities below 5 NTU, although disinfection should still be practiced if 5 NTU cannot be achieved. At turbidities of more than 1 NTU, higher chlorine doses or contact times will be required[a]
	Viruses	3	6	
	Protozoa, non-*Cryptosporidium*	3	5	
	Cryptosporidium	0	1	
Membrane, porous ceramic or composite filtration				
Porous ceramic and carbon block filtration	Bacteria	2	6	Varies with pore size, flow rate, filter medium and inclusion of augmentation with silver or other chemical agents
	Viruses	1	4	
	Protozoa	4	6	
Membrane filtration (microfiltration, ultrafiltration, nanofiltration, reverse osmosis)	Bacteria	2 MF; 3 UF, NF or RO	4 MF; 6 UF, NF or RO	Varies with membrane pore size, integrity of filter medium and filter seals, and resistance to chemical and biological ("grow-through") degradation; maximum reductions associated with filtered water turbidity of < 0.1 NTU[a]
	Viruses	0 MF; 3 UF, NF or RO	4 MF; 6 UF, NF or RO	
	Protozoa	2 MF; 3 UF, NF or RO	6 MF; 6 UF, NF or RO	
Fibre and fabric filtration (e.g. sari cloth filtration)	Bacteria	1	2	Particle or plankton association increases removal of microbes, notably copepod-associated guinea worm (*Dracunculus medinensis*) and plankton-associated *Vibrio cholerae*; larger protozoa (> 20 µm) may be removed; ineffective for viruses, dispersed bacteria and small protozoa (e.g. *Giardia intestinalis*, 8–12 µm, and *Cryptosporidium* 4–6 µm)
	Viruses	0	0	
	Protozoa	0	1	

Table 7.8 (continued)

Treatment process	Enteric pathogen group	Baseline removal (LRV)	Maximum removal (LRV)	Notes
Granular media filtration				
Rapid granular, diatomaceous earth, biomass and fossil fuel–based (granular and powdered activated carbon, wood and charcoal ash, burnt rice hulls, etc.) filters	Bacteria	1	4+	Varies considerably with media size and properties, flow rate and operating conditions; some options are more practical than others for use in developing countries
	Viruses	1	4+	
	Protozoa	1	4+	
Household-level intermittently operated slow sand filtration	Bacteria	1	3	Varies with filter maturity, operating conditions, flow rate, grain size and filter bed contact time
	Viruses	0.5	2	
	Protozoa	2	4	

Table 7.8 (continued)

Treatment process	Enteric pathogen group	Baseline removal (LRV)	Maximum removal (LRV)	Notes
Solar disinfection				
Solar disinfection (solar UV radiation + thermal effects)	Bacteria	3	5+	Varies depending on oxygenation, sunlight intensity, exposure time, temperature, turbidity and size of water vessel (depth of water)
	Viruses	2	4+	
	Protozoa	2	4+	
UV light technologies using lamps				
UV irradiation	Bacteria	3	5+	Effectiveness of disinfection depends on delivered fluence (dose), which varies with intensity, exposure time and UV wavelength. Excessive turbidity and certain dissolved species inhibit this process; hence, turbidity should be kept below 1 NTU to support effective disinfection. Where this is not practical, turbidities should be kept below 5 NTU with higher fluences[a]
	Viruses	2	5+	
	Protozoa	3	5+	
Thermal (heat) technologies				
Thermal (e.g. boiling)	Bacteria	6	9+	Values are based on vegetative cells; spores are more resistant to thermal inactivation than are vegetative cells; treatment to reduce spores by boiling must ensure sufficient temperature and time
	Viruses	6	9+	
	Protozoa	6	9+	
Sedimentation				
Simple sedimentation	Bacteria	0	0.5	Effective due to settling of particle-associated and large (sedimentable) microbes; varies with storage time and particulates in the water
	Viruses	0	0.5	
	Protozoa	0	1	
Combination treatment approaches				
Flocculation plus disinfection systems (e.g. commercial powder sachets or tablets)	Bacteria	7	9	Some removal of Cryptosporidium possible by coagulation
	Viruses	4.5	6	
	Protozoa	3	5	

LRV, $\log_{10}$ reduction value; MF, microfilter; NF, nanofilter; RO, reverse osmosis; UF, ultrafilter

[a] See *Turbidity: Information for regulators and operators of water supplies* (Annex 1).

The values in Table 7.8 do not account for post-treatment contamination of stored water, which may limit the effectiveness of some technologies where safe storage methods are not practised. The best options for water treatment at the household level will also employ means for safe storage, such as covered, narrow-mouthed vessels with a tap system or spout for dispensing stored water.

Validation, surveillance and certification of household water treatment and storage are recommended, just as they are for central water supplies and systems. The entities responsible for these activities for household water treatment systems may differ from those of central supplies. In addition, separate entities may be responsible for validation, independent surveillance and certification. Nevertheless, validation and surveillance as well as certification are critical for effective management of household

and other point-of-use and point-of-entry drinking-water supplies and their treatment and storage technologies, just as they are for central systems (see sections 2.3 and 5.2.3).

Non-piped water treatment technologies manufactured by or obtained from commercial or other external sources should be certified to meet performance or effectiveness requirements or guidelines, preferably by an independent, accredited certification body. If the treatment technologies are locally made and managed by the household itself, efforts to document effective construction and use and to monitor performance during use are recommended and encouraged.

7.4 Microbial monitoring

Microbial monitoring can be undertaken for a range of purposes, including:

- validation (see also section 4.1.7);
- operational monitoring (see also sections 2.2.2 and 4.2);
- verification (see also sections 2.4.1 and 4.3);
- surveillance (see chapter 5);
- source water monitoring for identifying performance targets (see sections 7.2 and 7.3.1);
- collecting data for QMRA (see also section 7.2.3 and the supporting document *Quantitative microbial risk assessment: application to water safety management*, Annex 1).

Owing to issues relating to complexity, sensitivity of detection, cost and timeliness of obtaining results, testing for specific pathogens is generally limited to assessing raw water quality as a basis for identifying performance targets and validation, where monitoring is used to determine whether a treatment or other process is effective in removing target organisms. Very occasionally, pathogen testing may be performed to verify that a specific treatment or process has been effective. However, microbial testing included in verification, operational and surveillance monitoring is usually limited to testing for indicator organisms.

Different methods can be employed for the detection of bacteria, viruses, protozoan parasites and helminths in water. The use of some methods, such as microscopy, relies on detection of the whole particle or organism. Other methods, such as molecular amplification using polymerase chain reaction (PCR), target the genomic material, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA). Still other methods, such as immunological detection methods (e.g. enzyme-linked immunosorbent assay [ELISA]), target proteins. Culture-based methods, such as broth cultures or agar-based bacterial media and cell cultures for viruses and phages, detect organisms by infection or growth.

Culture in broth or on solid media is largely applied to determine the number of viable bacteria in water. The best known examples are culture-based methods for indicators such as *E. coli*. Viruses can be detected by several methods. Using cell culture, the number of infectious viruses in water can be determined. Alternatively, viral genomes can be detected by use of PCR. Protozoan parasites are often detected by

immunomagnetic separation in combination with immunofluorescence microscopy. PCR can also be applied. Helminths are generally detected using microscopy.

In source investigation associated with waterborne infectious disease outbreaks, microbial hazards are generally typed by use of PCR, which can be followed by sequencing analysis to improve the precision of identification. One innovative approach is metagenome analysis (i.e. sequencing nucleic acid obtained directly from environmental samples). This can detect a multitude of microbial hazards in a water sample.

It is important to recognize that the different methods measure different properties of microorganisms. Culture-based methods detect living organisms, whereas microscopy, detection of nucleic acid and immunological assays measure the physical presence of microorganisms or components of them, and do not necessarily determine if what is detected is alive or infectious. This creates greater uncertainty regarding the significance of the human health risk compared with detection by culture-based methods. When using non-culture methods that do not measure in units indicative of culturability or infectivity, assumptions are often made about the fraction of pathogens or components detected that represent viable and infectious organisms.

The concept of using organisms such as *E. coli* as indicators of faecal pollution is a well-established practice in the assessment of drinking-water quality. The criteria determined for such faecal indicators are that they should not be pathogens themselves and they should:

Table 7.9 Use of indicator organisms in monitoring

	Type of monitoring		
Microorganism(s)	**Validation of process**	**Operational**	**Verification and surveillance**
E. coli (or thermotolerant coliforms)	Not applicable	Not applicable	Faecal indicator
Total coliforms	Not applicable	Indicator for cleanliness and integrity of distribution systems	Not applicable
Heterotrophic plate counts	Indicator for effectiveness of disinfection of bacteria	Indicator for effectiveness of disinfection processes and cleanliness and integrity of distribution systems	Not applicable
Clostridium perfringens[a]	Indicator for effectiveness of disinfection and physical removal processes for viruses and protozoa	Not applicable	Not applicable[b]
Coliphages *Bacteroides fragilis* phages Enteric viruses	Indicator for effectiveness of disinfection and physical removal processes for viruses	Not applicable	Not applicable[b]

[a] Use of *Clostridium perfringens* for validation will depend on the treatment process being assessed.
[b] Could be used for verification where source waters are known to be contaminated with enteric viruses and protozoa or where such contamination is suspected as a result of impacts of human faecal waste.

- be universally present in faeces of humans and animals in large numbers;
- not multiply in natural waters;
- persist in water in a similar manner to faecal pathogens;
- be present in higher numbers than faecal pathogens;
- respond to treatment processes in a similar fashion to faecal pathogens;
- be readily detected by simple, inexpensive culture methods.

These criteria reflect an assumption that the same organism could be used as an indicator of both faecal pollution and treatment/process efficacy. However, it has become clear that one indicator cannot fulfil these two roles and that a range of organisms should be considered for different purposes (Table 7.9). For example, heterotrophic bacteria can be used as operational indicators of disinfection effectiveness and distribution system cleanliness; *Clostridium perfringens* and coliphage can be used to validate the effectiveness of treatment systems.

Escherichia coli has traditionally been used to monitor drinking-water quality, and it remains an important parameter in monitoring undertaken as part of verification or surveillance. Thermotolerant coliforms can be used as an alternative to the test for *E. coli* in many circumstances. Water intended for human consumption should contain no faecal indicator organisms. In the majority of cases, monitoring for *E. coli* or thermotolerant coliforms provides a high degree of assurance because of their large numbers in polluted waters.

Table 7.10 Guideline values for verification of microbial quality[a] (see also Table 5.2)

Organisms	Guideline value
All water directly intended for drinking	
E. coli or thermotolerant coliform bacteria[b,c]	Must not be detectable in any 100 ml sample
Treated water entering the distribution system	
E. coli or thermotolerant coliform bacteria[b]	Must not be detectable in any 100 ml sample
Treated water in the distribution system	
E. coli or thermotolerant coliform bacteria[b]	Must not be detectable in any 100 ml sample

[a] Immediate investigative action must be taken if *E. coli* are detected.

[b] Although *E. coli* is the more precise indicator of faecal pollution, the count of thermotolerant coliform bacteria is an acceptable alternative. If necessary, proper confirmatory tests must be carried out. Total coliform bacteria are not acceptable as an indicator of the sanitary quality of water supplies, particularly in tropical areas, where many bacteria of no sanitary significance occur in almost all untreated supplies.

[c] It is recognized that in the great majority of rural water supplies, especially in developing countries, faecal contamination is widespread. Especially under these conditions, medium-term targets for the progressive improvement of water supplies should be set.

However, increased attention has focused on the shortcomings of traditional indicators, such as *E. coli*, as indicator organisms for enteric viruses and protozoa. Viruses and protozoa more resistant to conventional environmental conditions or treatment technologies, including filtration and disinfection, may be present in treated drinking-water in the absence of *E. coli*. Retrospective studies of waterborne disease outbreaks have shown that complete reliance on assumptions surrounding the absence or presence of *E. coli* may not ensure safety. Under certain circumstances, it may be desirable to include more resistant microorganisms, such as bacteriophages and/or bacterial spores, as indicators of persistent microbial hazards. Their inclusion in monitoring programmes, including control and surveillance programmes, should be evaluated in relation to local circumstances and scientific understanding. Such circumstances could include the use of source water known to be contaminated with enteric viruses and parasites or where such contamination is suspected as a result of the impacts of human and livestock waste.

Further discussion on indicator organisms is contained in the supporting document *Assessing microbial safety of drinking water* (Annex 1).

Table 7.10 presents guideline values for verification of the microbial quality of drinking-water. Individual values should not be used directly from the table. The guideline values should be used and interpreted in conjunction with the information contained in these Guidelines and other supporting documentation.

A consequence of variable susceptibility to pathogens is that exposure to drinking-water of a particular quality may lead to different health effects in different populations. For derivation of national standards, it is necessary to define reference populations or, in some cases, to focus on specific vulnerable subpopulations. National or local authorities may wish to apply specific characteristics of their populations in deriving national standards.

Table 7.11 International Organization for Standardization (ISO) standards for detection and enumeration of faecal indicator organisms in water

ISO standard	Title (water quality)
6461-1:1986	Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia)—Part 1: Method by enrichment in a liquid medium
6461-2:1986	Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia)—Part 2: Method by membrane filtration
7704:1985	Evaluation of membrane filters used for microbiological analyses
9308-1:2000	Detection and enumeration of *Escherichia coli* and coliform bacteria—Part 1: Membrane filtration method
9308-2:1990	Detection and enumeration of coliform organisms, thermotolerant coliform organisms and presumptive *Escherichia coli*—Part 2: Multiple tube (most probable number) method
9308-3:1998	Detection and enumeration of *Escherichia coli* and coliform bacteria—Part 3: Miniaturized method (most probable number) for the detection and enumeration of *E. coli* in surface and waste water
10705-1:1995	Detection and enumeration of bacteriophages—Part 1: Enumeration of F-specific RNA bacteriophages
10705-2:2000	Detection and enumeration of bacteriophages—Part 2: Enumeration of somatic coliphages
10705-3:2003	Detection and enumeration of bacteriophages—Part 3: Validation of methods for concentration of bacteriophages from water
10705-4:2001	Detection and enumeration of bacteriophages—Part 4: Enumeration of bacteriophages infecting *Bacteroides fragilis*

7.5 Methods of detection of faecal indicator organisms

Analysis for faecal indicator organisms provides a sensitive, although not the most rapid, indication of pollution of drinking-water supplies. Because the growth medium and the conditions of incubation, as well as the nature and age of the water sample, can influence the species isolated and the count, microbiological examinations may have variable accuracy. This means that the standardization of methods and of laboratory procedures is of great importance if criteria for the microbial quality of water are to be uniform in different laboratories and internationally.

International standard methods should be evaluated under local circumstances before being adopted. Established standard methods are available, such as those of the International Organization of Standardization (ISO) (Table 7.11) or methods of equivalent efficacy and reliability. It is desirable that established standard methods be used for routine examinations. Whatever method is chosen for detection of *E. coli* or thermotolerant coliforms, the importance of "resuscitating" or recovering environmentally damaged or disinfectant-damaged strains must be considered.

7.6 Identifying local actions in response to microbial water quality problems and emergencies

During an emergency in which there is evidence of faecal contamination of the drinking-water supply, it may be necessary either to modify the treatment of existing

sources or to temporarily use alternative sources of drinking-water. It may be necessary to increase disinfection at source, following treatment or during distribution.

If microbial quality cannot be maintained, it may be necessary to advise consumers to boil the water during the emergency (see section 7.6.1). Initiating superchlorination and undertaking immediate corrective measures may be preferable where the speed of response is sufficient to prevent significant quantities of contaminated water from reaching consumers.

During outbreaks of potentially waterborne disease or when faecal contamination of a drinking-water supply is detected, the concentration of free chlorine should be increased to greater than 0.5 mg/l throughout the system as a minimum immediate response. It is most important that decisions are taken in consultation with public health authorities and, where appropriate, civil authorities (see also sections 4.4.3, 6.2 and 8.7).

7.6.1 Boil water advisories

Boil water advisories share many features with water avoidance advisories used in the event of serious chemical contamination (see section 8.7). Water suppliers in conjunction with public health authorities should develop protocols for boil water orders. Protocols should be prepared prior to the occurrence of incidents and incorporated within management plans. Decisions to issue advisories are often made within a short period of time, and developing responses during an event can complicate decision-making, compromise communication and undermine public confidence. In addition to the information discussed in section 4.4.3, the protocols should deal with:

- criteria for issuing and rescinding advisories;
- information to be provided to the general public and specific groups;
- activities affected by the advisory.

Protocols should identify mechanisms for the communication of boil water advisories. The mechanisms may vary, depending on the nature of the supply and the size of the community affected, and could include:

- media releases through television, radio and newspapers;
- telephone, e-mail and fax contact of specific facilities, community groups and local authorities;
- posting of notices in conspicuous locations;
- personal delivery;
- mail delivery.

The methods chosen should provide a reasonable surety that all of those affected by the advisory, including residents, workers and travellers, are notified as soon as possible.

Boil water advisories should indicate that the water can be made safe by bringing it to a rolling boil. After boiling, the water should be allowed to cool down on its own without the addition of ice. This procedure is effective at all altitudes and with turbid water. The types of event that should lead to consideration of boil water advisories include:

- substantial deterioration in source water quality;

- major failures associated with treatment processes or the integrity of distribution systems;
- inadequate disinfection;
- detection of pathogens or faecal indicator organisms in drinking-water;
- epidemiological evidence suggesting that drinking-water is responsible for an outbreak of illness.

Boil water advisories are a serious measure that can have substantial adverse consequences. Advice to boil water can have negative public health consequences through scalding and increased anxiety, even after the advice is rescinded. In addition, not all consumers will follow the advice issued, even at the outset; if boil water advisories are issued frequently or are left in place for long periods, compliance will decrease. Hence, advisories should be issued only after careful consideration of all available information by the public health authority and the incident response team and conclusion that there is an ongoing risk to public health that outweighs any risk from the advice to boil water. For example, where microbial contamination is detected in samples of drinking-water, factors that should be considered in evaluating the need for an advisory include:

- reliability and accuracy of results;
- vulnerability of source water to contamination;
- evidence of deterioration in source water quality;
- source water monitoring results;
- results from operational monitoring of treatment and disinfection processes;
- disinfectant residuals;
- physical integrity of the distribution system.

The available information should be reviewed to determine the likely source of the contamination and the likelihood of recurrence or persistence.

When issued, a boil water advisory should be clear and easily understood by recipients, or it may be ignored. Advisories should normally include a description of the problem, potential health risks and symptoms, activities that are affected, investigative actions and corrective measures that have been initiated, as well as the expected time to resolve the problem. If the advisory is related to an outbreak of illness, specific information should be provided on the nature of the outbreak, the illness and the public health response.

Boil water advisories should identify both affected and unaffected uses of drinking-water supplies. Generally, the advisory will indicate that unboiled water should not be used for drinking, preparing cold drinks, making ice, preparing or washing food or brushing teeth. Unless heavily contaminated, unboiled water will generally be safe for bathing (providing swallowing of water is avoided) and washing clothes. A boil water advisory could include specific advice for vulnerable subpopulations, such as pregnant women and others who might be immunocompromised. Specific advice should also be provided to facilities such as dental clinics, dialysis centres, doctors' offices, hospitals and other health-care facilities, child-care facilities, schools, food suppliers and manufacturers, hotels, restaurants and operators of public swimming pools and spas.

Provision of alternative supplies of drinking-water, such as bottled water or bulk water, should be considered when temporary boil water advisories are in place. The protocols should identify sources of alternative supplies and mechanisms for delivery.

Protocols should include criteria for rescinding boil water advisories. Depending on the reason for issuing the advisory, the criteria could include one or more of the following:

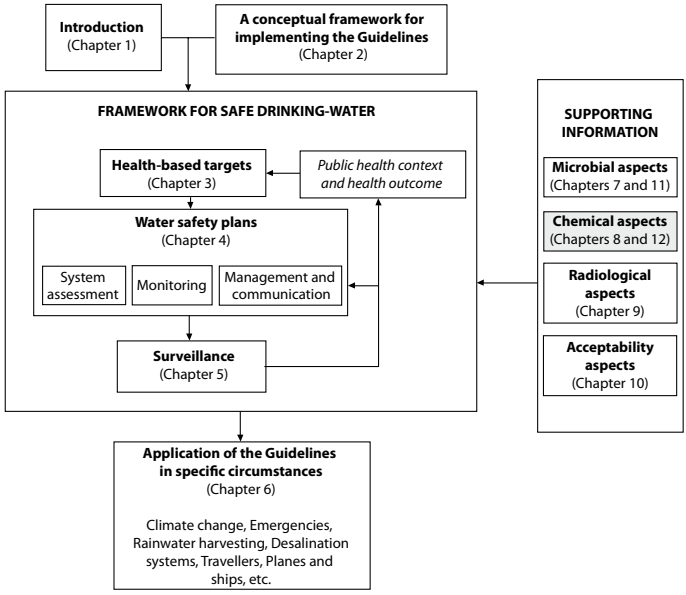
- evidence that source water quality has returned to normal;
- correction of failures associated with treatment processes or distribution systems;
- correction of faults in disinfection processes and restoration of normal disinfectant residuals;
- where detection of microbial contamination in drinking-water initiated the advisory, evidence that this contamination has been removed or inactivated;
- evidence that sufficient mains flushing or water displacement has removed potentially contaminated water and biofilms;
- epidemiological evidence indicating that an outbreak has concluded.

When boil water advisories are rescinded, information should be provided through similar channels and to the same groups that received the original advice. In addition, operators/managers or occupants of large buildings and buildings with storage tanks should be advised of the need to ensure that storages and extensive internal distribution systems are thoroughly flushed before normal uses are restored.

7.6.2 Actions following an incident

It is important that any incident be properly investigated and remedial action instigated to prevent its recurrence. The water safety plan will require revision to take into account the experience gained, and the findings may also be of importance in informing actions regarding other water supplies to prevent a similar event from occurring elsewhere. Where appropriate, epidemiological investigations by the health authority will also help to inform actions for the future.

8
Chemical aspects



Most chemicals arising in drinking-water are of health concern only after extended exposure of years, rather than months. The principal exception is nitrate. Typically, changes in water quality occur progressively, except for those substances that are discharged or leach intermittently to flowing surface waters or groundwater supplies from, for example, contaminated landfill sites.

In some cases, there are groups of chemicals that arise from related sources—for example, disinfection by-products (DBPs)—and it may not be necessary to set standards for all of the DBPs for which there are guideline values. If chlorination is practised, the trihalomethanes (THMs) and haloacetic acids (HAAs) will be the main DBPs. If bromide is present, brominated as well as chlorinated DBPs will be produced. Maintaining THM and HAA concentrations below the guideline values by controlling precursor compounds will provide adequate control over other chlorination by-products.

Several of the inorganic elements for which guideline values have been established are recognized to be essential elements in human nutrition. No attempt has been made here at this time to define a minimum desirable concentration of such substances in drinking-water, although the issue of nutritional essentiality is considered during the guideline development process.

Fact sheets for individual chemical contaminants are provided in chapter 12. For those contaminants for which a guideline value has been established, the fact sheets include a brief toxicological overview of the chemical, the basis for guideline derivation, treatment performance and analytical limit of detection. More detailed chemical reviews are available (http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/en/).

8.1 Chemical hazards in drinking-water

A few chemical contaminants have been shown to cause adverse health effects in humans as a consequence of prolonged exposure through drinking-water. However, this is only a very small proportion of the chemicals that may reach drinking-water from various sources.

> The lists of chemicals addressed in these Guidelines do not imply that all of these chemicals will always be present or that other chemicals not addressed will be absent.

The substances considered here have been assessed for possible health effects, and guideline values have been established only on the basis of health concerns. Additional consideration of the potential effects of chemical contaminants on the acceptability (i.e. taste, odour and appearance) of drinking-water to consumers is included in chapter 10. Some substances of health concern have effects on the acceptability of drinking-water that would normally lead to rejection of the water at concentrations significantly lower than those of health concern. For such substances, no formal guideline value is usually proposed, but a health-based value (see section 8.2) may be needed, for instance, in order to assist in judging the response required when problems are encountered and in some cases to provide reassurance to health authorities and consumers with regard to possible health risks.

Regulators are required to establish health-based targets that must be met through water safety plans. In the case of chemical contaminants, these are normally based on the guideline value, which is, in turn, based on health-related end-points. In this case, the guideline value and the local water quality target are similar, but not necessarily identical, because the latter value may need to be adjusted to take into account local sociocultural, economic and environmental/geological circumstances, as indicated in section 2.6. Guideline values provide a benchmark for the development of local water quality targets for chemicals (usually a national standard expressing a maximum allowable concentration). Guideline values may not directly reflect the target of 10^{-6} disability-adjusted life year (DALY),as these are frequently derived based on evidence indicating a no-adverse effect or negligible risk level. Some guideline values are based on extrapolation of the risk of cancer from exposures at which this can be measured to low exposures where measurement is currently not possible.

In section 2.6, it is stated that "In developing national drinking-water standards based on these Guidelines, it will be necessary to take account of a variety of environmental, social, cultural, economic, dietary and other conditions affecting potential exposure. This may lead to national standards that differ appreciably from these Guidelines." This is particularly applicable to chemical contaminants, for which there

is a long list, and setting standards for, or including, all of them in monitoring programmes is neither feasible nor desirable.

It is important that chemical contaminants be prioritized so that the most important in the country or local region are considered for inclusion in national standards and monitoring programmes.

The probability that any particular chemical may occur in significant concentrations in any particular setting must be assessed on a case-by-case basis. The presence of certain chemicals may already be known within a particular country, but others may be more difficult to assess.

In most countries, whether developing or industrialized, water sector professionals are likely to be aware of a number of chemicals that are present in significant concentrations in some drinking-water supplies. A body of local knowledge that has been built up by practical experience over a period of time is invaluable. Hence, the presence of a limited number of chemical contaminants in drinking-water is usually already known in many countries and in many local systems. Significant problems, even crises, can occur, however, when chemicals posing high health risk are widespread but their presence is unknown, because their long-term health effect is caused by chronic exposure as opposed to acute exposure. Such has been the case of arsenic in groundwater in Bangladesh and West Bengal, India, for example.

For many contaminants, there will be exposure from sources other than drinking-water, and this may need to be taken into account when setting, and considering the need for, standards. It may also be important when considering the need for monitoring. In some cases, drinking-water will be a minor source of exposure, and controlling levels in water will have little impact on overall exposure. In other cases, controlling a contaminant in water may be the most cost-effective way of reducing exposure. Drinking-water monitoring strategies should therefore not be considered in isolation from other potential routes of exposure to chemicals in the environment.

The scientific basis for each of the guideline values is summarized in chapter 12. This information is important in helping to adapt guideline values to suit national requirements or for assessing the health significance of a contaminant that is of a higher concentration than the guideline value.

Chemical contaminants in drinking-water may be categorized in various ways; however, the most appropriate is to consider the primary source of the contaminant—that is, to group chemicals according to where control may be effectively exercised. This aids in the development of approaches that are designed to prevent or minimize contamination, rather than those that rely primarily on the measurement of contaminant levels in final waters.

In general, approaches to the management of chemical hazards in drinking-water vary between those where the source water is a significant contributor (with control effected, for example, through source water selection, pollution control, treatment or blending) and those from materials and chemicals used in the production and distribution of drinking-water (controlled by process optimization or product specification). In these Guidelines, chemicals are therefore divided into five major source groups, as shown in Table 8.1.

Table 8.1 Categorization of source of chemical constituents

Source of chemical constituents	Examples of sources
Naturally occurring	Rocks, soils and the effects of the geological setting and climate; eutrophic water bodies (also influenced by sewage inputs and agricultural runoff)
Industrial sources and human dwellings	Mining (extractive industries) and manufacturing and processing industries, sewage (including a number of contaminants of emerging concern), solid wastes, urban runoff, fuel leakages
Agricultural activities	Manures, fertilizers, intensive animal practices and pesticides
Water treatment or materials in contact with drinking-water	Coagulants, DBPs, piping materials
Pesticides used in water for public health	Larvicides used in the control of insect vectors of disease

Categories may not always be clear-cut. The group of naturally occurring contaminants, for example, includes many inorganic chemicals that are found in drinking-water as a consequence of release from rocks and soils by rainfall, some of which may become problematical where there is environmental disturbance, such as in mining areas.

8.2 Derivation of chemical guideline values and health-based values

In order for a particular chemical constituent to be evaluated to determine whether a guideline value or health-based value should be derived, one of the following criteria must be satisfied:

- There is credible evidence of occurrence of the chemical in drinking-water, combined with evidence of actual or potential toxicity.
- The chemical is of significant international concern.
- The chemical is being considered for inclusion or is included in the WHO Pesticide Evaluation Scheme (WHOPES), which coordinates the testing and evaluation of pesticides for public health, including those applied directly to drinking-water for control of insect vectors of disease.

Guideline values are derived for many chemical constituents of drinking-water. A guideline value normally represents the concentration of a constituent that does not result in any significant risk to health over a lifetime of consumption. A number of provisional guideline values have been established at concentrations that are reasonably achievable through practical treatment approaches or in analytical laboratories; in these cases, the guideline value is above the concentration that would normally represent the calculated health-based value. Guideline values are also designated as provisional when there is a high degree of uncertainty in the toxicological and health data (see also section 8.2.5).

For some chemicals, no formal guideline value is proposed, on the grounds that occurrence is only at concentrations well below those that would be of concern for

health. Establishing a formal guideline value for such substances could encourage some Member States to incorporate the value into their national standards when this is neither necessary nor appropriate. However, to provide guidance for Member States should the chemical be found in drinking-water or in source water in the hazard identification phase of developing a WSP, a health-based value has been determined.

In addition, health-based values for acute exposures are now being developed for a small number of substances that may be implicated in emergency situations as a result of a spill, usually to surface water sources. The derivation of these acute health-based values is explained in section 8.7.5.

There are two principal sources of information on health effects resulting from exposure to chemicals that can be used in deriving guideline values. The first and preferred source is studies on human populations. However, the availability of such studies for most substances is limited, owing to the ethical barriers to conducting human toxicological studies and the lack of quantitative information on the concentration to which people have been exposed or on simultaneous exposure to other agents. However, for a few substances, such studies are the primary basis on which guideline values are developed. The second and most frequently used source of information is toxicological studies using laboratory animals. The limitations of toxicological studies include the relatively small number of experimental animals used and the relatively high doses administered, which create uncertainty as to the relevance of particular findings to human health. This uncertainty stems from the need to extrapolate the results from experimental animals to humans and to the low doses to which human populations are usually exposed. In most cases, the study used to derive the guideline value is supported by a range of other studies, including human data, and these are also considered in carrying out a health risk assessment.

In order to derive a guideline value to protect human health, it is necessary to select the most suitable study or studies. Data from well-conducted studies, where a clear dose–response relationship has been demonstrated, are preferred. Expert judgement, applied against criteria described in section 8.2.4, is exercised in the selection of the most appropriate studies from the range of information available. Safety or uncertainty factors using standard risk assessment principles are included to provide conservative guideline values that are considered to be protective.

8.2.1 Approaches taken

Two approaches to the derivation of guideline values are used: one for "threshold chemicals" and the other for "non-threshold chemicals" (mostly genotoxic carcinogens).

It is generally considered that the initiating event in the process of genotoxic chemical carcinogenesis is the induction of a mutation in the genetic material (deoxyribonucleic acid [DNA]) of somatic cells (i.e. cells other than ova or sperm) and that there is a theoretical risk at any level of exposure (i.e. no threshold). In contrast, there are carcinogens that are capable of producing tumours in experimental animals or humans without exerting a genotoxic activity, but acting through an indirect mechanism. It is generally believed that a demonstrable threshold dose exists for non-genotoxic carcinogens.

In deriving guideline values for carcinogens, consideration is given to the potential mechanisms by which the substance may cause cancer, in order to decide whether a threshold or non-threshold approach should be used (see sections 8.2.2 and 8.2.3).

The evaluation of the potential carcinogenicity of chemical substances is usually based on long-term laboratory animal studies. Sometimes data are available on carcinogenicity in humans, mostly from occupational exposure.

On the basis of the available evidence, the International Agency for Research on Cancer (IARC) categorizes chemical substances with respect to their potential carcinogenic risk into the following groups:

Group 1:	the agent is carcinogenic to humans
Group 2A:	the agent is probably carcinogenic to humans
Group 2B:	the agent is possibly carcinogenic to humans
Group 3:	the agent is not classifiable as to its carcinogenicity to humans
Group 4:	the agent is probably not carcinogenic to humans

According to IARC, these classifications represent a first step in carcinogenic risk assessment, which leads to a second step of quantitative risk assessment where possible. In establishing guideline values for drinking-water, the IARC evaluation of carcinogenic compounds, where available, is taken into consideration.

8.2.2 Threshold chemicals

For most kinds of toxicity, it is believed that there is a dose below which no adverse effect will occur. For chemicals that give rise to such toxic effects, a tolerable daily intake (TDI) should be derived as follows, using the most sensitive end-point in the most relevant study, preferably involving administration in drinking-water:

$$\text{TDI} = \frac{\text{NOAEL or LOAEL or BMDL}}{\text{UF and/or CSAF}}$$

where:

NOAEL	=	no-observed-adverse-effect level
LOAEL	=	lowest-observed-adverse-effect level
BMDL	=	lower confidence limit on the benchmark dose
UF	=	uncertainty factor
CSAF	=	chemical-specific adjustment factor

The guideline value (GV) is then derived from the TDI as follows:

$$\text{GV} = \frac{\text{TDI} \times \text{bw} \times \text{P}}{\text{C}}$$

where:

bw	=	body weight (see below)
P	=	fraction of the TDI allocated to drinking-water
C	=	daily drinking-water consumption (see below)

Tolerable daily intake

The TDI is an estimate of the amount of a substance in food and drinking-water, expressed on a body weight basis (milligram or microgram per kilogram of body weight), that can be ingested over a lifetime without appreciable health risk, and with a margin of safety.

Acceptable daily intakes (ADIs) are established for food additives and pesticide residues that occur in food for necessary technological purposes or plant protection reasons. For chemical contaminants, which usually have no intended function in drinking-water, the term "tolerable daily intake" is more appropriate than "acceptable daily intake", as it signifies permissibility rather than acceptability.

Over many years, the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) have developed certain principles in the derivation of ADIs (FAO/WHO, 2009). These principles have been adopted, where appropriate, in the derivation of TDIs used in developing guideline values for drinking-water quality.

As TDIs are regarded as representing a tolerable intake for a lifetime, they are not so precise that they cannot be exceeded for short periods of time. Short-term exposure to levels exceeding the TDI is not a cause for concern, provided the individual's intake averaged over longer periods of time does not appreciably exceed the level set. The large uncertainty factors generally involved in establishing a TDI (see below) serve to provide assurance that exposure exceeding the TDI for short periods is unlikely to have any deleterious effects upon health. However, consideration should be given to any potential acute effects that may occur if the TDI is substantially exceeded for short periods of time.

No-observed-adverse-effect level and lowest-observed-adverse-effect level

The NOAEL is defined as the highest dose or concentration of a chemical in a single study, found by experiment or observation, that causes no detectable adverse health effect. Wherever possible, the NOAEL is based on long-term studies, preferably of ingestion in drinking-water. However, NOAELs obtained from short-term studies and studies using other sources of exposure (e.g. food, air) may also be used.

If a NOAEL is not available, a LOAEL may be used, which is the lowest observed dose or concentration of a substance at which there is a detectable adverse health effect. When a LOAEL is used instead of a NOAEL, an additional uncertainty factor is normally applied (see below).

Benchmark dose

Increasingly, the preferred approaches for the derivation of TDIs/ADIs for threshold effects include the benchmark dose (BMD) or the lower confidence limit on the benchmark dose (BMDL) (IPCS, 1994). When appropriate data for mathematical modelling of dose–response relationships are available, BMDLs are used as alternatives to NOAELs in the calculation of health-based guideline values. In such a case, use of the BMDL could eliminate the need for application of an additional uncertainty factor to the LOAEL. The BMDL is the lower confidence limit of the dose that

Table 8.2 Source of uncertainty in derivation of guideline values

Source of uncertainty	Uncertainty factor
Interspecies variation (extrapolating from experimental animals to humans)	1–10
Intraspecies variation (accounting for individual variations within humans)	1–10
Adequacy of studies or database	1–10
Nature and severity of effect	1–10

produces a small increase (e.g. 5% or 10%) in the level of adverse effects. The BMDL is derived on a quantitative basis using data from the entire dose–response curve for the critical effect rather than from a single dose at the NOAEL or LOAEL and accounts for the statistical power and quality of the data (IPCS, 2009).

Uncertainty factors

The application of uncertainty or safety factors has been traditionally and successfully used in the derivation of ADIs and TDIs for food additives, pesticides and environmental contaminants. The derivation of these factors requires expert judgement and careful consideration of the available scientific evidence.

In the derivation of guideline values, uncertainty factors are applied to the NOAEL, LOAEL or BMD/BMDL for the response considered to be the most biologically significant.

In relation to exposure of the general population, the NOAEL or BMD/BMDL for the critical effect in experimental animals is normally divided by an uncertainty factor of 100. This comprises two 10-fold factors, one for interspecies differences and one for interindividual variability in humans (Table 8.2). Extra uncertainty factors may be incorporated to allow for database deficiencies and for the severity or irreversibility of effects.

Factors lower than 10 are used, for example, for interspecies variation when humans are known to be less sensitive than the experimental animal species studied. Inadequate studies or databases include those where a LOAEL is used instead of a NOAEL and studies considered to be shorter in duration than desirable. Situations in which the nature or severity of effect might warrant an additional uncertainty factor include studies in which the end-point is malformation of a fetus or in which the end-point determining the NOAEL is directly related to possible carcinogenicity. In the latter case, an additional uncertainty factor is usually applied for carcinogenic compounds for which the guideline value is derived using a TDI approach rather than a theoretical risk extrapolation approach.

For substances for which the uncertainty factors are greater than 1000, guideline values are designated as provisional in order to emphasize the higher level of uncertainty inherent in these values. A high uncertainty factor indicates that the guideline value may be considerably lower than the concentration at which health effects would actually occur in a real human population. Guideline values with high uncertainty are more likely to be modified as new information becomes available.

The selection and application of uncertainty factors are important in the derivation of guideline values for chemicals, as they can make a considerable difference in the

values set. For contaminants for which there is sufficient confidence in the database, the guideline value is derived using a small uncertainty factor. For most contaminants, however, there is greater scientific uncertainty, and a relatively large uncertainty factor is used. The use of uncertainty factors enables the particular attributes of the chemical and the data available to be considered in the derivation of guideline values.

Use of chemical-specific adjustment factors instead of uncertainty factors

Approaches to the derivation of TDIs are increasingly being based on understanding of a chemical's mode of action in order to reduce reliance on default assumptions. This approach provides a departure from the use of default uncertainty factors (such as a simple 10 for interspecies variation and 10 for intraspecies variation) and relies on the use of quantitative toxicokinetic and toxicodynamic data to derive CSAFs for use in interspecies and intraspecies extrapolations (IPCS, 2005). Previously, CSAFs were called "data-derived uncertainty factors". The part of the CSAF approach that is at present best developed is the use of physiologically based pharmacokinetic models to replace the default values for extrapolation between species and between differing routes of exposure (e.g. inhalation to oral).

Relative source allocation

Drinking-water is usually not the only source of human exposure to the chemicals for which guideline values have been derived. In many cases, the exposure to or intake of chemical contaminants from drinking-water is much lower than that from other sources, such as food, air and consumer products. Some consideration of the proportion of the ADI or TDI that may be attributed to different sources is therefore needed in developing guideline values and risk management strategies. This approach ensures that total daily intake from all sources (including drinking-water containing concentrations of the chemical at or near the guideline value) does not exceed the ADI or TDI.

Wherever possible or in an ideal situation, derivation of guideline values uses data on the proportion of total daily intake normally ingested in drinking-water (based on mean levels in food, drinking-water, consumer products, soil and air), or data on intakes estimated on the basis of physical and chemical properties of the substances of concern. As the primary sources of exposure to chemicals are generally food (e.g. pesticide residues) and water, it is important to quantify, whenever possible, the exposures from both sources. To inform this process, it is desirable to collect as much high-quality data as possible on food intake in different parts of the world as possible. The data collected can then be used to estimate the proportion of the intake that comes from food and the proportion that comes from drinking-water. However, for most contaminants, data from the various exposure sources, most notably food and drinking-water, are available only from developed countries.

In the absence of adequate exposure data or where documented evidence is available regarding widespread presence in one or more of the other media (i.e. air, food, soil or consumer products), the normal allocation of the total daily intake to drinking-water is 20% (floor value), which reflects a reasonable level of exposure based on broad experience, while still being protective (Krishnan & Carrier, 2013). This value reflects a change from the previous allocation of 10%, which was found to be exces-

sively conservative. As chemicals are progressively reassessed, overall exposure will be reconsidered, and a change in the default allocation factor from 10% to 20% will be made, if appropriate. Therefore, not all older guideline values reflect this change. In some circumstances, there is clear evidence that water is the main (and possibly only) source of exposure, such as for some of the DBPs; the allocation in such cases may be as high as 80% (ceiling value), which still allows for some exposure from other sources (Krishnan & Carrier, 2013). Where chemical and context-specific allocation factors can be developed using exposure data or models, the allocation factor applied should still be bounded by the floor and ceiling values (i.e. 20–80%).

For pesticides, even when available food exposure data suggest that exposure via this route is minimal, the default allocation factor of 20% is used to account for the fact that available food exposure data do not generally include information from developing countries, where exposure via this route may be higher.

A detailed explanation of the reasoning behind the choice of allocation factor is an essential component of the evaluation. This assists Member States in making appropriate decisions about incorporating or adapting guideline values into national standards where local circumstances need to be taken into account. It also provides assistance in making decisions regarding potential risks when a guideline value is exceeded. As a general principle, efforts should be made to keep contaminant concentrations as low as possible and not allow increases up to the guideline value.

Although the values chosen are, in most cases, sufficient to account for additional routes of intake (i.e. inhalation and dermal absorption) of contaminants in water, under certain circumstances (e.g. limited ventilation), authorities may wish to take inhalation and dermal exposure into account in adapting the guideline values to local conditions (see section 8.2.9).

Some elements are essential for human nutrition. In developing guideline values and in considering allocation factors, it is necessary to take into account the recommended minimum daily intake and exposures from food and to ensure that the allocation does not result in an apparent conflict with essentiality.

Default assumptions

There is variation in both the volume of water consumed daily and the body weight of consumers. It is therefore necessary to apply some assumptions in order to determine a guideline value. The default assumption for consumption by an adult is 2 litres of water per day, whereas the default assumption for body weight is 60 kg.

In some cases, the guideline value is based on children, where they are considered to be particularly vulnerable to a particular substance. In this event, a default intake of 1 litre is assumed for a body weight of 10 kg; where the most vulnerable group is considered to be bottle-fed infants, an intake of 0.75 litre is assumed for a body weight of 5 kg.

Significant figures

The calculated ADI or TDI is used to derive the guideline value, which is usually rounded to one significant figure. In calculating the guideline value, the unrounded ADI or TDI value should be used.

The guideline value is generally rounded to one significant figure to reflect the uncertainty in, for example, experimental animal toxicity data, exposure assumptions made and the uncertainty factors selected. In a few cases, rounding to two significant figures is appropriate because the practical impact of rounding depends on the units; for example, rounding from 1.5 to 2.0 µg/L has less influence on treatment requirements than rounding from 1.5 to 2.0 mg/L. These are considered on a case-by-case basis.

The general rounding rule for mid-way values (x.5) is to round up, in line with common convention. Examples for rounding to one significant figure are as follows: 1.25 becomes 1, 0.73 becomes 0.7 and 1.5 becomes 2.

8.2.3 Non-threshold chemicals

In the case of compounds considered to be genotoxic carcinogens, guideline values are normally determined using a mathematical model. Although several models exist, the linearized multistage model is generally adopted. Other models are considered more appropriate in certain cases. These models compute an estimate of risk at a particular level of exposure, along with upper and lower bounds of confidence on the calculation, which may include zero at the lower bound. Guideline values are conservatively presented as the concentrations in drinking-water associated with an estimated upper-bound excess lifetime cancer risk of 10^{-5} (or one additional case of cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). This value does not equate to the number of cases of cancer that will be caused by exposure to the substance at this level. It is the maximum potential risk, taking into account large uncertainties. It is highly probable that the actual level of risk is less than this, even approaching zero, but risks at low levels of exposure cannot be experimentally verified. The recognition that the cancer risk may approach zero or be indistinguishable from zero stems from the uncertainties associated with mechanisms of carcinogenesis, including the role of the chemical in the cancer process and the possibility of detoxification and repair mechanisms. Member States may consider that a different level of hypothetical risk is more appropriate to their circumstances, and values relating to risks of 10^{-4} or 10^{-6} additional cancer cases over a lifetime of exposure may be determined by respectively multiplying or dividing the guideline value by 10.

The mathematical models used for deriving guideline values for non-threshold chemicals cannot be verified experimentally, and they do not usually take into account a number of biologically important considerations, such as pharmacokinetics, pre-systemic and metabolic detoxification, DNA repair or protection by the immune system. They also assume the validity of a linear extrapolation of very high dose exposures in test animals to very low dose exposures in humans. As a consequence, the models used are conservative (i.e. err on the side of caution). The guideline values derived using these models should be interpreted differently from TDI-derived values because of the lack of precision of the models. Moderate short-term exposure to levels exceeding the guideline value for non-threshold chemicals does not significantly affect the risk.

8.2.4 Data quality

The following factors were taken into account in assessing the quality and reliability of available information:

- Oral studies are preferred (in particular, drinking-water studies), using the pure substance with appropriate dosing regime and a good quality clinical biochemistry and histopathology.

- The database should be sufficiently broad that all potential toxicological end-points of concern have been identified.
- The quality of the studies is such that they are considered reliable; for example, there has been adequate consideration of confounding factors in epidemiological studies.
- There is reasonable consistency between studies; the end-point and study used to derive a guideline value do not contradict the overall weight of evidence.
- For inorganic substances, there is some consideration of speciation in drinking-water.
- There is appropriate consideration of multimedia exposure in the case of epidemiological studies.

In the development of guideline values, existing international approaches are carefully considered. In particular, previous risk assessments developed by the International Programme on Chemical Safety (IPCS) in Environmental Health Criteria monographs and Concise International Chemical Assessment Documents, IARC, JMPR and JECFA are reviewed. These assessments are relied upon except where new information justifies a reassessment, but the quality of new data is critically evaluated before it is used in any risk assessment. Where international reviews are not available, other sources of data are used in the derivation of guideline values, including published reports from peer-reviewed open literature, national reviews recognized to be of high quality, information submitted by governments and other interested parties and, to a limited extent, unpublished proprietary data (primarily for the evaluation of pesticides).

8.2.5 Provisional guideline values

The use and designation of provisional guideline values are outlined in Table 8.3.

For non-threshold substances, in cases in which the concentration associated with an upper-bound excess lifetime cancer risk of 10^{-5} is not feasible as a result of inadequate analytical or treatment technology, a provisional guideline value (designated A or T, respectively) is recommended at a practicable level.

Table 8.3 Use and designation of provisional guideline values

Situations where a provisional guideline applies	Designation	
Significant scientific uncertainties regarding derivation of health-based guideline value	P	
Calculated guideline value is below the achievable analytical quantification level	A	*(Guideline value is set at the achievable quantification level)*
Calculated guideline value is below the level that can be achieved through practical treatment methods	T	*(Guideline value is set at the practical treatment level)*
Calculated guideline value may be exceeded as a result of disinfection procedures	D	*(Guideline value is set considering possible health effects and the need to maintain adequate disinfection. Adequate disinfection of drinking-water remains paramount)*

8.2.6 Chemicals with effects on acceptability

Some substances of health concern have effects on the taste, odour or appearance of drinking-water that would normally lead to rejection of water at concentrations significantly lower than those of concern for health. Such substances are not normally appropriate for routine monitoring. However, guideline values have been established for some substances that may cause taste or odour in drinking-water at concentrations much lower than the guideline values because there is such a wide range in the ability of consumers to detect them by taste or odour. For such substances, a fact sheet and health-based guideline value (see chapter 12) are presented in the usual way. In the fact sheet, the relationship between concentrations relevant to health and those relevant to the acceptability of the drinking-water is explained. In tables of guideline values, the health-based guideline values are designated with a "C". For other substances, health-based guideline values may be needed, for instance, in order to assist in judging the response that is required when problems are encountered and in some cases to provide reassurance to health authorities and consumers with regard to possible health risks.

8.2.7 Chemicals not included in the Guidelines

Additional information on many chemicals not included in these Guidelines is available from several credible sources, including WHO Environmental Health Criteria monographs and Concise International Chemical Assessment Documents (http://www.who.int/ipcs/en/), chemical risk assessment reports from JMPR, JECFA and IARC and published documents from a number of national sources, such as the United States Environmental Protection Agency. Although these information sources may not have been reviewed for these Guidelines, they have been peer reviewed and provide readily accessible information on the toxicology of many additional chemicals. They can help drinking-water suppliers and health officials decide upon the significance (if any) of a detected chemical and on the response that might be appropriate.

8.2.8 Mixtures

Chemical contaminants of drinking-water supplies are present with numerous other inorganic and organic constituents. The guideline values are calculated separately for individual substances, without specific consideration of the potential for interaction of each substance with other compounds present. Synergistic interactions between substances are usually selective and very limited, especially at the very low levels usually encountered in drinking-water. The large margin of uncertainty incorporated in the majority of the guideline values is considered to be sufficient to account for potential interactions. In addition, the majority of contaminants will not be continuously present at concentrations at or near their guideline value.

For many chemical contaminants, mechanisms of toxicity are different; consequently, there is no reason to assume that there are interactions. There may, however, be occasions when a number of contaminants with similar toxicological mechanisms are present at levels near their respective guideline values. In such cases, decisions concerning appropriate action should be made, taking into consideration local

circumstances. Unless there is evidence to the contrary, it is appropriate to assume that the toxic effects of these compounds are additive.

8.2.9 Adapting guideline values to local circumstances

In order to account for the variations in exposure from different sources in different parts of the world, default values, generally between 20% and 80%, are used to make an allocation of the TDI to drinking-water in setting guideline values for many chemicals. Where relevant exposure data are available, authorities are encouraged to develop context-specific guideline values that are tailored to local circumstances and conditions. For example, in areas where the intake of a particular contaminant in drinking-water is known to be much greater than that from other sources (e.g. air and food), it may be appropriate to allocate a greater proportion of the TDI to drinking-water to derive a guideline value more suited to the local conditions.

Daily water intake can vary significantly in different parts of the world, seasonally and particularly where consumers are involved in manual labour in hot climates. Local adjustments to the daily water consumption value may be needed in setting local standards, as in the case of fluoride, for example. For most other substances, the drinking-water intake range is very small (perhaps a factor of 2–4) compared with the much larger range in the toxicological uncertainty factors; hence, no such adjustment is necessary.

Volatile substances in water may be released to the atmosphere in showering and through a range of other household activities. Under such circumstances, inhalation may become a significant route of exposure. Some substances may also be absorbed through the skin during bathing, but this is not usually a major source of uptake. For those substances that are particularly volatile, such as chloroform, the correction factor would be approximately equivalent to a doubling of exposure, which is small in relation to the uncertainties inherent in the derivation of guideline values. However, in some parts of the world, houses have a very low rate of ventilation, and authorities may wish to take inhalation exposure into account in adapting the guideline values to local conditions, although other uncertainty factors used in the quantitative assessments may render this unnecessary. Where such exposure is shown to be important for a particular substance (i.e. high volatility, low ventilation rates and high rates of showering/bathing), it may be appropriate to adjust the guideline value accordingly.

8.3 Analytical achievability

As noted above, guideline values are not set at concentrations of substances that cannot reasonably be measured. In such circumstances, provisional guideline values are set at the reasonable analytical limits.

Guidance provided in this section and in Annex 4 is intended to assist readers to select appropriate analytical methods for specific circumstances. In carrying out hazard identification and risk assessment and for verification and auditing of the water safety plan for chemical contaminants, it is usually necessary to carry out some analysis. It is important that appropriate facilities are available to ensure that suitable methods are used in carrying out chemical analysis.

Various collections of "standard" or "recommended" methods for water analysis are published by a number of national and international agencies. It is often thought that adequate analytical accuracy can be achieved provided that all laboratories use the same standard method. Experience shows that this is not always the case, as a variety of factors may affect the accuracy of the results. Examples include reagent purity, apparatus type and performance, degree of modification of the method in a particular laboratory and the skill and care of the analyst. These factors are likely to vary both between laboratories and over time in an individual laboratory. Moreover, the precision and accuracy that can be achieved with a particular method frequently depend upon the adequacy of sampling and nature of the sample ("matrix"). While it is not essential to use standard methods, it is important that the methods used are properly validated and their precision and accuracy determined before significant decisions are made based on the results. In the case of "nonspecific" variables such as taste, odour, colour and turbidity, the result is method specific, and this needs to be considered when using the data to make comparisons.

A number of considerations are important in selecting methods:

- The overriding consideration is that the method chosen is demonstrated to have the required accuracy. Other factors, such as speed and convenience, should be considered only in selecting among methods that meet this primary criterion.
- Of primary importance is the expertise and diligence of the laboratories performing the analyses. They must utilize auditable quality control and quality assurance procedures for their results to be credible. External certification is highly desirable.
- There are a number of markedly different procedures for measuring and reporting the errors to which all methods are subject. This complicates and prejudices the effectiveness of method selection, and suggestions for standardizing such procedures have been made. It is therefore desirable that details of all analytical methods are published together with performance characteristics that can be interpreted unambiguously.
- If the analytical results from one laboratory are to be compared with those from others or with a numerical standard, it is obviously preferable for them not to have any associated systematic error. In practice, this is not possible, but each laboratory should select methods whose systematic errors have been thoroughly evaluated and shown to be acceptably small.

A qualitative ranking of analytical methods based on their degree of technical complexity is given in Table 8.4 for inorganic chemicals and in Table 8.5 for organic chemicals. These groups of chemicals are separated, as the analytical methods used differ greatly. The higher the ranking, the more complex the process in terms of equipment or operation. In general, higher rankings are also associated with higher total costs.

Analytical achievabilities, based on detection limits, of the inorganic and organic chemicals for which guideline values have been established are given in Annex 4, by source category.

Table 8.4 Ranking of complexity of analytical methods for inorganic chemicals

Ranking	Example of analytical methods
1	Volumetric method, colorimetric method
2	Electrode method
3	Ion chromatography
4	High-performance liquid chromatography
5	Flame atomic absorption spectrometry
6	Electrothermal atomic absorption spectrometry
7	Inductively coupled plasma atomic emission spectrometry
8	Inductively coupled plasma mass spectrometry

Table 8.5 Ranking of complexity of analytical methods for organic chemicals

Ranking	Example of analytical methods
1	High-performance liquid chromatography
2	Gas chromatography
3	Gas chromatography–mass spectrometry
4	Headspace gas chromatography–mass spectrometry
5	Purge-and-trap gas chromatography Purge-and-trap gas chromatography–mass spectrometry

Many kinds of field test kits are available to measure the concentrations of various chemicals in water. These are generally used for compliance examinations as well as for operational monitoring of drinking-water quality. Although the field test kits have the advantage of being simple to use in non-laboratory environments and are often available at relatively low prices, their analytical accuracy is generally less than that of the methods shown in Tables 8.4 and 8.5. However, when properly used, they provide valuable tools for rapidly assessing numerous contaminants in a non-formal laboratory setting at low cost compared with commercial laboratory tests. It is therefore necessary to check the validity of the field test kit before applying it.

A brief description of the analytical methods listed in Tables 8.4 and 8.5 is provided in Annex 4.

8.4 Treatment

As noted above, where a health-based guideline value cannot be achieved by reasonably practicable treatment, then the guideline value is designated as provisional and set at the concentration that can be reasonably achieved through treatment.

Collection, treatment, storage and distribution of drinking-water involve deliberate additions of numerous chemicals to improve the safety and quality of the finished drinking-water for consumers (direct additives). In addition, water is in constant contact with pipes, valves, taps and tank surfaces, all of which have the potential to impart additional chemicals to the water (indirect additives). The chemicals used in water treatment or from materials in contact with drinking-water are discussed in more detail in section 8.5.4.

Table 8.6 Ranking of technical complexity and cost of water treatment processes

Ranking	Examples of treatment processes
1	Simple chlorination Plain filtration (rapid sand, slow sand)
2	Prechlorination plus filtration Aeration
3	Chemical coagulation Process optimization for control of DBPs
4	Granular activated carbon treatment Ion exchange
5	Ozonation
6	Advanced oxidation processes Membrane treatment

8.4.1 Treatment performance

Treatment performance varies according to local conditions and circumstances. The ability to achieve a guideline value within a drinking-water supply depends on a number of factors, including:

- the concentration of the chemical in the raw water;
- control measures employed throughout the drinking-water system;
- nature of the raw water (groundwater or surface water, presence of natural organic matter and inorganic solutes and other components, such as turbidity);
- treatment processes already installed.

If a guideline value cannot be met with the existing system, then additional treatment may need to be considered, or water might need to be obtained from alternative sources.

The cost of achieving a guideline value will depend on the complexity of any additional treatment or other control measures required. It is not possible to provide general quantitative information on the cost of achieving individual guideline values. Treatment costs (capital and operating) will depend not only on the factors identified above, but also on issues such as plant throughput; local costs for labour, civil and mechanical works, chemicals and electricity; life expectancy of the plant; and so on. Guideline values may be progressively achieved in the long term through less capital-intensive non-treatment options, such as through agreements with land users to reduce application of chemicals (fertilizers, pesticides, etc.)

A qualitative ranking of treatment processes based on their degree of technical complexity is given in Table 8.6. The higher the ranking, the more complex the process in terms of plant or operation. In general, higher rankings are also associated with higher costs.

Annex 5 summarizes the treatment processes that are capable of removing chemical contaminants of health significance. The tables in Annex 5 include only those chemicals, by source category, for which some treatment data are available and for which guideline values have been established.

The tables in Annex 5 are provided to help inform decisions regarding the ability of existing treatment to meet guidelines and what additional treatment might need to be installed. They have been compiled on the basis of published literature, which includes mainly laboratory experiments, some pilot plant investigations and relatively few full-scale studies of water treatment processes. Consequently:

- Many of the treatments outlined are designed for larger treatment plants and may not necessarily be appropriate for smaller treatment plants or individual-type treatment. In these cases, the choice of technology must be made on a case-by-case basis.
- The information is probably "best case", as the data would have been obtained under laboratory conditions or with a carefully controlled plant for the purposes of experimentation.
- Actual process performance will depend on the concentration of the chemical in the raw water and on general raw water quality. For example, chlorination and removal of organic chemicals and pesticides using activated carbon or ozonation will be impaired if there is a high concentration of natural organic matter.
- For many contaminants, potentially several different processes could be appropriate, and the choice between processes should be made on the basis of technical complexity and cost, taking into account local circumstances. For example, membrane processes can remove a broad spectrum of chemicals, but simpler and cheaper alternatives are effective for the removal of most chemicals.
- It is normal practice to use a series of unit processes (e.g. coagulation, sedimentation, filtration, chlorination) to achieve desired water quality objectives. Each of these may contribute to the removal of chemicals. It may be technically and economically advantageous to use a combination of processes (e.g. ozonation plus granular activated carbon or membranes) to remove particular chemicals.
- The effectiveness of potential processes should be assessed using laboratory or pilot plant tests on the actual raw water concerned. These tests should be of sufficient duration to identify potential seasonal or other temporal variations in contaminant concentrations and process performance.
- These treatment technology characterizations are estimates and are not comprehensive, but are intended to provide some indications of the types of technologies that have shown greater or lesser capabilities for removing the indicated chemicals from drinking-water.

A brief description of the various treatment processes referred to in Table 8.6 is included in Annex 5.

8.4.2 Process control measures for disinfection by-products

All chemical disinfectants produce inorganic or organic DBPs that may be of concern.

The principal DBPs formed during chlorination are THMs, HAAs, haloketones and haloacetonitriles, as a result of chlorination of naturally occurring organic precursors such as humic substances. Monochloramine produces lower THM concentrations than chlorine but produces other DBPs, including cyanogen chloride.

In attempting to control DBP concentrations, it is of paramount importance that the efficiency of disinfection is not compromised and that a suitable residual level of disinfectant is maintained throughout the distribution system.

Chlorine and ozone oxidize bromide to produce hypohalous acids, which react with precursors to form brominated THMs. A range of other DBPs, including aldehydes and carboxylic acids, may also be formed. Of particular concern is bromate, formed by the oxidation of bromide. Bromate may also be present in some sources of hypochlorite, but usually at concentrations that will give rise to levels in final water that are below the guideline value.

The main by-products from the use of chlorine dioxide are chlorite ion, which is an inevitable decomposition product, and chlorate ion. Chlorate is also produced in hypochlorate as it ages.

The basic strategies that can be adopted for reducing the concentrations of DBPs are:

- changing the process conditions (including removal of precursor compounds prior to application);
- using a different chemical disinfectant with a lower propensity to produce by-products with the source water;
- using non-chemical disinfection;
- removing DBPs prior to distribution.

Changes to process conditions

The formation of THMs during chlorination can be reduced by removing precursors prior to contact with chlorine—for example, by installing or enhancing coagulation (this may involve using higher coagulant doses or lower coagulation pH values than are applied conventionally). DBP formation can also be reduced by lowering the applied chlorine dose; if this is done, it must be ensured that disinfection is still effective.

The pH value during chlorination affects the distribution of chlorinated by-products. Reducing the pH lowers the THM concentration, but at the expense of increased formation of HAAs. Conversely, increasing the pH reduces HAA production but leads to increased THM formation.

The formation of bromate during ozonation depends on several factors, including concentrations of bromide and ozone and the pH. It is not practicable to remove bromide from raw water, and it is difficult to remove bromate once formed, although granular activated carbon filtration has been reported to be effective under certain circumstances. Bromate formation can be minimized by using lower ozone dose, shorter contact time and a lower residual ozone concentration. Operating at lower pH (e.g. pH 6.5) followed by raising the pH after ozonation also reduces bromate formation, and addition of ammonia can also be effective. Addition of hydrogen peroxide can either increase or decrease bromate formation, depending on the point at which it is applied and local treatment conditions.

Changing disinfectants

It may be feasible to change disinfectant in order to achieve guideline values for DBPs. The extent to which this is possible will be dependent on the raw water quality and installed treatment (e.g. for precursor removal).

It may be effective to change from chlorine to monochloramine to provide a secondary disinfectant residual within distribution, in order to reduce THM formation and subsequent development within the distribution system. Although monochloramine provides a more stable residual within distribution, it is a less powerful disinfectant and should not be used as a primary disinfectant.

Chlorine dioxide can be considered as a potential alternative to both chlorine and ozone disinfection, although it does not provide a residual effect, as chlorine would. The main concerns with chlorine dioxide are with the residual concentrations of chlorine dioxide and the by-products chlorite and chlorate. These can be addressed by controlling the dose of chlorine dioxide at the treatment plant.

Non-chemical disinfection

Ultraviolet (UV) irradiation or membrane processes can be considered as alternatives to chemical disinfection. UV is particularly effective at inactivating *Cryptosporidium*, which is extremely resistant to chlorination. Neither of these provides any residual disinfection, and it may be considered appropriate to add a small dose of a persistent disinfectant such as chlorine or monochloramine to act as a preservative during distribution.

Removing DBPs prior to distribution

It is technically feasible to remove DBPs prior to distribution; however, this is the least attractive option for controlling DBP concentrations. Strategies for DBP control include source control, precursor removal, use of alternative disinfectants and removal of DBPs by technologies such as air stripping, activated carbon, UV light and advanced oxidation. These processes would need to be followed by a further disinfection step to guard against microbial contamination and to ensure a residual concentration of disinfectant within distribution.

8.4.3 Treatment for corrosion control

Corrosion is the partial dissolution of the materials constituting the treatment and supply systems, tanks, pipes, valves and pumps. In certain circumstances, all water can be corrosive. Corrosion may lead to structural failure, leaks, loss of capacity and deterioration of chemical and microbial water quality. The internal corrosion of pipes and fittings can have a direct impact on the concentration of water constituents, including lead and copper. Corrosion control is therefore an important aspect of the management of a drinking-water system for safety.

Corrosion control involves many parameters, including the concentrations of calcium, bicarbonate, carbonate and dissolved oxygen, as well as pH. The detailed requirements differ depending on water quality and the materials used in the distribution system. The pH controls the solubility and rate of reaction of most of the metal species involved in corrosion reactions. It is particularly important in relation to the

formation of a protective film at the metal surface. For some metals, alkalinity (carbonate and bicarbonate) and calcium (hardness) also affect corrosion rates.

Characterizing corrosivity

Most of the indices that have been developed to characterize the corrosion potential of waters are based on the assumption that water with a tendency to deposit a calcium carbonate scale on metal surfaces will be less corrosive. The Langelier index is the difference between the actual pH of a water and its "saturation pH", this being the pH at which a water of the same alkalinity and calcium hardness would be at equilibrium with solid calcium carbonate. Waters with a positive Langelier index are capable of depositing calcium carbonate scale from solution.

There is no corrosion index that applies to all materials, and corrosion indices, particularly those related to calcium carbonate saturation, have given mixed results. The parameters related to calcium carbonate saturation status are, strictly speaking, indicators of the tendency to deposit or dissolve calcium carbonate (calcite) scale, not indicators of the "corrosivity" of a water. For example, there are many waters with a negative Langelier index that are non-corrosive and many with a positive Langelier index that are corrosive. Nevertheless, there are many documented instances of the use of saturation indices for corrosion control based on the concept of laying down a protective "eggshell" scale of calcite in iron pipes. In general, waters with high pH, calcium and alkalinity are less corrosive, and this tends to be correlated with a positive Langelier index. However, these calcium carbonate precipitation indices are not necessarily considered to be good corrosion predictors for copper systems.

The ratio of the chloride and sulfate concentrations to the bicarbonate concentration (Larson ratio) has been shown to be helpful in assessing the corrosiveness of water to cast iron and steel. A similar approach has been used in studying zinc dissolution from brass fittings—the Turner diagram.

Water treatment for corrosion control

To control corrosion in water distribution networks, the methods most commonly applied are adjusting pH, increasing the alkalinity or hardness or adding corrosion inhibitors, such as polyphosphates, silicates and orthophosphates. The quality and maximum dose to be used should be in line with specifications for such water treatment chemicals. Although pH adjustment is an important approach, its possible impact on other aspects of water supply technology, including disinfection, must always be taken into account.

It is not always possible to achieve the desired values for all parameters. For example, the pH of hard waters cannot be increased too much, or softening will occur. The application of lime and carbon dioxide to soft waters can be used to increase both the calcium concentration and the alkalinity to at least 40 mg/l as calcium carbonate.

More detailed information on the corrosion of various metals commonly used in water treatment and distribution systems can be found in Annex 5.

8.4.4 Household treatment

The chemicals of greatest health concern in some natural waters are usually excess natural fluoride, nitrate/nitrite and arsenic.

Some commercial water treatment technologies are available for small applications for the removal of chemical contaminants. For example, anion exchange using activated alumina or iron-containing products will effectively reduce excess fluoride concentrations. Bone char has also been used to reduce fluoride concentrations. Arsenic is also removed by anion exchange processes similar to those employed for fluoride. Nitrates and nitrates, which are frequently present due to sewage contamination or agricultural runoff, are best managed by protecting the source water from contamination. They are difficult to remove, although disinfection will oxidize nitrite, the more toxic form, to nitrate. In addition, disinfection will sanitize the water and reduce the risk of gastrointestinal infection, which is a risk factor for methaemoglobinaemia caused by excess nitrate/nitrite exposure of infants up to approximately 3–6 months of age.

Cation exchange water softening is widely used in homes to remove excess hardness due to high calcium or magnesium, and it can also remove metals including iron and radium.

Synthetic and natural organic chemicals can be removed by granular activated carbon or carbon block technologies. The treatment systems must be well managed and replaced regularly, because their effectiveness is eventually lost, depending upon the types of contaminating chemicals and their concentrations in the water. Reverse osmosis technologies have general applicability for removal of most organic and inorganic chemicals; however, there is some selectivity, and also there is a significant amount of water wastage when low-pressure units are used in small-volume applications.

8.5 Guideline values for individual chemicals, by source category

8.5.1 Naturally occurring chemicals

There are a number of sources of naturally occurring chemicals in drinking-water. All natural water contains a range of inorganic and organic chemicals. The former derive from the rocks and soil through which water percolates or over which it flows. The latter derive from the breakdown of plant material or from algae and other microorganisms that grow in the water or on sediments. Most of the naturally occurring chemicals for which guideline values have been derived or that have been considered for guideline value derivation are inorganic. Only one, microcystin-LR, a toxin produced by cyanobacteria or blue-green algae, is organic. Cyanobacteria (see also section 11.5) occur widely in lakes, reservoirs, ponds and slow-flowing rivers. Many species are known to produce toxins, or "cyanotoxins", which are of concern for health. Cyanotoxins vary in structure and may be found within cells or released into water. There is wide variation in the toxicity of recognized cyanotoxins (including different structural variants within a group, such as microcystins), and it is likely that further toxins remain unrecognized, so control of blooms is the preferred control option.

The approach to dealing with naturally occurring chemicals will vary according to the nature of the chemical and the source. For inorganic contaminants that arise from rocks and sediments, it is important to screen possible water sources to determine whether the source is suitable for use or whether it will be necessary to treat the

Table 8.7 Naturally occurring chemicals for which guideline values have not been established

Chemical	Reason for not establishing a guideline value	Remarks
Bromide	Occurs in drinking-water at concentrations well below those of health concern	
Chloride	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Hardness	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Hydrogen sulfide	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Iron	Not of health concern at levels causing acceptability problems in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Manganese	Not of health concern at levels normally causing acceptability problems in drinking-water. However, there are circumstances where manganese may remain in solution at higher concentrations in some acidic or anaerobic waters, particularly groundwater	May affect acceptability of drinking-water (see chapter 10)
Molybdenum	Occurs in drinking-water at concentrations well below those of health concern	
pH	Not of health concern at levels found in drinking-water	An important operational water quality parameter
Potassium	Occurs in drinking-water at concentrations well below those of health concern	
Sodium	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Sulfate	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)
Total dissolved solids	Not of health concern at levels found in drinking-water	May affect acceptability of drinking-water (see chapter 10)

water to remove the contaminants of concern along with microbial contaminants. In some cases, where a number of sources may be available, dilution or blending of the water containing high levels of a contaminant with a water containing much lower levels may achieve the desired result.

A number of the most important chemical contaminants (i.e. those that have been shown to cause adverse health effects as a consequence of exposure through drinking-water) fall into the category of naturally occurring chemicals. Some naturally occurring chemicals have other primary sources and are therefore discussed in other sections of this chapter.

Guideline values have not been established for the naturally occurring chemicals listed in Table 8.7 for the reasons indicated in the table. Fact sheets are included in chapter 12.

Guideline values have been established for the naturally occurring chemicals listed in Table 8.8, which meet the criteria for inclusion. Fact sheets are included for each in chapter 12.

8.5.2 Chemicals from industrial sources and human dwellings

Chemicals from industrial sources can reach drinking-water directly from discharges or indirectly from diffuse sources arising from the use and disposal of materials and

Table 8.8 Guideline values for naturally occurring chemicals that are of health significance in drinking-water

Chemical	Guideline value		Remarks
	µg/l	mg/l	
Inorganic			
Arsenic	10 (A, T)	0.01 (A, T)	
Barium	1300	1.3	
Boron	2400	2.4	
Chromium	50 (P)	0.05 (P)	For total chromium
Fluoride	1500	1.5	Volume of water consumed and intake from other sources should be considered when setting national standards
Selenium	40 (P)	0.04 (P)	
Uranium	30 (P)	0.03 (P)	Only chemical aspects of uranium addressed
Organic			
Microcystin-LR	1 (P)	0.001 (P)	For total microcystin-LR (free plus cell-bound)

A, provisional guideline value because calculated guideline value is below the achievable quantification level; P, provisional guideline value because of uncertainties in the health database; T, provisional guideline value because calculated guideline value is below the level that can be achieved through practical treatment methods, source protection, etc.

products containing the chemicals. In some cases, inappropriate handling and disposal may lead to contamination (e.g. degreasing agents that are allowed to reach groundwater). Some of these chemicals, particularly inorganic substances, may also be encountered as a consequence of natural contamination, but this may also be a by-product of industrial activity, such as mining, that changes drainage patterns. Many of these chemicals are used in small industrial units within human settlements, and, particularly where such units are found in groups of similar enterprises, they may be a significant source of pollution. Petroleum oils are widely used in human settlements, and improper handling or disposal can lead to significant pollution of surface water and groundwater. Where plastic pipes are used, the smaller aromatic molecules in petroleum oils can sometimes penetrate the pipes where they are surrounded by earth soaked in the oil, with subsequent pollution of the local water supply.

A number of chemicals can reach water as a consequence of disposal of general household chemicals; in particular, a number of heavy metals may be found in domestic wastewater. Where wastewater is treated, these will usually partition out into the sludge. Some chemicals that are widely used both in industry and in materials used in a domestic setting are found widely in the environment (e.g. di(2-ethylhexyl)-phthalate), and these may be found in water sources, although usually at low concentrations.

Some chemicals that reach drinking-water from industrial sources or human settlements have other primary sources and are therefore discussed in other sections of this chapter. Where latrines and septic tanks are poorly sited, these can lead to contamination of drinking-water sources with nitrate (see section 8.5.3).

Identification of the potential for contamination by chemicals from industrial activities and human dwellings requires assessment of activities in the catchment and of

Table 8.9 Chemicals from industrial sources and human dwellings for which guideline values have not been established

Chemical	Reason for not establishing a guideline value
Beryllium	Rarely found in drinking-water at concentrations of health concern
Cyanide	Occurs in drinking-water at concentrations well below those of health concern, except in emergency situations following a spill to a water source
1,3-Dichlorobenzene	Available data inadequate to permit derivation of health-based guideline value
1,1-Dichloroethane	Available data inadequate to permit derivation of health-based guideline value
1,1-Dichloroethene	Occurs in drinking-water at concentrations well below those of health concern
Di(2-ethylhexyl)adipate	Occurs in drinking-water at concentrations well below those of health concern
Hexachlorobenzene	Occurs in drinking-water at concentrations well below those of health concern
Methyl tertiary-butyl ether	Any guideline that would be derived would be significantly higher than concentrations at which methyl tertiary-butyl ether would be detected by odour
Monochlorobenzene	Occurs in drinking-water at concentrations well below those of health concern, and health-based value would far exceed lowest reported taste and odour threshold
Nitrobenzene	Rarely found in drinking-water at concentrations of health concern
Petroleum products	Taste and odour will in most cases be detectable at concentrations below those of health concern, particularly with short-term exposure
Trichlorobenzenes (total)	Occur in drinking-water at concentrations well below those of health concern, and health-based value would exceed lowest reported odour threshold
1,1,1-Trichloroethane	Occurs in drinking-water at concentrations well below those of health concern

the risk that particular contaminants may reach water sources. The primary approach to addressing these contaminants is prevention of contamination by encouraging good practices. However, if contamination has occurred, then it may be necessary to consider the introduction of treatment.

Guideline values have not been established for the chemicals listed in Table 8.9 for the reasons indicated in the table. Fact sheets for each are included in chapter 12.

Guideline values have been established for the chemicals listed in Table 8.10, which meet all of the criteria for inclusion. Fact sheets for each are included in chapter 12.

8.5.3 Chemicals from agricultural activities

Chemicals are used in agriculture on crops and in animal husbandry. Nitrate may be present as a consequence of tillage when there is no growth to take up nitrate released from decomposing plants, from the application of excess inorganic or organic fertilizer and in slurry from animal production. Most chemicals that may arise from

Table 8.10 Guideline values for chemicals from industrial sources and human dwellings that are of health significance in drinking-water

Chemicals	Guideline value µg/l	Guideline value mg/l	Remarks
Inorganic			
Cadmium	3	0.003	
Mercury	6	0.006	For inorganic mercury
Organic			
Benzene	10[a]	0.01[a]	
Carbon tetrachloride	4	0.004	
1,2-Dichlorobenzene	1000 (C)	1 (C)	
1,4-Dichlorobenzene	300 (C)	0.3 (C)	
1,2-Dichloroethane	30[a]	0.03[a]	
1,2-Dichloroethene	50	0.05	
Dichloromethane	20	0.02	
Di(2-ethylhexyl)phthalate	8	0.008	
1,4-Dioxane	50[a]	0.05[a]	Derived using TDI approach as well as linear multistage modelling
Edetic acid	600	0.6	Applies to the free acid
Ethylbenzene	300 (C)	0.3 (C)	
Hexachlorobutadiene	0.6	0.0006	
Nitrilotriacetic acid	200	0.2	
Pentachlorophenol	9[a] (P)	0.009[a] (P)	
Styrene	20 (C)	0.02 (C)	
Tetrachloroethene	40	0.04	
Toluene	700 (C)	0.7 (C)	
Trichloroethene	20 (P)	0.02 (P)	
Xylenes	500 (C)	0.5 (C)	

C, concentrations of the substance at or below the health-based guideline value may affect the appearance, taste or odour of the water, leading to consumer complaints; P, provisional guideline value because of uncertainties in the health database

[a] For non-threshold substances, the guideline value is the concentration in drinking-water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional case of cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). Concentrations associated with estimated upper-bound excess lifetime cancer risks of 10^{-4} and 10^{-6} can be calculated by multiplying and dividing, respectively, the guideline value by 10.

agriculture are pesticides, although their presence will depend on many factors, and not all pesticides are used in all circumstances or climates. Contamination can result from application and subsequent movement following rainfall or from inappropriate disposal methods.

Some pesticides are also used in non-agricultural circumstances, such as the control of weeds on roads and railway lines. These pesticides are also included in this section.

Table 8.11 Chemicals from agricultural activities excluded from guideline value derivation

Chemical	Reason for exclusion
Amitraz	Degrades rapidly in the environment and is not expected to occur at measurable concentrations in drinking-water supplies
Chlorobenzilate	Unlikely to occur in drinking-water
Chlorothalonil	Unlikely to occur in drinking-water
Cypermethrin	Unlikely to occur in drinking-water
Deltamethrin	Unlikely to occur in drinking-water
Diazinon	Unlikely to occur in drinking-water
Dinoseb	Unlikely to occur in drinking-water
Ethylene thiourea	Unlikely to occur in drinking-water
Fenamiphos	Unlikely to occur in drinking-water
Formothion	Unlikely to occur in drinking-water
Hexachlorocyclohexanes (mixed isomers)	Unlikely to occur in drinking-water
MCPB[a]	Unlikely to occur in drinking-water
Methamidophos	Unlikely to occur in drinking-water
Methomyl	Unlikely to occur in drinking-water
Mirex	Unlikely to occur in drinking-water
Monocrotophos	Has been withdrawn from use in many countries and is unlikely to occur in drinking-water
Oxamyl	Unlikely to occur in drinking-water
Phorate	Unlikely to occur in drinking-water
Propoxur	Unlikely to occur in drinking-water
Pyridate	Not persistent and only rarely found in drinking-water
Pyriproxyfen	Unlikely to occur in drinking-water[b]
Quintozene	Unlikely to occur in drinking-water
Toxaphene	Unlikely to occur in drinking-water
Triazophos	Unlikely to occur in drinking-water
Tributyltin oxide	Unlikely to occur in drinking-water
Trichlorfon	Unlikely to occur in drinking-water

[a] 4-(4-chloro-o-tolyloxy)butyric acid.
[b] The use of pyriproxyfen as a larvicide for public health purposes is discussed further in section 8.6.

Guideline values have not been established for the chemicals listed in Table 8.11, as a review of the literature on occurrence or credibility of occurrence in drinking-water has shown evidence that the chemicals do not occur in drinking-water.

Guideline values have not been established for the chemicals listed in Table 8.12 for the reasons indicated in the table. However, health-based values and, in some

cases, acute health-based values have been developed for a number of these pesticides in order to provide guidance to Member States when there is a reason for local concern such as an emergency or spill situation (for further information on guideline values and health-based values, see section 8.2). Fact sheets for each are included in chapter 12.

Table 8.12 Chemicals from agricultural activities for which guideline values have not been established

Chemical	Reason for not establishing a guideline value
Ammonia	Occurs in drinking-water at concentrations well below those of health concern
Bentazone	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Carbaryl	Occurs in drinking-water at concentrations well below those of health concern
1,3-Dichloropropane	Available data inadequate to permit derivation of health-based guideline value
Dichlorvos	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Dicofol	Unlikely to occur in drinking-water or drinking-water sources[a]
Diquat	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Endosulfan	Occurs in drinking-water at concentrations well below those of health concern
Fenitrothion	Occurs in drinking-water at concentrations well below those of health concern
Glyphosate and AMPA[b]	Occur in drinking-water at concentrations well below those of health concern
Heptachlor and heptachlor epoxide	Occur in drinking-water at concentrations well below those of health concern
Malathion	Occurs in drinking-water at concentrations well below those of health concern
MCPA[c]	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Methyl parathion	Occurs in drinking-water at concentrations well below those of health concern
Parathion	Occurs in drinking-water at concentrations well below those of health concern
2-Phenylphenol and its sodium salt	Occurs in drinking-water at concentrations well below those of health concern
Propanil	Readily transformed into metabolites that are more toxic; a guideline value for the parent compound is considered inappropriate, and there are inadequate data to enable the derivation of guideline values for the metabolites

[a] Although dicofol does not fulfil one of the three criteria for evaluation in the Guidelines, a background document has been prepared, and a health-based value has been established, in response to a request from Member States for guidance.
[b] Aminomethylphosphonic acid.
[c] (2-Methyl-4-chlorophenoxy)acetic acid.

Guideline values have been established for the chemicals listed in Table 8.13, which meet the criteria for inclusion (see section 8.2). Fact sheets for each are included in chapter 12.

Guideline values and health-based values are protective against health effects resulting from lifetime exposure. Small exceedances for short periods would not normally constitute a health emergency. In the event of a spill, a higher allocation of the ADI to drinking-water could be justified. Alternatively, in cases where acute health-based values have been derived, normally based on JMPR evaluations, these may provide useful guidance (for further information, see section 8.7.5).

Routine monitoring of pesticides is generally not considered necessary. Member States should consider local usage and potential situations such as spills in deciding whether and where to monitor. In the event that monitoring results show levels above the guideline value or health-based value on a regular basis, it is advisable that a plan be developed and implemented to address the situation.

As a general principle, efforts should be made to keep the concentration of pesticides in water as low as possible, and to not allow concentrations to increase up to the guideline value or health-based value.

8.5.4 Chemicals used in water treatment or from materials in contact with drinking-water

Chemicals used in water treatment and chemicals arising from materials in contact with water may give rise to contaminants in the final water.

Some substances are deliberately added to water in the course of treatment (direct additives), some of which may be inadvertently retained in the finished water

Table 8.13 Guideline values for chemicals from agricultural activities that are of health significance in drinking-water

Chemical	Guideline value		Remarks
	µg/l	mg/l	
Non-pesticides			
Nitrate (as NO_3^-)	50 000	50	Based on short-term effects, but protective for long-term effects
Nitrite (as NO_2^-)	3 000	3	Based on short-term effects, but protective for long-term effects
Pesticides used in agriculture			
Alachlor	20[a]	0.02[a]	
Aldicarb	10	0.01	Applies to aldicarb sulfoxide and aldicarb sulfone
Aldrin and dieldrin	0.03	0.000 03	For combined aldrin plus dieldrin
Atrazine and its chloro-*s*-triazine metabolites	100	0.1	
Carbofuran	7	0.007	
Chlordane	0.2	0.000 2	
Chlorotoluron	30	0.03	
Chlorpyrifos	30	0.03	
Cyanazine	0.6	0.000 6	
2,4-D[b]	30	0.03	Applies to free acid
2,4-DB[c]	90	0.09	
1,2-Dibromo-3-chloropropane	1[a]	0.001[a]	
1,2-Dibromoethane	0.4[a] (P)	0.000 4[a] (P)	
1,2-Dichloropropane	40 (P)	0.04 (P)	
1,3-Dichloropropene	20[a]	0.02[a]	
Dichlorprop	100	0.1	
Dimethoate	6	0.006	
Endrin	0.6	0.000 6	
Fenoprop	9	0.009	
Hydroxyatrazine	200	0.2	Atrazine metabolite
Isoproturon	9	0.009	
Lindane	2	0.002	
Mecoprop	10	0.01	
Methoxychlor	20	0.02	
Metolachlor	10	0.01	

Table 8.13 (continued)

Chemical	Guideline value µg/l	Guideline value mg/l	Remarks
Molinate	6	0.006	
Pendimethalin	20	0.02	
Simazine	2	0.002	
2,4,5-T[d]	9	0.009	
Terbuthylazine	7	0.007	
Trifluralin	20	0.02	

P, provisional guideline value because of uncertainties in the health database

[a] For substances that are considered to be carcinogenic, the guideline value is the concentration in drinking-water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). Concentrations associated with estimated upper-bound excess lifetime cancer risks of 10^{-4} and 10^{-6} can be calculated by multiplying and dividing, respectively, the guideline value by 10.

[b] 2,4-Dichlorophenoxyacetic acid.

[c] 2,4-Dichlorophenoxybutyric acid.

[d] 2,4,5-Trichlorophenoxyacetic acid.

(e.g. salts, coagulant polymer residues or monomers). Chloramine and chlorine disinfectant residuals, for example, are deliberate additives, and their presence confers a benefit. Others, such as DBPs, are generated during chemical interactions between disinfectant chemicals and substances normally in water (Table 8.14). Chlorination by-products and other DBPs may also occur in swimming pools, from which exposure by inhalation and skin absorption will be of greater importance (WHO, 2006).

Other chemicals, such as lead or copper from pipes or brass taps and chemicals leaching from coatings, may be taken up from contact with surfaces during treatment or distribution (indirect or unintentional additives).

Some chemicals used in water treatment (e.g. aluminium) or in materials in contact with drinking-water (e.g. styrene) have other principal sources and are therefore discussed in detail in other sections of this chapter.

Many of these additives, both direct and indirect or unintentional, are components of processes for producing safe drinking-water. The approach to monitoring and management is preferably through control of the material or chemical. It is important to optimize treatment processes and to ensure that such processes remain optimized in order to control residuals of chemicals used in treatment and to control the formation of DBPs. Inadvertent contamination caused by poor quality materials is best controlled by applying specifications governing the composition of the products themselves rather than by setting limits on the quality of finished water, whereas contamination due to the inappropriate use of additives can be addressed by guidance on use. Similarly, regulations on the quality of pipe can avoid possible contamination of water by leachable materials. Control of contamination from in situ applied coatings requires suitable codes of practice on their application in addition to controls on the composition of materials.

Numerous national and third-party evaluation and approval systems for additives and materials for contact with drinking-water exist throughout the world; however,

Table 8.14 Disinfection by-products present in disinfected waters (based on IPCS, 2000)

Disinfectant	Significant organohalogen products	Significant inorganic products	Significant non-halogenated products
Chlorine/ hypochlorous acid (hypochlorite)	THMs, HAAs, haloaceto-nitriles, chloral hydrate, chloropicrin, chlorophenols, *N*-chloramines, halo-furanones, bromohydrins	Chlorate (mostly from hypochlorite use)	Aldehydes, cyanoalkanoic acids, alkanoic acids, benzene, carboxylic acids, *N*-nitrosodimethylamine
Chlorine dioxide		Reduced primarily to chlorite, chlorate and chloride in drinking-water, and to chlorite and chloride upon ingestion; the provisional guideline values for chlorite and chlorate are protective for potential toxicity from chlorine dioxide	Unknown
Chloramine	Haloacetonitriles, cyanogen chloride, organic chloramines, chloramino acids, chloral hydrate, haloketones	Nitrate, nitrite, chlorate, hydrazine	Aldehydes, ketones, *N*-nitrosodimethylamine
Ozone	Bromoform, monobromoacetic acid, dibromoacetic acid, dibromoacetone, cyanogen bromide	Chlorate, iodate, bromate, hydrogen peroxide, hypo-bromous acid, epoxides, ozonates	Aldehydes, ketoacids, ketones, carboxylic acids
Sodium dichloroisocyanurate	As for chlorine/ hypochlorous acid (hypochlorite)		Cyanuric acid

many countries do not have or operate such systems. Governments and other organizations should consider establishing or adapting additive management systems and setting product quality standards and guidance on use that would apply to determining acceptable water contact products. Ideally, harmonized standards between countries or reciprocal recognition would reduce costs and increase access to such standards (see also section 1.2.9).

Guideline values have not been established for the chemicals listed in Table 8.15 for the reasons indicated in the table. Fact sheets for each are included in chapter 12.

Guideline values have been established for the chemicals listed in Table 8.16, which meet the criteria for inclusion. Fact sheets for each are included in chapter 12.

Indicator substances for monitoring chlorination by-products

Although guideline values have been established for a number of chlorination by-products, data from drinking-water supplies indicate that THMs and HAAs are adequate as indicators of the majority of chlorination by-products. The most appro-

priate means of controlling chlorination by-products is to remove the organic precursors, which are largely of natural origin. Measurement of THMs and, if appropriate, HAAs (e.g. where water is chlorinated at a low pH) can be used to optimize treatment efficiency and to establish the boundaries of other operational parameters that can be used to monitor treatment performance. In these circumstances, monitoring frequencies of other chlorination by-products can be reduced. Although total organohalogen does not correlate well with either THMs or HAAs, it is a measure of total chlorination by-products and may be another potential indicator for operational purposes.

Table 8.15 Chemicals used in water treatment or materials in contact with drinking-water for which guideline values have not been established

Chemical	Reason for not establishing a guideline value
Disinfectants	
Chlorine dioxide	Reduced primarily to chlorite, chlorate and chloride in drinking-water, and to chlorite and chloride upon ingestion; the provisional guideline values for chlorite and chlorate are protective for potential toxicity from chlorine dioxide
Dichloramine	Available data inadequate to permit derivation of health-based guideline value
Iodine	Available data inadequate to permit derivation of health-based guideline value, and lifetime exposure to iodine through water disinfection is unlikely
Silver	Available data inadequate to permit derivation of health-based guideline value
Trichloramine	Available data inadequate to permit derivation of health-based guideline value
Disinfection by-products	
Bromochloroacetate	Available data inadequate to permit derivation of health-based guideline value
Bromochloroacetonitrile	Available data inadequate to permit derivation of health-based guideline value
Chloral hydrate	Occurs in drinking-water at concentrations well below those of health concern
Chloroacetones	Available data inadequate to permit derivation of health-based guideline values for any of the chloroacetones
2-Chlorophenol	Available data inadequate to permit derivation of health-based guideline value
Chloropicrin	Available data inadequate to permit derivation of health-based guideline value
Cyanogen chloride	Occurs in drinking-water at concentrations well below those of health concern
Dibromoacetate	Available data inadequate to permit derivation of health-based guideline value
2,4-Dichlorophenol	Available data inadequate to permit derivation of health-based guideline value
Formaldehyde	Occurs in drinking-water at concentrations well below those of health concern
Monobromoacetate	Available data inadequate to permit derivation of health-based guideline value
MX[a]	Occurs in drinking-water at concentrations well below those of health concern
Trichloroacetonitrile	Available data inadequate to permit derivation of health-based guideline value
Contaminants from treatment chemicals	
Aluminium	A health-based value of 0.9 mg/l could be derived, but this value exceeds practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants: 0.1 mg/l or less in large water treatment facilities and 0.2 mg/l or less in small facilities

Table 8.15 (continued)

Chemical	Reason for not establishing a guideline value
Contaminants from pipes and fittings	
Asbestos	No consistent evidence that ingested asbestos is hazardous to health
Dialkyltins	Available data inadequate to permit derivation of health-based guideline values for any of the dialkyltins
Fluoranthene[b]	Occurs in drinking-water at concentrations well below those of health concern
Inorganic tin	Occurs in drinking-water at concentrations well below those of health concern
Zinc	Not of health concern at levels found in drinking-water[c]

[a] 3-Chloro-4-dichloromethyl-5-hydroxy-2(5H)-furanone.
[b] See fact sheet on polynuclear aromatic hydrocarbons.
[c] May affect acceptability of drinking-water (see chapter 10).

Table 8.16 Guideline values for chemicals used in water treatment or materials in contact with drinking-water that are of health significance in drinking-water

	Guideline value[a]		
Chemical	**µg/l**	**mg/l**	**Remarks**
Disinfectants			
Chlorine	5 000 (C)	5 (C)	For effective disinfection, there should be a residual concentration of free chlorine of ≥ 0.5 mg/l after at least 30 min contact time at pH < 8.0. A chlorine residual should be maintained throughout the distribution system. At the point of delivery, the minimum residual concentration of free chlorine should be 0.2 mg/l.
Monochloramine	3 000	3	
Sodium dichloroisocyanurate	50 000	50	As sodium dichloroisocyanurate
	40 000	40	As cyanuric acid
Disinfection by-products			
Bromate	10[a] (A, T)	0.01[a] (A, T)	
Bromodichloromethane	60[a]	0.06[a]	
Bromoform	100	0.1	
Chlorate	700 (D)	0.7 (D)	
Chlorite	700 (D)	0.7 (D)	
Chloroform	300	0.3	
Dibromoacetonitrile	70	0.07	
Dibromochloromethane	100	0.1	
Dichloroacetate	50[a] (D)	0.05[a] (D)	
Dichloroacetonitrile	20 (P)	0.02 (P)	

Table 8.16 (continued)

Chemical	Guideline value[a] µg/l	mg/l	Remarks
Monochloroacetate	20	0.02	
N-Nitrosodimethylamine	0.1	0.0001	
Trichloroacetate	200	0.2	
2,4,6-Trichlorophenol	200[a] (C)	0.2[a] (C)	
Trihalomethanes			The sum of the ratio of the concentration of each to its respective guideline value should not exceed 1
Contaminants from treatment chemicals			
Acrylamide	0.5[a]	0.0005[a]	
Epichlorohydrin	0.4 (P)	0.0004 (P)	
Contaminants from pipes and fittings			
Antimony	20	0.02	
Benzo[*a*]pyrene	0.7[a]	0.0007[a]	
Copper	2000	2	Staining of laundry and sanitary ware may occur below guideline value
Lead	10 (A, T)	0.01 (A, T)	
Nickel	70	0.07	
Vinyl chloride	0.3[a]	0.0003[a]	

A, provisional guideline value because calculated guideline value is below the achievable quantification level; C. concentrations of the substance at or below the health-based guideline value may affect the appearance, taste or odour of the water, leading to consumer complaints; D, provisional guideline value because disinfection is likely to result in the guideline value being exceeded; P, provisional guideline value because of uncertainties in the health database; T, provisional guideline value because calculated guideline value is below the level that can be achieved through practical treatment methods, source control, etc.

[a] For substances that are considered to be carcinogenic, the guideline value is the concentration in drinking-water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional case of cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). Concentrations associated with estimated upper-bound excess lifetime cancer risks of 10^{-4} and 10^{-6} can be calculated by multiplying and dividing, respectively, the guideline value by 10.

In all circumstances, disinfection efficiency should not be compromised in trying to meet guidelines for DBPs, including chlorination by-products, or in trying to reduce concentrations of these substances.

Contaminants from storage and generation of hypochlorite solutions

Sodium hypochlorite solutions slowly decompose—more rapidly at warmer temperatures—to produce chlorate and chlorite ions. As the solution ages and the available chlorine concentration decreases, it is necessary to dose more product to achieve the desired residual chlorine concentration, with a consequent increase in the amounts of chlorate and chlorite added to the treated water. The decomposition of solid calcium hypochlorite is much slower, and consequently contamination is less likely to be significant. However, if calcium hypochlorite solutions are prepared and stored before use, then decomposition to form chlorate and chlorite would also occur.

Sodium hypochlorite is manufactured by electrolysing sodium chloride dissolved in water, which would naturally also contain small concentrations of sodium bromide. This results in the presence of bromate in the sodium hypochlorite solution and will contribute bromate to the treated water. The quality and acceptability of sodium hypochlorite will partly be a function of the concentration of the bromate residue. Industrial-grade product may not be acceptable for drinking-water applications. The sodium bromide naturally present in sodium chloride will also be oxidized to form bromate in systems using on-site electrochemical generation of hypochlorite.

Contaminants from use of ozone and chlorine dioxide

The use of ozone can lead to elevated bromate concentrations through oxidation of bromide present in the water. As a general rule, the higher the bromide concentration in the water, the more bromate that is produced.

Chlorine dioxide solutions can contain chlorate as a result of reactions that compete with the desired reaction for generation of chlorine dioxide. Chlorite ion is an inevitable decomposition product from the use of chlorine dioxide; typically, 60–70% of the applied dose is converted to chlorite in the treated water.

8.5.5 Chemicals of emerging concern

Pharmaceuticals

Pharmaceuticals can be introduced into water sources in sewage by excretion from individuals using these chemicals, from uncontrolled drug disposal (e.g. discarding drugs into toilets) and from agricultural runoff from livestock manure. They have become chemicals of emerging concern to the public because of their potential to reach drinking-water.

The specific types of pharmaceuticals and their metabolites in water sources can differ between countries or regions depending on social, cultural, technological and agricultural factors. Urban and rural areas may exhibit important differences in the occurrence and concentrations of these chemicals as a result of different usage patterns. The local physical and chemical characteristics of source waters can also affect the occurrence levels of pharmaceuticals by influencing their natural degradation.

Most occurrence data in drinking-water and source water have resulted from targeted investigations, rather than from systematic monitoring. Advancements in the sensitivity and accuracy of detection technologies and methodologies have led to increasing detection of trace amounts of pharmaceuticals, ranging from concentrations in the nanogram per litre to low microgram per litre range (although largely less than 0.1 μg/l) in drinking-water, surface water and groundwater. Higher concentrations of these contaminants are found in wastewater treatment effluents or wastewater discharges from poorly controlled manufacturing facilities.

The concentrations of pharmaceuticals found in drinking-water are typically orders of magnitude less than the lowest therapeutic doses. Therefore, exposure to individual compounds in drinking-water is unlikely to have appreciable adverse impacts on human health. Formal guideline values are therefore not proposed in these Guidelines.

Routine monitoring for pharmaceuticals in drinking-water and additional or specialized drinking-water treatment to reduce the concentrations of pharmaceuticals

in drinking-water are not considered necessary. However, where local circumstances indicate a potential for elevated concentrations of pharmaceuticals in drinking-water, investigative monitoring and surveys of impacted water sources can be undertaken to assess possible exposure. If undertaken, these surveys should be quality assured and should target pharmaceuticals that are of local significance—i.e. those that are commonly prescribed and used or manufactured locally. Based on the risk assessment, screening values can be developed to assess the potential risks from exposure through drinking-water, and possible control measures could be considered within the context of water safety plans. Practical difficulties with implementing monitoring programmes include lack of standardized sampling and analysis protocols, high costs and limited availability of technologies needed to detect the diverse range of pharmaceuticals that may be present.

Effective treatment of pharmaceuticals depends on the physicochemical properties of the specific compounds. Typically, conventional treatment processes are less effective than advanced treatment processes for the removal of many organic compounds, particularly those that are more water soluble.

Preventive measures, such as rational drug use and education of prescribers and the public to reduce disposal and discharges to the environment, will likely reduce human exposure.

Further information is available in *Pharmaceuticals in drinking-water* (see Annex 1).

8.6 Pesticides used in water for public health purposes

The control of insect vectors of disease (e.g. dengue fever) is vital in many countries, and there are occasions when vectors, particularly mosquitoes, breed in containers used for the storage and collection of drinking-water. Although actions should be taken to prevent access of vectors to or breeding of vectors in these containers, this is not always possible or may not always be fully effective, and use of mosquito larvicides may be indicated in certain settings.

WHOPES carries out evaluations of pesticides for public health uses. There are currently seven larvicidal compounds (diflubenzuron, methoprene, novaluron, pirimiphos-methyl, pyriproxyfen, spinosad and temephos) and a bacterial larvicide (*Bacillus thuringiensis israelensis*) that have been evaluated and listed by WHOPES for the control of container-breeding mosquitoes.

While it is not appropriate to set guideline values for pesticides used for vector control, it is valuable to provide information regarding their safety in use. Formulations of pesticides used for vector control in drinking-water should strictly follow the label recommendations and should only be those approved for such use by national authorities, taking into consideration the ingredients and formulants used in making the final product. In evaluating vector control pesticides for the Guidelines, an assessment is made of the potential exposure compared with the ADI. However, exceeding the ADI does not necessarily mean that this will result in adverse health effects. The diseases spread by vectors are significant causes of morbidity and mortality. It is therefore important to achieve an appropriate balance between the intake of the pesticide from drinking-water and the control of disease-carrying insects. It is stressed that every effort should be made to keep overall exposure and the concentration of

Table 8.17 Pesticides used for public health purposes for which guideline values have not been derived

Pesticide	Reason for not establishing a guideline value
Bacillus thuringiensis israelensis (Bti)	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Diflubenzuron	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Methoprene	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Novaluron	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Permethrin	Not recommended for direct addition to drinking-water as part of WHO's policy to exclude the use of any pyrethroids for larviciding of mosquito vectors of human disease
Pirimiphos-methyl	Not recommended for use for vector control in drinking-water
Pyriproxyfen	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Spinosad	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Temephos	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water

any larvicide no greater than that recommended by WHOPES and as low as possible commensurate with efficacy.

Member States should consider the use of larvicides within the context of their broad vector control strategy. The use of larvicides should be only part of a comprehensive management plan for household water storage and domestic waste management that does not rely exclusively on larviciding by insecticides, but also includes other environmental management measures and social behaviour change. Nevertheless, it would be valuable to obtain actual data on exposure to these substances under field conditions in order to carry out a more refined assessment of margins of exposure.

In addition to the use of larvicides approved for drinking-water application to control disease vector insects, other control measures should also be considered. For example, the stocking of fish of appropriate varieties (e.g. larvae-eating mosquitofish and predatory copepods) in water bodies may adequately control infestations and breeding of mosquitoes in those bodies. Other mosquito breeding areas where water collects should be managed by draining, especially after rainfall.

Those pesticides used for public health purposes for which guideline values have not been derived are listed in Table 8.17. Dichlorodiphenyltrichlorethane (DDT) has been used for public health purposes in the past. It is being reintroduced (but not for water applications) in some areas to control malaria-carrying mosquitoes. Its guideline value is shown in Table 8.18. A summary of the product formulations and dosage rates, with corresponding exposures, is provided in Table 8.19.

Fact sheets for all larvicides considered in the Guidelines are included in chapter 12.

Table 8.18 Guideline values for pesticides that were previously used for public health purposes and are of health significance in drinking-water

Pesticides previously used for public health purposes	Guideline value	
	µg/l	mg/l
DDT and metabolites	1	0.001

8.7 Identifying local actions in response to chemical water quality problems and emergencies

It is difficult to give comprehensive guidance concerning emergencies in which chemicals cause massive contamination of the drinking-water supply, caused either by accident or by deliberate action. Most of the guideline values recommended in these Guidelines (see section 8.5 and Annex 3) relate to a level of exposure that is regarded as tolerable throughout life. Acute toxic effects are considered for a limited number of chemicals. The length of time for which exposure to a chemical far in excess of the guideline value would have adverse effects on health will depend upon factors that vary from contaminant to contaminant. In an emergency situation, the public health authorities should be consulted about appropriate action.

The exceedance of a guideline value may not result in a significant or increased risk to health. Therefore, deviations above the guideline values in either the short or long term may not necessarily mean that the water is unsuitable for consumption. The amount by which, and the period for which, any guideline value can be exceeded without affecting public health depends upon the specific substance involved, and acceptability judgements need to be made by qualified health officials. However, exceedance should be a signal:

- as a minimum, to investigate the cause with a view to taking remedial action as necessary;
- to consult the authority responsible for public health for advice on suitable action, taking into account the intake of the substance from sources other than drinking-water, the toxicity of the substance, the likelihood and nature of any adverse effects and the practicality of remedial measures.

If a guideline value is to be exceeded by a significant amount or for more than a few days, it may be necessary to act rapidly so as to ensure that health protective action is taken and to inform consumers of the situation so that they can act appropriately.

The primary aim with regard to chemical contaminants when a guideline value is exceeded or in an emergency is to prevent exposure of the population to toxic concentrations of pollutants. However, in applying the Guidelines under such circumstances, an important consideration is that, unless there are appropriate alternative supplies of drinking-water available, maintenance of adequate quantities of water is a high priority. In the case of an incident in which chemical contaminants are spilt into a source water and enter a drinking-water supply or enter a supply through treatment or during distribution, the primary aim is to minimize the risk of adverse effects without unnecessarily disrupting the use of the water supply.

Table 8.19 WHO-recommended compounds and formulations for control of mosquito larvae in container habitats[a]

Insecticide	Formulation	Dosage (mg/l)[b]	ADI (mg/kg bw)	Exposure (mg/kg bw)[c]	Use in drinking-water
Bacillus thuringiensis israelensis (Bti)[d]	WG	1–5	—	Adult: 0.17 Child: 0.5 Infant: 0.75	Can be used at recommended doses
Diflubenzuron	DT, GR, WP	0.02–0.25	0–0.02	Adult: 0.008 Child: 0.025[e] Infant: 0.0375[e]	Can be used at recommended doses
Methoprene	EC	1	0–0.09	Adult: 0.033 Child: 0.1[e] Infant: 0.15[e]	Can be used at recommended doses
Novaluron	EC	0.01–0.05	0–0.01	Adult: 0.0017 Child: 0.005 Infant: 0.0075	Can be used at recommended doses
Pirimiphos-methyl	EC	1	0–0.03	Adult: 0.033 Child: 0.1[e] Infant: 0.15[e]	Not recommended for direct application to drinking-water
Pyriproxyfen	GR	0.01	0–0.1	Adult: 0.000 33 Child: 0.001 Infant: 0.0015	Can be used at recommended doses
Spinosad	DT, GR, SC	0.1–0.5[f]	0–0.02	Adult: 0.0017 Child: 0.0052 Infant: 0.0078	Can be used at recommended doses
Temephos	EC, GR	1	0.023[g]	Adult: 0.033 Child: 0.1[e] Infant: 0.15[e]	Can be used at recommended doses

bw, body weight; DT, tablet for direct application; EC, emulsifiable concentrate; GR, granule; SC, suspension concentration; WG, water dispersible granule; WP, wettable powder

[a] WHO recommendations on the use of pesticides in public health are valid only if linked to WHO specifications for their quality control. WHO specifications for public health pesticides are available at http://who.int/whopes/quality/en. Label instructions must always be followed when using insecticides.

[b] Active ingredient for control of container-breeding mosquitoes.

[c] Exposure at the maximum dosage in drinking-water for (a) a 60 kg adult drinking 2 litres of water per day, (b) a 10 kg child drinking 1 litre of water per day and (c) a 5 kg bottle-fed infant drinking 0.75 litre of water per day.

[d] Bti itself is not considered to pose a hazard to humans through drinking-water.

[e] Consideration should be given to using alternative sources of water for small children and bottle-fed infants for a period after application, where this is practical. However, exceeding the ADI will not necessarily result in adverse effects.

[f] The maximum concentration actually achieved with the slow-release formulation of spinosad was approximately 52 µg/l.

[g] This is a TDI rather than an ADI, as JMPR considered that the database was insufficiently robust to serve as the basis for establishing an ADI for temephos. For the purposes of these Guidelines, a TDI has been calculated from the lowest oral NOAEL in the critical study identified by JMPR.

Source: Adapted from WHO/TDR (2009)

This section of the Guidelines can be used to assist evaluation of the risks associated with a particular situation and—especially if a guideline value exists or an authoritative risk assessment is available from an alternative source—support appropriate decision-making on short- and medium-term actions. The approaches proposed provide a basis for discussion between various authorities and for judging the urgency of taking further action.

Normally, a specific review of the situation will be required and should call on suitable expertise. It is important to take local circumstances into account, including the availability of alternative water supplies and exposure to the contaminant from other sources, such as food. It is also important to consider what water treatment is applied or available and whether this will reduce the concentration of the substance.

Where the nature of contamination is unknown, expert opinion should be sought as quickly as possible to identify the contaminants, to determine what actions can be taken to prevent the contaminants from entering the supply and to minimize the exposure of the population and so minimize any potential for adverse effects.

A water safety plan should include planning for response to both predictable events and undefined "emergencies". Such planning facilitates rapid and appropriate response to events when they occur (see section 4.4).

Consideration of emergency planning and planning for response to incidents in which a guideline value is exceeded, covering both microbial and chemical contaminants, is discussed in section 4.4. Broader discussion of actions in emergency situations can be found in section 6.7 and, for microbial contamination, section 7.6.

8.7.1 Trigger for action

Triggers for action may include:

- detection of a spill by, or reporting of a spill to, the drinking-water supplier;
- an alarm raised by the observation of items, such as chemical drums, adjacent to a vulnerable part of the drinking-water supply;
- the detection of a substance in the water;
- a sudden change to water treatment;
- consumer complaints (e.g. an unusual odour, taste or discoloration).

8.7.2 Investigating the situation

Each incident is unique, and it is therefore important to determine associated facts, including what the contaminant is; what the likely concentration is, and by how much the guideline value has been exceeded, if at all; and the potential duration of the incident. These are important in determining the actions to be taken.

8.7.3 Talking to the right people

In any emergency, it is important that there be good communication between the various authorities, particularly the water supplier and health authorities. It will usually be the health authorities that make the final decisions, but knowledge of the water supply and the nature of the supply is vital in making the most appropriate decisions.

In addition, timely and clear communication with consumers is a vital part of successfully handling drinking-water problems and emergencies.

Liaison with key authorities is discussed in section 4.4. It is particularly important to inform the public health authority of any exceedance or likely exceedance of a guideline value or other conditions likely to affect human health and to ensure that the public health authority is involved in decision-making. In the event of actions that require all consumers to be informed or where the provision of temporary supplies of drinking-water is appropriate, civil authorities should also be involved. Planning for these actions is an important part of the development of water safety plans. Involving the public health authorities at an early stage enables them to obtain specialist information and to make the appropriate staff available.

8.7.4 Informing the public

Consumers may be aware of a potential problem with the safety of their drinking-water because of media coverage, their own senses or informal networks. Lack of confidence in the drinking-water or the authorities may drive consumers to alternative, potentially less safe sources. Not only do consumers have a right to information on the safety of their drinking-water, but they have an important role to play in assisting the authorities in an incident by their own actions and by carrying out the necessary measures at the household level. Trust and goodwill from consumers are extremely important in both the short and long term.

The health authorities should be involved whenever a decision to inform the public of health-based concerns or advice to adopt health protection measures such as boiling of water may be required. Such guidance needs to be both timely and clear.

8.7.5 Evaluating the significance to public health and individuals

In assessing the significance of an exceedance of a guideline value, account should be taken of:

- information underpinning the guideline value derivation;
- local exposure to the substance of concern through other routes (e.g. food);
- any sensitive subpopulations;
- locally relevant protective measures to prevent the chemical from entering the source water or supply in the case of a spill.

Information underpinning guideline value derivation

The derivation of guideline values for chemical contaminants is described in section 8.2.

Most guideline values are derived by calculating a TDI or using an existing TDI or ADI. A proportion of the TDI or ADI is then allocated to drinking-water to make allowance for exposure from other sources, particularly food. This allocation is often 20%, but it may be as low as 1% or as high as 80%. In many circumstances, a review of likely local sources of exposure may identify that sources other than drinking-water are less significant than assumed and that a larger proportion of total exposure can be safely allocated to drinking-water. The fact sheets in chapter 12 and background documents on all chemicals addressed in these Guidelines (http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/en/) provide further

information on likely sources of the chemicals concerned, including their allocation factors. When rapid decision-making is required for such chemicals, it is possible to allow 100% of the TDI to come from drinking-water for a short period (e.g. a few days) while undertaking a more substantive review. In the event that there is significant exposure from other sources or exposure is likely to be for more than a few days, then it is possible to allocate more than the allocation used in the guideline value derivation, but no more than 100%.

In some cases, the guideline value is derived from epidemiological or clinical studies in humans. In most cases (e.g. benzene, barium), these relate to long-term exposure, and short-term exposure to concentrations higher than the guideline value are unlikely to be of significant concern; however, it is important to seek expert advice. In other cases of guideline values derived from epidemiological studies, the associated health effects are acute in nature. For example:

- The guideline value for nitrate is 50 mg/L, (as nitrate ion), to be protective of the health of the most sensitive subpopulation, bottle-fed infants. This guideline value is based on the absence of adverse health effects (methaemoglobinaemia and thyroid effects) at concentrations below 50 mg/L in epidemiological studies. Although the guideline value is based on short-term effects, it is protective for long-term effects and in other population groups, such as older children and adults. Methaemoglobinaemia is complicated by the presence of microbial contamination and subsequent gastrointestinal infection, which can increase the risk for this group significantly. Authorities should therefore be all the more vigilant that water to be used for bottle-fed infants is microbiologically safe when nitrate is present at concentrations near or above the guideline value. It is also particularly important to ensure that these infants are not currently exhibiting symptoms of gastrointestinal infection (diarrhoea). In addition, because excessive boiling of water to ensure microbiological safety can concentrate levels of nitrate in the water, care should be taken to ensure that water is heated only until the water reaches a rolling boil. In extreme situations, alternative sources of water (e.g. bottled water) can be used.
- The guideline value for copper is also based on short-term exposure but is intended to protect against direct gastric irritation, which is a concentration-dependent phenomenon. The guideline value may be exceeded, but there will be an increasing risk of consumers suffering from gastrointestinal irritation as the concentration increases above the guideline value. The occurrence of such irritation can be assessed in exposed populations.

In some cases, the guideline value is derived from a cancer risk estimate derived from studies in laboratory animals. In these cases, short-term (a few months to a year) exposure to concentrations up to 10 times the guideline value would result in only a small increase in estimated risk of cancer. Because the estimate of risk varies over a wide range, there may be no, or a very small, increase in risk. In such a circumstance, accepting a 10-fold increase in the guideline value for a short period would have no discernible impact on the risk over a lifetime. However, care would be needed

to determine whether other toxicological end-points more relevant for short-term exposure, such as neurotoxicity, would become significant.

Health-based values for short-term exposures are now being developed for a small number of substances that are used in significant quantities and are frequently implicated in an emergency as a consequences of spills, usually to surface water sources. The methodology used in the derivation of these health-based values is described below.

Health-based values for use in emergencies

Health-based values for acute and short-term exposures (called acute and short-term health-based values) can be derived for any chemicals that are used in significant quantities and are involved in an emergency, such as a spill into surface water sources.

JMPR has provided guidance on the setting of acute reference doses (ARfDs) for pesticides (Solecki et al., 2005). These ARfDs can be used as a basis for deriving acute health-based values for pesticides in drinking-water, and the general guidance can also be applied to derive ARfDs for other chemicals. The JMPR ARfD is usually established to cover the whole population, and must be adequate to protect the embryo or fetus from possible in utero effects. An ARfD based on developmental (embryo/fetal) effects, which applies to women of childbearing age only, may be conservative and not relevant to other population subgroups.[1]

The ARfD can be defined as the amount of a chemical, normally expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer. Most of the scientific concepts applicable to the setting of ADIs or TDIs for chronic exposure apply equally to the setting of ARfDs. The toxicological end-points most relevant for a single or 1-day exposure should be selected. For ARfDs for pesticides, possible relevant end-points include haematotoxicity (including methaemoglobin formation), immunotoxicity, acute neurotoxicity, liver and kidney toxicity (observed in single-dose studies or early in repeated-dose studies), endocrine effects and developmental effects. The most relevant or adequate study in which these end-points have been determined (in the most sensitive species or most vulnerable subgroup) is selected, and NOAELs are established. The most relevant end-point providing the lowest NOAEL is then used in the derivation of the ARfD. Uncertainty factors are used to extrapolate from experimental animal data to the average human and to allow for variation in sensitivity within the human population. An ARfD derived in such a manner can then be used to establish an acute health-based value by allocating 100% of the ARfD to drinking-water, as follows:

$$\text{Acute health-based value} = \frac{\text{ARfD} \times \text{bw} \times \text{P}}{\text{C}}$$

where:

- bw = body weight (60 kg for adult, 10 kg for children, 5 kg for infants)
- P = fraction of the ARfD allocated to drinking-water (100%)
- C = daily drinking-water consumption (2 L for adults, 1 L for children, 0.75 L for bottle-fed infants)

However, available data sets do not allow the accurate evaluation of the acute toxicity for a number of compounds of interest. If appropriate single-dose or short-term data are lacking, an end-point from a repeated-dose toxicity study can be used. This is likely to be a more conservative approach, and this should be clearly stated in the health-based value derivation.

[1] ARfDs established for pesticides by JMPR may be found at http://apps.who.int/pesticide-residues-jmpr-database.

When a substance has been spilt into a drinking-water source, contamination may be present for a period longer than 24 hours, but is not usually present for longer than a few days. Under these circumstances, the use of data from repeated-dose toxicity studies is appropriate to derive a short-term health-based value (using the approach outlined in section 8.2.2). As the period of exposure used in these studies will often be much longer than a few days, this, too, is likely to be a conservative approach.

Where there is a need for a rapid response, and suitable data are not available to establish an ARfD but a guideline value or health-based value is available for the chemical of concern, a pragmatic approach would be to allocate a higher proportion of the ADI or TDI to drinking-water. As the ADI or TDI is intended to be protective of lifetime exposure, small exceedances of the ADI or TDI for short periods will not be of significant concern for health. In these circumstances, it would be reasonable to allow 100% of the ADI or TDI to come from drinking-water for a short period.

Assessing locally relevant sources of the substance of concern through other routes of exposure

The most useful sources of information regarding local exposure to substances through food and, to a lesser extent, air and other environmental routes are usually government departments dealing with food and environmental pollution. Other sources of information may include universities. In the absence of specific data, the Guidelines background documents consider the sources of exposure and give a generic assessment that can be used to make a local evaluation as to the potential use of a chemical and whether this would be likely to enter the food-chain. Further information is available in the supporting document *Chemical safety of drinking-water* (Annex 1).

Sensitive subpopulations

In some cases, there may be a specific subpopulation that is at greater risk from a substance than the rest of the population. These usually relate to high exposure relative to body weight (e.g. bottle-fed infants) or a particular sensitivity (e.g. fetal haemoglobin and nitrate/nitrite). However, some genetic subpopulations may show greater sensitivity to particular toxicity (e.g. glucose-6-phosphate dehydrogenase–deficient groups and oxidative stress on red blood cells). If the potential exposure from drinking-water in an incident is greater than the ADI or TDI or exposure is likely to be extended beyond a few days, then this would require consideration in conjunction with health authorities. In such circumstances, it may be possible to target action to avoid exposure of the specific group concerned, such as supplying bottled water for bottle-fed infants.

Specific mitigation measures affecting risk assessment

Such measures relate to actions taken locally or on a household basis that can have an impact on the presence of a particular contaminant. For example, the presence of a substance that is volatile or heat labile will be affected by heating the water for cooking or the preparation of beverages. Where such measures are routinely undertaken by the exposed population, the risk assessment may be modified accordingly. Alternatively,

such steps can be used on a household basis to reduce exposure and allow the continued use of the supply without interruption.

8.7.6 Determining appropriate action

Determining appropriate action means that various risks will need to be balanced. The interruption of water supply to consumers is a serious step and can lead to

risks associated with contamination of drinking-water stored in the household with pathogens and limiting use for purposes of hygiene and health protection. Issuing a "do not drink" notice may allow the use of the supply for hygiene purposes such as showering or bathing, but creates pressure on consumers and authorities to provide a safe alternative for drinking and cooking. In some cases, this option will be expensive and could divert resources from other, more important issues. Appropriate action will always be decided on a case-by-case basis in conjunction with other authorities, including the health protection and civil authorities, who may be required to participate in informing consumers, delivering alternative supplies or supervising the collection of water from bowsers and tankers. Responding to a potential risk to health from a chemical contaminant should not lead to an increase in overall health risk from disruption of supply, microbial contaminants or other chemical contaminants.

8.7.7 Consumer acceptability

Even though, in an emergency, supplying water that contains a substance present at higher concentrations than would normally be desirable may not result in an undue risk to health, the water may not be acceptable to consumers. A number of substances that can contaminate drinking-water supplies as a consequence of spills can give rise to severe problems with taste or odour. Under these circumstances, drinking-water may become so unpalatable as to render the water undrinkable or to cause consumers to turn to alternative drinking-water sources that may present a greater risk to health. In addition, water that is clearly contaminated may cause some consumers to feel unwell due to a perception of poor water quality. Consumer acceptability may be the most important factor in determining the advice given to consumers about whether or not the water should be used for drinking or cooking.

8.7.8 Ensuring remedial action, preventing recurrence and updating the water safety plan

The recording of an incident, the decisions taken and the reasons for them are essential parts of handling an incident. The water safety plan, as discussed in chapter 4, should be updated in the light of experience. This would include making sure that problem areas identified during an incident are corrected. Where possible, it would also mean that the cause of the incident is dealt with to prevent its recurrence. For example, if the incident has arisen as a consequence of a spill from industry, the source of the spill can be advised as to how to prevent another spill and the information passed on to other similar industrial establishments.

8.7.9 Mixtures

A spill may contain more than one contaminant of potential health concern (see section 8.2.8). Under these circumstances, it will be important to determine whether the substances present interact. Where the substances have a similar mechanism or mode of action, it is appropriate to consider them as additive. This may be particularly true of some pesticides, such as atrazine and simazine. In these circumstances,

appropriate action must take local circumstances into consideration. Specialist advice should generally be sought.

8.7.10 Water avoidance advisories

Water avoidance advisories share many features with boil water advisories (see section 7.6.1), but are less common. Like boil water advisories, they are a serious measure that should be instituted only when there is evidence that an advisory is necessary to reduce a substantial public health risk. In cases where alternative sources of water are recommended, particular consideration should be given to the potential for microbial hazards in those alternative sources. Water avoidance advisories are applied when the parameter of concern is not susceptible to boiling or when risks from dermal contact or inhalation of the contaminant are also significant. Water avoidance advisories may also be issued when an unknown agent or chemical substance is detected in the distribution system. It is important that the water avoidance advisories include the information that boiling is ineffective or insufficient to reduce the risk.

As with the case of boil water advisories, water suppliers in conjunction with public health authorities should develop protocols for water avoidance advisories. Protocols should be prepared before any incident occurs and incorporated within water safety plans. Decisions to issue advisories are often made within a short period of time, and developing responses during an event can complicate decision-making, compromise communication and undermine public confidence.

In addition to the information discussed in section 4.4.3, the protocols should provide information to the general public and specific groups on the following:

- criteria for issuing and rescinding an advisory;
- activities impacted by the advisory;
- alternative sources of safe water for drinking and other domestic uses.

Protocols should identify mechanisms for the communication of water avoidance advisories. The mechanisms may vary, depending on the nature of the supply and the size of the community affected, and could include:

- media releases through television, radio and newspapers;
- telephone, e-mail and fax contact of specific facilities, community groups and local authorities;
- posting of notices in conspicuous locations;
- personal delivery;
- mail delivery.

The methods chosen should provide a reasonable assurance that all of those affected by the advisory, including residents, workers and travellers, are notified as soon as possible.

The issuing of a water avoidance advisory may be necessary, for example, following contamination—for example, chemical or radiological—as a result of accidental, natural or malicious origin that leads to:

- a significant exceedance of a guideline value, which may pose a threat to health from short-term exposure;

- concentrations of a chemical with no guideline value that may pose a threat to health from short-term exposure;
- significant odour or taste that has no identified source or that will give rise to significant public anxiety.

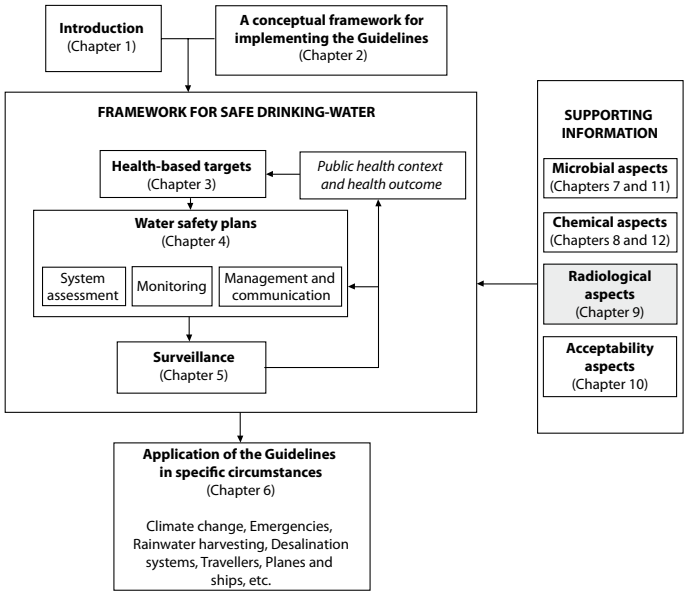
When issued, water avoidance advisories should provide information on the same issues included in boil water advisories (see section 7.6.1), although recommendations relating to affected uses and users will vary, depending on the nature of the problem. For example, for elevated concentrations of contaminants that are of concern only from a drinking or cooking perspective, the public could be advised to avoid using the water for drinking, food preparation, preparing cold drinks, making ice and hygienic uses, such as tooth brushing. Where the advisory applies to elevated levels of chemicals that can cause skin or eye irritation or gastrointestinal upsets, the public could be advised not to use the water for drinking, cooking, tooth brushing or bathing/showering. Alternatively, specific water avoidance advice might be issued where the contamination might affect subgroups of the population—for example, pregnant women or bottle-fed infants.

As for boil water advisories, specific advice may need to be issued for dentists, doctors, hospitals and other health-care facilities, child-care facilities, schools, food suppliers and manufacturers, hotels, restaurants and operators of public swimming pools.

Water avoidance advisories do not equate to cessation of supply; water will generally be suitable for flushing toilets and other uses, such as clothes washing. However, suitable alternative supplies of drinking-water, such as bottled water and carted or tankered water, will be required for drinking and other domestic uses.

Criteria for rescinding water avoidance advisories will generally be based on evidence that the source of elevated concentrations of hazardous contaminants has been removed, that distribution systems have been appropriately flushed and that the water is safe for drinking and other uses. In buildings, the flushing would extend to storages and internal plumbing systems.

9
Radiological aspects



Drinking-water may contain radioactive substances ("radionuclides") that could present a risk to human health. These risks are normally small compared with the risks from microorganisms and chemicals that may be present in drinking-water. Except in extreme circumstances, the radiation dose resulting from the ingestion of radionuclides in drinking-water is much lower than that received from other sources of radiation. The objective of this chapter is to provide criteria with which to assess the safety of drinking-water with respect to its radionuclide content and to provide guidance on reducing health risks by taking measures to decrease radionuclide concentrations, and therefore radiation doses, in situations where this is considered necessary.

In terms of health risk assessment, the Guidelines do not differentiate between radionuclides that occur naturally and those that arise from human activities. However, in terms of risk management, a differentiation is made because, in principle, human-made radionuclides are often controllable at the point at which they enter the water supply. Naturally occurring radionuclides, in contrast, can potentially enter the water supply at any point, or at several points, prior to consumption. For this reason, naturally occurring radionuclides in drinking-water are often less amenable to control.

Naturally occurring radionuclides in drinking-water usually give radiation doses higher than those provided by artificially produced radionuclides and are therefore of greater concern. Radiological risks are best controlled through a preventive risk management approach following the framework for safe drinking-water (see chapter 2) and the water safety plan approach (see chapter 4). When considering what action to take in assessing and managing radiological risks, care should be taken to ensure that scarce resources are not diverted away from other, more important public health concerns.

The screening levels and guidance levels for radioactivity presented in these Guidelines are based on the latest recommendations of the International Commission on Radiological Protection (ICRP, 2008).

Some drinking-water supplies, in particular those sourced from groundwater, may contain radon, a radioactive gas. Although radon can enter indoor air in buildings through its release from water from taps or during showering, the most significant source of radon in indoor air arises through natural accumulation from the environment. An evaluation of international research data (UNSCEAR, 2000) has concluded that, on average, 90% of the dose attributable to radon in drinking-water comes from inhalation rather than ingestion. Consequently, the setting of screening levels and guidance levels to limit the dose from ingestion of radon contained in drinking-water is not usually necessary. The screening measurements for gross alpha and gross beta activities will include the contribution from radon progeny, which is the principal source of dose from ingestion of radon present in drinking-water supplies. This is further discussed in section 9.7.

9.1 Sources[1] and health effects of radiation exposure

Radioactivity from several naturally occurring and human-made sources is present throughout the environment. Some chemical elements present in the environment are naturally radioactive. These are found in varying amounts in soils, water, indoor and outdoor air and even within our bodies, and so exposure to them is inevitable. In addition, Earth is constantly bombarded by high-energy particles originating both from the sun and from outside the solar system. Collectively, these particles are referred to as cosmic radiation. Everybody receives a dose from cosmic radiation, which is influenced by latitude, longitude and height above sea level.

The use of radiation in medicine for diagnosis and treatment is the largest human-made source of radiation exposure today. The testing of nuclear weapons, routine discharges from industrial and medical facilities and accidents such as Chernobyl have added human-made radionuclides to our environment.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 2008) has estimated that the global average annual dose per person from all sources of radiation in the environment is approximately 3.0 mSv/year (see Box 9.1). Of this, 80% (2.4 mSv) is due to naturally occurring sources of radiation, 19.6% (almost 0.6 mSv) is due to the use of radiation for medical diagnosis and the remaining 0.4%

[1] When the term "source" appears in this chapter without any other reference, it is used in the context of "radiation source". For any other purpose, additional information is provided (e.g. "water source").

Box 9.1 Key terms, quantities and units

Becquerel (Bq)—The becquerel is the unit of radioactivity in the International System of Units (abbreviated SI from the French *Système international d'unités*), corresponding to one radioactive disintegration per second. In the case of drinking-water, it is usual to talk about the activity concentration, expressed in units of Bq/l.

Effective dose—When radiation interacts with body tissues and organs, the radiation dose received is a function of factors such as the type of radiation, the part of the body affected and the exposure pathway. This means that 1 Bq of radioactivity will not always deliver the same radiation dose. A unit called "effective dose" has been developed to take account of the differences between different types of radiation so that their biological impacts can be compared directly. The effective dose is expressed in SI units called sieverts (Sv). The sievert is a very large unit, and it is often more practical to talk in terms of millisieverts (mSv). There are 1000 mSv in 1 Sv.

Effective half-life—Radioisotopes have a "physical" half-life, which is the period of time it takes for one half of the atoms to disintegrate. Physical half-lives for various radioisotopes can range from a few microseconds to billions of years. When a radioisotope is present in a living organism, it may be excreted. The rate of this elimination is influenced by biological factors and is referred to as the "biological" half-life. The effective half-life is the actual rate of halving the radioactivity in a living organism as determined by both the physical and biological half-lives. Whereas for certain radionuclides, the biological processes are dominant, for others, physical decay is the dominant influence.

(around 0.01 mSv) is due to other sources of human-made radiation (see Figure 9.1). There can be large variability in the dose received by individual members of the population, depending on where they live, their dietary preferences and other lifestyle choices. Individual radiation doses can also differ depending on medical treatments and occupational exposures. Annual average doses and typical ranges of individual doses from naturally occurring sources are presented in Table 9.1 (UNSCEAR, 2008).

9.1.1 Radiation exposure through ingestion of drinking-water

Water sources can contain radionuclides of natural and artificial origin (i.e. human-made):

- Natural radionuclides, including potassium-40, and those of the thorium and uranium decay series, in particular radium-226, radium-228, uranium-234, uranium-238 and lead-210, can be found in water as a result of either natural processes (e.g. absorption from the soil) or technological processes involving naturally occurring radioactive materials (e.g. the mining and processing of mineral sands or phosphate fertilizer production).
- Human-made radionuclides may be present in water from several sources, such as
  - — radionuclides discharged from nuclear fuel cycle facilities;
  - — manufactured radionuclides (produced and used in unsealed form in medicine or industry) entered into drinking-water supplies as a result of regular or incidental discharges;
  - — radionuclides released in the past into the environment, including drinking-water sources.

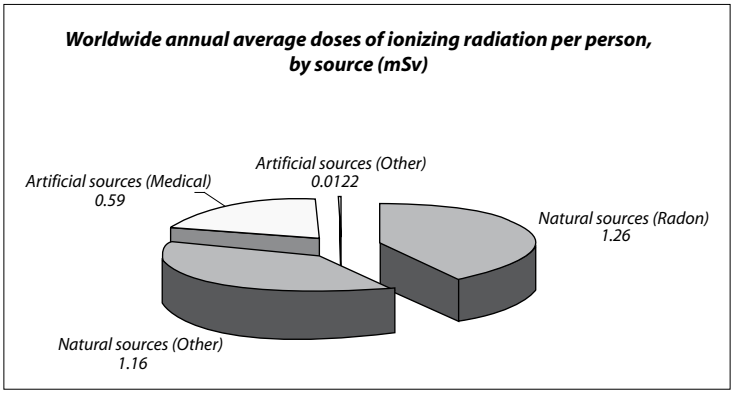


Figure 9.1 Distribution of average radiation exposure for the world population

Table 9.1 Average radiation dose from naturally occurring sources

Source	Worldwide average annual effective dose (mSv)	Typical annual effective dose range (mSv)
External exposure		
Cosmic rays	0.39	0.3–1[a]
Terrestrial radiation (outdoors and indoors)	0.48	0.3–1[b]
Internal exposure		
Inhalation (mainly radon)	1.26	0.2–10[c]
Ingestion (food and drinking-water)	0.29	0.2–1[d]
Total	**2.4**	**1–13**

[a] Range from sea level to high ground elevation.
[b] Depending on radionuclide composition of soil and building material.
[c] Depending on indoor accumulation of radon gas.
[d] Depending on radionuclide composition of foods and drinking-water.
Source: Adapted from UNSCEAR (2008)

9.1.2 Radiation-induced health effects through drinking-water

Radiation protection is based on the assumption that any exposure to radiation involves some level of risk. For prolonged exposures, as is the case for ingestion of drinking-water containing radionuclides over extended periods of time, evidence of an increased cancer risk in humans is available at doses above 100 mSv (Brenner et al., 2003). Below this dose, an increased risk has not been identified through epidemiological studies. It is assumed that there is a linear relationship between exposure and risk, with no threshold value below which there is no risk. The individual dose criterion (IDC) of 0.1 mSv/year represents a very low level of risk that is not expected to give rise to any detectable adverse health effect.

Box 9.2 Radiation exposure situations

The ICRP (2008) distinguishes between three types of radiation exposure situations—planned, existing and emergency exposure situations:

- A ***planned exposure*** situation is a situation that arises from the planned operation of a radiation source or from a planned activity that results in an exposure to a radiation source (e.g. exposure to a radiation source during a medical procedure for diagnosis or treatment).
- An ***existing exposure*** situation is a situation that already exists when a decision on the need for control has to be taken (e.g. exposure to indoor radon in dwellings).
- An ***emergency exposure*** situation is a situation that arises as a result of an accident, a malicious act or any other unexpected event. The present Guidelines do not apply during emergency exposure situations (see chapter 6).

Box 9.3 Individual dose criterion (IDC) and health risks

The additional risk to health from exposure to an annual dose of 0.1 mSv associated with the intake of radionuclides from drinking-water is considered to be low for the following reasons:

- Individual doses from natural radioactivity in the environment vary widely. The average is about 2.4 mSv/year, but in some parts of the world, average doses can be up to 10 times higher (i.e. 24 mSv/year) without any observed increase in health risks, as noted in long-term population studies (Tao, 2000; Nair et al., 2009). An IDC of 0.1 mSv/year therefore represents a small addition to natural levels.
- The nominal risk coefficient for radiation-induced cancer incidence is 5.5×10^{-2}/Sv (ICRP, 2008). Multiplying this by an IDC of 0.1 mSv/year from drinking-water gives an estimated annual cancer risk of approximately 5.5×10^{-6}.

9.2 Rationale for screening levels and guidance levels

The current Guidelines are based on the approach proposed by the ICRP in situations of prolonged radiation exposure of the public. According to the ICRP, in planned exposure situations (see Box 9.2), it is prudent to restrict the prolonged component of the individual dose to 0.1 mSv in any given year (ICRP, 2000). It is recognized that exposure to radionuclides in drinking-water may be a consequence of a planned exposure situation, but is more likely to be from an existing exposure situation. Rather than adopt a different approach depending on whether or not the radionuclides are naturally occurring or human-made, a pragmatic and conservative approach was adopted, with an IDC of 0.1 mSv from 1 year's consumption of drinking-water, regardless of the origin of the radionuclides (see Box 9.3).

Screening levels and guidance levels are conservative and should not be interpreted as mandatory limits. Exceeding a guidance level should be taken as a trigger for further investigation, but not necessarily as an indication that the drinking-water is unsafe.

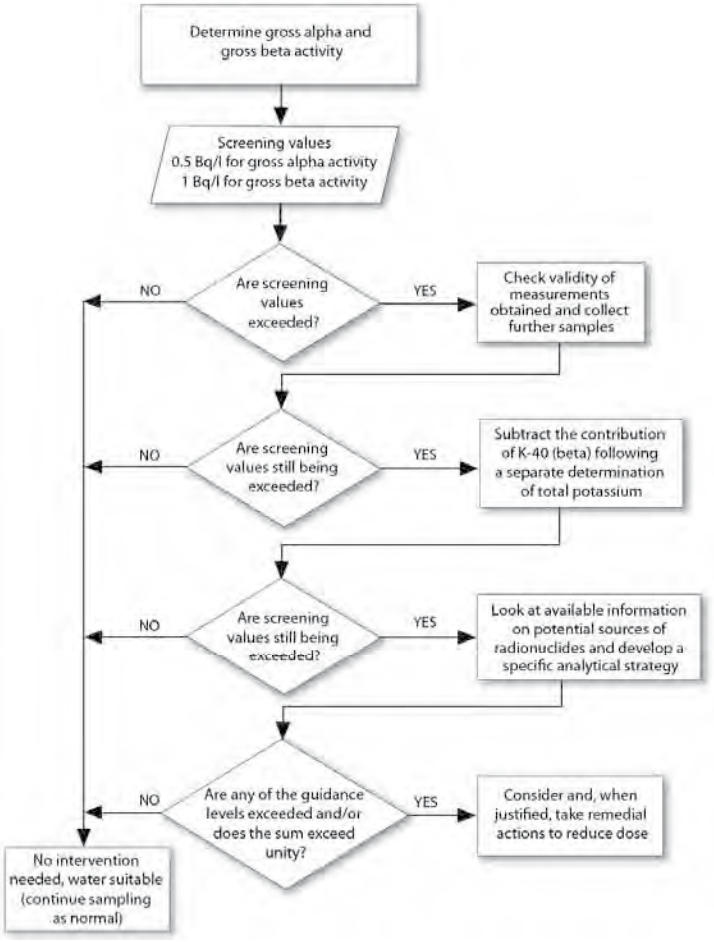


Figure 9.2 Application of screening and guidance levels for radionuclides in drinking-water

In the second edition of the Guidelines, the IDC of 0.1 mSv/year was based on screening levels for gross alpha activity and gross beta activity of 0.1 Bq/l and 1 Bq/l, respectively. This IDC represents less than 5% of the average annual dose attributable to radiation of natural origin (see section 9.1). Subsequent experience indicated that, in practice, the 0.1 mSv annual dose would usually not be exceeded if the gross alpha activity was equal to or below 0.5 Bq/l. For this reason, in the third edition of the Guidelines, the IDC was based on screening levels of 0.5 Bq/l for gross alpha activity and 1 Bq/l for gross beta activity. This change was carried forward to the current edition of the Guidelines.

9.3 Monitoring and assessment for dissolved radionuclides

The recommended assessment methodology for controlling radionuclide health risks from drinking-water is illustrated in Figure 9.2 and summarized in Box 9.4.

Box 9.4 Recommended assessment methodology

The recommended assessment methodology for controlling radionuclide health risks from drinking-water involves four steps:

1. An IDC[1] of 0.1 mSv from 1 year's consumption of drinking-water is adopted.
2. Initial screening is undertaken for both gross alpha activity and gross beta activity. If the measured activity concentrations are below the screening levels of 0.5 Bq/l for gross alpha activity and 1 Bq/l for gross beta activity, no further action is required.
3. If either of the screening levels is exceeded, the concentrations of individual radionuclides should be determined and compared with the guidance levels (see Table 9.2).
4. The outcome of this further evaluation may indicate that no action is required or that further evaluation is necessary before a decision can be made on the need for measures to reduce the dose.

9.3.1 Screening of drinking-water supplies

The process of identifying individual radionuclides in drinking-water and determining their concentration is time-consuming and expensive. Because, in most circumstances, the concentrations are low, such detailed analysis is normally not justified for routine monitoring. A more practical approach is to use a screening procedure, where the total radioactivity present in the form of alpha and beta radiation is first determined, without regard to the identity of specific radionuclides.

These measurements are suitable as a preliminary screening procedure to determine whether further radioisotope-specific analysis is necessary. They can also be used for detecting changes in the radiological characteristics of the drinking-water source as well as for identifying spatial and/or temporal trends in the radionuclide content of drinking-water.

Screening levels for drinking-water, below which no further action is required, are 0.5 Bq/l for gross alpha activity and 1 Bq/l for gross beta activity. If neither of these values is exceeded, the IDC of 0.1 mSv/year will also not be exceeded. The use of these screening levels is recommended, as this maximizes both the reliability and the cost-effectiveness of assessing the radionuclide content of drinking-water.

Radionuclides emitting low-energy beta activity, such as tritium, and some gaseous or volatile radionuclides, such as iodine, will not be detected by standard gross activity measurements. Routine analysis for these radionuclides is not necessary, but, if there are any reasons for believing that they may be present, radionuclide-specific sampling and measurement techniques should be used.[2]

Gross beta measurements include a contribution from potassium-40, a beta emitter that occurs naturally in a fixed ratio to stable potassium. Potassium is an essential element for humans and is absorbed mainly from ingested food. If the screening level of 1 Bq/l for gross beta is exceeded, the contribution of potassium-40 to beta activity should be subtracted following a separate determination of total potassium. The

[1] In the European Commission Drinking Water Directive (European Commission, 2001), this parameter is called the total indicative dose (TID), and the same value of 0.1 mSv/year is adopted.

[2] References for analytical methods and treatment technologies specific to radionuclides are provided in Annex 6.

beta activity of potassium-40 is 27.9 Bq/g of stable potassium, which is the factor that should be used to calculate the beta activity due to potassium-40.

9.3.2 Strategy for assessing drinking-water if screening levels are exceeded

If either of the screening levels is exceeded, then the specific radionuclides should be identified and their individual activity concentrations measured. This will allow the contribution from each radionuclide to the IDC to be calculated. If the following additive formula is satisfied, then no further action is required:

$$\sum_i \frac{C_i}{GL_i} \leq 1$$

where:

C_i = the measured activity concentration of radionuclide *i*, and
GL = the guidance level (see Tables 9.2 and A6.1 in Annex 6) of radionuclide *i* that, at an intake of 2 litres/day[1] for 1 year, will result in an effective dose of 0.1 mSv/year.

If any of the guidance levels is exceeded, then the sum will exceed unity. The sum may also exceed unity even if none of the individual guidance levels is exceeded. Where the sum exceeds unity for a single sample, the IDC of 0.1 mSv/year would be exceeded only if the exposure to the same measured concentrations were to continue for a full year. *Hence, such a result does not in itself imply that the water is unsuitable for consumption*.

9.3.3 Strategy for assessing drinking-water if guidance levels are exceeded

An annual dose of 0.1 mSv is a small percentage of the average radiation dose received by any individual. Both the screening levels and guidance levels are highly conservative values that allow national authorities to determine, without further consideration, that the drinking-water is fit for consumption from a radiological viewpoint. National experiences have shown that the vast majority of water supplies comply with these criteria.

Occasionally, the situation may arise where the guidance levels are consistently exceeded for one or a combination of specific radionuclides. National authorities will then need to make a decision regarding the need to implement remedial measures or to place some restriction on the continued use of the water supply for drinking purposes.

From a radiological point of view, one of the key considerations is the extent to which the guidance levels are exceeded. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources address drinking-water in the chapter on existing exposure situations and contain a requirement that the highest annual individual doses received from the consumption of

[1] Where national or regional consumption rates are known, the guidance level should be adjusted to take this into account.

Table 9.2 Guidance levels for common[a] natural and artificial radionuclides

Category	Radionuclide	Dose coefficient (Sv/Bq)	Guidance level[b] (Bq/l)
Natural occurring radioactive isotope that starts the uranium decay series[c]	Uranium-238	4.5×10^{-8}	10
Natural occurring radioactive isotopes belonging to the uranium decay series	Uranium-234	4.9×10^{-8}	1
	Thorium-230	2.1×10^{-7}	1
	Radium-226	2.8×10^{-7}	1
	Lead-210	6.9×10^{-7}	0.1
	Polonium-210	1.2×10^{-6}	0.1
Natural occurring radioactive isotope that starts the thorium decay series	Thorium-232	2.3×10^{-7}	1
Natural occurring radioactive isotopes belonging to the thorium decay series	Radium-228	6.9×10^{-7}	0.1
	Thorium-228	7.2×10^{-8}	1
Artificial radionuclides that can be released to the environment as part of the fission products found in reactor emissions or nuclear weapons tests	Caesium-134[d]	1.9×10^{-8}	10
	Caesium-137[d]	1.3×10^{-8}	10
	Strontium-90[d]	2.8×10^{-8}	10
Artificial radionuclide that can be released to the environment as a fission product (see above). It is also used in nuclear medicine procedures and thus can be released into water bodies through sewage effluent.	Iodine-131[d,e]	2.2×10^{-8}	10
Radioactive isotope of the hydrogen produced artificially as a fission product from nuclear power reactors and nuclear weapons tests. It may be naturally present in the environment in a very small amount. Its presence in a water source suggests potential industrial contamination.	Tritium[e]	1.8×10^{-11}	10 000
Naturally occurring radioactive isotope widely distributed in nature and present in organic compounds and in the human body.	Carbon-14	5.8×10^{-10}	100
Artificial isotope formed in nuclear reactors that also exists in trace quantities in *natural* uranium ores.	Plutonium-239[d]	2.5×10^{-7}	1
Artificial isotope by-product formed in nuclear reactors.	Americium-241[d]	2.0×10^{-7}	1

[a] This list is not exhaustive. In certain circumstances, other radionuclides should be investigated (see Annex 6).

[b] Guidance levels were rounded to the nearest order of magnitude by averaging the log scale values (to 10n if the calculated value was below 3×10^n and to 10^{n+1} if value was 3×10^n or above). For example, if the calculated value was 2 Bq/L (i.e. 2×10^0), the guidance level was rounded to 10^0 (i.e. = 1) whereas. if the calculated value was 3 Bq /L, (i.e. 3×10^0 or above) the guidance level was rounded to 10^1 (i.e. = 10).

[c] Separate guidance levels are provided for individual uranium radioisotopes in terms of radioactivity (i.e. expressed as Bq/l). The provisional guideline value for total content of uranium in drinking-water is 30 µg/l based on its chemical toxicity, which is predominant compared with its radiological toxicity (see chapter 12).

[d] These radionuclides either may not occur in drinking-water in normal situations or may be found at doses that are too low to be of significance to public health. Therefore, they are of lower priority for investigation following an exceedance of a screening level.

[e] Although iodine and tritium will not be detected by standard gross activity measure¬ments and routine analysis for these radionuclides is not necessary, if there are any reasons for believing that they may be present, radionuclide-specific sampling and measurement tech¬niques should be used. This is the reason for including them in this table.

drinking-water do not exceed a value of approximately 1 mSv.[1] This should not be regarded either as an "acceptable" dose or as a dose limit, and all reasonable efforts should be made to minimize the doses received. Each situation will be different, and non-radiological factors, such as the costs of remediation and the availability of other drinking-water supplies, will need to be taken into account in reaching a final decision. National authorities also need to be aware that radionuclides such as uranium are chemically toxic, and the allowable concentrations in drinking-water may be determined by a radioisotope's toxicological rather than its radioactive properties (see chapter 12).

9.3.4 Sampling frequency

Criteria for monitoring radiological contamination of drinking-water should be developed, taking into account available resources and the potential for radiological risks. It should not detract from the adequate assessment and management of microbial and chemical risks. New water supplies should be sampled to determine their suitability for drinking-water, whereas existing supplies would need monitoring occasionally. If the water supply is adequately characterized and measured concentrations are consistently below screening levels, then sampling frequency should be reduced. However, if sources of potential radionuclide contamination exist nearby or are expected to be changing rapidly with time, then the sampling should be more frequent. Sampling frequency should be maintained, or even increased, if concentrations are approaching the screening levels or if the sum of ratios of the observed concentrations of individual radionuclides to their guidance levels approaches unity (see below). A graded approach to sampling frequency should be developed commensurate with the degree of contamination, the source of supply (i.e. surface water or groundwater), the size of the population served, the expected variability of radionuclide concentrations and the availability and results of historical monitoring records. International standards are available relating to the assessment of radiological water quality, including sampling procedures (e.g. preservation and handling of samples) and programmes (Standards Australia & Standards New Zealand, 1998; ISO, 2003, 2006a,b, 2009a).

9.4 Guidance levels for radionuclides commonly found in drinking-water

Guidance levels established for naturally occurring and human-made radionuclides most commonly detected in drinking-water supplies as well as for human-made radionuclides potentially relevant for prolonged exposure situations resulting from past nuclear emergency situations are presented in Table 9.2. The respective dose coefficients for adults are also presented (IAEA, 1996; ICRP, 1996).

The guidance level for each radionuclide in Table 9.2 represents the concentration that, if present in the drinking-water consumed throughout the year, would result in an individual dose of 0.1 mSv.

The guidance levels were calculated using dose coefficients for adults. Insufficient evidence was found to introduce separate guidance levels for different age groups. Although infants and children consume a lower mean volume of drinking-water, the

[1] IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (revised edition, in preparation).

age-dependent dose coefficients for children are higher than those for adults, accounting for higher uptake or metabolic rates. In the case of prolonged contamination of the water source, an assessment of doses to infants and children may be considered.

The guidance levels apply to routine ("normal") operational conditions of existing or new drinking-water supplies. They do not apply during an emergency exposure situation involving the release of radionuclides into the environment. However, the guidance levels apply again once the relevant authorities have declared an end to the emergency exposure situation. Additional guidance is provided in section 6.7 and in several publications (IAEA, 2002; IAEA & WHO, 2005, 2010; ICRP, 2009a).

The guidance levels for radionuclides in drinking-water were calculated using the following equation:

$$GL = \frac{IDC}{h_{ing} \times q}$$

where:

- GL = guidance level of radionuclide in drinking-water (Bq/l)
- IDC = individual dose criterion, equal to 0.1 mSv/year for this calculation
- h_{ing} = dose coefficient for ingestion by adults (mSv/Bq)
- q = annual ingested volume of drinking-water, assumed to be 730 litres/year (equivalent to the standard World Health Organization drinking-water consumption rate of 2 litres/day)

9.5 Analytical methods

9.5.1 Measuring gross alpha and gross beta activity concentrations

To analyse drinking-water for gross alpha and gross beta activities (excluding radon), the most common approach is to evaporate a known volume of the sample to dryness and measure the activity of the residue. As alpha radiation is easily absorbed within a thin layer of solid material, the reliability and sensitivity of the method for alpha determination may be reduced in samples with high total dissolved solids (TDS) content. Where possible, standardized methods should be used to determine concentrations of gross alpha and gross beta activities. Procedures for this analysis are listed in Table 9.3.

The determination of gross beta activity using the evaporation method includes the contribution from potassium-40. An additional analysis of total potassium is therefore required if the gross beta screening value is exceeded.

The co-precipitation technique (APHA et al., 2005) excludes the contribution due to potassium-40; therefore, determination of total potassium is not necessary. This method is not applicable to assessment of water samples containing certain fission products, such as caesium-137. However, under normal circumstances, concentrations of fission products in drinking-water supplies are extremely low.

9.5.2 Measuring specific radionuclides

If either of the gross alpha and gross beta screening levels is exceeded, then the specific radionuclides should be identified and their individual activity concentrations measured.

Table 9.3 Methods for the analysis of gross alpha and gross beta activities in drinking-water

Method (reference)	Technique	Detection limit	Application
International Organization for Standardization: ISO 9696 for gross alpha (ISO, 2007) ISO 9697 for gross beta (ISO, 2008) ISO 10704 for gross alpha and gross beta (ISO, 2009b)	Evaporation	0.02–0.1 Bq/l	Groundwater with TDS less than 0.1 g/l
American Public Health Association (APHA et al., 2005)	Co-precipitation	0.02 Bq/l	Surface water and groundwater (TDS is not a factor)

References for analytical methods for specific radionuclides are provided in Annex 6. Information on measuring radon concentrations in water is provided in section 9.7.4.

9.6 Remedial measures

If the IDC of 0.1 mSv/year is being exceeded, then the options available to the regulatory authority to reduce the dose should be examined. Where remedial measures are contemplated, any strategy considered should first be justified (in the sense that it achieves a net benefit). Any decision that alters the radiation exposure situation should do more good than harm. This means that by reducing existing exposure, it will achieve sufficient individual or societal benefit to offset the detriment it causes (ICRP, 2008).

Once the remedial action is justified, then protection should be optimized in accordance with the recommendations of ICRP (2008). The principle of optimization of protection implies that the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking economic and societal factors into account.

When source water contains unacceptably high concentrations of radionuclides, control options include use of an alternative supply, controlled blending with another source or additional water treatment. Treatment plants with a combination of coagulation, sedimentation and sand filtration processes may remove up to 100% of the suspended radioactivity present in raw waters. Lime–soda ash softening plants can also remove practically all of the suspended radioactivity, depending on the radionuclide and on the proportion of radioactivity that might be associated with particulates.

A comprehensive review of the removal of dissolved radionuclides by water treatment processes has been undertaken (Brown, Hammond & Wilkins, 2008). The results summarized in that report are reproduced in Table 9.4. References for treatment technologies specific to radionuclides are provided in Annex 6.

9.7 Radon

9.7.1 Radon in air and water

Uranium, radium and radon are all soluble in water. Radon present in surface waters, such as lakes and rivers, is readily released into outdoor air by agitation as it passes

Table 9.4 Treatment performance for some common radionuclides[a]

Element	Coagulation	Sand filtration	Activated carbon	Precipitation softening	Ion exchange	Reverse osmosis
Strontium	xx	xx	x	xxxx	xxx	xxxx
Iodine	xx	xx	xxx	x	xxx	xxxx
Caesium	xx	xx	x	xx	xxx	xxxx
Radium	xx	xxx	xx	xxxx	xxxx	xxxx
Uranium	xxxx	x	xx	xxxx	xxxx	xxxx
Plutonium	xxxx	xx	xxx	x	xxxx	xxxx
Americium	xxxx	xx	xxx	x	xxxx	xxxx
Tritium	Not possible to remove					

[a] x = 0–10% removal; xx = 10–40% removal; xxx = 40–70% removal; xxxx = > 70% removal.

Box 9.5 Radon in drinking-water

- Some groundwater supplies may contain elevated concentrations of radon. High radon concentrations are seldom found in surface drinking-water supplies.
- Radon dissolved in drinking-water can be released into indoor air. Normally, a higher radon dose is received from inhaling the radon and radon progeny compared with their ingestion.
- Radon released from drinking-water is not the only source of radon in indoor air. Where high indoor radon concentrations exist, the underlying soil and building materials, rather than the drinking-water, are normally the predominant sources.
- Straightforward and effective techniques exist to reduce the concentration of radon in drinking-water supplies.
- In deciding whether or not to take steps to reduce the concentration of radon in drinking-water supplies, it is important to take account of the contribution of other sources of radon to the total radiation dose. Any action should be both justified and optimized and take account of local conditions.

over rocks and soils. Groundwater from wells and boreholes usually contains higher radon concentrations than surface waters. In some extreme circumstances, very high radon concentrations can be found in drinking-water supplies from these sources (see Box 9.5).

Radon is soluble in water, its solubility decreasing rapidly with an increase in temperature. When a tap or shower is turned on, some of the dissolved radon is released into indoor air. This adds to the radon present from other sources and will give rise to a radiation dose when inhaled.

An evaluation of international research data (UNSCEAR, 2000) has concluded that, on average, 90% of the dose attributable to radon in drinking-water comes from inhalation rather than ingestion. Therefore, controlling the inhalation pathway rather than the ingestion pathway is the most effective way to control doses from radon in drinking-water.

The percentage of radon present in drinking-water that is released into indoor air will depend on local conditions, such as the total consumption of water in the house, the volume of the house and its ventilation rate, and is likely to be highly variable. It has been estimated that a radon concentration of 1000 Bq/l in drinking-water discharged from a tap or shower will, on average, increase the radon concentration by 100 Bq/m^3 in indoor air (NAS, 1999; European Commission, 2001; Health Canada, 2009). This contribution is not constant, as it occurs only while the water is being discharged through the tap or shower. Radon in air also comes from other sources, in particular radon entering the home from the underlying soil.

9.7.2 Health risks from radon

Epidemiological studies have clearly shown that long-term exposure to high radon concentrations in indoor air increases the risk of lung cancer (WHO, 2009). Radon ingested in drinking-water will give a radiation dose to the lining of the stomach. Scientific studies have not shown a definitive link between consumption of drinking-water containing radon and an increased risk of stomach cancer (Ye et al., 1998; Auvinen et al., 2005; WHO, 2009).

9.7.3 Guidance on radon in drinking-water supplies

As the dose from radon present in drinking-water is normally received from inhalation rather than ingestion, it is more appropriate to measure the radon concentration in air than in drinking-water.

The World Health Organization reference level for radon concentration in indoor air is 100 Bq/m^3 in dwellings. If this level cannot be reached under prevailing country-specific conditions, the level should not exceed 300 Bq/m^3, corresponding to an annual dose of approximately 10 mSv (WHO, 2009). This recommendation is consistent with the International Basic Safety Standards[1] and with the most recent recommendations of the ICRP (2009b).

Screening levels for radon in water should be set on the basis of the national reference level for radon in air and the distribution of radon in the national housing stock. Where high radon concentrations are identified in indoor air, this is nearly always due to ingress of radon from the soil rather than degassing from the drinking-water supply. Nevertheless, in circumstances where high radon concentrations might be expected in drinking-water, it is prudent to measure for radon and, if high concentrations are identified, consider whether measures to reduce the concentrations present are justified.

The concentration of radon in groundwater supplies can vary considerably. Consequently, in situations where high radon concentrations have been identified or are suspected, the frequency of gross alpha and gross beta measurements may need to be increased so that the presence of radon progeny (in particular polonium-210), which can be major contributors to dose, can be assessed and monitored on an ongoing basis.

[1] International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (revised edition, in preparation).

9.7.4 Measuring radon in drinking-water

There are difficulties in deriving activity concentrations of radon in drinking-water because of the ease with which radon is released from water during handling. Stirring and transferring water from one container to another will release dissolved radon. Water that has been left to stand will have reduced radon activity, and boiling will also completely release radon from the water into the air. A variety of methods can be used to measure radon in water, including liquid scintillation counting, which is a sensitive and widely used method (WHO, 2009).

9.7.5 Decreasing radon concentrations in drinking-water

Reasonably simple measures are available to decrease radon concentrations in drinking-water by aeration. High-performance aeration is an effective means for the removal of radon in groundwater supplies and can achieve up to 99.9% removal. However, these methods may create a large source of airborne radon. Adsorption via granular activated carbon, with or without ion exchange, can also achieve high radon removal efficiencies, but is less efficient and requires large amounts of granular activated carbon.

9.8 Risk communication

9.8.1 Reporting results

The analytical results for each sample should contain the following information:

- sample identification code;
- sample collection date and time;
- standard analytical methods used or brief description of any non-standard analytical methods used;
- identification of the radionuclides or type of radioactivity and total radioactivity determined;
- measurement-based concentration or activity value calculated using the appropriate blank for each radionuclide;
- estimates of the counting uncertainty;
- a minimum detectable concentration for each radionuclide or parameter analysed;
- estimate of total projected uncertainty of the reported result, including the contributions from all the parameters within the analytical method (i.e. counting and other random and systematic uncertainties or errors).

9.8.2 Communicating risks

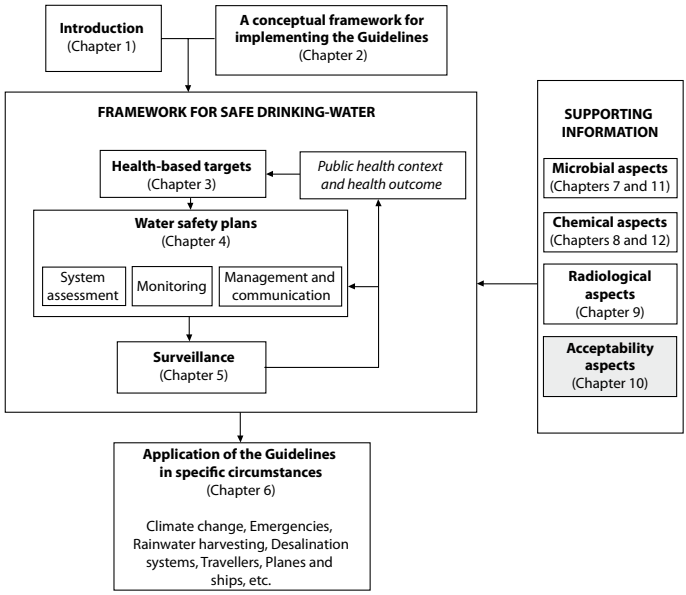
Communicating radiation risks clearly and effectively includes identifying target audiences (e.g. public, policy-makers and decision-makers) and tailoring the messages to them (WHO, 2002). Risk has different meaning for different people, but, in general, risk communication requires a description of the likelihood of harm and its severity.

Risk communication with the public should utilize plain language. The technical lexicon of radiation protection is not readily understood by non-specialists (Picano, 2008). In some situations, comparisons are helpful to explain radiation risks

(e.g. placing possible health risks from ingestion of drinking-water in the context of risk associated with exposure to natural radiation in different parts of the world). It should be clearly explained that guidance levels should not be interpreted as mandatory limits and that exceeding a guidance level may be taken as a trigger for further investigation, but it is not necessarily an indication that the drinking-water is unsafe.

The persons in charge of communicating risk should be skilled in interpersonal communication, able to convey empathy, effective listeners and respectful of people's concerns. They should be knowledgeable about the topic area with which they are dealing and be able to answer basic questions about the current as well as possible future risks. Guidance on radiation risk communication is provided elsewhere (USEPA, 2007; WHO, 2009).

10
Acceptability aspects: Taste, odour and appearance



The provision of drinking-water that is not only safe but also acceptable in appearance, taste and odour is of high priority. Water that is aesthetically unacceptable will undermine the confidence of consumers, will lead to complaints and, more importantly, could lead to the use of water from sources that are less safe.

To a large extent, consumers have no means of judging the safety of their drinking-water themselves, but their attitude towards their drinking-water supply and their drinking-water suppliers will be affected to a considerable extent by the aspects of water quality that they are able to perceive with their own senses. It is natural for consumers to regard with suspicion water that appears dirty or discoloured or that has an unpleasant taste or smell, even though these characteristics may not in themselves be of direct consequence to health.

> The appearance, taste and odour of drinking-water should be acceptable to the consumer. Water that is aesthetically unacceptable can lead to the use of water from sources that are aesthetically more acceptable, but potentially less safe.

Some substances of health concern have effects on the taste, odour or appearance of drinking-water that would normally lead to rejection of the water at concentrations significantly lower than those of concern for health. The concentration at which constituents are objectionable to consumers is variable and dependent on individual and local factors, including the quality of the water to which the community is accustomed and a variety of social, environmental and cultural considerations. Guideline values have not been established for constituents influencing water quality that have no direct link to adverse health impacts. However, guideline values have been established for some substances that may cause taste or odour in drinking-water at much lower concentrations than the guideline value because there is such a wide range in the ability of consumers to detect them by taste or odour. In the summaries in this chapter and the fact sheets in chapter 12, reference is made to levels likely to give rise to complaints from consumers. These are not precise numbers, and tastes or odours may be detectable by consumers at lower or higher levels, depending on individual and local circumstances.

Guideline values have not been established for constituents influencing water quality that have no direct link to adverse health impacts.

It is important to consider whether existing or proposed water treatment and distribution practices can affect the acceptability of drinking-water and to manage change and operations to minimize the risk of problems for acceptability as well as health. For example, chloramination that is not properly managed can lead to the formation of trichloramines, which can cause unacceptable taste and odour. Other problems may be indirect, such as the disturbance of internal pipe deposits and biofilms when the flow is disturbed or changed in distribution systems.

It is not normally appropriate to directly regulate or monitor substances of health concern whose effects on the acceptability of water would normally lead to rejection of the water at concentrations significantly lower than those of concern for health; rather, these substances may be addressed through a general requirement that water be acceptable to the majority of consumers. For such substances, a formal guideline value is not usually derived, but a health-based value is derived in order to assist in judging the response that is needed when problems are encountered and in some cases to provide reassurance to health authorities and consumers with regard to possible health risks. In the fact sheets in chapter 12, this is explained, and information on acceptability is described. In the tables of guideline values (see chapter 8 and Annex 3), for those chemicals for which health-based guideline values were derived, the guideline value is designated with a "C", with a footnote explaining that while the substance is of health significance, water would normally be rejected by consumers at concentrations well below the health-based guideline value. Monitoring of such substances should be undertaken in response to consumer complaints.

Taste and odour can originate from natural inorganic and organic chemical contaminants and biological sources or processes (e.g. aquatic microorganisms), from contamination by synthetic chemicals, from corrosion or as a result of problems with water treatment (e.g. chlorination). Taste and odour may also develop during storage and distribution as a result of microbial activity.

Taste and odour in drinking-water may be indicative of some form of pollution or of a malfunction during water treatment or distribution. It may therefore be an indication of the presence of potentially harmful substances. The cause should be investigated and the appropriate health authorities should be consulted, particularly if there is a sudden or substantial change.

Colour, cloudiness, particulate matter and visible organisms may also be noticed by consumers and may create concerns about the quality and acceptability of a drinking-water supply.

10.1 Biologically derived contaminants

There are a number of diverse organisms that often have no public health significance but which are undesirable because they produce taste and odour. As well as affecting the acceptability of the water, they indicate that water treatment and/or the state of maintenance and repair of the distribution system are insufficient.

Actinomycetes and fungi

Actinomycetes and fungi can be abundant in surface water sources, including reservoirs, and they can also grow on unsuitable materials in the water supply distribution systems, such as rubber. They can produce geosmin, 2-methyl isoborneol and other substances, resulting in objectionable tastes and odours in the drinking-water.

Cyanobacteria and algae

Blooms of cyanobacteria and other algae in reservoirs and in river waters may impede coagulation and filtration, causing coloration and turbidity of water after filtration. They can also produce geosmin, 2-methyl isoborneol and other chemicals, which have taste thresholds in drinking-water of a few nanograms per litre. Some other cyanobacterial products—cyanotoxins—are also of direct health significance (see section 8.5.1), but the production by cyanobacteria of chemicals with effects on taste does not seem to be linked to the production of cyanotoxins.

Invertebrate animal life[1]

Invertebrate animals are naturally present in many water resources used as sources for the supply of drinking-water and often infest shallow, open wells. Small numbers of invertebrates may also pass through water treatment works where the barriers to particulate matter are not completely effective and colonize filters or the distribution system. Their motility may enable them and their larvae to penetrate filters at the treatment works and vents on storage reservoirs.

The types of invertebrates concerned can be considered, for control purposes, as belonging to two groups. First, there are free-swimming organisms in the water itself or on water surfaces, such as the crustaceans *Gammarus pulex* (freshwater shrimp), *Crangonyx pseudogracilis*, *Cyclops* spp. and *Chydorus sphaericus*. Second, there are other invertebrates that either move along surfaces or are anchored to them (e.g. water

[1] The section was drawn largely from chapter 6 of the supporting document *Safe piped water* (Annex 1).

louse [*Asellus aquaticus*], snails, zebra mussel [*Dreissena polymorpha*], other bivalve molluscs and the bryozoan *Plumatella* sp.) or inhabit slimes (e.g. *Nais* spp., nematodes and the larvae of chironomids). In warm weather, slow sand filters can sometimes discharge the larvae of gnats (*Chironomus* and *Culex* spp.) into the water. In certain circumstances, these can reproduce parthenogenetically (i.e. asexual reproduction), which can exacerbate the problem in service reservoirs and distribution.

Many of these invertebrates can survive, deriving food from bacteria, algae and protozoa in the water or present on slimes on pipe and tank surfaces. Few water distribution systems are completely free of animals at all times. However, the density and composition of invertebrate populations vary widely, from heavy infestations, including readily visible species that are objectionable to consumers, to sparse occurrences of microscopic species.

The presence of invertebrates has largely been regarded by piped drinking-water suppliers in temperate regions as an acceptability problem, either directly or through their association with discoloured water. Large invertebrate populations also indicate high levels of organic material that may give rise to other water quality issues, such as microbial growth. In tropical and subtropical countries, in contrast, there are species of aquatic invertebrates that act as secondary hosts for parasites. For example, the small crustacean *Cyclops* is the intermediate host of the guinea worm (*Dracunculus medinensis*) (see sections 7.1.1 and 11.4). However, there is no evidence that guinea worm transmission occurs from piped drinking-water supplies. The presence of invertebrates in drinking-water, especially if visible, raises consumer concern about the quality of the drinking-water supply and should be controlled.

Penetration of waterworks and mains is more likely to be a problem when high-rate filtration processes are used, but problems can arise even at well-run treatment works. Regular cleaning of water mains by flushing and/or swabbing will usually control infestation.

Treatment of invertebrate infestations in piped distribution systems is discussed in detail in chapter 6 of the supporting document *Safe piped water* (Annex 1).

Iron bacteria

In waters containing ferrous and manganous salts, oxidation by iron bacteria (or by exposure to air) may cause rust-coloured deposits on the walls of tanks, pipes and channels and carry-over of deposits into the water.

10.2 Chemically derived contaminants

Aluminium

Naturally occurring aluminium as well as aluminium salts used as coagulants in drinking-water treatment are the primary sources of aluminium in drinking-water. The presence of aluminium at concentrations in excess of 0.1–0.2 mg/l often leads to consumer complaints as a result of deposition of aluminium hydroxide floc and the exacerbation of discoloration of water by iron. It is therefore important to optimize treatment processes in order to minimize any residual aluminium entering the distribution system. Under good operating conditions, aluminium concentrations of less

than 0.1 mg/l are achievable in many circumstances. Available evidence does not support the derivation of a health-based guideline value for aluminium in drinking-water (see sections 8.5.4 and 12.1).

Ammonia

The threshold odour concentration of ammonia at alkaline pH is approximately 1.5 mg/l, and a taste threshold of 35 mg/l has been proposed for the ammonium cation. Ammonia is not of direct relevance to health at these levels, and no health-based guideline value has been proposed (see sections 8.5.3 and 12.1). However, ammonia does react with chlorine to reduce free chlorine and to form chloramines.

Chloramines

Chloramines, such as monochloramine, dichloramine and trichloramine (nitrogen trichloride), are generated from the reaction of chlorine with ammonia. Among chloramines, monochloramine is the only useful chlorine disinfectant, and chloramination systems are operated to minimize the formation of dichloramine and trichloramine. Higher chloramines, particularly trichloramine, are likely to give rise to taste and odour complaints, except at very low concentrations.

For monochloramine, no odour or taste was detected at concentrations between 0.5 and 1.5 mg/l. However, slight organoleptic effects within this range and odour and taste thresholds of 0.65 and 0.48 mg/l have been reported. For dichloramine, the organoleptic effects between 0.1 and 0.5 mg/l were found to be "slight" and "acceptable". Odour and taste thresholds of 0.15 and 0.13 mg/l were reported, respectively. An odour threshold of 0.02 mg/l has been reported for trichloramine, and it has been described as "geranium".

A guideline value for monochloramine has been established (see sections 8.5.4 and 12.1).

Chloride

High concentrations of chloride give a salty taste to water and beverages. Taste thresholds for the chloride anion depend on the associated cation and are in the range of 200–300 mg/l for sodium, potassium and calcium chloride. Concentrations in excess of 250 mg/l are increasingly likely to be detected by taste, but some consumers may become accustomed to low levels of chloride-induced taste. No health-based guideline value is proposed for chloride in drinking-water (see sections 8.5.1 and 12.1).

Chlorine

Most individuals are able to taste or smell chlorine in drinking-water at concentrations well below 5 mg/l, and some at levels as low as 0.3 mg/l. The taste threshold for chlorine is below the health-based guideline value of 5 mg/l (see sections 8.5.4 and 12.1).

Chlorobenzenes

Taste and odour thresholds of 10–20 µg/l and odour thresholds ranging from 40 to 120 µg/l have been reported for monochlorobenzene. A health-based guideline value

has not been derived for monochlorobenzene (see sections 8.5.2 and 12.1), although the health-based value that could be derived far exceeds the lowest reported taste and odour threshold in water.

Odour thresholds of 2–10 and 0.3–30 µg/l have been reported for 1,2- and 1,4-dichlorobenzene, respectively. Taste thresholds of 1 and 6 µg/l have been reported for 1,2- and 1,4-dichlorobenzene, respectively. The health-based guideline values of 1 mg/l derived for 1,2-dichlorobenze and of 0.3 mg/l for 1,4-dichlorobenzene (see sections 8.5.2 and 12.1) far exceed the lowest reported taste and odour thresholds for these compounds.

Odour thresholds of 10, 5–30 and 50 µg/l have been reported for 1,2,3-, 1,2,4- and 1,3,5-trichlorobenzene, respectively. A taste and odour threshold concentration of 30 µg/l has been reported for 1,2,4-trichlorobenzene. A health-based guideline value was not derived for trichlorobenzenes, although the health-based value that could be derived (see sections 8.5.2 and 12.1) exceeds the lowest reported odour threshold in water of 5 µg/l.

Chlorophenols

Chlorophenols generally have very low taste and odour thresholds. The taste thresholds in water for 2-chlorophenol, 2,4-dichlorophenol and 2,4,6-trichlorophenol are 0.1, 0.3 and 2 µg/l, respectively. Odour thresholds are 10, 40 and 300 µg/l, respectively. If water containing 2,4,6-trichlorophenol is free from taste, it is unlikely to present a significant risk to health (see sections 8.5.4 and 12.1). Microorganisms in distribution systems may sometimes methylate chlorophenols to produce chlorinated anisoles, for which the odour threshold is considerably lower.

Colour

Drinking-water should ideally have no visible colour. Colour in drinking-water is usually due to the presence of coloured organic matter (primarily humic and fulvic acids) associated with the humus fraction of soil. Colour is also strongly influenced by the presence of iron and other metals, either as natural impurities or as corrosion products. It may also result from the contamination of the water source with industrial effluents and may be the first indication of a hazardous situation. The source of colour in a drinking-water supply should be investigated, particularly if a substantial change has taken place.

Most people can detect colour above 15 true colour units (TCU) in a glass of water. Levels of colour below 15 TCU are often acceptable to consumers. High colour from natural organic carbon (e.g. humics) could also indicate a high propensity to produce by-products from disinfection processes. No health-based guideline value is proposed for colour in drinking-water.

Copper

Copper in a drinking-water supply usually arises from the corrosive action of water leaching copper from copper pipes in buildings. High levels of dissolved oxygen have been shown to accelerate copper corrosion in some cases. Concentrations can vary significantly with the period of time the water has been standing in contact with the pipes; for example, first-draw water would be expected to have a higher copper con-

centration than a fully flushed sample. High concentrations can interfere with the intended domestic uses of the water. Staining of sanitary ware and laundry may occur at copper concentrations above 1 mg/l. At levels above 5 mg/l, copper also imparts a colour and an undesirable bitter taste to water. Although copper can give rise to taste, it should be acceptable at the health-based guideline value of 2 mg/l (see sections 8.5.4, 12.1 and A5.3 in Annex 5).

Dissolved oxygen

The dissolved oxygen content of water is influenced by the source, raw water temperature, treatment and chemical or biological processes taking place in the distribution system. Depletion of dissolved oxygen in water supplies can encourage the microbial reduction of nitrate to nitrite and sulfate to sulfide. It can also cause an increase in the concentration of ferrous iron in solution, with subsequent discoloration at the tap when the water is aerated. No health-based guideline value is recommended. However, very high levels of dissolved oxygen may exacerbate corrosion of metal pipes.

Ethylbenzene

Ethylbenzene has an aromatic odour; the reported odour threshold in water ranges from 2 to 130 µg/l. The lowest reported odour threshold is 100-fold lower than the health-based guideline value of 0.3 mg/l (see sections 8.5.2 and 12.1). The taste threshold ranges from 72 to 200 µg/l.

Hardness

Hardness caused by calcium and magnesium is usually indicated by precipitation of soap scum and the need for excess use of soap to achieve cleaning. Consumers are likely to notice changes in hardness. Public acceptability of the degree of hardness of water may vary considerably from one community to another. The taste threshold for the calcium ion is in the range of 100–300 mg/l, depending on the associated anion, and the taste threshold for magnesium is probably lower than that for calcium. In some instances, consumers tolerate water hardness in excess of 500 mg/l.

Depending on the interaction of other factors, such as pH and alkalinity, water with a hardness above approximately 200 mg/l may cause scale deposition in the treatment works, distribution system and pipework and tanks within buildings. It will also result in high soap consumption and subsequent "scum" formation. On heating, hard waters form deposits of calcium carbonate scale. Soft water, but not necessarily cation exchange softened water, with a hardness of less than 100 mg/l, may, in contrast, have a low buffering capacity and so be more corrosive for water pipes.

No health-based guideline value is proposed for hardness in drinking-water (see the supporting document *Calcium and magnesium in drinking-water*; Annex 1).

Hydrogen sulfide

The taste and odour thresholds of hydrogen sulfide in water are estimated to be between 0.05 and 0.1 mg/l. The "rotten eggs" odour of hydrogen sulfide is particularly

noticeable in some groundwaters and in stagnant drinking-water in the distribution system, as a result of oxygen depletion and the subsequent reduction of sulfate by bacterial activity.

Sulfide is oxidized rapidly to sulfate in well-aerated or chlorinated water, and hydrogen sulfide levels in oxygenated water supplies are normally very low. The presence of hydrogen sulfide in drinking-water can be easily detected by the consumer and requires immediate corrective action. It is unlikely that a person could consume a harmful dose of hydrogen sulfide from drinking-water; hence, a health-based guideline value has not been derived for this compound (see sections 8.5.1 and 12.1).

Iron

Anaerobic groundwater may contain ferrous iron at concentrations up to several milligrams per litre without discoloration or turbidity in the water when directly pumped from a well. On exposure to the atmosphere, however, the ferrous iron oxidizes to ferric iron, giving an objectionable reddish-brown colour to the water.

Iron also promotes the growth of "iron bacteria", which derive their energy from the oxidation of ferrous iron to ferric iron and in the process deposit a slimy coating on the piping. At levels above 0.3 mg/l, iron stains laundry and plumbing fixtures. There is usually no noticeable taste at iron concentrations below 0.3 mg/l, although turbidity and colour may develop. No health-based guideline value is proposed for iron (see sections 8.5.4 and 12.1).

Manganese

At levels exceeding 0.1 mg/l, manganese in water supplies may cause an undesirable taste in beverages and stains sanitary ware and laundry. The presence of manganese in drinking-water, like that of iron, may lead to the accumulation of deposits in the distribution system. Concentrations below 0.1 mg/l are usually acceptable to consumers. Even at a concentration of 0.2 mg/l, manganese will often form a coating on pipes, which may slough off as a black precipitate. The health-based value of 0.4 mg/l for manganese is higher than this acceptability threshold of 0.1 mg/l (see sections 8.5.1 and 12.1). However, under some conditions, manganese can be at concentrations above 0.1 mg/L and may remain in solution for a longer period compared with its usual solubility in most drinking-water.

Petroleum oils

Petroleum oils can give rise to the presence of a number of low molecular weight hydrocarbons that have low odour thresholds in drinking-water. Benzene, toluene, ethylbenzene and xylenes (BTEX) are considered individually in this section, as health-based guideline values have been derived for these chemicals. However, a number of other hydrocarbons, particularly alkylbenzenes such as trimethylbenzene, may give rise to a very unpleasant "diesel-like" odour at concentrations of a few micrograms per litre. There is experience indicating that the taste threshold of a mixture of low molecular weight aromatic hydrocarbons is lower than the threshold of individual substances. Diesel is a particularly rich source of such substances.

pH and corrosion

Although pH usually has no direct impact on consumers, it is one of the most important operational water quality parameters. Careful attention to pH control is ne-

cessary at all stages of water treatment to ensure satisfactory water clarification and disinfection (see the supporting document *Safe piped water*; Annex 1). For effective disinfection with chlorine, the pH should preferably be less than 8; however, lower-pH water (approximately pH 7 or less) is more likely to be corrosive. The pH of the water entering the distribution system must be controlled to minimize the corrosion of water mains and pipes in household water systems. Alkalinity and calcium management also contribute to the stability of water and control its aggressiveness to pipes and appliances. Failure to minimize corrosion can result in the contamination of drinking-water and in adverse effects on its taste and appearance. The optimum pH required will vary in different supplies according to the composition of the water and the nature of the construction materials used in the distribution system, but it is usually in the range 6.5–8.5 (see section 8.4.3). Extreme values of pH can result from accidental spills, treatment breakdowns and insufficiently cured cement mortar pipe linings or cement mortar linings applied when the alkalinity of the water is low. No health-based guideline value has been proposed for pH (see section 12.1).

Sodium

The taste threshold concentration of sodium in water depends on the associated anion and the temperature of the solution. At room temperature, the average taste threshold for sodium is about 200 mg/l. No health-based guideline value has been derived (see sections 8.5.1 and 12.1), as the contribution from drinking-water to daily intake is small.

Styrene

Styrene has a sweet/sickly odour, and reported odour thresholds for styrene in water range from 0.004 to 2.6 mg/l, depending on temperature. Styrene may therefore be detected in water at concentrations below its health-based guideline value of 0.02 mg/l (see sections 8.5.2 and 12.1).

Sulfate

The presence of sulfate in drinking-water can cause noticeable taste, and very high levels might cause a laxative effect in unaccustomed consumers. Taste impairment varies with the nature of the associated cation; taste thresholds have been found to range from 250 mg/l for sodium sulfate to 1000 mg/l for calcium sulfate. It is generally considered that taste impairment is minimal at levels below 250 mg/l. No health-based guideline value has been derived for sulfate (see sections 8.5.1 and 12.1).

Synthetic detergents

In many countries, persistent types of anionic detergent have been replaced by others that are more easily biodegraded, and hence the levels found in water sources have decreased substantially. The concentration of detergents in drinking-water should not be allowed to reach levels giving rise to either foaming or taste problems. The presence of any detergent may indicate contamination of source water with sewage or ingress of detergent solution into the distribution system, as a result of back-flow, for example.

Toluene

Toluene has a sweet, pungent, benzene-like odour. The reported taste threshold ranges from 0.04 to 0.12 mg/l. The reported odour threshold for toluene in water ranges from 0.024 to 0.17 mg/l. Toluene may therefore affect the acceptability of water at concentrations below its health-based guideline value of 0.7 mg/l (see sections 8.5.2 and 12.1).

Total dissolved solids

The palatability of water with a total dissolved solids (TDS) level of less than about 600 mg/l is generally considered to be good; drinking-water becomes significantly and increasingly unpalatable at TDS levels greater than about 1000 mg/l. The presence of high levels of TDS may also be objectionable to consumers, owing to excessive scaling in water pipes, heaters, boilers and household appliances. No health-based guideline value for TDS has been proposed (see sections 8.5.1 and 12.1).

Turbidity

Turbidity, typically expressed as nephelometric turbidity units (NTU), describes the cloudiness of water caused by suspended particles (e.g. clay and silts), chemical precipitates (e.g. manganese and iron), organic particles (e.g. plant debris) and organisms. Turbidity can be caused by poor source water quality, poor treatment and, within distribution systems, disturbance of sediments and biofilms or the ingress of dirty water through main breaks and other faults. At high levels, turbidity can lead to staining of materials, fittings and clothes exposed during washing, in addition to interfering with the effectiveness of treatment processes (see Tables 7.7 and 7.8 in chapter 7).

Increasing turbidity reduces the clarity of water to transmitted light. Below 4 NTU, turbidity can be detected only using instruments, but at 4 NTU and above, a milky-white, muddy, red-brown or black suspension can be visible. Large municipal supplies should consistently produce water with no visible turbidity (and should be able to achieve 0.5 NTU before disinfection at all times and average 0.2 NTU or less). However, small supplies, particularly those where resources are limited, may not be able to achieve such levels.

Visible turbidity reduces the acceptability of drinking-water. Although most particles that contribute to turbidity have no health significance (even though they may indicate the presence of hazardous chemical and microbial contaminants), many consumers associate turbidity with safety and consider turbid water as being unsafe to drink. This response is exacerbated when consumers have been used to receiving high-quality filtered water. If consumers lose confidence in a drinking-water supply, they may drink less water or use lower turbidity alternatives that may not be safe. Any complaints about unexpected turbidity should always be investigated because they could reflect significant faults or breaches in distribution systems.

Further information is available in *Turbidity: information for regulators and operators of water supplies* (see Annex 1).

Xylenes

Xylene concentrations in the range of 0.3 mg/l produce a detectable taste and odour. The odour threshold for xylene isomers in water has been reported to range from 0.02 to 1.8 mg/l. The lowest odour threshold is well below the health-based guideline value of 0.5 mg/l for xylene (see sections 8.5.2 and 12.1).

Zinc

Zinc imparts an undesirable astringent taste to water at a taste threshold concentration of about 4 mg/l (as zinc sulfate). Water containing zinc at concentrations in excess of 3–5 mg/l may appear opalescent and develop a greasy film on boiling. Although drinking-water seldom contains zinc at concentrations above 0.1 mg/l, levels in tap water can be considerably higher because of the zinc used in older galvanized plumbing materials; this may also be an indicator of elevated cadmium from such older

material. No health-based guideline value has been proposed for zinc in drinking-water (see sections 8.5.4 and 12.1).

10.3 Treatment of taste, odour and appearance problems

In many cases, aesthetic problems will be prevented by optimizing conventional treatment processes such as coagulation, sedimentation and chlorination. However, if specific treatment is deemed necessary, aeration, granular or powdered activated carbon and ozonation are generally effective techniques in removing organic chemicals and some inorganic chemicals, such as hydrogen sulfide, that cause tastes and odours. (see Annex 5).

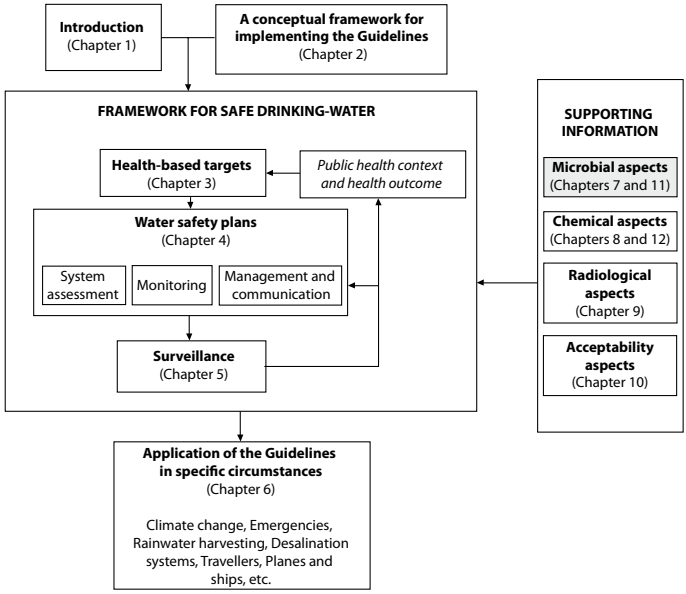
Tastes and odours caused by disinfectants are best controlled through careful operation of the disinfection process and pretreatment to remove precursors.

Manganese can be removed by chlorination followed by filtration. Techniques for removing hydrogen sulfide include aeration, granular activated carbon, filtration and oxidation. Ammonia can be removed by biological nitrification. Precipitation softening or cation exchange can reduce hardness. Other taste- and odour-causing inorganic chemicals (e.g. chloride and sulfate) are generally not amenable to treatment (see the supporting document *Chemical safety of drinking-water*; Annex 1).

10.4 Temperature

Cool water is generally more palatable than warm water, and temperature will have an impact on the acceptability of a number of other inorganic constituents and chemical contaminants that may affect taste. High water temperature enhances the growth of microorganisms and may increase problems related to taste, odour, colour and corrosion.

11
Microbial fact sheets



Fact sheets are provided on potential waterborne pathogens as well as on indicator microorganisms.

The waterborne microorganisms potentially causing illness include:

- bacteria, viruses, protozoa and helminths identified in Table 7.1 and Figure 7.1;
- potentially emerging pathogens, including *Helicobacter pylori*, *Tsukamurella*, *Isospora belli* and microsporidia, for which waterborne transmission is plausible but unconfirmed;
- hazardous cyanobacteria.

The human health effects caused by waterborne transmission vary in severity from mild gastroenteritis to severe and sometimes fatal diarrhoea, dysentery, hepatitis and typhoid fever. Contaminated water can be the source of large outbreaks of disease, including cholera, dysentery and cryptosporidiosis; for the majority of waterborne

pathogens, however, there are other important sources of infection, such as person-to-person contact and food.

Most waterborne pathogens are introduced into drinking-water supplies in human or animal faeces, do not grow in water and initiate infection in the gastrointestinal tract following ingestion. However, *Legionella*, atypical mycobacteria, *Burkholderia pseudomallei*, *Acanthamoeba* spp. and *Naegleria fowleri* are environmental organisms that can grow in water and soil. Besides ingestion, other routes of transmission can include inhalation, leading to infections of the respiratory tract (e.g. *Legionella*, atypical mycobacteria), and contact, leading to infections at sites as diverse as the skin and brain (e.g. *Naegleria fowleri*, *Burkholderia pseudomallei*).

Of all the waterborne pathogens, the helminth *Dracunculus medinensis* is unique in that it is the only pathogen that is solely transmitted through drinking-water.

The fact sheets on potential pathogens include information on human health effects, sources and occurrence, routes of transmission and the significance of drinking-water as a source of infection. The fact sheets on microorganisms that can be used as indicators of the effectiveness of control measures or of the potential presence of pathogenic microorganisms provide information on indicator value, source and occurrence, application and significance of detection.

11.1 Bacterial pathogens

Most bacterial pathogens potentially transmitted by water infect the gastrointestinal tract and are excreted in the faeces of infected humans and animals. However, there are also some waterborne bacterial pathogens, such as *Legionella*, *Burkholderia pseudomallei* and atypical mycobacteria, that can grow in water and soil. The routes of transmission of these bacteria include inhalation and contact (bathing), with infections occurring in the respiratory tract, in skin lesions or in the brain.

Acinetobacter

General description

Acinetobacter spp. are Gram-negative, oxidase-negative, non-motile coccobacilli (short plump rods). Owing to difficulties in naming individual species and biovars, the term *Acinetobacter calcoaceticus baumannii* complex is used in some classification schemes to cover all subgroups of this species, such as *A. baumannii*, *A. iwoffii* and *A. junii*.

Human health effects

Acinetobacter spp. are usually commensal organisms, but they occasionally cause infections, predominantly in susceptible patients in hospitals. They are opportunistic pathogens that may cause urinary tract infections, pneumonia, bacteraemia, secondary meningitis and wound infections. These diseases are predisposed by factors such as malignancy, burns, major surgery and weakened immune systems, such as in neonates and elderly individuals. The emergence and rapid spread of multidrug-resistant *A. calcoaceticus baumannii* complex, causing nosocomial infections, are of concern in health-care facilities.

Source and occurrence

Acinetobacter spp. are ubiquitous inhabitants of soil, water and sewage environments. *Acinetobacter* has been isolated from 97% of natural surface water samples in numbers of up to 100/ml. The organisms have been found to represent 1.0–5.5% of the heterotrophic plate count (HPC) flora in drinking-water samples and have been isolated from 5–92% of distribution water samples. In a survey of untreated groundwater supplies in the United States of America (USA), *Acinetobacter* spp. were detected in 38% of the groundwater supplies at an arithmetic mean density of 8/100 ml. The study also revealed that slime production, a virulence factor for *A. calcoaceticus*, was not significantly different between well water isolates and clinical strains, suggesting some degree of pathogenic potential for strains isolated from groundwater. *Acinetobacter* spp. are part of the natural microbial flora of the skin and occasionally the respiratory tract of healthy individuals.

Routes of exposure

Environmental sources within hospitals and person-to-person transmission are the likely sources for most outbreaks of hospital infections. Infection is most commonly associated with contact with wounds and burns or inhalation by susceptible individuals. In patients with *Acinetobacter* bacteraemia, intravenous catheters have also been identified as a source of infection. Outbreaks of infection have been associated with water baths and room humidifiers. Ingestion is not a usual source of infection.

Significance in drinking-water

Although *Acinetobacter* spp. are often detected in treated drinking-water supplies, an association between the presence of *Acinetobacter* spp. in drinking-water and clinical disease has not been confirmed. There is no evidence of gastrointestinal infection through ingestion of *Acinetobacter* spp. in drinking-water among the general population. However, transmission of non-gastrointestinal infections by drinking-water may be possible in susceptible individuals, particularly in settings such as health-care facilities and hospitals. As discussed in chapter 6, specific water safety plans should be developed for buildings, including hospitals and other health-care facilities. These plans need to take account of particular sensitivities of occupants. *Acinetobacter* spp. are sensitive to disinfectants such as chlorine, and numbers will be low in the presence of a disinfectant residual. Control measures that can limit growth of the bacteria in distribution systems include treatment to optimize organic carbon removal, restriction of the residence time of water in distribution systems and maintenance of disinfectant residuals. *Acinetobacter* spp. are detected by HPC, which can be used together with parameters such as disinfectant residuals to indicate conditions that could support growth of these organisms. However, *Escherichia coli* (or, alternatively, thermotolerant coliforms) cannot be used as an indicator for the presence/absence of *Acinetobacter* spp.

Selected bibliography

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Rusin PA et al. (1997) Risk assessment of opportunistic bacterial pathogens in drinking-water. *Reviews of Environmental Contamination and Toxicology*, 152:57–83.

Aeromonas

General description

Aeromonas spp. are Gram-negative, non-spore-forming, facultative anaerobic bacilli belonging to the family Vibrionaceae. They bear many similarities to the Enterobacteriaceae. The genus is divided into two groups. The group of psychrophilic non-motile aeromonads consists of only one species, *A. salmonicida*, an obligate fish pathogen that is not considered further here. The group of mesophilic motile (single polar flagellum) aeromonads is considered of potential human health significance and consists of the species *A. hydrophila*, *A. caviae*, *A. veronii* subsp. *sobria*, *A. jandaei*, *A. veronii* subsp. *veronii* and *A. schubertii*. The bacteria are normal inhabitants of fresh water and occur in water, soil and many foods, particularly meat and milk.

Human health effects

Aeromonas spp. can cause infections in humans, including septicaemia, particularly in immunocompromised patients, wound infections and respiratory tract infections. There have been some claims that *Aeromonas* spp. can cause gastrointestinal illness, but epidemiological evidence is not consistent. Despite marked toxin production by *Aeromonas* spp. in vitro, diarrhoea has not yet been introduced in test animals or human volunteers.

Source and occurrence

Aeromonas spp. occur in water, soil and food, particularly meat, fish and milk. *Aeromonas* spp. are generally readily found in most fresh waters, and they have been detected in many treated drinking-water supplies, mainly as a result of regrowth in distribution systems. The factors that affect the occurrence of *Aeromonas* spp. in water distribution systems are not fully understood, but organic content, temperature, the residence time of water in the distribution network and the presence of residual chlorine have been shown to influence population sizes.

Routes of exposure

Wound infections have been associated with contaminated soil and water-related activities, such as swimming, diving, boating and fishing. Septicaemia can follow from such wound infections. In immunocompromised individuals, septicaemia may arise from aeromonads present in their own gastrointestinal tract.

Significance in drinking-water

Despite frequent isolation of *Aeromonas* spp. from drinking-water, the body of evidence does not provide significant support for waterborne transmission. Aeromonads typically found in drinking-water do not belong to the same deoxyribonucleic acid (DNA) homology groups as those associated with cases of gastroenteritis. The presence of *Aeromonas* spp. in drinking-water supplies is generally considered a nuisance. Entry of aeromonads into distribution systems can be minimized by adequate disinfection. Control measures that can limit growth of the bacteria in distribution systems include treatment to optimize organic carbon removal, restriction of the residence time of water in distribution systems and maintenance of disinfectant residuals. *Aeromonas* spp. are detected by HPC, which can be used together with parameters such as disinfectant residuals to indicate conditions that could support growth of these organisms. However, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be used as an indicator for the presence/absence of *Aeromonas* spp.

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Burkholderia pseudomallei

General description

Burkholderia pseudomallei is a Gram-negative bacillus commonly found in soil and muddy water, predominantly in tropical regions such as northern Australia and south-east Asia. The organism is acid tolerant and survives in water for prolonged periods in the absence of nutrients.

Human health effects

Burkholderia pseudomallei can cause the disease melioidosis, which is endemic in northern Australia and other tropical regions. The most common clinical manifestation is pneumonia, which may be fatal. In some of these areas, melioidosis is the most common cause of community-acquired pneumonia. Cases appear throughout the year but peak during the rainy season. Many patients present with milder forms of pneumonia, which respond well to appropriate antibiotics, but some may present with a severe septicaemic pneumonia. Other symptoms include skin abscesses or ulcers, abscesses in internal organs and unusual neurological illnesses, such as brainstem encephalitis and acute paraplegia. Although melioidosis can occur in healthy children and adults, it occurs mainly in people whose defence mechanisms against infection are impaired by underlying conditions or poor general health associated with poor nutrition or living conditions.

Source and occurrence

The organism occurs predominantly in tropical regions, typically in soil or surface-accumulated muddy water, from where it may reach raw water sources and also drinking-water supplies. The number of organisms in drinking-water that would constitute a significant risk of infection is not known.

Routes of exposure

Most infections appear to be through contact of skin cuts or abrasions with contaminated water. In south-east Asia, rice paddies represent a significant source of infection. Infection may also occur via other routes, particularly through inhalation or ingestion. The relative importance of these routes of infection is not known.

Significance in drinking-water

In two Australian outbreaks of melioidosis, indistinguishable isolates of *B. pseudomallei* were cultured from cases and the drinking-water supply. The detection of the organisms in one drinking-water supply followed replacement of water pipes and chlorination failure, whereas the second supply was unchlorinated. Within a water safety plan, control measures that should provide effective protection against this organism include application of established treatment and disinfection processes for drinking-water coupled with protection of the distribution system from contamination, including during repairs and maintenance. HPC and disinfectant residual as measures of water treatment effectiveness and application of appropriate mains repair procedures could be used to indicate protection against *B. pseudomallei*. Because of the environmental occurrence of *B. pseudomallei*, *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of this organism.

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Campylobacter

General description

Campylobacter spp. are microaerophilic (require decreased oxygen) and capnophilic (require increased carbon dioxide), Gram-negative, curved spiral rods with a single unsheathed polar flagellum. *Campylobacter* spp. are one of the most important causes of acute gastroenteritis worldwide. *Campylobacter jejuni* is the most frequently isolated species from patients with acute diarrhoeal disease, whereas *C. coli*, *C. laridis* and *C. fetus* have also been isolated in a small proportion of cases. Two closely related genera, *Helicobacter* and *Archobacter*, include species previously classified as *Campylobacter* spp.

Human health effects

An important feature of *C. jejuni* is relatively high infectivity compared with other bacterial pathogens. As few as 1000 organisms can cause infection. Most symptomatic

infections occur in infancy and early childhood. The incubation period is usually 2–4 days. Clinical symptoms of *C. jejuni* infection are characterized by abdominal pain, diarrhoea (with or without blood or faecal leukocytes), vomiting, chills and fever. The infection is self-limited and resolves in 3–7 days. Relapses may occur in 5–10% of untreated patients. Other clinical manifestations of *C. jejuni* infections in humans include reactive arthritis and meningitis. Several reports have associated *C. jejuni* infection with Guillain-Barré syndrome, an acute demyelinating disease of the peripheral nerves.

Source and occurrence

Campylobacter spp. occur in a variety of environments. Wild and domestic animals, especially poultry, wild birds and cattle, are important reservoirs. Pets and other animals may also be reservoirs. Food, including meat and unpasteurized milk, are important sources of *Campylobacter* infections. Water is also a significant source. The occurrence of the organisms in surface waters has proved to be strongly dependent on rainfall, water temperature and the presence of waterfowl.

Routes of exposure

Most *Campylobacter* infections are reported as sporadic in nature, with food considered a common source of infection. Transmission to humans typically occurs by the consumption of animal products. Meat, particularly poultry products, and unpasteurized milk are important sources of infection. Contaminated drinking-water supplies have been identified as a source of outbreaks. The number of cases in these outbreaks ranged from a few to several thousand, with sources including unchlorinated or inadequately chlorinated surface water supplies and faecal contamination of water storage reservoirs by wild birds.

Significance in drinking-water

Contaminated drinking-water supplies have been identified as a significant source of outbreaks of campylobacteriosis. The detection of waterborne outbreaks and cases appears to be increasing. Waterborne transmission has been confirmed by the isolation of the same strains from patients and drinking-water they had consumed. Within a water safety plan, control measures that can be applied to manage potential risk from *Campylobacter* spp. include protection of raw water supplies from waste from humans and animals, adequate treatment and protection of water during distribution. Storages of treated and disinfected water should be protected from bird faeces. *Campylobacter* spp. are faecally borne pathogens and are not particularly resistant to disinfection. Hence, *E. coli* (or thermotolerant coliforms) is an appropriate indicator for the presence/absence of *Campylobacter* spp. in drinking-water supplies.

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Enterobacter sakazakii

General description

Enterobacter sakazakii is a motile, Gram-negative, non-spore-forming, rod-shaped bacterium that has been found in infant formulas as a contaminant. *Enterobacter* species are biochemically similar to *Klebsiella*; unlike *Klebsiella*, however, *Enterobacter* is ornithine positive. *Enterobacter sakazakii* has been found to be more resistant to osmotic and dry stress than other members of the Enterobacteriaceae family.

Human health effects

Enterobacter sakazakii has been associated with sporadic cases or small outbreaks of sepsis, meningitis, cerebritis and necrotizing enterocolitis. Most of the infections are seen in low-birth-weight infants (i.e. less than 2 kg) or infants born prematurely (i.e. less than 37 weeks of gestation). Mortality has been reported to be as high as 50% but has decreased to less than 20% in recent years.

Source and occurrence

The reservoir for *E. sakazakii* is unknown. Various environmental samples (surface water, soil, mud, bird faeces) have tested negative. *Enterobacter sakazakii* has been identified in the guts of certain flies. The organism has been frequently identified in factories that produce milk powder and other food substances and in households. Commercially produced non-sterile powdered infant formula has often been implicated as the source of the bacteria during outbreaks. In a study of 141 powdered infant formulas, 20 were found to be culture-positive for *E. sakazakii*, even though the formulas complied with Codex microbial requirements for coliforms (< 3 colony-forming units per gram). The bacteria have been found in samples from newly opened sealed cans. Although sources of the bacteria other than infant formula have not been identified, environmental sources probably exist.

Routes of exposure

Disease caused by *E. sakazakii* in infants has been associated with the consumption of commercially prepared non-sterile infant formula. Contamination has been linked back to either the infant formula itself or formula preparation equipment (e.g. blenders). Many of the outbreaks have occurred without identified hygienic lapses during formula preparation. The organism has not been found in drinking-water sources used to prepare the formula. There is no evidence for person-to-person or more general environmental transmission.

Significance in drinking-water

There is no evidence that these bacteria are transmitted through drinking-water, although it is plausible that the organism could be present in water of poor quality. *Enterobacter sakazakii* is sensitive to disinfectants, and its presence can be prevented by adequate treatment.

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Escherichia coli pathogenic strains

General description

Escherichia coli is present in large numbers in the normal intestinal flora of humans and animals, where it generally causes no harm. However, in other parts of the body, *E. coli* can cause serious disease, such as urinary tract infections, bacteraemia and meningitis. A limited number of enteropathogenic strains can cause acute diarrhoea. Several classes of enteropathogenic *E. coli* have been identified on the basis of different virulence factors, including enterohaemorrhagic *E. coli* (EHEC), enterotoxigenic *E. coli* (ETEC), enteropathogenic *E. coli* (EPEC), enteroinvasive *E. coli* (EIEC), enteroaggregative *E. coli* (EAEC) and diffusely adherent *E. coli* (DAEC). More is known about the first four classes named; the pathogenicity and prevalence of EAEC and DAEC strains are less well established.

Human health effects

EHEC serotypes, such as *E. coli* O157:H7 and *E. coli* O111, cause diarrhoea that ranges from mild and non-bloody to highly bloody, which is indistinguishable from haemorrhagic colitis. Between 2% and 7% of cases can develop the potentially fatal haemolytic uraemic syndrome, which is characterized by acute renal failure and haemolytic anaemia. Children under 5 years of age are at most risk of developing haemolytic uraemic syndrome. The infectivity of EHEC strains is substantially higher than that of the other strains. As few as 100 EHEC organisms can cause infection. ETEC produces heat-labile or heat-stable *E. coli* enterotoxin, or both toxins simultaneously, and is an important cause of diarrhoea in developing countries, especially in young children. Symptoms of ETEC infection include mild watery diarrhoea, abdominal cramps, nausea and headache. Infection with EPEC has been associated with severe, chronic, non-bloody diarrhoea, vomiting and fever in infants. EPEC infections are rare in developed countries, but occur commonly in developing countries, with infants presenting with malnutrition, weight loss and growth retardation. EIEC causes watery and occasionally bloody diarrhoea where strains invade colon cells by a pathogenic mechanism similar to that of *Shigella*.

Source and occurrence

Enteropathogenic *E. coli* are enteric organisms, and humans are the major reservoir, particularly of EPEC, ETEC and EIEC strains. Livestock, such as cattle and sheep and, to a lesser extent, goats, pigs and chickens, are a major source of EHEC strains. The latter have also been associated with raw vegetables, such as bean sprouts. The pathogens have been detected in a variety of water environments.

Routes of exposure

Infection is associated with person-to-person transmission, contact with animals, food and consumption of contaminated water. Person-to-person transmissions are particularly prevalent in communities where there is close contact between individuals, such as nursing homes and day-care centres.

Significance in drinking-water

Waterborne transmission of pathogenic *E. coli* has been well documented for recreational waters and contaminated drinking-water. A well-publicized waterborne outbreak of illness caused by *E. coli* O157:H7 (and *Campylobacter jejuni*) occurred in the farming community of Walkerton in Ontario, Canada. The outbreak took place in May 2000 and led to 7 deaths and more than 2300 illnesses. The drinking-water supply was contaminated by rainwater runoff containing cattle excreta. Within a water safety plan, control measures that can be applied to manage potential risk from enteropathogenic *E. coli* include protection of raw water supplies from human and animal waste, adequate treatment and protection of water during distribution. There is no indication that the response of enteropathogenic strains of *E. coli* to water treatment and disinfection procedures differs from that of other *E. coli*. Hence, conventional testing for *E. coli* (or, alternatively, thermotolerant coliform bacteria) provides an appropriate indicator for the enteropathogenic serotypes in drinking-water. This applies even though standard tests will generally not detect EHEC strains.

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Helicobacter pylori

General description

Helicobacter pylori, originally classified as *Campylobacter pylori*, is a Gram-negative, microaerophilic, spiral-shaped, motile bacterium. There are at least 14 species of *Helicobacter*, but only *H. pylori* has been identified as a human pathogen.

Human health effects

Helicobacter pylori is found in the stomach; although most infections are asymptomatic, the organism is associated with chronic gastritis, which may lead to complications such as peptic and duodenal ulcer disease and gastric cancer. Whether the organism

is truly the cause of these conditions remains unclear. The majority of *H. pylori* infections are initiated in childhood and without treatment are chronic. The infections are more prevalent in developing countries and are associated with overcrowded living conditions. Interfamilial clustering is common.

Source and occurrence

Humans appear to be the primary host of *H. pylori*. Other hosts may include domestic cats. There is evidence that *H. pylori* is sensitive to bile salts, which would reduce the likelihood of faecal excretion, although it has been isolated from faeces of young children. *Helicobacter pylori* has been detected in water. Although *H. pylori* is unlikely to grow in the environment, it has been found to survive for 3 weeks in biofilms and up to 20–30 days in surface waters. In a study conducted in the USA, *H. pylori* was found in the majority of surface water and shallow groundwater samples. The presence of *H. pylori* was not correlated with the presence of *E. coli*. Possible contamination of the environment can be through children with diarrhoea or through vomiting by children as well as adults.

Routes of exposure

Person-to-person contact within families has been identified as the most likely source of infection through oral–oral transmission. *Helicobacter pylori* can survive well in mucus or vomit. However, it is difficult to detect in mouth or faecal samples. Faecal–oral transmission is also considered possible.

Significance in drinking-water

Consumption of contaminated drinking-water has been suggested as a potential source of infection, but further investigation is required to establish any link with waterborne transmission. Humans are the principal source of *H. pylori*, and the organism is sensitive to oxidizing disinfectants. Hence, control measures that can be applied to protect drinking-water supplies from *H. pylori* include preventing contamination by human waste and adequate disinfection. *Escherichia coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator for the presence/absence of this organism.

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Klebsiella

General description

Klebsiella spp. are Gram-negative, non-motile bacilli that belong to the family Enterobacteriaceae. The genus *Klebsiella* consists of a number of species, including *K. pneumoniae*, *K. oxytoca*, *K. planticola* and *K. terrigena*. The outermost layer of *Klebsiella*

spp. consists of a large polysaccharide capsule that distinguishes the organisms from other members of the family. Approximately 60–80% of all *Klebsiella* spp. isolated from faeces and clinical specimens are *K. pneumoniae* and are positive in the thermotolerant coliform test. *Klebsiella oxytoca* has also been identified as a pathogen.

Human health effects

Klebsiella spp. have been identified as colonizing hospital patients, where spread is associated with the frequent handling of patients (e.g. in intensive-care units). Patients at highest risk are those with impaired immune systems, such as the elderly or very young, patients with burns or excessive wounds, those undergoing immunosuppressive therapy or those with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) infection. Colonization may lead to invasive infections. On rare occasions, *Klebsiella* spp., notably *K. pneumoniae* and *K. oxytoca*, may cause serious infections, such as destructive pneumonia.

Source and occurrence

Klebsiella spp. are natural inhabitants of many water environments, and they may multiply to high numbers in waters rich in nutrients, such as pulp mill wastes, textile finishing plants and sugar-cane processing operations. In drinking-water distribution systems, they are known to colonize washers in taps. The organisms can grow in water distribution systems. *Klebsiella* spp. are also excreted in the faeces of many healthy humans and animals, and they are readily detected in sewage-polluted water.

Routes of exposure

Klebsiella can cause nosocomial infections, and contaminated water and aerosols may be a potential source of the organisms in hospital environments and other health-care facilities.

Significance in drinking-water

Klebsiella spp. are not considered to represent a source of gastrointestinal illness in the general population through ingestion of drinking-water. *Klebsiella* spp. detected in drinking-water are generally biofilm organisms and are unlikely to represent a health risk. The organisms are reasonably sensitive to disinfectants, and entry into distribution systems can be prevented by adequate treatment. Growth within distribution systems can be minimized by strategies that are designed to minimize biofilm growth, including treatment to optimize organic carbon removal, restriction of the residence time of water in distribution systems and maintenance of disinfectant residuals. *Klebsiella* is a coliform and can be detected by traditional tests for total coliforms.

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Legionella

General description

The genus *Legionella*, a member of the family Legionellaceae, has at least 50 species comprising 70 distinct serogroups. Legionellae are Gram-negative, rod-shaped, non-spore-forming bacteria that require L-cysteine for growth and primary isolation. *Legionella* spp. are heterotrophic bacteria found in a wide range of water environments and can proliferate at temperatures above 25 °C.

Human health effects

Although all *Legionella* spp. are considered potentially pathogenic for humans, *L. pneumophila* is the major waterborne pathogen responsible for legionellosis, of which two clinical forms are known: Legionnaires' disease and Pontiac fever. The former is a pneumonic illness with an incubation period of 3–6 days. Host factors influence the likelihood of illness: males are more frequently affected than females, and most cases occur in the 40- to 70-year age group. Risk factors include smoking, alcohol abuse, cancer, diabetes, chronic respiratory or kidney disease and immunosuppression, as in transplant recipients. Pontiac fever is a milder, self-limiting disease with a high attack rate and an onset (5 hours to 3 days) and symptoms similar to those of influenza: fever, headache, nausea, vomiting, aching muscles and coughing. Studies of seroprevalence of antibodies indicate that many infections are asymptomatic.

Source and occurrence

Legionella spp. are members of the natural flora of many freshwater environments, such as rivers, streams and impoundments, where they occur in relatively low numbers. However, they thrive in certain human-made water environments, such as water cooling devices (cooling towers and evaporative condensers) associated with air-conditioning systems, hot water distribution systems and spas, which provide suitable temperatures (25–50 °C) and conditions for their multiplication. Devices that support multiplication of *Legionella* have been associated with outbreaks of Legionnaires' disease. *Legionella* survive and grow in biofilms and sediments and are more easily detected from swab samples than from flowing water. Legionellae can be ingested by trophozoites of certain amoebae such as *Acanthamoeba*, *Hartmanella* and *Naegleria*, which play an important role in their persistence in water environments.

Routes of exposure

The most common route of infection is the inhalation of aerosols containing the bacteria. Such aerosols can be generated by contaminated cooling towers, warm water showers, humidifiers and spas. Aspiration has also been identified as a route of infection in some cases associated with contaminated water, food and ice. There is no evidence of person-to-person transmission.

Significance in drinking-water

Legionella spp. are common waterborne organisms, and devices such as cooling towers, hot water systems and spas that utilize mains water have been associated with outbreaks of infection. Owing to the prevalence of *Legionella*, the potential for ingress

into drinking-water systems should be considered as a possibility, and control measures should be employed to reduce the likelihood of survival and multiplication. Disinfection strategies designed to minimize biofilm growth and temperature control can minimize the potential risk from *Legionella* spp. The organisms are sensitive to disinfection. Monochloramine has been shown to be particularly effective, probably due to its stability and greater effectiveness against biofilms. Water temperature is an important element of control strategies. Wherever possible, water temperatures should be kept outside the range of 25–50 °C and preferably 20–50 °C to prevent the growth of the organism. In hot water systems, temperatures leaving heaters should be above 60 °C, and temperatures above 50°C should be maintained throughout associated pipework. However, maintaining temperatures of hot water above 50 °C may represent a scalding risk in young children, the elderly and other vulnerable groups. Where temperatures in hot or cold water distribution systems cannot be maintained outside the range of 25–50 °C, greater attention to disinfection and strategies aimed at limiting development of biofilms are required. Accumulation of sludge, scale, rust, algae or slime deposits in water distribution systems supports the growth of *Legionella* spp., as does stagnant water. Systems that are kept clean and flowing are less likely to support excess growth of Legionella spp. Care should also be taken to select plumbing materials that do not support microbial growth and the development of biofilms.

Legionella spp. represent a particular concern in devices such as cooling towers and hot water systems in large buildings. As discussed in chapter 6, specific water safety plans incorporating control measures for *Legionella* spp. should be developed for these buildings. *Legionella* are not detected by HPC techniques, and *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of this organism.

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Leptospira

General description

Leptospires are aerobic spirochetes that are typically 0.1 μm in diameter and 5–25 μm in length. There are two genera: *Leptospira*, which includes the pathogenic *L. interrogans*, and *Leptonoma*. *Leptospira interrogans* causes the important zoonotic and widespread disease leptospirosis. Pathogenic leptospires are maintained in host animals but, depending on conditions, can survive for days to weeks in water. More than 200 pathogenic serovars have been identified, and these have been divided into 25 serogroups based on serologic relatedness.

Human health effects

Leptospirosis occurs globally, affecting people living in temperate and tropical climates in both rural and urban areas. The severity of illness and the types of symptoms vary widely. Infections are often subclinical or so mild that medical attention is not sought. Symptoms include fever, headache, muscle pain, chills, redness in the eyes, abdominal pain, jaundice, haemorrhages in skin and mucous membranes (including pulmonary bleeding), vomiting, diarrhoea and rash. Pulmonary bleeding has been recognized as a dangerous and often fatal result of leptospirosis, but the way it develops after infection remains unclear. Long-lasting sequelae have been identified, including depression, headaches, fatigue and joint pains. Weil disease, characterized by jaundice, renal failure, haemorrhage and myocarditis, has been used as an alternative term for leptospirosis, but it represents a subset of the manifestations. Estimates of case fatalities vary from less than 5% to 30%, but the figures are not considered reliable owing to uncertainties over case prevalence. Fatality rates are influenced by timeliness of treatment interventions. The number of cases is not well documented as a result of lack of awareness and adequate methods of diagnosis. It has been estimated that there are about 0.1–1 cases per 100 000 persons per year in temperate climates and up to 10–100 cases per 100 000 persons per year in tropical climates.

Source and occurrence

Pathogenic *Leptospira interrogans* are maintained in the renal tubules of many animal hosts. This can take the form of chronic asymptomatic infections, with excretion persisting for very long periods and even for life. Rats, especially the brown rat (*Rattus norvegicus*), serve as a reservoir for Leptospira interrogans serovars Icterohaemorrhagiae and Copenhageni. Cattle are the most important reservoir for serovar Hardjo, and field mice (*Microtus arvalis*) and muskrats (*Ondatra zibethicus*) are the most important reservoirs for serovar Grippotyphosa. Recent research has shown that the house mouse (*Crocidura russula*) may be a reservoir for serovar Mozdok (type 3). Water contaminated with urine and tissues of infected animals is an established source of pathogenic leptospires. Leptospires have a relatively low resistance to adverse environmental conditions (e.g. low pH, desiccation, direct sunlight); in the right circumstances (neutral pH, moderate temperatures), however, they can survive for months in water.

Routes of exposure

Leptospira interrogans can enter the body through cuts and abrasions or via the mucous membranes of the mouth, nose and eyes. It is not transmitted by the faecal–oral route. Leptospirosis is associated with a broad range of occupational activities predominantly associated with direct contact with dead or living animals, but also indirectly via urine-contaminated environments, especially surface water, plants and mud. Ingestion of contaminated food and water or inhalation of aerosols may occasionally cause infection. Direct person-to-person transmission is rarely observed. Sexual contact, transplacental transmission and mothers' milk are potential routes of exposure. Transmission via urine of infected patients could represent a risk to those who provide medical attention. There is an increasing trend of outbreaks associated

with recreational exposure to water contaminated with urine from infected animals. Outbreaks have also been associated with natural disasters involving flooding.

Significance in drinking-water

Waterborne leptospirosis is normally caused by contact with contaminated surface water. Leptospires are sensitive to disinfectants; within a water safety plan, control measures that should provide effective protection against this organism include application of standard disinfection processes for drinking-water together with protection of distribution systems from contamination associated with flooding events. Because leptospires are excreted in urine and persist in favourable environments, *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of this organism.

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Mycobacterium

General description

The tuberculous or "typical" species of *Mycobacterium*, such as *M. tuberculosis*, *M. bovis*, *M. africanum* and *M. leprae*, have only human or animal reservoirs and are not transmitted by water. In contrast, the non-tuberculous or "atypical" species of *Mycobacterium* are natural inhabitants of a variety of water environments. These aerobic, rod-shaped and acid-fast bacteria grow slowly in suitable water environments and on culture media. Typical examples include the species *M. gordonae*, *M. kansasii*, *M. marinum*, *M. scrofulaceum*, *M. xenopi*, *M. intracellulare* and *M. avium* and the more rapid growers *M. chelonae* and *M. fortuitum*. The term *M. avium* complex has been used to describe a group of pathogenic species including *M. avium* and *M. intracellulare*. However, other atypical mycobacteria are also pathogenic. A distinct feature of all *Mycobacterium* spp. is a cell wall with high lipid content, which is used in identification of the organisms using acid-fast staining.

Human health effects

Atypical *Mycobacterium* spp. can cause a range of diseases involving the skeleton, lymph nodes, skin and soft tissues, as well as the respiratory, gastrointestinal and genitourinary tracts. Manifestations include pulmonary disease, Buruli ulcer, osteomyelitis and septic arthritis in people with no known predisposing factors. These bacteria are a major cause of disseminated infections in immunocompromised patients and are a common cause of death in HIV-positive persons.

Source and occurrence

Atypical *Mycobacterium* spp. multiply in a variety of suitable water environments, notably biofilms. One of the most commonly occurring species is *M. gordonae*. Other

species have also been isolated from water, including *M. avium*, *M. intracellulare*, *M. kansasii*, *M. fortuitum* and *M. chelonae*. High numbers of atypical *Mycobacterium* spp. may occur in distribution systems after events that dislodge biofilms, such as flushing or flow reversals. They are relatively resistant to treatment and disinfection and have been detected in well-operated and well-maintained drinking-water supplies with HPC less than 500/ml and total chlorine residuals of up to 2.8 mg/l. The growth of these organisms in biofilms reduces the effectiveness of disinfection. In one survey, the organisms were detected in 54% of ice and 35% of public drinking-water samples.

Routes of exposure

Principal routes of infection appear to be inhalation, contact and ingestion of contaminated water. Infections by various species have been associated with their presence in drinking-water supplies. In 1968, an endemic of *M. kansasii* infections was associated with the presence of the organisms in the drinking-water supply, and the spread of the organisms was associated with aerosols from showerheads. In Rotterdam, the Netherlands, an investigation into the frequent isolation of *M. kansasii* from clinical specimens revealed the presence of the same strains, confirmed by phage type and weak nitrase activity, in tap water. An increase in numbers of infections by the *M. avium* complex in Massachusetts, USA, has also been attributed to their incidence in drinking-water. In all these cases, there is only circumstantial evidence of a causal relationship between the occurrence of the bacteria in drinking-water and human disease. Infections have been linked to contaminated water in spas.

Significance in drinking-water

Detections of atypical mycobacteria in drinking-water and the identified routes of transmission suggest that drinking-water supplies are a plausible source of infection. There are limited data on the effectiveness of control measures that could be applied to reduce the potential risk from these organisms. One study showed that a water treatment plant could achieve a 99% reduction in numbers of mycobacteria from raw water. Atypical mycobacteria are relatively resistant to disinfection. Persistent residual disinfectant should reduce numbers of mycobacteria in the water column but is unlikely to be effective against organisms present in biofilms. Control measures that are designed to minimize biofilm growth, including treatment to optimize organic carbon removal, restriction of the residence time of water in distribution systems and maintenance of disinfectant residuals, could result in less growth of these organisms. Mycobacteria are not detected by HPC techniques, and *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of this organism.

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Pseudomonas aeruginosa

General description

Pseudomonas aeruginosa is a member of the family Pseudomonadaceae and is a polarly flagellated, aerobic, Gram-negative rod. When grown in suitable media, it produces the non-fluorescent bluish pigment pyocyanin. Many strains also produce the fluorescent green pigment pyoverdin. *Pseudomonas aeruginosa*, like other fluorescent pseudomonads, produces catalase, oxidase and ammonia from arginine and can grow on citrate as the sole source of carbon.

Human health effects

Pseudomonas aeruginosa can cause a range of infections but rarely causes serious illness in healthy individuals without some predisposing factor. It predominantly colonizes damaged sites such as burn and surgical wounds, the respiratory tract of people with underlying disease and physically damaged eyes. From these sites, it may invade the body, causing destructive lesions or septicaemia and meningitis. Cystic fibrosis and immunocompromised patients are prone to colonization with *P. aeruginosa*, which may lead to serious progressive pulmonary infections. Water-related folliculitis and ear infections are associated with warm, moist environments such as swimming pools and spas. Many strains are resistant to a range of antimicrobial agents, which can increase the significance of the organism in hospital settings.

Source and occurrence

Pseudomonas aeruginosa is a common environmental organism and can be found in faeces, soil, water and sewage. It can multiply in water environments and also on the surface of suitable organic materials in contact with water. *Pseudomonas aeruginosa* is a recognized cause of hospital-acquired infections with potentially serious complications. It has been isolated from a range of moist environments such as sinks, water baths, hot water systems, showers and spa pools.

Routes of exposure

The main route of infection is by exposure of susceptible tissue, notably wounds and mucous membranes, to contaminated water or contamination of surgical instruments.

Cleaning of contact lenses with contaminated water can cause a form of keratitis. Ingestion of drinking-water is not an important source of infection.

Significance in drinking-water

Although *P. aeruginosa* can be significant in certain settings such as health-care facilities, there is no evidence that normal uses of drinking-water supplies are a source of infection in the general population. However, the presence of high numbers of *P. aeruginosa* in potable water, notably in packaged water, can be associated with complaints about taste, odour and turbidity. *Pseudomonas aeruginosa* is sensitive to disinfection, and entry into distribution systems can be minimized by adequate disinfection. Control measures that are designed to minimize biofilm growth, including treatment to optimize organic carbon removal, restriction of the residence time of water in distribution systems and maintenance of disinfectant residuals, should reduce the growth of these organisms. *Pseudomonas aeruginosa* is detected by HPC, which can be used together with parameters such as disinfectant residuals to indicate conditions that could support growth of these organisms. However, as *P. aeruginosa* is a common environmental organism, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be used for this purpose.

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Salmonella

General description

Salmonella spp. belong to the family Enterobacteriaceae. They are motile, Gram-negative bacilli that do not ferment lactose, but most produce hydrogen sulfide or gas from carbohydrate fermentation. Originally, they were grouped into more than 2000 species (serotypes) according to their somatic (O) and flagellar (H) antigens (Kauffmann-White classification). There has been much debate about nomenclature and taxonomy of *Salmonella*, but it is now considered that there are actually two species (*Salmonella enterica* and *Salmonella bongori*). Other previously named species, including *S.* Typhi and *S.* Paratyphi, are considered to be serovars.

Human health effects

Salmonella infections typically cause four clinical manifestations: gastroenteritis (ranging from mild to fulminant diarrhoea, nausea and vomiting), bacteraemia or septicaemia (high spiking fever with positive blood cultures), typhoid fever/enteric fever (sustained fever with or without diarrhoea) and a carrier state in persons with previous infections. With regard to enteric illness, *Salmonella* spp. can be divided into two fairly distinct groups: the typhoidal species/serovars (*S.* Typhi and *S.* Paratyphi) and

the remaining non-typhoidal species/serovars. Symptoms of non-typhoidal gastroenteritis appear from 6 to 72 hours after ingestion of contaminated food or water. Diarrhoea lasts 3–5 days and is accompanied by fever and abdominal pain. Usually the disease is self-limiting. The incubation period for typhoid fever can be 1–14 days but is usually 3–5 days. Typhoid fever is a more severe illness and can be fatal. Although typhoid is uncommon in areas with good sanitary systems, it is still prevalent elsewhere, and there are many millions of cases each year.

Source and occurrence

Salmonella spp. are widely distributed in the environment, but some species or serovars show host specificity. Notably, *S.* Typhi and generally *S.* Paratyphi are restricted to humans, although livestock can occasionally be a source of *S.* Paratyphi. A large number of serovars, including *S.* Typhimurium and *S.* Enteritidis, infect humans and also a wide range of animals, including poultry, cows, pigs, sheep, birds and even reptiles. The pathogens typically gain entry into water systems through faecal contamination from sewage discharges, livestock and wild animals. Contamination has been detected in a wide variety of foods and milk.

Routes of exposure

Salmonella is spread by the faecal–oral route. Infections with non-typhoidal serovars are primarily associated with person-to-person contact, the consumption of a variety of contaminated foods and exposure to animals. Infection by typhoid species is associated with the consumption of contaminated water or food, with direct person-to-person spread being uncommon.

Significance in drinking-water

Waterborne typhoid fever outbreaks have devastating public health implications. However, despite their widespread occurrence, non-typhoidal *Salmonella* spp. rarely cause drinking-water-borne outbreaks. Transmission, most commonly involving *S.* Typhimurium, has been associated with the consumption of contaminated groundwater and surface water supplies. In an outbreak of illness associated with a communal rainwater supply, bird faeces were implicated as a source of contamination. *Salmonella* spp. are relatively sensitive to disinfection. Within a water safety plan, control measures that can be applied to manage risk include protection of raw water supplies from human and animal waste, adequate treatment and protection of water during distribution. *Escherichia coli* (or, alternatively, thermotolerant coliforms) is a generally reliable indicator for *Salmonella* spp. in drinking-water supplies.

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Shigella

General description

Shigella spp. are Gram-negative, non-spore-forming, non-motile, rod-like members of the family Enterobacteriaceae, which grow in the presence or absence of oxygen. Members of the genus have a complex antigenic pattern, and classification is based on their somatic O antigens, many of which are shared with other enteric bacilli, including *E. coli*. There are four species: *S. dysenteriae*, *S. flexneri*, *S. boydii* and *S. sonnei*.

Human health effects

Shigella spp. can cause serious intestinal diseases, including bacillary dysentery. Over 2 million infections occur each year, resulting in about 600 000 deaths, predominantly in developing countries. Most cases of *Shigella* infection occur in children under 10 years of age. The incubation period for shigellosis is usually 24–72 hours. Ingestion of as few as 10–100 organisms may lead to infection, which is substantially less than the infective dose of most other enteric bacteria. Abdominal cramps, fever and watery diarrhoea occur early in the disease. All species can produce severe disease, but illness due to *S. sonnei* is usually relatively mild and self-limiting. In the case of *S. dysenteriae*, clinical manifestations may proceed to an ulceration process, with bloody diarrhoea and high concentrations of neutrophils in the stool. The production of Shiga toxin by the pathogen plays an important role in this outcome. *Shigella* spp. seem to be better adapted to cause human disease than most other enteric bacterial pathogens.

Source and occurrence

Humans and other higher primates appear to be the only natural hosts for the shigellae. The bacteria remain localized in the intestinal epithelial cells of their hosts. Epidemics of shigellosis occur in crowded communities and where hygiene is poor. Many cases of shigellosis are associated with day-care centres, prisons and psychiatric institutions. Military field groups and travellers to areas with poor sanitation are also prone to infection.

Routes of exposure

Shigella spp. are enteric pathogens predominantly transmitted by the faecal–oral route through person-to-person contact, contaminated food and water. Flies have also been identified as a transmission vector from contaminated faecal waste.

Significance in drinking-water

A number of large waterborne outbreaks of shigellosis have been recorded. As the organisms are not particularly stable in water environments, their presence in drinking-water indicates recent human faecal pollution. Available data on prevalence in water supplies may be an underestimate, because detection techniques generally used can have a relatively low sensitivity and reliability. The control of *Shigella* spp. in drinking-water supplies is of special public health importance in view of the severity of the disease caused. *Shigella* spp. are relatively sensitive to disinfection. Within a water safety plan, control measures that can be applied to manage potential risk include protection of raw water supplies from human waste, adequate treatment and protection of water

during distribution. *Escherichia coli* (or, alternatively, thermotolerant coliforms) is a generally reliable indicator for *Shigella* spp. in drinking-water supplies.

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Staphylococcus aureus

General description

Staphylococcus aureus is an aerobic or anaerobic, non-motile, non-spore-forming, catalase- and coagulase-positive, Gram-positive coccus, usually arranged in grapelike irregular clusters. The genus *Staphylococcus* contains at least 15 different species. Apart from *S. aureus*, the species *S. epidermidis* and *S. saprophyticus* are also associated with disease in humans.

Human health effects

Although *Staphylococcus aureus* is a common member of the human microflora, it can produce disease through two different mechanisms. One is based on the ability of the organisms to multiply and spread widely in tissues, and the other is based on the ability of the organisms to produce extracellular enzymes and toxins. Infections based on the multiplication of the organisms are a significant problem in hospitals and other health-care facilities. Multiplication in tissues can result in manifestations such as boils, skin sepsis, post-operative wound infections, enteric infections, septicaemia, endocarditis, osteomyelitis and pneumonia. The onset of clinical symptoms for these infections is relatively long, usually several days. Gastrointestinal disease (enterocolitis or food poisoning) is caused by a heat-stable staphylococcal enterotoxin and characterized by projectile vomiting, diarrhoea, fever, abdominal cramps, electrolyte imbalance and loss of fluids. Onset of disease in this case has a characteristic short incubation period of 1–8 hours. The same applies to the toxic shock syndrome caused by toxic shock syndrome toxin-1.

Source and occurrence

Staphylococcus aureus is relatively widespread in the environment but is found mainly on the skin and mucous membranes of animals. The organism is a member of the normal microbial flora of the human skin and is found in the nasopharynx of 20–30% of adults at any one time. Staphylococci are occasionally detected in the gastrointestinal tract and can be detected in sewage. *Staphylococcus aureus* can be released by human contact into water environments such as swimming pools, spa pools and other recreational waters. It has also been detected in drinking-water supplies.

Routes of exposure

Hand contact is by far the most common route of transmission. Inadequate hygiene can lead to contamination of food. Foods such as ham, poultry and potato and egg salads kept at room or higher temperature offer an ideal environment for the

multiplication of *S. aureus* and the release of toxins. The consumption of foods containing *S. aureus* toxins can lead to enterotoxin food poisoning within a few hours.

Significance in drinking-water

Although *S. aureus* can occur in drinking-water supplies, there is no evidence of transmission through the consumption of such water. Although staphylococci are slightly more resistant to chlorine residuals than *E. coli*, their presence in water is readily controlled by conventional treatment and disinfection processes. As faecal material is not their usual source, *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for *S. aureus* in drinking-water supplies.

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Tsukamurella

General description

The genus *Tsukamurella* belongs to the family Nocardiaceae. *Tsukamurella* spp. are Gram-positive, weakly or variably acid-fast, non-motile, obligate aerobic, irregular rod-shaped bacteria. They are actinomycetes related to *Rhodococcus*, *Nocardia* and *Mycobacterium*. The genus was created in 1988 to accommodate a group of chemically unique organisms characterized by a series of very long chain (68–76 carbons), highly unsaturated mycolic acids, *meso*-diaminopimelic acid and arabinogalactan, common to the genus *Corynebacterium*. The type species is *T. paurometabola*, and the following additional species were proposed in the 1990s: *T. wratislaviensis*, *T. inchonensis*, *T. pulmonis*, *T. tyrosinosolvens* and *T. strandjordae*.

Human health effects

Tsukamurella spp. cause disease mainly in immunocompromised individuals. Infections with these microorganisms have been associated with chronic lung diseases, immune suppression (leukaemia, tumours, HIV/AIDS infection) and post-operative wound infections. *Tsukamurella* were reported in four cases of catheter-related bacteraemia and in individual cases including chronic lung infection, necrotizing tenosynovitis with subcutaneous abscesses, cutaneous and bone infections, meningitis and peritonitis.

Source and occurrence

Tsukamurella spp. exist primarily as environmental saprophytes in soil, water and foam (thick stable scum on aeration vessels and sedimentation tanks) of activated sludge. *Tsukamurella* are represented in HPC populations in drinking-water.

Routes of exposure

Tsukamurella spp. appear to be transmitted through devices such as catheters or lesions. The original source of the contaminating organisms is unknown.

Significance in drinking-water

Tsukamurella organisms have been detected in drinking-water supplies, but the significance is unclear. There is no evidence of a link between organisms in water and illness. As *Tsukamurella* is an environmental organism, *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for this organism.

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Vibrio

General description

Vibrio spp. are small, curved (comma-shaped), Gram-negative bacteria with a single polar flagellum. Species are typed according to their O antigens. There are a number of pathogenic species, including *V. cholerae*, *V. parahaemolyticus* and *V. vulnificus*. *Vibrio cholerae* is the only pathogenic species of significance from freshwater environments. Although a number of serotypes can cause diarrhoea, only O1 and O139 currently cause the classical cholera symptoms in which a proportion of cases suffer fulminating and severe watery diarrhoea. The O1 serovar has been further divided into "classical" and "El Tor" biotypes. The latter is distinguished by features such as the ability to produce a dialysable heat-labile haemolysin, active against sheep and goat red blood cells. The classical biotype is considered responsible for the first six cholera pandemics, whereas the El Tor biotype is responsible for the seventh pandemic that commenced in 1961. Strains of *V. cholerae* O1 and O139 that cause cholera produce an enterotoxin (cholera toxin) that alters the ionic fluxes across the intestinal mucosa, resulting in substantial loss of water and electrolytes in liquid stools. Other factors associated with infection are an adhesion factor and an attachment pilus. Not all strains of serotypes O1 or O139 possess the virulence factors, and they are rarely possessed by non-O1/O139 strains.

Human health effects

Cholera outbreaks continue to occur in many areas of the developing world. Symptoms are caused by heat-labile cholera enterotoxin carried by toxigenic strains of *V. cholerae* O1/O139. A large percentage of infected persons do not develop illness; about 60% of the classical and 75% of the El Tor group infections are asymptomatic. Symptomatic illness ranges from mild or moderate to severe disease. The initial symptoms of cholera are an increase in peristalses followed by loose, watery and mucus-flecked "rice-water" stools that may cause a patient to lose as much as 10–15 litres of liquid per day. Decreasing gastric acidity by administration of sodium bicarbonate reduces the infective dose of *V. cholerae* O1 from more than 10^8 to about 10^4 organisms. Case

fatality rates vary according to facilities and preparedness. As many as 60% of untreated patients may die as a result of severe dehydration and loss of electrolytes, but well-established diarrhoeal disease control programmes can reduce fatalities to less than 1%. Non-toxigenic strains of *V. cholerae* can cause self-limiting gastroenteritis, wound infections and bacteraemia.

Source and occurrence

Non-toxigenic *V. cholerae* is widely distributed in water environments, but toxigenic strains are not distributed as widely. Humans are an established source of toxigenic *V. cholerae*; in the presence of disease, the organism can be detected in sewage. Although *V. cholerae* O1 can be isolated from water in areas without disease, the strains are not generally toxigenic. Toxigenic *V. cholerae* has also been found in association with live copepods as well as other aquatic organisms, including molluscs, crustaceans, plants, algae and cyanobacteria. Numbers associated with these aquatic organisms are often higher than in the water. Non-toxigenic *V. cholerae* has been isolated from birds and herbivores in areas far away from marine and coastal waters. The prevalence of *V. cholerae* decreases as water temperatures fall below 20 °C.

Routes of exposure

Cholera is typically transmitted by the faecal–oral route, and the infection is predominantly contracted by the ingestion of faecally contaminated water and food. The high numbers required to cause infection make person-to-person contact an unlikely route of transmission.

Significance in drinking-water

Contamination of water due to poor sanitation is largely responsible for transmission, but this does not fully explain the seasonality of recurrence, and factors other than poor sanitation must play a role. The presence of the pathogenic *V. cholerae* O1 and O139 serotypes in drinking-water supplies is of major public health importance and can have serious health and economic implications in the affected communities. *Vibrio cholerae* is highly sensitive to disinfection processes. Within a water safety plan, control measures that can be applied to manage potential risk from toxigenic *V. cholerae* include protection of raw water supplies from human waste, adequate treatment and protection of water during distribution. *Vibrio cholerae* O1 and non-O1 have been detected in the absence of *E. coli*, and this organism (or, alternatively, thermotolerant coliforms) is not a reliable indicator for *V. cholerae* in drinking-water.

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Yersinia

General description

The genus *Yersinia* is classified in the family Enterobacteriaceae and comprises seven species. The species *Y. pestis*, *Y. pseudotuberculosis* and certain serotypes of *Y. enterocolitica* are pathogens for humans. *Yersinia pestis* is the cause of bubonic plague through contact with rodents and their fleas. *Yersinia* spp. are Gram-negative rods that are motile at 25 °C but not at 37 °C.

Human health effects

Yersinia enterocolitica penetrates cells of the intestinal mucosa, causing ulcerations of the terminal ilium. Yersiniosis generally presents as an acute gastroenteritis with diarrhoea, fever and abdominal pain. Other clinical manifestations include greatly enlarged painful lymph nodes referred to as "buboes". The disease seems to be more acute in children than in adults.

Source and occurrence

Domestic and wild animals are the principal reservoir for *Yersinia spp*.; pigs are the major reservoir of pathogenic *Y. enterocolitica*, whereas rodents and small animals are the major reservoir of *Y. pseudotuberculosis*. Pathogenic *Y. enterocolitica* has been detected in sewage and polluted surface waters. However, *Y. enterocolitica* strains detected in drinking-water are more commonly non-pathogenic strains of probable environmental origin. At least some species and strains of *Yersinia* seem to be able to replicate in water environments if at least trace amounts of organic nitrogen are present, even at temperatures as low as 4 °C.

Routes of exposure

Yersinia spp. are transmitted by the faecal–oral route, with the major source of infection considered to be foods, particularly meat and meat products, milk and dairy products. Ingestion of contaminated water is also a potential source of infection. Direct transmission from person to person and from animals to humans is also known to occur.

Significance in drinking-water

Although most *Yersinia* spp. detected in water are probably non-pathogenic, circumstantial evidence has been presented to support transmission of *Y. enterocolitica* and *Y. pseudotuberculosis* to humans from untreated drinking-water. The most likely source of pathogenic *Yersinia* spp. is human or animal waste. The organisms are sensitive to disinfection processes. Within a water safety plan, control measures that can be used to minimize the presence of pathogenic *Yersinia* spp. in drinking-water supplies include protection of raw water supplies from human and animal waste, adequate disinfection and protection of water during distribution. Owing to the long survival and/or growth of some strains of *Yersinia* spp. in water, *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of these organisms in drinking-water.

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11.2 Viral pathogens

Viruses associated with waterborne transmission are predominantly those that can infect the gastrointestinal tract and are excreted in the faeces of infected humans (enteric viruses). With the exception of hepatitis E virus, humans are considered to be the only source of human infectious species. Enteric viruses typically cause acute disease with a short incubation period. Water may also play a role in the transmission of other viruses with different modes of action. As a group, viruses can cause a wide variety of infections and symptoms involving different routes of transmission, routes and sites of infection and routes of excretion. The combination of these routes and sites of infection can vary and will not always follow expected patterns. For example, viruses that are considered to primarily cause respiratory infections and symptoms are usually transmitted by person-to-person spread of respiratory droplets. However, some of these respiratory viruses may be discharged in faeces, leading to potential contamination of water and subsequent transmission through aerosols and droplets. Another example is viruses excreted in urine, such as polyomaviruses, which could contaminate and then be potentially transmitted by water, with possible long-term health effects, such as cancer, that are not readily associated epidemiologically with waterborne transmission.

Adenoviruses

General description

The family Adenoviridae is classified into the two genera *Mastadenovirus* (mammal hosts) and *Aviadenovirus* (avian hosts). Adenoviruses are widespread in nature, infecting birds, mammals and amphibians. To date, 51 antigenic types of human adenoviruses have been described. Human adenoviruses have been classified into six groups (A–F) on the basis of their physical, chemical and biological properties. Adenoviruses consist of a double-stranded DNA genome in a non-enveloped icosahedral capsid with a diameter of about 80 nm and unique fibres. The subgroups A–E grow readily in cell culture, but serotypes 40 and 41 are fastidious and do not grow well. Identification of serotypes 40 and 41 in environmental samples is generally based on polymerase chain reaction (PCR) techniques with or without initial cell culture amplification.

Human health effects

Human adenoviruses cause a wide range of infections with a spectrum of clinical manifestations. These include infections of the gastrointestinal tract (gastroenteritis), the respiratory tract (acute respiratory diseases, pneumonia, pharyngoconjunctival fever), the urinary tract (cervicitis, urethritis, haemorrhagic cystitis) and the eyes (epidemic keratoconjunctivitis, also known as "shipyard eye"; pharyngoconjunctival fever, also known as "swimming pool conjunctivitis"). Different serotypes are associated with specific illnesses; for example, types 40 and 41 are the main causes of enteric illness. Adenoviruses are an important source of childhood gastroenteritis. In general, infants and children are most susceptible to adenovirus infections, and many infections are asymptomatic. High attack rates in outbreaks imply that infecting doses are low.

Source and occurrence

Adenoviruses are excreted in large numbers in human faeces and are known to occur in sewage, raw water sources and treated drinking-water supplies worldwide. Although the subgroup of enteric adenoviruses (mainly types 40 and 41) is a major cause of gastroenteritis worldwide, notably in developing communities, little is known about the prevalence of these enteric adenoviruses in water sources. The limited availability of information on enteric adenoviruses is largely due to the fact that they are not detectable by conventional cell culture isolation.

Routes of exposure

Owing to the diverse epidemiology of the wide spectrum of human adenoviruses, exposure and infection are possible by a variety of routes. Person-to-person contact plays a major role in the transmission of illness; depending on the nature of the illness, this can include faecal–oral, oral–oral and hand–eye contact transmission, as well as indirect transfer through contaminated surfaces or shared utensils. There have been numerous outbreaks associated with hospitals, military establishments, childcare centres and schools. Symptoms recorded in most outbreaks were acute respiratory disease, keratoconjunctivitis and conjunctivitis. Outbreaks of gastroenteritis have also been reported. The consumption of contaminated food or water may be an important source of enteric illness, although there is no substantial evidence supporting this route of transmission. Eye infections may be contracted by the exposure of eyes to contaminated water, the sharing of towels at swimming pools or the sharing of goggles, as in the case of "shipyard eye". Confirmed outbreaks of adenovirus infections associated with water have been limited to pharyngitis or conjunctivitis, with exposure arising from use of swimming pools.

Significance in drinking-water

Human adenoviruses have been shown to occur in substantial numbers in raw water sources and treated drinking-water supplies. In one study, the incidence of human adenoviruses in such waters was exceeded only by the group of enteroviruses among viruses detectable by PCR-based techniques. In view of their prevalence as an enteric pathogen and detection in water, contaminated drinking-water represents a likely but unconfirmed source of human adenovirus infections. Human adenoviruses are also

considered important because they are exceptionally resistant to some water treatment and disinfection processes, notably ultraviolet (UV) light irradiation. Human adenoviruses have been detected in drinking-water supplies that met accepted specifications for treatment, disinfection and conventional indicator organisms. Within a water safety plan, control measures to reduce potential risk from human adenoviruses should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove human adenoviruses will require validation. Drinking-water supplies should also be protected from contamination during distribution. Because of the high resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of human adenoviruses in drinking-water supplies.

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Astroviruses

General description

Human and animal strains of astroviruses are single-stranded ribonucleic acid (RNA) viruses classified in the family Astroviridae. Astroviruses consist of a single-stranded RNA genome in a non-enveloped icosahedral capsid with a diameter of about 28 nm. In a proportion of the particles, a distinct surface star-shaped structure can be seen by electron microscopy. Eight different serotypes of human astroviruses have been described. The most commonly identified is human astrovirus serotype 1. Human astroviruses can be detected in environmental samples using PCR techniques with or without initial cell culture amplification.

Human health effects

Human astroviruses cause gastroenteritis, predominantly diarrhoea, mainly in children under 5 years of age, although it has also been reported in adults. Seroprevalence studies showed that more than 80% of children between 5 and 10 years of age have antibodies against human astroviruses. Occasional outbreaks in schools, nurseries and families have been reported. The illness is self-limiting, is of short duration and has a peak incidence in the winter. Human astroviruses are the cause of only a small proportion of reported gastroenteritis infections. However, the number of infections may be underestimated, as the illness is usually mild, and many cases will go unreported.

Source and occurrence

Infected individuals generally excrete large numbers of human astroviruses in faeces; hence, the viruses will be present in sewage. Human astroviruses have been detected in water sources and in drinking-water supplies.

Routes of exposure

Human astroviruses are transmitted by the faecal–oral route. Person-to-person spread is considered the most common route of transmission, and clusters of cases are seen in child-care centres, paediatric wards, families, homes for the elderly and military establishments. Ingestion of contaminated food or water could also be important.

Significance in drinking-water

The presence of human astroviruses in treated drinking-water supplies has been confirmed. As the viruses are typically transmitted by the faecal–oral route, transmission by drinking-water seems likely, but has not been confirmed. Human astroviruses have been detected in drinking-water supplies that met accepted specifications for treatment, disinfection and conventional indicator organisms. Within a water safety plan, control measures to reduce potential risk from human astroviruses should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove human astroviruses will require validation. Drinking-water supplies should also be protected from contamination during distribution. Owing to the higher resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of human astroviruses in drinking-water supplies.

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Caliciviruses

General description

The family Caliciviridae consists of four genera of single-stranded RNA viruses with a non-enveloped capsid (diameter 35–40 nm), which generally displays a typical surface morphology resembling cup-like structures. Human caliciviruses include the genera *Norovirus* (Norwalk-like viruses) and *Sapovirus* (Sapporo-like viruses). *Sapovirus* spp. demonstrate the typical calicivirus morphology and are called classical caliciviruses. Noroviruses generally fail to reveal the typical morphology and were in the past referred to as small round-structured viruses. The remaining two genera of the family contain viruses that infect animals other than humans. Human caliciviruses cannot be propagated in available cell culture systems. The viruses were originally

discovered by electron microscopy. Some *Norovirus* spp. can be detected by enzyme-linked immunosorbent assay using antibodies raised against baculovirus-expressed *Norovirus* capsid proteins. Several reverse transcriptase PCR procedures have been described for the detection of human caliciviruses.

Human health effects

Human caliciviruses are a major cause of acute viral gastroenteritis in all age groups. Symptoms include nausea, vomiting and abdominal cramps. Usually about 40% of infected individuals present with diarrhoea; some have fever, chills, headache and muscular pain. As some cases present with vomiting only and no diarrhoea, the condition is also known as "winter vomiting disease". Infections by human caliciviruses induce a short-lived immunity. The symptoms are usually relatively mild and rarely last for more than 3 days. High attack rates in outbreaks indicate that the infecting dose is low.

Source and occurrence

Human caliciviruses are excreted in faeces of infected individuals and will therefore be present in domestic wastewaters as well as faecally contaminated food and water, including drinking-water supplies.

Routes of exposure

The epidemiology of the disease indicates that person-to-person contact and the inhalation of contaminated aerosols and dust particles, as well as airborne particles of vomitus, are the most common routes of transmission. Drinking-water and a wide variety of foods contaminated with human faeces have been confirmed as major sources of exposure. Numerous outbreaks have been associated with contaminated drinking-water, ice, water on cruise ships and recreational waters. Shellfish harvested from sewage-contaminated waters have also been identified as a source of outbreaks.

Significance in drinking-water

Many human calicivirus outbreaks have been epidemiologically linked to contaminated drinking-water supplies. Within a water safety plan, control measures to reduce potential risk from human caliciviruses should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove human caliciviruses will require validation. Drinking-water supplies should also be protected from contamination during distribution. Owing to the higher resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of human caliciviruses in drinking-water supplies.

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Enteroviruses

General description

The genus *Enterovirus* is a member of the family Picornaviridae. This genus consists of 69 serotypes (species) that infect humans: poliovirus types 1–3, coxsackievirus types A1–A24, coxsackievirus types B1–B6, echovirus types 1–33 and the numbered enterovirus types EV68–EV73. Members of the genus are collectively referred to as enteroviruses. Other species of the genus infect animals other than humans—for instance, the bovine group of enteroviruses. Enteroviruses are among the smallest known viruses and consist of a single-stranded RNA genome in a non-enveloped icosahedral capsid with a diameter of 20–30 nm. Some members of the genus, notably poliovirus, coxsackievirus B, echovirus and enterovirus, are readily isolated by cytopathogenic effect in cell cultures.

Human health effects

Enteroviruses are one of the most common causes of human infections. They have been estimated to cause about 30 million infections in the USA each year. The spectrum of diseases caused by enteroviruses is broad and ranges from a mild febrile illness to myocarditis, meningoencephalitis, poliomyelitis, herpangina, hand-foot-and-mouth disease and neonatal multi-organ failure. The persistence of the viruses in chronic conditions such as polymyositis, dilated cardiomyopathy and chronic fatigue syndrome has been described. Most infections, particularly in children, are asymptomatic, but still lead to the excretion of large numbers of the viruses, which may cause clinical disease in other individuals.

Source and occurrence

Enteroviruses are excreted in the faeces of infected individuals. Among the types of viruses detectable by conventional cell culture isolation, enteroviruses are generally the most numerous in sewage, water resources and treated drinking-water supplies. The viruses are also readily detected in many foods.

Routes of exposure

Person-to-person contact and inhalation of airborne viruses or viruses in respiratory droplets are considered to be the predominant routes of transmission of enteroviruses in communities. Transmission from drinking-water could also be important, but this has not yet been confirmed. Waterborne transmission of enteroviruses (coxsackievirus A16 and B5) has been epidemiologically confirmed for only two outbreaks, and these were associated with children bathing in lake water in the 1970s.

Significance in drinking-water

Enteroviruses have been shown to occur in substantial numbers in raw water sources and treated drinking-water supplies. In view of their prevalence, drinking-water represents a likely, although unconfirmed, source of enterovirus infection. The limited

knowledge on the role of waterborne transmission could be related to a number of factors, including the wide range of clinical symptoms, frequent asymptomatic infection, the diversity of serotypes and the dominance of person-to-person spread. Enteroviruses have been detected in drinking-water supplies that met accepted specifications for treatment, disinfection and conventional indicator organisms. Within a water safety plan, control measures to reduce potential risk from enteroviruses should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove enteroviruses will require validation. Drinking-water supplies should also be protected from contamination during distribution. Owing to the higher resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of enteroviruses in drinking-water supplies.

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Hepatitis A virus

General description

Hepatitis A virus (HAV) is the only species of the genus *Hepatovirus* in the family Picornaviridae. The virus shares basic structural and morphological features with other members of the family, as described for enteroviruses. Human and simian HAVs are genotypically distinguishable. HAV cannot be readily detected or cultivated in conventional cell culture systems, and identification in environmental samples is based on the use of PCR techniques.

Human health effects

HAV is highly infectious, and the infecting dose is considered to be low. The virus causes the disease hepatitis A, commonly known as "infectious hepatitis". Like other members of the group enteric viruses, HAV enters the gastrointestinal tract by ingestion, where it infects epithelial cells. From here, the virus enters the bloodstream and reaches the liver, where it may cause severe damage to liver cells. In as many as 90% of cases, particularly in children, there is little, if any, liver damage, and the infection passes without clinical symptoms and elicits lifelong immunity. In general, the severity of illness increases with age. The damage to liver cells results in the release of liver-specific enzymes such as aspartate aminotransferase, which are detectable in the bloodstream and used as a diagnostic tool. The damage also results in the failure of the liver to remove bilirubin from the bloodstream; the accumulation of bilirubin causes the typical symptoms of jaundice and dark urine. After a relatively long incubation period of 28–30 days on average, there is a characteristic sudden onset of illness, including symptoms such as fever, malaise, nausea, anorexia, abdominal discomfort and eventually jaundice. Although mortality is generally less than 1%, repair of the liver

damage is a slow process that may keep patients incapacitated for 6 weeks or longer. This has substantial burden of disease implications. Mortality is higher in those over 50 years of age.

Source and occurrence

HAV occurs worldwide, but the prevalence of clinical disease has typical geographically based characteristics. HAV is excreted in faecal material of infected people, and there is strong epidemiological evidence that faecally contaminated food and water are common sources of the virus. In areas with poor sanitation, children are often infected at a very early age and become immune for life without clinical symptoms of disease. In areas with good sanitation, infection tends to occur later in life.

Routes of exposure

Person-to-person spread is probably the most common route of transmission, but contaminated food and water are important sources of infection. There is stronger epidemiological evidence for waterborne transmission of HAV than for any other virus. Foodborne outbreaks are also relatively common, with sources of infection including infected food handlers, shellfish harvested from contaminated water and contaminated produce. Travel of people from areas with good sanitation to those with poor sanitation provides a high risk of infection. Infection can also be spread in association with injecting and non-injecting drug use.

Significance in drinking-water

The transmission of HAV by drinking-water supplies is well established, and the presence of HAV in drinking-water constitutes a substantial health risk. Within a water safety plan, control measures to reduce potential risk from HAV should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove HAV will require validation. Drinking-water supplies should also be protected from contamination during distribution. Owing to the higher resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of HAV in drinking-water supplies.

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Hepatitis E virus

General description

Hepatitis E virus (HEV) consists of a single-stranded RNA genome in a non-enveloped icosahedral capsid with a diameter of 27–34 nm. HEV shares properties with a number of viruses, and classification is a challenge. At one stage, HEV was classified as a member of the family Caliciviridae, but most recently it has been placed in a separate family called hepatitis E–like viruses. There are indications of antigenic variation,

and possibly even differences in serotypes of the virus, whereas human HAV consists of only one clearly defined serotype. HEV cannot be readily detected or cultivated in conventional cell culture systems, and identification in environmental samples is based on the use of PCR techniques.

Human health effects

HEV causes hepatitis that is in many respects similar to that caused by HAV. However, the incubation period tends to be longer (average 40 days), and infections typically have a mortality rate of up to 25% in pregnant women. In endemic regions, first infections are typically seen in young adults rather than young children. Despite evidence of antigenic variation, single infection appears to provide lifelong immunity to HEV. Global prevalence has a characteristic geographic distribution. HEV is endemic and causes clinical diseases in certain developing parts of the world, such as India, Nepal, central Asia, Mexico and parts of Africa. In many of these areas, HEV is the most important cause of viral hepatitis. Although seroprevalence can be high, clinical cases and outbreaks are rare in certain parts of the world, such as Japan, South Africa, the United Kingdom, North and South America, Australasia and central Europe. The reason for the lack of clinical cases in the presence of the virus is unknown.

Source and occurrence

HEV is excreted in faeces of infected people, and the virus has been detected in raw and treated sewage. Contaminated water has been associated with very large outbreaks. HEV is distinctive, in that it is the only enteric virus with a meaningful animal reservoir, including domestic animals, particularly pigs, as well as cattle, goats and even rodents.

Routes of exposure

Secondary transmission of HEV from cases to contacts and particularly nursing staff has been reported, but appears to be much less common than for HAV. The lower level of person-to-person spread suggests that faecally polluted water could play a much more important role in the spread of HEV than of HAV. Waterborne outbreaks involving thousands of cases are on record. These include one outbreak in 1954 with approximately 40 000 cases in Delhi, India; one with more than 100 000 cases in 1986–1988 in the Xinjiang Uighar region of China; and one in 1991 with some 79 000 cases in Kanpur, India. Animal reservoirs may also serve as a route of exposure, but the extent to which humans contract HEV infection from animals remains to be elucidated.

Significance in drinking-water

The role of contaminated water as a source of HEV has been confirmed, and the presence of the virus in drinking-water constitutes a major health risk. There is no laboratory information on the resistance of the virus to disinfection processes, but data on waterborne outbreaks suggest that HEV may be as resistant as other enteric viruses. Within a water safety plan, control measures to reduce potential risk from HEV should focus on prevention of source water contamination by human and animal waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove HEV will require validation. Drinking-water supplies

should also be protected from contamination during distribution. Owing to the likelihood that the virus has a higher resistance to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of HEV in drinking-water supplies.

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Rotaviruses and orthoreoviruses

General description

Members of the genus Rotavirus consist of a segmented double-stranded RNA genome in a non-enveloped icosahedral capsid with a diameter of 50–65 nm. This capsid is surrounded by a double-layered shell, giving the virus the appearance of a wheel—hence the name rotavirus. The diameter of the entire virus is about 80 nm. *Rotavirus* and *Orthoreovirus* are the two genera of the family Reoviridae typically associated with human infection. Orthoreoviruses are readily isolated by cytopathogenic effect on cell cultures. The genus *Rotavirus* is serologically divided into seven groups, A–G, each of which consists of a number of subgroups; some of these subgroups specifically infect humans, whereas others infect a wide spectrum of animals. Groups A–C are found in humans, with group A being the most important human pathogens. Wild-type strains of rotavirus group A are not readily grown in cell culture, but there are a number of PCR-based detection methods available for testing environmental samples.

Human health effects

Human rotaviruses are the most important single cause of infant death in the world. Typically, 50–60% of cases of acute gastroenteritis of hospitalized children throughout the world are caused by human rotaviruses. The viruses infect cells in the villi of the small intestine, with disruption of sodium and glucose transport. Acute infection has an abrupt onset of severe watery diarrhoea with fever, abdominal pain and vomiting; dehydration and metabolic acidosis may develop, and the outcome may be fatal if the infection is not appropriately treated. The burden of disease of rotavirus infections is extremely high. Members of the genus *Orthoreovirus* infect many humans, but they are typical "orphan viruses" and not associated with any meaningful disease.

Source and occurrence

Human rotaviruses are excreted by patients in numbers up to 10^{11} per gram of faeces for periods of about 8 days. This implies that domestic sewage and any environments

polluted with the human faeces are likely to contain large numbers of human rotaviruses. The viruses have been detected in sewage, rivers, lakes and treated drinking-water. Orthoreoviruses generally occur in wastewater in substantial numbers.

Routes of exposure

Human rotaviruses are transmitted by the faecal–oral route. Person-to-person transmission and the inhalation of airborne human rotaviruses or aerosols containing the viruses would appear to play a much more important role than ingestion of contaminated food or water. This is confirmed by the spread of infections in children's wards in hospitals, which takes place much faster than can be accounted for by the ingestion of food or water contaminated by the faeces of infected patients. The role of contaminated water in transmission is lower than expected, given the prevalence of human rotavirus infections and presence in contaminated water. However, occasional waterborne and foodborne outbreaks have been described. Two large outbreaks in China in 1982–1983 were linked to contaminated water supplies.

Significance in drinking-water

Although ingestion of drinking-water is not the most common route of transmission, the presence of human rotaviruses in drinking-water constitutes a public health risk. There is some evidence that the rotaviruses are more resistant to disinfection than other enteric viruses. Within a water safety plan, control measures to reduce potential risk from human rotaviruses should focus on prevention of source water contamination by human waste, followed by adequate treatment and disinfection. The effectiveness of treatment processes used to remove human rotaviruses will require validation. Drinking-water supplies should also be protected from contamination during distribution. Owing to a higher resistance of the viruses to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator of the presence/absence of human rotaviruses in drinking-water supplies.

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11.3 Protozoan pathogens

Protozoa and helminths are among the most common causes of infection and disease in humans and animals. The diseases have a major public health and socioeconomic impact. Water plays an important role in the transmission of some of these pathogens. The control of waterborne transmission presents real challenges, because most of the pathogens produce cysts, oocysts or eggs that are extremely resistant to processes

generally used for the disinfection of water and in some cases can be difficult to remove by filtration processes. Some of these organisms cause "emerging diseases". In the last 30 years, the most notable example of an emerging disease caused by a protozoan pathogen is cryptosporidiosis. Other examples are diseases caused by microsporidia and *Cyclospora*. As evidence for waterborne transmission of "emerging diseases" has been reported relatively recently, some questions about their epidemiology and behaviour in water treatment and disinfection processes remain to be elucidated. It would appear that the role of water in the transmission of this group of pathogens may increase substantially in importance and complexity as human and animal populations grow and the demands for potable drinking-water escalate.

Further information on emerging diseases is provided in *Emerging issues in water and infectious disease* (WHO, 2003) and associated texts.

Acanthamoeba

General description

Acanthamoeba spp. are free-living amoebae (10–50 μm in diameter) common in aquatic environments and one of the prominent protozoa in soil. The genus contains some 20 species, of which *A. castellanii*, *A. polyphaga* and *A. culbertsoni* are known to be human pathogens. However, the taxonomy of the genus may change substantially when evolving molecular biological knowledge is taken into consideration. *Acanthamoeba* has a feeding, replicative trophozoite, which, under unfavourable conditions, such as an anaerobic environment, will develop into a dormant cyst that can withstand extremes of temperature (−20 to 56 °C), disinfection and desiccation.

Human health effects

Acanthamoeba culbertsoni causes granulomatous amoebic encephalitis, whereas *A. castellanii* and *A. polyphaga* are associated with acanthamoebic keratitis and acanthamoebic uveitis.

Granulomatous amoebic encephalitis is a multifocal, haemorrhagic and necrotizing encephalitis that is generally seen only in debilitated or immunodeficient persons. It is a rare, but usually fatal, disease. Early symptoms include drowsiness, personality changes, intense headaches, stiff neck, nausea, vomiting, sporadic low fevers, focal neurological changes, hemiparesis and seizures. This is followed by an altered mental status, diplopia, paresis, lethargy, cerebellar ataxia and coma. Death follows within a week to a year after the appearance of the first symptoms, usually as a result of bronchopneumonia. Associated disorders of granulomatous amoebic encephalitis include skin ulcers, liver disease, pneumonitis, renal failure and pharyngitis.

Acanthamoebic keratitis is a painful infection of the cornea and can occur in healthy individuals, especially among contact lens wearers. It is a rare disease that may lead to impaired vision, permanent blindness and loss of the eye. The prevalence of antibodies to *Acanthamoeba* and the detection of the organism in the upper airways of healthy persons suggest that infection may be common with few apparent symptoms in the vast majority of cases.

Source and occurrence

The wide distribution of *Acanthamoeba* in the natural environment makes soil, airborne dust and water all potential sources. *Acanthamoeba* can be found in many types of aquatic environments, including surface water, tap water, swimming pools and contact lens solutions. Depending on the species, *Acanthamoeba* can grow over a wide temperature range in water, with the optimum temperature for pathogenic species being 30 °C. Trophozoites can exist and replicate in water while feeding on bacteria, yeasts and other organisms.

Routes of exposure

Acanthamoebic keratitis has been associated with contact lenses being washed with contaminated home-made saline solutions or contamination of the contact lens containers. Although the source of the contaminating organisms has not been established, tap water is one possibility. Warnings have been issued by a number of health agencies that only sterile water should be used to prepare wash solutions for contact lenses. The mode of transmission of granulomatous amoebic encephalitis has not been established, but water is not considered to be a source of infection. The more likely routes of transmission are via the blood from other sites of colonization, such as skin lesions or lungs.

Significance in drinking-water

Cases of acanthamoebic keratitis have been associated with drinking-water due to use of tap water in preparing solutions for washing contact lenses. Cleaning of contact lenses is not considered to be a normal use for tap water, and a higher-quality water may be required. Compared with *Cryptosporidium* oocysts and *Giardia* cysts, *Acanthamoeba* cysts are relatively large and amenable to removal from raw water by filtration. Reducing the presence of biofilm organisms is likely to reduce food sources and growth of the organism in distribution systems, but the cyst is highly resistant to disinfection. However, as normal uses of drinking-water lack significance as a source of infection, setting a health-based target for *Acanthamoeba* spp. is not warranted.

Selected bibliography

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Balantidium coli

General description

Balantidium coli is a unicellular protozoan parasite with a length up to 200 µm, making it the largest of the human intestinal protozoa. The trophozoites are oval in shape and covered with cilia for motility. The cysts are 60–70 µm in length and resistant to unfavourable environmental conditions, such as pH and temperature extremes. *Balantidium coli* belongs to the largest protozoan group, the ciliates, with about 7200 species, of which only *B. coli* is known to infect humans.

Human health effects

Infections in humans are relatively rare, and most are asymptomatic. The trophozoites invade the mucosa and submucosa of the large intestine and destroy the host cells when multiplying. The multiplying parasites form nests and small abscesses that break down into oval, irregular ulcers. Clinical symptoms may include dysentery similar to amoebiasis, colitis, diarrhoea, nausea, vomiting, headache and anorexia. The infections are generally self-limiting, with complete recovery.

Source and occurrence

Humans seem to be the most important host of *B. coli*, and the organism can be detected in domestic sewage. Animal reservoirs, particularly swine, also contribute to the prevalence of the cysts in the environment. The cysts have been detected in water sources, but the prevalence in tap water is unknown.

Routes of exposure

Transmission of *B. coli* is by the faecal–oral route, from person to person, from contact with infected swine or by consumption of contaminated water or food. One waterborne outbreak of balantidiasis has been reported. This outbreak occurred in 1971 when a drinking-water supply was contaminated with stormwater runoff containing swine faeces after a typhoon.

Significance in drinking-water

Although water does not appear to play an important role in the spread of this organism, one waterborne outbreak is on record. *Balantidium coli* is large and amenable to removal by filtration, but cysts are highly resistant to disinfection. Within a water safety plan, control measures to reduce potential risk from *B. coli* should focus on prevention of source water contamination by human and swine waste, followed by adequate treatment. Owing to resistance to disinfection, *E. coli* (or, alternatively, thermotolerant coliforms) is not a reliable indicator for the presence/absence of *B. coli* in drinking-water supplies.

Selected bibliography

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Blastocystis

General description

Blastocystis is a common anaerobic intestinal parasite that was first described in the early 1900s. Despite this long history, there are large gaps in knowledge about the organism, and the issue of pathogenicity remains a subject of some debate. *Blastocystis* spp. have been detected in a range of animal hosts, with isolates from humans identified as *Blastocystis hominis*. However, molecular studies suggest that there is considerable antigenic and genetic heterogeneity within *B. hominis* and *Blastocystis* spp. *Blastocystis hominis* lives in the colon and has several morphological forms, including a faecal cyst that is believed to be the infective form.

Human health effects

Blastocystis hominis is probably the most common protozoan detected in human faecal samples worldwide. Infection occurs in both immunocompetent and immunocompromised individuals. Reported prevalence ranges from 2% to 50%, with the highest rates reported for developing countries with poor environmental hygiene. Infection appears to be more common in adults than in children. However, one study showed that peak infection occurs at 10 years of age and then later in life. Pathogenicity of *B. hominis* is controversial because of the nonspecific symptoms and prevalence of asymptomatic infections. Some case–control studies of individuals with and without symptoms show no difference in the prevalence of *B. hominis*. Symptoms attributed to *B. hominis* include watery or loose stools, diarrhoea, abdominal pain, anal itching, weight loss and excess gas. Duration of infection is not well known; some infections can last for weeks, months or years. In some patients, the symptoms resolve, even though *Blastocystis* can still be detected in stools. It has been suggested that *B. hominis* may be a commensal organism that becomes pathogenic when the host is immunosuppressed, is malnourished or has other infections.

Source and occurrence

The source of human infectious *Blastocystis* is uncertain. *Blastocystis* occurs in many animals, including insects, reptiles, birds and mammals. Some evidence suggests that *Blastocystis* may not be host specific and that animal-to-human transmission is possible. A recent survey in Malaysia showed that animal handlers and abattoir workers were at greater risk of infection than a control group of high-rise city dwellers. *Blastocystis* is excreted as a cyst, which could be environmentally persistent, but there are no data on its survival in the environment. *Blastocystis* has been identified in sewage samples.

Routes of exposure

The routes of transmission have not been established, but the faecal–oral route is considered to be the main mode of transmission. Studies of transmission between mice indicate infection after oral inoculation of faecal cysts. Water and foodborne transmission have been suggested, but not confirmed.

Significance in drinking-water

The role of drinking-water as a source of *Blastocystis* infections has not been established. However, an investigation in Thailand provided evidence of waterborne transmission, and identification in sewage samples suggests potential for this to occur. Within a water safety plan, control measures focused on prevention of source water contamination by human and animal waste should reduce potential risks. There is little information on the removal and/or inactivation of *Blastocystis* by water and wastewater treatment processes. The morphology of *Blastocystis* varies over a broad range, and size estimates vary. Faecal cysts can be as small as 3–10 μm in diameter, and these are likely to be removed by conventional granular media-based filtration methods in a similar manner to *Cryptosporidium* oocysts that are 4–6 μm in diameter. It has been reported that *Blastocystis* cysts are relatively resistant to chlorine. Because of this resistance, *E. coli* (or, alternatively, thermotolerant coliforms) should

not be relied upon as an indicator of the presence/absence of *Blastocystis* in drinking-water sources.

Selected bibliography

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Cryptosporidium

General description

Cryptosporidium is an obligate, intracellular, coccidian parasite with a complex life cycle including sexual and asexual replication. Thick-walled oocysts with a diameter of 4–6 µm are shed in faeces. The genus *Cryptosporidium* has about 13 species, with human infections predominantly caused by *C. hominis* and the cattle genotype of *C. parvum*. Other *Cryptosporidium* species have been reported to cause infrequent infections. *Cryptosporidium* was discovered to infect humans in 1976, and waterborne transmission was confirmed for the first time in 1984.

Human health effects

Cryptosporidium generally causes self-limiting diarrhoea, sometimes including nausea, vomiting and fever, which usually resolves within a week in normally healthy people, but can last for a month or more. Severity of cryptosporidiosis varies according to age and immune status, and infections in severely immunocompromised people can be life-threatening. The impact of cryptosporidiosis outbreaks is relatively high due to the large numbers of people that may be involved and the associated socioeconomic implications. The total cost of illness associated with the 1993 outbreak in Milwaukee, USA, has been estimated at US$ 96.2 million.

Source and occurrence

A large range of animals are reservoirs of *C. hominis/parvum*, but humans and livestock, particularly young animals, are the most significant source of human infectious organisms. Calves can excrete 10^{10} oocysts per day. Concentrations of oocysts as high as 14 000 per litre for raw sewage and 5800 per litre for surface water have been reported. Oocysts can survive for weeks to months in fresh water. *Cryptosporidium* oocysts have been detected in many drinking-water supplies. However, in most cases, there is little information about whether human infectious species were present. The currently available standard analytical techniques provide an indirect measure of viability and no indication of human infectivity. Oocysts also occur in recreational waters.

Routes of exposure

Cryptosporidium is transmitted by the faecal–oral route. The major route of infection is person-to-person contact. Other sources of infection include the consumption of contaminated food and water and direct contact with infected farm animals and possibly domestic pets. Contaminated drinking-water, recreational water and, to a lesser extent, food have been associated with outbreaks. In 1993, *Cryptosporidium* caused the largest waterborne outbreak of disease on record, when more than 400 000 people were infected by the drinking-water supply of Milwaukee, USA. The infectivity of *Cryptosporidium* oocysts is relatively high. Studies on healthy human volunteers revealed that ingestion of fewer than 10 oocysts can lead to infection.

Significance in drinking-water

The role of drinking-water in the transmission of *Cryptosporidium*, including in large outbreaks, is well established. Attention to these organisms is therefore important. The oocysts are extremely resistant to oxidizing disinfectants such as chlorine, but investigations based on assays for infectivity have shown that UV light irradiation inactivates oocysts. Within a water safety plan, control measures to reduce potential risk from *Cryptosporidium* should focus on prevention of source water contamination by human and livestock waste, adequate treatment and protection of water during distribution. Because of their relatively small size, the oocysts represent a challenge for removal by conventional granular media–based filtration processes. Acceptable removal requires well-designed and well-operated systems. Membrane filtration processes that provide a direct physical barrier may represent a viable alternative for the effective removal of *Cryptosporidium* oocysts. Owing to the exceptional resistance of the oocysts to disinfectants, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator for the presence/absence of *Cryptosporidium* oocysts in drinking-water supplies.

Selected bibliography

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Cyclospora cayetanensis

General description

Cyclospora cayetanensis is a single-celled, obligate, intracellular, coccidian protozoan parasite, which belongs to the family Eimeriidae. It produces thick-walled oocysts of

8–10 µm in diameter that are excreted in the faeces of infected individuals. *Cyclospora cayetanensis* is considered an emerging waterborne pathogen.

Human health effects

Sporozoites are released from the oocysts when ingested and penetrate epithelial cells in the small intestine of susceptible individuals. Clinical symptoms of cyclosporiasis include watery diarrhoea, abdominal cramping, weight loss, anorexia, myalgia and occasionally vomiting and/or fever. Relapsing illness often occurs.

Source and occurrence

Humans are the only host identified for this parasite. The unsporulated oocysts pass into the external environment with faeces and undergo sporulation, which is complete in 7–12 days, depending on environmental conditions. Only the sporulated oocysts are infectious. Owing to the lack of a quantification technique, there is limited information on the prevalence of *Cyclospora* in water environments. However, *Cyclospora* has been detected in sewage and water sources.

Routes of exposure

Cyclospora cayetanensis is transmitted by the faecal–oral route. Person-to-person transmission is virtually impossible, because the oocysts must sporulate outside the host to become infectious. The primary routes of exposure are contaminated water and food. The initial source of organisms in foodborne outbreaks has generally not been established, but consumption of food crops irrigated with contaminated water has been implicated in several cases. Drinking-water has also been implicated as a cause of outbreaks. The first report was among staff of a hospital in Chicago, USA, in 1990. The infections were associated with drinking tap water that had possibly been contaminated with stagnant water from a rooftop storage reservoir. Another outbreak was reported from Nepal, where drinking-water consisting of a mixture of river and municipal water was associated with infections in 12 of 14 soldiers.

Significance in drinking-water

Transmission of the pathogens by drinking-water has been confirmed. The oocysts are resistant to disinfection and are not inactivated by chlorination practices generally applied in the production of drinking-water. Within a water safety plan, control measures that can be applied to manage potential risk from *Cyclospora* include prevention of source water contamination by human waste, followed by adequate treatment and protection of water during distribution. Owing to the resistance of the cysts to disinfectants, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator of the presence/absence of *Cyclospora* in drinking-water supplies.

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Entamoeba histolytica

General description

Entamoeba histolytica is the most prevalent intestinal protozoan pathogen worldwide and belongs to the superclass Rhizopoda in the subphylum Sarcodina. *Entamoeba* has a feeding, replicative trophozoite (diameter 10–60 µm), which, under unfavourable conditions, will develop into a dormant cyst (diameter 10–20 µm). Infection is contracted by the ingestion of cysts. Recent studies with RNA and DNA probes demonstrated genetic differences between pathogenic and non-pathogenic *E. histolytica*; the latter has been separated and reclassified as *E. dispar*.

Human health effects

About 85–95% of human infections with *E. histolytica* are asymptomatic. Acute intestinal amoebiasis has an incubation period of 1–14 weeks. Clinical disease results from the penetration of the epithelial cells in the gastrointestinal tract by the amoebic trophozoites. Approximately 10% of infected individuals present with dysentery or colitis. Symptoms of amoebic dysentery include diarrhoea with cramping, lower abdominal pain, low-grade fever and the presence of blood and mucus in the stool. The ulcers produced by the invasion of the trophozoites may deepen into the classic flask-shaped ulcers of amoebic colitis. *Entamoeba histolytica* may invade other parts of the body, such as the liver, lungs and brain, sometimes with fatal outcome.

Source and occurrence

Humans are the reservoir of infection, and there would not appear to be other meaningful animal reservoirs of *E. histolytica*. In the acute phase of infection, patients excrete only trophozoites that are not infectious. Chronic cases and asymptomatic carriers who excrete cysts are more important sources of infection and can discharge up to 1.5×10^7 cysts daily. *Entamoeba histolytica* can be present in sewage and contaminated water. Cysts may remain viable in suitable aquatic environments for several months at low temperature. The potential for waterborne transmission is greater in the tropics, where the carrier rate sometimes exceeds 50%, compared with more temperate regions, where the prevalence in the general population may be less than 10%.

Routes of exposure

Person-to-person contact and contamination of food by infected food handlers appear to be the most significant means of transmission, although contaminated water

also plays a substantial role. Ingestion of faecally contaminated water and consumption of food crops irrigated with contaminated water can both lead to transmission of amoebiasis. Sexual transmission, particularly among male homosexuals, has also been documented.

Significance in drinking-water

The transmission of *E. histolytica* by contaminated drinking-water has been confirmed. The cysts are relatively resistant to disinfection and may not be inactivated by chlorination practices generally applied in the production of drinking-water. Within a water safety plan, control measures that can be applied to manage potential risk from *E. histolytica* include prevention of source water contamination by human waste, followed by adequate treatment and protection of water during distribution. Owing to the resistance of the cysts to disinfectants, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator of the presence/absence of *E. histolytica* in drinking-water supplies.

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Giardia intestinalis

General description

Giardia spp. are flagellated protozoa that parasitize the gastrointestinal tract of humans and certain other animals. The genus *Giardia* consists of a number of species, but human infection (giardiasis) is usually assigned to *G. intestinalis*, also known as *G. lamblia* or *G. duodenalis*. *Giardia* has a relatively simple life cycle consisting of a flagellate trophozoite that multiplies in the gastrointestinal tract and an infective thick-walled cyst that is shed intermittently but in large numbers in faeces. The trophozoites are bilaterally symmetrical and ellipsoidal in shape. The cysts are ovoid in shape and 8–12 μm in diameter.

Human health effects

Giardia has been known as a human parasite for 200 years. After ingestion and excystation of cysts, the trophozoites attach to surfaces of the gastrointestinal tract. Infections in both children and adults may be asymptomatic. In day-care centres, as many as 20% of children may carry *Giardia* and excrete cysts without clinical symptoms. The symptoms of giardiasis may result from damage caused by the trophozoites, although the mechanisms by which *Giardia* causes diarrhoea and intestinal malabsorption remain controversial. Symptoms generally include diarrhoea and abdominal cramps; in severe cases, however, malabsorption deficiencies in the small intestine may be present, mostly among young children. Giardiasis is self-limiting in most cases, but it may be chronic in some patients, lasting more than 1 year, even in otherwise healthy people. Studies on human volunteers revealed that fewer than 10 cysts constitute a meaningful risk of infection.

Source and occurrence

Giardia can multiply in a wide range of animal species and humans, which excrete cysts into the environment. Numbers of cysts as high as 88 000 per litre in raw sewage and 240 per litre in surface water resources have been reported. These cysts are robust and can survive for weeks to months in fresh water. The presence of cysts in raw water sources and drinking-water supplies has been confirmed. However, there is no information on whether human infectious species were present. The currently available standard analytical techniques provide an indirect measure of viability and no indication of human infectivity. Cysts also occur in recreational waters and contaminated food.

Routes of exposure

By far the most common route of transmission of *Giardia* is person-to-person contact, particularly between children. Contaminated drinking-water, recreational water and, to a lesser extent, food have been associated with outbreaks. Animals have been implicated as a source of human infectious *G. intestinalis*, but further investigations are required to determine their role.

Significance in drinking-water

Waterborne outbreaks of giardiasis have been associated with drinking-water supplies for over 30 years; at one stage, *Giardia* was the most commonly identified cause of waterborne outbreaks in the USA. *Giardia* cysts are more resistant than enteric bacteria to oxidative disinfectants such as chlorine, but they are not as resistant as *Cryptosporidium* oocysts. The time required for 90% inactivation at a free chlorine residual of 1 mg/l is about 25–30 minutes. Within a water safety plan, control measures that can be applied to manage potential risk from *Giardia* include prevention of source water contamination by human and animal waste, followed by adequate treatment and disinfection and protection of water during distribution. Owing to the resistance of the cysts to disinfectants, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator of the presence/absence of *Giardia* in drinking-water supplies.

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Isospora belli

General description

Isospora is a coccidian, single-celled, obligate parasite related to *Cryptosporidium* and *Cyclospora*. There are many species of Isospora that infect animals, but only *I. belli* is known to infect humans, the only known host for this species. *Isospora belli* is one of the few coccidia that undergo sexual reproduction in the human intestine. Sporulated oocysts are ingested, and, after complete asexual and sexual life cycles in the mucosal epithelium of the upper small intestine, unsporulated oocysts are released in faeces.

Human health effects

Illness caused by *I. belli* is similar to that caused by *Cryptosporidium* and *Giardia*. About 1 week after ingestion of viable oocysts, a low-grade fever, lassitude and malaise may appear, followed soon by mild diarrhoea and vague abdominal pain. The infection is usually self-limited after 1–2 weeks, but occasionally diarrhoea, weight loss and fever may last for 6 weeks to 6 months. Symptomatic isosporiasis is more common in children than in adults. Infection is often associated with immunocompromised patients, in whom symptoms are more severe and likely to be recurrent or chronic, leading to malabsorption and weight loss. Infections are usually sporadic and most common in the tropics and subtropics, although they also occur elsewhere, including industrialized countries. They have been reported from Central and South America, Africa and south-east Asia.

Source and occurrence

Unsporulated oocysts are excreted in the faeces of infected individuals. The oocysts sporulate within 1–2 days in the environment to produce the potentially infectious form of the organism. Few data are available on numbers of oocysts in sewage and raw and treated water sources. This is largely because sensitive and reliable techniques for the quantitative enumeration of oocysts in water environments are not available. Little is known about the survival of oocysts in water and related environments.

Routes of exposure

Poor sanitation and faecally contaminated food and water are the most likely sources of infection, but waterborne transmission has not been confirmed. The oocysts are less likely than *Cryptosporidium* oocysts or *Giardia* cysts to be transmitted directly from person to person, because freshly shed *I. belli* oocysts require 1–2 days in the environment to sporulate before they are capable of infecting humans.

Significance in drinking-water

The characteristics of *I. belli* suggest that illness could be transmitted by contaminated drinking-water supplies, but this has not been confirmed. No information is available on the effectiveness of water treatment processes for removal of *I. belli*, but it is likely that the organism is relatively resistant to disinfectants. It is considerably larger than *Cryptosporidium* and should be easier to remove by filtration. Within a water safety plan, control measures that can be applied to manage potential risk from

I. belli include prevention of source water contamination by human waste, followed by adequate treatment and disinfection and protection of water during distribution. Owing to the likely resistance of the oocysts to disinfectants, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator of the presence/absence of *I. belli* in drinking-water supplies.

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Microsporidia

General description

Microsporidia are eukaryotic obligate intracellular parasites belonging to the phylum Microspora. Although microsporidia were initially considered to be protozoa, the scientific classification is uncertain, with recent studies indicating that they could be classified as fungi. More than 100 microsporidial genera and almost 1000 species have been identified. Infections occur in every major animal group, including vertebrates and invertebrates. A number of genera have been implicated in human infections, including *Enterocytozoon*, *Encephalitozoon* (including *Septata*), *Nosema*, *Pleistophora*, *Vittaforma* and *Trachipleistophora*, as well as a collective group of unclassified microsporidia referred to as microsporidium. Microsporidia are among the smallest eukaryotes. They produce unicellular spores with a diameter of 1.0–4.5 μm and a characteristic coiled polar filament for injecting the sporoplasm into a host cell to initiate infection. Within an infected cell, a complex process of multiplication takes place, and new spores are produced and released in faeces, urine, respiratory secretions or other body fluids, depending on the type of species and the site of infection.

Human health effects

Microsporidia are emerging human pathogens identified predominantly in persons with AIDS, but their ability to cause disease in immunologically normal hosts has been recognized. Reported human infections are globally dispersed and have been documented in persons from all continents. The most common clinical manifestation in AIDS patients is a severe enteritis involving chronic diarrhoea, dehydration and weight loss. Prolonged illness for up to 48 months has been reported. Infections in the general population are less pronounced. *Enterocytozoon* infection generally appears to be limited to intestinal enterocytes and biliary epithelium. *Encephalitozoon* spp. infect a variety of cells, including epithelial and endothelial cells, fibroblasts, kidney tubule cells, macrophages and possibly other cell types. Unusual complications include keratoconjunctivitis, myositis and hepatitis.

Source and occurrence

The sources of microsporidia infecting humans are uncertain. Spores are likely to be excreted in faeces and are also excreted in urine and respiratory secretions. Owing to the lack of a quantification technique, there is limited information on the prevalence of microsporidia spores in water environments. However, microsporidia have been detected in sewage and water sources. Indications are that their numbers in raw sewage may be similar to those of *Cryptosporidium* and *Giardia*, and they may survive in certain water environments for many months. Certain animals, notably swine, may serve as a host for human infectious species.

Routes of exposure

Little is known about transmission of microsporidia. Person-to-person contact and ingestion of spores in water or food contaminated with human faeces or urine are probably important routes of exposure. A waterborne outbreak of microsporidiosis has been reported involving about 200 cases in Lyon, France, during the summer of 1995. However, the source of the organism and faecal contamination of the drinking-water supply were not demonstrated. Transmission by the inhalation of airborne spores or aerosols containing spores seems possible. The role of animals in transmission to humans remains unclear. Epidemiological and experimental studies in mammals suggest that *Encephalitozoon* spp. can be transmitted transplacentally from mother to offspring. No information is available on the infectivity of the spores. However, in view of the infectivity of spores of closely related species, the infectivity of microsporidia may be high.

Significance in drinking-water

Waterborne transmission has been reported, and infection arising from contaminated drinking-water is plausible but unconfirmed. Little is known about the response of microsporidia to water treatment processes. One study has suggested that the spores may be susceptible to chlorine. The small size of the organism is likely to make them difficult to remove by filtration processes. Within a water safety plan, control measures that can be applied to manage potential risk from microsporidia include prevention of source water contamination by human and animal waste, followed by adequate treatment and disinfection and protection of water during distribution. Owing to the lack of information on sensitivity of infectious species of microsporidia to disinfection, the reliability of *E. coli* (or, alternatively, thermotolerant coliforms) as an indicator for the presence/absence of these organisms from drinking-water supplies is unknown.

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Naegleria fowleri

General description

Naegleria are free-living amoeboflagellates distributed widely in the environment. There are several species of *Naegleria*, of which *N. fowleri* is the primary infectious species. *Naegleria* spp. exist as a trophozoite, a flagellate and a cyst stage. The trophozoite (10–20 μm) moves by eruptive pseudopod formation, feeding on bacteria, and reproduces by binary fission. The trophozoite can transform into a flagellate stage with two anterior flagella. The flagellate does not divide but reverts to the trophozoite stage. Under adverse conditions, the trophozoite transforms into a circular cyst (7–15 μm), which is resistant to unfavourable conditions.

Human health effects

Naegleria fowleri causes primary amoebic meningoencephalitis in healthy individuals. The amoeba enters the brain by penetrating the olfactory mucosa and cribiform plate. The disease is acute, and patients often die within 5–10 days and before the infectious agent can be diagnosed. Treatment is difficult. Although the infection is rare, new cases are reported every year.

Source and occurrence

Naegleria fowleri is thermophilic and grows well at temperatures up to 45 °C. It occurs naturally in fresh water of suitable temperature, and prevalence is only indirectly related to human activity, inasmuch as such activity may modify temperature or promote bacterial (food source) production. The pathogen has been reported from many countries, usually associated with thermally polluted water environments such as geothermal water or heated swimming pools. However, the organism has been detected in drinking-water supplies, particularly where water temperature can exceed 25–30 °C. Water is the only known source of infection. The first cases of amoebic meningitis were diagnosed in 1965 in Australia and Florida. Since that time, about 100 cases of primary amoebic meningoencephalitis have been reported throughout the world.

Routes of exposure

Infection with *N. fowleri* is almost exclusively contracted by exposure of the nasal passages to contaminated water. Infection is predominantly associated with recreational use of water, including swimming pools and spas, as well as surface waters naturally heated by the sun, industrial cooling waters and geothermal springs. In a limited number of cases, a link to recreational water exposure is lacking. The occurrence of primary amoebic meningoencephalitis is highest during hot summer months, when many people engage in water recreation and when the temperature of water is conducive to growth of the organism. Consumption of contaminated water or food and person-to-person spread have not been reported as routes of transmission.

Significance in drinking-water

Naegleria fowleri has been detected in drinking-water supplies. Although unproven, a direct or indirect role of drinking-water-derived organisms—for example, through use of drinking-water in swimming pools—is possible. Any water supply that seasonally exceeds 30 °C or that continually exceeds 25 °C can potentially support the growth of *N. fowleri*. In such cases, a periodic prospective study would be valuable. Free chlorine or monochloramine residuals in excess of 0.5 mg/l have been shown to control *N. fowleri*, providing the disinfectant persists through the water distribution system. In addition to maintaining persistent disinfectant residuals, other control measures aimed at limiting the presence of biofilm organisms will reduce food sources and hence growth of the organism in distribution systems. Owing to the environmental nature of this amoeba, *E. coli* (or, alternatively, thermotolerant coliforms) cannot be relied upon as an indicator for the presence/absence of *N. fowleri* in drinking-water supplies.

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Toxoplasma gondii

General description

Toxoplasma gondii is a coccidian parasite, and the cat is the definitive host. Felid animals harbour the parasite in the intestinal tract, where sexual reproduction takes place. The actively multiplying asexual form in the human host is an obligate, intracellular parasite (diameter 3–6 μm) called a tachyzoite. A chronic phase of the disease develops as the tachyzoites transform into slowly replicating bradyzoites, which eventually become cysts in the host tissue. In the natural cycle, mice and rats containing infective cysts are eaten by cats, which host the sexual stage of the parasite. The cyst wall is digested, and bradyzoites penetrate epithelial cells of the small intestine. Several generations of intracellular multiplication lead to the development of microgametes and macrogametes. Fertilization of the latter leads to the development of oocysts that are excreted in faeces as early as 5 days after a cat has ingested the cysts. Oocysts require 1–5 days to sporulate in the environment. Sporulated oocysts and tissue-borne cysts can both cause infections in susceptible hosts.

Human health effects

Toxoplasmosis is usually asymptomatic in humans. In a small percentage of cases, flu-like symptoms, lymphadenopathy and hepatosplenomegaly present 5–23 days after

the ingestion of cysts or oocysts. Dormant cysts, formed in organ tissue after primary infection, can be reactivated when the immune system becomes suppressed, producing disseminated disease involving the central nervous system and lungs and leading to severe neurological disorders or pneumonia. When these infection sites are involved, the disease can be fatal in immunocompromised patients. Congenital toxoplasmosis is mostly asymptomatic, but can produce chorioretinitis, cerebral calcifications, hydrocephalus, severe thrombocytopenia and convulsions. Primary infection during early pregnancy can lead to spontaneous abortion, stillbirth or fetal abnormality.

Source and occurrence

Toxoplasmosis is found worldwide. Estimates indicate that in many parts of the world, 15–30% of lamb and pork meat is infected with cysts. The prevalence of oocyst-shedding cats may be 1%. By the third decade of life, about 50% of the European population is infected, and in France this proportion is close to 80%. *Toxoplasma gondii* oocysts may occur in water sources and supplies contaminated with the faeces of infected cats. Owing to a lack of practical methods for the detection of *T. gondii* oocysts, there is little information on the prevalence of the oocysts in raw and treated water supplies. Details on the survival and behaviour of the oocysts in water environments are also not available. However, qualitative evidence of the presence of oocysts in faecally polluted water has been reported, and results suggest that *T. gondii* oocysts may be as resistant to unfavourable conditions in water environments as the oocysts of related parasites.

Routes of exposure

Both *T. gondii* oocysts that sporulate after excretion by cats and tissue-borne cysts are potentially infectious. Humans can become infected by ingestion of oocysts excreted by cats by direct contact or through contact with contaminated soil or water. Two outbreaks of toxoplasmosis have been associated with consumption of contaminated water. In Panama, creek water contaminated by oocysts from jungle cats was identified as the most likely source of infection, whereas in 1995, an outbreak in Canada was associated with a drinking-water reservoir being contaminated by excreta from domestic or wild cats. A study in Brazil during 1997–1999 identified the consumption of unfiltered drinking-water as a risk factor for *T. gondii* seropositivity. More commonly, humans contract toxoplasmosis through the consumption of undercooked or raw meat and meat products containing *T. gondii* cysts. Transplacental infection also occurs.

Significance in drinking-water

Contaminated drinking-water has been identified as a source of toxoplasmosis outbreaks. Little is known about the response of *T. gondii* to water treatment processes. The oocysts are larger than *Cryptosporidium* oocysts and should be amenable to removal by filtration. Within a water safety plan, control measures to manage potential risk from *T. gondii* should be focused on prevention of source water contamination by wild and domesticated cats. If necessary, the organisms can be removed by filtration. Owing to the lack of information on sensitivity of *T. gondii* to disinfection, the reliability of *E. coli* (or, alternatively, thermotolerant coliforms) as an indicator for the presence/absence of these organisms in drinking-water supplies is unknown.

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11.4 Helminth pathogens

The word "helminth" comes from the Greek word meaning "worm" and refers to all types of worms, both free-living and parasitic. The major parasitic worms are classified primarily in the phylum Nematoda (roundworms) and the phylum Platyhelminthes (flatworms including trematodes and cestodes). Helminth parasites infect a large number of people and animals worldwide. For most helminths, drinking-water is not a significant route of transmission. There are two exceptions: *Dracunculus medinensis* (guinea worm) and *Fasciola* spp. (*F. hepatica* and *F. gigantica*) (liver flukes). Dracunculiasis and fascioliasis both require intermediate hosts to complete their life cycles but are transmitted through drinking-water by different mechanisms. Other helminthiases can be transmitted through water contact (schistosomiasis) or are associated with the use of untreated wastewater in agriculture (ascariasis, trichuriasis, hookworm infections and strongyloidiasis) but are not usually transmitted through drinking-water.

Dracunculus medinensis

Dracunculus medinensis, commonly known as "guinea worm", belongs to the phylum Nematoda and is the only nematode associated with significant transmission by drinking-water.

The eradication of guinea worm infection from the world by 1995 was a target of the International Drinking Water Supply and Sanitation Decade (1981–1990), and the World Health Assembly formally committed itself to this goal in 1991. The Dracunculus Eradication Programme has achieved a massive reduction in the number of cases. There were an estimated 3.3 million cases in 1986, 625 000 cases in 1990, fewer than 60 000 cases in 2002 and only 3190 cases in 2009, with the majority occurring in Sudan. Dracunculiasis is restricted to a central belt of countries in sub-Saharan Africa.

General description

The *D. medinensis* worms inhabit the cutaneous and subcutaneous tissues of infected individuals, the female reaching a length of up to 700 mm, and the male, 25 mm. When the female is ready to discharge larvae (embryos), its anterior end emerges from a blister or ulcer, usually on the foot or lower limb, and releases large numbers of rhabditiform larvae when the affected part of the body is immersed in water. The larvae can move about in water for approximately 3 days and during that time can

be ingested by many species of *Cyclops* (cyclopoid Copepoda, Crustacea). The larvae penetrate into the haemocoelom, moult twice and are infective to a new host in about 2 weeks. If the *Cyclops* (0.5–2.0 mm) are swallowed in drinking-water, the larvae are released in the stomach, penetrate the intestinal and peritoneal walls and inhabit the subcutaneous tissues.

Human health effects

The onset of symptoms occurs just prior to the local eruption of the worm. The early manifestations of urticaria, erythema, dyspnoea, vomiting, pruritus and giddiness are of an allergic nature. In about 50% of cases, the whole worm is extruded in a few weeks; the lesion then heals rapidly, and disability is of limited duration. In the remaining cases, however, complications ensue, and the track of the worm becomes secondarily infected, leading to a severe inflammatory reaction that may result in abscess formation with disabling pain that lasts for months. Mortality is extremely rare, but permanent disability can result from contractures of tendons and chronic arthritis. The economic impact can be substantial. One study reported an 11% annual reduction in rice production from an area of eastern Nigeria, at a cost of US$ 20 million.

Source and occurrence

Infection with guinea worm is geographically limited to a central belt of countries in sub-Saharan Africa. Drinking-water containing infected *Cyclops* is the only source of infection with *Dracunculus*. The disease typically occurs in rural areas where piped water supplies are not available. Transmission tends to be highly seasonal, depending on changes in water sources. For instance, transmission is highest in the early rainy season in a dry savannah zone of Mali with under 800 mm annual rainfall but in the dry season in the humid savannah area of southern Nigeria with over 1300 mm annual rainfall. The eradication strategy combines a variety of interventions, including integrated surveillance systems, intensified case containment measures, provision of safe water and health education.

Routes of exposure

The only route of exposure is the consumption of drinking-water containing *Cyclops* spp. carrying infectious *Dracunculus* larvae.

Significance in drinking-water

Dracunculus medinensis is the only human parasite that may be eradicated in the near future by the provision of safe drinking-water. Infection can be prevented by a number of relatively simple control measures. These include intervention strategies to prevent the release of *D. medinensis* larvae from female worms in infected patients into water and control of *Cyclops* spp. in water resources by means of fish. Prevention can also be achieved through the provision of boreholes and safe wells. Wells and springs should be surrounded by cement curbings, and bathing and washing in these waters should be avoided. Other control measures include filtration of water carrying infectious *Dracunculus* larvae through a fine mesh cloth to remove *Cyclops* spp. or inactivation of *Cyclops* spp. in drinking-water by treatment with chlorine.

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Fasciola spp.

Fascioliasis is caused by two trematode species of the genus Fasciola: *F. hepatica*, present in Europe, Africa, Asia, the Americas and Oceania, and *F. gigantica*, mainly distributed in Africa and Asia. Human fascioliasis was considered a secondary zoonotic disease until the mid-1990s. In most regions, fascioliasis is a foodborne disease. However, the discovery of floating metacercariae in hyperendemic regions (including the Andean Altiplano region in South America) indicates that drinking-water may be a significant transmission route for fascioliasis in certain locations.

General description

The life cycle of *F. hepatica* and *F. gigantica* takes about 14–23 weeks and requires two hosts. The life cycle comprises four phases. In the first phase, the definitive host ingests metacercariae. The metacercariae excyst in the intestinal tract and then migrate to the liver and bile ducts. After 3–4 months, the flukes attain sexual maturity and produce eggs, which are excreted into the bile and intestine. Adult flukes can live for 9–14 years in the host. In the second phase, the eggs are excreted by the human or animal. Once in fresh water, a miracidium develops inside. In the third phase, miracidia penetrate a snail host and develop into cercaria, which are released into the water. In the fourth and final phase, cercariae swim for a short period of time until they reach a suitable attachment site (aquatic plants), where they encyst to form metacercariae, which become infective within 24 hours. Some metacercariae do not attach to plants but remain floating in the water.

Human health effects

The parasites inhabit the large biliary passages and the gall-bladder. Disease symptoms are different for the acute and chronic phases of the infection. The invasive or acute phase may last from 2 to 4 months and is characterized by symptoms such as dyspepsia, nausea and vomiting, abdominal pain and a high fever (up to 40 °C). Anaemia and allergic responses (e.g. pruritis, urticaria) may also occur. In children, the acute infection can be accompanied by severe symptoms and sometimes causes death. The obstructive or chronic phase (after months to years of infection) may be characterized by painful liver enlargement and in some cases obstructive jaundice, chest pains, loss of weight and cholelithiasis. The most important pathogenic sequelae are hepatic lesions and fibrosis and chronic inflammation of the bile ducts. Immature flukes may deviate during migration, enter other organs and cause ectopic fascioliasis in a range of subcutaneous tissues. Fascioliasis can be treated with triclabendazole.

Source and occurrence

Human cases have been increasing in 51 countries on five continents. Estimates of the numbers of humans with fascioliasis range from 2.4 to 17 million people or even higher, depending on unquantified prevalence in many African and Asian countries.

Analysis of the geographical distribution of human cases shows that the correlation between human fascioliasis and fascioliasis in animals occurs only at a basic level. High prevalences in humans are not necessarily related to areas where fascioliasis is a great veterinary problem. Major health problems associated with fascioliasis occur in Andean countries (the Plurinational State of Bolivia, Peru, Chile, Ecuador), the Caribbean (Cuba), northern Africa (Egypt), the Near East (the Islamic Republic of Iran and neighbouring countries) and western Europe (Portugal, France and Spain).

Routes of exposure

Humans can contract fascioliasis when they ingest infective metacercariae by eating raw aquatic plants (and, in some cases, terrestrial plants, such as lettuce, irrigated with contaminated water), drinking contaminated water, using utensils washed in contaminated water or eating raw liver infected with immature flukes.

Significance in drinking-water

Water is often cited as a human infection source. In the Bolivian Altiplano, 13% of metacercariae isolates are floating. Untreated drinking-water in hyperendemic regions often contains floating metacercariae; for example, a small stream crossing in the Altiplano region of the Plurinational State of Bolivia contained up to 7 metacercariae per 500 ml. The importance of fascioliasis transmission through water is supported by indirect evidence. There are significant positive associations between liver fluke infection and infection by other waterborne protozoans and helminths in Andean countries and in Egypt. In many human hyperendemic areas of the Americas, people do not have a history of eating watercress or other water plants. In the Nile Delta region, people living in houses with piped water had a higher infection risk. Metacercariae are likely to be resistant to chlorine disinfection but should be removed by various filtration processes. For example, in Tiba, Egypt, human prevalence was markedly decreased after filtered water was supplied to specially constructed washing units.

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Free-living nematodes

General description

Nematodes are the most numerous metazoan (many-celled) animals on Earth. Many of them are parasites of insects, plants or animals, including humans. Free-living species are abundant in aquatic environments, both freshwater and saltwater, and soil habitats. Not only are the vast majority of species encountered poorly understood biologically, but there may be thousands more unknown species of nematodes yet to be discovered. Nematodes are structurally simple, with the digestive tract run-

ning from the mouth on the anterior end to the posterior opening near the tail, being characterized as a tube in a tube. Nematodes found in drinking-water systems range in size from 0.1 mm to over 0.6 mm.

About 20 different orders have been distinguished within the phylum Nematoda. Four of these orders (Rhabditida, Tylenchida, Aphelenchida and Dorylaimida) are particularly common in soil. Non-pathogenic free-living nematodes that have been found in drinking-water include *Cheilobus*, *Diplogaster*, *Tobrilus*, *Aphelenchus* and *Rhabditis*.

Human health effects

The presence of free-living nematodes in drinking-water does not necessarily indicate a direct health threat. It has largely been regarded by water suppliers as an "aesthetic" problem, either directly or through their association with discoloured water. High concentrations of nematodes in drinking-water have been reported to impart an unpleasant taste to the drinking-water. The presence of free-living nematodes in drinking-water reduces its acceptability to the consumer.

It has been suggested that free-living nematodes could carry pathogenic bacteria in their gut. Such bacteria would be protected from chlorine disinfection and might therefore present a health hazard. Enterobacteriaceae have been isolated from the microflora in the guts of nematodes taken from a treated water supply and from the raw water from which it was derived. However, they were of non-pathogenic genera. Opportunistic pathogens such as *Nocardia* and *Mycobacterium* may also be carried in the gut of the free-living nematodes. There is no reason to suppose that pathogens would be selectively favoured. The microorganisms present in the gut of the free-living nematodes are much more likely to reflect those in the sediments and biofilms where they are feeding.

In some cases, the motile larvae of parasitic nematodes such as hookworms (*Necator americanus* and *Ancylostoma duodenale*) and threadworms (*Strongyloides stercoralis*) are capable of moving themselves through sand filters or may be introduced into drinking-water during distribution as the result of faecal contamination. There are also some other species of nematodes that theoretically could infect humans through ingestion of contaminated water. Such a source of infection, however, is difficult to prove. *Dracunculus medinensis* is a noticeable parasitic nematode that may occur in drinking-water. This parasite is reported elsewhere in this section.

Source and occurrence

Because free-living nematodes are ubiquitous, they, as an egg or free-living larval or adult form, can enter the drinking-water supply at the storage, treatment, distribution or household level. The concentration of free-living nematodes in the raw water source generally corresponds to the turbidity of the water. The higher the turbidity, the larger the concentration of free-living nematodes there will be.

In warm or even temperate weather, slow sand filters may discharge nematodes—and Origochaetes (e.g. *Aeolosoma* spp.), insect larvae (e.g. *Chironomus* spp.) and mosquitoes (*Culex* spp.)—by drawdown into the filtered water. Aquatic animals that successfully penetrate drinking-water treatment processes are largely benthic species, living on the bottoms or margins of water bodies.

Routes of exposure

Potential health concerns arise from exposure to the nematodes through ingestion of drinking-water, during recreation and potentially through consumption of fresh vegetables fertilized with sewage that received non-lethal treatment. Distinguishing pathogenic larvae of the hookworm and threadworm from free-living non-pathogenic nematodes in water is difficult and requires special knowledge of nematology.

Significance in drinking-water

Large numbers of nematodes are not normally found in well-maintained, piped drinking-water systems. Eggs or infective larvae from species parasitic to humans (*Ascaris*, *Trichuris*, *Ancylostoma*, *Necator* and *Strongyloides*) and the many non-pathogenic nematodes are not usually present in protected groundwater sources or are generally removed during treatment processes.

In some circumstances, when the water contains a high nutrient or organic matter content and the ambient temperatures are appropriate, it may be possible for free-living nematodes to feed on microbial growth in the biofilms or slimes in treatment processes or in water mains and thus multiply within the system. This is particularly true if drinking-water sources have not been adequately protected, treatment systems are not adequate or not operated and maintained properly, the distribution system is leaking or there are many stagnant areas or "dead zones" in the distribution system. Detection of large numbers of nematodes (live and dead) in drinking-water indicates that there is a problem that needs to be resolved, without necessarily implying a direct health risk.

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Schistosoma spp.

General description

The genus *Schistosoma* is a member of the class Trematoda, commonly known as trematodes or blood flukes. The life cycle takes about 3–4 months and requires two

hosts. There are about 20 species of Schistosoma, and adult flukes are found in humans, other mammals and birds. Unlike other trematode species, *Schistosoma* has two distinct sexual forms. In the most important human schistosomes, adult flukes are 12–20 mm in length and 0.3–0.6 mm in width; male flukes are shorter and thicker than the females. Adult worms of schistosomes reside in the mesenteric blood vessels of the definitive host. Once the worms mature, they mate, and the females produce eggs that are round or oval and vary in length from 50 to 200 μm. Depending on the infecting species, a large number of eggs released by the females reach either the intestine or the bladder and are excreted in faeces or urine, respectively. The eggs hatch in fresh water, and the larvae (miracidia) invade snail hosts, where they undergo asexual reproduction and develop into the infective larvae (cercariae). Cercariae have pear-shaped heads and forked tails and are 400–600 μm in length. They emerge into the water from snails and invade the final hosts, including humans.

Human health effects

Schistosomiasis, also known as bilharzia, is a group of infectious diseases caused by five major species of *Schistosoma* in humans. Intestinal schistosomiasis is caused by *Schistosoma mansoni*, *S. japonicum*, *S. mekongi* and *S. intercalatum*, whereas urinary schistosomiasis is caused by *S. haematobium*. Most of the symptoms of schistosomiasis are the manifestation of the body's reaction to the eggs laid and are due to the intensity of the immune response of the host, not to the worms themselves. Therefore, the symptoms depend on the amount and location of eggs in the human host, and light infections can be asymptomatic. In some people, an initial allergic reaction (Katayama fever), including fever, chills, muscle pains and cough, can begin within 1–2 months of infection immediately before and during initial egg deposition. Chronic infections with *S. mansoni*, *S. japonicum*, *S. intercalatum* and *S. mekongi* result primarily in intestinal and hepatic symptoms, including bloody diarrhoea (bilharzial dysentery), abdominal pains and hepatosplenomegaly, whereas *S. haematobium* infection leads to urinary manifestation, including dysuria and haematuria. Important life-threatening complications that arise from chronic infections include liver fibrosis and portal hypertension. Later development of bladder cancer and renal failure is associated with urinary schistosomiasis. Rarely, eggs are found in the brain or spinal cord and can cause cerebral symptoms, such as seizures and paralysis. Anaemia and malnutrition are also found in young infected cases. Impaired growth, impaired development and poor cognition are signs of morbidity in infected school-age children. In total, more than 200 million people are infected in 75 countries. The number of deaths associated with schistosomiasis is estimated at 20 000 annually. Schistosomiasis is of great public health and socioeconomic importance in developing countries where it is endemic.

Source and occurrence

Schistosomes occur in tropical and subtropical freshwater sources. *Schistosoma mansoni* is found in Africa, the Arabian Peninsula, Brazil, Suriname, the Bolivarian Republic of Venezuela and some Caribbean islands; *S.haematobium* is found in Africa and the Middle East; *S. japonicum* is found in China, the Philippines and the Sulawesi

Island of Indonesia; *S. intercalatum* is found in some countries of Central Africa; and *S. mekongi* is limited to the Mekong River in Cambodia and the Lao People's Democratic Republic. Water resource development projects, including dam construction, have been identified as potential sources of elevated rates of schistosomiasis as a result of the production of increased habitats for freshwater snails. Humans are the principal reservoirs of *S. haematobium*, *S. intercalatum* and *S. mansoni*, although the latter has been reported in rodents. Various animals, such as humans, dogs, cats, rodents, pigs, cattle and water buffalo, are potential reservoirs of *S. japonicum*, whereas humans and dogs are potential reservoirs of *S. mekongi*.

Routes of exposure

Infection occurs through skin penetration when people are exposed to free-swimming cercariae in infested water used for agricultural, domestic and recreational activities. Infection does not occur through consumption of drinking-water. Cercariae of human infectious schistosomes penetrate the skin rapidly and transform into schistosomules, which migrate to the lungs through the circulatory system and develop into adult flukes in the mesenteric veins. If cercariae of non-human infectious schistosomes come in contact with human skin, they do not survive but can cause an inflammatory response, especially in hosts that have been exposed previously. Papular rash, known as schistosome cercarial dermatitis, can result at points of penetration of cercariae. The cercariae of avian schistosomes and probably bovine schistosomes are responsible for a majority of cases of this dermatitis, which has been reported throughout the world. Person-to-person transmission does not occur.

Significance in drinking-water

Most infections occur in poor communities without access to safe drinking-water and adequate sanitation. Ready availability of safe drinking-water contributes to disease prevention by replacing use of infested water for domestic purposes. Within a water safety plan, control measures include prevention of source water contamination by human waste, snail control programmes and adequate treatment. *Schistosoma* cercariae can be removed by filtration and inactivated by chlorination.

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Table 11.1 Cyanotoxins produced by cyanobacteria

Toxic species	Cyanotoxins
Anabaena spp.	Microcystins, saxitoxins, anatoxin-a, anatoxin-a(s)
Aphanizomenon spp.	Anatoxin-a, saxitoxins, cylindrospermopsins
Cylindrospermum spp.	Anatoxin-a
Cylindrospermopsis spp.	Cylindrospermopsins, saxitoxins
Lyngbya spp.	Cylindrospermopsins, saxitoxins, lyngbyatoxins
Microcystis spp.	Microcystins, anatoxin-a (minor amounts)
Nodularia spp.	Nodularins
Nostoc spp.	Microcystins
Oscillatoria spp.	Anatoxin-a, microcystins
Planktothrix spp.	Anatoxin-a, homoanatoxin-a, microcystins
Raphidiopsis curvata	Cylindrospermopsins
Umezakia natans	Cylindrospermopsins

11.5 Toxic cyanobacteria

Detailed information on toxic cyanobacteria is available in the supporting document *Toxic cyanobacteria in water* (Annex 1).

General description

Cyanobacteria are photosynthetic bacteria that share some properties with algae. Notably, they possess chlorophyll a and liberate oxygen during photosynthesis. The species used for early nomenclature were blue-green in colour; hence, a common term for these organisms is blue-green algae. However, owing to the production of different pigments, there are a large number that are not blue-green, and they can range in colour from blue-green to yellow-brown to red. Most cyanobacteria are phototrophs, but some exhibit heterotrophic growth. They may grow as separate cells or in multicellular filaments or colonies. They can be identified by their morphology to genus or even to species level under a microscope. Some species form surface blooms or scums, whereas others are evenly dispersed throughout the mixed layers of the water body or are bottom dwelling (benthic). Some cyanobacteria possess the ability to regulate their buoyancy via intracellular gas vacuoles, and some species can fix elemental nitrogen dissolved in water. The most notable feature of cyanobacteria in terms of public health impact is that a range of species can produce toxins.

Human health effects

Many cyanobacteria produce potent toxins, as shown in Table 11.1. Cyanobacterial toxins are also discussed in section 8.5.1. Each toxin has specific properties, with distinct concerns including liver damage, neurotoxicity and tumour promotion. Acute symptoms reported after exposure include gastrointestinal disorders, fever and irritations of the skin, ears, eyes, throat and respiratory tract. Cyanobacteria do not multiply in the human body and hence are not infectious.

Source and occurrence

Cyanobacteria are widespread and found in a diverse range of environments, including soils, seawater and, most notably, freshwater environments. Some environmental

conditions, including sunlight, high nutrient levels, low turbulence and warm weather, can promote growth. Depending on the species, this may result in greenish discoloration of water due to a high density of suspended cells and, in some cases, the formation of surface scums. Such cell accumulations may lead to high toxin concentrations.

Routes of exposure

Potential health concerns arise from exposure to the toxins through ingestion of drinking-water, during recreation, through showering and potentially through consumption of algal food supplement tablets. Repeated or chronic exposure is the primary concern for many of the cyanotoxins; in some cases, however, acute toxicity is more important (e.g. lyngbyatoxins and the neurotoxins saxitoxin and anatoxin). Human fatalities have occurred through use of inadequately treated water containing high cyanotoxin levels for renal dialysis. Dermal exposure may lead to irritation of the skin and mucous membranes and possibly also to allergic reactions.

Significance in drinking-water

Cyanobacteria occur in low cell density in most surface waters. However, under environmental conditions supporting their proliferation, high-density "blooms" can occur. Eutrophication (increased biological growth associated with increased nutrients) can support the development of cyanobacterial blooms. Control measures to reduce the potential for "blooms" include catchment management to minimize nutrient inputs to source waters, maintaining flow in regulated rivers and water mixing techniques, both to eliminate stratification and to reduce nutrient release from sediments in reservoirs.

Selected bibliography

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11.6 Indicator organisms

Indicator organisms are used for a range of purposes, including as indicators of:

- faecal pollution in verification and surveillance monitoring;
- the effectiveness of processes such as filtration or disinfection in validation;
- integrity and cleanliness of distribution systems in operational monitoring.

Further discussion on indicator organisms is contained in section 7.4 and the supporting document *Assessing microbial safety of drinking water* (Annex 1).

Total coliform bacteria

General description

Total coliform bacteria include a wide range of aerobic and facultatively anaerobic, Gram-negative, non-spore-forming bacilli capable of growing in the presence of

relatively high concentrations of bile salts with the fermentation of lactose and production of acid or aldehyde within 24 hours at 35–37 °C. *Escherichia coli* and thermotolerant coliforms are a subset of the total coliform group that can ferment lactose at higher temperatures (see below). As part of lactose fermentation, total coliforms produce the enzyme β-galactosidase. Traditionally, coliform bacteria were regarded as belonging to the genera *Escherichia*, *Citrobacter*, *Klebsiella* and *Enterobacter*, but the group is more heterogeneous and includes a wider range of genera, such as *Serratia* and *Hafnia*. The total coliform group includes both faecal and environmental species.

Indicator value

Total coliforms include organisms that can survive and grow in water. Hence, they are not useful as an indicator of faecal pathogens, but they can be used to assess the cleanliness and integrity of distribution systems and the potential presence of biofilms. However, there are better indicators for these purposes. It has been proposed that total coliforms could be used as a disinfection indicator. However, the test for total coliforms is far slower and less reliable than direct measurement of disinfectant residual. In addition, total coliforms are far more sensitive to disinfection than are enteric viruses and protozoa. HPC measurements detect a wider range of microorganisms and are generally considered a better indicator of distribution system integrity and cleanliness.

Source and occurrence

Total coliform bacteria (excluding *E. coli*) occur in both sewage and natural waters. Some of these bacteria are excreted in the faeces of humans and animals, but many coliforms are heterotrophic and able to multiply in water and soil environments. Total coliforms can also survive and grow in water distribution systems, particularly in the presence of biofilms.

Application in practice

Total coliforms are generally measured in 100 ml samples of water. A variety of relatively simple procedures are available based on the production of acid from lactose or the production of the enzyme β-galactosidase. The procedures include membrane filtration followed by incubation of the membranes on selective media at 35–37 °C and counting of colonies after 24 hours. Alternative methods include most probable number procedures using tubes or microtitre plates and presence/absence tests. Field test kits are available.

Significance in drinking-water

Total coliforms should be absent immediately after disinfection, and the presence of these organisms indicates inadequate treatment. The presence of total coliforms in distribution systems and stored water supplies can reveal regrowth and possible biofilm formation or contamination through ingress of foreign material, including soil or plants.

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Escherichia coli and thermotolerant coliform bacteria

General description

Total coliform bacteria that are able to ferment lactose at 44–45 °C are known as thermotolerant coliforms. In most waters, the predominant genus is *Escherichia*, but some types of *Citrobacter*, *Klebsiella* and *Enterobacter* are also thermotolerant. *Escherichia coli* can be differentiated from the other thermotolerant coliforms by the ability to produce indole from tryptophan or by the production of the enzyme β-glucuronidase. *Escherichia coli* is present in very high numbers in human and animal faeces and is rarely found in the absence of faecal pollution, although there is some evidence for growth in tropical soils. Thermotolerant coliform species other than *E. coli* can include environmental organisms.

Indicator value

Escherichia coli is considered the most suitable indicator of faecal contamination. In most circumstances, populations of thermotolerant coliforms are composed predominantly of *E. coli*; as a result, this group is regarded as a less reliable but acceptable indicator of faecal pollution. *Escherichia coli* (or, alternatively, thermotolerant coliforms) is the first organism of choice in monitoring programmes for verification, including surveillance of drinking-water quality. These organisms are also used as disinfection indicators, but testing is far slower and less reliable than direct measurement of disinfectant residual. In addition, *E. coli* is far more sensitive to disinfection than are enteric viruses and protozoa.

Source and occurrence

Escherichia coli occurs in high numbers in human and animal faeces, sewage and water subject to recent faecal pollution. Water temperatures and nutrient conditions present in drinking-water distribution systems are highly unlikely to support the growth of these organisms.

Application in practice

Escherichia coli (or, alternatively, thermotolerant coliforms) are generally measured in 100 ml samples of water. A variety of relatively simple procedures are available based on the production of acid and gas from lactose or the production of the enzyme β-glucuronidase. The procedures include membrane filtration followed by incubation of the membranes on selective media at 44–45 °C and counting of colonies after 24 hours. Alternative methods include most probable number procedures using tubes or microtitre plates and presence/absence tests, some for volumes of water larger than 100 ml. Field test kits are available.

Significance in drinking-water

The presence of *E. coli* (or, alternatively, thermotolerant coliforms) provides evidence of recent faecal contamination, and detection should lead to consideration of further action, which could include further sampling and investigation of potential sources such as inadequate treatment or breaches in distribution system integrity.

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Heterotrophic plate counts

A substantial review of the use of HPC is available (see the supporting document *Heterotrophic plate counts and drinking-water safety*; Annex 1).

General description

HPC measurement detects a wide spectrum of heterotrophic microorganisms, including bacteria and fungi, based on the ability of the organisms to grow on rich growth media, without inhibitory or selective agents, over a specified incubation period and at a defined temperature. The spectrum of organisms detected by HPC testing includes organisms sensitive to disinfection processes, such as coliform bacteria; organisms resistant to disinfection, such as spore formers; and organisms that rapidly proliferate in treated water in the absence of residual disinfectants. The tests detect only a small proportion of the microorganisms that are present in water. The population recovered will differ according to the method and conditions applied. Although standard methods have been developed, there is no single universal HPC measurement. A range of media is available, incubation temperatures used vary from 20 °C to 37 °C and incubation periods range from a few hours to 7 days or more.

Indicator value

The test has little value as an indicator of pathogen presence but can be useful in operational monitoring as a treatment and disinfectant indicator, where the objective is to keep numbers as low as possible. In addition, HPC measurement can be used in assessing the cleanliness and integrity of distribution systems and the presence of biofilms.

Source and occurrence

Heterotrophic microorganisms include both members of the natural (typically non-hazardous) microbial flora of water environments and organisms present in a range

of pollution sources. They occur in large numbers in raw water sources. The actual organisms detected by HPC tests vary widely between locations and between consecutive samples. Some drinking-water treatment processes, such as coagulation and sedimentation, reduce the number of HPC organisms in water. However, the organisms proliferate in other treatment processes, such as biologically active carbon and sand filtration. Numbers of HPC organisms are reduced significantly by disinfection practices, such as chlorination, ozonation and UV light irradiation. However, in practice, none of the disinfection processes sterilizes water; under suitable conditions, such as the absence of disinfectant residuals, HPC organisms can grow rapidly. HPC organisms can grow in water and on surfaces in contact with water as biofilms. The principal determinants of growth or "regrowth" are temperature, availability of nutrients, including assimilable organic carbon, lack of disinfectant residual and stagnation.

Application in practice

No sophisticated laboratory facilities or highly trained staff are required. Results on simple aerobically incubated agar plates are available within hours to days, depending on the characteristics of the procedure used.

Significance in drinking-water

After disinfection, numbers would be expected to be low; for most uses of HPC test results, however, actual numbers are of less value than changes in numbers at particular locations. In distribution systems, increasing numbers can indicate a deterioration in cleanliness, possibly stagnation and the potential development of biofilms. HPC can include potentially "opportunistic" pathogens such as *Acinetobacter*, *Aeromonas*, *Flavobacterium*, *Klebsiella*, *Moraxella*, *Serratia*, *Pseudomonas* and *Xanthomonas*. However, there is no evidence of an association of any of these organisms with gastrointestinal infection through ingestion of drinking-water in the general population.

Selected bibliography

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Intestinal enterococci

General description

Intestinal enterococci are a subgroup of the larger group of organisms defined as faecal streptococci, comprising species of the genus *Streptococcus*. These bacteria are Gram-positive and relatively tolerant of sodium chloride and alkaline pH levels. They are facultatively anaerobic and occur singly, in pairs or as short chains. Faecal streptococci including intestinal enterococci all give a positive reaction with Lancefield's

Group D antisera and have been isolated from the faeces of warm-blooded animals. The subgroup intestinal enterococci consists of the species *Enterococcus faecalis*, *E. faecium*, *E. durans* and *E. hirae*. This group was separated from the rest of the faecal streptococci because they are relatively specific for faecal pollution. However, some intestinal enterococci isolated from water may occasionally also originate from other habitats, including soil, in the absence of faecal pollution.

Indicator value

The intestinal enterococci group can be used as an indicator of faecal pollution. Most species do not multiply in water environments. The numbers of intestinal enterococci in human faeces are generally about an order of magnitude lower than those of *E. coli*. Important advantages of this group are that they tend to survive longer in water environments than *E. coli* (or thermotolerant coliforms), are more resistant to drying and are more resistant to chlorination. Intestinal enterococci have been used in testing of raw water as an indicator of faecal pathogens that survive longer than *E. coli* and in drinking-water to augment testing for *E. coli*. In addition, they have been used to test water quality after repairs to distribution systems or after new mains have been laid.

Source and occurrence

Intestinal enterococci are typically excreted in the faeces of humans and other warm-blooded animals. Some members of the group have also been detected in soil in the absence of faecal contamination. Intestinal enterococci are present in large numbers in sewage and water environments polluted by sewage or wastes from humans and animals.

Application in practice

Enterococci are detectable by simple, inexpensive cultural methods that require basic bacteriology laboratory facilities. Commonly used methods include membrane filtration with incubation of membranes on selective media and counting of colonies after incubation at 35–37 °C for 48 hours. Other methods include a most probable number technique using microtitre plates where detection is based on the ability of intestinal enterococci to hydrolyse 4-methyl-umbelliferyl-β-D-glucoside in the presence of thallium acetate and nalidixic acid within 36 hours at 41 °C.

Significance in drinking-water

The presence of intestinal enterococci provides evidence of recent faecal contamination, and detection should lead to consideration of further action, which could include further sampling and investigation of potential sources such as inadequate treatment or breaches in distribution system integrity.

Selected bibliography

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Clostridium perfringens

General description

Clostridium spp. are Gram-positive, anaerobic, sulfite-reducing bacilli. They produce spores that are exceptionally resistant to unfavourable conditions in water environments, including UV irradiation, temperature and pH extremes, and disinfection processes, such as chlorination. The characteristic species of the genus, *C. perfringens*, is a member of the normal intestinal flora of 13–35% of humans and other warm-blooded animals. Other species are not exclusively of faecal origin. Like *E. coli*, *C. perfringens* does not multiply in most water environments and is a highly specific indicator of faecal pollution.

Indicator value

In view of the exceptional resistance of *C. perfringens* spores to disinfection processes and other unfavourable environmental conditions, *C. perfringens* has been proposed as an indicator of protozoa in treated drinking-water supplies. In addition, *C. perfringens* can serve as an indicator of faecal pollution that took place previously and hence can indicate sources liable to intermittent contamination. The evidence that *Clostridium* is a reliable indicator for enteric viruses is limited and inconsistent, largely based on one study of reductions by drinking-water treatment. Results should be treated with some caution, as the exceptionally long survival times of its spores are likely to far exceed those of enteric pathogens. *Clostridium perfringens* spores are smaller than protozoan (oo)cysts and may be useful indicators of the effectiveness of filtration processes.

Source and occurrence

Clostridium perfringens and its spores are virtually always present in sewage. The organism does not multiply in water environments. *Clostridium perfringens* is present more often and in higher numbers in the faeces of some animals, such as dogs, than in the faeces of humans and less often in the faeces of many other warm-blooded animals. The numbers excreted in faeces are normally substantially lower than those of *E. coli*.

Application in practice

Vegetative cells and spores of *C. perfringens* are usually detected by membrane filtration techniques in which membranes are incubated on selective media under strict anaerobic conditions. These detection techniques are not as simple and inexpensive as those for other indicators, such as *E. coli* and intestinal enterococci.

Significance in drinking-water

The presence of *C. perfringens* in drinking-water can be an indicator of intermittent faecal contamination. Potential sources of contamination should be investigated.

Filtration processes designed to remove enteric viruses or protozoa should also remove *C. perfringens*. Detection in water immediately after treatment should lead to investigation of filtration plant performance.

Selected bibliography

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Payment P, Franco E (1993) Clostridium perfringens and somatic coliphages as indicators of the efficiency of drinking-water treatment for viruses and protozoan cysts. *Applied and Environmental Microbiology*, 59:2418–2424.

Coliphages

General description

Bacteriophages (phages) are viruses that use only bacteria as hosts for replication. Coliphages use *E. coli* and closely related species as hosts and hence can be released by these bacterial hosts into the faeces of humans and other warm-blooded animals. Coliphages used in water quality assessment are divided into the major groups of somatic coliphages and F-RNA coliphages. Differences between the two groups include the route of infection.

Somatic coliphages initiate infection by attaching to receptors permanently located on the cell wall of hosts. They replicate more frequently in the gastrointestinal tract of warm-blooded animals but can also replicate in water environments. Somatic coliphages consist of a wide range of phages (members of the phage families Myoviridae, Siphoviridae, Podoviridae and Microviridae) with a spectrum of morphological types.

F-RNA coliphages initiate infection by attaching to fertility (F-, sex) fimbriae on *E. coli* hosts. These F-fimbriae are produced only by bacteria carrying the fertility (F-) plasmid. As F-fimbriae are produced only in the logarithmic growth phase at temperatures above 30 °C, F-RNA phages are not likely to replicate in environments other than the gastrointestinal tract of warm-blooded animals. F-RNA coliphages comprise a restricted group of closely related phages, which belong to the family Leviviridae, and consist of a single-stranded RNA genome and an icosahedral capsid that is morphologically similar to that of picornaviruses. F-RNA coliphages have been divided into serological types I–IV, which can be identified as genotypes by molecular techniques such as gene probe hybridization. Members of groups I and IV have to date been found exclusively in (non-human) animal faeces, and group III in human faeces. Group II phages have been detected in human faeces and no animal faeces other than about 28% of porcine faeces. This specificity, which is not fully understood, offers a potential tool to distinguish between faecal pollution of human and animal origin under certain conditions and limitations.

Indicator value

Phages share many properties with human viruses, notably composition, morphology, structure and mode of replication. As a result, coliphages are useful models or surrogates to assess the behaviour of enteric viruses in water environments and the sensitivity to treatment and disinfection processes. In this regard, they are superior to faecal bacteria and could be considered for inclusion in verification and surveillance monitoring where source waters are known to be affected by human faecal waste. However, there is no direct correlation between numbers of coliphages and numbers of enteric viruses. In addition, coliphages cannot be absolutely relied upon as an indicator for enteric viruses. This has been confirmed by the isolation of enteric viruses from treated and disinfected drinking-water supplies that yielded negative results in conventional tests for coliphages.

F-RNA coliphages provide a more specific indicator of faecal pollution than somatic phages. In addition, F-RNA coliphages are better indicators of the behaviour of enteric viruses in water environments and their response to treatment and disinfection processes than are somatic coliphages. This has been confirmed by studies in which the behaviour and survival of F-RNA coliphages, somatic phages, faecal bacteria and enteric viruses have been compared. Available data indicate that the specificity of F-RNA serogroups (genotypes) for human and animal excreta may prove useful in the distinction between faecal pollution of human and animal origin. However, there are shortcomings and conflicting data that need to be resolved, and the extent to which this tool can be applied in practice remains to be elucidated. Owing to the limitations of coliphages, they are best used in laboratory investigations, pilot trials and possibly validation testing. They are not suitable for operational or verification (including surveillance) monitoring.

Source and occurrence

Coliphages are excreted by humans and animals in relatively low numbers. As a result of their respective modes of replication and host specificity, somatic coliphages are generally excreted by most humans and animals, whereas F-RNA coliphages are excreted by a variable and generally lower percentage of humans and animals. Available data indicate that in some communities, F-RNA phages are detectable in 10% of human, 45% of bovine, 60% of porcine and 70% of poultry faecal specimens. Somatic coliphages have been found to generally outnumber F-RNA phages in water environments by a factor of about 5 and cytopathogenic human viruses by a factor of about 500, although these ratios vary considerably. Sewage contains somatic coliphages in numbers of the order of 10^6–10^8 per litre; in one study, slaughterhouse wastewater was found to contain somatic coliphages in numbers up to 10^{10} per litre. There are indications that they may multiply in sewage, and somatic coliphages may multiply in natural water environments using saprophytic hosts. Somatic phages and F-RNA phages have been detected in numbers up to 10^5 per litre in lake and river water.

Application in practice

Somatic coliphages are detectable by relatively simple and inexpensive plaque assays, which yield results within 24 hours. Plaque assays for F-RNA coliphages are not quite

as simple, because the culture of host bacteria has to be in the logarithmic growth phase at a temperature above 30 °C to ensure that F-fimbriae are present. Plaque assays using large petri dishes have been designed for the quantitative enumeration of plaques in 100 ml samples, and presence/absence tests have been developed for volumes of water of 500 ml or more.

Significance in drinking-water

As coliphages typically replicate in the gastrointestinal tract of humans and warm-blooded animals, their presence in drinking-water provides an indicator of faecal pollution and hence the potential presence of enteric viruses and possibly also other pathogens. The presence of coliphages in drinking-water also indicates shortcomings in treatment and disinfection processes designed to remove enteric viruses. F-RNA coliphages provide a more specific indicator for faecal pollution. The absence of coliphages from treated drinking-water supplies does not confirm the absence of pathogens such as enteric viruses and protozoan parasites.

Selected bibliography

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***Bacteroides fragilis* phages**

General description

The bacterial genus *Bacteroides* inhabits the human gastrointestinal tract in greater numbers than E. coli. Faeces can contain 10^9–10^{10} *Bacteroides* per gram compared with 10^6–10^8 *E. coli* per gram. *Bacteroides* are rapidly inactivated by environmental oxygen levels, but *Bacteroides* bacteriophages are resistant to unfavourable conditions. Two groups of *B. fragilis* phages are used as indicators in water quality assessment. One is a restricted group of phages that specifically uses *B. fragilis* strain HSP40 as host. This group of phages appears unique, because it is found only in human faeces and not in faeces of animals. The numbers of these phages in sewage appear to be relatively low, and they are almost absent in some geographical areas. The *B. fragilis* HSP40 phages belong to the family Siphoviridae, with flexible non-contractile tails, double-stranded DNA and capsids with a diameter of up to 60 nm. The second group of *Bacteroides* phages used as indicators is those that use *B. fragilis* strain RYC2056 as a host. This

group includes a substantially wider spectrum of phages, occurring in the faeces of humans and many animals. The numbers of these phages in sewage are generally substantially higher than those of *B. fragilis* HSP40 phages.

Indicator value

Bacteroides bacteriophages have been proposed as a possible indicator of faecal pollution as a result of their specific association with faecal material and exceptional resistance to environmental conditions. In particular, *B. fragilis* HSP40 phages are found only in human faeces. *Bacteroides fragilis* phage B40-8, a typical member of the group of *B. fragilis* HSP40 phages, has been found to be more resistant to inactivation by chlorine than poliovirus type 1, simian rotavirus SA11, coliphage f2, *E. coli* and *Streptococcus faecalis*. *Bacteroides fragilis* strain RYC2056 phages seem to be likewise relatively resistant to disinfection. Indicator shortcomings of *B. fragilis* phages include relatively low numbers in sewage and polluted water environments. This applies in particular to *B. fragilis* HSP40 phages. Human enteric viruses have been detected in drinking-water supplies that yielded negative results in conventional tests for *B. fragilis* HSP40 phages. Owing to the limitations of *Bacteroides* bacteriophages, they are best used in laboratory investigations, pilot trials and possibly validation testing.

Source and occurrence

Bacteroides fragilis HSP40 phages are excreted by about 10–20% of humans in certain parts of the world; consequently, their numbers in sewage are substantially lower than those of somatic and even F-RNA coliphages. A mean count of 67 *B. fragilis* HSP40 phages per litre in a sewage-polluted river has been reported. In some parts of the world, *B. fragilis* HSP40 phages would appear not to be detectable in sewage at all. Phages using *B. fragilis* RYC2056 as host are excreted in larger numbers and seem to occur more universally. On average, these phages are excreted by more than 25% of humans. In a survey of water environments, *B. fragilis* HSP40 phages have been found to outnumber cytopathogenic enteric viruses on average by only about 5-fold. Theoretically, wastewaters could be expected to contain higher levels of *B. fragilis* phages than those detected. The reason for the discrepancy may be due to failure in maintaining sufficiently anaerobic conditions during the performance of plaque assays. Improvement of detection methods may result in the recording of higher numbers of *B. fragilis* phages in sewage and polluted water environments.

Application in practice

Disadvantages of *B. fragilis* phages are that the detection methods are more complex and expensive than those for coliphages. Costs are increased by the need to use antibiotics for purposes of selection and to incubate cultures and plaque assays under absolute anaerobic conditions. Results of plaque assays are usually available after about 24 hours compared with about 8 hours for coliphages.

Significance in drinking-water

The presence of *B. fragilis* phages in drinking-water is sound evidence of faecal pollution as well as shortcomings in water treatment and disinfection processes. In addition, the presence of *B. fragilis* HSP40 phages strongly indicates faecal pollution of

human origin. However, *B. fragilis* phages occur in relatively low numbers in sewage, polluted water environments and drinking-water supplies. This implies that the absence of *B. fragilis* phages from treated drinking-water supplies does not confirm the absence of pathogens such as enteric viruses and protozoan parasites.

Selected bibliography

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Enteric viruses

General description

The viruses referred to here are a combined group of those that infect the human gastrointestinal tract and are predominantly transmitted by the faecal–oral route. Well-known members of this group include the enteroviruses, astroviruses, enteric adenoviruses, orthoreoviruses, rotaviruses, caliciviruses and hepatitis A and E viruses. The enteric viruses cover a wide spectrum of viruses, members of which are a major cause of morbidity and mortality worldwide. Members of the group of enteric viruses differ with regard to structure, composition, nucleic acid and morphology. There are also differences in the numbers and frequency of excretion, survival in the environment and resistance to water treatment processes. Enteric viruses have robust capsids that enable them to survive unfavourable conditions in the environment as well as allowing passage through the acidic and proteolytic conditions in the stomach on their way to the duodenum, where they infect susceptible epithelial cells.

Indicator value

The use of enteric viruses as indicator organisms is based on the shortcomings of the existing choices. The survival of faecal bacteria in water environments and the sensitivity to treatment and disinfection processes differ substantially from those of enteric viruses. Monitoring based on one or more representatives of the large group of enteric viruses themselves would therefore be more valuable for assessment of the presence of any of the enteric viruses in water and the response to control measures.

Source and occurrence

Enteric viruses are excreted by individuals worldwide at a frequency and in numbers that result in many of these viruses being universally present in substantial numbers

in wastewater. However, the prevalence of individual members may vary to a large extent as a result of variations in rates of infection and excretion. Much higher numbers would be present during outbreaks.

Application in practice

Practical methods are not yet available for the routine monitoring of water supplies for a broad spectrum of enteric viruses. Viruses that are more readily detectable include members of the enterovirus, adenovirus and orthoreovirus groups. These viruses occur in polluted environments in relatively high numbers and can be detected by reasonably practical and moderate-cost techniques based on cytopathogenic effect in cell culture that yield results within 3–12 days (depending on the type of virus). In addition, progress in technology and expertise is decreasing costs. The cost for the recovery of enteric viruses from large volumes of drinking-water has been reduced extensively. Some techniques—for instance, those based on glass wool adsorption–elution—are inexpensive. The cost of cell culture procedures has also been reduced. Consequently, the cost of testing drinking-water supplies for cytopathogenic viruses has become acceptable for certain purposes. Testing could be used to validate the effectiveness of treatment processes and, in certain circumstances, as part of specific investigations to verify the performance of processes. The incubation times, cost and relative complexity of testing mean that enteric virus testing is not suitable for operational or verification (including surveillance) monitoring. Orthoreoviruses, and at least the vaccine strains of polioviruses detected in many water environments, also have the advantage of not constituting a health risk to laboratory workers.

Significance in drinking-water

The presence of any enteric viruses in drinking-water should be regarded as an indicator for the potential presence of other enteric viruses, is conclusive evidence of faecal pollution and also provides evidence of shortcomings in water treatment and disinfection processes.

Selected bibliography

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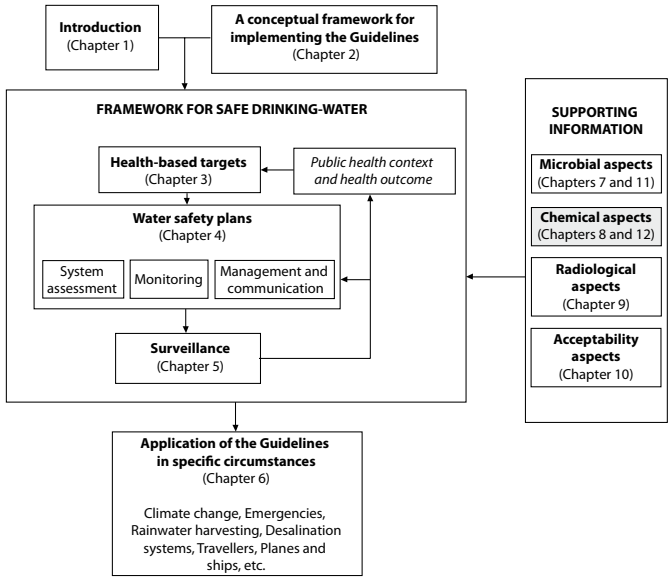
12
Chemical fact sheets

The background documents referred to in this chapter (as the principal reference for each fact sheet) may be found on the Water, Sanitation, Hygiene and Health web site at http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/en/. A complete list of references cited in this chapter, including the background documents for each chemical, is provided in Annex 2.



12.1 Chemical contaminants in drinking-water

Acrylamide

Residual acrylamide monomer occurs in polyacrylamide coagulants used in the treatment of drinking-water. In general, the maximum authorized dose of polymer is 1 mg/l. At a monomer content of 0.05%, this corresponds to a maximum theoretical concentration of 0.5 µg/l of the monomer in water. Practical concentrations may be lower by a factor of 2–3. This applies to the anionic and non-ionic polyacrylamides, but residual levels from cationic polyacrylamides may be higher. Polyacrylamides are also used as grouting agents in the construction of drinking-water reservoirs and wells. Human exposure is much greater from food than from drinking-water, owing to the formation of acrylamide in foods (e.g. breads, fried and roasted foods) cooked at high temperatures.

Guideline value	0.0005 mg/l (0.5 µg/l)
Occurrence	Concentrations up to a few micrograms per litre occasionally detected in tap water
Basis of guideline value derivation	Combined mammary, thyroid and uterine tumours observed in female rats in a drinking-water study, and using the linearized multistage model
Limit of detection	0.032 µg/l by gas chromatography (GC); 0.2 µg/l by high-performance liquid chromatography (HPLC); 10 µg/l by HPLC with ultraviolet (UV) detection
Treatment performance	Conventional treatment processes do not remove acrylamide. Acrylamide concentrations in drinking-water are usually controlled by limiting either the acrylamide content of polyacrylamide flocculants or the dose used, or both. Advances in analytical techniques are also beginning to allow control by direct measurement (see background document).
Additional comments	Every effort should be made to limit free acrylamide monomer in polyacrylamide used for water treatment, and water suppliers should also make every effort to ensure that residual acrylamide in drinking-water is kept as low as is technically feasible. In particular, if acrylamide is controlled by limiting the amount dosed, overdosing should always be avoided.
Assessment date	2011
Principal references	FAO/WHO (2011) *Evaluation of certain contaminants in food* WHO (2011) *Acrylamide in drinking-water*

Following ingestion, acrylamide is readily absorbed from the gastrointestinal tract and widely distributed in body fluids. Acrylamide can cross the placenta. It is neurotoxic, affects germ cells and impairs reproductive function. In mutagenicity assays, acrylamide was negative in the Ames test but induced gene mutations in mammalian cells and chromosomal aberrations in vitro and in vivo. In a long-term carcinogenicity study in rats exposed via drinking-water, acrylamide induced scrotal, thyroid and adrenal tumours in males and mammary, thyroid and uterine tumours in females. The International Agency for Research on Cancer (IARC) has placed acrylamide in Group 2A (probably carcinogenic to humans). The Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) has recently noted concerns regarding the carcinogenicity and neurotoxicity of acrylamide and concluded that dietary exposure should be reduced to as low a level as technically achievable. Recent data have shown that exposure to acrylamide from cooked food is much higher than previously thought. As it is difficult to control the intake of acrylamide from food, it is very important that the acrylamide content of polyacrylamide used as a coagulant aid in water treatment, the most important source of drinking-water contamination by acrylamide, be as low as possible and that polyacrylamide not be overdosed in an attempt to take a shortcut to improving coagulation.

Alachlor

Alachlor (Chemical Abstracts Service [CAS] No. 15972-60-8) is a pre-emergence and post-emergence herbicide used to control annual grasses and many broad-leaved weeds

in maize and a number of other crops. It is lost from soil mainly through volatilization, photodegradation and biodegradation. Many alachlor degradation products have been identified in soil. Alachlor was included in the Prior Informed Consent procedure of the Rotterdam Convention on the basis of the final regulatory actions taken by the European Community and by Canada to ban alachlor as a pesticide.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Has been detected in groundwater and surface water; has also been detected in drinking-water at levels below 0.002 mg/l
Basis of guideline value derivation	Calculated by applying the linearized multistage model to data on the incidence of nasal tumours in rats
Limit of detection	0.1 µg/l by gas–liquid chromatography with electrolytic conductivity detection in the nitrogen mode or by capillary column GC with a nitrogen–phosphorus detector
Treatment performance	0.001 mg/l should be achievable using granular activated carbon (GAC)
Assessment date	1993
Principal reference	WHO (2003) *Alachlor in drinking-water*

On the basis of available experimental data, evidence for the genotoxicity of alachlor is considered to be equivocal. However, a metabolite of alachlor, 2,6-diethylaniline, has been shown to be mutagenic. Available data from two studies in rats clearly indicate that alachlor is carcinogenic, causing benign and malignant tumours of the nasal turbinate, malignant stomach tumours and benign thyroid tumours.

Aldicarb

Aldicarb (CAS No. 116-06-3) is a systemic pesticide used to control nematodes in soil and insects and mites on a variety of crops. It is very soluble in water and highly mobile in soil. It degrades mainly by biodegradation and hydrolysis, persisting for weeks to months.

Guideline value	0.01 mg/l (10 µg/l)
Occurrence	Frequently found as a contaminant in groundwater in the vicinity of application areas, particularly when associated with sandy soil; concentrations in well water as high as 500 µg/l have been measured; aldicarb sulfoxide and aldicarb sulfone residues are found in an approximately 1:1 ratio in groundwater
Acceptable daily intake (ADI)	0–0.003 mg/kg body weight based on cholinesterase depression in a single oral dose study in human volunteers
Limit of detection	0.001 mg/l by reversed-phase HPLC with fluorescence detection
Treatment performance	0.001 mg/l should be achievable using GAC or ozonation
Guideline value derivation	
• allocation to water	10% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day

Additional comments	The guideline value derived from the 1992 assessment of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was very similar to the guideline value derived in the second edition, which was therefore retained.
Assessment date	2003
Principal references	FAO/WHO (1993) *Pesticide residues in food—1992 evaluations* WHO (2003) *Aldicarb in drinking-water*

Aldicarb is one of the most acutely toxic pesticides in use, although the only consistently observed toxic effect with both long-term and single-dose administration is acetylcholinesterase inhibition. It is converted to the sulfoxide and sulfone. Aldicarb sulfoxide is a more potent inhibitor of acetylcholinesterase than aldicarb itself, whereas aldicarb sulfone is considerably less toxic than either aldicarb or the sulfoxide. The weight of evidence indicates that aldicarb, aldicarb sulfoxide and aldicarb sulfone are not genotoxic or carcinogenic. IARC has concluded that aldicarb is not classifiable as to its carcinogenicity (Group 3).

Aldrin and dieldrin

Aldrin (CAS No. 309-00-2) and dieldrin (CAS No. 60-57-1) are chlorinated pesticides that are used against soil-dwelling pests, for wood protection and, in the case of dieldrin, against insects of public health importance. Since the early 1970s, many countries have either severely restricted or banned the use of both compounds, particularly in agriculture. The two compounds are closely related with respect to their toxicology and mode of action. Aldrin is rapidly converted to dieldrin under most environmental conditions and in the body. Dieldrin is a highly persistent organochlorine compound that has low mobility in soil, can be lost to the atmosphere and bioaccumulates. Dietary exposure to aldrin/dieldrin is very low and decreasing.

Guideline value	*Aldrin and dieldrin (combined):* 0.000 03 mg/l (0.03 µg/l)
Occurrence	Seldom detected in drinking water; concentrations of aldrin and dieldrin in drinking-water normally less than 0.01 µg/l; rarely present in groundwater
Provisional tolerable daily intake (PTDI)	0.1 µg/kg body weight (combined total for aldrin and dieldrin), based on no-observed-adverse-effect levels (NOAELs) of 1 mg/kg diet in the dog and 0.5 mg/kg diet in the rat, which are equivalent to 0.025 mg/kg body weight per day in both species, and applying an uncertainty factor of 250 based on concern about carcinogenicity observed in mice
Limit of detection	0.003 µg/l for aldrin and 0.002 µg/l for dieldrin by GC with electron capture detector (ECD)
Treatment performance	0.02 µg/l should be achievable using coagulation, GAC or ozonation
Guideline value derivation	
• allocation to water	1% of PTDI (In view of the reduction in exposure from food this value is probably very conservative.)
• weight	60 kg adult
• consumption	2 litres/day

Additional comments	Aldrin and dieldrin are listed under the Stockholm Convention on Persistent Organic Pollutants. Hence, monitoring may occur in addition to that required by drinking-water guidelines.
Assessment date	2003
Principal references	FAO/WHO (1995) *Pesticide residues in food—1994 evaluations* WHO (2003) *Aldrin and dieldrin in drinking-water*

Both compounds are highly toxic in experimental animals, and cases of poisoning in humans have occurred. Aldrin and dieldrin have more than one mechanism of toxicity. The target organs are the central nervous system and the liver. In long-term studies, dieldrin was shown to produce liver tumours in both sexes of two strains of mice. It did not produce an increase in tumours in rats and does not appear to be genotoxic. IARC has classified aldrin and dieldrin in Group 3 (not classifiable as to its carcinogenicity to humans). Exposure through food has decreased significantly with the dramatic reduction in use.

Aluminium

Aluminium is the most abundant metallic element and constitutes about 8% of Earth's crust. Aluminium salts are widely used in water treatment as coagulants to reduce organic matter, colour, turbidity and microorganism levels. Such use may lead to increased concentrations of aluminium in finished water. Where residual concentrations are high, undesirable colour and turbidity may ensue. Concentrations of aluminium at which such problems may occur are highly dependent on a number of water quality parameters and operational factors at the water treatment plant. Aluminium intake from foods, particularly those containing aluminium compounds used as food additives, represents the major route of aluminium exposure for the general public. The contribution of drinking-water to the total oral exposure to aluminium is usually less than 5% of the total intake.

Reason for not establishing a guideline value	A health-based value of 0.9 mg/l could be derived from the JECFA provisional tolerable weekly intake (PTWI), but this value exceeds practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants: 0.1 mg/l or less in large water treatment facilities and 0.2 mg/l or less in small facilities
Assessment date	2009
Principal references	FAO/WHO (2007) Aluminium (from all sources, including food additives) IPCS (1997) *Aluminium* WHO (2010) *Aluminium in drinking-water*

There is little indication that orally ingested aluminium is acutely toxic to humans despite the widespread occurrence of the element in foods, drinking-water and many antacid preparations. It has been hypothesized that aluminium exposure is a risk factor for the development or acceleration of onset of Alzheimer disease in humans. The 1997 WHO Environmental Health Criteria document for aluminium concludes that:

> On the whole, the positive relationship between aluminium in drinking-water and AD [Alzheimer disease], which was demonstrated in several epidemiological studies, cannot be totally dismissed. However, strong reservations about inferring a causal relationship are warranted in view of the failure of these studies to account for demonstrated confounding factors and for total aluminium intake from all sources.
>
> Taken together, the relative risks for AD from exposure to aluminium in drinking-water above 100 μg/l, as determined in these studies, are low (less than 2.0). But, because the risk estimates are imprecise for a variety of methodological reasons, a population-attributable risk cannot be calculated with precision. Such imprecise predictions may, however, be useful in making decisions about the need to control exposures to aluminium in the general population.

In 2007, JECFA developed a PTWI for aluminium from all sources of 1 mg/kg body weight. JECFA concluded the following:

> … the available studies have many limitations and are not adequate for defining the dose–response relationships. The Committee therefore based its evaluation on the combined evidence from several studies. The relevance of studies involving administration of aluminium compounds by gavage was unclear because the toxicokinetics after gavage were expected to differ from toxicokinetics after dietary administration, and the gavage studies generally did not report total aluminium exposure including basal levels in the feed. The studies conducted with dietary administration of aluminium compounds were considered most appropriate for the evaluation. The lowest LOELs [lowest-observed-effect levels] for aluminium in a range of different dietary studies in mice, rats and dogs were in the region of 50–75 mg/kg bw [body weight] per day expressed as Al.
>
> The Committee applied an uncertainty factor of 100 to the lower end of this range of LOELs (50 mg/kg bw per day expressed as Al) to allow for inter- and intraspecies differences. There are deficiencies in the database, notably the absence of NOELs [no-observed-effect levels] in the majority of the studies evaluated and the absence of long-term studies on the relevant toxicological end-points. The deficiencies are counterbalanced by the probable lower bioavailability of the less soluble aluminium species present in food. Overall, an additional uncertainty factor of three was considered to be appropriate. The Committee confirmed that the resulting health-based guidance value should be expressed as a PTWI, because of the potential for bioaccumulation. The Committee established a PTWI of 1 mg/kg bw for Al, which applies to all aluminium compounds in food, including additives.

A health-based value derived from the JECFA PTWI would be 0.9 mg/l (rounded value), based on an allocation of 20% of the PTWI to drinking-water and assuming a 60 kg adult drinking 2 litres of water per day. However, there remain uncertainties as to the extent of aluminium absorption from drinking-water, which depends on a number of parameters, such as the aluminium salt administered, pH (for aluminium speciation and solubility), bioavailability and dietary factors.

The beneficial effects of the use of aluminium as a coagulant in water treatment are recognized. Taking this into account, and considering the health concerns about aluminium (i.e. its potential neurotoxicity), a practicable level is derived, based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants, to minimize aluminium levels in finished water.

Several approaches are available for minimizing residual aluminium concentrations in treated water. These include use of optimum pH in the coagulation process, avoiding excessive aluminium dosage, good mixing at the point of application of the coagulant, optimum paddle speeds for flocculation and efficient filtration of the aluminium floc. Under good operating conditions, concentrations of aluminium of 0.1 mg/l or less are achievable in large water treatment facilities. Small facilities (e.g. those serving fewer than 10 000 people) might experience some difficulties in attaining this level, because the small size of the plant provides little buffering for fluctuation in operation; moreover, such facilities often have limited resources and limited access to the expertise needed to solve specific operational problems. For these small facilities, 0.2 mg/l or less is a practicable level for aluminium in finished water.

As indicated above, a health-based value derived from the JECFA PTWI would be 0.9 mg/l (rounded value) based on an allocation of 20% of the PTWI to drinking-water and assuming a 60 kg adult drinking 2 litres of water per day. However, as also noted above, practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants are less than 0.1 mg/l in large water treatment facilities and less than 0.2 mg/l in small facilities. In view of the importance of optimizing coagulation to prevent microbial contamination and the need to minimize deposition of aluminium floc in distribution systems, it is important to ensure that average residuals do not exceed these values.

Ammonia

The term ammonia includes the non-ionized (NH_3) and ionized (NH_4^+) species. Ammonia in the environment originates from metabolic, agricultural and industrial processes and from disinfection with chloramine. Natural levels in groundwater and surface water are usually below 0.2 mg/l. Anaerobic groundwaters may contain up to 3 mg/l. Intensive rearing of farm animals can give rise to much higher levels in surface water. Ammonia contamination can also arise from cement mortar pipe linings. Ammonia in water is an indicator of possible bacterial, sewage and animal waste pollution.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	1993
Principal reference	WHO (2003) *Ammonia in drinking-water*

Ammonia is a major component of the metabolism of mammals. Exposure from environmental sources is insignificant in comparison with endogenous synthesis of ammonia. Toxicological effects are observed only at exposures above about 200 mg/kg body weight.

Ammonia in drinking-water is not of immediate health relevance, and therefore no health-based guideline value is proposed. However, ammonia can compromise disinfection efficiency, result in nitrite formation in distribution systems, cause the failure of filters for the removal of manganese and cause taste and odour problems (see also chapter 10).

Antimony

Elemental antimony forms very hard alloys with copper, lead and tin. Antimony compounds have various therapeutic uses. Antimony is used in solders as a replacement for lead, but there is little evidence of any significant contribution to drinking-water concentrations from this source. Total exposure from environmental sources, food and drinking-water is very low compared with occupational exposure.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Concentrations in groundwater less than 0.001 µg/l; concentrations in surface water less than 0.2 µg/l; concentrations in drinking-water appear to be less than 5 µg/l
Tolerable daily intake (TDI)	6 µg/kg body weight, based on a NOAEL of 6.0 mg/kg body weight per day for decreased body weight gain and reduced food and water intake in a 90-day study in which rats were administered potassium antimony tartrate in drinking-water, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation, 10 for the short duration of the study)
Limit of detection	0.01 µg/l by electrothermal atomic absorption spectrometry (AAS); 0.1–1 µg/l by inductively coupled plasma mass spectrometry (ICP-MS); 0.8 µg/l by graphite furnace AAS; 5 µg/l by hydride generation AAS
Treatment performance	Conventional treatment processes do not remove antimony. However, antimony is not normally a raw water contaminant. As the most common source of antimony in drinking-water appears to be dissolution from metal plumbing and fittings, control of antimony from such sources would be by product control.
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	2003
Principal reference	WHO (2003) *Antimony in drinking-water*

There has been a significant increase in the toxicity data available since the previous review, although much of it pertains to the intraperitoneal route of exposure. The form of antimony in drinking-water is a key determinant of the toxicity, and it would appear that antimony leached from antimony-containing materials would be in the form of the antimony(V) oxo-anion, which is the less toxic form. The subchronic toxicity of antimony trioxide is lower than that of potassium antimony tartrate, which is the most soluble form. Antimony trioxide, owing to its low bioavailability, is genotoxic only in some in vitro tests, but not in vivo, whereas soluble antimony(III) salts exert genotoxic effects in vitro and in vivo. Animal experiments from which the carcinogenic potential of soluble or insoluble antimony compounds may be quantified are not available. IARC has concluded that antimony trioxide is possibly carcinogenic to humans (Group 2B) on the basis of an inhalation study in rats, but that antimony trisulfide was not classifiable as to its carcinogenicity to humans (Group 3). However,

chronic oral uptake of potassium antimony tartrate may not be associated with an additional carcinogenic risk, as antimony after inhalation exposure was carcinogenic only in the lung but not in other organs and is known to cause direct lung damage following chronic inhalation as a consequence of overload with insoluble particulates. Although there is some evidence for the carcinogenicity of certain antimony compounds by inhalation, there are no data to indicate carcinogenicity by the oral route.

Arsenic[1]

Arsenic is found widely in Earth's crust in oxidation states of –3, 0, +3 and +5, often as sulfides or metal arsenides or arsenates. In water, it is mostly present as arsenate (+5), but in anaerobic conditions, it is likely to be present as arsenite (+3). It is usually present in natural waters at concentrations of less than 1–2 µg/l. However, in waters, particularly groundwaters, where there are sulfide mineral deposits and sedimentary deposits deriving from volcanic rocks, the concentrations can be significantly elevated.

Arsenic is found in the diet, particularly in fish and shellfish, in which it is found mainly in the less toxic organic form. There are only limited data on the proportion of inorganic arsenic in food, but these indicate that approximately 25% is present in the inorganic form, depending on the type of food. Apart from occupational exposure, the most important routes of exposure are through food and drinking-water, including beverages that are made from drinking-water. Where the concentration of arsenic in drinking-water is 10 µg/l or greater, this will be the dominant source of intake. In circumstances where soups or similar dishes are a staple part of the diet, the drinking-water contribution through preparation of food will be even greater.

Provisional guideline value	0.01 mg/l (10 µg/l)
	The guideline value is designated as provisional on the basis of treatment performance and analytical achievability.
Occurrence	Levels in natural waters generally range between 1 and 2 µg/l, although concentrations may be elevated (up to 12 mg/l) in areas containing natural sources
Basis of guideline value derivation	There remains considerable uncertainty over the actual risks at low concentrations, and available data on mode of action do not provide a biological basis for using either linear or non-linear extrapolation. In view of the practical difficulties in removing arsenic from drinking-water, as well as the practical quantification limit in the region of 1–10 µg/l, the guideline value of 10 µg/l is retained and designated as provisional.
Limit of detection	0.1 µg/l by ICP-MS; 2 µg/l by hydride generation AAS or flame AAS
Treatment performance	It is technically feasible to achieve arsenic concentrations of 5 µg/l or lower using any of several possible treatment methods. However, this requires careful process optimization and control, and a more reasonable expectation is that 10 µg/l should be achievable by conventional treatment (e.g. coagulation).

[1] As arsenic is one of the chemicals of greatest health concern in some natural waters, its chemical fact sheet has been expanded.

Assessment date	2011
Principal references	FAO/WHO (2011) *Evaluation of certain contaminants in food* IARC (1987) *Overall evaluations of carcinogenicity* IPCS (2001) *Arsenic and arsenic compounds* ISO (1982) *Water quality—determination of total arsenic* USNRC (2001) *Arsenic in drinking water, 2001 update* WHO (2011) *Arsenic in drinking-water*

Both pentavalent and trivalent soluble arsenic compounds are rapidly and extensively absorbed from the gastrointestinal tract. Metabolism is characterized by 1) reduction of pentavalent to trivalent arsenic and 2) oxidative methylation of trivalent arsenic to form monomethylated, dimethylated and trimethylated products. Methylation of inorganic arsenic facilitates the excretion of inorganic arsenic from the body, as the end-products monomethylarsonic acid and dimethylarsinic acid are readily excreted in urine. There are major qualitative and quantitative interspecies differences in methylation, but in humans and most common laboratory animals, inorganic arsenic is extensively methylated, and the metabolites are excreted primarily in the urine. There is large interindividual variation in arsenic methylation in humans, probably due to a wide difference in the activity of methyltransferases and possible polymorphism. Ingested organoarsenicals are much less extensively metabolized and more rapidly eliminated in urine than inorganic arsenic.

Arsenic has not been demonstrated to be essential in humans. The acute toxicity of arsenic compounds in humans is predominantly a function of their rate of removal from the body. Arsine is considered to be the most toxic form, followed by the arsenites, the arsenates and organic arsenic compounds. Acute arsenic intoxication associated with the ingestion of well water containing very high concentrations (21.0 mg/l) of arsenic has been reported.

Signs of chronic arsenicism, including dermal lesions such as hyperpigmentation and hypo¬pigmentation, peripheral neuropathy, skin cancer, bladder and lung cancers and peripheral vascular disease, have been observed in populations ingesting arsenic-contaminated drinking-water. Dermal lesions were the most commonly observed symptom, occurring after minimum exposure periods of approximately 5 years. Effects on the cardiovascular system were observed in children consuming arsenic-contaminated water (mean concentration 0.6 mg/l) for an average of 7 years.

Numerous epidemiological studies have examined the risk of cancers associated with arsenic ingestion through drinking-water. Many are ecological-type studies, and many suffer from methodological flaws, particularly in the measurement of exposure. However, there is overwhelming evidence that consumption of elevated levels of arsenic through drinking-water is causally related to the development of cancer at several sites. Nevertheless, there remain considerable uncertainty and controversy over both the mechanism of carcinogenicity and the shape of the dose–response curve at low intakes. The International Programme on Chemical Safety (IPCS) concluded that long-term exposure to arsenic in drinking-water is causally related to increased risks of cancer in the skin, lungs, bladder and kidney, as well as other skin changes, such

as hyperkeratosis and pigmentation changes. These effects have been demonstrated in many studies using different study designs. Exposure–response relationships and high risks have been observed for each of these end-points. The effects have been most thoroughly studied in Taiwan, China, but there is considerable evidence from studies on populations in other countries as well. Increased risks of lung and bladder cancer and of arsenic-associated skin lesions have been reported to be associated with ingestion of drinking-water at concentrations below 50 µg of arsenic per litre. There is a need for more analytical epidemiological studies to determine the dose–time response for skin lesions, as well as cancer, in order to assist in developing suitable interventions and determining practical intervention policies.

Inorganic arsenic compounds are classified by IARC in Group 1 (carcinogenic to humans) on the basis of sufficient evidence for carcinogenicity in humans and limited evidence for carcinogenicity in animals. Although there is a substantial database on the association between both internal and skin cancers and the consumption of arsenic in drinking-water, there remains considerable uncertainty over the actual risks at low concentrations. In its updated evaluation, the United States National Research Council concluded that "the available mode-of-action data on arsenic do not provide a biological basis for using either a linear or nonlinear extrapolation". The maximum likelihood estimates, using a linear extrapolation, for bladder and lung cancer for populations in the United States of America (USA) exposed to arsenic at concentrations of 10 µg/l in drinking-water are, respectively, 12 and 18 per 10 000 population for females and 23 and 14 per 10 000 population for males. The actual numbers indicated by these estimated risks would be very difficult to detect by current epidemiological methods. There is also uncertainty over the contribution of arsenic in food—a higher intake of inorganic arsenic from food would lead to a lower risk estimate for water—and the impact of factors such as variation in the metabolism of arsenic and nutritional status. Some studies in areas with arsenic concentrations somewhat above 50 µg/l have not detected arsenic-related adverse effects in the residents. It remains possible that the estimates of cancer risk associated with various arsenic intakes are overestimates. The concentration of arsenic in drinking-water below which no effects can be observed remains to be determined, and there is an urgent need for identification of the mechanism by which arsenic causes cancer, which appears to be the most sensitive toxicity end-point.

The practical quantification limit for arsenic is in the region of 1–10 µg/l, and removal of arsenic to concentrations below 10 µg/l is difficult in many circumstances. In view of the practical difficulties in removing arsenic from drinking-water, particularly from small supplies, and the practical quantification limit for arsenic, the guideline value of 10 µg/l is retained as a goal and designated as provisional.

The provisional guideline value of 10 µg/l was previously supported by a JECFA PTWI of 15 µg/kg body weight, assuming an allocation of 20% to drinking-water. However, JECFA recently re-evaluated arsenic and concluded that the existing PTWI was very close to the lower confidence limit on the benchmark dose for a 0.5% response ($BMDL_{0.5}$) calculated from epidemiological studies and was therefore no longer appropriate. The PTWI was therefore withdrawn. Nevertheless, given that, in many countries, even the provisional guideline value may not be attainable, it is retained on

the basis of treatment performance and analytical achievability with the proviso that every effort should be made to keep concentrations as low as reasonably possible.

Practical considerations

A silver diethyldithiocarbamate spectrophotometric method (ISO 6595:1982) is available for the determination of arsenic; the detection limit is about 1 µg/l. Graphite furnace AAS, hydride generation AAS and ICP-MS are more sensitive. HPLC in combination with ICP-MS can also be used to determine various arsenic species.

It is technically feasible to achieve arsenic concentrations of 5 µg/l or lower using any of several possible treatment methods. However, this requires careful process optimization and control, and a more reasonable expectation is that 10 µg/l should be achievable by conventional treatment (e.g. coagulation). For local non-piped water supplies, the first option is often substitution by, or dilution with, microbially safe low-arsenic sources. It may also be appropriate to use alternative sources for drinking and cooking but to use the contaminated sources for purposes such as washing and laundry. There are also an increasing number of effective small-scale treatment techniques, usually based around coagulation and precipitation or adsorption, available at relatively low cost for removal of arsenic from small supplies.

Asbestos

Asbestos is introduced into water by the dissolution of asbestos-containing minerals and ores as well as from industrial effluents, atmospheric pollution and asbestos-cement pipes in the distribution system. Exfoliation of asbestos fibres from asbestos-cement pipes is related to the aggressiveness of the water supply. Limited data indicate that exposure to airborne asbestos released from tap water during showers or humidification is negligible.

Reason for not establishing a guideline value	No consistent evidence that ingested asbestos is hazardous to health
Assessment date	1993
Principal reference	WHO (2003) *Asbestos in drinking-water*

Asbestos is a known human carcinogen by the inhalation route. Although it has been well studied, there is little convincing evidence of the carcinogenicity of ingested asbestos in epidemiological studies of populations with drinking-water supplies containing high concentrations of asbestos. Moreover, in extensive studies in experimental animal species, asbestos has not consistently increased the incidence of tumours of the gastrointestinal tract. There is therefore no consistent evidence that ingested asbestos is hazardous to health, and thus it is concluded that there is no need to establish a health-based guideline value for asbestos in drinking-water. The primary issue surrounding asbestos-cement pipes is for people working on the outside of the pipes (e.g. cutting pipe), because of the risk of inhalation of asbestos dust.

Atrazine and its metabolites

Atrazine is a selective systemic herbicide of the chlorotriazine class, used for the control of annual broadleaf and grassy weeds. Atrazine and its chloro-*s*-triazine metabolites—deethyl-atrazine, deisopropyl-atrazine and diaminochlorotriazine—have been found in surface water and groundwater as a result of the use of atrazine as a pre-emergent or early post-emergent herbicide. The metabolite hydroxyatrazine is more commonly detected in groundwater than in surface water.

Guideline values	*Atrazine and its chloro-s-triazine metabolites:* 0.1 mg/l (100 µg/l)
	Hydroxyatrazine: 0.2 mg/l (200 µg/l)
Occurrence	Concentrations rarely exceed 2 µg/l and are commonly well below 0.1 µg/l
Group ADI for atrazine and its chloro-s-triazine metabolites	0–0.02 mg/kg body weight based on the NOAEL for atrazine of 1.8 mg/kg body weight per day identified on the basis of luteinizing hormone surge suppression and subsequent disruption of the estrous cycle seen at 3.6 mg/kg body weight per day in a 6-month study in rats, using a safety factor of 100
ADI for hydroxyatrazine	0–0.04 mg/kg body weight based on the NOAEL of 1.0 mg/kg body weight per day identified on the basis of kidney toxicity at 7.8 mg/kg body weight per day in a 24-month study in rats, using a safety factor of 25, based on kinetic considerations
Limit of detection	*Atrazine:* 1 ng/l, isotope dilution MS with solid-phase extraction; 10 ng/l, GC-MS with solid-phase extraction; 50 ng/l, liquid chromatography (LC)–MS with solid-phase extraction; 100 ng/l, GC with nitrogen–phosphorus detection
	Metabolites: 5 ng/l, capillary GC with nitrogen thermionic specific detection and HPLC with photodiode array absorption detection following extraction with styrene-divinylbenzene sorbents and elution with acetone
Treatment performance	0.1 µg/l can be achieved using GAC or powdered activated carbon (PAC); bankside filtration and nanofiltration are also effective
Guideline value derivation	
• allocation to water	20% of upper limit of ADI
• body weight	60 kg adult
• consumption	2 litres/day
Additional comments	JMPR considered that the NOAEL for atrazine is protective for the consequences of neuroendocrine and other adverse effects caused by prolonged exposure to atrazine and its chloro-s-triazine metabolites.
	JMPR was not able to assess the source allocation of atrazine to drinking-water. As such, the default 20% allocation was chosen, as it will be very conservative in most countries; in addition, it is expected that exposure of the public will be primarily through drinking-water.
Assessment date	2011
Principal references	FAO/WHO (2009) *Pesticide residues in food—2007 evaluations* WHO (2011) *Atrazine and its metabolites in drinking-water*

JMPR agreed that it is unlikely that atrazine is genotoxic and concluded that atrazine is not likely to pose a carcinogenic risk to humans, as the mode of carcinogenic action in certain susceptible rat strains is not relevant for human risk assessment. The weight of evidence from the epidemiological studies also did not support a causal association between exposure to atrazine and the occurrence of cancer in humans.

In special studies of reproductive toxicity, exposure of rats during early pregnancy (i.e. the luteinizing hormone–dependent period) caused increased pre-implantation or post-implantation losses, including full-litter resorptions. Attenuation of the luteinizing hormone surge and subsequent disruption of the estrous cycle (characterized by an increase in days in estrus) were observed at and above 3.65 mg/kg body weight per day, with a NOAEL of 1.8 mg/kg body weight per day. The effects on the luteinizing hormone surge and disruption of the estrous cycle were further supported by a number of short-term mechanistic studies. Additional experiments suggested that the effects of atrazine on luteinizing hormone and prolactin secretion are mediated via a hypothalamic site of action. JMPR concluded that atrazine was not teratogenic.

Studies using a variety of test systems in vitro and in vivo indicated that modulation of the immune system occurs after exposure to atrazine. However, effects suggestive of impaired function of the immune system were observed only at doses greater than those shown to affect neuroendocrine function, leading to disruption of the estrous cycle or developmental effects.

The toxicity profiles and mode of action of the chloro-*s*-triazine metabolites are similar to those of atrazine; the potency of these metabolites with regard to their neuroendocrine-disrupting properties appeared to be similar to that of the parent compound.

The metabolite hydroxyatrazine does not have the same mode of action or toxicity profile as atrazine and its chloro-*s*-triazine metabolites. The main effect of hydroxyatrazine was kidney toxicity (owing to its low solubility in water, resulting in crystal formation and a subsequent inflammatory response), and there was no evidence that hydroxyatrazine has neuroendocrine-disrupting properties. There was no evidence of carcinogenicity, and hydroxyatrazine did not show genotoxicity in an adequate range of tests in vitro and in vivo.

Barium

Barium compounds are present in nature as ore deposits and in igneous and sedimentary rocks, and are used in a variety of industrial applications. Barium in water comes primarily from natural sources, although barium also enters the environment from industrial emissions and anthropogenic uses. Food is the primary source of intake for the non-occupationally exposed population. However, where barium concentrations in water are high, drinking-water may contribute significantly to total intake.

Guideline value	1.3 mg/l (1300 µg/l)
Occurrence	Concentrations in drinking-water are generally below 100 µg/l, although concentrations above 1 mg/l have been measured in drinking-water derived from groundwater

TDI	0.21 mg/kg bw per day, derived by applying an uncertainty factor of 300 to account for intraspecies variation (10), interspecies variation (10) and database deficiencies (3 for the lack of a developmental toxicity study) to a $BMDL_{05}$ of 63 mg/kg bw per day for nephropathy in mice in a 2-year study
Limit of detection	0.004–0.8 µg/l by ICP-MS; 1.0 µg/l by ICP-AES
Treatment performance	Ion exchange, lime softening or direct filtration with chemical precipitation may be able to remove barium to below 1 mg/l
Guideline value derivation	
• allocation to water	20% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	As rounding can have significant practical implications at milligram per litre levels, it was concluded that a guideline value with two significant figures was reasonable in this case.
	The guideline value derived based on the long-term mouse study is not inconsistent with health-based values that could be derived from limited human studies.
Assessment date	2016
Principal references	IPCS (2001). *Barium and barium compounds* USEPA (2005). Toxicological review of barium and compounds. In support of summary information on the Integrated Risk Information System (IRIS). WHO (2016). *Barium in drinking-water*

There is no evidence that barium is carcinogenic or genotoxic. Acute hypertension has been observed in case reports, but the effects may be secondary to hypokalaemia. The critical study that had been identified previously for deriving the guideline value has several limitations (e.g. no effect observed at the single dose evaluated, limitations in the exposure methodology and design, no control for important risk factors for hypertension). Another human study that reported no effects on hypertension at 10 mg/l is limited by the small study size and short exposure duration. Barium has been shown to cause nephropathy in laboratory animals, and this was selected as the toxicological end-point of concern for the current guideline.

Bentazone

Bentazone (CAS No. 25057-89-0) is a post-emergence herbicide used for selective control of broadleaf weeds and sedges occurring among a variety of crops. It is highly soluble in water and very resistant to hydrolysis; it is also very mobile in soil. However, photodegradation occurs in both soil and water. Bentazone may leach from soil into groundwater, particularly during heavy rainfall, and may contaminate surface water through effluents from production plants, drainage waters and actual use in the water (rice fields). Exposure from food is likely to be low.

Reason for not establishing a guideline value	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Health-based value*	0.5 mg/l
Acute health-based value**	Unnecessary, as no ARfD established
Occurrence	Concentrations up to 120 µg/l in groundwater and up to 14 µg/l in surface water have been measured
ADI	0–0.09 mg/kg bw, based on a NOAEL of 9 mg/kg bw per day for prolonged blood coagulation and clinical chemistry changes indicative of effects on liver and kidney from a 2-year toxicity and carcinogenicity study in rats and application of a safety factor of 100
ARfD	Unnecessary, as no effects observed that could be due to a single dose
Limit of detection	0.1 µg/l by GC with ECD after liquid–liquid extraction; limit of quantification of 0.01 µg/l by LC-MS/MS
Treatment performance	Conventional treatment, including coagulation and filtration, not effective; activated carbon may be effective under certain circumstances
Health-based value derivation	
• allocation to water	20% of upper bound of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The default allocation factor of 20% has been used to account for the fact that the available food exposure data, which suggest that exposure via this route is low, do not generally include information from developing countries, where exposure via this route may be higher
	Guidance on interpreting the health-based value and deciding when to monitor can be found in section 8.5.3
Assessment date	2016
Principal references	WHO (2013). *Pesticide residues in food – 2012 evaluations* WHO (2016). *Bentazone in drinking-water*

* When a formal guideline value is not established, a "health-based value" may be determined in order to provide guidance to Member States when there is reason for local concern. Establishing a formal guideline value for such substances may encourage Member States to incorporate a value into their national standards when this may be unnecessary.

** For more information on acute health-based values, see section 8.7.5.

Bentazone is not carcinogenic in rats or mice, and showed no evidence of genotoxicity in a range of in vitro and in vivo assays. Consistent observations in repeated-dose toxicity studies in mice, rats and dogs are effects on haematology and blood coagulation (e.g. prolongation of prothrombin time and partial thromboplastin time).

Benzene

Benzene is used principally in the production of other organic chemicals. It is present in petrol, and vehicular emissions constitute the main source of benzene in the environment. Benzene may be introduced into water by industrial effluents and atmospheric pollution.

Guideline value	0.01 mg/l (10 µg/l)
Occurrence	Concentrations in drinking-water, when present, generally much less than 5 µg/l
Basis of guideline value derivation	Robust linear extrapolation model (because of statistical lack of fit of some of the data with the linearized multistage model) applied to leukaemia and lymphomas in female mice and oral cavity squamous cell carcinomas in male rats in a 2-year gavage study
Limit of detection	0.2 µg/l by GC with photoionization detection and confirmation by MS
Treatment performance	0.01 mg/l should be achievable using GAC or air stripping
Additional comments	Lower end of estimated range of concentrations in drinking-water corresponding to an upper-bound excess lifetime cancer risk of 10^{-5} (10–80 µg/l) corresponds to the estimate derived from data on leukaemia from epidemiological studies involving inhalation exposure, which formed the basis for the previous guideline value. The previous guideline value is therefore retained.
Assessment date	1993
Principal reference	WHO (2003) *Benzene in drinking-water*

Acute exposure of humans to high concentrations of benzene primarily affects the central nervous system. At lower concentrations, benzene is toxic to the haematopoietic system, causing a continuum of haematological changes, including leukaemia. Because benzene is carcinogenic to humans, IARC has classified it in Group 1. Haematological abnormalities similar to those observed in humans have been observed in experimental animal species exposed to benzene. In animal studies, benzene was shown to be carcinogenic following both inhalation and ingestion. It induced several types of tumours in both rats and mice in a 2-year carcinogenesis bioassay by gavage in corn oil. Benzene has not been found to be mutagenic in bacterial assays, but it has been shown to cause chromosomal aberrations in vivo in a number of species, including humans, and to be positive in the mouse micronucleus test.

Beryllium

The primary source of beryllium compounds in water appears to be release from coal burning and other industries using beryllium. Other sources of beryllium in surface water include deposition of atmospheric beryllium and weathering of rocks and soils

containing beryllium. Beryllium is not likely to be found in natural water above trace levels as a result of the insolubility of beryllium oxides and hydroxides in the normal pH range.

Reason for not establishing a guideline value	Rarely found in drinking-water at concentrations of health concern
Assessment date	2009
Principal references	IPCS (2001) *Beryllium and beryllium compounds* WHO (2009) *Beryllium in drinking-water*

As beryllium is rarely, if ever, found in drinking-water at concentrations of concern, it is not considered necessary to set a formal guideline value.

A health-based value for beryllium in drinking-water of 12 µg/l can be calculated based on an allocation of 20% of the TDI of 2 µg/kg body weight, derived from a long-term study in which dogs exhibited lesions of the small intestine, to drinking-water and assuming a 60 kg adult drinking 2 litres of water per day. This allocation is probably conservative, as the limited data on food indicate that exposure from this source is likely to be well below the TDI.

Although beryllium appears to be found in drinking-water sources and drinking-water at low concentrations, the database on occurrence is limited, and there may be specific circumstances in which concentrations can be elevated due to natural sources where the pH is either below 5 or above 8 or there is high turbidity.

Boron

Boron compounds are used in the manufacture of glass, soaps and detergents and as flame retardants. Naturally occurring boron is present in groundwater primarily as a result of leaching from rocks and soils containing borates and borosilicates. The borate content of surface water can be increased as a result of wastewater discharges, but this use has decreased significantly, and levels of boron in wastewater discharges continue to fall.

Guideline value	2.4 mg/l (2400 µg/l)
Occurrence	Concentrations vary widely and depend on the surrounding geology and wastewater discharges; for most of the world, the concentration of boron in drinking-water is judged to be below 0.5 mg/l
TDI	0.17 mg/kg body weight, based on a $BMDL_{05}$ of 10.3 mg/kg body weight per day for developmental toxicity (decreased fetal body weight in rats) and an uncertainty factor of 60 (10 for interspecies variation and 6 for intraspecies variation)
Limit of detection	0.15 µg/l by ICP-MS; 6–10 µg/l by ICP–atomic emission spectrometry (AES)
Treatment performance	Conventional water treatment (coagulation, sedimentation, filtration) does not significantly remove boron, and special methods need to be used in order to remove boron from waters with high boron concentrations. Ion exchange and reverse osmosis processes may enable substantial reduction but are likely to be prohibitively expensive. Blending with low-boron supplies may be the only economical method to reduce boron concentrations in waters where these concentrations are high.

Guideline value derivation	
allocation to water	40% of TDI (because intake from other sources is low)
body weight	60 kg adult
consumption	2 litres/day
Additional comments	Because it will be difficult to achieve the guideline value of 2.4 mg/l in some desalinated supplies and in areas with high natural boron levels, local regulatory and health authorities should consider a value in excess of 2.4 mg/l by assessing exposure from other sources.
Assessment date	2009
Principal reference	WHO (2009) *Boron in drinking-water*

Short- and long-term oral exposures to boric acid or borax in laboratory animals have demonstrated that the male reproductive tract is a consistent target of toxicity. Testicular lesions have been observed in rats, mice and dogs given boric acid or borax in food or drinking-water. Developmental toxicity has been demonstrated experimentally in rats, mice and rabbits. Negative results in a large number of mutagenicity assays indicate that boric acid and borax are not genotoxic. In long-term studies in mice and rats, boric acid and borax caused no increase in tumour incidence.

Bromate

Sodium and potassium bromate are powerful oxidizers used mainly in permanent wave neutralizing solutions and the dyeing of textiles using sulfur dyes. Potassium bromate has also been used as an oxidizer to mature flour during milling, in treating barley in beer making and in fish paste products, although JECFA has concluded that the use of potassium bromate in food processing is not appropriate. Bromate is not normally found in water, but can occur as a result of pollution from industrial sources, sometimes as a consequence of its presence in contaminated soil. However, the main source in drinking-water is its formation during ozonation when the bromide ion is present in water. Bromate may also be formed in hypochlorite solutions produced by electrolysis of bromide-containing salt.

Provisional guideline value	0.01 mg/l (10 µg/l)
	The guideline value is provisional because of limitations in available analytical and treatment methods.
Occurrence	Has been reported in drinking-water with a variety of source water characteristics after ozonation at concentrations ranging from less than 2 to 293 µg/l, depending on bromide ion concentration, ozone dosage, pH, alkalinity and dissolved organic carbon; can also be formed in the electrolytic generation of chlorine and hypochlorite from brine with a high level of bromide contamination
Basis of guideline value derivation	Upper-bound estimate of cancer potency for bromate is 0.19 per mg/kg body weight per day, based on low-dose linear extrapolation (a one-stage Weibull time-to-tumour model was applied to the incidence of mesotheliomas, renal tubule tumours and thyroid follicular tumours in male rats given potassium bromate in drinking-water, using the 12-, 26-, 52- and 77-week interim kill data). A health-based value of 2 µg/l is associated with the upper-bound excess cancer risk of 10^{-5}. A similar conclusion may be reached through several other methods of extrapolation, leading to values in the range 2–6 µg/l.

Limit of detection	0.2 µg/l by ion chromatography with UV/visible absorbance detection; 0.3 µg/l by ion chromatography with detection by ICP-MS; 1.5 µg/l by ion chromatography with suppressed conductivity detection
Treatment performance	Bromate is difficult to remove once formed. By appropriate control of disinfection conditions, it is possible to achieve bromate concentrations below 0.01 mg/l.
Assessment date	2003
Principal reference	WHO (2003) *Bromate in drinking-water*

IARC has concluded that although there is inadequate evidence of carcinogenicity in humans, there is sufficient evidence for the carcinogenicity of bromate from high-dose studies in experimental animals; IARC has classified bromate in Group 2B (possibly carcinogenic to humans). Bromate is mutagenic both in vitro and in vivo. At this time, there is not sufficient evidence to conclude as to the mode of carcinogenic action for bromate. Observation of tumours at a relatively early time and the positive response of bromate in a variety of genotoxicity assays suggest that the predominant mode of action at low doses is due to oxidative deoxyribonucleic acid (DNA) damage. Although there is evidence to suggest that the DNA reactivity in kidney tumours may have a non-linear dose–response relationship, there is no evidence to suggest that this same dose–response relationship operates in the development of mesotheliomas or thyroid tumours. Oxidative stress may play a role in the formation of kidney tumours, but the evidence is insufficient to establish lipid peroxidation and free radical production as key events responsible for the induction of kidney tumours. However, emerging evidence points to rapid decomposition of bromate in the gastrointestinal tract, blood and liver, which supports a non-linear dose–response relationship at low doses.

Bromide

Bromide is commonly found in nature along with sodium chloride, owing to their similar physical and chemical properties, but in smaller quantities. Bromide concentrations in seawater range from 65 mg/l to well over 80 mg/l, in fresh water from trace amounts to about 0.5 mg/l and in desalinated waters up to 1 mg/l.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2009
Principal reference	WHO (2009) *Bromide in drinking-water*

Inorganic bromide was evaluated in 1966 by JMPR, which recommended an ADI of 0–1 mg/kg body weight, based on a minimum pharmacologically effective dosage in humans of about 900 mg of potassium bromide, equivalent to 600 mg of bromide ion. The JMPR ADI was reaffirmed with new data in 1988.

The results of human studies suggest a conservative no-observed-effect level (NOEL) (for marginal effect within normal limits of electroencephalograms in

females) of 4 mg/kg body weight per day, giving an ADI of 0–0.4 mg/kg body weight, including a safety factor of 10 for population diversity.

The upper limit of the ADI of 0–0.4 mg/kg body weight yields an acceptable total daily intake of 24 mg/person for a 60 kg person. Assuming a relative source contribution of 50%, the drinking-water value for a 60 kg adult consuming 2 litres/day would be up to 6 mg/l; for a 10 kg child consuming 1 litre/day, the value would be up to 2 mg/l. However, the dietary bromide contribution for a 10 kg child would probably be less than that for an adult. These are reasonably conservative values, and they are unlikely to be encountered in drinking-water supplies.

Bromide can be involved in the reaction between chlorine and naturally occurring organic matter in drinking-water, forming brominated and mixed chloro-bromo by-products, such as trihalomethanes (THMs) and halogenated acetic acids (HAAs), or it can react with ozone to form bromate. The levels of bromide that can result in the formation of these substances are well below the health-based values suggested above. This guidance applies specifically to inorganic bromide ion and not to bromate or organohalogen compounds, for which individual health-based guideline values have been developed.

Brominated acetic acids

Brominated acetic acids are formed during disinfection of water that contains bromide ions and organic matter. Bromide ions occur naturally in surface water and groundwater and exhibit seasonal fluctuations in levels. Bromide ion levels can increase as a result of either saltwater intrusion resulting from drought conditions or pollution. Brominated acetates are generally present in surface water and groundwater distribution systems at mean concentrations below 5 μg/l.

Reason for not establishing guideline values	Available data inadequate to permit derivation of health-based guideline values
Assessment date	2003
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2004) *Brominated acetic acids in drinking-water*

The database for dibromoacetic acid is considered inadequate for the derivation of a guideline value. There are no systemic toxicity studies of subchronic duration or longer. The database also lacks suitable toxicokinetic studies, a carcinogenicity study, a developmental study in a second species and a multigeneration reproductive toxicity study. Available mutagenicity data suggest that dibromoacetate is genotoxic.

Data are also limited on the oral toxicity of monobromoacetic acid and bromochloroacetic acid. Limited mutagenicity and genotoxicity data give mixed results for monobromoacetic acid and generally positive results for bromochloroacetic acid. Data gaps include subchronic or chronic toxicity studies, multigeneration reproductive toxicity studies, standard developmental toxicity studies and carcinogenicity studies. The available data are considered inadequate to establish guideline values for these chemicals.

Cadmium

Cadmium metal is used in the steel industry and in plastics. Cadmium compounds are widely used in batteries. Cadmium is released to the environment in wastewater, and diffuse pollution is caused by contamination from fertilizers and local air pollution. Contamination in drinking-water may also be caused by impurities in the zinc of galvanized pipes and solders and some metal fittings. Food is the main source of daily exposure to cadmium. The daily oral intake is 10–35 µg. Smoking is a significant additional source of cadmium exposure.

Guideline value	0.003 mg/l (3 µg/l)
Occurrence	Levels in drinking-water usually less than 1 µg/l
PTMI	25 µg/kg body weight, based on the relationship between β_2-microglobulin excretion in urine and cadmium excretion in urine for individuals who are 50 years of age and older
Limit of detection	0.01 µg/l by ICP-MS; 2 µg/l by flame AAS
Treatment performance	0.002 mg/l should be achievable using coagulation or precipitation softening
Guideline value derivation	
• allocation to water	10% of provisional tolerable monthly intake (PTMI) because of high intake from food
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Although new information indicates that a proportion of the general population may be at increased risk for tubular dysfunction when exposed at the current PTMI, the risk estimates that can be made at present are imprecise.
	It is recognized that the margin between the PTMI and the actual monthly intake of cadmium by the general population is small and that this margin may be even smaller in smokers.
Assessment date	2011
Principal references	FAO/WHO (2011) *Evaluation of certain food additives and contaminants* WHO (2003) *Cadmium in drinking-water*

Absorption of cadmium compounds is dependent on the solubility of the compounds. Cadmium accumulates primarily in the kidneys and has a long biological half-life in humans of 10–35 years. There is evidence that cadmium is carcinogenic by the inhalation route, and IARC has classified cadmium and cadmium compounds in Group 2A (probably carcinogenic to humans). However, there is no evidence of carcinogenicity by the oral route and no clear evidence for the genotoxicity of cadmium. The kidney is the main target organ for cadmium toxicity.

In its recent evaluation of cadmium, JECFA found that data relating excretion of the biomarker β_2-microglobulin in urine to cadmium excretion in urine for individuals who are 50 years of age and older provided the most reliable basis on which to determine a critical concentration of cadmium in the urine. Urinary excretion of less

than 5.24 µg of cadmium per gram creatinine was not associated with an increased excretion of β_2-microglobulin, and the dietary exposure that would result in a urinary cadmium concentration at the breakpoint of 5.24 µg/g creatinine was estimated to be 0.8 µg/kg body weight per day or about 25 µg/kg body weight per month. Because of cadmium's exceptionally long half-life, the previous PTWI of 7 µg/kg body weight was withdrawn, and a PTMI of 25 µg/kg body weight was established.

Carbaryl

Carbaryl (CAS No. 63-25-2) is a broad-spectrum carbamate insecticide that is used to control insect pests in crops, trees and ornamental plants. It also has some uses in public health and veterinary practice. Carbaryl has not been reported in drinking-water; however, it could occur following overspraying or spillage into surface water. Exposure through drinking-water is therefore considered to be low unless in exceptional circumstances. The major route of carbaryl intake for the general population is food, but residues are considered to be relatively low.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2006
Principal references	FAO/WHO (2002) *Pesticide residues in food—2001 evaluations* WHO (2008) *Carbaryl in drinking-water*

Carbaryl acts through inhibition of brain cholinesterase, and this is also its primary mode of toxicity. However, carbaryl is also considered to be a non-genotoxic carcinogen in mice, in which it causes vascular tumours in males. On this basis, JMPR established an ADI of 0–0.008 mg/kg body weight. This was based on a lowest-observed-adverse-effect level (LOAEL) of 15 mg/kg body weight per day and application of a safety factor of 2000 (10 for interspecies variation, 10 for intraspecies variation and 20 to reflect the occurrence of the rare and malignant tumour for which a no-effect level could not be identified).

A health-based value of 50 µg/l (rounded value) can be determined from the JMPR ADI of 0–0.008 mg/kg body weight, assuming a 60 kg adult drinking 2 litres of water per day and allowing 20% of the upper limit of the ADI from drinking-water. However, carbaryl does not appear to be found in drinking-water at significant concentrations, and so it is not considered necessary to propose a formal guideline value.

Carbofuran

Carbofuran (CAS No. 1563-66-2) is used worldwide as a pesticide for many crops. Residues in treated crops are generally very low or not detectable. The physicochemical properties of carbofuran and the few data on occurrence indicate that drinking-water from both groundwater and surface water sources is potentially the major route of exposure.

Guideline value	0.007 mg/l (7 µg/l)
Occurrence	Has been detected in surface water, groundwater and drinking-water, generally at levels of a few micrograms per litre or lower; highest concentration (30 µg/l) measured in groundwater
ADI	0–0.002 mg/kg body weight based on a NOAEL of 0.22 mg/kg body weight per day for acute (reversible) effects in dogs in a short-term (4-week) study conducted as an adjunct to a 13-week study in which inhibition of erythrocyte acetylcholinesterase activity was observed, and using an uncertainty factor of 100
Limit of detection	0.1 µg/l by GC with a nitrogen–phosphorus detector; 0.9 µg/l by reversed-phase HPLC with a fluorescence detector
Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Use of a 4-week study was considered appropriate because the NOAEL is based on a reversible acute effect; the NOAEL will also be protective for chronic effects.
Assessment date	1998
Principal references	FAO/WHO (1997) *Pesticide residues in food—1996 evaluations* WHO (2004) *Carbofuran in drinking-water*

Carbofuran is highly toxic after acute oral administration. The main systemic effect of carbofuran poisoning in short-term and long-term toxicity studies appears to be cholinesterase inhibition. No evidence of teratogenicity has been found in reproductive toxicity studies. On the basis of available studies, carbofuran does not appear to be carcinogenic or genotoxic.

Carbon tetrachloride

Carbon tetrachloride is used mainly in the production of chlorofluorocarbon refrigerants, foam-blowing agents and solvents. However, since the Montreal Protocol on Substances that Deplete the Ozone Layer (1987) and its amendments (1990 and 1992) established a timetable for the phase-out of the production and consumption of carbon tetrachloride, manufacture and use have dropped and will continue to drop. Carbon tetrachloride is released mostly into the atmosphere but also into industrial wastewater. Although it readily migrates from surface water to the atmosphere, levels in anaerobic groundwater may remain elevated for months or even years. Although available data on concentrations in food are limited, the intake from air is expected to be much greater than that from food or drinking-water.

Guideline value	0.004 mg/l (4 µg/l)
Occurrence	Concentrations in drinking-water generally less than 5 µg/l

TDI	1.4 µg/kg body weight, based on a NOAEL of 1 mg/kg body weight per day for hepatotoxic effects in a 12-week oral gavage study in rats, adjusting for daily dosing and applying an uncertainty factor of 500 (100 for interspecies and intraspecies variation, 10 for the duration of the study and a modifying factor of 0.5 because it was a bolus study)
Limit of detection	0.1–0.3 µg/l by GC-ECD or GC-MS
Treatment performance	0.001 mg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value is lower than the range of values associated with upper-bound lifetime excess cancer risks of 10^{-4}, 10^{-5} and 10^{-6} calculated by linear extrapolation.
Assessment date	2003
Principal references	IPCS (1999) *Carbon tetrachloride* WHO (2004) *Carbon tetrachloride in drinking-water*

The primary targets for carbon tetrachloride toxicity are liver and kidney. In experiments with mice and rats, carbon tetrachloride proved to be capable of inducing hepatomas and hepatocellular carcinomas. The doses inducing hepatic tumours were higher than those inducing cell toxicity. It is likely that the carcinogenicity of carbon tetrachloride is secondary to its hepatotoxic effects. On the basis of available data, carbon tetrachloride can be considered to be a non-genotoxic compound. Carbon tetrachloride is classified by IARC as being possibly carcinogenic to humans (Group 2B): there is sufficient evidence that carbon tetrachloride is carcinogenic in laboratory animals, but inadequate evidence in humans.

Chloral hydrate

Chloral hydrate, or trichloroacetaldehyde, can be formed as a by-product of the chlorination of water containing organic precursor material, such as fulvic and humic acids. It has been found in drinking-water at concentrations of up to 100 µg/l, but concentrations are usually below 10 µg/l. Concentrations are generally higher in surface water than in groundwater, and concentrations appear to increase during distribution.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2004
Principal references	IPCS (2000) *Chloral hydrate* IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2005) *Chloral hydrate in drinking-water*

Chloral hydrate is used as an intermediate in the production of insecticides, herbicides and hypnotic drugs. It has also been widely used as a sedative or hypnotic drug in humans at oral doses of up to about 750–1000 mg/day. Although intake from clinical use is considerably higher than intake from drinking-water, clinical exposure is of shorter-term duration.

No epidemiological or carcinogenic studies were found in humans that associated exposure to chloral hydrate with cancer, despite the fact that chloral hydrate has been used for many decades (and still is used) as a sedative and hypnotic drug in adults and children (specifically for dental procedures). IARC classified chloral hydrate as not classifiable as to its carcinogenicity to humans (Group 3), based on inadequate evidence in humans and limited evidence in experimental animals. There is equivocal evidence for the genotoxicity of chloral hydrate.

A health-based value of 0.1 mg/l (rounded figure) can be calculated on the basis of a TDI of 0.0045 mg/kg body weight derived based on an increased incidence of liver histopathology observed in mice in a 2-year drinking-water study, allocating 80% of the TDI to drinking-water (because most exposure to chloral hydrate is from drinking-water) and assuming a 60 kg adult consuming 2 litres of water per day. However, because chloral hydrate usually occurs in drinking-water at concentrations well below those of health concern, it is not considered necessary to derive a guideline value.

Chloral hydrate levels in drinking-water can be controlled by changes to disinfection practice (e.g. enhanced coagulation and softening to remove organic precursor compounds, moving the point of disinfection to reduce the reaction between chlorine and precursor compounds and using chloramines for residual disinfection instead of chlorine) and by GAC treatment.

Chloramines (monochloramine, dichloramine, trichloramine)

Monochloramine, dichloramines and trichloramines are considered by-products of drinking-water chlorination, being formed when chlorine and ammonia are added to water. Monochloramine may also be added to maintain residual disinfection activity in potable water distribution systems. Because higher chloramines are formed only occasionally and cause taste and odour problems at concentrations lower than those at which monochloramine causes taste and odour problems, only monochloramine has been considered for development of a health-based guideline value. Chloramine is rapidly decomposed in the stomach by gastric juice. The use of chloramines for disinfection instead of chlorine reduces the formation of THMs in drinking-water supplies. However, formation of other by-products, such as haloketones, chloropicrin, cyanogen chloride, HAAs, haloacetonitriles, aldehydes and chlorophenols, has been reported. Monochloramine, the most abundant chloramine, is recognized as a less effective disinfectant than chlorine and is used as a secondary disinfectant to maintain a residual in distribution systems.

Guideline value	*Monochloramine:* 3 mg/l (3000 µg/l)
Occurrence	Typical chloramine concentrations of 0.5–2 mg/l are found in drinking-water supplies where chloramine is used as a primary disinfectant or to provide a chlorine residual in the distribution system

TDI	94 µg/kg body weight, based on a NOAEL of 9.4 mg/kg body weight per day, the highest dose administered to male rats in a 2-year United States National Toxicology Program (NTP) drinking-water study (although mean body weights of rats given the highest dose were lower than those of their respective control groups, it is probable that the lower body weights were caused by the unpalatability of the drinking-water)
Limit of detection	10 µg/l by colorimetric methods
Treatment performance	It is possible to reduce the concentration of chloramine effectively to zero (< 0.1 mg/l) by reduction; however, it is normal practice to supply water with a chloramine residual of a few tenths of a milligram per litre to act as a preservative during distribution.
Guideline value derivation	
allocation to water	100% of TDI
weight	60 kg adult
consumption	2 litres/day
Additional comments	An additional uncertainty factor for possible carcinogenicity was not applied because equivocal cancer effects reported in the NTP study in only one species and in only one sex were within the range observed in historical controls.
	Most individuals are able to taste chloramines at concentrations below 5 mg/l, and some at levels as low as 0.3 mg/l.
Assessment date	2003
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2004) *Monochloramine in drinking-water*

Reason for not establishing guideline values	Available data inadequate to permit derivation of health-based guideline values for *dichloramine* and *trichloramine*
Assessment date	1993
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products*

Monochloramine

Although monochloramine has been shown to be mutagenic in some in vitro studies, it has not been found to be genotoxic in vivo. IARC has classified chloramine in Group 3 (not classifiable as to its carcinogenicity to humans). In the NTP bioassay in two species, the incidence of mononuclear cell leukaemias in female rats was increased, but no other increases in tumour incidence were observed. IPCS did not consider the increase in mononuclear cell leukaemia to be treatment related.

Dichloramine and trichloramine

Dichloramine and trichloramine have not been extensively studied, and available data are inadequate to permit derivation of health-based guideline values for either of these chemicals. However, these substances can cause taste and odour problems (see chapter 10) if formation of monochloramine is not controlled adequately.

Chlordane

Chlordane (CAS No. 57-47-9) is a broad-spectrum insecticide that has been used since 1947. Its use has recently been increasingly restricted in many countries, and it is now used mainly to destroy termites by subsurface injection into soil. Chlordane may be a low-level source of contamination of groundwater when applied by subsurface injection. Technical chlordane is a mixture of compounds, with the *cis* and *trans* forms of chlordane predominating. It is very resistant to degradation, highly immobile in soil and unlikely to migrate to groundwater, where it has only rarely been found. It is readily lost to the atmosphere. Although levels of chlordane in food have been decreasing, it is highly persistent and has a high bioaccumulation potential.

Guideline value	0.0002 mg/l (0.2 µg/l)
Occurrence	Has been detected in both drinking-water and groundwater, usually at levels below 0.1 µg/l
PTDI	0.5 µg/kg body weight based on a NOAEL of 50 µg/kg body weight per day for increased liver weights, serum bilirubin levels and incidence of hepatocellular swelling, derived from a long-term dietary study in rats, and using an uncertainty factor of 100 (10 each for interspecies and intraspecies variation)
Limit of detection	0.014 µg/l by GC with ECD
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	1% of PTDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Chlordane is listed under the Stockholm Convention on Persistent Organic Pollutants. Hence, monitoring may occur in addition to that required by drinking-water guidelines.
Assessment date	2003
Principal references	FAO/WHO (1995) *Pesticide residues in food—1994 evaluations* WHO (2003) *Chlordane in drinking-water*

In experimental animals, prolonged exposure in the diet causes liver damage. Chlordane produces liver tumours in mice, but the weight of evidence indicates that it is not genotoxic. Chlordane can interfere with cell communication in vitro, a characteristic of many tumour promoters. IARC re-evaluated chlordane in 1991 and concluded that there is inadequate evidence for its carcinogenicity in humans and sufficient evidence for its carcinogenicity in animals, classifying it in Group 2B.

Chloride

Chloride in drinking-water originates from natural sources, sewage and industrial effluents, urban runoff containing de-icing salt and saline intrusion.

The main source of human exposure to chloride is the addition of salt to food, and the intake from this source is usually greatly in excess of that from drinking-water.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) *Chloride in drinking-water*

Excessive chloride concentrations increase rates of corrosion of metals in the distribution system, depending on the alkalinity of the water. This can lead to increased concentrations of metals in the supply.

No health-based guideline value is proposed for chloride in drinking-water. However, chloride concentrations in excess of about 250 mg/l can give rise to detectable taste in water (see chapter 10).

Chlorine

Chlorine is produced in large amounts and widely used both industrially and domestically as an important disinfectant and bleach. In particular, it is widely used in the disinfection of swimming pools and is the most commonly used disinfectant and oxidant in drinking-water treatment. In water, chlorine reacts to form hypochlorous acid and hypochlorites. Concentrations of chlorate and some perchlorates increase in hypochlorite solutions upon storage at high ambient temperatures or when new hypochlorite is added to old hypochlorite.

Guideline value	5 mg/l (5000 µg/l)
Occurrence	Present in most disinfected drinking-water at concentrations of 0.2–1 mg/l
TDI	150 µg/kg body weight, derived from a NOAEL for the absence of toxicity in rodents ingesting chlorine in drinking-water for 2 years
Limit of detection	0.01 µg/l following pre-column derivatization to 4-bromoacetanilide by HPLC; 10 µg/l as free chlorine by colorimetry; 200 µg/l by ion chromatography
Treatment performance	It is possible to reduce the concentration of chlorine effectively to zero (< 0.1 mg/l) by reduction. However, it is normal practice to supply water with a chlorine residual of a few tenths of a milligram per litre to act as a preservative during distribution.
Guideline value derivation	
• allocation to water	100% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value is conservative, as no adverse effect level was identified in the critical study.
	Most individuals are able to taste chlorine at the guideline value.

Assessment date	1993
Principal reference	WHO (2003) *Chlorine in drinking-water*

In humans and experimental animals exposed to chlorine in drinking-water, no specific adverse treatment-related effects have been observed. IARC has classified hypochlorite in Group 3 (not classifiable as to its carcinogenicity to humans).

Chlorine dioxide, chlorite and chlorate

Chlorite and chlorate are DBPs resulting from the use of chlorine dioxide as a disinfectant and for odour and taste control in water. Sodium chlorite and sodium chlorate are both used in the production of chlorine dioxide as well as for other commercial purposes. Chlorite and chlorate are also formed during the decomposition of hypochlorite solutions that are stored for long periods, particularly at warm temperatures. Where hypochlorite or chlorine dioxide is used as a disinfectant, the major route of environmental exposure to chlorite and chlorate is expected to be through drinking-water.

Provisional guideline values	*Chlorite:* 0.7 mg/l (700 µg/l)
	Chlorate: 0.7 mg/l (700 µg/l)
	The guideline values for chlorite and chlorate are designated as provisional because use of aged hypochlorite or of chlorine dioxide as disinfectants may result in the chlorite and chlorate guideline values being exceeded, and difficulties in meeting the guideline values must never be a reason for compromising adequate disinfection
Occurrence	When chlorine dioxide is used as the final disinfectant at typical doses, the resulting chlorite concentration would normally be less than 0.2 mg/l. Chlorate concentrations above 1 mg/l have been reported when hypochlorite was used, but such high concentrations would be unusual unless hypochlorite is stored under adverse conditions.
ADIs	*Chlorite:* 0–0.03 mg/kg bw based on a NOAEL of 3 mg/kg bw per day for reduced liver weight of F_0 females and F_1 males and females in a two-generation reproductive toxicity study in rats and using a safety factor of 100 (10 each for interspecies and intraspecies variability)
	Chlorate: 0–0.01 mg/kg bw based on a $BMDL_{10}$ of 1.1 mg/kg bw per day for non-neoplastic effects on the thyroid of male rats in a carcinogenicity study and using a safety factor of 100 (10 to allow for intraspecies variability and an additional factor of 10 to allow for the deficiencies in the database; a safety factor for interspecies variation was not considered necessary because humans are likely to be less sensitive than rats to these effects)
Limit of detection	MDLs as low as 0.45 µg/l for chlorite and 0.78 µg/l for chlorate (IC with conductivity detection) and 78 µg/l for chlorine dioxide (UV/visible spectrophotometric method)

Prevention and treatment	When using hypochlorite, the following control approach is recommended to minimize formation of chlorite and chlorate: purchase fresh solutions that are of an appropriate quality, store them in a cool place and out of direct sunlight, and use the hypochlorite as soon as possible after purchase (e.g. within a month, if possible). Further, new hypochlorite solutions should not be added to containers containing old hypochlorite solutions, as this will accelerate chlorate formation. It is possible to reduce the concentration of chlorine dioxide and chlorite effectively to zero (<0.1 mg/l) by reduction; however, it is normal practice to supply water with a chlorine dioxide residual of a few tenths of a milligram per litre to provide some protection against microbial regrowth during distribution. With chlorine dioxide disinfection, the concentrations of chlorate and chlorite depend on process conditions (in both the chlorine dioxide generator and the water treatment plant) and applied dose of chlorine dioxide. As there is no low-cost option for reducing concentrations of chlorate once it is formed, control of chlorate concentration must rely on preventing its addition (from sodium hypochlorite) or formation (from chlorine dioxide). If chlorine dioxide is used as a pre-oxidant, the resulting chlorite concentration may need to be reduced using ferrous iron, sulfur reducing agents or activated carbon.
Guideline value derivation	
• allocation to water	80% of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Concentrations should be maintained as low as reasonably practical, without compromising adequate disinfection. Although a health-based value of 0.3 mg/l could be derived from the ADI for chlorate, in some circumstances, it may not be possible to adequately disinfect potable water and maintain chlorate concentrations at or below the health-based value as chlorate is a byproduct of hypochlorite. Therefore, the previous provisional guideline value is retained. Moreover, even this provisional guideline value may be exceeded when aged hypochlorite is used and difficulties in meeting the guideline value must never be a reason for compromising adequate disinfection.
Assessment date	2016
Principal references	IPCS (2000). *Disinfectants and disinfectant by-products* WHO (2008). *Acidified sodium chlorite* WHO (2016). *Chlorine dioxide, chlorate and chlorite in drinking-water*

Chlorine dioxide

Any chlorine dioxide remaining at the consumer's tap will be reduced to chlorite and chloride upon ingestion. Consequently, a guideline value for chlorine dioxide has not been established. The provisional guideline values for chlorite and chlorate are adequately protective for potential toxicity from chlorine dioxide. The taste and odour threshold for chlorine dioxide is 0.2–0.4 mg/l.

Chlorite

IARC has concluded that chlorite is not classifiable as to its carcinogenicity to humans. The primary and most consistent finding arising from exposure to chlorite in a

number of species was oxidative stress resulting in changes in the red blood cells. This observation was supported by a number of biochemical studies conducted in vitro. Studies with human volunteers for up to 12 weeks did not identify any effect on blood parameters at the highest dose tested, 36 µg/kg bw per day.

Chlorate

Although chlorate has also been reported to have effects on red blood cells, the most sensitive effects observed in rats administered sodium chlorate in drinking-water for 21 or 90 days were changes in thyroid histology (e.g. colloid depletion, hypertrophy, incidence and severity of hyperplasia) and in thyroid hormones. As with chlorite, a chlorate dose of 36 µg/kg bw per day for 12 weeks did not result in any adverse effects in human volunteers.

Chloroacetones

1,1-Dichloroacetone is formed from the reaction between chlorine and organic precursors and has been detected in chlorinated drinking-water. Concentrations are estimated to be less than 10 µg/l and usually less than 1 µg/l.

Reason for not establishing guideline values	Available data inadequate to permit derivation of health-based guideline values for any of the chloroacetones
Assessment date	1993
Principal reference	WHO (2003) *Chloroacetones in drinking-water*

The toxicological data on 1,1-dichloroacetone are very limited, although studies with single doses indicate that it affects the liver.

There are insufficient data at present to permit the setting of guideline values for 1,1-dichloroacetone or any of the other chloroacetones.

Chlorophenols (2-chlorophenol, 2,4-dichlorophenol, 2,4,6-trichlorophenol)

Chlorophenols are present in drinking-water as a result of the chlorination of phenols, as by-products of the reaction of hypochlorite with phenolic acids, as biocides or as degradation products of phenoxy herbicides. Those most likely to occur in drinking-water as by-products of chlorination are 2-chlorophenol, 2,4-dichlorophenol and 2,4,6-trichlorophenol. The taste thresholds for chlorophenols in drinking-water are low.

Guideline value	*2,4,6-Trichlorophenol:* 0.2 mg/l (200 µg/l)
Occurrence	Concentrations of chlorophenols in drinking-water usually less than 1 µg/l
Basis of guideline value derivation	Applying the linearized multistage model to leukaemias in male rats observed in a 2-year feeding study (hepatic tumours found in this study were not used for risk estimation because of the possible role of contaminants in their induction)
Limit of detection	0.5–5 µg/l by formation of pentafluorobenzyl ether derivatives; 0.01 µg/l using GC with ECD
Treatment performance	2,4,6-Trichlorophenol concentrations can be reduced using GAC
Additional comments	The guideline value for 2,4,6-trichlorophenol exceeds its lowest reported taste threshold.
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenols in drinking-water*

Reason for not establishing guideline values	Available data inadequate to permit derivation of health-based guideline values for *2-chlorophenol* and *2,4-dichlorophenol*
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenols in drinking-water*

2-Chlorophenol

Data on the toxicity of 2-chlorophenol are limited. Therefore, no health-based guideline value has been derived.

2,4-Dichlorophenol

Data on the toxicity of 2,4-dichlorophenol are limited. Therefore, no health-based guideline value has been derived.

2,4,6-Trichlorophenol

2,4,6-Trichlorophenol has been reported to induce lymphomas and leukaemias in male rats and hepatic tumours in male and female mice. The compound has not been shown to be mutagenic in the Ames test but has shown weak mutagenic activity in other in vitro and in vivo studies. IARC has classified 2,4,6-trichlorophenol in Group 2B (possibly carcinogenic to humans).

Chloropicrin

Chloropicrin, or trichloronitromethane, is formed by the reaction of chlorine with humic and amino acids and with nitrophenols. Its formation is increased in the presence of nitrates. Limited data from the USA indicate that concentrations in drinking-water are usually less than 5 µg/l.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value
Assessment date	1993
Principal reference	WHO (2003) *Chloropicrin in drinking-water*

Decreased survival and body weights have been reported following long-term oral exposure in laboratory animals. Chloropicrin has been shown to be mutagenic in bacterial tests and in in vitro assays in lymphocytes. Because of the high mortality in a carcinogenesis bioassay and the limited number of end-points examined in the 78-week toxicity study, the available data were considered inadequate to permit the establishment of a guideline value for chloropicrin.

Chlorotoluron

Chlorotoluron (CAS No. 15545-48-9) is a pre emergence or early post emergence herbicide that is slowly biodegradable and mobile in soil. There is only very limited exposure to this compound from food.

Guideline value	0.03 mg/l (30 µg/l)
Occurrence	Detected in drinkingwater at concentrations of less than 1 µg/l
TDI	11.3 µg/kg body weight, derived from a NOAEL of 11.3 mg/kg body weight per day for systemic effects in a 2-year feeding study in mice using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for evidence of carcinogenicity)

Limit of detection	0.1 µg/l by separation by reversed-phase HPLC followed by UV and electrochemical detection
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Chlorotoluron in drinking-water*

Chlorotoluron is of low toxicity following single, short-term and long-term exposures in experimental animals, but it has been shown to cause an increase in adenomas and carcinomas of the kidneys of male mice given high doses for 2 years. As no carcinogenic effects were reported in a 2-year study in rats, it has been suggested that chlorotoluron has a carcinogenic potential that is both species and sex specific. Chlorotoluron and its metabolites have shown no evidence of genotoxicity.

Chlorpyrifos

Chlorpyrifos (CAS No. 2921-88-2) is a broad-spectrum organophosphorus insecticide used for the control of mosquitoes, flies, various crop pests in soil and on foliage, household pests and aquatic larvae. Although it is not recommended for addition to water for public health purposes by the WHO Pesticide Evaluation Scheme (WHOPES), it may be used in some countries as an aquatic larvicide for the control of mosquito larvae. Chlorpyrifos is strongly absorbed by soil and does not readily leach from it, degrading slowly by microbial action. It has a low solubility in water and great tendency to partition from aqueous phases into organic phases in the environment.

Guideline value	0.03 mg/l (30 µg/l)
Occurrence	Detected in surface waters in the USA, usually at concentrations below 0.1 µg/l; also detected in groundwater in less than 1% of the wells tested, usually at concentrations below 0.01 µg/l
ADI	0–0.01 mg/kg body weight on the basis of a NOAEL of 1 mg/kg body weight per day for inhibition of brain acetylcholinesterase activity in studies in mice, rats and dogs, using a 100-fold uncertainty factor, and on the basis of a NOAEL of 0.1 mg/kg body weight per day for inhibition of erythrocyte acetylcholinesterase activity in a study of human subjects exposed for 9 days, using a 10-fold uncertainty factor
Limit of detection	1 µg/l by GC using ECD or flame photometric detection
Treatment performance	No data available; should be amenable to treatment by coagulation (10–20% removal), activated carbon adsorption and ozonation
Guideline value derivation	
• allocation to water	10% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day

Assessment date	2003
Principal references	FAO/WHO (2000) *Pesticide residues in food—1999 evaluations* WHO (2003) *Chlorpyrifos in drinking-water*

JMPR concluded that chlorpyrifos is unlikely to pose a carcinogenic risk to humans. Chlorpyrifos was not genotoxic in an adequate range of studies in vitro and in vivo. In long-term studies, inhibition of cholinesterase activity was the main toxicological finding in all species.

Chromium

Chromium is widely distributed in Earth's crust. It can exist in valences of +2 to +6. In general, food appears to be the major source of intake. Chromium(III) is an essential nutrient.

Provisional guideline value	*Total chromium:* 0.05 mg/l (50 µg/l)
	The guideline value is designated as provisional because of uncertainties in the toxicological database.
Occurrence	Total chromium concentrations in drinking-water usually less than 2 µg/l, although concentrations as high as 120 µg/l have been reported
Basis of guideline value derivation	There are no adequate toxicity studies available to provide a basis for a NOAEL. The guideline value was first proposed in 1958 for hexavalent chromium, based on health concerns, but was later changed to a guideline for total chromium because of difficulties in analysing for the hexavalent form only.
Limit of detection	0.05–0.2 µg/l for total chromium by AAS
Treatment performance	0.015 mg/l should be achievable using coagulation
Assessment date	1993
Principal reference	WHO (2003) *Chromium in drinking-water*

In a long-term carcinogenicity study in rats given chromium(III) by the oral route, no increase in tumour incidence was observed. In rats, chromium(VI) is a carcinogen via the inhalation route, although an NTP study has shown evidence for carcinogenicity via the oral route at high doses. However, there is evidence that the dose–response relationship at low doses is non-linear, because chromium(VI) is reduced to chromium(III) in the stomach and gastrointestinal tract. In epidemiological studies, an association has been found between exposure to chromium(VI) by the inhalation route and lung cancer. IARC has classified chromium(VI) in Group 1 (human carcinogen) and chromium(III) in Group 3 (not classifiable as to its carcinogenicity to humans). Chromium(VI) compounds are active in a wide range of in vitro and in vivo genotoxicity tests, whereas chromium(III) compounds are not.

Copper

Copper is both an essential nutrient and a drinking-water contaminant. It is used to make pipes, valves and fittings and is present in alloys and coatings. Copper sulfate

pentahydrate is sometimes added to surface water for the control of algae. Copper concentrations in drinking-water vary widely, with the primary source most often being the corrosion of interior copper plumbing. Levels in running or fully flushed water tend to be low, whereas those in standing or partially flushed water samples are more variable and can be substantially higher (frequently above 1 mg/l). Copper concentrations in treated water often increase during distribution, especially in systems with an acid pH or high-carbonate waters with an alkaline pH. Food and water are the primary sources of copper exposure in developed countries. Consumption of standing or partially flushed water from a distribution system that includes copper pipes or fittings can considerably increase total daily copper exposure, especially for infants fed formula reconstituted with tap water.

Guideline value	2 mg/l (2000 µg/l)
Occurrence	Concentrations in drinking-water range from ≤ 0.005 to > 30 mg/l, primarily as a result of the corrosion of interior copper plumbing
Basis of guideline value derivation	To be protective against acute gastrointestinal effects of copper and provide an adequate margin of safety in populations with normal copper homeostasis
Limit of detection	0.02–0.1 µg/l by ICP-MS; 0.3 µg/l by ICP–optical emission spectroscopy; 0.5 µg/l by flame AAS
Treatment performance	Copper is not removed by conventional treatment processes. However, copper is not normally a raw water contaminant.
Additional comments	For adults with normal copper homeostasis, the guideline value should permit consumption of 2 or 3 litres of water per day, use of a nutritional supplement and copper from foods without exceeding the tolerable upper intake level of 10 mg/day or eliciting an adverse gastrointestinal response.
	Staining of laundry and sanitary ware occurs at copper concentrations above 1 mg/l. At levels above 2.5 mg/l, copper imparts an undesirable bitter taste to water; at higher levels, the colour of water is also impacted.
	In most instances where copper tubing is used as a plumbing material, concentrations of copper will be below the guideline value. However, there are some conditions, such as highly acidic or aggressive waters, that will give rise to much higher copper concentrations, and the use of copper tubing may not be appropriate in such circumstances.
Assessment date	2003
Principal references	IPCS (1998) *Copper* WHO (2004) *Copper in drinking-water*

IPCS concluded that the upper limit of the acceptable range of oral intake in adults is uncertain but is most likely in the range of several (more than 2 or 3 mg/day), but not many, milligrams per day in adults. This evaluation was based solely on studies of gastrointestinal effects of copper-contaminated drinking-water. The available data on toxicity in experimental animals were not considered helpful in establishing the upper limit of the acceptable range of oral intake owing to uncertainty about an appropriate model for humans, but they help to establish a mode of action for the

response. The data on the gastrointestinal effects of copper must be used with caution, as the effects observed are influenced by the concentration of ingested copper to a greater extent than the total mass or dose ingested in a 24-hour period. Recent studies have delineated the threshold for the effects of copper in drinking-water on the gastrointestinal tract, but there is still some uncertainty regarding the long-term effects of copper on sensitive populations, such as carriers of the gene for Wilson disease and other metabolic disorders of copper homeostasis.

Cyanazine

Cyanazine (CAS No. 21725-46-2) is a member of the triazine family of herbicides. It is used as a pre-emergence and post-emergence herbicide for the control of annual grasses and broadleaf weeds. It can be degraded in soil and water by microorganisms and by hydrolysis.

Guideline value	0.0006 mg/l (0.6 µg/l)
Occurrence	Has been detected in surface water and groundwater, usually at concentrations of a few micrograms per litre, although levels as high as 1.3 and 3.5 mg/l have been measured in surface water and groundwater, respectively
TDI	0.198 µg/kg body weight based on a NOAEL of 0.198 mg/kg body weight for hyperactivity in male rats in a 2-year toxicity/carcinogenicity study, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for limited evidence of carcinogenicity)
Limit of detection	0.01 µg/l by GC-MS
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1998
Principal reference	WHO (2003) *Cyanazine in drinking-water*

On the basis of the available mutagenicity data on cyanazine, evidence for genotoxicity is equivocal. Cyanazine causes mammary gland tumours in rats but not in mice. The mechanism of mammary gland tumour development in rats is currently under investigation and may prove to be hormonal. Cyanazine is also teratogenic in rats at dose levels of 25 mg/kg body weight per day and higher.

Cyanide

Cyanides can be found in some foods, particularly in some developing countries, and they are occasionally found in drinking-water, but usually only at very low concentrations. However, there are occasions on which large spills of cyanide, associated with industry, occur, and these can give rise to very high concentrations in drinking-water source waters, particularly surface waters.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern, except in emergency situations following a spill to a water source
Assessment date	2009
Principal references	IPCS (2004) *Hydrogen cyanide and cyanides* WHO (2009) *Cyanide in drinking-water*

Cyanide is highly acutely toxic. It is detoxified in the liver by first-pass metabolism following oral exposure. As a consequence, exposure to a dose spread over a longer period, through a day, for example, will result in lower toxicity, or higher tolerance, than the same dose given in a single bolus dose. Exposure to high doses can give rise to thyroid toxicity as a secondary effect of exposure due to the inhibition of iodine uptake from the thiocyanate generated through the detoxifying action of rhodanese. It is difficult to interpret human data in view of the difficulty in assessing the actual absorbed dose in humans following acute fatal intoxication and the lack of well-conducted studies on sublethal toxicity.

There is a need for guidance regarding concentrations that would not be of concern for public health following short-term exposure to cyanide. However, because cyanide is unlikely to occur in drinking-water at concentrations of health concern, it is considered unnecessary to derive a formal guideline value for short-term exposure to cyanide.

The data on acute exposure to cyanide are unsuitable for use in deriving a health-based value for short-term exposure because of the high uncertainty surrounding the data. Using the NOAEL for effects on the reproductive organs of male rats in a 13-week study and an uncertainty factor of 100, a TDI of 0.045 mg/kg body weight can be derived. Because this health-based value is intended for short-term use and exposure would not exceed 5 days, it is considered to be acceptable to allocate 40% of the TDI to drinking-water to allow for exposure to cyanogenic glycosides in food. Therefore, assuming a 60 kg adult drinking 2 litres of water per day with an allocation of 40% of the TDI to drinking-water, a health-based value of 0.5 mg/l (rounded value) for short-term exposure can be calculated.

This health-based value is well below the level that is normally considered to be of health concern for humans. Cyanide is rapidly detoxified, and exposure spread throughout the day will further reduce the potential for effects. This health-based value would be suitable for use for a limited period of up to 5 days, which is the longest period likely to be required under the circumstances of such an emergency. However, it is probable that, in most circumstances, this value will be highly conservative for short-term exposure.

It should be noted that the lowest reported odour threshold for cyanide in drinking-water is 0.17 mg/l, which is below the short-term health-based value. It is therefore possible that a small number of individuals will detect cyanide by odour at concentrations below the health-based value.

The health-based value relates to total cyanide concentration at the tap, including cyanide from cyanogen chloride in drinking-water as a by-product of disinfection with chlorine. Cyanogen chloride rapidly breaks down to cyanide in the distribution system or when ingested. As the low levels of cyanide normally found in drinking-water

are mostly a consequence of the presence of cyanogen chloride, it is not considered necessary to develop a guideline value for long-term exposure to cyanide.

Cyanobacterial toxins: Microcystin-LR

Among the cyanobacterial toxins, microcystins are the best-researched group and probably occur most frequently in fresh waters. Many practical considerations for the abatement of microcystins apply similarly to the other cyanotoxins (i.e. cylindrospermopsins, saxitoxins, anatoxin-a and anatoxin-a(s)), with one key difference that is relevant to the efficacy of their removal in drinking-water treatment: microcystins are usually cell-bound, and substantial amounts are released to the surrounding water only in situations of cell rupture (i.e. lysis), whereas the other cyanotoxins may occur to a larger extent dissolved in water.

Although microcystins may occur in fish, molluscs and shellfish from water bodies with cyanobacterial proliferation, human exposure to microcystins is largely through drinking-water or recreational use of water bodies with cyanobacterial blooms.

Among the more than 80 microcystins identified to date, only a few occur frequently and in high concentrations. Microcystin-LR is among the most frequently occurring and most toxic microcystin congeners. It is the only one for which enough toxicological data are available with which to derive a provisional guideline value. Frequently occurring cyanobacterial genera that may contain microcystins are *Microcystis*, *Planktothrix* and *Anabaena* (see also section 11.5).

Provisional guideline value	*Total microcystin-LR (free plus cell-bound):* 0.001 mg/l (1 µg/l)
	The guideline value is provisional, as it covers only microcystin-LR, the database is limited and new data for the toxicity of cyanobacterial toxins are being generated.
TDI	0.04 µg/kg body weight, based on liver pathology observed in a 13-week study in mice and applying an uncertainty factor of 1000, taking into consideration limitations in the database, in particular lack of data on chronic toxicity and carcinogenicity
Limit of detection	0.1–1 µg/l by HPLC following extraction of cells with 75% aqueous methanol or following concentration of microcystins from liquid samples on C-18; will allow differentiation between variants where standards are available
	0.1–0.5 µg/l by commercially available immunoassay kits (enzyme-linked immunosorbent assay) for microcystins dissolved in water or in aqueous extracts of cells; will detect most microcystins; these are less precise in quantification than HPLC, but useful for screening
	0.5–1.5 µg/l by protein phosphatase assay for microcystins dissolved in water or in aqueous extracts of cells; will detect all microcystins; this assay is less precise in quantification and identification than HPLC, but useful for screening
Monitoring	The preferred approach is visual monitoring (including microscopy for potentially microcystin-containing genera) of source water for evidence of increasing cyanobacterial cell density (blooms) or bloom-forming potential and increased vigilance where such events occur

Prevention and treatment	Actions to decrease the probability of bloom occurrence include catchment and source water management, such as reducing nutrient loading or changing reservoir stratification and mixing. Treatment effective for the removal of cyanobacteria includes filtration to remove intact cells. Treatment effective against free microcystins in water (as well as most other free cyanotoxins) includes oxidation through ozone or chlorine at sufficient concentrations and contact times, as well as GAC and some PAC applications (see the supporting document *Management of cyanobacteria in drinking-water supplies*; Annex 1).
Guideline value derivation	
• allocation to water	80% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	2003
Principal references	Chorus & Bartram (1999) *Toxic cyanobacteria in water* WHO (2003) *Cyanobacterial toxins: Microcystin-LR in drinking-water*

Microcystin-LR is a potent inhibitor of eukaryotic protein serine/threonine phosphatases 1 and 2A. The primary target for microcystin toxicity is the liver, as microcystins cross cell membranes chiefly through the bile acid transporter. Guideline value derivation was based on an oral 13-week study with mice, supported by an oral 44-day study with pigs. A large number of poisonings of livestock and wildlife have been recorded. Evidence of tumour promotion has been published. In 2006, IARC classified microcystin-LR as a possible carcinogen (Group 2B).

Practical considerations

Cyanobacteria occur widely in lakes, reservoirs, ponds and slow-flowing rivers. Where their excessive growth leads to high cell numbers, sometimes termed "bloom" events, their toxins can reach concentrations in raw water that are potentially hazardous to human health. Blooms occur if concentrations of nutrients (phosphorus and nitrogen) are elevated, particularly in stagnant or very slowly flowing water bodies. Blooms tend to recur in the same water bodies. Cells of some cyanobacterial species may accumulate at the surface as scums or at the thermocline of thermally stratified reservoirs. Such accumulations may develop rapidly, and they may be of very variable duration (hours to weeks). In many circumstances, blooms and accumulations are seasonal.

A variety of resource protection and source management actions are available to decrease the probability of bloom occurrence. Among these, the most sustainable and effective measure is to reduce nutrient (particularly phosphorus) concentrations in the water body to levels sufficiently low to substantially limit the amount of cyanobacterial biomass that can grow. This is achieved by controlling nutrient loads from sewage effluents and from land areas. The latter involves controlling erosion as well as the amount of manure and fertilizers spread in the catchment. Further, hydrological management actions such as water body mixing and flushing can render hydrophysical conditions less suitable for cyanobacteria and thus shift plankton species from cyanobacteria to others (i.e. planktonic algae such as diatoms) that are less relevant to human health.

As microcystins almost always occur largely cell-bound, any drinking-water treatment that removes particles—i.e. soil or riverbank filtration, flocculation and filtration or dissolved air filtration—controls them effectively if the process is optimized to target their removal. This also applies to the cell-bound fraction of other cyanotoxins. Process operation should avoid cell rupture and toxin release. Hazardously high concentrations of dissolved cyanotoxins appear to occur less frequently. They are well removed by most types of activated carbon. Chlorination and ozonation are effective for the removal of many cyanotoxins at sufficiently high doses and contact times, but not very effective for saxitoxins. Potassium permanganate is effective for microcystins, whereas limited or no data are available at present for other toxins. Chlorine dioxide and chloramine are ineffective for removing cyanotoxins.

Cyanotoxin monitoring is most effectively based on surveillance of source water for evidence of cyanobacterial blooms or bloom-forming potential (i.e. nutrient levels and phytoplankton species composition), with vigilance increased where such events occur. In contrast, monitoring finished water against target cyanotoxin concentrations is unsatisfactory for determining whether or not it is safe, because of the large variety of toxins (particularly of microcystins), the lack of guideline values for all but one (i.e. microcystin-LR) against which to monitor and the lack of analytical standards for many. Analysis of cyanotoxins is particularly useful for validating and optimizing the efficacy of control measures such as riverbank filtration or treatment. A caveat in cyanotoxin analysis is the need for extraction of the cell-bound fraction from the cells; although this is easy to do, particularly for microcystins, neglecting extraction from cells will lead to dramatic underestimation of concentrations.

Cyanogen chloride

Cyanogen chloride may be formed as a by-product of chloramination or chlorination of water. It is also formed by the chlorination of cyanide ion present in raw water.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2009
Principal references	IPCS (2004) *Hydrogen cyanide and cyanides* WHO (2009) *Cyanogen chloride in drinking-water*

Cyanogen chloride is rapidly metabolized to cyanide in the body. There are few data available on the oral toxicity of cyanogen chloride.

As cyanogen chloride is unlikely to be found in drinking-water at concentrations that are of health concern, it is considered unnecessary to develop a formal guideline value for cyanogen chloride. Instead, for guidance purposes, a health-based value is derived based on cyanide.

Using a NOAEL for cyanide of 4.5 mg/kg body weight per day for minor changes in the testis in a subchronic study in which rats were exposed through their drinking-water and an uncertainty factor of 100, a TDI for cyanide of 0.045 mg/kg body weight (corresponding to a cyanogen chloride dose of 0.11 mg/kg body weight) can be

derived. In view of the minor nature of the changes observed and the NOAEL in a previous chronic study, it is not considered necessary to include an additional uncertainty factor to allow for the length of the study. Further, it appears that a dose that may be toxic in acute poisoning would certainly be tolerated under chronic conditions, owing to efficient detoxification. Assuming a 60 kg adult drinking 2 litres of water per day and allowing 20% of the TDI to come from water because of the potential for exposure to cyanogenic glycosides in food, the health-based value for long-term exposure is 0.3 mg/l for cyanide or 0.6 mg/l for cyanogen chloride (rounded values).

Although low concentrations of cyanide in raw waters will be converted to cyanogen chloride by chlorination, cyanogen chloride may also be formed during the production of chloramines in situ as a residual disinfectant to maintain the hygienic condition of the distribution system. It is important that treatment be optimized to minimize the formation of cyanogen chloride while maintaining adequate chloramine residuals where chloramination is practised.

2,4-D

The term 2,4-D is used here to refer to the free acid, 2,4-dichlorophenoxyacetic acid (CAS No. 94-75-7). Commercial 2,4-D products are marketed as the free acid, alkali and amine salts and ester formulations. 2,4-D itself is chemically stable, but its esters are rapidly hydrolysed to the free acid. 2,4-D is a systemic herbicide used for control of broad-leaved weeds, including aquatic weeds. 2,4-D is rapidly biodegraded in the environment. Residues of 2,4-D in food rarely exceed a few tens of micrograms per kilogram.

Guideline value	0.03 mg/l (30 µg/l)
Occurrence	Levels in water usually below 0.5 µg/l, although concentrations as high as 30 µg/l have been measured
ADI	0–0.01 mg/kg body weight for the sum of 2,4-D and its salts and esters, expressed as 2,4-D, on the basis of a NOAEL of 1 mg/kg body weight per day in a 1-year study of toxicity in dogs (for a variety of effects, including histopathological lesions in kidneys and liver) and a 2-year study of toxicity and carcinogenicity in rats (for renal lesions)
Limit of detection	0.1 µg/l by gas–liquid chromatography with electrolytic conductivity detection
Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value applies to 2,4-D, as salts and esters of 2,4-D are rapidly hydrolysed to the free acid in water.
Assessment date	1998
Principal references	FAO/WHO (1997) *Pesticide residues in food—1996 evaluations* WHO (2003) *2,4-D in drinking-water*

Epidemiological studies have suggested an association between exposure to chlorophenoxy herbicides, including 2,4-D, and two forms of cancer in humans: soft tissue sarcomas and non-Hodgkin lymphoma. The results of these studies, however, are inconsistent; the associations found are weak, and conflicting conclusions have been reached by the investigators. Most of the studies did not provide information on exposure specifically to 2,4-D, and the risk was related to the general category of chlorophenoxy herbicides, a group that includes 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), which was potentially contaminated with dioxins. JMPR concluded that it was not possible to evaluate the carcinogenic potential of 2,4-D on the basis of the available epidemiological studies. JMPR also concluded that 2,4-D and its salts and esters are not genotoxic. The toxicity of the salts and esters of 2,4-D is comparable to that of the acid.

2,4-DB

The half-lives for degradation of chlorophenoxy herbicides, including 2,4-DB, or 2,4-dichlorophenoxybutyric acid (CAS No. 94-82-6), in the environment are in the order of several days. Chlorophenoxy herbicides are not often found in food.

Guideline value	0.09 mg/l (90 µg/l)
Occurrence	Chlorophenoxy herbicides not frequently found in drinking-water; when detected, concentrations usually no greater than a few micrograms per litre
TDI	30 µg/kg body weight, based on a NOAEL of 3 mg/kg body weight per day for effects on body and organ weights, blood chemistry and haematological parameters in a 2-year study in rats, with an uncertainty factor of 100 (for interspecies and intraspecies variation)
Limit of detection	1 µg/l to 1 mg/l for various methods commonly used for the determination of chlorophenoxy herbicides in water, including solvent extraction, separation by GC, gas–liquid chromatography, thin-layer chromatography or HPLC, with ECD or UV detection
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The NOAEL used in the guideline value derivation is similar to the NOAEL of 2.5 mg/kg body weight per day obtained in a short-term study in dogs and the NOAEL for hepatocyte hypertrophy of 5 mg/kg body weight per day obtained in a 3-month study in rats.
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenoxy herbicides (excluding 2,4-D and MCPA) in drinking-water*

Chlorophenoxy herbicides, as a group, have been classified in Group 2B (possibly carcinogenic to humans) by IARC. However, the available data from studies in exposed populations and experimental animals do not permit assessment of the carcinogenic potential to humans of any specific chlorophenoxy herbicide. Therefore, drinking-water guidelines for these compounds are based on a threshold approach for other toxic effects.

DDT and metabolites

The structure of dichlorodiphenyltrichloroethane, or DDT (CAS No. 107917-42-0), permits several different isomeric forms; commercial products consist predominantly of *p*,*p′*-DDT. Its use has been restricted or banned in several countries, although DDT is still used in some countries for the control of vectors that transmit yellow fever, sleeping sickness, typhus, malaria and other insect-transmitted diseases. DDT and its metabolites are persistent in the environment and resistant to complete degradation by microorganisms. Food is the major source of intake of DDT and related compounds for the general population, although exposure has significantly decreased as a consequence of the greatly reduced use of DDT for all except specialist applications.

Guideline value	0.001 mg/l (1 µg/l)
Occurrence	Detected in surface water at concentrations below 1 µg/l; also detected in drinking-water at 100-fold lower concentrations
PTDI	0.01 mg/kg body weight based on a NOAEL of 1 mg/kg body weight per day for developmental toxicity in rats, applying an uncertainty factor of 100 (for interspecies and intraspecies variation)
Limit of detection	0.011 µg/l by GC using ECD
Treatment performance	0.1 µg/l should be achievable using coagulation or GAC
Guideline value derivation	
• allocation to water	1% of PTDI
• weight	10 kg child
• consumption	1 litre/day
Additional comments	DDT is listed under the Stockholm Convention on Persistent Organic Pollutants. Hence, monitoring may occur in addition to that required by drinking-water guidelines.
	It should be noted that the level of DDT and its metabolites in food has been falling steadily, and the allocation of 1% of the PTDI may be very conservative.
	The guideline value is derived on the basis of a 10 kg child consuming 1 litre of drinking-water per day, because infants and children may be exposed to greater amounts of chemicals in relation to their body weight and because of concern over the bioaccumulation of DDT.
	It should be emphasized that the benefits of DDT use in malaria and other vector control programmes outweigh any health risk from the presence of DDT in drinking-water.

Assessment date	2003
Principal references	FAO/WHO (2001) *Pesticide residues in food—2000 evaluations* WHO (2004) *DDT and its derivatives in drinking-water*

A working group convened by IARC classified the DDT complex (the mixture of the various isomers of DDT and associated compounds) as a non-genotoxic carcinogen in rodents and a potent promoter of liver tumours. IARC has concluded that there is insufficient evidence in humans and sufficient evidence in experimental animals for the carcinogenicity of DDT (Group 2B) based upon liver tumours observed in rats and mice. The results of epidemiological studies of pancreatic cancer, multiple myeloma, non-Hodgkin lymphoma and uterine cancer did not support the hypothesis of an association with environmental exposure to the DDT complex. Conflicting data were obtained with regard to some genotoxic end-points. In most studies, DDT did not induce genotoxic effects in rodent or human cell systems, nor was it mutagenic to fungi or bacteria. The United States Agency for Toxic Substances and Disease Registry concluded that the DDT complex could impair reproduction and development in several species. Hepatic effects of DDT in rats include increased liver weights, hypertrophy, hyperplasia, induction of microsomal enzymes, including cytochrome P450, cell necrosis, increased activity of serum liver enzymes and mitogenic effects, which might be related to a regenerative liver response to high doses of DDT.

Dialkyltins

The group of chemicals known as the organotins is composed of a large number of compounds with differing properties and applications. The most widely used organotins are the disubstituted compounds, which are employed as stabilizers in plastics, including polyvinyl chloride (PVC) water pipes, and the trisubstituted compounds, which are widely used as biocides.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline values for any of the dialkyltins
Assessment date	2003
Principal reference	WHO (2004) *Dialkyltins in drinking-water*

The disubstituted compounds that may leach from PVC water pipes at low concentrations for a short time after installation are primarily immunotoxins, although they appear to be of low general toxicity. The data available are insufficient to permit the proposal of guideline values for individual dialkyltins.

1,2-Dibromo-3-chloropropane

1,2-Dibromo-3-chloropropane (CAS No. 96-12-8), or DBCP, is a soil fumigant that is highly soluble in water. It has a taste and odour threshold in water of 10 µg/l. DBCP was detected in vegetables grown in treated soils, and low levels have been detected in air.

Guideline value	0.001 mg/l (1 µg/l)
Occurrence	Limited survey found levels of up to a few micrograms per litre in drinking-water
Basis of guideline value derivation	Linearized multistage model was applied to the data on the incidence of stomach, kidney and liver tumours in the male rat in a 104-week dietary study
Limit of detection	0.02 µg/l by GC with ECD
Treatment performance	1 µg/l should be achievable using air stripping followed by GAC
Additional comments	The guideline value of 1 µg/l should be protective for the reproductive toxicity of DBCP.
Assessment date	1993
Principal reference	WHO (2003) *1,2-Dibromo-3-chloropropane in drinking-water*

On the basis of data from different strains of rats and mice, DBCP was determined to be carcinogenic in both sexes by the oral, inhalation and dermal routes. DBCP was also determined to be a reproductive toxicant in humans and several species of laboratory animals. DBCP was found to be genotoxic in a majority of in vitro and in vivo assays. IARC has classified DBCP in Group 2B based upon sufficient evidence of carcinogenicity in animals. Recent epidemiological evidence suggests an increase in cancer mortality in individuals exposed to high levels of DBCP.

1,2-Dibromoethane

1,2-Dibromoethane (CAS No. 106-93-4), or ethylene dibromide, is used as a lead scavenger in tetraalkyl lead petrol and antiknock preparations and as a fumigant for soils, grains and fruits. However, with the phasing out of leaded petrol and of the use of 1,2-dibromoethane in agricultural applications in many countries, use of this substance has declined significantly. In addition to its continued use as a petrol additive in some countries, 1,2-dibromoethane is currently used principally as a solvent and as an intermediate in the chemical industry.

Provisional guideline value	0.0004 mg/l (0.4 µg/l)
	The guideline value is provisional owing to serious limitations of the critical studies.
Occurrence	Detected in groundwater following its use as a soil fumigant at concentrations as high as 100 µg/l
Basis of guideline value derivation	Lower end of the range (and thus more conservative estimate) of lifetime low-dose cancer risks calculated by linearized multistage modelling of the incidences of haemangiosarcomas and tumours in the stomach, liver, lung and adrenal cortex (adjusted for the observed high early mortality, where appropriate, and corrected for the expected rate of increase in tumour formation in rodents in a standard bioassay of 104 weeks) of rats and mice exposed by gavage
Limit of detection	0.01 µg/l by microextraction GC-MS; 0.03 µg/l by purge-and-trap GC with halogen-specific detector; 0.8 µg/l by purge-and-trap capillary column GC with photoionization and electrolytic conductivity detectors in series

Treatment performance	0.1 µg/l should be achievable using GAC
Assessment date	2003
Principal references	IPCS (1995) *Report of the 1994 meeting of the Core Assessment Group* IPCS (1996) *1,2-Dibromoethane* WHO (2003) *1,2-Dibromoethane in drinking-water*

1,2-Dibromoethane has induced an increased incidence of tumours at several sites in all carcinogenicity bioassays identified in which rats or mice were exposed to the compound by gavage, ingestion in drinking-water, dermal application and inhalation. However, many of these studies were characterized by high early mortality, limited histopathological examination, small group sizes or use of only one exposure level. The substance acted as an initiator of liver foci in an initiation/promotion assay but did not initiate skin tumour development. 1,2-Dibromoethane was consistently genotoxic in in vitro assays, although results of in vivo assays were mixed. Biotransformation to active metabolites, which have been demonstrated to bind to DNA, is probably involved in the induction of tumours. Available data do not support the existence of a non-genotoxic mechanism of tumour induction. The available data thus indicate that 1,2-dibromoethane is a genotoxic carcinogen in rodents. Data on the potential carcinogenicity in humans are inadequate; however, it is likely that 1,2-dibromoethane is metabolized similarly in rodent species and in humans (although there may be varying potential for the production of active metabolites in humans, owing to genetic polymorphism). IARC classified 1,2-dibromoethane in Group 2A (probably carcinogenic to humans).

Dichloroacetic acid

Chlorinated acetic acids, including dichloroacetic acid (DCA), are formed from organic material during water chlorination. DCA has been used as a therapeutic agent to treat lactic acidosis, diabetes and familial hyperlipidaemia in humans.

Provisional guideline value	0.05 mg/l (50 µg/l)
	The guideline value is designated as provisional on the basis of technical achievability.
Occurrence	Found in groundwater and surface water distribution systems at concentrations up to about 100 µg/l, with mean concentrations below 20 µg/l
Basis of guideline value derivation	Linear multistage model applied to combined data for carcinomas and adenomas in male mice exposed to doses up to 429 mg/kg body weight per day for up to 2 years
Limit of detection	< 0.1–0.4 µg/l by GC with ECD; practical quantification limit 1 µg/l
Treatment performance	Concentrations may be reduced by installing or optimizing coagulation to remove precursors or by controlling the pH during chlorination.
Additional comments	The concentration associated with a 10^{-5} upper-bound excess lifetime cancer risk is 40 µg/l. In some circumstances, however, it may not be possible to adequately disinfect potable water and maintain DCA levels below 40 µg/l, so the provisional guideline value of 50 µg/l is retained.

Assessment date	2004
Principal reference	WHO (2005) *Dichloroacetic acid in drinking-water*

IARC reclassified DCA as Group 2B (possibly carcinogenic to humans) in 2002, based on the absence of data on human carcinogenicity and sufficient evidence of its carcinogenicity in experimental animals. This classification was based primarily on findings of liver tumours in rats and mice. Genotoxicity data are considered to be inconclusive, particularly at lower doses. Glycogen deposition, peroxisome proliferation, changes in signal transduction pathways and DNA hypomethylation have all been observed following DCA exposure and have been hypothesized to be involved in its carcinogenicity. However, the available data are not sufficient to establish a cancer mode of action with reasonable certainty, especially at the very low exposure levels expected to apply to humans ingesting chlorinated drinking-water. Recent data suggest that there may be more than one mechanism leading to tumours, as altered hepatic foci from treated mice were found to have three different types of cellular characteristics.

Dichlorobenzenes (1,2-dichlorobenzene, 1,3-dichlorobenzene, 1,4-dichlorobenzene)

The dichlorobenzenes (DCBs) are widely used in industry and in domestic products such as odour-masking agents, chemical dyestuffs and pesticides. Sources of human exposure are predominantly air and food.

Guideline values	*1,2-Dichlorobenzene:* 1 mg/l (1000 µg/l)
	1,4-Dichlorobenzene: 0.3 mg/l (300 µg/l)
Occurrence	Have been found in raw water sources at levels as high as 10 µg/l and in drinking-water at concentrations up to 3 µg/l; much higher concentrations (up to 7 mg/l) present in contaminated groundwater
TDIs	*1,2-Dichlorobenzene:* 429 µg/kg body weight, based on a NOAEL of 60 mg/kg body weight per day for tubular degeneration of the kidney identified in a 2-year mouse gavage study, adjusting for daily dosing and using an uncertainty factor of 100 (for interspecies and intraspecies variation)
	1,4-Dichlorobenzene: 107 µg/kg body weight, based on a LOAEL of 150 mg/kg body weight per day for kidney effects identified in a 2-year rat study, adjusting for daily dosing and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the use of a LOAEL instead of a NOAEL and the carcinogenicity end-point)
Limit of detection	0.01–0.25 µg/l by gas–liquid chromatography with ECD; 3.5 µg/l by GC using a photoionization detector
Treatment performance	0.01 mg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day

Additional comments	Guideline values for both 1,2- and 1,4-DCB far exceed their lowest reported taste thresholds in water of 1 and 6 µg/l, respectively.
Assessment date	1993
Principal reference	WHO (2003) *Dichlorobenzenes in drinking-water*

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value for *1,3-dichlorobenzene*
Assessment date	1993
Principal reference	WHO (2003) *Dichlorobenzenes in drinking-water*

1,2-Dichlorobenzene

1,2-DCB is of low acute toxicity by the oral route of exposure. Oral exposure to high doses of 1,2-DCB affects mainly the liver and kidneys. The balance of evidence suggests that 1,2-DCB is not genotoxic, and there is no evidence for its carcinogenicity in rodents.

1,3-Dichlorobenzene

There are insufficient toxicological data on this compound to permit a guideline value to be proposed, but it should be noted that it is rarely found in drinking-water.

1,4-Dichlorobenzene

1,4-DCB is of low acute toxicity, but there is evidence that it increases the incidence of renal tumours in rats and of hepatocellular adenomas and carcinomas in mice after long-term exposure. IARC has placed 1,4-DCB in Group 2B (possibly carcinogenic to humans). 1,4-DCB is not considered to be genotoxic, and the relevance for humans of the tumours observed in experimental animals is doubtful.

1,1-Dichloroethane

1,1-Dichloroethane is used as a chemical intermediate and solvent. There are limited data showing that it can be present at concentrations of up to 10 µg/l in drinking-water. It is primarily of concern for groundwater.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value
Assessment date	1993
Principal reference	WHO (2003) *1,1-Dichloroethane in drinking-water*

1,1-Dichloroethane is rapidly metabolized by mammals to acetic acid and a variety of chlorinated compounds. It is of relatively low acute toxicity, and limited data are available on its toxicity from short-term and long-term studies. There is limited in vitro evidence of genotoxicity. One carcinogenicity study by gavage in mice and rats provided no conclusive evidence of carcinogenicity, although there was some evidence of an increased incidence of haemangiosarcomas in treated animals.

In view of the very limited database on toxicity and carcinogenicity, it was concluded that no guideline value should be proposed.

1,2-Dichloroethane

1,2-Dichloroethane is used mainly as an intermediate in the production of vinyl chloride and other chemicals and to a lesser extent as a solvent. It was used as a scavenger for tetraethyl lead in gasoline. It may enter surface waters via effluents from industries that manufacture or use the substance. It may also enter groundwater, where it may persist for long periods, following disposal in waste sites. It is found in urban air.

Guideline value	0.03 mg/l (30 µg/l)
Occurrence	Has been found in drinking-water at levels of up to a few micrograms per litre
Basis of guideline value derivation	Applying the linearized multistage model to haemangiosarcomas observed in male rats in a 78-week gavage study
Limit of detection	0.03 µg/l by GC with photoionization detection; 0.03–0.2 µg/l by GC with electrolytic conductivity detector; 0.06–2.8 µg/l by GC-MS; 5 µg/l by GC with flame ionization detection (FID)
Treatment performance	0.0001 mg/l should be achievable using GAC
Additional comments	The guideline value of 0.03 mg/l is consistent with the value derived from IPCS (1998), based on a 10^{-5} risk level.
Assessment date	2003
Principal references	IPCS (1995) *1,2-Dichloroethane, 2nd ed.* IPCS (1998) *1,2-Dichloroethane* WHO (2003) *1,2-Dichloroethane in drinking-water*

IARC has classified 1,2-dichloroethane in Group 2B (possible human carcinogen). It has been shown to produce statistically significant increases in a number of tumour types in laboratory animals, including the relatively rare haemangiosarcoma, and the balance of evidence indicates that it is potentially genotoxic. Targets of 1,2-dichloroethane toxicity in orally exposed animals included the immune system, central nervous sytem, liver and kidney. Data indicate that 1,2-dichloroethane is less potent when inhaled.

1,1-Dichloroethene

1,1-Dichloroethene, or vinylidene chloride, is used mainly as a monomer in the production of polyvinylidene chloride co-polymers and as an intermediate in the synthesis of other organic chemicals. It is an occasional contaminant of drinking-water, usually being found together with other chlorinated hydrocarbons. There are no data on levels in food, but levels in air are generally less than 40 ng/m^3 except at some manufacturing sites. 1,1-Dichloroethene is detected in finished drinking-water taken from groundwater sources at median concentrations of 0.28–1.2 µg/l and in public drinking-water supplies at concentrations up to 0.5 µg/l.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2004
Principal references	IPCS (2003) *1,1-Dichloroethene (vinylidene chloride)* WHO (2005) *1,1-Dichloroethene in drinking-water*

1,1-Dichloroethene is a central nervous system depressant and may cause liver and kidney toxicity in occupationally exposed humans. It causes liver and kidney damage in laboratory animals. IARC has placed 1,1-dichloroethene in Group 3 (not classifiable as to its carcinogenicity to humans). It was found to be genotoxic in a number of test systems in vitro but was not active in the dominant lethal and micronucleus assays in vivo. It induced kidney tumours in mice in one inhalation study but was reported not to be carcinogenic in a number of other studies, including several in which it was given in drinking-water.

A health-based value of 140 µg/l (rounded value) can be calculated on the basis of a TDI of 0.046 mg/kg body weight, derived using the benchmark dose (BMD) approach from a study in which the critical effect was minimal hepatocellular midzonal fatty change in female rats. However, this value is significantly higher than the concentrations of 1,1-dichloroethene normally found in drinking-water. It is therefore considered unnecessary to set a formal guideline value for 1,1-dichloroethene in drinking-water.

1,2-Dichloroethene

1,2-Dichloroethene exists in a *cis* and a *trans* form. The *cis* form is more frequently found as a water contaminant. The presence of these two isomers, which are metabolites of other unsaturated halogenated hydrocarbons in wastewater and anaerobic groundwater, may indicate the simultaneous presence of other organochlorine chemicals, such as vinyl chloride. Accordingly, their presence indicates that more intensive monitoring should be conducted. There are no data on exposure from food. Concentrations in air are low, with higher concentrations, in the microgram per cubic metre range, near production sites. The *cis* isomer was previously used as an anaesthetic.

Guideline value	0.05 mg/l (50 µg/l)
Occurrence	Has been found in drinking-water supplies derived from groundwater at levels up to 120 µg/l
TDI	17 µg/kg body weight, based on a NOAEL (for increases in serum alkaline phosphatase levels and increased thymus weight) of 17 mg/kg body weight from a 90-day study in mice administered *trans*-1,2-dichloroethene in drinking-water, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the short duration of the study)
Limit of detection	0.17 µg/l by GC-MS

Treatment performance	0.01 mg/l should be achievable using GAC or air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Data on the *trans* isomer were used to calculate a joint guideline value for both isomers because toxicity for the *trans* isomer occurred at a lower dose than for the *cis* isomer and because data suggest that the mouse is a more sensitive species than the rat.
Assessment date	1993
Principal reference	WHO (2003) *1,2-Dichloroethene in drinking-water*

There is little information on the absorption, distribution or excretion of 1,2-dichloroethene. However, by analogy with 1,1-dichloroethene, 1,2-dichloroethene would be expected to be readily absorbed, distributed mainly to the liver, kidneys and lungs and rapidly excreted. The *cis* isomer is more rapidly metabolized than the *trans* isomer in in vitro systems. Both isomers have been reported to cause increased serum alkaline phosphatase levels in rodents. In a 3-month study in mice given the *trans* isomer in drinking-water, there was a reported increase in serum alkaline phosphatase and reduced thymus and lung weights. Transient immunological effects were also reported, the toxicological significance of which is unclear. *Trans*-1,2-dichloroethene also caused reduced kidney weights in rats, but at higher doses. Only one rat toxicity study is available for the *cis* isomer, which produced toxic effects in rats similar in magnitude to those induced by the trans isomer in mice, but at higher doses. There are limited data to suggest that both isomers may possess some genotoxic activity. There is no information on carcinogenicity.

Dichloromethane

Dichloromethane, or methylene chloride, is widely used as a solvent for many purposes, including coffee decaffeination and paint stripping. Exposure from drinking-water is likely to be insignificant compared with that from other sources.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Has been found in surface water samples at concentrations ranging from 0.1 to 743 µg/l; levels usually higher in groundwater because volatilization is restricted, with concentrations as high as 3600 µg/l reported; mean concentrations in drinking-water less than 1 µg/l
TDI	6 µg/kg body weight, derived from a NOAEL of 6 mg/kg body weight per day for hepatotoxic effects in a 2-year drinking-water study in rats, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for concern about carcinogenic potential)
Limit of detection	0.3 µg/l by purge-and-trap GC with MS detection (note that dichloromethane vapour readily penetrates tubing during the procedure)

Treatment performance	20 µg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Dichloromethane in drinking-water*

Dichloromethane is of low acute toxicity. An inhalation study in mice provided conclusive evidence of carcinogenicity, whereas drinking-water studies in rats and mice provided only suggestive evidence. IARC has placed dichloromethane in Group 2B (possible human carcinogen); however, the balance of evidence suggests that it is not a genotoxic carcinogen and that genotoxic metabolites are not formed in relevant amounts in vivo.

1,2-Dichloropropane

1,2-Dichloropropane (CAS No. 78-87-5), or 1,2-DCP, is used as an insecticide fumigant on grain and soil and to control peach tree borers. It is also used as an intermediate in the production of tetrachloroethene and other chlorinated products and as a solvent. 1,2-DCP is relatively resistant to hydrolysis, is poorly adsorbed onto soil and can migrate into groundwater.

Provisional guideline value	0.04 mg/l (40 µg/l)
	The guideline value is provisional owing to limitations of the toxicological database.
Occurrence	Detected in groundwater and drinking-water, usually at concentrations below 20 µg/l, although levels as high as 440 µg/l have been measured in well water
TDI	14 µg/kg body weight based on a LOAEL of 71.4 mg/kg body weight per day (100 mg/kg body weight per day adjusted for daily dosing) for changes in haematological parameters in a 13-week study in male rats, with an uncertainty factor of 5000 (100 for interspecies and intraspecies variation, 10 for use of a LOAEL and 5 to reflect limitations of the database, including the limited data on in vivo genotoxicity and use of a subchronic study)
Limit of detection	0.02 µg/l by purge-and-trap GC with an electrolytic conductivity detector or GC-MS
Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1998

Principal reference	WHO (2003) *1,2-Dichloropropane (1,2-DCP) in drinking-water*

1,2-DCP was evaluated by IARC in 1986 and 1987. The substance was classified in Group 3 (not classifiable as to its carcinogenicity to humans) on the basis of limited evidence for its carcinogenicity in experimental animals and insufficient data with which to evaluate its carcinogenicity in humans. Results from in vitro assays for mutagenicity were mixed. The in vivo studies, which were limited in number and design, were negative. In accordance with the IARC evaluation, the evidence from the long-term carcinogenicity studies in mice and rats was considered limited, and it was concluded that the use of a threshold approach for the toxicological evaluation of 1,2-DCP was appropriate.

1,3-Dichloropropane

1,3-Dichloropropane (CAS No. 142-28-9) has several industrial uses and may be found as a contaminant of soil fumigants containing 1,3-dichloropropene. It is rarely found in water.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value
Assessment date	1993
Principal reference	WHO (2003) *1,3-Dichloropropane in drinking-water*

1,3-Dichloropropane is of low acute toxicity. There is some indication that it may be genotoxic in bacterial systems. No short-term, long-term, reproductive or developmental toxicity data pertinent to exposure via drinking-water could be located in the literature. The available data are considered insufficient to permit recommendation of a guideline value.

1,3-Dichloropropene

1,3-Dichloropropene (CAS Nos. 542-75-6 isomer mixture; 10061-01-5 *cis* isomer; 10061-02-6 *trans* isomer) is a soil fumigant, the commercial product being a mixture of *cis* and *trans* isomers. It is used to control a wide variety of soil pests, particularly nematodes in sandy soils. Notwithstanding its high vapour pressure, it is soluble in water at the gram per litre level and can be considered a potential water contaminant.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Has been found in surface water and groundwater at concentrations of a few micrograms per litre
Basis of guideline value derivation	Calculated by applying the linearized multistage model to the observation of lung and bladder tumours in female mice in a 2-year gavage study
Limit of detection	0.34 and 0.20 µg/l by purge-and-trap packed column GC using an electrolytic conductivity detector or microcoulometric detector for the *cis* and *trans* isomers, respectively

Treatment performance	No information found on removal from water
Assessment date	1993
Principal reference	WHO (2003) *1,3-Dichloropropene in drinking-water*

1,3 Dichloropropene is a direct-acting mutagen that has been shown to produce forestomach tumours following long term oral gavage exposure in rats and mice. Tumours have also been found in the bladder and lungs of female mice and the liver of male rats. Long term inhalation studies in the rat have proved negative, whereas some benign lung tumours have been reported in inhalation studies in mice. IARC has classified 1,3 dichloropropene in Group 2B (possible human carcinogen).

Dichlorprop

The half-lives for degradation of chlorophenoxy herbicides, including dichlorprop (CAS No. 120-36-5), or 2,4-DP, in the environment are in the order of several days. Chlorophenoxy herbicides are not often found in food.

Guideline value	0.1 mg/l (100 µg/l)
Occurrence	Chlorophenoxy herbicides not frequently found in drinking-water; when detected, concentrations usually no greater than a few micrograms per litre
TDI	36.4 µg/kg body weight, based on a NOAEL of 3.64 mg/kg body weight per day for renal toxicity in a 2-year dietary study in rats, applying an uncertainty factor of 100 (for intraspecies and interspecies variation)
Limit of detection	1 µg/l to 1 mg/l for various methods commonly used for the determination of chlorophenoxy herbicides in water, including solvent extraction, separation by GC, gas–liquid chromatography, thin-layer chromatography or HPLC, with ECD or UV detection
Treatment performance	No information found on removal from water
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenoxy herbicides (excluding 2,4-D and MCPA) in drinking-water*

Chlorophenoxy herbicides, as a group, have been classified in Group 2B (possible human carcinogen) by IARC. However, the available data from studies in exposed populations and experimental animals do not permit assessment of the carcinogenic potential to humans of any specific chlorophenoxy herbicide. Therefore, drinking-water guidelines for these compounds are based on a threshold approach for other toxic effects. In dietary studies in rats, slight liver hypertrophy was observed in a

3-month study, and effects in a 2-year study included hepatocellular swelling, mild anaemia, increased incidence of brown pigment in the kidneys (possibly indicative of slight degeneration of the tubular epithelium) and decreased urinary specific gravity and protein.

Dichlorvos

Dichlorvos (CAS No. 62-73-7) is a broad-spectrum organophosphorus insecticide used primarily for controlling household pests and for protecting stored products from insects. It is no longer approved for use in some jurisdictions because of concerns over its acute toxicity. Dichlorvos is expected to be very mobile in soils. It is rapidly degraded by microbial activity and hydrolysis in soil, and does not adsorb to sediments. Degradation in water occurs primarily through hydrolysis. There are relatively few studies on its occurrence in source waters. Exposure from food varies widely, depending on local circumstances and usage. Dichlorvos can be inhaled from its use as a domestic insecticide.

Reason for not establishing a guideline value	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Health-based value*	0.02 mg/l
Acute health-based value**	3 mg/l
Occurrence	Concentrations in surface water in the range 10–50 ng/l, but sometimes as high as 1500 ng/l, have been measured
ADI	0–0.004 mg/kg bw, based on a NOAEL of 0.04 mg/kg bw per day for the inhibition of erythrocyte acetylcholinesterase activity in a 21-day study in male volunteers and application of a safety factor of 10
ARfD	0.1 mg/kg bw, based on a NOAEL of 1 mg/kg bw for erythrocyte acetylcholinesterase inhibition in an acute oral study in male volunteers and application of a safety factor of 10
Limit of detection	0.01 µg/l (limit of quantification) based on solvent extraction and GC analysis; 0.1 µg/l (reporting limit) based on GC-MS
Treatment performance	Conventional treatment, including coagulation, filtration and chlorination, not effective; removal by membranes depends on membrane type and operational conditions. Removal by nanofiltration membranes has variable effectiveness (removal rates from 4 to 60%). Reverse osmosis would be expected to be effective (removal rates > 85%) based on removal studies and predictions.
Health-based value derivation	
• allocation to water	20% of upper bound of ADI
• weight	60 kg adult
• consumption	2 litres/day
Acute health-based value derivation	
• allocation to water	100% of ARfD
• weight	60 kg adult
• consumption	2 litres/day

Additional comments	The default allocation factor of 20% has been used to account for the fact that the available food exposure data, which suggest that exposure via this route is low, do not generally include information from developing countries, where exposure via this route may be higher, and as potential exposure via inhalation from indoor air resulting from use of dichlorvos as a domestic insecticide is unknown
	Guidance on interpreting the health-based value and deciding when to monitor can be found in section 8.5.3
Assessment date	2016
Principal references	WHO (2012). *Pesticide residues in food – 2011 evaluations* WHO (2016). *Dichlorvos in drinking-water*

* When a formal guideline value is not established, a "health-based value" may be determined in order to provide guidance to Member States when there is reason for local concern. Establishing a formal guideline value for such substances may encourage Member States to incorporate a value into their national standards when this may be unnecessary.

** For more information on acute health-based values, see section 8.7.5.

As with other organophosphorus insecticides, the inhibition of cholinesterase activity, causing neurotoxicity, is the most sensitive toxicological end-point following acute or repeated exposures to dichlorvos. Dichlorvos is unlikely to be genotoxic in vivo or to pose a carcinogenic risk to humans. Some reproductive toxicity has been observed in rats, but dichlorvos was not found to cause developmental toxicity or to be teratogenic.

Dicofol

Dicofol (CAS No. 115-32-2) is an organochlorine acaricide that has been registered for broad-spectrum contact, non-systemic control of plant-eating mites in cotton, tea and a wide variety of fruit, vegetable and ornamental crops. Products containing dicofol, which is manufactured from DDT, are being phased out in the USA and are no longer approved for use in the European Union. Dicofol is unlikely to reach water, but may do so if bound to particulate matter subject to runoff. Dicofol is only slightly soluble in water and binds strongly to soil. There are few data on the occurrence of dicofol in water. Exposure from food varies widely, depending on local circumstances and usage. Dicofol has been proposed as a persistent organic pollutant under the Stockholm Convention.

Reason for not establishing a guideline value	Unlikely to be found in drinking-water or drinking-water sources*
Health-based value**	0.01 mg/l
Acute health-based value***	6 mg/l
Occurrence	Not detected in limited groundwater monitoring
ADI	0–0.002 mg/kg bw, based on a NOAEL of 0.22 mg/kg bw per day for histopathological changes in the liver and adrenal gland in a 2-year toxicity and carcinogenicity study in rats and application of a safety factor of 100

ARfD	0.2 mg/kg bw, based on a NOAEL of 15 mg/kg bw for decreased body weight and decreased feed intake in an acute neurotoxicity study in rats and application of a safety factor of 100
Limit of detection	Solvent extraction followed by GC-ECD may be effective (limit of quantification 5 ng/l)
Treatment performance	Should be removed by adsorption onto activated carbon, and any dicofol adsorbed onto particulate matter would likely be removed during coagulation
Health-based value derivation	
• allocation to water	20% of the upper bound of the ADI
• weight	60 kg adult
• consumption	2 litres/day
Acute health-based value derivation	
• allocation to water	100% of the ARfD
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The default allocation factor of 20% has been used to account for the fact that the available food exposure data, which suggest that exposure via this route is low, do not generally include information from developing countries, where exposure via this route may be higher
	Guidance on interpreting the health-based value and deciding when to monitor can be found in section 8.5.3
Assessment date	2016
Principal references	WHO (2012). *Pesticide residues in food – 2011 evaluations* WHO (2016). *Dicofol in drinking-water*

* Although dicofol does not fulfil one of the three criteria for evaluation in the Guidelines, a background document has been prepared, and a health-based value has been established, in response to a request from Member States for guidance.

** When a formal guideline value is not established, a "health-based value" may be determined in order to provide guidance to Member States when there is reason for local concern. Establishing a formal guideline value for such substances may encourage Member States to incorporate a value into their national standards when this may be unnecessary.

*** For more information on acute health-based values, see section 8.7.5.

The primary effects of dicofol after short- or long-term exposure of experimental animals were body weight reduction associated with decreased feed intake, and increased liver weight accompanied by changes in liver enzyme activities. Dicofol caused liver tumours in male mice at doses associated with significant enzyme induction and liver hypertrophy. However, on the basis of the absence of genotoxicity in an adequate range of in vitro genotoxicity and in vivo chromosomal aberration tests, the absence of carcinogenic effects in rats and the expectation that the adenomas present in mice will exhibit a threshold, dicofol is unlikely to pose a carcinogenic risk to humans at anticipated dietary exposure levels. There is a margin of 20 000 between the upper bound of the ADI and the LOAEL for liver adenomas in the male mouse.

Di(2-ethylhexyl)adipate

Di(2-ethylhexyl)adipate (DEHA) is used mainly as a plasticizer for synthetic resins such as PVC. Reports of the presence of DEHA in surface water and drinking-water are scarce, but DEHA has occasionally been identified in drinking-water at levels of a few micrograms per litre. As a consequence of its use in PVC films, food is the most important source of human exposure (up to 20 mg/day).

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal reference	WHO (2003) *Di(2-ethylhexyl)adipate in drinking-water*

DEHA is of low short-term toxicity; however, dietary levels above 6000 mg/kg of feed induce peroxisomal proliferation in the liver of rodents. This effect is often associated with the development of liver tumours. DEHA induced liver carcinomas in female mice at very high doses, but not in male mice or rats. It is not genotoxic. IARC has placed DEHA in Group 3 (not classifiable as to its carcinogenicity to humans).

A health-based value of 80 µg/l can be calculated for DEHA on the basis of a TDI of 280 µg/kg body weight, based on fetotoxicity in rats, and allocating 1% of the TDI to drinking-water. However, because DEHA occurs at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value.

Di(2-ethylhexyl)phthalate

Di(2-ethylhexyl)phthalate (DEHP) is used primarily as a plasticizer. Exposure among individuals may vary considerably because of the broad nature of products into which DEHP is incorporated. In general, food will be the main exposure route.

Guideline value	0.008 mg/l (8 µg/l)
Occurrence	Found in surface water, groundwater and drinking-water in concentrations of a few micrograms per litre; in polluted surface water and groundwater, concentrations of hundreds of micrograms per litre have been reported
TDI	25 µg/kg body weight, based on a NOAEL of 2.5 mg/kg body weight per day for peroxisomal proliferation in the liver in rats, using an uncertainty factor of 100 for interspecies and intraspecies variation
Limit of detection	0.1 µg/l by GC-MS

Treatment performance	No information found on removal from water
Guideline value derivation	
• allocation to water	1% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The reliability of some data on environmental water samples is questionable because of secondary contamination during sampling and working-up procedures. Concentrations that exceed the solubility more than 10-fold have been reported.
Assessment date	1993
Principal reference	WHO (2003) *Di(2-ethylhexyl)phthalate in drinking-water*

In rats, DEHP is readily absorbed from the gastrointestinal tract. In primates (including humans), absorption after ingestion is lower. Species differences are also observed in the metabolic profile. Most species excrete primarily the conjugated mono-ester in urine. Rats, however, predominantly excrete terminal oxidation products. DEHP is widely distributed in the body, with highest levels in liver and adipose tissue, without showing significant accumulation. The acute oral toxicity is low. The most striking effect in short-term toxicity studies is the proliferation of hepatic peroxisomes, indicated by increased peroxisomal enzyme activity and histopathological changes. The available information suggests that primates, including humans, are far less sensitive to this effect than rodents. In long-term oral carcinogenicity studies, hepatocellular carcinomas were found in rats and mice. IARC has concluded that DEHP is possibly carcinogenic to humans (Group 2B). In 1988, JECFA evaluated DEHP and recommended that human exposure to this compound in food be reduced to the lowest level attainable. JECFA considered that this might be achieved by using alternative plasticizers or alternatives to plastic material containing DEHP. In a variety of in vitro and in vivo studies, DEHP and its metabolites have shown no evidence of genotoxicity, with the exception of induction of aneuploidy and cell transformation.

Dimethoate

Dimethoate (CAS No. 60-51-5) is an organophosphorus insecticide used to control a broad range of insects in agriculture, as well as the housefly. It has a half-life of 18 hours to 8 weeks and is not expected to persist in water, although it is relatively stable at pH 2–7. A total daily intake from food of 0.001 µg/kg body weight has been estimated.

Guideline value	0.006 mg/l (6 µg/l)
Occurrence	Detected at trace levels in a private well in Canada, but not detected in a Canadian survey of surface water or drinking-water supplies
ADI	0–0.002 mg/kg body weight based on an apparent NOAEL of 1.2 mg/kg body weight per day for reproductive performance in a study of reproductive toxicity in rats, applying an uncertainty factor of 500 (100 for interspecies and intraspecies variation, 5 to take into consideration concern regarding whether the NOAEL could be a LOAEL)

Assessment date	2003
Principal references	FAO/WHO (1997) *Pesticide residues in food—1996 evaluations* WHO (2004) *Dimethoate in drinking-water*

In studies with human volunteers, dimethoate has been shown to be a cholinesterase inhibitor and a skin irritant. Dimethoate is not carcinogenic to rodents. JMPR concluded that although in vitro studies indicate that dimethoate has mutagenic potential, this potential does not appear to be expressed in vivo. In a multigeneration study of reproductive toxicity in rats, the NOAEL appeared to be 1.2 mg/kg body weight per day, but there was some indication that reproductive performance may have been affected at lower doses. No data were available to assess whether the effects on reproductive performance were secondary to inhibition of cholinesterase. JMPR concluded that it was not appropriate to base the ADI on the results of the studies of volunteers, as the crucial end-point (reproductive performance) has not been assessed in humans. It was suggested that there may be a need to re-evaluate the toxicity of dimethoate after the periodic review of the residue and analytical aspects of dimethoate has been completed if it is determined that omethoate is a major residue.

1,4-Dioxane

1,4-Dioxane is used as a stabilizer in chlorinated solvents and as a solvent for resins, oils and waxes, for agricultural and biochemical intermediates and for adhesives, sealants, cosmetics, pharmaceuticals, rubber chemicals and surface coatings.

Guideline value	0.05 mg/l (50 µg/l)
Occurrence	Has been measured in surface water at concentrations up to 40 µg/l and in groundwater at concentrations up to 80 µg/l
TDI	16 µg/kg body weight, based on a NOAEL of 16 mg/kg body weight per day for hepatocellular tumours observed in a long-term drinking-water study in rats, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for non-genotoxic carcinogenicity)
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Basis of guideline value derivation based on carcinogenicity	Linear multistage model applied to data for hepatic tumours from drinking-water studies in rats
Limit of detection	0.1–50 µg/l by GC-MS
Treatment performance	Not removed using conventional water treatment processes; effectively removed by biological activated carbon treatment

Additional comments	Similar guideline values were derived using the TDI approach (assuming 1,4-dioxane is not genotoxic in humans at low doses) and linear multistage modelling (because the compound clearly induces multiple tumours in various organs).
Assessment date	2004
Principal reference	WHO (2005) *1,4-Dioxane in drinking-water*

1,4-Dioxane caused hepatic and nasal cavity tumours in rodents in most long-term oral studies conducted. Tumours in peritoneum, skin and mammary gland were also observed in rats given a high dose. Lung tumours were specifically detected after intraperitoneal injection. Although cohort studies of workers did not reveal any elevation in the incidence of death by cancer, a significant increase in the incidence of liver cancer was found in a comparative mortality study. However, the evidence is inadequate for human carcinogenicity assessment because of small samples or lack of exposure data. A possibly weak genotoxic potential of 1,4-dioxane has been suggested. IARC has classified 1,4-dioxane in Group 2B (possibly carcinogenic to humans).

Diquat

Diquat (CAS No. 85-00-7; CAS No. 2764-72-9 for diquat ion) is a non-selective, quick-acting contact herbicide that is used for weed control on several food crops, for residential weed control on lawns and ornamental plants, and as an aquatic herbicide for the control of free-floating and submerged aquatic weeds in ponds and irrigation ditches. It is highly soluble in water but is strongly adsorbed to soil and is resistant to degradation in the sorbed state. Photochemical degradation in soil and water occurs in the presence of sunlight. Exposure from food is likely to be low.

Reason for not establishing a guideline value	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Health-based value*	0.03 mg/l
Acute health-based value**	20 mg/l
Occurrence	Rarely detected in surface water
ADI	0–0.006 mg/kg bw (expressed as the diquat ion), based on a NOAEL of 0.58 mg/kg bw per day for cataracts in a 2-year toxicity and carcinogenicity study in rats and application of a safety factor of 100
ARfD	0.8 mg/kg bw (expressed as the diquat ion), based on a NOAEL of 75 mg/kg bw for clinical signs and decreased body weight gain in the 1st week and decreased feed consumption in a neurotoxicity study in rats and application of a safety factor of 100
Limit of detection	1 µg/l using HPLC with UV absorbance detection after solid sorbent cartridge extraction; practical quantification limit of 1 µg/l using LC-MS analysis after solid-phase extraction
Treatment performance	Conventional treatment, including coagulation and filtration, not effective; activated carbon may be effective

Health-based value derivation	
• allocation to water	20% of upper bound of unrounded ADI (0.0058 mg/kg bw)
• weight	60 kg adult
• consumption	2 litres/day
Acute health-based value derivation	
• allocation to water	100% of unrounded ARfD (0.75 mg/kg bw)
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The default allocation factor of 20% has been used to account for the fact that the available food exposure data, , which suggest that exposure via this route is low, do not generally include information from developing countries, where exposure via this route may be higher
	Guidance on interpreting the health-based value and deciding when to monitor can be found in section 8.5.3
Assessment date	2016
Principal references	WHO (2014). *Pesticide residues in food – 2013 evaluations* WHO (2016). *Diquat in drinking-water*

* When a formal guideline value is not established, a "health-based value" may be determined in order to provide guidance to Member States when there is reason for local concern. Establishing a formal guideline value for such substances may encourage Member States to incorporate a value into their national standards when this may be unnecessary.

** For more information on acute health-based values, see section 8.7.5.

The eye is the main target organ following short-term repeated exposure in rats and dogs. Effects on kidney, liver and haematological parameters are also observed. Diquat is not carcinogenic in mice or rats. In tests for genotoxicity, diquat gave equivocal or positive responses in the mammalian cell cytogenetic assay, but was negative in the in vivo mouse micronucleus assay and dominant lethal assay. No reproductive effects were observed in a two-generation reproductive toxicity study in rats, and diquat was not teratogenic in rats or rabbits.

Edetic acid

Human exposure to edetic acid, also known as ethylenediaminetetraacetic acid or EDTA, arises directly from its use in food additives, medicines and personal care and

hygiene products. Exposure to EDTA from drinking-water will be mostly very low in comparison with that from other sources. Once EDTA is present in the aquatic environment, its speciation will depend on the water quality and the presence of trace metals with which it will combine. The removal of EDTA from communal wastewater by biodegradation in sewage purification plants is very limited.

Guideline value	*EDTA (as the free acid):* 0.6 mg/l (600 µg/l)
Occurrence	Present in surface waters generally at concentrations below 70 µg/l, although higher concentrations (900 µg/l) have been measured; detected in drinking-water prepared from surface waters at concentrations of 10–30 µg/l
ADI	0–1.9 mg/kg body weight as the free acid (ADI of 0–2.5 mg/kg body weight proposed by JECFA for calcium disodium edetate as a food additive)
Limit of detection	1 µg/l by potentiometric stripping analyis
Treatment performance	0.01 mg/l using GAC plus ozonation
Guideline value derivation	
• allocation to water	1% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Concern has been expressed over the ability of EDTA to complex and therefore reduce the availability of zinc. However, this is of significance only at elevated doses substantially in excess of those encountered in the environment.
Assessment date	1998
Principal reference	WHO (2003) *Edetic acid (EDTA) in drinking-water*

Calcium disodium edetate is poorly absorbed from the gut. The long-term toxicity of EDTA is complicated by its ability to chelate essential and toxic metals. Those toxicological studies that are available indicate that the apparent toxicological effects of EDTA have in fact been due to zinc deficiency as a consequence of complexation. EDTA does not appear to be teratogenic or carcinogenic in experimental animals. The vast clinical experience of the use of EDTA in the treatment of metal poisoning has demonstrated its safety in humans.

Endosulfan

Endosulfan (CAS No. 115-29-7) is an insecticide used in countries throughout the world to control pests on fruit, vegetables and tea and on non-food crops such as tobacco and cotton. In addition to its agricultural use, it is used in the control of the tsetse fly, as a wood preservative and for the control of home garden pests. Endosulfan contamination does not appear to be widespread in the aquatic environment, but the chemical has been found in agricultural runoff and rivers in industrialized areas

where it is manufactured or formulated, as well as in surface water and groundwater samples collected from hazardous waste sites in the USA. Surface water samples in the USA generally contain less than 1 µg/l. The main source of exposure of the general population is food, but residues have generally been found to be well below the FAO/WHO maximum residue limits. Another important route of exposure to endosulfan for the general population is the use of tobacco products.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1999) *Pesticide residues in food—1998 evaluations* WHO (2004) *Endosulfan in drinking-water*

JMPR concluded that endosulfan is not genotoxic, and no carcinogenic effects were noted in long-term studies using mice and rats. The kidney is the target organ for toxicity. Several recent studies have shown that endosulfan, alone or in combination with other pesticides, may bind to estrogen receptors and perturb the endocrine system. A health-based value of 20 µg/l can be calculated for endosulfan on the basis of an ADI of 0–0.006 mg/kg body weight, based on results from a 2-year dietary study of toxicity in rats and supported by a 78-week study in mice, a 1-year study in dogs and a developmental toxicity study in rats. However, because endosulfan occurs at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value.

Endrin

Endrin (CAS No. 72-20-8) is a broad-spectrum foliar insecticide that acts against a wide range of agricultural pests. It is also used as a rodenticide. There is now very little use of endrin. Small amounts of endrin are present in some foods, but the total intake from food has decreased significantly.

Guideline value	0.0006 mg/l (0.6 µg/l)
Occurrence	Traces of endrin found in the drinking-water supplies of several countries
PTDI	0.2 µg/kg body weight, based on a NOAEL of 0.025 mg/kg body weight per day in a 2-year study in dogs and applying an uncertainty factor of 100 for interspecies and intraspecies variation
Limit of detection	0.002 µg/l by GC with ECD
Treatment performance	0.2 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of PTDI
• weight	60 kg adult
• consumption	2 litres/day

Additional comments	Endrin is listed under the Stockholm Convention on Persistent Organic Pollutants. Hence, monitoring may occur in addition to that required by drinking-water guidelines.
Assessment date	2003
Principal references	FAO/WHO (1995) *Pesticide residues in food—1994 evaluations* IPCS (1992) *Endrin* WHO (2004) *Endrin in drinking-water*

Toxicological data are insufficient to indicate whether endrin is a carcinogenic hazard to humans. The primary site of action of endrin is the central nervous system.

Epichlorohydrin

Epichlorohydrin is used for the manufacture of glycerol, unmodified epoxy resins and water treatment coagulant polymers and some ion exchange resins. No quantitative data are available on its occurrence in food or drinking-water. Epichlorohydrin is slowly hydrolysed in aqueous media.

Provisional guideline value	0.0004 mg/l (0.4 µg/l)
	The guideline value is considered to be provisional because of the uncertainties surrounding the toxicity of epichlorohydrin and the use of a large uncertainty factor in deriving the guideline value.
Occurrence	No quantitative data available
TDI	0.14 µg/kg body weight, on the basis of a LOAEL of 2 mg/kg body weight per day for forestomach hyperplasia observed in a 2-year gavage study in rats, adjusting for daily dosing and using an uncertainty factor of 10 000 to take into consideration interspecies and intraspecies variation (100), the use of a LOAEL instead of a NOAEL (10) and carcinogenicity (10)
Limit of detection	0.01 µg/l by GC with ECD; 0.1 and 0.5 µg/l by GC-MS; 10 µg/l by GC with FID
Treatment performance	Conventional treatment processes do not remove epichlorohydrin. Epichlorohydrin concentrations in drinking-water are controlled by limiting either the epichlorohydrin content of polyamine flocculants or the dose used, or both.
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Although epichlorohydrin is a genotoxic carcinogen, the use of the linearized multistage model for estimating cancer risk was considered inappropriate because tumours are seen only at the site of administration, where epichlorohydrin is highly irritating.
Assessment date	2003
Principal reference	WHO (2004) *Epichlorohydrin in drinking-water*

Epichlorohydrin is rapidly and extensively absorbed following oral, inhalation or dermal exposure. It binds easily to cellular components. Major toxic effects are local irritation and damage to the central nervous system. It induces squamous cell carcinomas in the nasal cavity by inhalation and forestomach tumours by the oral route. It has been shown to be genotoxic in vitro and in vivo. IARC has placed epichlorohydrin in Group 2A (probably carcinogenic to humans).

Ethylbenzene

The primary sources of ethylbenzene in the environment are the petroleum industry and the use of petroleum products. Because of its physicochemical properties, more than 96% of ethylbenzene in the environment can be expected to be present in air. Values of up to 26 μg/m^3 in air have been reported. Ethylbenzene is found in trace amounts in surface water, groundwater, drinking-water and food.

Guideline value	0.3 mg/l (300 μg/l)
Occurrence	Concentrations in drinking-water generally below 1 μg/l; levels up to 300 μg/l have been reported in groundwater contaminated by point emissions
TDI	97.1 μg/kg body weight, based on a NOAEL of 136 mg/kg body weight per day for hepatotoxicity and nephrotoxicity observed in a limited 6-month study in rats, adjusting for daily dosing and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the limited database and short duration of the study)
Limit of detection	0.002–0.005 μg/l by GC with photoionization detector; 0.03–0.06 μg/l by GC-MS
Treatment performance	0.001 mg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value exceeds the lowest reported odour threshold for ethylbenzene in drinking-water (0.002 mg/l).
Assessment date	1993
Principal reference	WHO (2003) *Ethylbenzene in drinking-water*

Ethylbenzene is readily absorbed by the oral, inhalation or dermal route. In humans, storage in fat has been reported. Ethylbenzene is almost completely converted to soluble metabolites, which are excreted rapidly in urine. The acute oral toxicity is low. No definite conclusions can be drawn from limited teratogenicity data. No data on reproduction, long-term toxicity or carcinogenicity are available. Ethylbenzene has shown no evidence of genotoxicity in in vitro or in vivo systems.

Fenitrothion

Fenitrothion (CAS No. 122-14-5) is mainly used in agriculture for controlling insects on rice, cereals, fruits, vegetables, stored grains and cotton and in forest areas. It is also

used for the control of flies, mosquitoes and cockroaches in public health programmes and indoor use. Fenitrothion is stable in water only in the absence of sunlight or microbial contamination. In soil, biodegradation is the primary route of degradation, although photolysis may also play a role. Fenitrothion residues detected in water were low (maximum 1.30 µg/l) during the spruce budworm spray programme. Following the spraying of forests to control spruce budworm, water samples did not contain detectable amounts of fenitrothion; post-spray samples contained less than 0.01 µg/l. Levels of fenitrothion residues in fruits, vegetables and cereal grains decline rapidly after treatment, with a half-life of 1–2 days. Intake of fenitrothion appears to be primarily (95%) from food.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (2001) *Pesticide residues in food—2000 evaluations* WHO (2004) *Fenitrothion in drinking-water*

On the basis of testing in an adequate range of studies in vitro and in vivo, JMPR concluded that fenitrothion is unlikely to be genotoxic. It also concluded that fenitrothion is unlikely to pose a carcinogenic risk to humans. In long-term studies of toxicity, inhibition of cholinesterase activity was the main toxicological finding in all species. A health-based value of 8 µg/l can be calculated for fenitrothion on the basis of an ADI of 0–0.005 mg/kg body weight, based on a NOAEL of 0.5 mg/kg body weight per day for inhibition of brain and erythrocyte cholinesterase activity in a 2-year study of toxicity in rats and supported by a NOAEL of 0.57 mg/kg body weight per day for inhibition of brain and erythrocyte cholinesterase activity in a 3-month study of ocular toxicity in rats and a NOAEL of 0.65 mg/kg body weight per day for reduced food consumption and body weight gain in a study of reproductive toxicity in rats, and allocating 5% of the upper limit of the ADI to drinking-water. However, because fenitrothion occurs at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value.

Fenoprop

The half-lives for degradation of chlorophenoxy herbicides, including fenoprop (CAS No. 93-72-1), also known as 2,4,5-trichlorophenoxy propionic acid or 2,4,5-TP, in the environment are in the order of several days. Chlorophenoxy herbicides are not often found in food.

Guideline value	0.009 mg/l (9 µg/l)
Occurrence	Chlorophenoxy herbicides not frequently found in drinking-water; when detected, concentrations usually no greater than a few micrograms per litre
TDI	3 µg/kg body weight, based on a NOAEL of 0.9 mg/kg body weight for adverse effects on the liver in a study in which dogs were administered fenoprop in the diet for 2 years, with an uncertainty factor of 300 (100 for interspecies and intraspecies variation and 3 for limitations of the database)

Limit of detection	0.2 µg/l by either packed or capillary column GC with ECD
Treatment performance	0.001 mg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenoxy herbicides (excluding 2,4-D and MCPA) in drinking-water*

Chlorophenoxy herbicides, as a group, have been classified in Group 2B (possibly carcinogenic to humans) by IARC. However, the available data from studies in exposed populations and experimental animals do not permit assessment of the carcinogenic potential to humans of any specific chlorophenoxy herbicide. Therefore, drinking-water guidelines for these compounds are based on a threshold approach for other toxic effects. Effects observed in long-term studies with dogs given fenoprop in the diet include mild degeneration and necrosis of hepatocytes and fibroblastic proliferation in one study and severe liver pathology in another study. In rats, increased kidney weight was observed in two long-term dietary studies.

Fluoride[1]

Fluorine is a common element that is widely distributed in Earth's crust and exists in the form of fluorides in a number of minerals, such as fluorspar, cryolite and fluorapatite. Traces of fluorides are present in many waters, with higher concentrations often associated with groundwaters. In some areas rich in fluoride-containing minerals, well water may contain up to about 10 mg of fluoride per litre, although much higher concentrations can be found. High fluoride concentrations can be found in many parts of the world, particularly in parts of India, China, Central Africa and South America, but high concentrations can be encountered locally in most parts of the world. Virtually all foodstuffs contain at least traces of fluorine. All vegetation contains some fluoride, which is absorbed from soil and water. Tea in particular can contain high fluoride concentrations, and levels in dry tea are on average 100 mg/kg.

Fluoride is widely used in dental preparations to combat dental caries, particularly in areas of high sugar intake. These can be in the form of tablets, mouthwashes, toothpaste, varnishes or gels for local application. In some countries, fluoride may also be added to table salt or drinking-water in order to provide protection against dental caries. The amounts added to drinking-water are such that final concentrations are usually between 0.5 and 1 mg/l. The fluoride in final water is always present as fluoride ions, whether from natural sources or from artificial fluoridation.

[1] As fluoride is one of the chemicals of greatest health concern in some natural waters, its chemical fact sheet has been expanded.

Total daily fluoride exposure can vary markedly from one region to another. This will depend on the concentration of fluoride in drinking-water and the amount drunk, levels in foodstuffs and the use of fluoridated dental preparations. In addition, fluoride exposure in some areas is considerably higher as a consequence of a range of practices, including the consumption of brick tea and the cooking and drying of food with high-fluoride coal.

Guideline value	1.5 mg/l (1500 µg/l)
Occurrence	In groundwater, concentrations vary with the type of rock through which the water flows but do not usually exceed 10 mg/l; highest natural level reported is 2800 mg/l
Basis of guideline value derivation	Epidemiological evidence that concentrations above this value carry an increasing risk of dental fluorosis and that progressively higher concentrations lead to increasing risks of skeletal fluorosis. The value is higher than that recommended for artificial fluoridation of water supplies, which is usually 0.5–1.0 mg/l.
Limit of detection	0.01 mg/l by ion chromatography; 0.1 mg/l by ion-selective electrodes or the sulfo phenyl azo dihydroxy naphthalene disulfonic acid colorimetric method
Treatment performance	1 mg/l should be achievable using activated alumina (not a "conventional" treatment process, but relatively simple to install filters)
Additional comments	A management guidance document on fluoride is available.
	In setting national standards for fluoride or in evaluating the possible health consequences of exposure to fluoride, it is essential to consider the intake of water by the population of interest and the intake of fluoride from other sources (e.g. from food, air and dental preparations). Where the intakes from other sources are likely to approach, or be greater than, 6 mg/day, it would be appropriate to consider setting standards at concentrations lower than the guideline value.
	In areas with high natural fluoride levels in drinking-water, the guideline value may be difficult to achieve, in some circumstances, with the treatment technology available.
Assessment date	2003
Principal references	Fawell et al. (2006) *Fluoride in drinking-water* IPCS (2002) *Fluorides* USNRC (2006) *Fluoride in drinking water* WHO (2004) *Fluoride in drinking-water*

After oral uptake, water-soluble fluorides are rapidly and almost completely absorbed from the gastrointestinal tract, although this may be reduced by complex formation with aluminium, phosphorus, magnesium or calcium. There is no difference in absorption between natural or added fluoride in drinking-water. Fluoride in inhaled particles—from high-fluoride coal, for example—is also absorbed, depending on the particle size and solubility of the fluoride compounds present. Absorbed fluoride is rapidly distributed throughout the body, where it is incorporated into teeth and bones, with virtually no storage in soft tissues. Fluoride in teeth and bone can be

mobilized after external exposure has ceased or been reduced. Fluoride is excreted via urine, faeces and sweat.

Fluoride may be an essential element for humans; however, essentiality has not been demonstrated unequivocally. Meanwhile, there is evidence of fluoride being a beneficial element with regard to the prevention of dental caries.

To produce signs of acute fluoride intoxication, minimum oral doses of about 1 mg of fluoride per kilogram of body weight were required. Many epidemiological studies of possible adverse effects of the long-term ingestion of fluoride via drinking-water have been carried out. These studies clearly establish that high fluoride intakes primarily produce effects on skeletal tissues (bones and teeth). Low concentrations provide protection against dental caries, both in children and in adults. The protective effects of fluoride increase with concentration up to about 2 mg of fluoride per litre of drinking-water; the minimum concentration of fluoride in drinking-water required to produce it is approximately 0.5 mg/l. However, fluoride can also have an adverse effect on tooth enamel and may give rise to mild dental fluorosis (prevalence: 12–33%) at drinking-water concentrations between 0.9 and 1.2 mg/l, depending on drinking-water intake and exposure to fluoride from other sources. Mild dental fluorosis may not be detectable except by specialist examination. The risk of dental fluorosis will depend on the total intake of fluoride from all sources and not just the concentration in drinking-water.

Elevated fluoride intakes can have more serious effects on skeletal tissues. Skeletal fluorosis (with adverse changes in bone structure) may be observed when drinking-water contains 3–6 mg of fluoride per litre, particularly with high water consumption. Crippling skeletal fluorosis usually develops only where drinking-water contains over 10 mg of fluoride per litre. IPCS concluded that there is clear evidence from India and China that skeletal fluorosis and an increased risk of bone fractures occur at a total intake of 14 mg of fluoride per day. This conclusion was supported by a review by the United States National Research Council in 2006. The relationship between exposure and response for adverse effects in bone is frequently difficult to ascertain because of inadequacies in most of the epidemiological studies. IPCS concluded from estimates based on studies from China and India that for a total intake of 14 mg/day, there is a clear excess risk of skeletal adverse effects; and there is suggestive evidence of an increased risk of effects on the skeleton at total fluoride intakes above about 6 mg/day.

Several epidemiological studies are available on the possible association between fluoride in drinking-water and cancer. IPCS evaluated these studies and concluded that, overall, the evidence of carcinogenicity in laboratory animals is inconclusive and that the available evidence does not support the hypothesis that fluoride causes cancer in humans; however, the data on bone cancer are limited. The results of several epidemiological studies on the possible adverse effects of fluoride in drinking-water on pregnancy outcome indicate that there is no relationship between the rates of Down syndrome or congenital malformation and the consumption of fluoridated drinking-water.

There is no evidence to suggest that the guideline value of 1.5 mg/l set in 1984 and reaffirmed in 1993 needs to be revised. Concentrations above this value carry an increasing risk of dental fluorosis, and much higher concentrations lead to skeletal

fluorosis. The value is higher than that recommended for artificial fluoridation of water supplies, which is usually 0.5–1.0 mg/l.

In setting national standards or local guidelines for fluoride or in evaluating the possible health consequences of exposure to fluoride, it is essential to consider the average daily intake of water by the population of interest and the intake of fluoride from other sources (e.g. from food and air). Where the intakes are likely to approach, or be greater than, 6 mg/day, it would be appropriate to consider setting a standard or local guideline at a concentration lower than 1.5 mg/l.

Practical considerations

Fluoride is usually determined by means of an ion-selective electrode, which makes it possible to measure the total amount of free and complex-bound fluoride dissolved in water. The method can detect fluoride concentrations in water well below the guideline value. However, appropriate sample preparation is a critical step in the accurate quantification of fluoride, especially where only the free fluoride ion is measured.

A range of treatment technologies are available for both large and small supplies. Different methods for small supplies are favoured in different countries; these are based on bone charcoal, contact precipitation, activated alumina and clay. However, in some areas with high natural fluoride levels in drinking-water, the guideline value may be difficult to achieve in some circumstances with the treatment technology available. Large supplies tend to rely on activated alumina or advanced treatment processes such as reverse osmosis.

Formaldehyde

Formaldehyde occurs in industrial effluents and is emitted into air from plastic materials and resin glues. Formaldehyde in drinking-water results primarily from the oxidation of natural organic matter during ozonation and chlorination. Concentrations of up to 30 µg/l have been found in ozonated drinking-water. Formaldehyde can also be found in drinking-water as a result of release from polyacetal plastic fittings. Formaldehyde's physicochemical properties suggest that it is unlikely to volatilize from water, so exposure by inhalation during showering is expected to be low.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2004
Principal references	IPCS (2002) *Formaldehyde* WHO (2005) *Formaldehyde in drinking-water*

Rats and mice exposed to formaldehyde by inhalation exhibited an increased incidence of carcinomas of the nasal cavity at doses that caused irritation of the nasal epithelium. Ingestion of formaldehyde in drinking-water for 2 years caused stomach irritation in rats. Papillomas of the stomach associated with severe tissue irritation were observed in one study. IARC has classified formaldehyde in Group 1 (carcinogenic to

humans). The weight of evidence indicates that formaldehyde is not carcinogenic by the oral route.

Owing to formaldehyde's high reactivity, effects in the tissue of first contact following ingestion are more likely to be related to the concentration of the formaldehyde consumed than to its total intake. A tolerable concentration of 2.6 mg/l for ingested formaldehyde has been established based on a NOEL of 260 mg/l for histopathological effects in the oral and gastric mucosa of rats administered formaldehyde in their drinking-water for 2 years, using an uncertainty factor of 100 (for interspecies and intraspecies variation). In view of the significant difference between the expected concentrations of formaldehyde in drinking-water and the tolerable concentration, it is not considered necessary to set a formal guideline value for formaldehyde.

Glyphosate and AMPA

Glyphosate (CAS No. 1071-83-6) is a broad-spectrum herbicide used in both agriculture and forestry and for aquatic weed control. Microbial biodegradation of glyphosate occurs in soil, aquatic sediment and water, the major metabolite being aminomethylphosphonic acid (AMPA) (CAS No. 1066-51-9). Glyphosate is chemically stable in water and is not subject to photochemical degradation. The low mobility of glyphosate in soil indicates minimal potential for the contamination of groundwater. Glyphosate can, however, enter surface and subsurface waters after direct use near aquatic environments or by runoff or leaching from terrestrial applications.

Reason for not establishing guideline values	Occur in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1998) *Pesticide residues in food—1997 evaluations* IPCS (1994) *Glyphosate* WHO (2005) *Glyphosate and AMPA in drinking-water*

Glyphosate and AMPA have similar toxicological profiles, and both are considered to exhibit low toxicity. A health-based value of 0.9 mg/l can be derived based on the group ADI for AMPA alone or in combination with glyphosate of 0–0.3 mg/kg body weight, based upon a NOAEL of 32 mg/kg body weight per day, the highest dose tested, identified in a 26-month study of toxicity in rats fed technical-grade glyphosate and using an uncertainty factor of 100 (for interspecies and intraspecies variation).

Because of their low toxicity, the health-based value derived for AMPA alone or in combination with glyphosate is orders of magnitude higher than concentrations of glyphosate or AMPA normally found in drinking-water. Under usual conditions, therefore, the presence of glyphosate and AMPA in drinking-water does not represent a hazard to human health. For this reason, the establishment of a formal guideline value for glyphosate and AMPA is not deemed necessary.

Halogenated acetonitriles (dichloroacetonitrile, dibromoacetonitrile, bromochloroacetonitrile, trichloroacetonitrile)

Halogenated acetonitriles are produced during water chlorination or chloramination from naturally occurring substances, including algae, fulvic acid and proteinaceous material. In general, increasing temperature or decreasing pH is associated with increasing concentrations of halogenated acetonitriles. Ambient bromide levels appear to influence, to some degree, the speciation of halogenated acetonitrile compounds. Dichloroacetonitrile is by far the most predominant halogenated acetonitrile species detected in drinking-water.

Provisional guideline value	*Dichloroacetonitrile:* 0.02 mg/l (20 µg/l)
	The guideline value for dichloroacetonitrile is provisional owing to limitations of the toxicological database.
Guideline value	*Dibromoacetonitrile:* 0.07 mg/l (70 µg/l)
Occurrence	Concentrations of individual halogenated acetonitriles can exceed 0.01 mg/l, although levels of 0.002 mg/l or less are more usual
TDIs	*Dichloroacetonitrile:* 2.7 µg/kg body weight based on a LOAEL of 8 mg/kg body weight per day for increased relative liver weight in male and female rats in a 90-day study, using an uncertainty factor of 3000 (taking into consideration intraspecies and interspecies variation, the short duration of the study, the use of a minimal LOAEL and database deficiencies)
	Dibromoacetonitrile: 11 µg/kg body weight, based on a NOAEL of 11.3 mg/kg body weight per day for decreased body weight in male rats in a 90-day drinking-water study and an uncertainty factor of 1000 (accounting for interspecies and intraspecies variation, subchronic to chronic extrapolation and database insufficiencies)
Limit of detection	0.03 µg/l by GC with ECD
Treatment performance	Reduction of organic precursors will reduce the formation of halogenated acetonitriles.
Guideline value derivation	
• allocation to water	20% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	2003
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2004) *Halogenated acetonitriles in drinking-water*

Reason for not establishing guideline values	Available data inadequate to permit derivation of health-based guideline values for *bromochloroacetonitrile* and *trichloroacetonitrile*
Assessment date	2003
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2004) *Halogenated acetonitriles in drinking-water*

IARC has concluded that dichloroacetonitrile, dibromoacetonitrile, bromochloroacetonitrile and trichloroacetonitrile are not classifiable as to their carcinogenicity in humans. Dichloroacetonitrile and bromochloroacetonitrile have been shown to be mutagenic in bacterial assays, whereas results for dibromoacetonitrile and trichloroacetonitrile were negative. All four of these halogenated acetonitriles induced sister chromatid exchange and DNA strand breaks and adducts in mammalian cells in vitro but were negative in the mouse micronucleus test.

The majority of reproductive and developmental toxicity studies of the halogenated acetonitriles were conducted using tricaprylin as a vehicle for gavage administration of the compound under study. As tricaprylin was subsequently demonstrated to be a developmental toxicant that potentiated the effects of trichloroacetonitrile and, presumably, other halogenated acetonitriles, results reported for developmental studies using tricaprylin as the gavage vehicle are likely to overestimate the developmental toxicity of these halogenated acetonitriles.

Dichloroacetonitrile

Dichloroacetonitrile induced decreases in body weight and increases in relative liver weight in short-term studies. Although developmental toxicity has been demonstrated, the studies used tricaprylin as the vehicle for gavage administration.

Dibromoacetonitrile

Dibromoacetonitrile is currently under analysis for chronic toxicity in mice and rats. None of the available reproductive or developmental studies were adequate to use in the quantitative dose–response assessment. The data gap may be particularly relevant because cyanide, a metabolite of dibromoacetonitrile, induces male reproductive system toxicity and because of uncertainty regarding the significance of the testes effects observed in a 14-day NTP rat study.

Bromochloroacetonitrile

Available data are insufficient to serve as a basis for derivation of a guideline value for bromochloroacetonitrile.

Trichloroacetonitrile

Available data are also insufficient to serve as a basis for derivation of a guideline value for trichloroacetonitrile. The previous provisional guideline value of 1 μg/l was based on a developmental toxicity study in which trichloroacetonitrile was administered by gavage in tricaprylin vehicle, and a re-evaluation judged this study to be unreliable in light of the finding in a more recent study that tricaprylin potentiates the developmental and teratogenic effects of halogenated acetonitriles and alters the spectrum of malformations in the fetuses of treated dams.

Hardness

Hardness in water is caused by a variety of dissolved polyvalent metallic ions, predominantly calcium and magnesium cations. It is usually expressed as milligrams of calcium carbonate per litre. Hardness is the traditional measure of the capacity of

water to react with soap, hard water requiring considerably more soap to produce a lather.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993, revised in 2011
Principal reference	WHO (2011) *Hardness in drinking-water*

Natural and treated waters have a wide range of mineral content, from very low levels in rainwater and naturally soft and softened water to higher levels in naturally hard waters. Bottled and packaged waters can be naturally mineralized or naturally soft or demineralized. Thus, the mineral consumption from drinking-water and cooking water will vary widely, depending upon location, treatment and water source.

The degree of hardness of drinking-water is important for aesthetic acceptability by consumers (see chapter 10) and for economic and operational considerations. Many hard waters are softened for those reasons using several applicable technologies. The choice of the most appropriate conditioning technology will depend on local circumstances (e.g. water quality issues, piping materials, corrosion) and will be applied either centrally or in individual homes as a consumer preference.

Consumers should be informed of the mineral composition of their water, whether or not it is modified. The contribution of drinking-water minerals to mineral nutrition should be considered where changes in supply are proposed or where less traditional sources, such as recycled water, seawater or brackish water, are processed and exploited for drinking-water. The treatments used remove most minerals, and stabilization of water is always necessary prior to distribution.

Drinking-water can be a contributor to calcium and magnesium intake and could be important for those who are marginal for calcium and magnesium. Where drinking-water supplies are supplemented with or replaced by demineralized water that requires conditioning, consideration should be given to adding calcium and magnesium salts to achieve concentrations similar to those that the population received from the original supply. Modification of calcium and magnesium concentrations in drinking-water for health reasons should comply with the technical requirements to provide water suitable for distribution.

Although there is evidence from epidemiological studies for a protective effect of magnesium or hardness on cardiovascular mortality, the evidence is being debated and does not prove causality. Further studies are being conducted. There are insufficient data to suggest either minimum or maximum concentrations of minerals at this time, as adequate intake will depend on a range of other factors. Therefore, no guideline values are proposed.

Heptachlor and heptachlor epoxide

Heptachlor (CAS No. 76-44-8) is a broad-spectrum insecticide, the use of which has been banned or restricted in many countries. At present, the major use of heptachlor

is for termite control by subsurface injection into soil. Heptachlor is quite persistent in soil, where it is mainly transformed to its epoxide. Heptachlor epoxide (CAS No. 1024-57-3) is very resistant to further degradation. Heptachlor and heptachlor epoxide bind to soil particles and migrate very slowly. Heptachlor and heptachlor epoxide have been found in drinking-water at nanogram per litre levels. Diet is considered to represent the major source of exposure to heptachlor, although intake is decreasing significantly, as its use has substantially declined.

Reason for not establishing a guideline value	Occur in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1992) *Pesticide residues in food—1991 evaluations* FAO/WHO (1995) *Pesticide residues in food—1994 evaluations* WHO (2003) *Heptachlor and heptachlor epoxide in drinking-water*

Prolonged exposure to heptachlor has been associated with damage to the liver and central nervous system toxicity. In 1991, IARC reviewed the data on heptachlor and concluded that the evidence for carcinogenicity was sufficient in animals and inadequate in humans, classifying it in Group 2B (possibly carcinogenic to humans). A health-based value of 0.03 μg/l can be calculated for heptachlor and heptachlor epoxide on the basis of a PTDI of 0.1 μg/kg body weight, based on a NOAEL for heptachlor of 0.025 mg/kg body weight per day from two studies in the dog, taking into consideration inadequacies of the database and allocating 1% of the PTDI to drinking-water. However, because heptachlor and heptachlor epoxide occur at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value. It should also be noted that concentrations below 0.1 μg/l are generally not achievable using conventional treatment technology.

Hexachlorobenzene

The major agricultural application for hexachlorobenzene (CAS No. 118-74-1), or HCB, was as a seed dressing for crops to prevent the growth of fungi, but its use is now uncommon. At present, it appears mainly as a by-product of several chemical processes or an impurity in some pesticides. HCB is distributed throughout the environment because it is mobile and resistant to degradation. It bioaccumulates in organisms because of its physicochemical properties and its slow elimination. HCB is commonly detected at low levels in food, and it is generally present at low concentrations in ambient air. It has been detected only infrequently, and at very low concentrations (below 0.1 μg/l), in drinking-water supplies.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	IPCS (1997) *Hexachlorobenzene* WHO (2004) *Hexachlorobenzene in drinking-water*

IARC has evaluated the evidence for the carcinogenicity of HCB in animals and humans and assigned it to Group 2B (possibly carcinogenic to humans). HCB has been shown to induce tumours in three animal species and at a variety of sites. A health-based value of 1 µg/l can be derived for HCB by applying the linearized multistage low-dose extrapolation model to liver tumours observed in female rats in a 2-year dietary study. Using an alternative (tumorigenic $dose_{05}$, or TD_{05}) approach, a TDI of 0.16 µg/kg body weight can be calculated, which corresponds to a health-based value of approximately 0.05 µg/l, if one assumes a 1% allocation of the TDI to drinking-water. It should be noted that concentrations in food have been falling steadily, and this allocation factor may be considered very conservative.

Because the health-based values derived from both of these approaches are considerably higher than the concentrations at which HCB is detected in drinking-water (i.e. sub-nanograms per litre), when it is detected, it is not considered necessary to establish a formal guideline value for HCB in drinking-water. HCB is listed under the Stockholm Convention on Persistent Organic Pollutants.

Hexachlorobutadiene

Hexachlorobutadiene, or HCBD, is used as a solvent in chlorine gas production, a pesticide, an intermediate in the manufacture of rubber compounds and a lubricant. Concentrations of up to 6 µg/l have been reported in the effluents from chemical manufacturing plants. HCBD is also found in air and food.

Guideline value	0.0006 mg/l (0.6 µg/l)
Occurrence	Has been detected in surface water at concentrations of a few micrograms per litre and in drinking-water at concentrations below 0.5 µg/l
TDI	0.2 µg/kg body weight, based on a NOAEL of 0.2 mg/kg body weight per day for renal toxicity in a 2-year feeding study in rats, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for limited evidence of carcinogenicity and genotoxicity of some metabolites)
Limit of detection	0.01 µg/l by GC-MS; 0.18 µg/l by GC with ECD
Treatment performance	0.001 mg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The practical quantification limit for HCBD is of the order of 2 µg/l, but concentrations in drinking-water can be controlled by specifying the HCBD content of products coming into contact with it.
Assessment date	2003
Principal references	IPCS (1994) *Hexachlorobutadiene* WHO (2003) *Hexachlorobutadiene in drinking-water*

HCBD is easily absorbed and metabolized via conjugation with glutathione. This conjugate can be further metabolized to a nephrotoxic derivative. Kidney tumours were observed in a long-term oral study in rats. HCBD has not been shown to be carcinogenic by other routes of exposure. IARC has placed HCBD in Group 3 (not classifiable as to its carcinogenicity to humans). Positive and negative results for HCBD have been obtained in bacterial assays for point mutation; however, several metabolites have given positive results.

Hydrogen sulfide

Hydrogen sulfide is a gas with an offensive "rotten eggs" odour that is detectable at very low concentrations, below 0.8 μg/m^3 in air. It is formed when sulfides are hydrolysed in water. However, the level of hydrogen sulfide found in drinking-water will usually be low, because sulfides are readily oxidized in well-aerated or chlorinated water.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) *Hydrogen sulfide in drinking-water*

The acute toxicity to humans of hydrogen sulfide following inhalation of the gas is high; eye irritation can be observed at concentrations of 15–30 mg/m^3. Although oral toxicity data are lacking, it is unlikely that a person could consume a harmful dose of hydrogen sulfide from drinking-water. Consequently, no guideline value is proposed. However, hydrogen sulfide can be easily detected in drinking-water by taste or odour (see chapter 10).

Inorganic tin

Tin is used principally in the production of coatings used in the food industry. Food, particularly canned food, therefore represents the major route of human exposure to tin. For the general population, drinking-water is not a significant source of tin, and levels in drinking-water greater than 1–2 μg/l are exceptional. However, there is increasing use of tin in solder, which may be used in domestic plumbing, and tin has been proposed for use as a corrosion inhibitor.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal reference	WHO (2004) *Inorganic tin in drinking-water*

Tin and inorganic tin compounds are poorly absorbed from the gastrointestinal tract, do not accumulate in tissues and are rapidly excreted, primarily in faeces.

No increased incidence of tumours was observed in long-term carcinogenicity studies conducted in mice and rats fed tin(II) chloride. Tin has not been shown to be teratogenic or fetotoxic in mice, rats or hamsters. In rats, the NOAEL in a long-term feeding study was 20 mg/kg body weight per day.

The main adverse effect on humans of excessive levels of tin in canned beverages (above 150 mg/kg) or other canned foods (above 250 mg/kg) has been acute gastric irritation. There is no evidence of adverse effects in humans associated with chronic exposure to tin.

In 1989, JECFA established a PTWI of 14 mg/kg body weight from a TDI of 2 mg/kg body weight on the basis that the problem with tin is associated with acute gastrointestinal irritancy, the threshold for which is about 200 mg/kg in food. This was reaffirmed by JECFA in 2000. In view of its low toxicity, the presence of tin in drinking-water does not, therefore, represent a hazard to human health. For this reason, the establishment of a guideline value for inorganic tin is not deemed necessary.

Iodine

Iodine occurs naturally in water in the form of iodide. Traces of iodine are produced by oxidation of iodide during water treatment. Iodine is occasionally used for water disinfection in the field or in emergency situations.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value, and lifetime exposure to iodine through water disinfection is unlikely
Assessment date	1993
Principal reference	WHO (2003) *Iodine in drinking-water*

Iodine is an essential element for the synthesis of thyroid hormones. Estimates of the dietary requirement for adult humans range from 80 to 150 μg/day; in many parts of the world, there are dietary deficiencies in iodine, resulting in severe adverse effects on neurological development. In 1988, JECFA set a provisional maximum tolerable daily intake (PMTDI) for iodine of 1 mg/day (17 μg/kg body weight per day) from all sources, based primarily on data on the effects of iodide. However, recent data from studies in rats indicate that the effects of iodine in drinking-water on thyroid hormone concentrations in the blood differ from those of iodide.

Available data therefore suggest that derivation of a guideline value for iodine on the basis of information on the effects of iodide is inappropriate, and there are few relevant data on the effects of iodine. Because iodine is not recommended for long-term disinfection, lifetime exposure to iodine concentrations such as might occur from water disinfection is unlikely. For these reasons, a guideline value for iodine has not been established at this time. There is, however, a need for guidance concerning the use of iodine as a disinfectant in emergency situations and for travellers.

Iron

Iron is one of the most abundant metals in Earth's crust. It is found in natural fresh waters at levels ranging from 0.5 to 50 mg/l. Iron may also be present in drinking-water

as a result of the use of iron coagulants or the corrosion of steel and cast iron pipes during water distribution.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) Iron in drinking-water

Iron is an essential element in human nutrition, particularly in the iron(II) oxidation state. Estimates of the minimum daily requirement for iron depend on age, sex, physiological status and iron bioavailability and range from about 10 to 50 mg/day.

As a precaution against storage in the body of excessive iron, in 1983, JECFA established a PMTDI of 0.8 mg/kg body weight, which applies to iron from all sources except for iron oxides used as colouring agents and iron supplements taken during pregnancy and lactation or for specific clinical requirements. An allocation of 10% of this PMTDI to drinking-water gives a value of about 2 mg/l, which does not present a hazard to health. The taste and appearance of drinking-water will usually be affected below this level (see chapter 10).

No guideline value for iron in drinking-water is proposed.

Isoproturon

Isoproturon (CAS No. 34123-59-6) is a selective, systemic herbicide used in the control of annual grasses and broad-leaved weeds in cereals. It can be photodegraded, hydrolysed and biodegraded and persists for periods ranging from days to weeks. It is mobile in soil. There is evidence that exposure to this compound through food is low.

Guideline value	0.009 mg/l (9 µg/l)
Occurrence	Has been detected in surface water and groundwater, usually at concentrations below 0.1 µg/l; levels above 0.1 µg/l have occasionally been detected in drinking-water
TDI	3 µg/kg body weight based on a NOAEL of approximately 3 mg/kg body weight in a 90-day study in dogs and a 2-year feeding study in rats, with an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for evidence of non-genotoxic carcinogenicity in rats)
Limit of detection	10–100 ng/l by reversed-phase HPLC followed by UV or electrochemical detection
Treatment performance	0.1 µg/l should be achievable using ozonation
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day

Assessment date	1993
Principal reference	WHO (2003) *Isoproturon in drinking-water*

Isoproturon is of low acute toxicity and low to moderate toxicity following short-term and long-term exposures. It does not possess significant genotoxic activity, but it causes marked enzyme induction and liver enlargement. Isoproturon caused an increase in hepatocellular tumours in male and female rats, but this was apparent only at doses that also caused liver toxicity. Isoproturon appears to be a tumour promoter rather than a complete carcinogen.

Lead

Lead is used principally in the production of lead-acid batteries, solder and alloys. The organolead compounds tetraethyl and tetramethyl lead have also been used extensively as antiknock and lubricating agents in petrol, although their use for these purposes in many countries has largely been phased out. Owing to the decreasing use of lead-containing additives in petrol and of lead-containing solder in the food processing industry, concentrations in air and food are declining; in most countries, lead levels in blood are also declining unless there are specific sources, such as dust from leaded paint or occupational/household recycling of lead-containing materials. Lead is rarely present in tap water as a result of its dissolution from natural sources; rather, its presence is primarily from corrosive water effects on household plumbing systems containing lead in pipes, solder or fittings (including alloy fittings with high lead content), or from the service connections to homes. The amount of lead dissolved from the plumbing system depends on several factors, including pH, temperature, alkalinity, scale in pipe and standing time of the water, with soft, acidic water being the most plumbosolvent. Free chlorine residuals in drinking-water tend to form more insoluble lead-containing deposits, whereas chloramine residuals may form more soluble sediments in lead pipe. Accordingly, significant changes in the water quality of a supply, resulting from, for example, changes in treatment or changes of source, can result in changes in plumbosolvency or solubilization of lead deposits, or both.

Provisional guideline value	0.01 mg/l (10 µg/l)
	The guideline value is designated as provisional on the basis of treatment performance and analytical achievability. As this is no longer a health-based guideline value, concentrations should be maintained as low as reasonably practical. New sources of lead, such as service connections and lead solder, should not be introduced into any system, and low lead alloy fittings should be used in repairs and new installations.
Occurrence	Concentrations in drinking-water are generally below 5 µg/l, although much higher concentrations (above 100 µg/l) have been measured where lead service connections or fittings are present. The primary source of lead is from service connections and plumbing in buildings; therefore, lead should be measured at the tap. Lead concentrations can also vary according to the period in which the water has been in contact with the lead-containing materials.

Basis of guideline derivation	The guideline value was previously based on a JECFA PTWI, which has since been withdrawn, and no new PTWI has been established, on the basis that there does not appear to be a threshold for the key effects of lead. However, substantial efforts have been made to reduce lead exposure from a range of sources, including drinking-water. The guideline value is maintained at 10 µg/l but is designated as provisional on the basis of treatment performance and analytical achievabiilty because it is extremely difficult to achieve a lower concentration than this by central conditioning, such as phosphate dosing.
Limit of detection	1 µg/l by AAS; practical quantification limit in the region of 1–10 µg/l
Treatment performance	Not a raw water contaminant; treatment not applicable
Additional comments	Infants and children are considered to be the most sensitive subgroups of the population
	Lead is exceptional compared with other chemical hazards, in that most lead in drinking-water arises from lead service connections and plumbing in buildings, and the remedy consists principally of removing service connections, plumbing and fittings containing lead. This requires much time and money, and it is recognized that not all water will meet the guideline value immediately. Meanwhile, all other practical measures to reduce total exposure to lead, including corrosion control, should be implemented. In new installations or repairs, lead-free service connections and solder and low lead alloy fittings should be used to prevent the introduction of contamination.
	The sampling protocol adopted – e.g. first draw, random daytime sampling or flushed – will depend on the objective of taking the samples. Where there is a need to verify that lead solder and/or high-lead fittings have not been installed in new or repaired systems, the approach used is to take a worst-case sample that reflects an extended period of stagnation, to maximize the chance of identifying the presence of lead.
Assessment date	2011, revised 2016
Principal references	FAO/WHO (2011) *Evaluation of certain food additives and contaminants* WHO (2016) *Lead in drinking-water*

Exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Impaired neurodevelopment in children is generally associated with lower blood lead concentrations than the other effects, the weight of evidence is greater for neurodevelopmental effects than for other health effects and the results across studies are more consistent than those for other effects. For adults, the adverse effect associated with lowest blood lead concentrations for which the weight of evidence is greatest and most consistent is a lead-associated increase in systolic blood pressure. JECFA concluded that the effects on neurodevelopment and systolic blood pressure provided the appropriate bases for dose–response analyses.

Based on the dose–response analyses, JECFA estimated that the previously established PTWI of 25 µg/kg body weight is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of

approximately 3 mmHg (0.4 kPa) in adults. These changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. JECFA therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn.

Because the dose–response analyses do not provide any indication of a threshold for the key effects of lead, JECFA concluded that it was not possible to establish a new PTWI that would be considered to be health protective. JECFA reaffirmed that because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead.

It needs to be recognized that lead is exceptional compared with other chemical hazards, in that most lead in drinking-water arises from lead service connections and plumbing in buildings, and the remedy consists principally of removing plumbing and fittings containing lead, which requires much time and money. It is therefore emphasized that all other practical measures to reduce total exposure to lead, including corrosion control, should be implemented. New sources of lead, such as lead service connections and solder, should not be introduced into any system, and low lead alloy fittings should be used in repairs and new installations.

In terms of monitoring, if the monitoring objective is to identify the presence of lead in the internal plumbing of a building, then the sample should be from the tap. The sampling protocols also depend on the objective of taking the samples. First-draw samples typically will have the highest lead concentrations, but this may not be reflected in normal use if the same system provides water for toilet flushing, etc. Flushed samples, in contrast, give consistent values, but reflect the minimum contact time between the water and the lead-containing material. The random daytime samples, although most truly reflecting the water that the consumer drinks, give the most variable levels; hence, it is necessary to collect more samples to determine the mean level of exposure. Where there is a need to verify that lead service connections, lead solder and/or high-lead fittings have not been installed in new or repaired systems, the approach used is to take a worst-case sample that reflects an extended period of stagnation and to maximize the chance of identifying the presence of lead. Extended stagnation with sequential volume can also be used to identify sources or locations of lead as an investigative activity.

Lindane

Lindane (γ-hexachlorocyclohexane; γ-HCH) (CAS No. 58-89-9) is used as an insecticide on fruit and vegetable crops, for seed treatment and in forestry. It is also used as a therapeutic pesticide in humans and animals. Several countries have restricted the use of lindane. Lindane can be degraded in soil and rarely leaches to groundwater. In surface waters, it can be removed by evaporation. Exposure of humans occurs mainly via food, but this is decreasing. There may also be exposure from its use in public health and as a wood preservative.

Guideline value	0.002 mg/l (2 µg/l)
Occurrence	Has been detected in both surface water and groundwater, usually at concentrations below 0.1 µg/l, although concentrations as high as 12 µg/l have been measured in wastewater-contaminated rivers
ADI	0–0.005 mg/kg body weight on the basis of a NOAEL of 0.47 mg/kg body weight per day in a 2-year toxicity/carcinogenicity study in rats in which an increased incidence of periacinar hepatocellular hypertrophy, increased liver and spleen weights and increased mortality occurred at higher doses, using an uncertainty factor of 100 (for interspecies and intraspecies variation)
Limit of detection	0.01 µg/l using GC
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	1% of upper limit of ADI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	It should be noted that concentrations in food have been falling steadily, and the 1% allocation factor may be considered very conservative.
Assessment date	2003
Principal references	FAO/WHO (2003) *Pesticide residues in food—2002 evaluations* WHO (2003) *Lindane in drinking-water*

Lindane was toxic to the kidney and liver after administration orally, dermally or by inhalation in short-term and long-term studies of toxicity and reproductive toxicity in rats. The renal toxicity of lindane was specific to male rats and was considered not to be relevant to human risk assessment, as it is a consequence of accumulation of α_{2u}-globulin, a protein that is not found in humans. Hepatocellular hypertrophy was observed in a number of studies in mice, rats and rabbits and was reversed only partially after recovery periods of up to 6 weeks. Lindane did not induce a carcinogenic response in rats or dogs, but it caused an increased incidence of adenomas and carcinomas of the liver in agouti and pseudoagouti mice, but not in black or any other strains of mice, in a study of the role of genetic background in the latency and incidence of tumorigenesis. JMPR concluded that there was no evidence of genotoxicity. In the absence of genotoxicity and on the basis of the weight of the evidence

from the studies of carcinogenicity, JMPR concluded that lindane is not likely to pose a carcinogenic risk to humans. Further, in an epidemiological study designed to assess the potential association between breast cancer and exposure to chlorinated pesticides, no correlation with lindane was found.

Malathion

Malathion (CAS No. 121-75-5) is commonly used to control mosquitoes and a variety of insects that attack fruits, vegetables, landscaping plants and shrubs. It can also be found in other pesticide products used indoors, on pets to control ticks and insects and to control human head and body lice. Under least favourable conditions (i.e. low pH and little organic content), malathion may persist in water with a half-life of months or even years. However, under most conditions, the half-life appears to be roughly 7–14 days. Malathion has been detected in surface water and drinking-water at concentrations below 2 µg/l.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1998) *Pesticide residues in food—1997 evaluations* WHO (2003) *Malathion in drinking-water*

Malathion inhibits cholinesterase activity in mice, rats and human volunteers. It increased the incidence of liver adenomas in mice when administered in the diet. Most of the evidence indicates that malathion is not genotoxic, although some studies indicate that it can produce chromosomal aberrations and sister chromatid exchange in vitro. JMPR has concluded that malathion is not genotoxic.

A health-based value of 0.9 mg/l can be calculated for malathion based on an allocation of 10% of the upper limit of the JMPR ADI—based on a NOAEL of 29 mg/kg body weight per day in a 2-year study of toxicity and carcinogenicity in rats, using an uncertainty factor of 100 for interspecies and intraspecies variation and supported by a NOAEL of 25 mg/kg body weight per day in a developmental toxicity study in rabbits—to drinking-water. However, intake of malathion from all sources is generally low and well below the upper limit of the ADI. As the chemical occurs in drinking-water at concentrations much lower than the health-based value, the presence of malathion in drinking-water under usual conditions is unlikely to represent a hazard to human health. For this reason, it is considered unnecessary to derive a formal guideline value for malathion in drinking-water.

Manganese

Manganese is one of the most abundant metals in Earth's crust, usually occurring with iron. It is used principally in the manufacture of iron and steel alloys, as an oxidant for cleaning, bleaching and disinfection (as potassium permanganate) and as an ingredient in various products. More recently, it has been used in an organic compound, methylcyclopentadienyl manganese tricarbonyl, or MMT, as an octane

enhancer in petrol in North America. Manganese greensands are used in some locations for potable water treatment. Manganese is naturally occurring in many surface water and groundwater sources, particularly in anaerobic or low oxidation conditions, and this is the most important source for drinking-water. Manganese occurs naturally in many food sources, and the greatest exposure to manganese is usually from food.

Reason for not establishing a guideline value	Not of health concern at levels normally causing acceptability problems in drinking-water. However, there are circumstances where manganese can remain in solution at higher concentrations in some acidic or anaerobic waters, particularly groundwater.
Assessment date	2003, revised 2011
Principal references	IPCS (1999) *Manganese and its compounds* WHO (2011) *Manganese in drinking-water*

Manganese is an essential element for humans and other animals. Several epidemiological studies have suggested that soluble manganese is associated with adverse effects on learning in children. These findings remain to be confirmed and the association has yet to be demonstrated as causal. Experimental animal data, especially rodent data, are not appropriate for human risk assessment because the physiological requirements for manganese vary among different species. Further, rodents are of limited value in assessing neurobehavioural effects, because the neurological effects (e.g. tremor, gait disorders) seen in primates are often preceded or accompanied by psychological symptoms (e.g. irritability, emotional lability), that are not apparent in rodents. The only primate study is of limited use in a quantitative risk assessment because only one dose group was studied in a small number of animals and the manganese content in the basal diet was not provided.

A health-based value of 0.4 mg/l can be derived for manganese based on the upper range value of manganese intake of 11 mg/day, identified using dietary surveys, at which there are no observed adverse effects, using an uncertainty factor of 3 to take into consideration the possible increased bioavailability of manganese from water, allocating 20% of the TDI to drinking-water and assuming the consumption of 2 litres of water per day by a 60 kg adult. As this health-based value is well above concentrations of manganese normally causing acceptability problems in drinking-water (see chapter 10), it is not considered necessary to derive a formal guideline value. Accordingly, aesthetic as well as health aspects should be considered when setting national standards and regulations, and confirming the acceptability of drinking-water. There are circumstances, however, where manganese can remain in solution at higher concentrations in some acidic or anaerobic waters, particularly groundwater.

MCPA

MCPA is a phenoxyacetic acid herbicide that is found in various formulations: as the free acid (CAS No. 94-74-6), as a dimethylamine salt (CAS No. 2039-46-5), as a sodium salt (CAS No. 3653-48-3) and as a 2-ethylhexyl ester (CAS No. 29450-45-1). It is a post-emergence herbicide that is widely used against broadleaf weeds in agricul-

ture and horticulture and on grassland and lawns. All forms of MCPA will dissociate in water to the acid (anion) form. MCPA is highly soluble in water. Biological degradation is an important process in determining MCPA's environmental fate. Chlorophenols and chlorocresols are potential soil metabolites and may, if present in water, give rise to unacceptable tastes. Surface water may be contaminated via spray drift and runoff, whereas groundwater may be contaminated via leaching from soil. Exposure from food is likely to be low.

Reason for not establishing a guideline value	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Health-based value*	0.7 mg/l
Acute health-based value**	20 mg/l
Occurrence	Concentrations in surface water usually less than 1 µg/l; concentrations in drinking-water usually below 0.1 µg/l
ADI	0–0.1 mg/kg bw for MCPA ion, based on an overall NOAEL of 12 mg/kg bw per day for changes in clinical chemistry parameters indicative of effects on the kidneys from four subchronic studies in rats and application of a safety factor of 100 ADI established for the sum of MCPA and its salts and esters, expressed as MCPA acid equivalents
ARfD	0.6 mg/kg bw for MCPA ion, based on the overall NOAEL of 60 mg/kg bw for maternal and developmental toxicity in rats and application of a safety factor of 100 ARfD established for the sum of MCPA and its salts and esters, expressed as MCPA acid equivalents
Limit of detection	0.8 µg/L using HPLC with a photodiode array UV detector; 0.09 µg/l using derivatization and GC with ECD; limit of quantification of 0.0005 µg/l for LC-MS/MS
Treatment performance	Conventional treatment not effective; activated carbon adsorption and/or ozonation and advanced oxidation processes (e.g. UV with hydrogen peroxide) are effective; membrane filtration processes (e.g. reverse osmosis) may be effective
Health-based value derivation	
• allocation to water	20% of upper bound of unrounded ADI (0.12 mg/kg bw)
• weight	60 kg adult
• consumption	2 litres/day
Acute health-based value derivation	
• allocation to water	100% of ARfD
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The default allocation factor of 20% has been used to account for the fact that the available food exposure data, which suggest that exposure via this route is low, do not generally include information from developing countries, where exposure via this route may be higher Guidance on interpreting the health-based value and deciding when to monitor can be found in section 8.5.3

Assessment date	2016
Principal references	WHO (2013). *Pesticide residues in food – 2012 evaluations* WHO (2016). *MCPA in drinking-water*

* When a formal guideline value is not established, a "health-based value" may be determined in order to provide guidance to Member States when there is reason for local concern. Establishing a formal guideline value for such substances may encourage Member States to incorporate a value into their national standards when this may be unnecessary.

** For more information on acute health-based values, see section 8.7.5.

The target organs for the MCPA ion are the kidney, liver and blood. MCPA is not carcinogenic in mice or rats, and the MCPA ion exhibits no genotoxic potential. In multigeneration studies in rats, there was no evidence of reproductive toxicity up to the highest dose tested. The MCPA ion was not teratogenic in rats or rabbits.

Mecoprop

The half-lives for degradation of chlorophenoxy herbicides, including mecoprop (CAS No. 93-65-2; 7085-19-0 racemic mixture), also known as 2(2-methyl-chlorophenoxy) propionic acid or MCPP, in the environment are in the order of several days. Chlorophenoxy herbicides are not often found in food.

Guideline value	0.01 mg/l (10 µg/l)
Occurrence	Chlorophenoxy herbicides not frequently found in drinking-water; when detected, concentrations usually no greater than a few micrograms per litre
TDI	3.33 µg/kg body weight, based on a NOAEL of 1 mg/kg body weight for effects on kidney weight in 1- and 2-year studies in rats, with an uncertainty factor of 300 (100 for interspecies and intraspecies variation and 3 for limitations in the database)
Limit of detection	0.01 µg/l by GC-MS; 0.01–0.02 µg/l by GC with ECD
Treatment performance	0.1 µg/l should be achievable using GAC or ozonation

Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenoxy herbicides (excluding 2,4-D and MCPA) in drinking-water*

Chlorophenoxy herbicides, as a group, have been classified in Group 2B (possibly carcinogenic to humans) by IARC. However, the available data from studies in exposed populations and experimental animals do not permit assessment of the carcinogenic potential to humans of any specific chlorophenoxy herbicide. Therefore, drinking-water guidelines for these compounds are based on a threshold approach for other toxic effects. Effects of dietary administration of mecoprop in short-term and long-term studies include decreased relative kidney weight (rats and dogs), increased relative liver weight (rats), effects on blood parameters (rats and dogs) and depressed body weight gain (dogs).

Mercury

Mercury is used in the electrolytic production of chlorine, in electrical appliances, in dental amalgams and as a raw material for various mercury compounds. Methylation of inorganic mercury has been shown to occur in fresh water and in seawater, although almost all mercury in uncontaminated drinking-water is thought to be in the form of Hg^{2+}. Thus, it is unlikely that there is any direct risk of the intake of organic mercury compounds, especially of alkylmercurials, as a result of the ingestion of drinking-water. However, there is a possibility that methylmercury will be converted into inorganic mercury. Food is the main source of mercury in non-occupationally exposed populations; the mean dietary intake of mercury in various countries ranges from 2 to 20 µg/day per person.

Guideline value	0.006 mg/l (6 µg/l) for inorganic mercury
Occurrence	Mercury is present in the inorganic form in surface water and groundwater at concentrations usually below 0.5 µg/l, although local mineral deposits may produce higher levels in groundwater
TDI	2 µg/kg body weight for inorganic mercury based on a NOAEL of 0.23 mg/kg body weight per day for kidney effects in a 26-week study in rats and applying an uncertainty factor of 100 (for interspecies and intraspecies variation) after adjusting for daily dosing
Limit of detection	0.05 µg/l by cold vapour AAS; 0.6 µg/l by ICP; 5 µg/l by flame AAS
Treatment performance	It should be possible to achieve a concentration below 1 µg/l by treatment of raw waters that are not grossly contaminated with mercury using methods that include coagulation/sedimentation/filtration, PAC and ion exchange.

Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	A similar TDI may be obtained by applying an uncertainty factor of 1000 (an additional uncertainty factor of 10 for adjustment from a LOAEL to a NOAEL) to the LOAEL for renal effects of 1.9 mg/kg body weight per day in a 2-year NTP study in rats.
	The current guideline value applies to inorganic mercury, which is the form found in drinking-water, whereas the previous guideline value applied to total (inorganic and organic) mercury.
Assessment date	2004
Principal references	IPCS (2003) *Elemental mercury and inorganic mercury compounds* WHO (2005) *Mercury in drinking-water*

The toxic effects of inorganic mercury compounds are seen mainly in the kidney in both humans and laboratory animals following short-term and long-term exposure. In rats, effects include increased absolute and relative kidney weights, tubular necrosis, proteinuria and hypoalbuminaemia. In humans, acute oral poisoning results primarily in haemorrhagic gastritis and colitis; the ultimate damage is to the kidney. The overall weight of evidence is that mercury(II) chloride has the potential to increase the incidence of some benign tumours at sites where tissue damage is apparent and that it possesses weak genotoxic activity but does not cause point mutations.

Methoxychlor

Methoxychlor (CAS No. 72-43-5) is an insecticide used on vegetables, fruit, trees, fodder and farm animals. It is poorly soluble in water and highly immobile in most agricultural soils. Under normal conditions of use, methoxychlor does not seem to be of environmental concern. Daily intake from food and air is expected to be below 1 µg per person. Environmental metabolites are formed preferentially under anaerobic rather than aerobic conditions and include mainly the dechlorinated and demethylated products. There is some potential for the accumulation of the parent compound and its metabolites in surface water sediments.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Detected occasionally in drinking-water, at concentrations as high as 300 µg/l in rural areas
TDI	5 µg/kg body weight, based on a systemic NOAEL of 5 mg/kg body weight in a teratology study in rabbits, with an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 reflecting concern for threshold carcinogenicity and the limited database)
Limit of detection	0.001–0.01 µg/l by GC
Treatment performance	0.1 µg/l should be achievable using GAC

Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2004) *Methoxychlor in drinking-water*

The genotoxic potential of methoxychlor appears to be negligible. In 1979, IARC assigned methoxychlor to Group 3. Subsequent data suggest a carcinogenic potential of methoxychlor for liver and testes in mice. This may be due to the hormonal activity of proestrogenic mammalian metabolites of methoxychlor and may therefore have a threshold. The study, however, was inadequate, because only one dose was used and because this dose may have been above the maximum tolerated dose. The database for studies on long-term, short-term and reproductive toxicity is inadequate. A teratology study in rabbits reported a systemic NOAEL of 5 mg/kg body weight per day, which is lower than the LOAELs and NOAELs from other studies. This NOAEL was therefore selected for use in the derivation of a TDI.

Methyl parathion

Methyl parathion (CAS No. 298-00-0) is a non-systemic insecticide and acaricide that is produced throughout the world and has been registered for use on many crops, in particular cotton. It partitions mainly to air and soil in the environment. There is virtually no movement through soil, and neither the parent compound nor its breakdown products will reach groundwater. By far the most important route for the environmental degradation of methyl parathion is microbial degradation. Half-lives of methyl parathion in water are in the order of weeks to months. Concentrations of methyl parathion in natural waters of agricultural areas in the USA ranged up to 0.46 μg/l, with highest levels in summer. The general population can come into contact with methyl parathion via air, water or food.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1996) *Pesticide residues in food—1995 evaluations.* IPCS (1992) *Methyl parathion* WHO (2004) *Methyl parathion in drinking-water*

A NOAEL of 0.3 mg/kg body weight per day was derived from the combined results of several studies conducted in humans, based on the depression of erythrocyte and plasma cholinesterase activities. Methyl parathion decreased cholinesterase activities in long-term studies in mice and rats, but did not induce carcinogenic effects. Methyl parathion was mutagenic in bacteria, but there was no evidence of genotoxicity in a limited range of studies in mammalian systems.

A health-based value of 9 µg/l can be calculated for methyl parathion on the basis of an ADI of 0–0.003 mg/kg body weight, based on a NOAEL of 0.25 mg/kg body weight per day in a 2-year study in rats for retinal degeneration, sciatic nerve demyelination, reduced body weight, anaemia and decreased brain acetylcholinesterase activity, using an uncertainty factor of 100 for interspecies and intraspecies variation. As the toxicological end-points seen in experimental animals were other than acetylcholinesterase inhibition, it was considered more appropriate to use these data rather than the NOAEL derived for cholinesterase inhibition in humans.

Intake of methyl parathion from all sources is generally low and well below the upper limit of the ADI. As the health-based value is much higher than concentrations of methyl parathion likely to be found in drinking-water, the presence of methyl parathion in drinking-water under usual conditions is unlikely to represent a hazard to human health. For this reason, the establishment of a formal guideline value for methyl parathion is not deemed necessary.

Methyl tertiary-butyl ether

The major use of methyl *tert*-butyl ether, or MTBE, is as a gasoline additive. Surface water can be contaminated by gasoline spills; however, owing to the high volatility of MTBE, most is lost to evaporation. Spills and leaking storage tanks can cause more serious problems in groundwater, where MTBE is more persistent. MTBE has been detected in groundwater and drinking-water at concentrations in the nanogram to microgram per litre range.

Reason for not establishing a guideline value	Any guideline that would be derived would be significantly higher than concentrations at which MTBE would be detected by odour
Assessment date	2004
Principal references	IPCS (1998) *Methyl tertiary-butyl ether* WHO (2005) *Methyl tertiary-butyl ether (MTBE) in drinking-water*

No human cancer studies have been published for either the general population or occupationally exposed cohorts. There have been a number of human studies of neurological and clinical effects of exposure to MTBE by inhalation, with mixed results. In general, no objective changes could be seen at levels of MTBE normally found, even in such microenvironments as gasoline filling stations.

The weight of evidence suggests that MTBE is not genotoxic. A large number of studies using in vitro and in vivo mammalian and non-mammalian systems have been conducted to assess the mutagenicity of MTBE, almost all of which have produced negative results. These results suggest that the mechanism of action of MTBE is more likely to be non-genotoxic than genotoxic, although no one mechanism appears to explain all of the observed effects.

It has been concluded that MTBE should be considered a rodent carcinogen but that it is not genotoxic, and the carcinogenic response is evident only at high levels of exposure that also induce other adverse effects. The available data are therefore considered inconclusive and prohibit their use for human carcinogenic risk assessment.

A health-based guideline value has not been derived for MTBE, owing to the fact that any guideline value that would be derived would be significantly higher than the concentration at which it would be detected by odour (15 µg/l is the lowest level eliciting a response in a study using taste- and odour-sensitive participants).

Metolachlor

Metolachlor (CAS No. 51218-45-2) is a selective pre-emergence herbicide used on a number of crops. It can be lost from the soil through biodegradation, photodegradation and volatilization. It is fairly mobile and under certain conditions can contaminate groundwater, but it is mostly found in surface water.

Guideline value	0.01 mg/l (10 µg/l)
Occurrence	Detected in surface water and groundwater at concentrations that can exceed 10 µg/l
TDI	3.5 µg/kg body weight, based on a NOAEL of 3.5 mg/kg body weight for an apparent decrease in kidney weight at the two highest dose levels in a 1-year dog study, with an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 reflecting some concern regarding carcinogenicity)
Limit of detection	0.75–0.01 µg/l by GC with nitrogen–phosphorus detection
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Metolachlor in drinking-water*

In a 1-year study in dogs, administration of metolachlor resulted in decreased kidney weight at the two highest dose levels. In 2-year studies with rodents fed metolachlor in the diet, the only toxicological effects observed in mice were decreased body weight gain and decreased survival in females at the highest dose level, whereas rats showed decreased body weight gain and food consumption at the highest dose level. There is no evidence from available studies that metolachlor is carcinogenic in mice. In rats, an increase in liver tumours in females as well as a few nasal tumours in males have been observed. Metolachlor is not genotoxic.

Molinate

Molinate (CAS No. 2212-67-1) is a herbicide used to control broad-leaved and grassy weeds in rice. The available data suggest that groundwater pollution by molinate is restricted to some rice growing regions. Data on the occurrence of molinate in the environment are limited. Molinate is of low persistence in water and soil, with a half life of about 5 days.

Guideline value	0.006 mg/l (6 µg/l)
Occurrence	Concentrations in water rarely exceed 1 µg/l
TDI	2 µg/kg body weight, based on a NOAEL for reproductive toxicity in the rat of 0.2 mg/kg body weight, with an uncertainty factor of 100 (for interspecies and intraspecies variation)
Limit of detection	0.01 µg/l by GC-MS
Treatment performance	0.001 mg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Molinate in drinking-water*

On the basis of the limited information available, molinate does not seem to be carcinogenic or mutagenic in experimental animals. Evidence suggests that impairment of the reproductive performance of the male rat represents the most sensitive indicator of molinate exposure. However, epidemiological data based on the examination of workers involved in molinate production do not indicate any effect on human fertility.

Molybdenum

Molybdenum is found naturally in soil and is used in the manufacture of special steels and in the production of tungsten and pigments, and molybdenum compounds are used as lubricant additives and in agriculture to prevent molybdenum deficiency in crops. Concentrations in drinking-water are usually less than 0.01 mg/l, although concentrations as high as 200 µg/l have been reported in areas near mining sites.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	1993, revised in 2011
Principal references	WHO (2011) *Molybdenum in drinking-water*

Molybdenum is considered to be an essential element, with an estimated daily requirement of 0.1–0.3 mg for adults.

As molybdenum occurs at very low concentrations in drinking-water, it is not considered necessary to set a formal guideline value. For guidance purposes, a health-based value can be derived.

In a 2-year study of humans exposed via drinking-water, the NOAEL was found to be 0.2 mg/l, but there are some concerns about the quality of this study. As molybdenum is an essential element, a factor of 3 is considered to be adequate to reflect intraspecies variation. This gives a health-based value of 0.07 mg/l (rounded figure), which is in the same range as that derived on the basis of the results of toxicological studies in experimental animals and is consistent with the essential daily requirement for molybdenum.

Monochloroacetic acid

Chlorinated acetic acids are formed from organic material during water chlorination.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Present in surface water–derived drinking-water at concentrations up to 82 µg/l (mean 2.1 µg/l)
TDI	3.5 µg/kg body weight, based on a LOAEL of 3.5 mg/kg body weight per day from a study in which increased absolute and relative spleen weights were observed in male rats exposed to monochloroacetic acid in drinking-water for 2 years, using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for use of a minimal LOAEL instead of a NOAEL and database deficiencies, including the lack of a multigeneration reproductive toxicity study)
Limit of detection	2 µg/l by GC with ECD; 5 µg/l by GC-MS
Treatment performance	No information available
Guideline value derivation	
• allocation to water	20% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	2003
Principal reference	WHO (2004) *Monochloroacetic acid in drinking-water*

No evidence of carcinogenicity of monochloroacetate was found in 2-year gavage bioassays with rats and mice. Monochloroacetate has given mixed results in a limited number of mutagenicity assays and has been negative for clastogenicity in genotoxicity studies. IARC has not classified the carcinogenicity of monochloroacetic acid.

Monochlorobenzene

Releases of monochlorobenzene (MCB) to the environment are thought to be mainly due to volatilization losses associated with its use as a solvent in pesticide formulations, as a degreasing agent and from other industrial applications. MCB has been detected in surface water, groundwater and drinking-water; mean concentrations were less than 1 µg/l in some potable water sources (maximum 5 µg/l) in Canada. The major source of human exposure is probably air.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern, and health-based value would far exceed lowest reported taste and odour threshold
Assessment date	2003
Principal reference	WHO (2004) *Monochlorobenzene in drinking-water*

MCB is of low acute toxicity. Oral exposure to high doses of MCB results in effects mainly on the liver, kidneys and haematopoietic system. There is limited evidence of

carcinogenicity in male rats, with high doses increasing the occurrence of neoplastic nodules in the liver. The majority of evidence suggests that MCB is not mutagenic; although it binds to DNA in vivo, the level of binding is low.

A health-based value of 300 µg/l can be calculated for MCB on the basis of a TDI of 85.7 µg/kg body weight, based on neoplastic nodules identified in a 2-year rat study with dosing by gavage, and taking into consideration the limited evidence of carcinogenicity. However, because MCB occurs at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value. It should also be noted that the health-based value far exceeds the lowest reported taste and odour threshold for MCB in water.

MX

MX, which is the common name for 3-chloro-4-dichloromethyl-5-hydroxy-2-(5H)-furanone, is formed by the reaction of chlorine with complex organic matter in drinking-water. It has been identified in chlorinated humic acid solutions and drinking-water in Finland, the United Kingdom and the USA and was found to be present in 37 water sources at levels of 2–67 ng/l. Five drinking-water samples from different Japanese cities contained MX at concentrations ranging from less than 3 to 9 ng/l.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* WHO (2003) *MX in drinking-water*

MX is a potent mutagen in bacteria and in cells in vitro and has undergone a lifetime study in rats in which some tumorigenic responses were observed. These data indicate that MX induces thyroid and bile duct tumours. IARC has classified MX in Group 2B (possibly carcinogenic to humans) on the basis of rat tumorigenicity and its strong mutagenicity.

A health-based value of 1.8 µg/l can be calculated for MX on the basis of the increase in cholangiomas and cholangiocarcinomas in female rats using the linearized multistage model (without a body surface area correction). However, this is significantly above the concentrations that would be found in drinking-water, and, in view of the analytical difficulties in measuring this compound at such low concentrations, it is considered unnecessary to propose a formal guideline value for MX in drinking-water.

Nickel

Nickel is used mainly in the production of stainless steel and nickel alloys. Food is the dominant source of nickel exposure in the non-smoking, non-occupationally exposed population; water is generally a minor contributor to the total daily oral intake. However, where there is heavy pollution, where there are areas in which nickel that occurs naturally in groundwater is mobilized or where there is use of certain types of kettles,

of non-resistant material in wells or of water that has come into contact with nickel- or chromium-plated taps, the nickel contribution from water may be significant.

Guideline value	0.07 mg/l (70 µg/l)
Occurrence	Concentration in drinking-water normally less than 0.02 mg/l, although nickel released from taps and fittings may contribute up to 1 mg/l; in special cases of release from natural or industrial nickel deposits in the ground, concentrations in drinking-water may be higher
TDI	12 µg/kg body weight, derived from a LOAEL established after oral provocation of fasted patients with an empty stomach
Limit of detection	0.1 µg/l by ICP-MS; 0.5 µg/l by flame AAS; 10 µg/l by ICP-AES
Treatment performance	20 µg/l should be achievable by conventional treatment (e.g. coagulation). Where naturally occurring nickel is mobilized in groundwater, removal is by ion exchange or adsorption. Where nickel leaches from alloys in contact with drinking-water or from chromium- or nickel-plated taps, control is by appropriate control of materials in contact with the drinking-water and flushing taps before using the water.
Guideline value derivation	
allocation to water	20% of TDI
weight	60 kg adult
consumption	2 litres/day
Additional comments	Although the guideline value is close to the acute LOAEL, the LOAEL is based on total exposure from drinking-water, and absorption from drinking-water on an empty stomach is 10- to 40-fold higher than absorption from food. Basing the total acceptable intake for oral challenge from studies using drinking-water on an empty stomach in fasted patients can therefore be considered a worst-case scenario.
	A general toxicity value of 130 µg/l could be determined from a well-conducted two-generation study in rats. However, this general toxicity value may not be sufficiently protective of individuals sensitized to nickel, for whom a sufficiently high oral challenge has been shown to elicit an eczematous reaction.
Assessment date	2004
Principal reference	WHO (2005) *Nickel in drinking-water*

IARC concluded that inhaled nickel compounds are carcinogenic to humans (Group 1) and that metallic nickel is possibly carcinogenic (Group 2B). However, there is a lack of evidence of a carcinogenic risk from oral exposure to nickel. In a well-conducted two-generation reproductive study in rats administered nickel by gavage, a clear NOEL was observed for adult rats and their offspring for all the end-points studied, including integrity and performance of male and female reproductive systems, growth and development of offspring and post-implantation/perinatal lethality. Allergic contact dermatitis is the most prevalent effect of nickel in the general population.

Nitrate and nitrite[1]

Nitrate (NO_3^-) is found naturally in the environment and is an important plant nutrient. It is present at varying concentrations in all plants and is a part of the nitrogen cycle. Nitrite (NO_2^-) is not usually present in significant concentrations except in a reducing environment, because nitrate is the more stable oxidation state. It can be formed by the microbial reduction of nitrate and in vivo by reduction from ingested nitrate. Nitrite can also be formed chemically in distribution pipes by *Nitrosomonas* bacteria during stagnation of nitrate-containing and oxygen-poor drinking-water in galvanized steel pipes, or if chloramination is used to provide a residual disinfectant. An excess of free ammonia entering the distribution system can lead to nitrification and the potential increase of nitrate and nitrite in drinking-water. Nitrate can reach both surface water and groundwater as a consequence of agricultural activity (including excess application of inorganic nitrogenous fertilizers and manures), from wastewater disposal and from oxidation of nitrogenous waste products in human and other animal excreta, including septic tanks. Nitrate can also occasionally reach groundwater as a consequence of natural vegetation. Surface water nitrate concentrations can change rapidly owing to surface runoff of fertilizer, uptake by phytoplankton and denitrification by bacteria, but groundwater concentrations generally show relatively slow changes. Nitrate and nitrite can also be produced as a result of nitrification in source water or distribution systems.

In general, the most important source of human exposure to nitrate and nitrite is through vegetables (nitrate and nitrite) and through meat in the diet (nitrite is used as a preservative in many cured meats). In some circumstances, however, drinking-water can make a significant contribution to nitrate and, occasionally, nitrite intake. In the case of bottle-fed infants, drinking-water can be the major external source of exposure to nitrate and nitrite.

Guideline values[2]	*Nitrate:* 50 mg/l as nitrate ion, to be protective against methaemoglobinaemia and thyroid effects in the most sensitive subpopulation, bottle-fed infants, and, consequently, other population subgroups
	Nitrite: 3 mg/l as nitrite ion, to be protective against methaemoglobinaemia induced by nitrite from both endogenous and exogenous sources in bottle-fed infants, the most sensitive subpopulation, and, consequently, the general population
	Combined nitrate plus nitrite: The sum of the ratios of the concentrations of each of nitrate and nitrite to its guideline value should not exceed 1
Occurrence	Nitrate levels vary significantly, but levels in well water are often higher than those in surface water and, unless heavily influenced by surface water, are less likely to fluctuate. Concentrations often approach or exceed 50 mg/l where there are significant sources of contamination. Nitrite levels are normally lower, less than a few milligrams per litre.

[1] As nitrate and nitrite are chemicals of significant concern in some natural waters, the chemical fact sheet on nitrate and nitrite has been expanded.

[2] Conversion factors: 1 mg/l as nitrate = 0.226 mg/l as nitrate-nitrogen; 1 mg/l as nitrite = 0.304 mg/l as nitrite-nitrogen.

Basis of guideline value derivation	*Nitrate (bottle-fed infants):* In epidemiological studies, no adverse health effects (methaemoglobinaemia or thyroid effects) were reported in infants in areas where drinking-water consistently contained nitrate at concentrations below 50 mg/l
	Nitrite (bottle-fed infants): Based on: 1) no incidence of methaemoglobinaemia at nitrate concentrations below 50 mg/l (as nitrate ion) in drinking-water for bottle-fed infants less than 6 months of age (assuming body weight of 2 kg); 2) converting 50 mg/l as nitrate to corresponding molar concentration for nitrite; 3) multiplying by a factor of 0.1 to account for the estimated conversion rate of nitrate to nitrite in infants where nitrite is formed endogenously from nitrate at a rate of 5–10%; and 4) multiplying by a source allocation factor for drinking-water of 100% or 1, as a bottle-fed infant's primary exposure to nitrite is through consumption of formula reconstituted with drinking-water that contains nitrate or nitrite. As the guideline value is based on the most sensitive subgroup of the population (bottle-fed infants less than 6 months of age), application of an uncertainty factor is not deemed necessary.
	Combined nitrate plus nitrite: To account for the possibility of the simultaneous occurrence of nitrate and nitrite in drinking-water
Limit of detection	MDLs of 0.009 mg/l as nitrate ion and 0.013 mg/l as nitrite ion by IC; MDL of 0.04–4.4 mg/l as nitrate ion by automated cadmium reduction with colorimetry (recommended for the analysis of nitrate at concentrations below 0.4 mg/l)
Treatment performance	*Nitrate:* Effective central treatment technologies involve the physical/chemical and biological removal of nitrate and include ion exchange, reverse osmosis, biological denitrification and electrodialysis, which are capable of removing over 80% of nitrate from water to achieve effluent nitrate concentrations as low as 13 mg/l; conventional treatment processes (coagulation, sedimentation, filtration and chlorination) are not effective
	Nitrite: Treatment usually focuses on nitrate, because nitrite is readily converted to nitrate by many disinfectants
Additional comments	The guideline values for both nitrate and nitrite are based on short-term effects; however, they are also considered protective for any possible long-term effects .
	Methaemoglobinaemia is complicated by the presence of microbial contamination and subsequent gastrointestinal infection, which can increase the risk for bottle-fed infants significantly. Authorities should therefore be all the more vigilant that water to be used for bottle-fed infants is microbiologically safe when nitrate is present at concentrations near or above the guideline value. It is particularly important to ensure that these infants are not currently exhibiting symptoms of gastrointestinal infection (diarrhoea). Also, as excessive boiling of water to ensure microbiological safety can concentrate levels of nitrate in the water, care should be taken to ensure that water is heated only until it reaches a rolling boil. In extreme situations, alternative sources of water (e.g. bottled water) can be used.
	Nitrite is relatively unstable and can be rapidly oxidized to nitrate. Nitrite can occur in the distribution system at higher concentrations when chloramination is used, but the occurrence is almost invariably intermittent. Methaemoglobinaemia is therefore the most important consideration, and the guideline value derived for protection against methaemoglobinaemia would be the most appropriate under these circumstances, allowing for any nitrate that may also be present.

	All water systems that practise chloramination should closely and regularly monitor their systems to verify disinfectant levels, microbiological quality and nitrite levels. If nitrification is detected (e.g. reduced disinfectant residuals and increased nitrite levels), steps can be taken to modify the treatment train or water chemistry in order to minimize nitrite formation. Effective disinfection must never be compromised. Excessively high levels may occur in small supplies; where this is suspected from the risk assessment, testing may be appropriate.
Assessment date	2016
Principal references	Health Canada (2013). *Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Nitrate and nitrite* WHO (2016). *Nitrate and nitrite in drinking-water*

Absorption of nitrate ingested from vegetables, meat or water is rapid and in excess of 90%; final excretion is in the urine. In humans, about 25% of ingested nitrate is recirculated in saliva, of which about 20% is converted to nitrite by the action of bacteria in the mouth. There is also endogenous formation of nitrate from nitric oxide and protein breakdown as part of normal metabolism. In normal healthy adults, this endogenous synthesis leads to the excretion of about 62 mg of nitrate ion per day in the urine. Endogenous formation of nitrate or nitrite can be significantly increased in the presence of infections, particularly gastrointestinal infections. When nitrate intake is low, endogenous formation may be the major source of nitrate in the body. Nitrate metabolism is different in humans and rats, as rats may not actively secrete nitrate in their saliva.

Nitrate probably has a role in protecting the gastrointestinal tract against a variety of gastrointestinal pathogens, as nitrous oxide and acidified nitrite have antibacterial properties. It may have other beneficial physiological roles. Hence, there may be a benefit from exogenous nitrate uptake, and there remains a need to balance the potential risks with the potential benefits.

Significant bacterial reduction of nitrate to nitrite does not normally take place in the stomach, except in individuals with low gastric acidity or with gastrointestinal infections. These may include individuals using antacids, particularly those that block acid secretion. In humans, methaemoglobinaemia is a consequence of the reaction of nitrite with haemoglobin in the red blood cells to form methaemoglobin, which binds oxygen tightly and does not release it, thus blocking oxygen transport. Although most absorbed nitrite is oxidized to nitrate in the blood, residual nitrite can react with haemoglobin. High levels of methaemoglobin (>10%) formation in infants can give rise to cyanosis, referred to as blue-baby syndrome. Although clinically significant methaemoglobinaemia can occur as a result of extremely high nitrate intake in adults and children, the most familiar situation is its occurrence in bottle-fed infants. This was considered to be primarily a consequence of high levels of nitrate in water, although there have been cases of methaemoglobinaemia in weaned infants, associated with high nitrate intake from vegetables. Bottle-fed infants are considered to be at greater risk because the intake of water in relation to body weight is high and, in infants, the development of repair enzymes is limited. In clinical epidemiological studies of

methaemoglobinaemia and subclinical increases in methaemoglobin levels associated with drinking-water nitrate, 97% of cases occurred at concentrations in excess of 44.3 mg/l, with clinical symptoms associated with the higher concentrations. The affected individuals were almost exclusively under 3 months of age.

Although drinking-water nitrate may be an important risk factor for methaemoglobinaemia in bottle-fed infants, there is compelling evidence that the risk of methaemoglobinaemia is primarily increased in the presence of simultaneous gastrointestinal infections, which increase endogenous nitrite formation, may increase reduction of nitrate to nitrite and may also increase the intake of water in combatting dehydration. Cases have been described in which gastrointestinal infection seems to have been the primary cause of methaemoglobinaemia. Most cases of methaemoglobinaemia reported in the literature are associated with contaminated private wells (predominantly when the drinking-water is anaerobic) that also have a high probability of microbial contamination, which should not occur if it is properly disinfected.

Although numerous epidemiological studies have investigated the relationship between exposure to nitrate or nitrite in drinking-water and cancer occurrence, the weight of evidence does not support an association between cancer and exposure to nitrate or nitrite per se. Nitrite can react with nitrosatable compounds, primarily secondary amines, in the body to form *N*-nitroso compounds. A number of these are considered to be carcinogenic to humans, whereas others, such as *N*-nitrosoproline, are not. Several studies have been carried out on the formation of *N*-nitroso compounds in relation to nitrate intake in humans, but there is large variation in the intake of nitrosatable compounds and in gastric physiology. Higher mean levels of *N*-nitroso compounds, along with high nitrate levels, have been found in the gastric juice of individuals who are achlorhydric (i.e. have very low levels of hydrochloric acid in the stomach). However, other studies have been largely inconclusive, and there appears to be no clear relationship with drinking-water nitrate compared with overall nitrate intake in relation to formation of *N*-nitroso compounds. Moderate consumption of a number of dietary antioxidant components, such as ascorbic acid and green tea, appears to reduce endogenous *N*-nitrosamine formation.

A significant number of epidemiological studies have been carried out on the association of nitrate intake with primarily gastric cancers. Although the epidemiological data are considered to be inadequate to allow definitive conclusions to be drawn regarding all cancers, there is no convincing evidence of a causal association with any cancer site. The weight of evidence indicates that there is unlikely to be a causal association between gastric cancer and nitrate in drinking-water. This is consistent with the conclusion by IARC that ingested nitrate or nitrite under conditions that result in endogenous nitrosation is probably carcinogenic to humans (Group 2A), but not nitrate alone.

There have been suggestions that nitrate in drinking-water could be associated with congenital malformations, but the overall weight of evidence does not support this.

Nitrate appears to competitively inhibit iodine uptake, with the potential for an adverse effect on the thyroid. Current evidence also suggests that exposure to nitrate in drinking-water may alter human thyroid gland function by competitively inhibiting

thyroidal iodide uptake, leading to altered thyroid hormone concentrations and functions. Although studies found that exposure to nitrate concentrations above 50 mg/l are weakly associated with altered thyroid function, the evidence is limited, conflicting and based on studies with important methodological limitations. Mode of action data suggest that pregnant women and infants are the most sensitive populations, owing primarily to the importance of adequate thyroid hormones for normal neurodevelopment in the fetus and infant, but also to increased thyroid hormone turnover and low intrathyroidal stores in fetal and early life.

There have been suggestions of an association between nitrate in drinking-water and the incidence of childhood diabetes mellitus. However, subsequent studies have not found a significant relationship, and no mechanism has been identified.

In some studies on rats treated with high doses of nitrite, a dose-related hypertrophy of the zona glomerulosa of the adrenal was seen; one strain of rats appeared to be more sensitive than others. However, this minimal hyperplasia was considered to be due to physiological adaptation to small fluctuations in blood pressure in response to high nitrite doses.

Nitrate is not carcinogenic in laboratory animals. Nitrite has been frequently studied, and there have been suggestions of carcinogenic activity, but only at very high doses. The most recent long-term studies have shown only equivocal evidence of carcinogenicity in the forestomach of female mice, but not in rats or male mice. In view of the lack of evidence for genotoxicity, this led to the conclusion that sodium nitrite was not carcinogenic in mice and rats. In addition, as humans do not possess a forestomach and the doses were high, the significance of these data for humans is very doubtful.

The guideline value for nitrate of 50 mg/l, as nitrate ion, is based on an absence of health effects (methaemoglobinaemia and thyroid effects) in epidemiological studies and is protective for bottle-fed infants and, consequently, other parts of the population. Methaemoglobinaemia is complicated by the presence of microbial contamination and subsequent gastrointestinal infection, which can increase the risk for this group significantly. Authorities should therefore be all the more vigilant that water to be used for bottle-fed infants is microbiologically safe when nitrate is present at concentrations near the guideline value. It is particularly important to ensure that these infants are not currently exhibiting symptoms of significant gastrointestinal infection (diarrhoea). Also, as excessive boiling of water to ensure microbiological safety can concentrate levels of nitrate in the water, care should be taken to ensure that water is heated only until it reaches a rolling boil. In extreme situations, alternative sources of water (e.g. bottled water) can be used.

The guideline for nitrite of 3 mg/l, as nitrite ion, is based on: 1) no incidence of methaemoglobinaemia at nitrate concentrations below 50 mg/l in drinking-water for bottle-fed infants less than 6 months of age (assuming body weight of 2 kg), 2) converting 50 mg/l nitrate to the corresponding molar concentration for nitrite, 3) multiplying by a factor of 0.1 to account for the estimated conversion rate of nitrate to nitrite in infants where nitrite is formed endogenously from nitrate at a rate of 5–10% and 4) multiplying by a source allocation factor for drinking water of 100% or 1, as a bottle-fed infant's primary exposure to nitrite is through consumption of for-

mula reconstituted with nitrate- or nitrite-containing drinking-water. As the health-based value is based on the most sensitive subgroup of the population (bottle-fed infants less than 6 months of age), application of an uncertainty factor is not deemed necessary.

Because of the possibility of the simultaneous occurrence of nitrate and nitrite in drinking-water, the sum of the ratios of the concentration (C) of each to its guideline value (GV) should not exceed 1:

$$\frac{C_{nitrate}}{GV_{nitrate}} + \frac{C_{nitrite}}{GV_{nitrite}} \leq 1$$

The guideline values are based on short-term effects; however, they are also considered protective for long-term effects.

Practical considerations

The most appropriate means of controlling nitrate concentrations, particularly in groundwater, is the prevention of contamination. This may take the form of appropriate management of agricultural practices (e.g. management of fertilizer and manure application and storage of animal manures) and sanitation practices (e.g. the careful siting of pit latrines and septic tanks, sewer leakage control).

Methaemoglobinaemia has most frequently been associated with private wells. It is particularly important to ensure that septic tanks and pit latrines are not sited near a well or where a well is to be dug and to ensure that animal manure is kept at a sufficient distance to ensure that runoff cannot enter the well or the ground near the well. It is particularly important that the household use of manures and fertilizers on small plots near wells should be managed with care to avoid potential contamination. The well should be sufficiently protected to prevent runoff from entering the well. Where there are elevated concentrations of nitrate or where inspection of the well indicated that there are sources of nitrate close by that could be causing contamination, particularly where there are also indications that microbiological quality might also be poor, a number of actions can be taken. As noted above, water should be heated only until the water reaches a rolling boil or disinfected by an appropriate means before consumption. Where alternative supplies are available for bottle-fed infants, these can be used, taking care to ensure that they are microbiologically safe. Steps should then be taken to protect the well and ensure that sources of both nitrate and microbial contamination are removed from the vicinity of the well.

In areas where household wells are common, health authorities may wish to take a number of steps to ensure that nitrate contamination is not or does not become a problem. Such steps could include targeting mothers, particularly expectant mothers, with appropriate information about water safety, assisting with visual inspection of wells to determine whether a problem may exist, providing testing facilities where a problem is suspected, providing guidance on disinfecting water or, where nitrate levels are particularly high, providing bottled water from safe sources or providing advice as to where such water can be obtained.

With regard to piped supplies, where nitrate is present, the first potential approach to treatment of drinking-water supplies, if source substitution is not feasible,

is to dilute the contaminated water with a low-nitrate source. Where blending is not feasible, a number of treatment techniques are available for drinking-water. The first is disinfection, which may serve to oxidize nitrite to the less toxic nitrate as well as minimize the pathogenic and non-pathogenic reducing bacterial population in the water. Nitrate removal methods include ion exchange, biological denitrification, reverse osmosis and electrodialysis. However, there are disadvantages associated with all of these approaches, including cost, operational complexities and the need for disposal of resin, brine or reject water. Conventional municipal water treatment processes (coagulation, sedimentation, filtration and chlorination) are not effective for nitrate removal, as nitrate is a stable and highly soluble ion with low potential for co-precipitation and adsorption.

In systems with a water source containing naturally occurring ammonia or that add ammonia for chloramination, free ammonia entering the distribution system can be one of the causative factors of nitrification and the potential increase of nitrate and nitrite in the distribution system. Care should be taken with the use of chloramination for providing a residual disinfectant in the distribution system. It is important to manage this to minimize nitrite formation, either in the main distribution system or in the distribution systems of buildings.

Nitrilotriacetic acid

Nitrilotriacetic acid, or NTA, is used primarily in laundry detergents as a replacement for phosphates and in the treatment of boiler water to prevent accumulation of mineral scale.

Guideline value	0.2 mg/l (200 µg/l)
Occurrence	Concentrations in drinking-water usually do not exceed a few micrograms per litre, although concentrations as high as 35 µg/l have been measured
TDI	10 µg/kg body weight, based on nephritis and nephrosis in a 2-year study in rats and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for carcinogenic potential at high doses)
Limit of detection	0.2 µg/l using GC with a nitrogen-specific detector
Treatment performance	No information found on removal from water
Guideline value derivation	
• allocation to water	50% of TDI
• weight	60 kg adult
• consumption	2 litres/day

Assessment date	1993
Principal reference	WHO (2003) *Nitrilotriacetic acid in drinking-water*

NTA is not metabolized in experimental animals and is rapidly eliminated, although some may be briefly retained in bone. It is of low acute toxicity to experimental animals, but it has been shown to produce kidney tumours in rodents following long-term exposure to doses higher than those required to produce nephrotoxicity. IARC has placed NTA in Group 2B (possibly carcinogenic to humans). It is not genotoxic, and the reported induction of tumours is believed to be due to cytotoxicity resulting from the chelation of divalent cations such as zinc and calcium in the urinary tract, leading to the development of hyperplasia and subsequently neoplasia.

Nitrobenzene

Nitrobenzene is used primarily in the production of aniline, but it is also used as a solvent, as an ingredient of metal polishes and soaps and in the synthesis of other organic compounds, including acetaminophen. Nitrobenzene can be released to water during these production processes.

Concentrations of nitrobenzene in environmental samples, such as surface water, groundwater and air, are generally low, except in areas with industrial pollution. Based on limited data, it appears that the potential for contamination is greater for groundwater than for surface water.

The general population can be exposed to variable concentrations of nitrobenzene in air and possibly drinking-water. Only populations in the vicinity of manufacturing activities and petroleum refining plants are likely to have any significant exposure to nitrobenzene; however, people living in and around abandoned hazardous waste sites may also have potential for higher exposure, due to possible groundwater and soil contamination and uptake of nitrobenzene by plants.

Reason for not establishing a guideline value	Rarely found in drinking-water at concentrations of health concern
Assessment date	2009
Principal reference	WHO (2009) *Nitrobenzene in drinking-water*

Nitrobenzene is toxic to humans by the inhalation, dermal and oral routes of exposure. The main systemic effect associated with human exposure to nitrobenzene is methaemoglobinaemia. Although some recent studies have reported positive results in mutagenicity tests, it cannot be excluded that nitrobenzene is a non-genotoxic chemical. No long-term oral administration studies are available. Based on inhalation studies, IARC concluded that there was inadequate evidence in humans but sufficient evidence in experimental animals for the carcinogenicity of nitrobenzene and classified nitrobenzene in Group 2B (possibly carcinogenic to humans).

Because nitrobenzene occurrence in drinking-water at concentrations above trace levels is infrequent, it is not considered necessary to derive a formal guideline value. However, health-based values can be calculated to provide guidance in the event

of spills and where there are higher concentrations in industrial areas. Two health-based values are derived based on the limited available information: one for short-term exposure (30 µg/l) and the other for long-term exposure (8–63 µg/l, depending on end-point and approach used). It should be emphasized that the derivation of the long-term health-based values includes large uncertainties because of the dose metric conversion from inhalation studies and the possibility of increased metabolism to aniline in the gastrointestinal tract.

It should be emphasized that nitrobenzene is a potent methaemoglobinaemic agent in humans, which is of particular concern for bottle-fed infants. Currently, data are not adequate to determine a separate health-based value for this end-point.

It should also be noted that the reported odour threshold for nitrobenzene in water is 30–110 µg/l.

N-Nitrosodimethylamine

N-Nitrosodimethylamine, or NDMA, can occur in drinking-water through the degradation of dimethylhydrazine (a component of rocket fuel) as well as from several other industrial processes. It is also a contaminant of certain pesticides. NDMA has recently been identified as a disinfection by-product of chloramination (by the reaction of monochloramine with dimethylamine, a ubiquitous component of waters affected by wastewater discharges) and, to some extent, chlorination. NDMA can also be formed as a by-product of anion exchange treatment of water.

Guideline value	0.0001 mg/l (0.1 µg/l)
Occurrence	Where chloramination is used, distribution system samples can have much higher levels of NDMA than the finished water at the treatment plant; levels as high as 0.16 µg/l have been measured in the distribution system, but concentrations in water at the treatment plant are generally less than 0.01 µg/l
Basis of guideline value derivation	Hepatic biliary cystadenomas in female rats, the most sensitive carcinogenic end-point, observed in a drinking-water study, using a multistage model
Limit of detection	0.028 ng/l by capillary column GC and chemical ionization tandem MS; 0.4 ng/l by capillary column GC and high-resolution MS; 0.7–1.6 ng/l by GC-MS and ammonia positive chemical ionization detection
Treatment performance	The most common process for NDMA removal is UV irradiation. A concentration below 0.005 µg/l should be achievable by UV irradiation provided that the water is not grossly contaminated. NDMA is not removable by air stripping, activated carbon adsorption, reverse osmosis or biodegradation.
Additional comments	Potential methods for reducing the formation of NDMA during disinfection include avoiding the use of chloramination, use of breakpoint chlorination and removal of ammonia prior to chlorination.
Assessment date	2006
Principal references	IPCS (2002) *N-Nitrosodimethylamine* WHO (2008) *N-Nitrosodimethylamine in drinking-water*

There is conclusive evidence that NDMA is a potent carcinogen in experimental animals by several routes of exposure, including through ingestion of drinking-water. NDMA has been classified by IARC as probably carcinogenic to humans. The mechanism by which NDMA produces cancer is well understood to involve biotransformation by liver microsomal enzymes, generating the methyldiazonium ion. This reactive metabolite forms DNA adducts, with most evidence pointing to O^6-methylguanine as the likely proximal carcinogenic agent. As a consequence of the clear evidence of carcinogenicity, there have been few studies of other possible toxicity end-points.

There is also ample evidence that NDMA is genotoxic both in vivo and in vitro. Activation by liver microsomal S9 fractions is necessary for a positive in vitro result. The recent observation that human S9 fractions are much more active in promoting genotoxicity in the Ames test than rat S9 fractions suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

Although there have been several case–control studies and one cohort study of NDMA in humans, none of them can be used to derive a quantitative risk of cancer. The results are supportive of the assumption that NDMA consumption is positively associated with either gastric or colorectal cancer. However, none of the studies focused on drinking-water as the route of exposure; instead, they used estimations of total dietary intake of NDMA.

Parathion

Parathion (CAS No. 56-38-2) is a non-systemic insecticide that is used in many countries throughout the world. It is used as a fumigant and acaricide and as a pre-harvest soil and foliage treatment on a wide variety of crops, both outdoors and in greenhouses. Parathion released to the environment will adsorb strongly to the top layer of soil and is not likely to leach significantly. Parathion disappears from surface waters in about a week. The general population is not usually exposed to parathion from air or water. Parathion residues in food are the main source of exposure.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (1996) *Pesticide residues in food—1995 evaluations* WHO (2004) *Parathion in drinking-water*

Parathion inhibits cholinesterase activity in all species tested. There has been no evidence of carcinogenicity in 2-year rat studies. JMPR concluded that parathion is not genotoxic.

A health-based value of 10 µg/l can be calculated for parathion on the basis of an ADI of 0–0.004 mg/kg body weight based on a NOAEL of 0.4 mg/kg body weight per day in a 2-year study in rats for retinal atrophy and inhibition of brain acetylcholinesterase at the next higher dose, and using an uncertainty factor of 100 for interspecies and intraspecies variation. Lower NOAELs in experimental animals, based only on inhibition of erythrocyte or brain acetylcholinesterase, were not considered relevant

because of the availability of a NOAEL for erythrocyte acetylcholinesterase inhibition in humans, which was 0.1 mg/kg body weight per day.

Intake of parathion from all sources is generally low and well below the upper limit of the ADI. As the health-based value is much higher than concentrations of parathion likely to be found in drinking-water, the presence of parathion in drinking-water under usual conditions is unlikely to represent a hazard to human health. For this reason, the establishment of a formal guideline value for parathion is not deemed necessary.

Pendimethalin

Pendimethalin (CAS No. 40487-42-1) is a pre-emergence herbicide that is fairly immobile and persistent in soil. It is used in large amounts in Japan (5000 tonnes per year). It is lost through photodegradation, biodegradation and volatilization. The leaching potential of pendimethalin appears to be very low, but little is known about its more polar degradation products.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Rarely found in drinking-water in the limited studies available
TDI	5 µg/kg body weight, based on evidence of slight liver toxicity even at the lowest dose tested (5 mg/kg body weight) in a long-term rat feeding study, with an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for a combination of the use of a LOAEL instead of a NOAEL and limitations of the database)
Limit of detection	0.01 µg/l by GC-MS
Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Pendimethalin in drinking-water*

In a short-term dietary study in rats, a variety of indications of hepatotoxicity as well as increased kidney weights in males were observed at the highest dose level. In a long-term dietary study, some toxic effects (hyperglycaemia in the mouse and hepatotoxicity in the rat) were present even at the lowest dose level. On the basis of available data, pendimethalin does not appear to have significant mutagenic activity. Long-term studies in mice and rats have not provided evidence of carcinogenicity; however, these studies have some important methodological limitations.

Pentachlorophenol

Pentachlorophenol (CAS No. 87-86-5), or PCP, and other chlorophenols are used primarily for protecting wood from fungal growth. Food is usually the major source of exposure to PCP unless there is a specific local contamination of drinking-water by PCP or exposure from log homes treated with PCP.

Provisional guideline value	0.009 mg/l (9 µg/l)
	The guideline value is considered provisional because of the variations in metabolism between experimental animals and humans.
Occurrence	Concentrations in water samples are usually below 10 µg/l, although much higher concentrations in groundwater may be measured under certain conditions
Basis of guideline value derivation	Multistage modelling of tumour incidence in an NTP bioassay without incorporation of a body surface area correction, recognizing that there are interspecies differences in metabolism between experimental animals and humans, with an important metabolite formed in rats being only a minor metabolite in humans
Limit of detection	0.005–0.01 µg/l by GC with ECD
Treatment performance	0.4 µg/l should be achievable using GAC
Additional comments	The concentration of PCP associated with a 10^{-5} upper-bound excess lifetime cancer risk is similar to the guideline value established in the second edition, so that guideline value is retained.
Assessment date	1998
Principal reference	WHO (2003) *Pentachlorophenol in drinking-water*

IARC classified PCP in Group 2B (possibly carcinogenic to humans) on the basis of inadequate evidence of carcinogenicity in humans but sufficient evidence in experimental animals. There is suggestive, although inconclusive, evidence of the carcinogenicity of PCP from epidemiological studies of populations exposed to mixtures that include PCP. Conclusive evidence of carcinogenicity has been obtained in one animal species (mice). Although there are notable variations in metabolism between experimental animals and humans, it was considered prudent to treat PCP as a potential carcinogen.

Perchlorate

Perchlorate is a naturally occurring anion that is frequently detected in the environment. It is used primarily as an oxidizer for solid rocket fuels, automotive airbags, fireworks and road flares. Perchlorate is found in water due to contamination from perchlorate manufacturing or use, natural deposits of perchlorate, use of fertilizers containing natural deposits of perchlorate, and natural formation of perchlorate in the atmosphere and its deposition during rain or snow events. It also forms in hypochlorite solutions to varying degrees, depending on the hypochlorite concentration, age and storage conditions.

Guideline value	0.07 mg/l (70 µg/l)
Occurrence	Generally found in drinking-water at concentrations below 10 µg/l, although concentrations above 40 µg/l have been measured
PMTDI	0.01 mg/kg bw, based on a $BMDL_{50}$ of 0.11 mg/kg bw per day for 50% inhibition of iodide uptake, derived from a human clinical study on healthy adult volunteers administered perchlorate in drinking-water, and using an uncertainty factor of 10 to account for inter-individual differences

Limit of detection	20–50 ng/l (method reporting limits) by LC-MS; 4 µg/l (method reporting limit) by IC with suppressed conductivity detection
Treatment performance	The perchlorate anion is highly stable in water and is difficult to remove using conventional water treatment technologies. Treatment technologies that have been shown to effectively remove perchlorate from water include nanofiltration and reverse osmosis membranes, anaerobic biodegradation and ion exchange.
Guideline value derivation	
• allocation to water	20% of unrounded PMTDI (0.011 mg/kg bw)
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	2016
Principal references	EFSA (2014). *Scientific opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables* FAO/WHO (2011). *Safety evaluation of certain contaminants in food* *WHO (2016). Perchlorate in drinking-water*

The primary effect of perchlorate is its ability to competitively inhibit uptake of iodide by the thyroid gland. Inhibition of iodide uptake by perchlorate reduces the amount of iodide available for the synthesis of thyroid hormones. Sustained reduction in iodide uptake by the thyroid may result in hypothyroidism, which has adverse implications for structural and functional brain development in the fetus, infant and child, and for metabolism and the functioning of the cardiovascular, gastrointestinal, skeletal, neuromuscular and reproductive systems in adults. As the rat is not a good model for humans for substances known to affect the thyroid and having a mode of action involving inhibition of the uptake of iodide, the guideline value was derived from human studies.

Petroleum products

Petroleum products are used in large quantities, primarily as fuels. They are complex mixtures of chemicals derived from crude oil by distillation and fractionation. They consist primarily of a wide range of aliphatic and aromatic hydrocarbons, many of which are of extremely low solubility in water. Petroleum products are widely stored and handled and are often spilt. The primary concern for drinking-water is the potential for spills into source water, penetration of distribution systems and contamination of drinking-water treatment works.

Reason for not establishing a guideline value	Taste and odour will in most cases be detectable at concentrations below those of health concern, particularly with short-term exposure
Assessment date	2004
Principal reference	WHO (2008) *Petroleum products in drinking-water*

Exposure to the constituents of petroleum products through drinking-water is frequently short term, as the result of an accidental spill or short-term incident. Such incidents may lead to high concentrations of total petroleum hydrocarbons. However,

a number of the most soluble aromatic hydrocarbons will be detectable by taste or odour at concentrations below those concentrations of concern for health, particularly for short-term exposure. Substances such as the alkyl benzenes and the alkyl naphthalenes have taste and odour thresholds of a few micrograms per litre. In view of the above, it is not considered appropriate to set a formal health-based guideline value for petroleum products in drinking-water.

In the event of a spill, it may be necessary to carry out a context-specific assessment of the risk to health. The fact that petroleum products are complex mixtures of many individual hydrocarbons is a complicating factor in determining the potential risks to consumers. The traditional approach of evaluating individual chemicals in assessing the risks from drinking-water is therefore largely inappropriate. In order to overcome this difficulty, it is more practical to consider a series of hydrocarbon fractions and to determine appropriate tolerable concentrations for those fractions. The most widely accepted approach is that developed by the Total Petroleum Hydrocarbons Criteria Working Group in the USA, which divided total petroleum hydrocarbons into a series of aliphatic and aromatic fractions based on the number of carbon atoms and the boiling point, to give equivalent carbon numbers.

This pragmatic approach provides a suitable basis for assessing the potential health risks associated with larger-scale contamination of drinking-water by petroleum products. The allocation of 10% of each of the reference doses, equivalent to TDIs, for the various fractions to drinking-water provides a conservative assessment of the risks. Although the approach is based on the analysis of hydrocarbon fractions, most are of low solubility, and the most soluble fractions, consisting largely of lower molecular weight aromatic hydrocarbons, will be present in the greatest concentration.

pH

No health-based guideline value is proposed for pH. Although pH usually has no direct impact on consumers, it is one of the most important operational water quality parameters (see chapter 10).

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	An important operational water quality parameter
Assessment date	1993
Principal reference	WHO (2007) *pH in drinking-water*

2-Phenylphenol and its sodium salt

2-Phenylphenol (CAS No. 90-43-7) is used as a disinfectant, bactericide and virucide. In agriculture, it is used in disinfecting fruits, vegetables and eggs. It is also used as a general surface disinfectant in hospitals, nursing homes, veterinary hospitals, poultry farms, dairy farms, commercial laundries, barbershops and food processing plants. 2-Phenylphenol is readily degraded in surface waters, with a half-life of about 1 week in river water.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal references	FAO/WHO (2000) *Pesticide residues in food—1999 evaluations* WHO (2003) *2-Phenylphenol and its sodium salt in drinking-water*

2-Phenylphenol has been determined to be of low toxicity. Both 2-phenylphenol and its sodium salt are carcinogenic in male rats, and 2-phenylphenol is carcinogenic in male mice. However, urinary bladder tumours observed in male rats and liver tumours observed in male mice exposed to 2-phenylphenol appear to be threshold phenomena that are species and sex specific. JMPR concluded that 2-phenylphenol is unlikely to represent a carcinogenic risk to humans. Although a working group convened by IARC classified 2-phenylphenol, sodium salt, in Group 2B (possibly carcinogenic to humans) and 2-phenylphenol in Group 3 (not classifiable as to its carcinogenicity to humans), JMPR noted that the IARC classification is based on hazard identification, not risk assessment, and is furthermore limited to published literature, excluding unpublished studies on toxicity and carcinogenicity. JMPR also concluded that there are unresolved questions about the genotoxic potential of 2-phenylphenol.

A health-based value of 1 mg/l can be calculated for 2-phenylphenol on the basis of an ADI of 0–0.4 mg/kg body weight, based on a NOAEL of 39 mg/kg body weight per day in a 2-year toxicity study on the basis of decreased body weight gain and hyperplasia of the urinary bladder and carcinogenicity of the urinary bladder in male rats, using an uncertainty factor of 100 for interspecies and intraspecies variation. Because of its low toxicity, however, the health-based value derived for 2-phenylphenol is much higher than concentrations of 2-phenylphenol likely to be found in drinking-water. Under usual conditions, therefore, the presence of 2-phenylphenol in drinking-water is unlikely to represent a hazard to human health. For this reason, the establishment of a formal guideline value for 2-phenylphenol is not deemed necessary.

Polynuclear aromatic hydrocarbons

Polynuclear aromatic hydrocarbons, or PAHs, form a class of diverse organic compounds each containing two or more fused aromatic rings of carbon and hydrogen atoms. Most PAHs enter the environment via the atmosphere from a variety of combustion processes and pyrolysis sources. Owing to their low solubility and high affinity for particulate matter, they are not usually found in water in notable concentrations. The main source of PAH contamination in drinking-water is usually the coal tar coating of drinking-water distribution pipes, used to protect the pipes from corrosion. Fluoranthene is the most commonly detected PAH in drinking-water and is associated primarily with coal tar linings of cast iron or ductile iron distribution pipes. PAHs have been detected in a variety of foods as a result of the deposition of airborne PAHs and in fish from contaminated waters. PAHs are also formed during some methods of food preparation, such as char-broiling, grilling,

roasting, frying or baking. For the general population, the major routes of exposure to PAHs are from food and ambient and indoor air. The use of open fires for heating and cooking, which is common especially in developing countries, may increase PAH exposure. Where there are elevated levels of contamination by coal tar coatings of water pipes, PAH intake from drinking-water could equal or even exceed that from food.

Guideline value	*Benzo[a]pyrene:* 0.0007 mg/l (0.7 µg/l)
Occurrence	PAH levels in uncontaminated groundwater usually in range 0–5 ng/l; concentrations in contaminated groundwater may exceed 10 µg/l; typical concentration range for sum of selected PAHs in drinking-water is from about 1 ng/l to 11 µg/l
Basis of guideline value derivation	Based on an oral carcinogenicity study in mice and calculated using a two-stage birth–death mutation model, which incorporates variable dosing patterns and time of killing; quantification of dose–response for tumours, on the basis of new studies in which the carcinogenicity of benzo[*a*]pyrene was examined following oral administration in mice, but for which the number of dose groups was smaller, confirms this value
Limit of detection	0.01 µg/l by GC-MS and reversed-phase HPLC with a fluorescence detector
Treatment performance	0.05 µg/l should be achievable using coagulation
Additional comments	The presence of significant concentrations of benzo[a]pyrene in drinking-water in the absence of very high concentrations of fluoranthene indicates the presence of coal tar particles, which may arise from seriously deteriorating coal tar pipe linings.
	It is recommended that the use of coal tar–based and similar materials for pipe linings and coatings on storage tanks be discontinued.
Assessment date	1998
Principal reference	WHO (2003) *Polynuclear aromatic hydrocarbons in drinking-water*

Reason for not establishing a guideline value	*Fluoranthene:* Occurs in drinking-water at concentrations well below those of health concern
Assessment date	1998
Principal reference	WHO (2003) *Polynuclear aromatic hydrocarbons in drinking-water*

Evidence that mixtures of PAHs are carcinogenic to humans comes primarily from occupational studies of workers following inhalation and dermal exposure. No data are available for humans for the oral route of exposure. There are few data on the oral toxicity of PAHs other than benzo[*a*]pyrene, particularly in drinking-water. Relative potencies of carcinogenic PAHs have been determined by comparison of data from dermal and other studies. The order of potencies is consistent, and this scheme therefore provides a useful indicator of PAH potency relative to that of benzo[*a*]pyrene.

A health-based value of 4 µg/l can be calculated for fluoranthene on the basis of a NOAEL of 125 mg/kg body weight per day for increased serum glutamate–pyruvate transaminase levels, kidney and liver pathology, and clinical and haematological changes in a 13-week oral gavage study in mice, using an uncertainty factor of 10 000 (100 for interspecies and intraspecies variation, 10 for the use of a subchronic study and inadequate database and 10 because of clear evidence of co-carcinogenicity with benzo[*a*]pyrene in mouse skin painting studies). However, this health-based value is significantly above the concentrations normally found in drinking-water. Under usual conditions, therefore, the presence of fluoranthene in drinking-water does not represent a hazard to human health. For this reason, the establishment of a formal guideline value for fluoranthene is not deemed necessary.

Potassium

Potassium is an essential element in humans and is seldom, if ever, found in drinking-water at levels that could be a concern for healthy humans. The recommended daily requirement is greater than 3000 mg. Potassium occurs widely in the environment, including all natural waters. It can also occur in drinking-water as a consequence of the use of potassium permanganate as an oxidant in water treatment. In some countries, potassium chloride is being used in ion exchange for household water softening in place of, or mixed with, sodium chloride, so potassium ions would exchange with calcium and magnesium ions. Possible replacement or partial replacement of sodium salts with potassium salts for conditioning desalinated water has been suggested. The latter seems to be an unlikely development at this stage, in view of the cost difference.

Reason for not establishing a guideline value	Occurs in drinking-water at concentrations well below those of health concern
Assessment date	2009
Principal reference	WHO (2009) *Potassium in drinking-water*

Currently, there is no evidence that potassium levels in municipally treated drinking-water, even water treated with potassium permanganate, are likely to pose any risk for the health of consumers. It is not considered necessary to establish a health-based guideline value for potassium in drinking-water.

Although potassium may cause some health effects in susceptible individuals, potassium intake from drinking-water is well below the level at which adverse health effects may occur. Health concerns would be related to the consumption of drinking-water treated by potassium-based water treatment (principally potassium chloride for regeneration of ion exchange water softeners), affecting only individuals in high-risk groups (i.e. individuals with kidney dysfunction or other diseases, such as heart disease, coronary artery disease, hypertension, diabetes, adrenal insufficiency, pre-existing hyperkalaemia; people taking medications that interfere with normal potassium-dependent functions in the body; and older individuals or infants). It is recommended that susceptible individuals seek medical advice to determine whether they should avoid the consumption of water (for drinking or cooking) treated by water softeners using potassium chloride.

When high-risk individuals have been advised by a physician to avoid elevated potassium intake from water, the recommended strategy is to limit the addition of potassium to water that will be ingested or to avoid ingesting such water. This can be done by having a proportion of the water bypass the softener altogether; this approach is recommended by several countries. Although technologies are available to remove potassium, they are generally more expensive and redundant when combined with the softening treatment.

Propanil

Propanil (CAS No. 709-98-8) is a contact post-emergence herbicide used to control broad-leaved and grassy weeds, mainly in rice. It is a mobile compound with affinity for the water compartment. Propanil is not, however, persistent, being easily transformed under natural conditions to several metabolites. Two of these metabolites, 3,4-dichloroaniline and 3,3′,4,4′-tetrachloroazobenzene, are more toxic and more persistent than the parent compound. Although used in a number of countries, propanil has only occasionally been detected in groundwater.

Reason for not establishing a guideline value	Readily transformed into metabolites that are more toxic; a guideline value for the parent compound is considered inappropriate, and there are inadequate data to enable the derivation of guideline values for the metabolites
Assessment date	2003
Principal reference	WHO (2003) *Propanil in drinking-water*

Although a health-based value for propanil can be derived, this has not been done, because propanil is readily transformed into metabolites that are more toxic. Therefore, a guideline value for the parent compound is considered inappropriate, and there are inadequate data on the metabolites to allow the derivation of guideline values for them. Authorities should consider the possible presence in water of more toxic environmental metabolites.

Selenium

Selenium is present in Earth's crust, often in association with sulfur-containing minerals. Selenium is an essential trace element, and foodstuffs such as cereals, meat and fish are the principal source of selenium for the general population. Levels in food also vary greatly according to geographical area of production. However, even in high-selenium areas, the relative contribution of selenium from drinking-water is likely to be small in comparison with that from locally produced food.

Provisional guideline value	0.04 mg/l (40 µg/l)
	The guideline value is designated as provisional because of the uncertainties inherent in the scientific database.
Occurrence	Most drinking-water contains concentrations of selenium that are much lower than 10 µg/l, except in certain seleniferous areas

Basis of guideline value derivation	An allocation of 20% of the upper tolerable intake of 400 µg/day to drinking-water provides a sensible balance that will assist regulators and suppliers in making decisions about whether further action is needed
Limit of detection	0.5 µg/l by hydride generation AAS
Treatment performance	Selenium is not removed by conventional treatment processes; significant removals of selenium from water using activated alumina adsorption, ion exchange, reverse osmosis and nanofiltration have been reported.
Guideline value derivation	
• allocation to water	20% of upper tolerable intake
• consumption	2 litres/day
Additional comments	It is important that a proper balance be achieved between recommended intakes and undesirable intakes in determining an appropriate guideline value for selenium in drinking-water. While for most parts of the world, the concentration of selenium in drinking-water will not exceed 10 µg/l, there are circumstances in which selenium may be elevated significantly above normal concentrations, and guidance may be required. Where selenium intake from the diet is known, this should be used in determining a concentration that ensures that intake is safe and sufficient. Where selenium intake from the diet is not known, guidance may be required.
	For most Member States, a drinking-water guideline for selenium is unnecessary. Where there are regions of high intake from a number of sources, of which drinking-water may be one, then Member States should take into consideration exposure from all sources in determining actions to reduce exposure. For drinking-water, this may include using alternative sources, blending low-selenium sources with high-selenium sources as well as considering selenium removal.
Assessment date	2010
Principal references	FAO/WHO (2004) *Vitamin and mineral requirements in human nutrition* WHO (2011) *Selenium in drinking-water*

Selenium is an essential element for humans, and there are indications that selenium status may be marginal in many parts of the world, including western Europe. The potential for adverse effects from selenium deficiency appears to be dependent on a number of factors, including overall health and nutritional status. Very low selenium status in humans has been associated with a juvenile, multifocal myocarditis called Keshan disease and a chondrodystrophy called Kaschin-Beck disease. Several studies have also found blood selenium levels to be inversely associated with the prevalence of several types of cancer.

High intakes of selenium are also associated with a number of specific diseases and the potential for adverse effects, but, again, this seems to be strongly influenced by other factors. Symptoms in people with high urinary selenium levels included gastrointestinal disturbances, discoloration of the skin, decayed teeth, hair or nail loss, nail abnormalities and changes in peripheral nerves. Slight biochemical changes have also been observed. One case of selenium toxicity directly attributable to a water source (well water containing selenium at a concentration of 9 mg/l) has been reported. The

average dietary intake that is associated with selenosis has been found to be in excess of 900 μg/day.

As selenium is an essential element, various national and international organizations have established recommended daily intakes of selenium. A joint FAO/WHO consultation recommended intakes of 6–21 μg of selenium per day for infants and children, according to age, 26 and 30 μg of selenium per day for adolescent females and males, respectively, and 26 and 35 μg of selenium per day for adult females and males, respectively.

Because of concern about the adverse effects resulting from exposure to excessive levels of selenium, various national and international organizations have established upper limits of exposure for selenium. FAO/WHO established an upper tolerable limit for selenium of 400 μg/day.

Silver

Silver occurs naturally, mainly in the form of its very insoluble and immobile oxides, sulfides and some salts. It has occasionally been found in groundwater, surface water and drinking-water at concentrations above 5 μg/l. Levels in drinking-water treated with silver for disinfection may be above 50 μg/l. Recent estimates of daily intake are about 7 μg per person.

Reason for not establishing a guideline value	Available data inadequate to permit derivation of health-based guideline value
Assessment date	1993
Principal reference	WHO (2003) *Silver in drinking-water*

Only a small percentage of silver is absorbed. Retention rates in humans and laboratory animals range between 0% and 10%.

The only obvious sign of silver overload is argyria, a condition in which skin and hair are heavily discoloured by silver in the tissues. An oral NOAEL for argyria in humans for a total lifetime intake of 10 g of silver was estimated on the basis of human case reports and long-term experiments with laboratory animals.

The low levels of silver in drinking-water, generally below 5 μg/l, are not relevant to human health with respect to argyria. In contrast, special situations exist where silver salts may be used to maintain the bacteriological quality of drinking-water. Higher levels of silver, up to 0.1 mg/l (this concentration gives a total dose over 70 years of half the human NOAEL of 10 g), could be tolerated in such cases without risk to health.

There are no adequate data with which to derive a health-based guideline value for silver in drinking-water.

Simazine

Simazine (CAS No. 122-34-9) is a pre-emergence herbicide used on a number of crops as well as in non-crop areas. It is fairly resistant to physical and chemical dissipation processes in the soil. It is persistent and mobile in the environment.

Guideline value	0.002 mg/l (2 µg/l)
Occurrence	Frequently detected in groundwater and surface water at concentrations of up to a few micrograms per litre
TDI	0.52 µg/kg body weight, based on a NOAEL of 0.52 mg/kg body weight from a long-term study in the rat (based on weight changes, effects on haematological parameters and an increase in mammary tumours) and an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for possible non-genotoxic carcinogenicity)
Limit of detection	0.01 µg/l by GC-MS; 0.1–0.2 µg/l by GC with flame thermionic detection
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Simazine in drinking-water*

Simazine does not appear to be genotoxic in mammalian systems. Recent studies have shown an increase in mammary tumours in the female rat but no effects in the mouse. IARC has classified simazine in Group 3 (not classifiable as to its carcinogenicity to humans).

Sodium

Sodium salts (e.g. sodium chloride) are found in virtually all food (the main source of daily exposure) and drinking-water. Although concentrations of sodium in potable water are typically less than 20 mg/l, they can greatly exceed this in some countries. The levels of sodium salts in air are normally low in relation to those in food or water. It should be noted that some water softeners can add significantly to the sodium content of drinking-water.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) *Sodium in drinking-water*

No firm conclusions can be drawn concerning the possible association between sodium in drinking-water and the occurrence of hypertension. Therefore, no health-based guideline value is proposed. However, concentrations in excess of 200 mg/l may give rise to unacceptable taste (see chapter 10).

Sodium dichloroisocyanurate

Sodium dichloroisocyanurate is the sodium salt of a chlorinated hydroxytriazine and is used as a source of free available chlorine, in the form of hypochlorous acid, for the disinfection of water. It is widely used as a stable source of chlorine for the disinfection of swimming pools and in the food industry. It is also used as a means of disinfecting drinking-water, primarily in emergencies, when it provides an easy-to-use source of free chlorine, and, more recently, as the form of chlorine for household point-of-use water treatment.

Guideline values	*Sodium dichloroisocyanurate:* 50 mg/l (50 000 µg/l)
	Cyanuric acid: 40 mg/l (40 000 µg/l)
Occurrence	Where sodium dichloroisocyanurate is used for the disinfection of drinking-water, exposure will be to both the chlorinated species and residual cyanuric acid. The concentrations will relate directly to the quantities added to achieve adequate disinfection.
TDI	2.2 mg/kg body weight for anhydrous sodium dichloroisocyanurate and 1.54 mg/kg body weight for cyanuric acid, based on a NOEL of 154 mg/kg body weight per day (equivalent to 220 mg/kg body weight per day as anhydrous sodium dichloroisocyanurate) for urinary tract and cardiac lesions from a 2-year study of rats exposed to sodium cyanurate and using an uncertainty factor of 100 for interspecies and intraspecies variation
Limit of detection	0.001 mg/l by GC with flame thermionic specific detection; 0.05 mg/l by reversed-phase LC with UV detection; 0.09 mg/l by GC with MS selective ion monitoring
Treatment performance	At very high chlorine doses (up to 10 mg/l), the sodium cyanurate concentration would be below 11 mg/l. In emergency situations, "topping up" might be done in an attempt to maintain a free chlorine residual, but this practice should be discouraged. In this case, it would be possible for the sodium cyanurate concentration to build up to undesirable levels. In such cases, it would be very desirable to monitor the concentration of sodium cyanurate.
Guideline value derivation	
• allocation to water	80% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The controlling factors are the level of free chlorine and the residue of cyanuric acid, particularly if there is topping up of chlorine in a static system under emergency conditions. The concentration of free chlorine should normally be such that it should not give rise to unacceptable tastes and should not normally exceed the guideline value of 5 mg/l for free chlorine.
	Sodium dichloroisocyanurate used for disinfecting drinking-water should be of adequate purity so that there is no increase in any inorganic or organic contaminants in the drinking-water. The amounts of sodium dichloroisocyanurate used should be the lowest consistent with adequate disinfection, and the concentrations of cyanuric acid should be managed to be kept as low as is reasonably possible.

Assessment date	2007
Principal references	FAO/WHO (2004) *Evaluation of certain food additives and contaminants* WHO (2008) *Sodium dichloroisocyanurate in drinking-water*

Studies of the toxicity of sodium cyanurate are appropriate for assessing the safety of sodium dichloroisocyanurate, because any residues of intact sodium dichloroisocyanurate in drinking-water would be rapidly converted to cyanuric acid on contact with saliva. Both sodium dichloroisocyanurate and sodium cyanurate have low acute oral toxicity. Sodium cyanurate does not induce any genotoxic, carcinogenic or teratogenic effects. The NOEL from which the guideline value was derived was based on multiple lesions of the urinary tract (calculi and hyperplasia, bleeding and inflammation of the bladder epithelium, dilated and inflamed ureters and renal tubular nephrosis) and cardiac lesions (acute myocarditis, necrosis and vascular mineralization) in male rats exposed at the next higher dose.

Styrene

Styrene, which is used primarily for the production of plastics and resins, is found in trace amounts in surface water, drinking-water and food. In industrial areas, exposure via air can result in intake of a few hundred micrograms per day. Smoking may increase daily exposure by up to 10-fold.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Has been detected in drinking-water and surface water at concentrations below 1 µg/l
TDI	7.7 µg/kg body weight, based on a NOAEL of 7.7 mg/kg body weight per day for decreased body weight observed in a 2-year drinking-water study in rats, and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the carcinogenicity and genotoxicity of the reactive intermediate styrene-7,8-oxide)
Limit of detection	0.3 µg/l by GC with photoionization detection and confirmation by MS
Treatment performance	0.02 mg/l may be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	May affect the acceptability of drinking-water at the guideline value
Assessment date	1993
Principal reference	WHO (2003) *Styrene in drinking-water*

Following oral or inhalation exposure, styrene is rapidly absorbed and widely distributed in the body, with a preference for lipid depots. It is metabolized to the active intermediate styrene-7,8-oxide, which is conjugated with glutathione or further metabolized. Metabolites are rapidly and almost completely excreted in urine. Styrene

has a low acute toxicity. In short-term toxicity studies in rats, impairment of glutathione transferase activity and reduced glutathione concentrations were observed. In in vitro tests, styrene has been shown to be mutagenic in the presence of metabolic activation only. In in vitro as well as in vivo studies, chromosomal aberrations have been observed, mostly at high doses of styrene. The reactive intermediate styrene-7,8-oxide is a direct-acting mutagen. In long-term studies, orally administered styrene increased the incidence of lung tumours in mice at high dose levels but had no carcinogenic effect in rats. Styrene-7,8-oxide was carcinogenic in rats after oral administration. IARC has classified styrene in Group 2B (possibly carcinogenic to humans). The available data suggest that the carcinogenicity of styrene is due to overloading of the detoxification mechanism for styrene-7,8-oxide (e.g. glutathione depletion).

Sulfate

Sulfates occur naturally in numerous minerals and are used commercially, principally in the chemical industry. They are discharged into water in industrial wastes and through atmospheric deposition; however, the highest levels usually occur in groundwater and are from natural sources. In general, the average daily intake of sulfate from drinking-water, air and food is approximately 500 mg, food being the major source. However, in areas with drinking-water supplies containing high levels of sulfate, drinking-water may constitute the principal source of intake.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	2003
Principal reference	WHO (2004) *Sulfate in drinking-water*

The existing data do not identify a level of sulfate in drinking-water that is likely to cause adverse human health effects. The data from a liquid diet study with piglets and from tap water studies with human volunteers indicate a laxative effect at concentrations of 1000–1200 mg/l, but no increase in diarrhoea, dehydration or weight loss.

No health-based guideline is proposed for sulfate. However, because of the gastrointestinal effects resulting from ingestion of drinking-water containing high sulfate levels, it is recommended that health authorities be notified of sources of drinking-water that contain sulfate concentrations in excess of 500 mg/l. The presence of sulfate in drinking-water may also cause noticeable taste (see chapter 10) and may contribute to the corrosion of distribution systems.

2,4,5-T

The half-lives for degradation of chlorophenoxy herbicides, including 2,4,5-T (CAS No. 93-76-5), also known as 2,4,5-trichlorophenoxyacetic acid, in the environment are in the order of several days. Chlorophenoxy herbicides are not often found in food.

Guideline value	0.009 mg/l (9 µg/l)
Occurrence	Chlorophenoxy herbicides not frequently found in drinking-water; when detected, concentrations usually no greater than a few micrograms per litre
TDI	3 µg/kg body weight, based on a NOAEL of 3 mg/kg body weight for reduced body weight gain, increased liver and kidney weights and renal toxicity in a 2-year study in rats, with an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 to take into consideration the suggested association between 2,4,5-T and soft tissue sarcoma and non-Hodgkin lymphoma in epidemiological studies)
Limit of detection	0.02 µg/l by GC with ECD
Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Chlorophenoxy herbicides (excluding 2,4-D and MCPA) in drinking-water*

Chlorophenoxy herbicides, as a group, have been classified in Group 2B (possibly carcinogenic to humans) by IARC. However, the available data from studies in exposed populations and experimental animals do not permit assessment of the carcinogenic potential to humans of any specific chlorophenoxy herbicide. Therefore, drinking-water guidelines for these compounds are based on a threshold approach for other toxic effects. The NOAEL for reproductive effects (reduced neonatal survival, decreased fertility, reduced relative liver weights and thymus weights in litters) of dioxin-free (< 0.03 µg/kg) 2,4,5-T in a three-generation reproduction study in rats is the same as the NOAEL for reduced body weight gain, increased liver and kidney weights and renal toxicity in a toxicity study in which rats were fed 2,4,5-T (practically free from dioxin contamination) in the diet for 2 years.

Terbuthylazine

Terbuthylazine (CAS No. 5915-41-3), or TBA, a herbicide that belongs to the chlorotriazine family, is used in both pre-emergence and post-emergence treatment of a variety of agricultural crops and in forestry. Degradation of TBA in natural water depends on the presence of sediments and biological activity.

Guideline value	0.007 mg/l (7 µg/l)
Occurrence	Concentrations in water seldom exceed 0.2 µg/l, although higher concentrations have been observed.
TDI	2.2 µg/kg body weight, based on a NOAEL of 0.22 mg/kg body weight for decreased body weight gain at the next higher dose in a 2-year toxicity/carcinogenicity study in rats, with an uncertainty factor of 100 (for interspecies and intraspecies variation)

Limit of detection	0.1 µg/l by HPLC with UV detection
Treatment performance	0.1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1998
Principal reference	WHO (2003) *Terbuthylazine in drinking-water*

There is no evidence that TBA is carcinogenic or mutagenic. In long-term dietary studies in rats, effects on red blood cell parameters in females, an increased incidence of non-neoplastic lesions in the liver, lung, thyroid and testis and a slight decrease in body weight gain were observed.

Tetrachloroethene

Tetrachloroethene has been used primarily as a solvent in dry cleaning industries and to a lesser extent as a degreasing solvent. It is widespread in the environment and is found in trace amounts in water, aquatic organisms, air, foodstuffs and human tissue. The highest environmental levels of tetrachloroethene are found in the commercial dry cleaning and metal degreasing industries. Emissions can sometimes lead to high concentrations in groundwater. Tetrachloroethene in anaerobic groundwater may degrade to more toxic compounds, including vinyl chloride.

Guideline value	0.04 mg/l (40 µg/l)
Occurrence	Concentrations in drinking-water are generally below 3 µg/l, although much higher concentrations have been detected in well water (23 mg/l) and in contaminated groundwater (1 mg/l)
TDI	14 µg/kg body weight, based on hepatotoxic effects observed in a 6-week gavage study in male mice and a 90-day drinking-water study in male and female rats, and taking into consideration carcinogenic potential (but not the short length of the study, in view of the database and considerations regarding the application of the dose via drinking-water in one of the two critical studies)
Limit of detection	0.2 µg/l by GC with ECD; 4.1 µg/l by GC-MS
Treatment performance	0.001 mg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Assessment date	1993
Principal reference	WHO (2003) *Tetrachloroethene in drinking-water*

At high concentrations, tetrachloroethene causes central nervous system depression. Lower concentrations of tetrachloroethene have been reported to damage the liver and the kidneys. IARC has classified tetrachloroethene in Group 2A (probably carcinogenic to humans). Tetrachloroethene has been reported to produce liver tumours in male and female mice, with some evidence of mononuclear cell leukaemia in male and female rats and kidney tumours in male rats. The overall evidence from studies conducted to assess the genotoxicity of tetrachloroethene, including induction of single-strand DNA breaks, mutation in germ cells and chromosomal aberrations in vitro and in vivo, indicates that tetrachloroethene is not genotoxic.

Toluene

Most toluene (in the form of benzene–toluene–ethylbenzene–xylene mixtures) is used in the blending of petrol. It is also used as a solvent and as a raw material in chemical production. The main exposure is via air. Exposure is increased by smoking and in traffic.

Guideline value	0.7 mg/l (700 µg/l)
Occurrence	Concentrations of a few micrograms per litre have been found in surface water, groundwater and drinking-water; point emissions can lead to higher concentrations in groundwater (up to 1 mg/l); it may also penetrate plastic pipes from contaminated soil
TDI	223 µg/kg body weight, based on a LOAEL of 312 mg/kg body weight per day for marginal hepatotoxic effects observed in a 13-week gavage study in mice, adjusting for daily dosing and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the short duration of the study and use of a LOAEL instead of a NOAEL)
Limit of detection	0.13 µg/l by GC with FID; 6 µg/l by GC-MS
Treatment performance	0.001 mg/l should be achievable using air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value exceeds the lowest reported odour threshold for toluene in water.
Assessment date	2003
Principal reference	WHO (2003) *Toluene in drinking-water*

Toluene is absorbed completely from the gastrointestinal tract and rapidly distributed in the body, with a preference for adipose tissue. Toluene is rapidly metabolized and, following conjugation, excreted predominantly in urine. With occupational exposure to toluene by inhalation, impairment of the central nervous system and irritation of mucous membranes are observed. The acute oral toxicity is low. Toluene exerts embryotoxic and fetotoxic effects, but there is no clear evidence of teratogenic activity in laboratory animals and humans. In long-term inhalation studies in rats

and mice, there is no evidence for carcinogenicity of toluene. Genotoxicity tests in vitro were negative, whereas in vivo assays showed conflicting results with respect to chromosomal aberrations. IARC has concluded that there is inadequate evidence for the carcinogenicity of toluene in both experimental animals and humans and classified it as Group 3 (not classifiable as to its carcinogenicity to humans).

Total dissolved solids

Total dissolved solids (TDS) comprise inorganic salts (principally calcium, magnesium, potassium, sodium, bicarbonates, chlorides and sulfates) and small amounts of organic matter that are dissolved in water. TDS in drinking-water originates from natural sources, sewage, urban runoff and industrial wastewater. Salts used for road de-icing in some countries may also contribute to the TDS content of drinking-water. Concentrations of TDS in water vary considerably in different geological regions owing to differences in the solubilities of minerals.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) *Total dissolved solids in drinking-water*

Reliable data on possible health effects associated with the ingestion of TDS in drinking-water are not available, and no health-based guideline value is proposed. However, the presence of high levels of TDS in drinking-water may be objectionable to consumers (see chapter 10).

Trichloroacetic acid

Chlorinated acetic acids are formed from organic material during water chlorination.

Guideline value	0.2 mg/l (200 µg/l)
Occurrence	Detected in groundwater and surface water distribution systems in the USA at mean concentrations of 5.3 µg/l (up to a maximum of 80 µg/l) and 16 µg/l (up to a maximum of 174 µg/l), respectively; maximum concentration (200 µg/l) measured in chlorinated water in Australia
TDI	32.5 µg/kg body weight, based on a NOAEL of 32.5 mg/kg body weight per day from a study in which decreased body weight, increased liver serum enzyme activity and liver histopathology were seen in rats exposed to trichloroacetate in drinking-water for 2 years, incorporating an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for database deficiencies, including the absence of a multigeneration reproductive study, the lack of a developmental study in a second species and the absence of full histopathological data in a second species)
Limit of detection	1 µg/l by GC-MS or GC-ECD

Treatment performance	Concentrations may be reduced by installing or optimizing coagulation to remove precursors or by controlling the pH during chlorination.
Guideline value derivation	
• allocation to water	20% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	A similar TDI for trichloroacetate was established by IPCS based on a NOAEL for hepatic toxicity in a long-term study in mice.
Assessment date	2003
Principal reference	WHO (2003) *Trichloroacetic acid in drinking-water*

Trichloroacetic acid has been shown to induce tumours in the liver of mice. It has given mixed results in in vitro assays for mutations and chromosomal aberrations and has been reported to cause chromosomal aberrations in in vivo studies. IARC has classified trichloroacetic acid in Group 3, not classifiable as to its carcinogenicity to humans. The weight of evidence indicates that trichloroacetic acid is not a genotoxic carcinogen.

Trichlorobenzenes (total)

Releases of trichlorobenzenes (TCBs) into the environment occur through their manufacture and use as industrial chemicals, chemical intermediates and solvents. TCBs are found in drinking-water, but rarely at levels above 1 µg/l. General population exposure will primarily result from air and food.

Reason for not establishing a guideline value	Occur in drinking-water at concentrations well below those of health concern, and health-based value would exceed lowest reported odour threshold
Assessment date	2003
Principal reference	WHO (2003) *Trichlorobenzenes in drinking-water*

The TCBs are of moderate acute toxicity. After short-term oral exposure, all three isomers show similar toxic effects, predominantly on the liver. Long-term toxicity and carcinogenicity studies via the oral route have not been carried out, but the data available suggest that all three isomers are non-genotoxic.

A health-based value of 20 µg/l can be calculated for total TCBs on the basis of a TDI of 7.7 µg/kg body weight, based on liver toxicity identified in a 13-week rat study, taking into consideration the short duration of the study. However, because TCBs occur at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value. It should be noted that the health-based value exceeds the lowest reported odour threshold in water.

1,1,1-Trichloroethane

1,1,1-Trichloroethane is widely used as a cleaning solvent for electrical equipment, as a solvent for adhesives, coatings and textile dyes and as a coolant and lubricant. It is

found mainly in the atmosphere, although it is mobile in soils and readily migrates to groundwaters. 1,1,1-Trichloroethane has been found in only a small proportion of surface waters and groundwaters, usually at concentrations of less than 20 µg/l; higher concentrations (up to 150 µg/l) have been observed in a few instances. There appears to be increasing exposure to 1,1,1-trichloroethane from other sources.

Reason for not establishing a guideline value	Occur in drinking-water at concentrations well below those of health concern
Assessment date	2003
Principal reference	WHO (2003) *1,1,1-Trichloroethane in drinking-water*

1,1,1-Trichloroethane is rapidly absorbed from the lungs and gastrointestinal tract, but only small amounts—about 6% in humans and 3% in experimental animals—are metabolized. Exposure to high concentrations can lead to hepatic steatosis (fatty liver) in both humans and laboratory animals. In a well-conducted oral study in mice and rats, effects included reduced liver weight and changes in the kidney consistent with hyaline droplet neuropathy. IARC has placed 1,1,1-trichloroethane in Group 3. 1,1,1-Trichloroethane does not appear to be mutagenic.

A health-based value of 2 mg/l can be calculated for 1,1,1-trichloroethane on the basis of a TDI of 0.6 mg/kg body weight, based on changes in the kidney that were consistent with hyaline droplet nephropathy observed in a 13-week oral study in male rats, and taking into account the short duration of the study. However, because 1,1,1-trichloroethane occurs at concentrations well below those of health concern, it is not considered necessary to derive a formal guideline value.

Trichloroethene

Trichloroethene is used primarily in metal degreasing. It is emitted mainly to the atmosphere, but it may also be introduced into groundwater and, to a lesser extent, surface water in industrial effluents. Poor handling as well as improper disposal of trichloroethene in landfills have been the main causes of groundwater contamination. It is expected that exposure to trichloroethene from air will be greater than that from food or drinking-water, unless the drinking-water contains trichloroethene at levels above about 10 µg/l.

Provisional guideline value	0.02 mg/l (20 µg/l)
	The guideline value is designated as provisional because of deficiencies in the toxicological database.
Occurrence	Owing to its high volatility, concentrations are normally low (< 1 µg/l) in surface water; concentrations may be higher (usually below 100 µg/l) in groundwater systems where volatilization and biodegradation are limited
TDI	1.46 µg/kg body weight per day in a developmental toxicity study in rats, based on a $BMDL_{10}$ (the lower 95% confidence limit corresponding to a 10% increase in extra risk of fetal heart malformations over background) of 0.146 mg/kg body weight per day and using an uncertainty factor of 100 for intraspecies and interspecies variation

Limit of detection	0.01–3.0 µg/l by purge-and-trap capillary GC with photoionization detectors or with photoionization detectors and ECD in series; 0.5 µg/l by purge-and-trap capillary GC with MS; 0.01 µg/l by liquid–liquid extraction and GC-ECD; practical quantification limit considered to be achievable by most good laboratories is 5 µg/l
Treatment performance	0.002 mg/l should be achievable by air stripping, possibly in combination with GAC adsorption
Guideline value derivation	
• allocation to water	50% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value is protective for both cancer and non-cancer end-points.
	In countries with low rates of ventilation in houses and high rates of showering and bathing, authorities may wish to take the additional exposures through the dermal and inhalation routes into consideration in developing national standards from the provisional guideline value.
Assessment date	2004
Principal reference	WHO (2005) *Trichloroethene in drinking-water*

Although trichloroethene appears to be weakly genotoxic in in vitro and in vivo assays, several of its metabolites are genotoxic, and some are established as known or likely human carcinogens. In view of the sufficient weight of evidence of carcinogenicity in two species of experimental animals with supporting human data, IARC classified trichloroethene as Group 2A (probably carcinogenic to humans). Developmental toxicity is considered to be the critical non-cancer effect, because of the low adverse effect level, the severity of the end-point (heart malformations) and the presence of evidence for similar effects (e.g. cardiac anomalies) from epidemiological studies.

Trifluralin

Trifluralin (CAS No. 1582-09-8) is a pre-emergence herbicide used in a number of crops. It has low water solubility and a high affinity for soil. However, biodegradation and photodegradation processes may give rise to polar metabolites that may contaminate drinking water sources. Although this compound is used in many countries, relatively few data are available concerning contamination of drinking water.

Guideline value	0.02 mg/l (20 µg/l)
Occurrence	Not detected in the small number of drinking-water samples analysed; has been detected in surface water at concentrations above 0.5 µg/l and rarely in groundwater
TDI	7.5 µg/kg body weight, based on a NOAEL of 0.75 mg/kg body weight for mild hepatic effects in a 1year feeding study in dogs, with an uncertainty factor of 100 (for interspecies and intraspecies variation)
Limit of detection	0.05 µg/l by GC with nitrogen–phosphorus detection

Treatment performance	1 µg/l should be achievable using GAC
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	Authorities should note that some impure technical grades of trifluralin could contain potent carcinogenic compounds and therefore should not be used.
Assessment date	1993
Principal reference	WHO (2003) *Trifluralin in drinking-water*

Trifluralin of high purity does not possess mutagenic properties. Technical trifluralin of low purity may contain nitroso contaminants and has been found to be mutagenic. No evidence of carcinogenicity was demonstrated in a number of long-term toxicity/carcinogenicity studies with pure (99%) test material. IARC has assigned technical-grade trifluralin to Group 3 (not classifiable as to its carcinogenicity to humans).

Trihalomethanes (bromoform, bromodichloromethane, chloroform, dibromochloromethane)

THMs are formed in drinking-water primarily as a result of chlorination of organic matter present naturally in raw water supplies. The rate and degree of THM formation increase as a function of the chlorine and humic acid concentration, temperature, pH and bromide ion concentration. Chloroform is the most common THM and the principal disinfection by-product in chlorinated drinking-water. In the presence of bromides, brominated THMs are formed preferentially, and chloroform concentrations decrease proportionally. It is assumed that most THMs present in water are ultimately transferred to air as a result of their volatility. For chloroform, for example, individuals may be exposed during showering to elevated concentrations from chlorinated tap water. For the volatile THMs, approximately equal contributions to total exposure come from four areas: ingestion of drinking-water, inhalation of indoor air largely due to volatilization from drinking-water, inhalation and dermal exposure during showering or bathing and ingestion of food, with all but food exposure arising primarily from drinking-water. Indoor air exposure to the volatile THMs is particularly important in countries with low rates of ventilation in houses and high rates of showering and bathing.

Guideline values	*Chloroform:* 0.3 mg/l (300 µg/l)
	Bromoform: 0.1 mg/l (100 µg/l)
	Dibromochloromethane (DBCM): 0.1 mg/l (100 µg/l)
	Bromodichloromethane (BDCM): 0.06 mg/l (60 µg/l)

Occurrence	THMs are not expected to be found in raw water (unless near a pollution source), but are usually present in finished or chlorinated water; concentrations are generally below 100 µg/l; in most circumstances, chloroform is the dominant compound
TDIs	*Chloroform:* 15 µg/kg body weight, derived from the lower 95% confidence limit for 5% incidence of hepatic cysts, generated by physiologically based pharmacokinetic modelling, in dogs that ingested chloroform in toothpaste for 7.5 years, using an uncertainty factor of 25 (10 for intraspecies differences in toxicokinetics and toxicodynamics and 2.5 for differences in interspecies toxicodynamics)
	Bromoform: 17.9 µg/kg body weight, based on the absence of histopathological lesions in the liver in a well-conducted and well-documented 90-day study in rats, using an uncertainty factor of 1000 (100 for intraspecies and interspecies variation and 10 for possible carcinogenicity and short duration of exposure)
	DBCM: 21.4 µg/kg body weight, based on the absence of histopathological effects in the liver in a well-conducted and well-documented 90-day study in rats, using an uncertainty factor of 1000 (100 for intraspecies and interspecies variation and 10 for the short duration of the study); an additional uncertainty factor for potential carcinogenicity was not applied because of the questions regarding mouse liver tumours from corn oil vehicles and inconclusive evidence of genotoxicity
Basis of guideline value derivation	*BDCM:* Application of the linearized multistage model for the observed increases in incidence of kidney tumours in male mice observed in an NTP bioassay
Limit of detection	0.1–0.2 µg/l (method detection limits) by purge-and-trap and liquid–liquid extraction and direct aqueous injection in combination with a chromatographic system; 0.1 µg/l by GC-ECD; 2.2 µg/l by GC-MS
Treatment performance	Concentrations can be reduced by changes to disinfection practice (e.g. reducing organic THM precursors) or using air stripping.
Guideline value derivation	
• allocation to water	20% of TDI for bromoform and DBCM 75% of TDI for chloroform
• weight	60 kg adult
• consumption	2 litres/day
Additional comments on THMs	For authorities wishing to establish a total THM standard to account for additive toxicity, the following fractionation approach could be taken: $\frac{C_{bromoform}}{GV_{bromoform}} + \frac{C_{DBCM}}{GV_{DBCM}} + \frac{C_{BDCM}}{GV_{BDCM}} + \frac{C_{chloroform}}{GV_{chloroform}} \leq 1$ where C = concentration and GV = guideline value. Authorities wishing to use a guideline value for total THMs should not simply add up the guideline values for the individual compounds in order to arrive at a standard.
	It is emphasized that adequate disinfection should never be compromised in attempting to meet guidelines for THMs. Nevertheless, in view of the potential link between adverse reproductive outcomes and THMs, particularly brominated THMs, it is recommended that THM levels in drinking-water be kept as low as practicable.

Additional comments on chloroform	In countries with low rates of ventilation in houses and high rates of showering and bathing, the guideline value could be lowered to account for the additional exposures from inhalation of indoor air largely due to volatilization from drinking-water and inhalation and dermal exposure during showering or bathing.
	The guideline value is based on the same study as in the third edition; the increase in value is primarily a result of an increase in the allocation of exposure in drinking-water from 50% to 75% to account for the fact that chloroform is used less now than it was in 1993 when the original guideline was developed.
Additional comments on BDCM	Although a health-based value of 21 µg/l is derived, the previous guideline value of 60 µg/l has been retained for two reasons: 1) both calculations were based on the same study, the only differences being the model and model assumptions used to derive the guideline value; there is therefore no scientific basis on which to justify a change in the guideline value; and 2) BDCM concentrations below 50 µg/l may be difficult to achieve using currently available technology without compromising the effectiveness of disinfection.
	As with chloroform, countries with low rates of ventilation and high rates of showering and bathing may wish to lower the guideline value to account for dermal and inhalation exposures, although, as noted above, concentrations below 50 µg/l may be difficult to achieve using currently available technology without compromising the effectiveness of disinfection.
	As BDCM was negative for carcinogenicity in a recent NTP bioassay in which it was dosed in drinking-water, exceedances of the guideline value are not likely to result in an increased risk of cancer.
Assessment date	2004
Principal references	IPCS (2000) *Disinfectants and disinfectant by-products* IPCS (2004) *Chloroform* USNTP (1987). *Toxicology and carcinogenesis studies of bromodichloromethane in F344/N rats and B6C3F1 mice (gavage studies)* WHO (2005) *Trihalomethanes in drinking-water*

Chloroform

The weight of evidence for genotoxicity of chloroform is considered negative. IARC has classified chloroform as possibly carcinogenic to humans (Group 2B) based on limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in experimental animals. The weight of evidence for liver tumours in mice is consistent with a threshold mechanism of induction. Although it is plausible that kidney tumours in rats may similarly be associated with a threshold mechanism, there are some limitations of the database in this regard. The most universally observed toxic effect of chloroform is damage to the centrilobular region of the liver. The severity of these effects per unit dose administered depends on the species, vehicle and method by which the chloroform is administered.

Bromoform

In an NTP bioassay, bromoform induced a small increase in relatively rare tumours of the large intestine in rats of both sexes but did not induce tumours in mice. Data from

a variety of assays on the genotoxicity of bromoform are equivocal. IARC has classified bromoform in Group 3 (not classifiable as to its carcinogenicity to humans).

Dibromochloromethane

In an NTP bioassay, DBCM induced hepatic tumours in female mice and possibly in male mice but not in rats. The genotoxicity of DBCM has been studied in a number of assays, but the available data are considered inconclusive. IARC has classified DBCM in Group 3 (not classifiable as to its carcinogenicity to humans).

Bromodichloromethane

IARC has classified BDCM in Group 2B (possibly carcinogenic to humans). BDCM gave both positive and negative results in a variety of in vitro and in vivo genotoxicity assays. In an NTP bioassay, BDCM induced renal adenomas and adenocarcinomas in both sexes of rats and male mice, rare tumours of the large intestine (adenomatous polyps and adenocarcinomas) in both sexes of rats and hepatocellular adenomas and adenocarcinomas in female mice. However, BDCM was negative for carcinogenicity in a recent NTP bioassay in which it was dosed in drinking-water. Exposure to BDCM has also been linked to a possible increase in reproductive effects (increased risk for spontaneous abortion or stillbirth).

Uranium

Uranium is widespread in nature, occurring in granites and various other mineral deposits. It is used mainly as fuel in nuclear power stations. Uranium is present in the environment as a result of leaching from natural deposits, release in mill tailings, emissions from the nuclear industry, the combustion of coal and other fuels and the use of phosphate fertilizers that contain uranium. Intake of uranium through air is low, and it appears that intake through food is between 1 and 4 µg/day. Intake through drinking-water is normally extremely low; however, in circumstances in which uranium is present in a drinking-water source, the majority of intake can be through drinking-water.

Provisional guideline value	0.03 mg/l (30 µg/l)
	The guideline value is designated as provisional because of scientific uncertainties surrounding uranium toxicity.
Occurrence	Levels in drinking-water are generally less than 1 µg/l, although concentrations as high as 700 µg/l have been measured in private supplies.
TDI	60 µg, derived from the lower 95% confidence limit on the 95th percentile uranium exposure distribution in a study from Finland, using an uncertainty factor of 10 for intraspecies variation
Limit of detection	0.01 µg/l by ICP-MS; 0.1 µg/l by solid fluorimetry with either laser excitation or UV light; 0.2 µg/l by ICP using adsorption with chelating resin
Treatment performance	1 µg/l should be achievable using conventional treatment (e.g. coagulation or ion exchange)

Guideline value derivation	
• consumption	2 litres/day
Additional comments	Where supplies exceed 30 µg/l, it is important that precipitate action be avoided. Consideration should first be given to exposure from all sources and the availability of alternative safe sources.
	Only chemical, not radiological, aspects of uranium toxicity have been addressed here; for radiological aspects, see chapter 9.
Assessment date	2003, revised in 2011
Principal reference	WHO (2012) *Uranium in drinking-water*

There are insufficient data regarding the carcinogenicity of uranium in humans and experimental animals. Nephritis is the primary chemically induced effect of uranium in humans. Little information is available on the chronic health effects of exposure to environmental uranium in humans. A number of epidemiological studies of populations exposed to uranium in drinking-water have shown a correlation with alkaline phosphatase and β-microglobulin in urine along with modest alterations in proximal tubular function. However, the actual measurements were still within the normal physiological range, and these findings are not consistent between studies.

No clear no-effect concentration has emerged from the human studies to date. This is not surprising, as most of the study populations are quite small, and there is substantial normal variation in the measured parameters in the human population. However, the overall indications are that there is no clear evidence of effects below an exposure concentration of 30 µg/l. In fact, the evidence for effects on the kidney, which appears to be the most sensitive organ, is equivocal until much higher exposure concentrations.

The provisional guideline value of 30 µg/l, which is derived from new epidemiological studies on populations exposed to high uranium concentrations, replaces the previous value derived from experimental animal studies and designated as provisional on the basis of uncertainties regarding the toxicology and epidemiology of uranium as well as difficulties concerning its technical achievability in smaller supplies. It is noted that studies on human populations, when available and of good quality, are the preferred source of health-related information to be used in deriving guideline values.

Vinyl chloride

Vinyl chloride is used primarily for the production of PVC. Owing to its high volatility, vinyl chloride has rarely been detected in surface waters, except in contaminated areas. Unplasticized PVC is increasingly being used in some countries for water mains supplies. Migration of vinyl chloride monomer from unplasticized PVC is a possible source of vinyl chloride in drinking-water. It appears that inhalation is the most important route of vinyl chloride intake, although drinking-water may contribute a substantial portion of daily intake where PVC piping with a high residual content of vinyl chloride monomer is used in the distribution network. Vinyl chloride has been reported in groundwater as a degradation product of the chlorinated solvents trichloroethene and tetrachloroethene.

Guideline value	0.0003 mg/l (0.3 µg/l)
Occurrence	Rarely detected in surface waters, the concentrations measured generally not exceeding 10 µg/l; much higher concentrations found in groundwater and well water in contaminated areas; concentrations up to 10 µg/l detected in drinking-water
Basis of guideline value derivation	Application of a linear extrapolation by drawing a straight line between the dose, determined using a pharmocokinetic model, resulting in tumours in 10% of animals in rat bioassays involving oral exposure and the origin (zero dose), determining the value associated with the upper-bound risk of 10^{-5} and assuming a doubling of the risk for exposure from birth
Limit of detection	0.01 µg/l by GC-ECD or GC-FID with MS for confirmation
Treatment performance	0.001 mg/l should be achievable using air stripping
Additional comments	The results of the linear extrapolation are nearly identical to those derived using the linearized multistage model.
	As vinyl chloride is a known human carcinogen, exposure to this compound should be avoided as far as practicable, and levels should be kept as low as technically feasible.
	Vinyl chloride is primarily of concern as a potential contaminant from some grades of PVC pipe and is best controlled by specification of material quality.
Assessment date	2003
Principal references	IPCS (1999) *Vinyl chloride* WHO (2004) *Vinyl chloride in drinking-water*

There is sufficient evidence of the carcinogenicity of vinyl chloride in humans from industrial populations exposed to high concentrations via the inhalation route, and IARC has classified vinyl chloride in Group 1 (carcinogenic to humans). Studies of workers employed in the vinyl chloride industry showed a marked exposure–response for all liver cancers, angiosarcomas and hepatocellular carcinoma, but no strong relationship between cumulative vinyl chloride exposure and other cancers. Experimental animal data show vinyl chloride to be a multisite carcinogen. When administered orally or by inhalation to mice, rats and hamsters, it produced tumours in the mammary gland, lungs, Zymbal gland and skin, as well as angiosarcomas of the liver and other sites. Evidence indicates that vinyl chloride metabolites are genotoxic, interacting directly with DNA. DNA adducts formed by the reaction of DNA with a vinyl chloride metabolite have also been identified. Occupational exposure has resulted in chromosomal aberrations, micronuclei and sister chromatid exchanges; response levels were correlated with exposure levels.

Xylenes

Xylenes are used in blending petrol, as a solvent and as a chemical intermediate. They are released to the environment largely via air. Exposure to xylenes is mainly from air, and exposure is increased by smoking.

Guideline value	0.5 mg/l (500 µg/l)
Occurrence	Concentrations of up to 8 µg/l have been reported in surface water, groundwater and drinking-water; levels of a few milligrams per litre were found in groundwater polluted by point emissions; xylenes can also penetrate plastic pipe from contaminated soil
TDI	179 µg/kg body weight, based on a NOAEL of 250 mg/kg body weight per day for decreased body weight in a 103-week gavage study in rats, adjusting for daily dosing and using an uncertainty factor of 1000 (100 for interspecies and intraspecies variation and 10 for the limited toxicological end-points)
Limit of detection	0.1 µg/l by GC-MS; 1 µg/l by GC-FID
Treatment performance	0.005 mg/l should be achievable using GAC or air stripping
Guideline value derivation	
• allocation to water	10% of TDI
• weight	60 kg adult
• consumption	2 litres/day
Additional comments	The guideline value exceeds the lowest reported odour threshold for xylenes in drinking-water.
Assessment date	1993
Principal reference	WHO (2003) *Xylenes in drinking-water*

Xylenes are rapidly absorbed by inhalation. Data on oral exposure are lacking. Xylenes are rapidly distributed in the body, predominantly in adipose tissue. They are almost completely metabolized and excreted in urine. The acute oral toxicity of xylenes is low. No convincing evidence for teratogenicity has been found. Long-term carcinogenicity studies have shown no evidence for carcinogenicity. In vitro as well as in vivo mutagenicity tests have proved negative.

Zinc

Zinc is an essential trace element found in virtually all food and potable water in the form of salts or organic complexes. The diet is normally the principal source of zinc. Although levels of zinc in surface water and groundwater normally do not exceed 0.01 and 0.05 mg/l, respectively, concentrations in tap water can be much higher as a result of dissolution of zinc from pipes.

Reason for not establishing a guideline value	Not of health concern at levels found in drinking-water
Additional comments	May affect acceptability of drinking-water
Assessment date	1993
Principal reference	WHO (2003) *Zinc in drinking-water*

In 1982, JECFA proposed a PMTDI for zinc of 1 mg/kg body weight. The daily requirement for adult men is 15–20 mg/day. It was considered that, taking into account

recent studies on humans, the derivation of a formal guideline value is not required at this time. However, drinking-water containing zinc at levels above 3 mg/l may not be acceptable to consumers (see chapter 10).

12.2 Pesticides used for vector control in drinking-water sources and containers

In setting local guidelines or standards in the context of local storage practices and realistic insecticide application regimes, health authorities should take into consideration the potential for higher rates of water consumption in the area or region under consideration. However, exceeding the ADIs will not necessarily result in adverse effects. The diseases spread by vectors are significant causes of morbidity and mortality. It is therefore important to achieve an appropriate balance between the intake of the pesticides from drinking-water and the control of disease-carrying insects. Better than establishing guideline values are the formulation and implementation of a comprehensive management plan for household water storage and domestic waste management that does not rely exclusively on larviciding by insecticides, but also includes other environmental management measures and social behavioural changes.

Formulations of pesticides used for vector control in drinking-water should strictly follow the label recommendations and should only be those approved for such a use by national authorities, taking into consideration the ingredients and formulants used in making the final product. National authorities should note that these assessments refer only to the active ingredients and do not consider the additives in different formulations.

Bacillus thuringensis israelensis

Two *Bacillus thuringiensis israelensis* (Bti) (strain AM65-52) products (water-dispersible granule and ready-to-use tablet) have been evaluated by WHOPES and recommended as mosquito larvicides, including their use against container-breeding mosquitoes. Quality control specifications and efficacy evaluations for Bti water-dispersible granule have been published. WHO recommendations on the use of pesticides in public health are valid only if linked to WHO specifications for their quality control.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2009
Principal references	IPCS (1999) *Bacillus thuringiensis* WHO (2004) *Report of the seventh WHOPES working group meeting* WHO (2006) *Report of the ninth WHOPES working group meeting* WHO (2007) *WHO specifications and evaluations for public health pesticides* WHO (2009) *Bacillus thuringiensis israelensis (Bti) in drinking-water*

Preparations of Bti are widely used against mosquitoes, chironomids and blackflies, and this specific activity against disease vector species has resulted in the use of

Bti in water. Bti is recommended under WHOPES for use in vector control, including against container-breeding mosquitoes, and can be used in drinking-water that will receive little or no further treatment for control of *Aedes aegypti*. It is essential that Bti for larvicidal use be prepared under carefully controlled conditions and properly assayed before use for evidence of potency, for excessive levels of expressed Bti constituents or metabolites that are toxic and for contamination by other undesirable microbes.

Bti itself is not considered to pose a hazard to humans through drinking-water. Therefore, it is not considered necessary or appropriate to establish a health-based value for its use for controlling vector larvae in drinking-water. However, it is vital that authorities can be assured that Bti has been prepared to the highest quality and hygienic standards under appropriate conditions that will meet the WHOPES specifications. It is important that the possible risks are set against the risks from vector-borne diseases such as dengue fever.

Application should be carried out by trained applicators and Bti used in conjunction with other approaches to vector control, including exclusion of mosquitoes from containers and other control options.

Diflubenzuron

Diflubenzuron is a direct-acting insecticide normally applied directly to plants or water. It is used in public health applications against mosquito and noxious fly larvae. WHO is considering diflubenzuron for use as a mosquito larvicide in drinking-water in containers, particularly to control dengue fever. The recommended dosage of diflubenzuron in potable water in containers should not exceed 0.25 mg/l under WHOPES.

It is reported that public exposure to diflubenzuron through either food or drinking-water is negligible. However, there is a potential for direct exposure through drinking-water when diflubenzuron is directly applied to drinking-water storage containers.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2007
Principal references	FAO/WHO (2002) *Pesticide residues in food—2001 evaluations* WHO (2008) *Diflubenzuron in drinking-water*

Diflubenzuron is considered to be of very low acute toxicity. The primary target for toxicity is the erythrocytes, although the mechanism of haematotoxicity is uncertain. There is no evidence that diflubenzuron is either genotoxic or carcinogenic. It also does not appear to be fetotoxic or teratogenic and does not show significant signs of reproductive toxicity. There is evidence that young animals are not significantly more sensitive than adults to the effects of diflubenzuron.

It is not considered appropriate to set a formal guideline value for diflubenzuron used as a vector control agent in drinking-water. Where diflubenzuron is used for vector control in potable water, this will involve considerably less than lifetime exposure.

The ADI determined by JMPR in 2001 was 0–0.02 mg/kg body weight. The maximum dosage in drinking-water of 0.25 mg/l would be equivalent to approximately 40% of the upper limit of the ADI allocated to drinking-water for a 60 kg adult drinking 2 litres of water per day. For a 10 kg child drinking 1 litre of water, the exposure would be 0.25 mg, compared with an exposure of 0.2 mg at the upper limit of the ADI. For a 5 kg bottle-fed infant drinking 0.75 litre per day, the exposure would be 0.19 mg, compared with an exposure of 0.1 mg at the upper limit of the ADI. Diflubenzuron is unlikely to remain in solution at the maximum recommended applied dose, and the actual levels of exposure are likely to be much lower than those calculated.

Consideration should be given to using alternative sources of water for bottle-fed infants for a period after an application of diflubenzuron, where this is practical. However, exceeding the ADI will not necessarily result in adverse effects.

Methoprene

WHO has assessed methoprene for use as a mosquito larvicide in drinking-water in containers, particularly to control dengue fever. The recommended dosage of methoprene in potable water in containers should not exceed 1 mg/l under WHOPES.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2007
Principal references	FAO/WHO (2002) *Pesticide residues in food—2001 evaluations* WHO (2008) *Methoprene in drinking-water*

In 2001, JMPR reaffirmed the basis of the ADI for racemic methoprene established in 1987, but lowered the value to 0–0.09 mg/kg body weight to correct for the purity of the racemate tested. The basis for the ADI was the NOAEL of 500 mg/kg diet, equivalent to 8.6 mg/kg body weight per day (corrected for purity), in a 90-day study in dogs (the main effect was increased relative liver weight) and a safety factor of 100. Young animals do not appear to be significantly more sensitive than adults. As no bridging studies with repeated doses were available for (*S*)-methoprene, JMPR made the conservative assumption that, in the absence of any information to the contrary, all the toxicity of the racemate was due to the S enantiomer. On this basis, JMPR established an ADI for (*S*)-methoprene of 0–0.05 mg/kg body weight, equal to one half the ADI for the racemate (which is a 1:1 mixture of the R and S enantiomers).

It is not considered appropriate to set a formal guideline value for methoprene used as a vector control agent in drinking-water. Where methoprene is used for vector control in potable water, this will involve less than lifetime exposure. The maximum dosage in drinking-water of 1 mg/l would be equivalent to approximately 66% of the upper limit of the ADI (0.033 mg/kg body weight) for a 60 kg adult drinking 2 litres of water per day. The exposure for a 10 kg child drinking 1 litre of water would be approximately 0.1 mg/kg body weight, and for a 5 kg bottle-fed infant, the exposure

would be approximately 0.15 mg/kg body weight, compared with the upper limit of the ADI of 0.05 mg/kg body weight. However, the low solubility and the high log octanol–water partition coefficient of methoprene indicate that it is unlikely to remain in solution at the maximum recommended applied dose, and the actual levels of exposure are likely to be much lower than those calculated. Exposure from food is considered to be low.

Consideration should be given to using alternative sources of water for small children and bottle-fed infants for a period after an application of methoprene, where this is practical. However, exceeding the ADI will not necessarily result in adverse effects.

Novaluron

Novaluron has been registered as an insecticide for food crops and ornamentals in a number of countries. WHO has assessed novaluron for use as a mosquito larvicide in drinking-water in containers, particularly to control dengue fever. The recommended dosage of novaluron in potable water in containers should not exceed 0.05 mg/l under WHOPES.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2007
Principal references	FAO/WHO (2006) *Pesticide residues in food—2005 evaluations* WHO (2008) *Novaluron in drinking-water.*

In view of the absence of a carcinogenic potential in rodents and the lack of genotoxic potential in vitro and in vivo, JMPR concluded that novaluron is unlikely to pose a carcinogenic risk to humans. JMPR also concluded that novaluron is not a developmental toxicant. JMPR established an ADI of 0–0.01 mg/kg body weight on the basis of the NOAEL of 1.1 mg/kg body weight per day for erythrocyte damage and secondary splenic and liver changes in a 2-year dietary study in rats, using a safety factor of 100.

It is not considered appropriate to set a formal guideline value for novaluron as a vector control agent in drinking-water. At the maximum recommended dosage for drinking-water of 0.05 mg/l, the intake of a 60 kg adult drinking 2 litres of water would represent only 17% of the upper limit of the ADI. Similarly, the intake for a 10 kg child drinking 1 litre of water would be 50% of the upper limit of the ADI, whereas a 5 kg bottle-fed infant drinking 0.75 litre of water would receive an intake of 75% of the upper limit of the ADI.

The high log octanol–water partition coefficient of 4.3 indicates that novaluron is likely to adsorb to the sides of containers, and so the actual concentration is likely to be less than the recommended dose. Exposure to novaluron through food is not expected to be significant.

Permethrin

Permethrin (CAS No. 52645-53-1) is a contact insecticide effective against a broad range of pests in agriculture, forestry and public health. It has been used as a larvicide to control aquatic invertebrates in water mains. Permethrin is photodegraded both in water and on soil surfaces. In soil, permethrin is rapidly degraded by hydrolysis and microbial action under aerobic conditions. Exposure of the general population to permethrin is mainly via the diet.

Reason for not establishing a guideline value	Not recommended for direct addition to drinking-water as part of WHO's policy to exclude the use of any pyrethroids for larviciding of mosquito vectors of human disease
Assessment date	2011
Principal references	FAO/WHO (2000) *Pesticide residues in food—1999 evaluations* WHO (2011) *Permethrin in drinking-water*

Technical-grade permethrin is of low acute toxicity. The *cis* isomer is considerably more toxic than the *trans* isomer. IARC has classified permethrin in Group 3 (not classifiable as to its carcinogenicity to humans), as there are no human data and only limited data from experimental animal studies. Permethrin is not genotoxic. JMPR concluded that technical-grade permethrin is not a reproductive or developmental toxin.

For guidance purposes, a health-based value can be derived from an ADI of 0–0.05 mg/kg body weight, established for technical-grade permethrin with *cis:trans* ratios of 25:75 to 40:60 on the basis of a NOAEL of 5 mg/kg body weight per day in a 2-year dietary study in rats, which was based on clinical signs and changes in body and organ weights and blood chemistry at the next higher dose, and a NOAEL of 5 mg/kg body weight per day in a 1-year study in dogs, based on reduced body weight at 100 mg/kg body weight per day, and applying an uncertainty factor of 100 for interspecies and intraspecies variation. Assuming a 60 kg adult drinking 2 litres of water per day and allocating 20% of the upper limit of the ADI to drinking-water, a health-based value of 0.3 mg/l can be derived.

Adding permethrin directly to drinking-water for public health purposes is not recommended by WHO, as part of its policy to exclude the use of any pyrethroids for larviciding of mosquito vectors of human disease. This policy is based on concern over the possible accelerated development of vector resistance to synthetic pyrethroids, which, in their application to insecticide-treated mosquito nets, are crucial in the current global anti-malaria strategy.

Pirimiphos-methyl

Pirimiphos-methyl is an organophosphorus compound that is used in a wide range of pesticidal applications. Pirimiphos-methyl is being considered by WHO for addition to potable water in containers as a mosquito larvicide treatment, particularly to control dengue fever. The manufacturer recommends the direct addition of 1 mg/l to water.

Reason for not establishing a guideline value	Not recommended for direct application to drinking-water unless no other effective and safe treatments are available
Assessment date	2007
Principal references	FAO/WHO (1993) *Pesticide residues in food—1992 evaluations* FAO/WHO (2008) *Pesticide residues in food—2006 evaluations* WHO (2008) *Pirimiphos-methyl in drinking-water*

The only biochemical effect consistently observed with pirimiphos-methyl in acute, short-term or long-term studies is cholinesterase inhibition. Studies with mice, rats and dogs showed NOAELs of 0.5 mg/kg body weight per day and above. Young animals do not appear to be significantly more sensitive than adults. In human studies, no cholinesterase inhibition was seen at 0.25 mg/kg body weight per day (the highest dose tested). On this basis, JMPR revised the ADI to 0–0.03 mg/kg body weight by applying a 10-fold safety factor to the NOAEL in the human studies.

At the maximum recommended dosage for drinking-water of 1 mg/l, a 60 kg adult drinking 2 litres of water would have an intake of 0.033 mg/kg body weight, compared with the upper limit of the ADI of 0.03 mg/kg body weight. The intake for a 10 kg child drinking 1 litre of water would be 0.1 mg/kg body weight; for a 5 kg bottle-fed infant drinking 0.75 litre, it would be 0.15 mg/kg body weight. There is uncertainty regarding the level that would cause effects in humans, as the NOAEL on which the ADI is based was the highest dose tested, and so the ADI may be more conservative than is at first apparent. These intake figures are all below the acute reference dose of 0.2 mg/kg body weight and would not result in an acute exposure risk from the initial application of pirimiphos-methyl to drinking-water containers at the recommended dose. In addition, the low solubility and the high log octanol–water partition coefficient of pirimiphos-methyl indicate that the larvicide is very unlikely to remain in solution at the maximum recommended applied dose, so the actual levels of exposure are expected to be lower than those calculated. Exposure from food is generally considered to be low, but occasional high exposures can be experienced.

Based on the above calculations, pirimiphos-methyl is not recommended for direct application to drinking-water unless no other effective and safe treatments are available. If pirimiphos-methyl is applied directly to drinking-water, consideration should be given to using alternative sources of water for bottle-fed infants and small children for a period after its application, where this is practical. However, it is noted that exceeding the ADI will not necessarily result in adverse effects.

Pyriproxyfen

Pyriproxyfen is a broad-spectrum insect growth regulator with insecticidal activity against public health insect pests, including mosquitoes. WHO has assessed pyriproxyfen for use as a mosquito larvicide in drinking-water in containers, particularly to control dengue fever. The recommended dosage of pyriproxyfen in potable water in containers should not exceed 0.01 mg/l under WHOPES.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2007
Principal references	FAO/WHO (2000) *Pesticide residues in food—1999 evaluations* WHO (2008) *Pyriproxyfen in drinking-water*

JMPR evaluated pyriproxyfen and concluded that it was not genotoxic and does not pose a carcinogenic risk to humans. Young animals do not appear to be significantly more sensitive than adults.

JMPR established an ADI of 0–0.1 mg/kg body weight on the basis of an overall NOAEL of 10 mg/kg body weight per day, based on increased relative liver weight and increased total plasma cholesterol concentration in male dogs in two 1-year studies of toxicity and using a safety factor of 100.

It is not considered appropriate to set a formal guideline value for pyriproxyfen used for vector control in drinking-water. The maximum recommended dosage in drinking-water of 0.01 mg/l would be equivalent to less than 1% of the upper limit of the ADI allocated to drinking-water for a 60 kg adult drinking 2 litres of water per day. For a 10 kg child drinking 1 litre of water, the exposure would be 0.01 mg, compared with an exposure of 1 mg at the upper limit of the ADI. For a 5 kg bottle-fed infant drinking 0.75 litre per day, the exposure would be 0.0075 mg, compared with an exposure of 0.5 mg at the upper limit of the ADI. The low solubility and the high log octanol–water partition coefficient of pyriproxyfen indicate that it is unlikely to remain in solution at the maximum recommended applied dose, and the actual levels of exposure are likely to be even lower than those calculated.

Spinosad

Spinosad is a natural product derived from the bacterium *Saccharopolyspora spinosa*. Spinosad DT is a mixture of spinosyn A and spinosyn D. It is used for mosquito control in potable water in containers.

Spinosad DT 7.48% is specified for use as a vector control agent in drinking-water sources against *Aedes aegypti* by WHO under WHOPES. Formulations for control of vectors are specified by WHO at a dose of 0.25–0.5 mg/l. The expected duration of efficacy under field conditions is 4–6 weeks.

Three formulations of spinosad have been evaluated by WHOPES for mosquito larviciding. WHO specifications for quality control and international trade have been published for the three formulations: i.e. spinosad granules (636/GR), aqueous suspension concentrate (636/SC) and tablets for direct application (636/DT). Only the tablet formulation is used for mosquito larviciding in potable water at the dosage of 0.25–0.5 mg/l of the active ingredient.

In a 14-day study conducted by the manufacturer, a single tablet was added to a 200-litre container of water, and 10% of the water in this container was replenished each day of the study. The concentration of spinosad was found to be in the range 26.5–51.7 µg/l.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2009
Principal references	FAO/WHO (2002) *Pesticide residues in food—2001 evaluations* WHO (2010) *Spinosad in drinking-water*

It is not appropriate to set a formal guideline value for spinosad DT for use to control vectors breeding in drinking-water containers; however, it is appropriate to compare the probable intakes with the ADI of 0–0.02 mg/kg body weight, with no acute reference dose set because of its low acute toxicity. The maximum concentration actually achieved with the slow-release formulation was approximately 52 µg/l. The intake would therefore be:

- 39 µg for a 5 kg bottle-fed infant assuming consumption of 0.75 litre = 7.8 µg/kg body weight
- 52 µg for a 10 kg child assuming consumption of 1 litre = 5.2 µg/kg body weight
- 104 µg for a 60 kg adult assuming consumption of 2 litres = 1.7 µg/kg body weight.

However, this could be higher if drinking-water consumption is also higher.

This means that the exposure is well below the upper limit of the ADI for all sectors of the population. Even the application of a double dose would result in exposure below the upper limit of the ADI.

The ADI is, of course, set for lifetime exposure, and the average exposure over time will be lower than the exposures indicated above.

Temephos

Temephos is an organophosphorus insecticide that is used mainly as a larvicide to control mosquitoes on ponds, marshes and swamps and midges, black flies and other insects in public health. It is also used for mosquito control in potable water in containers. It is specified for use as a vector control agent in drinking-water sources by WHO under WHOPES. Formulations for control of vectors are specified by WHO, and only those approved by WHOPES should be used for this purpose. The recommendation for the use of temephos in potable water is that the dosage should not exceed 1 mg/l.

Reason for not establishing a guideline value	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Assessment date	2009
Principal references	FAO/WHO (2008) *Pesticide residues in food—2006 evaluations* WHO (2009) *Temephos in drinking-water*

The NOAEL for human risk assessment for temephos is 2.3 mg/kg body weight per day on the basis of inhibition of brain acetylcholinesterase activity in rats, as determined by JMPR in 2006. Although JMPR considered that the database was

insufficiently robust to serve as the basis for establishing an ADI, for the purposes of these Guidelines, a TDI of 0.023 mg/kg body weight can be calculated from this NOAEL, using an uncertainty factor of 100. Young animals do not appear to be significantly more sensitive than adults, and exposure from food is considered to be low.

It is not appropriate to set a formal guideline value for temephos used as a vector control agent in drinking-water. Where temephos is used for vector control in potable water, this will involve less than lifetime exposure. The maximum dosage in drinking-water of 1 mg/l for a 60 kg adult drinking 2 litres of water per day would be equivalent to approximately 0.033 mg/kg body weight, compared with the TDI of 0.023 mg/kg body weight. The exposure for a 10 kg child drinking 1 litre of water would be approximately 0.1 mg/kg body weight; for a 5 kg bottle-fed infant, the exposure would be approximately 0.15 mg/kg body weight, compared with the TDI of 0.023 mg/kg body weight.

Consideration should be given to using alternative sources of water for small children and bottle-fed infants for a period after an application of temephos, where this is practical.

However, exceeding the TDI does not necessarily mean that this will result in adverse effects. Indeed, the low solubility and the high log octanol–water partition coefficient of temephos indicate that it is unlikely to remain in solution at the maximum recommended applied dose, and the use of the slow-release formulation should result in very much lower concentrations than the approved dose of 1 mg/l and actual exposures much lower than the theoretical exposures calculated above.

ANNEX 1

Supporting documentation to the Guidelines

The *Guidelines for drinking-water quality* are accompanied by separate texts that provide background information substantiating the derivation of the Guidelines and providing guidance on good practice towards effective implementation. These are available as published texts, through the Internet (http://www.who.int/water_sanitation_health/water-quality/guidelines/drinking-water-guidelines-publications/en/) and on CD-ROM. These can be ordered at http://www.who.int/bookorders.

Published supporting documents

A practical guide to auditing water safety plans
Published in 2015 by the World Health Organization
Provides guidance on developing and implementing a WSP auditing scheme, including examples, case studies and tools from more than a dozen low-, middle- and high-income countries with WSP auditing experience
http://www.who.int/water_sanitation_health/publications/auditing-water-safety-plans/en/

Assessing microbial safety of drinking water: Improving approaches and methods
Edited by A. Dufour et al.
Published in 2003 by IWA Publishing on behalf of the World Health Organization and the Organisation for Economic Co-operation and Development
A state-of-the-art review of approaches and methods used in assessing the microbial safety of drinking-water.
http://www.who.int/water_sanitation_health/publications/assessing-microbial-safety-of-drinking-water/en/

Boil water
Published in 2015 by the World Health Organization
Provides the scientific basis for the efficacy of boiling water
http://www.who.int/water_sanitation_health/publications/boiling-water/en/

Calcium and magnesium in drinking-water: Public health significance
Edited by J. Cotruvo and J. Bartram
Published in 2009 by the World Health Organization

A review of the contribution of drinking-water to total daily intake of calcium and magnesium, and an assessment of possible health benefits, including reducing cardiovascular disease mortality and osteoporosis.
http://www.who.int/water_sanitation_health/publications/publication_9789241563550/en/

Chemical safety of drinking-water: Assessing priorities for risk management
T. Thompson et al.
Published in 2007 by the World Health Organization
A tool to assist in undertaking a systematic assessment of water supply systems to prioritize, control or eliminate chemicals in drinking-water.
http://www.who.int/water_sanitation_health/publications/dwchem_safety/en/

Domestic water quantity, service level and health
G. Howard and J. Bartram
Published in 2003 by the World Health Organization
Requirements for water for health-related purposes to determine acceptable minimum needs for consumption (hydration and food preparation) and basic hygiene.
http://www.who.int/water_sanitation_health/publications/wsh0302/en/

Evaluating household water treatment options: Health-based targets and microbiological performance specifications
J. Brown and M. Sobsey
Published in 2011 by the World Health Organization
Establishes health-based targets and testing protocols for point-of-use water treatment approaches, including to inform development of country certification programmes.
http://www.who.int/water_sanitation_health/publications/household_water/en/

Evaluation of the H_2S method for detection of fecal contamination of drinking water
M. Sobsey and F. Pfaender
Published in 2002 by the World Health Organization
The scientific basis, validity, available data and other information concerning the use of "H_2S tests" as measures or indicators of faecal contamination in drinking-water.
http://www.who.int/water_sanitation_health/publications/h2s-method-for-detection-of-fecal-contamination/en/

Fluoride in drinking-water
J.K. Fawell et al.
Published in 2006 by IWA Publishing on behalf of the World Health Organization
Provides information on the occurrence of fluoride in drinking-water, its health effects, ways of reducing excess levels and methods for analysis of fluoride in water.
http://www.who.int/water_sanitation_health/publications/fluoride-in-drinking-water/en/

Guide to hygiene and sanitation in aviation, 3rd edition. Module 1: Water; Module 2: Cleaning and disinfection of facilities
Published in 2009 by the World Health Organization
Addresses water and cleaning and disinfection of facilities with the ultimate goal of assisting all types of airport and aircraft operators and other responsible bodies in achieving high standards of hygiene and sanitation, to protect travellers.
http://www.who.int/water_sanitation_health/publications/aviation_guide/en/

Guide to ship sanitation, 3rd edition
Published in 2011 by the World Health Organization
Presents the public health significance of ships in terms of disease and highlights the importance of applying appropriate control measures.
http://www.who.int/water_sanitation_health/publications/ship_sanitation_guide/en/

Hazard characterization for pathogens in food and water: Guidelines
Published in 2003 by the Food and Agriculture Organization of the United Nations and the World Health Organization
A practical framework and structured approach for the characterization of microbial hazards in food and water, to assist governmental and research scientists.
http://www.who.int/water_sanitation_health/publications/hazard-characterization-for-pathogens/en/

Health aspects of plumbing

Published in 2006 by the World Health Organization and the World Plumbing Council

A description of the processes involved in the design, installation and maintenance of effective plumbing systems and consideration of the microbial, chemical, physical and financial concerns associated with plumbing.

http://www.who.int/water_sanitation_health/publications/plumbing-health-aspects/en/

Heterotrophic plate counts and drinking-water safety: The significance of HPCs for water quality and human health

Edited by J. Bartram et al.

Published in 2003 by IWA Publishing on behalf of the World Health Organization

Assessment of the role of the heterotrophic plate count measurement in drinking-water safety management.

http://www.who.int/water_sanitation_health/publications/hpc/en/

Legionella and the prevention of legionellosis

Edited by J. Bartram et al.

Published in 2007 by the World Health Organization

An overview of the sources, ecology and laboratory detection of *Legionella* bacteria, risk assessment and risk management of susceptible environments, the necessary measures to prevent or adequately control the risks and the policies and practices for outbreak management.

http://www.who.int/water_sanitation_health/publications/legionella/en/

Management of cyanobacteria in drinking-water supplies: information for regulators and water suppliers

Published in 2015 by the World Health Organization

Guidance for regulators and water suppliers to prevent and manage cyanobacterial blooms

http://www.who.int/water_sanitation_health/publications/cyanobacteria_in_drinking-water/en/

Managing water in the home: Accelerated health gains from improved water supply

M. Sobsey

Published in 2002 by the World Health Organization

A review of the various methods and systems for household water collection, treatment and storage.

http://www.who.int/water_sanitation_health/publications/wsh0207/en/

Pathogenic mycobacteria in water: A guide to public health consequences, monitoring and management

Edited by J. Bartram et al.

Published in 2004 by IWA Publishing on behalf of the World Health Organization

A description of the distribution, routes of transmission and infection, and guidance on the control of pathogenic environmental mycobacteria in water and other parts of the environment.

http://www.who.int/water_sanitation_health/publications/pathogenic-mycobacteria-in-water/en/

Pharmaceuticals in drinking-water

Published in 2012 by the World Health Organization

Provides evidence-based, practical guidance and recommendations for managing pharmaceuticals in drinking-water.

http://www.who.int/water_sanitation_health/publications/pharmaceuticals-in-drinking-water/en/

Protecting groundwater for health: Managing the quality of drinking-water sources
Edited by O. Schmoll et al.
Published in 2006 by the World Health Organization
An analysis of the hazards to groundwater quality, and the risk they may present to a specific supply. This is a tool for developing strategies to protect groundwater for health by managing the quality of drinking-water sources.
http://www.who.int/water_sanitation_health/publications/protecting_groundwater/en/

Protecting surface water for health: identifying, assessing and managing drinking-water quality risks in surface water catchments
Published in 2016 by the World Health Organization
Provides a structured approach to understanding surface waters and their catchments to support the identification, assessment and prioritization of the risks, and the development of management strategies for their control, as a basis for providing safe drinking-water
http://www.who.int/water_sanitation_health/publications/pswh/en

Quantifying public health risk in the WHO Guidelines for drinking-water quality: A burden of disease approach
A.H. Havelaar and J.M. Melse
Published in 2003 by the National Institute for Public Health and the Environment of the Netherlands
A discussion paper on the concepts and methodology of disability-adjusted life years (DALYs) as a common public health metric and its usefulness for drinking-water quality.
http://www.who.int/water_sanitation_health/publications/quantifyinghealthrisks/en/

Quantitative microbial risk assessment: application for water safety management
Published in 2016 by the World Health Organization
Synthesizes the current knowledge on quantitative microbial risk assessment (QMRA) to facilitate its application in the practice of water supply, water reuse and water recreation to support the management of risks associated with faecal pathogens in the water-related context.
http://www.who.int/water_sanitation_health/publications/qmra/en

Rapid assessment of drinking-water quality: A handbook for implementation

Published in 2011 by the World Health Organization and the United Nations Children's Fund

A practical guide to rapidly monitor water quality and safety, incorporating statistical methods, sanitary survey, and field approaches.

http://www.who.int/water_sanitation_health/publications/rapid_assessment/en/

Review of latest available evidence on potential transmission of avian influenza (H5N1) through water and sewage and ways to reduce the risks to human health

Published in 2006 by the World Health Organization

A summary of the latest available studies and findings on avian influenza (H5N1) pertaining to water resources, water supplies, sanitation (human excreta, sewerage systems and health-care waste) and hygiene.

http://www.who.int/water_sanitation_health/publications/potential-transmission-of-avian-influenza/en/

Risk assessment of Cryptosporidium in drinking water

G. Medema et al.

Published in 2009 by the World Health Organization

A text supporting the Guidelines for drinking-water quality by providing further data on Cryptosporidium to assist country authorities in setting health-based targets and water suppliers in determining required performance of water treatment processes as part of a system-specific water safety plan.

http://www.who.int/water_sanitation_health/publications/cryptoRA/en/

Safe drinking-water from desalination

Published in 2011 by the World Health Organization

Highlights the principal health risks related to different desalination processes and provides guidance on appropriate risk assessment and risk management procedures in order to ensure the safety of desalinated drinking-water.

http://www.who.int/water_sanitation_health/publications/desalination_guidance/en/

Safe piped water: Managing microbial water quality in piped distribution systems

Edited by R. Ainsworth

Published in 2004 by IWA Publishing on behalf of the World Health Organization

A report on microbial contaminants and growth of microorganisms in distribution networks and the practices that contribute to ensuring drinking-water safety in piped distribution systems.

http://www.who.int/water_sanitation_health/publications/safe-piped-water/en/

Scaling up household water treatment among low-income populations

T. Clasen

Published in 2009 by the World Health Organization

Examines the evidence to date regarding the scalability of household water treatment systems. Its primary aims are to review the development and evolution of leading household water treatment technologies in their efforts to achieve scale, identify the main constraints that they have encountered and recommend ways forward.

http://www.who.int/water_sanitation_health/publications/household_water_treatment/en/

Toxic cyanobacteria in water: A guide to their public health consequences, monitoring and management

Edited by I. Chorus and J. Bartram
Published in 1999 by E & FN Spon on behalf of the World Health Organization
A report on all aspects of risk management, detailing the information needed for protecting drinking-water sources and recreational water bodies from the health hazards caused by cyanobacteria and their toxins.
http://www.who.int/water_sanitation_health/publications/toxicyanobact/en/

Turbidity: information for regulators and operators of water supplies

Published in 2017 by the World Health Organization
Provides information on the uses and significance of turbidity, and is intended for regulators and operators of drinking-water supplies.

Upgrading water treatment plants

E.G. Wagner and R.G. Pinheiro
Published in 2001 by Spon Press on behalf of the World Health Organization
A practical guide to improving the performance of water treatment plants.
http://www.who.int/water_sanitation_health/publications/treatplants/en/

Water quality—Guidelines, standards and health: Assessment of risk and risk management for water-related infectious disease

Edited by L. Fewtrell and J. Bartram
Published in 2001 by IWA Publishing on behalf of the World Health Organization
Guidance on issues relating to microbial water quality and health, including environmental and public health scientists, water scientists, policy-makers and those responsible for developing standards and regulations.
http://www.who.int/water_sanitation_health/publications/whoiwa/en/

Water safety in buildings

Edited by D. Cunliffe et al.
Published in 2011 by the World Health Organization
Provides guidance for managing water supplies in buildings (e.g. hospitals, schools, care facilities, hotels) where people may drink water; use water for food preparation; wash, shower, swim or use water for other recreational activities; or be exposed to aerosols produced by water-using devices, such as cooling towers.
http://www.who.int/water_sanitation_health/publications/9789241548106/en/

Water safety in distribution systems

Published in 2014 by the World Health Organization
A reference tool to help water suppliers and regulators who are familiar with the water safety plan approach to enhance risk assessment and management and investment planning for their water distribution systems.
http://www.who.int/water_sanitation_health/publications/water-safety-in-distribution-system/en/

Water safety plan: a field guide to improving drinking-water safety in small communities

Published in 2014 by the World Health Organization Regional Office for Europe
Contains short explanations of the water safety planning process (including practical templates and tips) that support WSP development and implementation in small communities
http://www.euro.who.int/en/health-topics/environment-and-health/water-and-sanitation/publications/2014/water-safety-plan-a-field-guide-to-improving-drinking-water-safety-in-small-communities

Water safety plan manual: Step-by-step risk management for drinking-water suppliers
J. Bartram et al.
Published in 2009 by the World Health Organization
Guidance on developing and implementing a water safety plan through 11 learning modules, each representing a key step in the water safety plan development and implementation process.
http://www.who.int/water_sanitation_health/publications/publication_9789241562638/en/

Water safety planning for small community water supplies
Published in 2012 by the World Health Organization
Step-by-step guidance for the planning, design and implementation of water safety plans by and for rural and remote communities, including communities with piped schemes, those served by point sources and community-wide water supply services using various technical options.
http://www.who.int/water_sanitation_health/publications/small-comm-water_supplies/en/

Water safety plans: Managing drinking-water quality from catchment to consumer
A. Davison et al.
Published in 2005 by the World Health Organization

Guidance on improved strategies for the preventive management, control and monitoring of drinking-water quality.
http://who.int/water_sanitation_health/publications/wsp0506/en/

Water treatment and pathogen control: Process efficiency in achieving safe drinking-water
M.W. LeChevallier and K.K. Au
Published in 2004 by IWA Publishing on behalf of the World Health Organization
A critical analysis of the removal and inactivation of pathogenic microbes in water to aid the water quality specialist and design engineer in making decisions regarding microbial water quality.
http://www.who.int/water_sanitation_health/publications/water-treatment-and-pathogen-control/en/

Waterborne zoonoses: Identification, causes and control
Edited by J.A. Cotruvo et al.
Published in 2004 by IWA Publishing on behalf of the World Health Organization
An invaluable tool for all professionals concerned with assessing and managing waterborne zoonoses, which are diseases caused by microorganisms of animal origin that also infect humans.
http://www.who.int/water_sanitation_health/publications/waterborne-zoonoses/en/

ANNEX 2

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Howard G et al. (2002) *Healthy villages: A guide for communities and community health workers*. Geneva, World Health Organization (http://www.who.int/water_sanitation_health/publications/healthvillages/en/).

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Prüss A et al. (2002) Estimating the burden of disease from water, sanitation, and hygiene at a global level. *Environmental Health Perspectives*, 110:537–542.

[1] This list includes all references cited in the text, except for the supporting documents to the Guidelines, which are listed separately in Annex 1, and the selected bibliographic references in chapter 11, which are cited following each microbial fact sheet in that chapter.

[2] The web links given in this annex were current as of January 2011.

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ANNEX 3

Chemical summary tables

Table A3.1 Chemicals excluded from guideline value derivation

Chemical	Reason for exclusion
Amitraz	Degrades rapidly in the environment and is not expected to occur at measurable concentrations in drinking-water supplies
Chlorobenzilate	Unlikely to occur in drinking-water
Chlorothalonil	Unlikely to occur in drinking-water
Cypermethrin	Unlikely to occur in drinking-water
Deltamethrin	Unlikely to occur in drinking-water
Diazinon	Unlikely to occur in drinking-water
Dinoseb	Unlikely to occur in drinking-water
Ethylene thiourea	Unlikely to occur in drinking-water
Fenamiphos	Unlikely to occur in drinking-water
Formothion	Unlikely to occur in drinking-water
Hexachlorocyclohexanes (mixed isomers)	Unlikely to occur in drinking-water
MCPB[a]	Unlikely to occur in drinking-water
Methamidophos	Unlikely to occur in drinking-water
Methomyl	Unlikely to occur in drinking-water
Mirex	Unlikely to occur in drinking-water
Monocrotophos	Has been withdrawn from use in many countries and is unlikely to occur in drinking-water
Oxamyl	Unlikely to occur in drinking-water
Phorate	Unlikely to occur in drinking-water
Propoxur	Unlikely to occur in drinking-water
Pyridate	Not persistent and only rarely found in drinking-water
Quintozene	Unlikely to occur in drinking-water
Toxaphene	Unlikely to occur in drinking-water
Triazophos	Unlikely to occur in drinking-water
Tributyltin oxide	Unlikely to occur in drinking-water
Trichlorfon	Unlikely to occur in drinking-water

[a] 4-(4-chloro-o-tolyloxy)butyric acid.

Table A3.2 Chemicals for which guideline values have not been established

Chemical	Reason for not establishing a guideline value
Aluminium	A health-based value of 0.9 mg/l could be derived, but this value exceeds practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants: 0.1 mg/l or less in large water treatment facilities and 0.2 mg/l or less in small facilities
Ammonia	Occurs in drinking-water at concentrations well below those of health concern
Asbestos	No consistent evidence that ingested asbestos is hazardous to health
Bentazone	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Beryllium	Rarely found in drinking-water at concentrations of health concern
Bromide	Occurs in drinking-water at concentrations well below those of health concern
Bromochloroacetate	Available data inadequate to permit derivation of health-based guideline value
Bromochloroacetonitrile	Available data inadequate to permit derivation of health-based guideline value
Bacillus thuringiensis israelensis (Bti)	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Carbaryl	Occurs in drinking-water at concentrations well below those of health concern
Chloral hydrate	Occurs in drinking-water at concentrations well below those of health concern
Chloride	Not of health concern at levels found in drinking-watera
Chlorine dioxide	Reduced primarily to chlorite, chlorate and chloride in drinking-water, and to chlorite and chloride upon ingestion; the provisional guideline values for chlorite and chlorate are protective for potential toxicity from chlorine dioxide
Chloroacetones	Available data inadequate to permit derivation of health-based guideline values for any of the chloroacetones
2-Chlorophenol	Available data inadequate to permit derivation of health-based guideline value
Chloropicrin	Available data inadequate to permit derivation of health-based guideline value
Cyanide	Occurs in drinking-water at concentrations well below those of health concern, except in emergency situations following a spill to a water source
Cyanogen chloride	Occurs in drinking-water at concentrations well below those of health concern
Dialkyltins	Available data inadequate to permit derivation of health-based guideline values for any of the dialkyltins
Dibromoacetate	Available data inadequate to permit derivation of health-based guideline value

Table A3.2 (continued)

Chemical	Reason for not establishing a guideline value
Dichloramine	Available data inadequate to permit derivation of health-based guideline value
1,3-Dichlorobenzene	Available data inadequate to permit derivation of health-based guideline value
1,1-Dichloroethane	Available data inadequate to permit derivation of health-based guideline value
1,1-Dichloroethene	Occurs in drinking-water at concentrations well below those of health concern
2,4-Dichlorophenol	Available data inadequate to permit derivation of health-based guideline value
1,3-Dichloropropane	Available data inadequate to permit derivation of health-based guideline value
Dichlorvos	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Dicofol	Unlikely to occur in drinking-water or drinking-water sources[b]
Di(2-ethylhexyl)adipate	Occurs in drinking-water at concentrations well below those of health concern
Diflubenzuron	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Diquat	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Endosulfan	Occurs in drinking-water at concentrations well below those of health concern
Fenitrothion	Occurs in drinking-water at concentrations well below those of health concern
Fluoranthene	Occurs in drinking-water at concentrations well below those of health concern
Formaldehyde	Occurs in drinking-water at concentrations well below those of health concern
Glyphosate and AMPA[c]	Occur in drinking-water at concentrations well below those of health concern
Hardness	Not of health concern at levels found in drinking-water[a]
Heptachlor and heptachlor epoxide	Occur in drinking-water at concentrations well below those of health concern
Hexachlorobenzene	Occurs in drinking-water at concentrations well below those of health concern
Hydrogen sulfide	Not of health concern at levels found in drinking-water[a]
Inorganic tin	Occurs in drinking-water at concentrations well below those of health concern
Iodine	Available data inadequate to permit derivation of health-based guideline value, and lifetime exposure to iodine through water disinfection is unlikely
Iron	Not of health concern at levels causing acceptability problems in drinking-water[a]

Table A3.2 (continued)

Chemical	Reason for not establishing a guideline value
Malathion	Occurs in drinking-water at concentrations well below those of health concern

Table A3.2 (continued)

Chemical	Reason for not establishing a guideline value
Manganese	Not of health concern at levels normally causing acceptability problems in drinking-water. However, there are circumstances where manganese can remain in solution at higher concentrations in some acidic or anaerobic waters, particularly groundwater.
MCPA[d]	Occurs in drinking-water or drinking-water sources at concentrations well below those of health concern
Methoprene	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Methyl parathion	Occurs in drinking-water at concentrations well below those of health concern
Methyl *tertiary*-butyl ether (MTBE)	Any guideline that would be derived would be significantly higher than concentrations at which MTBE would be detected by odour
Molybdenum	Occurs in drinking-water at concentrations well below those of health concern
Monobromoacetate	Available data inadequate to permit derivation of health-based guideline value
Monochlorobenzene	Occurs in drinking-water at concentrations well below those of health concern, and health-based value would far exceed lowest reported taste and odour threshold
MX	Occurs in drinking-water at concentrations well below those of health concern
Nitrobenzene	Rarely found in drinking-water at concentrations of health concern
Novaluron	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Parathion	Occurs in drinking-water at concentrations well below those of health concern
Permethrin	Not recommended for direct addition to drinking-water as part of WHO's policy to exclude the use of any pyrethroids for larviciding of mosquito vectors of human disease
Petroleum products	Taste and odour will in most cases be detectable at concentrations below those of health concern, particularly with short-term exposure
pH	Not of health concern at levels found in drinking-water[e]
2-Phenylphenol and its sodium salt	Occurs in drinking-water at concentrations well below those of health concern
Pirimiphos-methyl	Not recommended for direct application to drinking-water unless no other effective and safe treatments are available
Potassium	Occurs in drinking-water at concentrations well below those of health concern
Propanil	Readily transformed into metabolites that are more toxic; a guideline value for the parent compound is considered inappropriate, and there are inadequate data to enable the derivation of guideline values for the metabolites
Pyriproxyfen	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water

Table A3.2 (continued)

Chemical	Reason for not establishing a guideline value
Silver	Available data inadequate to permit derivation of health-based guideline value
Sodium	Not of health concern at levels found in drinking-water[a]

Table A3.2 (continued)

Chemical	Reason for not establishing a guideline value
Spinosad	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Sulfate	Not of health concern at levels found in drinking-water[a]
Temephos	Not considered appropriate to set guideline values for pesticides used for vector control in drinking-water
Total dissolved solids	Not of health concern at levels found in drinking-water[a]
Trichloramine	Available data inadequate to permit derivation of health-based guideline value
Trichloroacetonitrile	Available data inadequate to permit derivation of health-based guideline value
Trichlorobenzenes (total)	Occurs in drinking-water at concentrations well below those of health concern, and health-based value would exceed lowest reported odour threshold
1,1,1-Trichloroethane	Occurs in drinking-water at concentrations well below those of health concern
Zinc	Not of health concern at levels found in drinking-water[a]

[a] May affect acceptability of drinking-water (see chapter 10).
[b] Although dicofol does not fulfil one of the three criteria for evaluation in the Guidelines, a background document has been prepared and a health-based value has been established, in response to a request from Member States for guidance.
[c] Aminomethylphosphonic acid.
[d] (2-Methyl-4-chlorophenoxy)acetic acid.
[e] An important operational water quality parameter.

Table A3.3 Guideline values for chemicals that are of health significance in drinking-water

	Guideline value		
Chemical	**mg/l**	**µg/l**	**Remarks**
Acrylamide	0.0005[a]	0.5[a]	
Alachlor	0.02[a]	20[a]	
Aldicarb	0.01	10	Applies to aldicarb sulfoxide and aldicarb sulfone
Aldrin and dieldrin	0.000 03	0.03	For combined aldrin plus dieldrin
Antimony	0.02	20	
Arsenic	0.01 (A, T)	10 (A, T)	
Atrazine and its chloro-*s*-triazine metabolites	0.1	100	
Barium	1.3	1 300	
Benzene	0.01[a]	10[a]	
Benzo[*a*]pyrene	0.0007[a]	0.7[a]	
Boron	2.4	2 400	
Bromate	0.01[a] (A, T)	10[a] (A, T)	
Bromodichloromethane	0.06[a]	60[a]	
Bromoform	0.1	100	

Table A3.3 (continued)

Chemical	Guideline value		Remarks
	mg/l	µg/l	
Cadmium	0.003	3	
Carbofuran	0.007	7	
Carbon tetrachloride	0.004	4	

Table A3.3 (continued)

Chemical	Guideline value		Remarks
	mg/l	µg/l	
Chlorate	0.7 (D)	700 (D)	
Chlordane	0.0002	0.2	
Chlorine	5 (C)	5 000 (C)	For effective disinfection, there should be a residual concentration of free chlorine of ≥ 0.5 mg/l after at least 30 min contact time at pH < 8.0. A chlorine residual should be maintained throughout the distribution system. At the point of delivery, the minimum residual concentration of free chlorine should be 0.2 mg/l.
Chlorite	0.7 (D)	700 (D)	
Chloroform	0.3	300	
Chlorotoluron	0.03	30	
Chlorpyrifos	0.03	30	
Chromium	0.05 (P)	50 (P)	For total chromium
Copper	2	2 000	Staining of laundry and sanitary ware may occur below guideline value
Cyanazine	0.0006	0.6	
2,4-D[b]	0.03	30	Applies to free acid
2,4-DB[c]	0.09	90	
DDT[d] and metabolites	0.001	1	
Dibromoacetonitrile	0.07	70	
Dibromochloromethane	0.1	100	
1,2-Dibromo-3-chloropropane	0.001[a]	1[a]	
1,2-Dibromoethane	0.0004[a] (P)	0.4[a] (P)	
Dichloroacetate	0.05[a] (D)	50[a] (D)	
Dichloroacetonitrile	0.02 (P)	20 (P)	
1,2-Dichlorobenzene	1 (C)	1 000 (C)	
1,4-Dichlorobenzene	0.3 (C)	300 (C)	
1,2-Dichloroethane	0.03a	30[a]	
1,2-Dichloroethene	0.05	50	
Dichloromethane	0.02	20	
1,2-Dichloropropane	0.04 (P)	40 (P)	
1,3-Dichloropropene	0.02[a]	20[a]	
Dichlorprop	0.1	100	
Di(2-ethylhexyl)phthalate	0.008	8	
Dimethoate	0.006	6	
1,4-Dioxane	0.05[a]	50[a]	Derived using tolerable daily intake approach as well as linearized multistage modelling

Table A3.3 (continued)

Chemical	Guideline value mg/l	Guideline value µg/l	Remarks
Edetic acid	0.6	600	Applies to the free acid
Endrin	0.0006	0.6	
Epichlorohydrin	0.0004 (P)	0.4 (P)	
Ethylbenzene	0.3 (C)	300 (C)	
Fenoprop	0.009	9	
Fluoride	1.5	1 500	Volume of water consumed and intake from other sources should be considered when setting national standards
Hexachlorobutadiene	0.0006	0.6	
Hydroxyatrazine	0.2	200	Atrazine metabolite
Isoproturon	0.009	9	
Lead	0.01 (A, T)	10 (A, T)	
Lindane	0.002	2	
Mecoprop	0.01	10	
Mercury	0.006	6	For inorganic mercury
Methoxychlor	0.02	20	
Metolachlor	0.01	10	
Microcystin-LR	0.001 (P)	1 (P)	For total microcystin-LR (free plus cell-bound)
Molinate	0.006	6	
Monochloramine	3	3 000	
Monochloroacetate	0.02	20	
Nickel	0.07	70	
Nitrate (as NO_3^-)	50	50 000	Based on short-term effects, but protective for long-term effects
Nitrilotriacetic acid	0.2	200	
Nitrite (as NO_2^-)	3	3 000	Based on short-term effects, but protective for long-term effects
N-Nitrosodimethylamine	0.0001	0.1	
Pendimethalin	0.02	20	
Pentachlorophenol	0.009[a] (P)	9[a] (P)	
Perchlorate	0.07	70	
Selenium	0.04 (P)	40 (P)	
Simazine	0.002	2	
Sodium dichloroisocyanurate	50	50 000	As sodium dichloroisocyanurate
	40	40 000	As cyanuric acid
Styrene	0.02 (C)	20 (C)	
2,4,5-T[e]	0.009	9	
Terbuthylazine	0.007	7	

Table A3.3 (continued)

Chemical	Guideline value		Remarks
	mg/l	µg/l	
Tetrachloroethene	0.04	40	

Table A3.3 (continued)

Chemical	Guideline value		Remarks
	mg/l	µg/l	
Toluene	0.7 (C)	700 (C)	
Trichloroacetate	0.2	200	
Trichloroethene	0.02 (P)	20 (P)	
2,4,6-Trichlorophenol	0.2[a] (C)	200[a] (C)	
Trifluralin	0.02	20	
Trihalomethanes			The sum of the ratio of the concentration of each to its respective guideline value should not exceed 1
Uranium	0.03 (P)	30 (P)	Only chemical aspects of uranium addressed
Vinyl chloride	0.0003[a]	0.3[a]	
Xylenes	0.5 (C)	500 (C)	

A, provisional guideline value because calculated guideline value is below the achievable quantification level; C, concentrations of the substance at or below the health-based guideline value may affect the appearance, taste or odour of the water, leading to consumer complaints; D, provisional guideline value because effective disinfection may result in the guideline value being exceeded; P, provisional guideline value because of uncertainties in the health database; T, provisional guideline value because calculated guideline value is below the level that can be achieved through practical treatment methods, source protection, etc.

[a] For substances that are considered to be carcinogenic, the guideline value is the concentration in drinking-water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional case of cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). Concentrations associated with upper-bound estimated excess lifetime cancer risks of 10^{-4} and 10^{-6} can be calculated by multiplying and dividing, respectively, the guideline value by 10.

[b] 2,4-Dichlorophenoxyacetic acid.

[c] 2,4-Dichlorophenoxybutyric acid.

[d] Dichlorodiphenyltrichlorethane.

[e] 2,4,5-Trichlorophenoxyacetic acid.

ANNEX 4

Analytical methods and achievability

A4.1 Analytical methods

In *volumetric titration*, chemicals are analysed by titration with a standardized titrant. The titration end-point is identified by the development of colour resulting from the reaction with an indicator, by the change of electrical potential or by the change of pH value.

Colorimetric methods are based on measuring the intensity of colour of a coloured target chemical or reaction product. The optical absorbance is measured using light of a suitable wavelength. The concentration is determined by means of a calibration curve obtained using known concentrations of the determinant. The ultraviolet (UV) method is similar to this method except that UV light is used. For ionic materials, the ion concentration can be measured using an *ion selective electrode*. The measured potential is proportional to the logarithm of the ion concentration. Some organic compounds absorb UV light (wavelength 190–380 nm) in proportion to their concentration. *UV absorption* is useful for qualitative estimation of organic substances, because a strong correlation may exist between UV absorption and organic carbon content.

Atomic absorption spectrometry (AAS) is used for the determination of metals. It is based on the phenomenon that the atom in the ground state absorbs the light of wavelengths that are characteristic to each element when light is passed through the atoms in the vapour state. Because this absorption of light depends on the concentration of atoms in the vapour, the concentration of the target element in the water sample is determined from the measured absorbance. The Beer-Lambert law describes the relationship between concentration and absorbance.

In *flame atomic absorption spectrometry (FAAS)*, a sample is aspirated into a flame and atomized. A light beam from a hollow cathode lamp of the same element as the target metal is radiated through the flame, and the amount of absorbed light is measured by the detector. This method is much more sensitive than other methods and free from spectral or radiation interference by co-existing elements. Pretreatment is either unnecessary or straightforward. However, it is not suitable for simultaneous analysis of many elements, because the light source is different for each target element.

Electrothermal atomic absorption spectrometry (EAAS) is based on the same principle as FAAS, but an electrically heated atomizer or graphite furnace replaces the standard burner head for determination of metals. In comparison with FAAS, EAAS gives higher sensitivities and lower detection limits, and a smaller sample volume is required. EAAS suffers from more interference through light scattering by co-existing elements and requires a longer analysis time than FAAS.

The principle of *inductively coupled plasma atomic emission spectrometry (ICP-AES)* for determination of metals is as follows. An ICP source consists of a flowing stream of argon gas ionized by an applied radio frequency. A sample aerosol is generated in a nebulizer and spray chamber and then carried into the plasma through an injector tube. A sample is heated and excited in the high-temperature plasma. The high temperature of the plasma causes the atoms to become excited. On returning to the ground state, the excited atoms produce ionic emission spectra. A monochromator is used to separate specific wavelengths corresponding to different elements, and a detector measures the intensity of radiation of each wavelength. A significant reduction in chemical interference is achieved. In the case of water with low pollution, simultaneous or sequential analysis is possible without special pretreatment to achieve low detection limits for many elements. This, coupled with the extended dynamic range from three digits to five digits, means that multielement determination of metals can be achieved. ICP-AES has similar sensitivity to FAAS or EAAS.

In *inductively coupled plasma mass spectrometry* (ICP-MS), elements are atomized and excited as in ICP-AES, then passed to a mass spectrometer. Once inside the mass spectrometer, the ions are accelerated by high voltage and passed through a series of ion optics, an electrostatic analyser and, finally, a magnet. By varying the strength of the magnet, ions are separated according to mass/charge ratio and passed through a slit into the detector, which records only a very small atomic mass range at a given time. By varying the magnet and electrostatic analyser settings, the entire mass range can be scanned within a relatively short period of time. In the case of water with low pollution, simultaneous or sequential analysis is possible without special pretreatment to achieve low detection limits for many elements. This, coupled with the extended dynamic range from three digits to five digits, means that multielement determination of metals can be achieved.

Chromatography is a separation method based on the affinity difference between two phases, the stationary and mobile phases. A sample is injected into a column, either packed or coated with the stationary phase, and separated by the mobile phase based on the difference in interaction (distribution or adsorption) between compounds and the stationary phase. Compounds with a low affinity for the stationary phase move more quickly through the column and elute earlier. The compounds that elute from the end of the column are determined by a suitable detector.

In *ion chromatography*, an ion exchanger is used as the stationary phase, and the eluant for determination of anions is typically a dilute solution of sodium hydrogen carbonate and sodium carbonate. Colorimetric, electrometric or titrimetric detectors can be used for determining individual anions. In suppressed ion chromatography, anions are converted to their highly conductive acid forms; in the carbonate–bicarbonate

eluant, anions are converted to weakly conductive carbonic acid. The separated acid forms are measured by conductivity and identified on the basis of retention time as compared with their standards.

High-performance liquid chromatography (HPLC) is an analytical technique using a liquid mobile phase and a column containing a liquid stationary phase. Detection of the separated compounds is achieved through the use of absorbance detectors for organic compounds and through conductivity or electrochemical detectors for metallic and inorganic compounds.

Gas chromatography (GC) permits the identification and quantification of trace organic compounds. In GC, gas is used as the mobile phase, and the stationary phase is a liquid that is coated either on an inert granular solid or on the walls of a capillary column. When the sample is injected into the column, the organic compounds are vaporized and moved through the column by the carrier gas at different rates depending on differences in partition coefficients between the mobile and stationary phases. The gas exiting the column is passed to a suitable detector. A variety of detectors can be used, including flame ionization (FID), electron capture (ECD) and nitrogen–phosphorus. As separation ability is good in this method, mixtures of substances with similar structure are systematically separated, identified and determined quantitatively in a single operation.

The *gas chromatography/mass spectrometry (GC-MS)* method is based on the same principle as the GC method, using a mass spectrometer as the detector. As the gas emerges from the end of the GC column opening, it flows through a capillary column interface into the MS. The sample then enters the ionization chamber, where a collimated beam of electrons impacts the sample molecules, causing ionization and fragmentation. The next component is a mass analyser, which uses a magnetic field to separate the positively charged particles according to their mass. Several types of separating techniques exist; the most common are quadrupoles and ion traps. After the ions are separated according to their masses, they enter a detector.

The *purge-and-trap packed column GC-MS* method or purge-and-trap packed column GC method is applicable to the determination of various purgeable organic compounds that are transferred from the aqueous to the vapour phase by bubbling purge gas through a water sample at ambient temperature. The vapour is trapped with a cooled trap. The trap is heated and backflushed with the same purge gas to desorb the compounds onto a GC column. The principles of GC or GC-MS are as referred to above.

The principle of *enzyme-linked immunosorbent assay (ELISA)* is as follows. The protein (antibody) against the chemical of interest (antigen) is coated onto the solid material. The target chemical in the water sample binds to the antibody, and a second antibody with an enzyme attached is also added that will attach to the chemical of interest. After washing to remove any of the free reagents, a chromogen is added that will give a colour reaction due to cleavage by the enzyme that is proportional to the quantity of the chemical of interest. The ELISA method can be used to determine microcystin and synthetic surfactants.

A4.2 Analytical achievability for chemicals for which guideline values have been established

Analytical achievability for chemicals for which guideline values have been established is given in Tables A4.1–A4.6.

Table A4.1 Analytical achievability for inorganic chemicals for which guideline values have been established, by source category[a]

	Field methods		Laboratory methods				
	Col	Absor	IC	FAAS	EAAS	ICP	ICP-MS
Naturally occurring chemicals							
Arsenic	+++	#		++(H)	+	++(H)	+++
Barium				++	+++	+++	+++
Boron		++				+++	+++
Chromium		#			++	++	+++
Fluoride	#	+	+++				
Selenium		#		++(H)	++	++(H)	+++
Uranium							+++
Chemicals from industrial sources and human dwellings							
Cadmium		#			++	++	+++
Mercury				+++			
Chemicals from agricultural activities							
Nitrate/nitrite	+++	+++	+++				
Chemicals used in water treatment or materials in contact with drinking-water							
Antimony				+++(H)		++(H)	+++
Copper	#	+++		+++	+++	+++	+++
Lead		#			+	+	+++
Nickel		+		+	++	++	+++

[a] For definitions and notes to Table A4.1, see below Table A4.6.

Table A4.2 Analytical achievability for organic chemicals from industrial sources and human dwellings for which guideline values have been established[a]

	Col	GC	(PT-) GC-PD	(PT-) GC-ECD	GC-FID	GC-FPD	GC-TID	GC-MS	PT-GC-MS	HPLC	HPLC -FD	HPLC-UVPAD	EAAS	IC-FD	IC-SCD	LC-MS
Benzene			+++						+++							
Carbon tetrachloride				+++					+++							
1,2-Dichlorobenzene			+++	+++				+++	+++							
1,4-Dichlorobenzene			+++	+++				+++	+++							
1,2-Dichloroethane				+++					+++							
1,2-Dichloroethene			+++	+++					+++							
Dichloromethane				+++					+++							
Di(2-ethylhexyl)phthalate								++								
1,4-Dioxane								+++								
Edetic acid								+++								
Ethylbenzene			+++						+++							
Hexachlorobutadiene			++	++					++							
Nitrilotriacetic acid		+++						+++								
Pentachlorophenol				+++				+			+					
Perchlorate															++	+++
Styrene			+++						+++							
Tetrachloroethene			+++	+++				+++	+++							
Toluene			+++						+++							
Trichloroethene			+++	+++				+++	+++							
Xylenes			+++						+++							

[a] For definitions and notes to Table A4.2, see below Table A4.6.

Table A4.3 Analytical achievability for organic chemicals from agricultural activities for which guideline values have been established[a,b]

	Col	GC	(PT-) GC-PD	(PT-) GC-ECD	GC-FID	GC-FPD	GC-TID	GC-MS	PT-GC-MS	HPLC	HPLC-FD	HPLC-UVPAD	EAAS	IC-FD
Alachlor				+++				+++						
Aldicarb											+++			
Aldrin and dieldrin				++				++						
Atrazine and its chloro-*s*-triazine metabolites				+++				+++				+++		
Carbofuran		++												
Chlordane				+++				+++						
Chlorotoluron								+++				+++		
Cyanazine				+++				+++				+		
2,4-D				+++				+++				++		
2,4-DB				+++				++				++		
1,2-Dibromo-3-chloro-propane				+++				+++	+++					
1,2-Dibromoethane				++				++	+++					
1,2-Dichloropropane				+++					+++					
1,3-Dichloropropene				+++					+++					
Dichlorprop				+++				+++						
Dimethoate								+++						
Endrin				+++				+++						
Fenoprop				+++								+		
Hydroxyatrazine							+++					+++		
Isoproturon								+++				+++		
Lindane				+++				+++						

Table A4.3 (continued)

	Col	GC	(PT-) GC-PD	(PT-) GC-ECD	GC-FID	GC-FPD	GC-TID	GC-MS	PT-GC-MS	HPLC	HPLC-FD	HPLC-UVPAD	EAAS	IC-FD
Mecoprop				+++				+++						
Methoxychlor								+++						
Metolachlor				+++				+++						
Molinate		+++						+++						
Pendimethalin								+++						
Simazine				+++				+++						
2,4,5-T				+++								+		
Terbuthylazine								+++				++		
Trifluralin		+++		+++				+++						

[a] For definitions and notes to Table A4.3, see below Table A4.6.
[b] LC-MS is also applicable for many of these agricultural chemicals.

Table A4.4 Analytical achievability for chemicals used in water treatment or from materials in contact with water for which guideline values have been established[a]

	Col	GC	(PT-) GC-PD	(PT-) GC-ECD	GC-FID	GC-FPD	GC-TID	GC-MS	PT- GC-MS	HPLC	HPLC-FD	HPLC-UVPAD	EAAS	IC
Disinfectants														
Monochloramine	+++													
Chlorine	+++													
Sodium dichloroisocyanurate							+++	+++				+++		
Disinfection by-products														
Bromate														++
Bromodichloromethane				+++				+++	+++					
Bromoform				+++				+++	+++					
Chlorate														+++

Table A4.4 (continued)

	Col	GC	(PT-) GC-PD	(PT-) GC-ECD	GC-FID	GC-FPD	GC-TID	GC-MS	PT- GC-MS	HPLC	HPLC-FD	HPLC-UVPAD	EAAS	IC
Chlorite														+++
Chloroform				+++				+++	+++					
Dibromoacetonitrile				+++				+++						
Dibromochloromethane				+++				+++	+++					
Dichloroacetic acid				+++				+++						
Dichloroacetonitrile				+++				+++						
Monochloroacetic acid				+++				++						
N-Nitrosodimethylamine								+++						
Trichloroacetic acid				+++				+++						
2,4,6-Trichlorophenol				+++				+++						
Trihalomethanes[b]				+++				+++	+++					
Organic contaminants from treatment chemicals														
Acrylamide							+				+			
Epichlorohydrin				+++	+++				+					
Organic contaminants from pipes and fittings														
Benzo[*a*]pyrene								++			++			
Vinyl chloride			++	++					+					

[a] For definitions and notes to Table A4.4, see below Table A4.6.
[b] See also individual trihalomethanes.

Table A4.5 Analytical achievability for pesticides used in water for public health purposes for which guideline values have been established[a]

	Col	GC	GC-PD	GC-EC	GC-FID	GC-FPD	GC-TID	GC-MS	PT-GC-MS	HPLC	HPLC-FD	HPLC-UVPAD	EAAS	IC/FD
Chlorpyrifos				+++		++	++	+++						
DDT (and metabolites)				++				++						

[a] For definitions and notes to Table A4.5, see below Table A4.6.

Table A4.6 Analytical achievability for cyanobacterial toxins for which guideline values have been established

	PPA	ELISA	GC-MS	HPLC-UVPAD	LC-MS
Microcystin-LR	+	++	+	++	++

Definitions to Tables A4.1–A4.6

Absor	Absorptiometry	HPLC	High-performance liquid chromatography
Col	Colorimetry	HPLC-FD	High-performance liquid chromatography–fluorescence detector
EAAS	Electrothermal atomic absorption spectrometry	HPLC-UVPAD	High-performance liquid chromatography–ultraviolet photodiode array detector
ELISA	Enzyme-linked immunosorbent assay	IC	Ion chromatography
FAAS	Flame atomic absorption spectrometry	IC-FAAS	Ion chromatography–flame atomic absorption spectrometry
GC	Gas chromatography	IC-FD	Ion chromatography–fluorescence detector
GC-ECD	Gas chromatography–electron capture detector	IC-SCD	Ion chromatography-suppressed conductivity detection
GC-FID	Gas chromatography–flame ionization detector	ICP	Inductively coupled plasma
GC-FPD	Gas chromatography–flame photodiode detector	ICP-MS	Inductively coupled plasma mass spectrometry
GC-MS	Gas chromatography–mass spectrometry	LC-MS	Liquid chromatography–mass spectrometry
GC-PD	Gas chromatography–photoionization detector	PPA	Protein phosphatase assay
GC-TID	Gas chromatography–thermal ionization detector	PT-GC-MS	Purge-and-trap gas chromatography–mass spectrometry

Notes to Tables A4.1–A4.6

+	The detection limit is between the guideline value and 1/10th of its value.
++	The detection limit is between 1/10th and 1/50th of the guideline value.
+++	The detection limit is under 1/100th of the guideline value.
#	The analytical method is available for detection of the guideline value concentration, but it is difficult to detect the concentration of 1/10 of the guideline value.
(H)	This method is applicable to the determination by conversion to their hydrides by hydride generator.

ANNEX 5

Treatment methods and performance

A5.1 Treatment methods

A5.1.1 Chlorination

Chlorination can be achieved by using liquefied chlorine gas, sodium hypochlorite solution or calcium hypochlorite granules and on-site chlorine generators. Liquefied chlorine gas is supplied in pressurized containers. The gas is withdrawn from the cylinder and dosed into water by a chlorinator, which both controls and measures the gas flow rate. Sodium hypochlorite solution is dosed using a positive-displacement electric dosing pump or gravity feed system. Calcium hypochlorite has to be dissolved in water, then mixed with the main supply. Chlorine, whether in the form of chlorine gas from a cylinder, sodium hypochlorite or calcium hypochlorite, dissolves in water to form hypochlorous acid (HOCl) and hypochlorite ion (OCl^-).

Different techniques of chlorination can be used, including breakpoint chlorination, marginal chlorination and superchlorination/dechlorination. Breakpoint chlorination is a method in which the chlorine dose is sufficient to rapidly oxidize all the ammonia nitrogen in the water and to leave a suitable free residual chlorine available to protect the water against reinfection from the point of chlorination to the point of use. Superchlorination/dechlorination is the addition of a large dose of chlorine to effect rapid disinfection and chemical reaction, followed by reduction of excess free chlorine residual. Removing excess chlorine is important to prevent taste problems. It is used mainly when the bacterial load is variable or the detention time in a tank is not enough. Marginal chlorination is used where water supplies are of high quality and is the simple dosing of chlorine to produce a desired level of free residual chlorine. The chlorine demand in these supplies is very low, and a breakpoint might not even occur.

Chlorination is employed primarily for microbial disinfection. However, chlorine also acts as an oxidant and can remove or assist in the removal or chemical conversion of some chemicals—for example, decomposition of easily oxidized pesticides, such as aldicarb; oxidation of dissolved species (e.g. manganese(II)) to form insoluble products that can be removed by subsequent filtration; and oxidation of dissolved species to more easily removable forms (e.g. arsenite to arsenate).

A disadvantage of chlorine is its ability to react with natural organic matter to produce trihalomethanes and other halogenated disinfection by-products. However, by-product formation may be controlled by optimization of the treatment system.

A5.1.2 Ozonation

Ozone is a powerful oxidant and has many uses in water treatment, including oxidation of organic chemicals. Ozone can be used as a primary disinfectant. Ozone gas (O_3) is formed by passing dry air or oxygen through a high-voltage electric field. The resultant ozone-enriched air is dosed directly into the water by means of porous diffusers at the base of baffled contactor tanks. The contactor tanks, typically about 5 m deep, provide 10–20 minutes of contact time. Dissolution of at least 80% of the applied ozone should be possible, with the remainder contained in the off-gas, which is passed through an ozone destructor and vented to the atmosphere.

The performance of ozonation relies on achieving the desired concentration after a given contact period. For oxidation of organic chemicals, such as some oxidizable pesticides, a residual of about 0.5 mg/l after a contact time of up to 20 minutes is typically used. The doses required to achieve this vary with the type of water but are typically in the range 2–5 mg/l. Higher doses are needed for untreated waters, because of the ozone demand of the natural background organics.

Ozone reacts with natural organics to increase their biodegradability, measured as assimilable organic carbon. To avoid undesirable bacterial growth in distribution, ozonation is normally used with subsequent treatment, such as biological filtration or granular activated carbon (GAC), to remove biodegradable organics, followed by a chlorine residual, as ozone does not provide a disinfectant residual. Ozone is effective for the degradation of a wide range of pesticides and other organic chemicals.

A5.1.3 Other disinfection processes

Other disinfection methods include chloramination, the use of chlorine dioxide and UV radiation, as well as alternative disinfection techniques that may be used in smaller-scale applications, such as for household water.

Chloramines (monochloramine, dichloramine and trichloramine, or nitrogen trichloride) are produced by the reaction of aqueous chlorine with ammonia. Monochloramine is the only useful chloramine disinfectant, and conditions employed for chloramination are designed to produce only monochloramine. Monochloramine is a less effective disinfectant than free chlorine, but it is persistent, and it is therefore an attractive secondary disinfectant for the maintenance of a stable distribution system residual.

Chlorine dioxide has been used in recent years because of concerns about disinfection by-product production associated with chlorine disinfection. Typically, chlorine dioxide is generated immediately prior to application by the addition of chlorine gas or an aqueous chlorine solution to aqueous sodium chlorite. Chlorine dioxide decomposes in water to form chlorite and chlorate.

UV radiation, emitted by a low-pressure or medium-pressure mercury arc lamp, is biocidal between wavelengths of 180 and 320 nm. It can be used to inactivate protozoa, bacteria, bacteriophage, yeast, viruses, fungi and algae. Turbidity can inhibit UV

disinfection. UV radiation can act as a catalyst in oxidation reactions when used in conjunction with ozone or hydrogen peroxide.

Numerous possible disinfection techniques are being developed and are typically used in smaller-scale applications, such as household point-of-use and point-of-entry water treatment systems. Some of these, including bromine and iodine, show promise for expanded use. Bromine and iodine are halogens, like chlorine, and they are well-known biocides. Iodine is commonly used for short-term applications, such as by travellers in areas where water quality is questionable. Some forms of silver may have applications as bacteriostats or possibly as slow-acting disinfectants for some microorganisms; however, there are not good peer-reviewed published data to quantify the latter. It will be necessary to develop a more thorough analysis of the biocidal efficacy, potential disinfection by-products and risks from long-term exposures and application conditions for these lesser-used treatment chemicals to provide appropriate guidance as to their potential for wider applications.

A5.1.4 Filtration

Particulate matter can be removed from raw waters by rapid gravity, horizontal, pressure or slow sand filters. Slow sand filtration is essentially a biological process, whereas the others are physical treatment processes.

Rapid gravity, horizontal and pressure filters can be used for filtration of raw water, without pretreatment. Rapid gravity and pressure filters are commonly used to filter water that has been pretreated by coagulation and sedimentation. An alternative process is direct filtration, in which coagulation is added to the water, which then passes directly onto the filter where the precipitated floc (with contaminants) is removed; the application of direct filtration is limited by the available storage within the filter to accommodate solids.

Rapid gravity filters

Rapid gravity sand filters usually consist of open rectangular tanks (usually < 100 m^2) containing silica sand (size range 0.5–1.0 mm) to a depth of between 0.6 and 2.0 m. The water flows downwards, and solids become concentrated in the upper layers of the bed. The flow rate is generally in the range 4–20 $m^3/m^2 \cdot h$. Treated water is collected via nozzles in the floor of the filter. The accumulated solids are removed periodically by backwashing with treated water, sometimes preceded by scouring of the sand with air. A dilute sludge that requires disposal is produced.

In addition to single-medium sand filters, dual-media or multimedia filters are used. Such filters incorporate different materials, such that the structure is from coarse to fine as the water passes through the filter. Materials of suitable density are used in order to maintain the segregation of the different layers following backwashing. A common example of a dual-media filter is the anthracite–sand filter, which typically consists of a 0.2 m deep layer of 1.5 mm anthracite over a 0.6 m deep layer of silica sand. Anthracite, sand and garnet can be used in multimedia filters. The advantage of dual-media and multimedia filters is that there is more efficient use of the whole bed depth for particle retention—the rate of headloss development can be half that of

single-medium filters, which can allow higher flow rates without increasing headloss development.

Rapid gravity filters are most commonly used to remove floc from coagulated waters (see section A5.1.6). They may also be used to reduce turbidity (including adsorbed chemicals) and oxidized iron and manganese from raw waters.

Roughing filters

Roughing filters can be applied as pre-filters prior to other processes such as slow sand filters. Roughing filters with coarse gravel or crushed stones as the filter medium can successfully treat water of high turbidity (> 50 nephelometric turbidity units). The main advantage of roughing filtration is that as the water passes through the filter, particles are removed by both filtration and gravity settling. Horizontal filters can be up to 10 m long and are operated at filtration rates of 0.3–1.0 $m^3/m^2 \cdot h$.

Pressure filters

Pressure filters are sometimes used where it is necessary to maintain head in order to eliminate the need for pumping into supply. The filter bed is enclosed in a cylindrical shell. Small pressure filters, capable of treating up to about 15 m^3/h, can be manufactured in glass-reinforced plastics. Larger pressure filters, up to 4 m in diameter, are manufactured in specially coated steel. Operation and performance are generally as described for the rapid gravity filter, and similar facilities are required for backwashing and disposal of the dilute sludge.

Slow sand filters

Slow sand filters usually consist of tanks containing sand (effective size range 0.15–0.3 mm) to a depth of between 0.5 and 1.5 m. The raw water flows downwards, and turbidity and microorganisms are removed primarily in the top few centimetres of the sand. A biological layer, known as the "schmutzdecke", develops on the surface of the filter and can be effective in removing microorganisms. Treated water is collected in underdrains or pipework at the bottom of the filter. The top few centimetres of sand containing the accumulated solids are removed and replaced periodically. Slow sand filters are operated at a water flow rate of between 0.1 and 0.3 $m^3/m^2 \cdot h$.

Slow sand filters are more suitable for low-turbidity water or water that has been pre-filtered. They are used to remove algae and microorganisms, including protozoa, and, if preceded by microstraining or coarse filtration, to reduce turbidity (including adsorbed chemicals). Slow sand filtration is effective for the removal of some organics, including certain pesticides and also ammonia.

Bank filtration

Bank filtration is a process that produces an influx of surface water through the groundwater, via the bed and banks of the surface water body. This is commonly achieved through abstraction from boreholes adjacent to the surface water source. It is a relatively simple and low-cost means for removing particulates and microorganisms from surface water by placing pumping wells in alluvial sediments of the river or stream banks. The sediments act as both a filter and biofilter, trapping and reducing the concentrations of microorganisms and many organic pollutants. Bank filtration wells can

be either horizontal or vertical, depending upon the hydrogeological circumstances and required production rate. Horizontal wells are often used where alluvial deposits are shallow or where high pumping rates are required.

Bank filtration can remove particles, bacteria, viruses, parasites, heavy metals and easily biodegradable compounds. Bank filtration attenuates concentration peaks, providing uniform quality of raw water feed to downstream treatment. The performance of bank filtration can be highly dependent upon several factors, including soil and geological conditions as well as the quality of the source water. Bank filters can become clogged, resulting in pressure drops. Site-specific testing is needed to determine whether the appropriate geology is present as well as the effectiveness and operational parameters.

A5.1.5 Aeration

Aeration processes are designed to achieve removal of gases and volatile compounds by air stripping. Transfer can usually be achieved using a simple cascade or diffusion of air into water, without the need for elaborate equipment. Stripping of gases or volatile compounds, however, may require a specialized plant that provides a high degree of mass transfer from the liquid phase to the gas phase.

Cascade or step aerators are designed so that water flows in a thin film to achieve efficient mass transfer. Cascade aeration may introduce a significant headloss; design requirements are between 1 and 3 m to provide a loading of 10–30 $m^3/m^2 \cdot h$. Alternatively, compressed air can be diffused through a system of submerged perforated pipes. These types of aerator are used for oxidation and precipitation of iron and manganese.

Air stripping can be used for removal of volatile organics (e.g. solvents), some taste- and odour-causing compounds and radon. Aeration processes to achieve air stripping need to be much more elaborate to provide the necessary contact between the air and water. The most common technique is cascade aeration, usually in packed towers in which water is allowed to flow in thin films over plastic media with air blown counter-current. The required tower height and diameter are functions of the volatility and concentration of the compounds to be removed and the flow rate. Increasing the dissolved oxygen content of a water can increase its corrosivity towards some metallic materials used in distribution pipes and plumbing, and this should be taken into account when considering aeration as a treatment process.

A5.1.6 Chemical coagulation

Chemical coagulation-based treatment is the most common approach for treatment of surface waters and is almost always based on the following unit processes.

Chemical coagulants, usually salts of aluminium or iron, are dosed to the raw water under controlled conditions to form a solid flocculent metal hydroxide. Typical coagulant doses are 2–5 mg/l as aluminium or 4–10 mg/l as iron. The precipitated floc removes suspended and dissolved contaminants by mechanisms of charge neutralization, adsorption and entrapment. The efficiency of the coagulation process depends on raw water quality, the coagulant or coagulant aids used and operational factors, including mixing conditions, coagulation dose and pH. The floc is removed from the

treated water by subsequent solid–liquid separation processes such as sedimentation or flotation and/or rapid or pressure gravity filtration.

Effective operation of the coagulation process depends on selection of the optimum coagulant dose and also the pH value. The required dose and pH can be determined by using small-scale batch coagulation tests, often termed "jar tests". Increasing doses of coagulant are applied to raw water samples that are stirred and allowed to settle. The optimum dose is selected as that which achieves adequate removal of colour and turbidity; the optimum pH can be selected in a similar manner. These tests have to be conducted at a sufficient frequency to keep pace with changes in raw water quality and hence coagulant demand.

Powdered activated carbon (PAC) may be dosed during coagulation to adsorb organic chemicals, such as some hydrophobic pesticides. The PAC will be removed as an integral fraction of the floc and disposed of with the waterworks sludge.

The floc may be removed by sedimentation to reduce the solids loading to the subsequent rapid gravity filters. Sedimentation is most commonly achieved in horizontal flow or floc blanket clarifiers. Alternatively, floc may be removed by dissolved air flotation, in which solids are contacted with fine bubbles of air that attach to the floc, causing them to float to the surface of the tank, where they are removed periodically as a layer of sludge. The treated water from either process is passed to rapid gravity filters (see section A5.1.4), where remaining solids are removed. Filtered water may be passed to a further stage of treatment, such as additional oxidation and filtration (for removal of manganese), ozonation and/or GAC adsorption (for removal of pesticides and other trace organics), prior to final disinfection before the treated water enters the supply.

Coagulation is suitable for removal of particulates and bound microorganisms, certain heavy metals and low-solubility organic chemicals, such as certain organochlorine pesticides. For other organic chemicals, coagulation is generally ineffective, except where the chemical is bound to humic material or adsorbed onto particulates.

A5.1.7 Activated carbon adsorption

Activated carbon is produced by the controlled thermalization of carbonaceous material, normally wood, coal, coconut shells or peat. This activation produces a porous material with a large surface area (500–1500 m^2/g) and a high affinity for organic compounds. It is normally used in either powdered (PAC) or granular (GAC) form. When the adsorption capacity of the carbon is exhausted, it can be reactivated by burning off the organics in a controlled manner. However, PAC (and some GAC) is normally used only once before disposal. Different types of activated carbon have different affinities for types of contaminants.

The choice between PAC and GAC will depend upon the relative cost-effectiveness, frequency and dose required. PAC would generally be preferred in the case of seasonal or intermittent contamination or where low dosage rates are required.

PAC is dosed as a slurry into the water and removed by subsequent treatment processes, together with the waterworks sludge. Its use is therefore restricted to surface water treatment works with existing filters. GAC in fixed-bed adsorbers is used much more efficiently than PAC dosed into the water, and the effective carbon use per water

volume treated would be much lower than the dose of PAC required to achieve the same removal.

GAC is used for taste and odour control. It is normally used in fixed beds, either in purpose-built adsorbers for chemicals or in existing filter shells by replacement of sand with GAC of a similar particle size. Although at most treatment works it would be cheaper to convert existing filters rather than build separate adsorbers, use of existing filters usually allows only short contact times, and they are not capable of facile reactivation. It is therefore common practice to install additional GAC adsorbers (in some cases preceded by ozonation) between the rapid gravity filters and final disinfection. Most groundwater sources do not have existing filters, and separate adsorbers would need to be installed.

The service life of a GAC bed is dependent on the capacity of the carbon used and the contact time between the water and the carbon, the empty bed contact time, controlled by the flow rate of the water. Empty bed contact times are usually in the range 5–30 minutes. GACs vary considerably in their capacity for specific organic compounds, which can have a significant effect upon their service life. A guide to capacity can be obtained from published isotherm data. Carbon capacity is strongly dependent on the water source and is greatly reduced by the presence of background organic compounds. The properties of a chemical that influence its adsorption onto activated carbon include the water solubility and octanol–water partition coefficient. As a general rule, chemicals with low solubilities and high log octanol–water partition coefficients are well adsorbed.

Activated carbon is used for the removal of pesticides and other organic chemicals, taste and odour compounds, cyanobacterial toxins and total organic carbon.

A5.1.8 Ion exchange

Ion exchange is a process in which ions of like charge are exchanged between the water phase and the solid resin phase. Water softening is achieved by cation exchange. Water is passed through a bed of cationic resin, and the calcium ions and magnesium ions in the water are replaced by sodium ions. When the ion exchange resin is exhausted (i.e. the sodium ions are depleted), it is regenerated using a solution of sodium chloride. The process of "dealkalization" can also soften water. Water is passed through a bed of weakly acidic resin, and the calcium and magnesium ions are replaced by hydrogen ions. The hydrogen ions react with the carbonate and bicarbonate ions to produce carbon dioxide. The hardness of the water is thus reduced without any increase in sodium levels. Anion exchange can be used to remove contaminants such as nitrate, fluoride, arsenate and uranium (as the uranyl anion), which are exchanged for chloride. Several appropriate resins are available for this purpose.

An ion exchange plant normally consists of two or more resin beds contained in pressure shells with appropriate pumps, pipework and ancillary equipment for regeneration. The pressure shells are typically up to 4 m in diameter, containing 0.6–1.5 m depth of resin.

Cation exchange can be used for removal of certain heavy metals. Potential applications of anionic resins, in addition to nitrate removal, are for removal of arsenic and selenium species.

A5.1.9 Membrane processes

The membrane processes of most significance in water treatment are reverse osmosis, ultrafiltration, microfiltration and nanofiltration. These processes have traditionally been applied to the production of water for industrial or pharmaceutical applications, but are now being applied to the treatment of drinking-water.

High-pressure processes

If two solutions are separated by a semipermeable membrane (i.e. a membrane that allows the passage of the solvent but not of the solute), the solvent will naturally pass from the lower-concentration solution to the higher-concentration solution. This process is known as osmosis. It is possible, however, to force the flow of solvent in the opposite direction, from the higher to the lower concentration, by increasing the pressure on the higher-concentration solution. The required pressure differential is known as the osmotic pressure, and the process is known as reverse osmosis.

Reverse osmosis results in the production of a treated water stream and a relatively concentrated waste stream. Typical operating pressures are in the range 15–50 bar, depending on the application. Reverse osmosis rejects monovalent ions and organics of molecular weight greater than about 50 daltons (membrane pore sizes are less than 0.002 μm). The most common application of reverse osmosis is desalination of brackish water and seawater.

Nanofiltration uses a membrane with properties between those of reverse osmosis and ultrafiltration membranes; pore sizes are typically 0.001–0.01 μm. Nanofiltration membranes allow monovalent ions such as sodium or potassium to pass but reject a high proportion of divalent ions such as calcium and magnesium and some higher molecular weight organics. Operating pressures are typically about 5 bar. Nanofiltration may be effective for the removal of colour-forming organic compounds.

Lower-pressure processes

Ultrafiltration is similar in principle to reverse osmosis, but the membranes have much larger pore sizes (typically 0.002–0.03 μm) and operate at lower pressures. Ultrafiltration membranes reject organic molecules of molecular weight above about 800 daltons and usually operate at pressures less than 5 bar.

Microfiltration is a direct extension of conventional filtration into the submicrometre range. Microfiltration membranes have pore sizes typically in the range 0.01–12 μm and do not separate molecules but reject colloidal and suspended material at operating pressures of 1–2 bar. Microfiltration is capable of sieving out particles greater than 0.05 μm. It has been used for water treatment in combination with coagulation or PAC to remove particulates and some dissolved organic carbon prior to reverse osmosis membranes and to improve permeate flux.

A5.1.10 Other treatment processes

Processes aimed at generating hydroxyl radicals are known collectively as advanced oxidation processes and can be effective for the destruction of chemicals that are difficult to treat using other methods, such as ozone alone. Hydrogen peroxide with UV is also a source of hydroxyl radicals. Chemicals can react either directly with molecular

ozone or with the hydroxyl radical (HO·), which is a product of the decomposition of ozone in water and is an exceedingly powerful indiscriminate oxidant that reacts readily with a wide range of organic chemicals. The formation of hydroxyl radicals can be encouraged by using ozone at high pH. One advanced oxidation process using ozone or UV plus hydrogen peroxide involves dosing hydrogen peroxide simultaneously with ozone at a rate of approximately 0.4 mg of hydrogen peroxide per litre per milligram of ozone dosed per litre (the theoretical optimum ratio for hydroxyl radical production) and bicarbonate.

Other treatment processes that can be used in certain applications include:

- precipitation softening (addition of lime, lime plus sodium carbonate or sodium hydroxide to precipitate hardness at high pH);
- ion exchange softening;
- biological denitrification for removal of nitrate from surface waters;
- biological nitrification for removal of ammonia from surface waters;
- activated alumina (or other adsorbents) for specialized applications, such as removal of fluoride and arsenic.

A5.2 Treatment performance for chemicals for which guideline values have been established

Treatment performance for chemicals for which guideline values have been established is given in Tables A5.1–A5.5.

A5.3 Corrosion of metals used in water treatment and distribution

A5.3.1 Brass

The main corrosion problem with brasses is dezincification, which is the selective dissolution of zinc from duplex brass, leaving behind copper as a porous mass of low mechanical strength. Meringue dezincification, in which a voluminous corrosion product of basic zinc carbonate forms on the brass surface, largely depends on the ratio of chloride to alkalinity. Meringue dezincification can be controlled by maintaining a low zinc to copper ratio (1:3 or lower) and by keeping pH below 8.3.

General dissolution of brass can also occur, releasing metals, including lead, into the water. Impingement attack can occur under conditions of high water velocity with waters that form poorly protective corrosion product layers and that contain large amounts of dissolved or entrained air.

A5.3.2 Concrete and cement

Concrete is a composite material consisting of a cement binder in which an inert aggregate is embedded. Cement is primarily a mixture of calcium silicates and aluminates together with some free lime. Cement mortar, in which the aggregate is fine sand, is used as a protective lining in iron and steel water pipes. In asbestos–cement pipe, the aggregate is asbestos fibres, which are not of concern in drinking-water (see also asbestos fact sheet in chapter 12). Cement is subject to deterioration on prolonged exposure to aggressive water, due either to the dissolution of lime and other soluble compounds

Table A5.1 Treatment performance for naturally occurring chemicals for which guideline values have been established[a,b]

	Chlorination	Coagulation	Ion exchange	Precipitation softening	Activated alumina	Activated carbon	Ozonation	Membranes
Arsenic[c]		++ <0.005	+++ <0.005	++ <0.005	+++ <0.005			+++[d] <0.005
Fluoride		++			+++ <1			+++ <1
Selenium		++	+++ <0.01		+++ <0.01			+++ <0.01
Uranium		++	+++ <0.001	++	+++ <0.001			

[a] Symbols are as follows:
++ Approximately 50% or more removal
+++ Approximately 80% or more removal

[b] The table includes chemicals for which some treatment data are available. A blank entry in the table indicates either that the process is completely ineffective or that there are no data on the effectiveness of the process. For the most effective processes, the table estimates the concentration of the chemical (in mg/l) that could be achievable in an ideal water.

[c] Iron oxide–based and iron hydroxide–based media have been shown to be very effective for both arsenate and arsenite forms.

[d] Reverse osmosis membranes are more effective for removal of arsenate than arsenite. However, arsenite is readily oxidized to arsenate by disinfectants (e.g. chlorine).

Table A5.2 Treatment performance for chemicals from industrial sources and human dwellings for which guideline values have been established[a,b]

	Air stripping	Coagulation	Ion exchange	Precipitation softening	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[c]	UV irradia-tion
Cadmium		+++ <0.002	+++ <0.002	+++ <0.002				+++ <0.002		
Mercury		+++ <0.0001		+++ <0.0001	+++ <0.0001			+++ <0.0001		
Benzene	+++ <0.01				+++ <0.01	+++ <0.01	Yes[d]			
Carbon tetrachloride	+++ <0.001				+++ <0.001			+		
1,2-Dichlorobenzene	+++ <0.01				+++ <0.01	+++ <0.01		Yes[d]		
1,4-Dichlorobenzene	+++ <0.01				+++ <0.01	+++ <0.01		Yes[d]		
1,2-Dichloroethane	+++				+++ <0.01		+			
1,2-Dichloroethene	+++ <0.01				+++ <0.01	+++ <0.01				
1,4-Dioxane					+		+++ 0.05			
Edetic acid					+++ <0.01					
Ethylbenzene	++ <0.001	+			+++ <0.001	+++ <0.001	++	+	++	
Hexachlorobutadiene					+++ <0.001			+		

Table A5.2 (continued)

	Air stripping	Coagulation	Ion exchange	Precipitation softening	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[c]	UV irradia-tion
Nitrilotriacetic acid					++				++	
N-Nitrosodimethylamine					+		++			+
Pentachlorophenol					+++ <0.0004			++		
Perchlorate			yes[d]					yes[d]	yes[d]	
Styrene	+++ <0.02				+++ <0.002	++		+	+	
Tetrachloroethene	+++ <0.001				+++ <0.001			+		
Toluene	+++ <0.001				+++ <0.001	+++ <0.001	+++[e] <0.001		++ <0.001	
Trichloroethene	+++ <0.02				+++ <0.02	+++ <0.02	+++[e] <0.02			
Xylenes	+++ <0.005				+++ <0.005		+++[e] <0.005		++	

[a] Symbols are as follows:
+ Limited removal
++ Approximately 50% or more removal
+++ Approximately 80% or more removal

[b] The table includes only those chemicals for which some treatment data are available. A blank entry in the table indicates either that the process is completely ineffective or that there are no data on the effectiveness of the process. For the most effective processes, where data are available, the table indicates the concentration of the chemical (in mg/l) that should be achievable.

[c] Biological treatment includes slow sand filtration and bank filtration.

[d] Yes means known or likely to be effective, but performance was not quantified.

[e] Might be effective, but other techniques would be more likely to be applied due to cost.

Table A5.3 Treatment performance for chemicals from agricultural activities for which guideline values have been established[a,b]

	Chlorination	Air stripping	Coagulation	Ion exchange	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[c]
Nitrate				+++ <5				+++ <5	+++ <5
Nitrite	+++ <0.1							+	+++
Alachlor					+++ <0.001	++	+++ <0.001	+++ <0.001	
Aldicarb					+++ <0.001	+++ <0.001		+++ <0.001	
Aldrin/dieldrin			+		+++ <0.000 02	++ <0.000 02		+++ <0.00002	
Atrazine and its chloro-*s*-triazine metabolites			+		+++ <0.0001	Yes[d]	+++ <0.0001	+++ <0.0001	+++[e] <0.0001
Carbofuran	+				+++ <0.001	Yes[d]		+++ <0.001	
Chlordane					+++ <0.0001	++ <0.0001		Yes[d]	
Chlorotoluron					+++ <0.0001	+++ <0.0001			
Cyanazine					+++ <0.0001	+		+++ <0.0001	
2,4-D					+++ <0.001	+++ <0.001		Yes[d]	
1,2-Dibromo-3-chloropropane		++ <0.001			+++ <0.0001				

Table A5.3 (continued)

	Chlorination	Air stripping	Coagulation	Ion exchange	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[c]
1,2-Dibromoethane		+++ <0.0001			+++ <0.0001				
1,2-Dichloropropane		Yes			+++ <0.001	+			
Dimethoate	+++ <0.001				++	++			
Endrin			+		+++ <0.0002			Yes[d]	
Hydroxyatrazine							+++ <0.001	Yes[d]	
Isoproturon	++				+++ <0.0001	+++ <0.0001	+++ <0.0001	+++ <0.0001	+
Lindane					+++ <0.0001	++		Yes[d]	++
Mecoprop					+++ <0.0001	+++ <0.0001			+++ <0.0001
Methoxychlor			++		+++ <0.0001	+++ <0.0001		Yes[d]	
Metalochlor					+++ <0.0001	++		Yes[d]	++
Simazine					+++ <0.0001	++	+++ <0.0001	+++ <0.0001	

Table A5.3 (continued)

	Chlorination	Air stripping	Coagulation	Ion exchange	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[c]
2,4,5-T					+++ <0.001			Yes[d]	
Terbuthylazine			+		+++ <0.0001	++			
Trifluralin					+++ <0.0001			+++[f] <0.0001	

[a] Symbols are as follows:
+ Limited removal
++ Approximately 50% or more removal
+++ Approximately 80% or more removal

[b] The table includes only those chemicals for which some treatment data are available. A blank entry in the table indicates either that the process is completely ineffective or that there are no data on the effectiveness of the process. For the most effective processes, the table indicates the concentration of the chemical (in mg/l) that should be achievable.

[c] Biological treatment includes slow sand filtration, bank filtration and biological denitrification (for nitrate removal).

[d] Yes means known or likely to be effective, but performance was not quantified.

[e] For bank filtration; slow sand filtration is not effective.

[f] Might be effective, but other techniques would be more likely to be applied due to cost.

Table A5.4 Treatment performance for pesticides used in water for public health for which guideline values have been established[a,b]

	Chlorination	Coagulation	Activated carbon	Ozonation	Advanced oxidation	Membranes
DDT and metabolites		+	+++ <0.0001	+	+++[c] <0.0001	+++[c] <0.0001

[a] Symbols are as follows:
+ Limited removal
+++ Approximately 80% or more removal
[b] For the most effective processes, the table indicates the concentration of the chemical (in mg/l) that should be achievable.
[c] Might be effective, but other techniques would be more likely to be applied due to cost.

Table A5.5 Treatment performance for cyanobacterial cells and cyanotoxins for which guideline values have been established[a,b,c]

	Chlorination	Coagulation	Activated carbon	Ozonation	Advanced oxidation	Membranes	Biological treatment[d]
Cyanobacterial cells		+++				+++	
Cyanotoxins	+++		+++	+++	+++		+++

[a] Chlorination or ozonation may release cyanotoxins.
[b] +++ = 80% or more removal.
[c] The table includes only those chemicals for which some treatment data are available. A blank entry in the table indicates either that the process is completely ineffective or that there are no data on the effectiveness of the process.
[d] Biological treatment includes slow sand filtration and bank filtration.

or to chemical attack by aggressive ions such as chloride or sulfate, and this may result in structural failure. Newly installed cement materials will leach lime, with consequent increases in pH, alkalinity and hardness. Cement contains a variety of metals that can be leached into the water. Aggressiveness to cement is related to the "aggressivity index", which has been used specifically to assess the potential for the dissolution of concrete. A pH of 8.5 or higher may be necessary to control cement corrosion.

A5.3.3 Copper

The corrosion of copper pipework and hot water cylinders can cause blue water, blue or green staining of bathroom fittings and, occasionally, taste problems. Copper tubing may be subject to general corrosion, impingement attack and pitting corrosion.

General corrosion is most often associated with soft, acidic waters; waters with pH below 6.5 and hardness of less than 60 mg of calcium carbonate per litre are very aggressive to copper. Copper, like lead, can enter water by dissolution of the corrosion product, basic copper carbonate. The solubility is mainly a function of pH and total inorganic carbon. Solubility decreases with increase in pH, but increases with increase in concentrations of carbonate species. Raising the pH to between 8 and 8.5 is the usual procedure to overcome these difficulties.

Impingement attack is the result of excessive flow velocities and is aggravated in soft water at high temperature and low pH.

The pitting of copper is commonly associated with hard groundwaters having a carbon dioxide concentration above 5 mg/l and high dissolved oxygen. Phosphates have been used to suppress copper corrosion in those cases. Surface waters with organic colour may also be associated with pitting corrosion. Copper pipes can fail by pitting corrosion, which involves highly localized attacks leading to perforations with negligible loss of metal. Two main types of attack are recognized. Type I pitting affects cold water systems (below 40 °C) and is associated, particularly, with hard borehole waters and the presence of a carbon film in the bore of the pipe, derived from the manufacturing process. Tubes that have had the carbon removed by cleaning are immune from Type I pitting. Type II pitting occurs in hot water systems (above 60 °C) and is associated with soft waters. A high proportion of general and pitting corrosion problems are associated with new pipe in which a protective oxide layer has not yet formed. Calcium carbonate precipitation indices such as Langelier and Ryznar are not good predictors of corrosion for copper systems.

A5.3.4 Iron

Iron (either cast or ductile) is frequently used in water distribution systems, and its corrosion is of concern. While structural failure as a result of iron corrosion is rare, water quality problems (e.g. "red water") can arise as a result of excessive corrosion of iron pipes. The corrosion of iron is a complex process that involves the oxidation of the metal, normally by dissolved oxygen, ultimately to form a precipitate of iron(III). This leads to the formation of tubercules on the pipe surface. The major water quality factors that determine whether the precipitate forms a protective scale are pH and alkalinity. The concentrations of calcium, chloride and sulfate also influence iron corrosion. Successful control of iron corrosion has been achieved by adjusting the pH to

the range 6.8–7.3, hardness and alkalinity to at least 40 mg/l (as calcium carbonate), oversaturation with calcium carbonate of 4–10 mg/l and a ratio of alkalinity to chloride plus sulfate of at least 5 (when both are expressed as calcium carbonate).

Silicates and polyphosphates are often described as "corrosion inhibitors", but there is no guarantee that they will inhibit corrosion in water distribution systems. However, they can complex dissolved iron (in the iron(II) state) and prevent its precipitation as visibly obvious red "rust". These compounds may act by masking the effects of corrosion rather than by preventing it. Orthophosphate is a possible corrosion inhibitor and, like polyphosphates, is used to prevent "red water".

A5.3.5 Lead

Lead corrosion (plumbosolvency) is of particular concern. Lead piping is still common in old houses in some countries, lead solders have been used widely for jointing copper tubing and brass fittings can contain substantial amounts of lead. Galvanized iron pipe plumbing can accumulate incoming lead and release it at a later time as particulates. The solubility of lead is governed by the formation of lead carbonates as pipe deposits. Wherever practicable, lead pipework should be replaced. Lead can also leach from lead-based solders and brass and bronze fittings.

The solubility of corrosion-related lead salts increases markedly as the pH increases above or decreases below 8.3 because of the substantial decrease in the equilibrium carbonate concentration. Thus, plumbosolvency tends to be at a maximum in waters with a low pH and low alkalinity, and a useful interim control procedure, pending pipe replacement, is to increase the pH to 8.0–8.5 after chlorination prior to distribution. Orthophosphate and other phosphates are effective in suppressing dissolution of lead.

Lead concentrations increase with increasing standing time of water in lead pipe. Flushing the pipework before drawing water for consumption can be used as an interim measure to reduce exposure to lead. Showering, bathing and flushing the toilet can be used to flush out the system.

Lead can corrode more rapidly when it is coupled to copper. The rate of such galvanic corrosion is faster than that of simple oxidative corrosion, and lead concentrations are not limited by the solubility of the corrosion products. The rate of galvanic corrosion is affected principally by chloride concentration. Galvanic corrosion is less easily controlled but can be reduced by dosing zinc in conjunction with orthophosphate and by adjustment of pH.

Treatment to reduce plumbosolvency usually involves pH adjustment. When the water is very soft (calcium carbonate concentration less than 50 mg/l), the optimum pH is about 8.0–8.5. Alternatively, dosing with orthophosphoric acid or sodium orthophosphate might be more effective, particularly when plumbosolvency occurs in non-acidic waters. Calcium carbonate precipitation indices such as Langelier and Ryznar are not considered to be necessarily good predictors of corrosion for lead.

A5.3.6 Nickel

Nickel in water may arise due to the leaching of nickel from new nickel/chromium-plated taps. Low concentrations may also arise from stainless steel pipes and fittings.

Nickel leaching falls off over time. An increase of pH to control corrosion of other materials should also reduce leaching of nickel.

A5.3.7 Zinc

Galvanized pipes will release zinc (from the galvanizing layer) and can also leach cadmium and lead. Corrosion can be a particular problem where galvanized steel or iron piping is connected to dissimilar materials, such as brass, in taps and fittings.

The solubility of zinc in water is a function of pH and total inorganic carbon concentrations; the solubility of basic zinc carbonate decreases with increase in pH and concentrations of carbonate species. For low-alkalinity waters, an increase of pH to 8.5 should be sufficient to control the dissolution of zinc.

With galvanized iron, the zinc layer initially protects the steel by corroding preferentially. In the long term, a protective deposit of basic zinc carbonate forms; however, galvanized pipe is also prone to uncontrolled deposition and clogging. Recent findings have shown that lead can accumulate on galvanized pipe particulates and become resuspended by physical disruption, such as water hammer. Protective deposits do not form in soft waters where the alkalinity is less than 50 mg/l as calcium carbonate or waters containing high carbon dioxide concentrations (> 25 mg/l), and galvanized steel is unsuitable for these waters. Electrolytic corrosion can occur where galvanized steel or iron pipes or fittings are connected with copper tube or brass fittings.

ANNEX 6

Supporting information on radionuclides

A6.1 Guidance levels for radionuclides in drinking-water

Table A6.1 Guidance levels for radionuclides in drinking-water

Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]
^{3}H	10 000	^{71}Ge	10 000	^{105}Rh	1 000	^{129}Cs	1 000
^{7}Be	10 000	^{73}As	1 000	^{103}Pd	1 000	^{131}Cs	1 000
^{14}C	100	^{74}As	100	^{105}Ag	100	^{132}Cs	100
^{22}Na	100	^{76}As	100	^{110m}Ag	100	^{134}Cs	10
^{32}P	100	^{77}As	1 000	^{111}Ag	100	^{135}Cs	100
^{33}P	1 000	^{75}Se	100	^{109}Cd	100	^{136}Cs	100
^{35}S	100	^{82}Br	100	^{115}Cd	100	^{137}Cs	10
^{36}Cl	100	^{86}Rb	100	^{115m}Cd	100	^{131}Ba	1 000
^{45}Ca	100	^{85}Sr	100	^{111}In	1 000	^{140}Ba	100
^{47}Ca	100	^{89}Sr	100	^{114m}In	100	^{140}La	100
^{46}Sc	100	^{90}Sr	10	^{113}Sn	100	^{139}Ce	1 000
^{47}Sc	100	^{90}Y	100	^{125}Sn	100	^{141}Ce	100
^{48}Sc	100	^{91}Y	100	^{122}Sb	100	^{143}Ce	100
^{48}V	100	^{93}Zr	100	^{124}Sb	100	^{144}Ce	10
^{51}Cr	10 000	^{95}Zr	100	^{125}Sb	100	^{143}Pr	100
^{52}Mn	100	^{93m}Nb	1 000	^{123m}Te	100	^{147}Nd	100
^{53}Mn	10 000	^{94}Nb	100	^{127}Te	1 000	^{147}Pm	1 000
^{54}Mn	100	^{95}Nb	100	^{127m}Te	100	^{149}Pm	100
^{55}Fe	1 000	^{93}Mo	100	^{129}Te	1 000	^{151}Sm	1 000
^{59}Fe	100	^{99}Mo	100	^{129m}Te	100	^{153}Sm	100
^{56}Co	100	^{96}Tc	100	^{131}Te	1 000	^{152}Eu	100
^{57}Co	1 000	^{97}Tc	1 000	^{131m}Te	100	^{154}Eu	100
^{58}Co	100	^{97m}Tc	100	^{132}Te	100	^{155}Eu	1 000
^{60}Co	100	^{99}Tc	100	^{125}I	10	^{153}Gd	1 000
^{59}Ni	1 000	^{97}Ru	1 000	^{126}I	10	^{160}Tb	100
^{63}Ni	1 000	^{103}Ru	100	^{129}I	1	^{169}Er	1 000
^{65}Zn	100	^{106}Ru	10	^{131}I	10	^{171}Tm	1 000

Table A6.1 Guidance levels for radionuclides in drinking-water

Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]	Radio-nuclide	Guidance level (Bq/l)[a]
^{175}Yb	1 000	^{210}Pb[b]	0.1	^{231}U	1 000	^{243}Am	1
182Ta	100	^{206}Bi	100	^{232}U	1	^{242}Cm	10
^{181}W	1 000	^{207}Bi	100	^{233}U	1	^{243}Cm	1
^{185}W	1 000	^{210}Bi[b]	100	^{234}U[b]	1	^{244}Cm	1
^{186}Re	100	^{210}Po[b]	0.1	^{235}U[b]	1	^{245}Cm	1
^{185}Os	100	^{223}Ra[b]	1	^{236}U[b]	1	^{246}Cm	1
^{191}Os	100	^{224}Ra[b]	1	^{237}U	100	^{247}Cm	1
^{193}Os	100	^{225}Ra	1	^{238}U[b,c]	10	^{248}Cm	0.1
^{190}Ir	100	^{226}Ra[b]	1	^{237}Np	1	^{249}Bk	100
^{192}Ir	100	^{228}Ra[b]	0.1	^{239}Np	100	^{246}Cf	100
^{191}Pt	1 000	^{227}Th[b]	10	^{236}Pu	1	^{248}Cf	10
^{193m}Pt	1 000	^{228}Th[b]	1	^{237}Pu	1 000	^{249}Cf	1
^{198}Au	100	^{229}Th	0.1	^{238}Pu	1	^{250}Cf	1
^{199}Au	1 000	^{230}Th[b]	1	^{239}Pu	1	^{251}Cf	1
^{197}Hg	1 000	^{231}Th[b]	1 000	^{240}Pu	1	^{252}Cf	1
^{203}Hg	100	^{232}Th[b]	1	^{241}Pu	10	^{253}Cf	100
^{200}Tl	1 000	^{234}Th[b]	100	^{242}Pu	1	^{254}Cf	1
^{201}Tl	1 000	^{230}Pa	100	^{244}Pu	1	^{253}Es	10
^{202}Tl	1 000	^{231}Pa[b]	0.1	^{241}Am	1	^{254}Es	10
^{204}Tl	100	^{233}Pa	100	^{242}Am	1 000	^{254m}Es	100
^{203}Pb	1 000	^{230}U	1	^{242m}Am	1		

[a] Guidance levels were rounded to the nearest order of magnitude by averaging the log scale values (to 10^n if the calculated value was below 3×10^n and to 10^{n+1} if the value was 3×10 or above). For example, if the calculated value was 2 Bq/L (i.e. 2×10^0), the guidance level was rounded to 10^0 (i.e. = 1) whereas, if the calculated value was 3 Bq /L (i.e. 3×10^0 or above), the guidance level was rounded to 10^1 (i.e. = 10).

[b] Natural radionuclides.

[c] The provisional guideline value for uranium in drinking-water is 30 µg/l based on its chemical toxicity for the kidney (see section 8.5).

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ANNEX 7

Contributors to the development of the *Guidelines for drinking-water quality*: fourth edition incorporating the first addendum

This annex lists the names of those who have contributed to the development of the fourth edition of the *Guidelines for drinking-water quality* and to the first addendum to the fourth edition, through participation at relevant meetings, authorship or peer review of text in the Guidelines themselves or its supporting documents, or through provision of intellectual advice. The list of contributors begins with the first meeting at which the fourth edition was discussed, held in Berlin, Germany, in 2007. All those who contributed to the third edition of the Guidelines as well as the first and second addenda to the third edition, which constitute a major portion of this fourth edition, are listed in Annex 2 of the third edition incorporating the first and second addenda, available on the WHO web site at: http://apps.who.int/iris/handle/10665/204411. Sincere apologies are extended to any contributors whose names have inadvertently been omitted from these lists.

C. Abbot, United Utilities, United Kingdom
H. Abouzaid, WHO, Egypt
L. Achene, Istituto Superiore di Sanità, Italy
J. Adams, Liverpool School of Tropical Medicine, United Kingdom
E. Addai, United Nations Children's Fund (UNICEF), Senegal
A. Adin, Hebrew University of Jerusalem, Israel
S. Adrian, Environmental Protection Agency, USA
R. Aertgeerts, formerly WHO Regional Office for Europe, Germany
F. Ahmed, Bangladesh University of Engineering and Technology, Bangladesh
K.M. Ahmed, University of Dhaka, Bangladesh
A. Aitio, WHO, Switzerland
H. Al-Hasni, Public Authority for Electricity and Water, Oman
N. Al-Hmoud, Princess Sumaya University for Technology, Jordan
L. Ali, WHO, Maldives
T. Alimamedova, WHO, Tajikistan

D. Allély-Fermé, WHO, Switzerland
G. Allgood, The Proctor & Gamble Company, USA
B.M. Altura, New York Downstate Medical Center, USA
B.T. Altura, New York Downstate Medical Center, USA
L. Alves Campos, National Sanitary Control Agency (ANVISA), Brazil
S. Al-Wahaibi, Ministry of Health, Oman
M. Amazonas, The Coca-Cola Company, USA
R. Anderson, WHO, Switzerland
K.B. Andrus, Air Transport Association of America, Inc., USA
S. Appleyard, Department of Environment Regulation of Western Australia, Australia
G. Ardon, Ministry of Housing, Spatial Planning and Environment, the Netherlands
F. Arellano, Maynilad Water, Philippines
T. Ariyananda, Lanka Rain Water Harvesting Forum, Sri Lanka
M. Asami, National Institute of Public Health, Japan
N. Ashbolt, School of Public Health, University of Alberta, Canada
S. Atkinson, McMaster University, Canada
D. Baguma, African Rural University, Uganda
C.D. Baker, Centre for Affordable Water and Sanitation Technology (CAWST), Canada
H. Bakir, WHO Regional Centre for Environmental Health Activities, Jordan
E. Barrenberg, formerly WHO, Switzerland
L. Barrott, MWH, United Kingdom
J. Barrow, Centers for Disease Control and Prevention, USA
J. Bartram, University of North Carolina, USA
R. Bastos, Universidade Federal de Vicosa, Brazil
H.K. Bates, Research Association, USA
G. Bateman, Environment Agency, United Kingdom
A. Bathija, Environmental Protection Agency, USA
J. Baumgartner, University of Wisconsin, USA
A.S. Baweja, Health Canada, Canada
P. A. Bawono, Ministry of Health, Indonesia
D. Bennitz, Health Canada, Canada
M.J. Benoliel. Empresa Portuguesa das Águas Livres, SA (EPAL), Portugal
M. Berglund, Karolinska Institute of Environmental Medicine, Sweden
R.J. Bevan, Cranfield University (currently Independent Consultant), United Kingdom
J. Bhagwan, Water Research Commission, South Africa S. Bickel, United Nations Children's Fund (UNICEF), USA
S. Bish, United Nations Children's Fund, USA
E. Blanton, PATH, USA
M. Blokker, Kiwa Water Research, the Netherlands
V.L. Bombeta, Local Water Utilities Administration (LWUA), Philippines
L. Bonadonna, Istituto Superiore di Sanità, Italy
R. Bos, WHO, Switzerland (currently International Water Association, the Netherlands)
M. Bowman, Water Corporation, USA
B. Breach, Independent Consultant, United Kingdom

E. Briand, Ministère du Travail, de l'Emploi et de la Santé, France
J.D. Brookes, The University of Adelaide, Australia
T. Brooks, Health Canada, Canada
J. Brown, Public Health England (currently independent consultant), United Kingdom
J. Brown, London School of Hygiene & Tropical Medicine, United Kingdom (currently Georgia Institute of Technology, USA)
C. Browne, Ministry of Health, St Michael, West Indies
G. Brundrett, Brundrett Associates, United Kingdom
T. Bruursema, NSF International, USA
P. Byleveld, New South Wales Department of Health, Australia
E. Calderon, Sanitary Engineering Institute, Argentina
M.E. Calderon, Peru
R. Calderon, Environmental Protection Agency, USA
P. Callan, Independent Consultant, Australia
D. Calmet, International Organization for Standardization and Nuclear Advisor of the Permanent Mission of France at United Nations, Austria
D. Campbell-Lendrum, WHO, Switzerland
E. Carden, Department of Health and Human Services, Australia
Z. Carr, WHO, Switzerland
V. Casey, WaterAid, United Kingdom
C. Castell-Exner, German Technical and Scientific Association for Gas and Water, Germany
C Chaffey, Health Canada, Canada
R. Chalmers, Public Health Wales Microbiology, United Kingdom
P. Charles, Centre International de Recherche Sur l'eau et l'Environnement – Suez Environnement, France
R. Charron, Health Canada, Canada
Y. Chartier, formerly WHO, Switzerland
P. Chave, Pollution Control, United Kingdom
J. Chen, Health Canada, Canada
C.K. Chew, WHO, Switzerland
T. Chhoden, Ministry of Works and Human Settlement, Bhutan
M.L. Chong, WHO, Philippines (currently PUB, the national water agency, Singapore)
I. Chorus, Federal Environment Agency, Germany
D. Chuckman, International Flight Services Association, Canada
G. Cissé, Swiss Tropical and Public Health Institute, Switzerland
T. Clasen, Emory University, USA
L. Coccagna, Independent Consultant, Italy
J. Colbourne, Drinking Water Inspectorate, United Kingdom
A. Colgan, International Atomic Energy Agency, Australia
G. Combs, United States Department of Agriculture, USA
J. Cooper, Health Canada, Canada
L. Corrales, Centers for Disease Control and Prevention, USA
R. Costello, National Institutes of Health, USA
P. Costrop, Syngenta Crop Protection, Switzerland

J. Cotruvo, Joseph Cotruvo & Associates/NSF International Collaborating Centre, USA
M. Couper, formerly WHO, Switzerland
D Court Marques, European Food Safety Authority, Italy
C. Cox, Caribbean Environmental Health Institute, St Lucia
P. Cox, Sydney Water, Australia
A. Cronin, University of Surrey, United Kingdom
D. Crump, Cranfield University
D. Cunliffe, Department of Health, Australia
F. Dangendorf, University of Bonn, Germany
L. D'Anglada, Environmental Protection Agency, USA
T. Darlow, MWH, United Kingdom
D. Davidson, Center for Food Safety and Applied Nutrition, Food and Drug Administration, USA
A. Davison, Risk Edge, Australia
C. de Bazigan, Antenna, Switzerland
L.R. de Dios, Department of Health, Philippines
D. Deere, Water Futures Pty Ltd, Australia
J. De France, WHO, Switzerland
D. de Jager, Ministry of Health, New Zealand
M. Del Rosario Perez, WHO, Switzerland
J. Dennis, Thames Water Utilities, United Kingdom
A.M. de Roda Husman, National Institute of Public Health and the Environment, the Netherlands
P. de Souza, Emanti Management, South Africa
K. de Vette, International Water Association, the Netherlands
D. Deere, Water Futures Pty. Ltd., Australia
H. Dieter, formerly Federal Environment Agency, Germany
P. Donlon, Water Services Association, Australia
J. Donohue, Environmental Protection Agency, USA
T. Dooley, United Nations Children's Fund, USA
F. Douchin, DASS de Seine Maritime, France
N. Dowdall, British Airways, United Kingdom
P. Drechsel, International Water Management Institute, Sri Lanka
J. Drewes, Colorado School of Mines, USA
D. Drury, Independent Consultant, United Kingdom
I. Dublineau, Institut de Radioprotection et de Sûreté Nucléaire, France
N.T. Duong, Vietnam Water Supply and Sewerage Association (VWSA), Viet Nam
L. Düster, Federal Institute of Hydrology, Germany
K. Dziekan, Federal Environment Agency, Germany
A. Eckhardt, Federal Environment Agency, Germany
C. Edgar, Cranfield University, United Kingdom
P. Edmondson, Medentech Ltd, United Kingdom
C. Eidhin, Environmental Protection Agency, Ireland
A. Eleveld, Safe Water and AIDS Project, Kenya
R. Elin, University of Louisville, USA

T. Endo, Ministry of Health, Labour and Welfare, Japan
S. Enkhtsetseg, WHO Regional Office for Europe, Germany
J. Escamilla, WHO, Panama
A. Evans, International Civil Aviation Organization, Canada
M. Exner, Institute for Hygiene and Public Health, University of Bonn, Germany
A. Eyring, Philadelphia Water Department, USA
J. Falkinham, Virginia Tech, USA
Z. Fang, Department of Health Quarantine, General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, China
J. Fastner, Federal Environment Agency, Germany
J. Fawell, Cranfield University, United Kingdom
D. Fayzieva, Uzbekistan Academy of Science, Uzbekistan
T. Fengthong, Ministry of Health, Lao People's Democratic Republic
L. Ferenc, Institute for Water Pollution Control, Water Resources Research Centre, Hungary
C. Fergusson, Department of Primary Industries, Australia
E. Ferretti, Istituto Superiore di Sanità, Italy
I. Feuerpfeil, formerly Federal Environment Agency, Germany
L. Fewtrell, Aberystwyth University, United Kingdom
M. Foran, Centre for Affordable Water and Sanitation Technology (CAWST), Canada
K. Ford, Rio Tinto, United Kingdom
M. Forson, United Nations Children's Fund (UNICEF), USA
P. Fosselard, European Federation of Bottled Water, Belgium
C. Frambøl, Danish Water and Waste Water Association (DANVA), Denmark
M. Frobel, IM System, Germany
D. Frost, Aqua Focus Ltd, United Kingdom
D. Fujise Waterworks Bureau Kawasaki City, Japan
D. Gamper, Airports Council International, Switzerland
R. Gangaraju, Health Canada, Canada
D. Gatel, EUREAU, Belgium
M. Gately, Medentech, Ireland
R.J. Gelting, Centers for Disease Control and Prevention, USA
M. Giddings, Health Canada, Canada
Karina Gin, Nanyang Technological University, Singapore
S. Gitahi, United Nations Children's Fund (UNICEF), Ghana
S. Godfrey, Water and Sanitation Expert, Ethiopia
C. Gollnisch, Akkreditierte Hygieneinspektionsstelle für Trinkwassersysteme, Germany
R. Goossens, Compagnie Intercommunale Bruxelloise des Eaux, Belgium
B. Gordon, WHO, Switzerland
F. Gore, WHO, Switzerland
E. Goslan, Cranfield University, United Kingdom
W. Grabow, retired (formerly of University of Pretoria, South Africa)
J. Grace, Air Safety, Health and Security Department, Association of Flight Attendants-CWA, USA

A.C. Grandjean, Center for Human Nutrition, USA
O. Green, wca environment limited, United Kingdom
P. Greiner, NSF International, USA
R. Grey-Gardner, formerly Centre for Appropriate Technology, Australia
A. Growers, WRc, United Kingdom
C. Güler, Hacettepe University, Turkey
M. Gunnarsdóttir, University of Iceland, Iceland
R. Gupta, Visvesvaraya National Institute of Technology, India
C. Hadjichristodoulou, University of Thessaly, Greece
L. Hamilton, formerly Ministry of Health, New Zealand
S. Harris, International Life Sciences Institute, USA
P. Hartemann, Faculté de Médicine de Nancy, France
T. Hasan, Pacific Islands Applied Geoscience Commission, FijiS. Hauswirth, Public Health Service, Germany
R.P. Heaney, Creighton University, USA
J. Hearn, ALS Water Resources Group, Australia
P. Heaton, formerly Power and Water Corporation, Australia
H. Heijnen, Consultant, c/o United Nations Children's Fund (UNICEF), Lao People's Democratic Republic
J. Hejzlar, Czech Academy of Sciences, Czech Republic
L. Heller, Oswaldo Cruz Foundation, Brazil
K. Hellier, Melbourne Water, Australia
S. Herbst, Institute for Hygiene and Public Health, University of Bonn, Germany
O. Hernandez, FHI 360, USA
A. Hill, Vestergaard Frandsen, Switzerland
M.R. Hipsey, The University of Western Australia, Australia
A. Hirose, National Institute of Health Sciences, Japan
E.J. Hoekstra, Institute for Health and Consumer Protection, Italy
C. Hollister, Air Transport Association of Canada, Canada
H. Holstag, 300 in 6, the Netherlands
L. Hope, WHO, Switzerland
R. Hossain, WHO, Switzerland
G. Howard, Department for International Development, United Kingdom
S. Hrudey, University of Alberta, Canada
L.C. Hsiang, National Environment Agency, Singapore
J. Huff, National Institute of Environmental Health Sciences, USA
A. Humpage, South Australian Water Corporation, Australia
P. Hunter, University of East Anglia, United Kingdom
A. Hussain, Ministry of Housing and Environment, Maldives
F. Husson, Solar Solutions LLC, USA
S.A. Ibrahim, Ministry of Housing and Environment, Maldives
S. Iddings, formerly WHO South Pacific Office, Fiji
P. Illig, Centers for Disease Control and Prevention, USA
A. Illmer, United Nations Children's Fund (UNICEF), USA
T. Inoue, Japan Water Forum, Japan

F. Istace, Euoprean Food Safety Authority (EFSA), Italy
M. Itoh, National Institute of Public Health, Japan
S. Itoh, Kyoto University, Japan
D. Jackson, Consultant, Nepal
P. Jackson WRc-NSF Ltd, United Kingdom
C. Jacobsson, Swedish University of Agricultural Sciences, Sweden
P. Jagals, University of Queensland, Australia
A. Jayaratne, Yarra Valley Water, Australia
E. Jesuthasan, WHO, Switzerland
H.E. Jianzhong, National University of Singapore, Singapore
B. Jiménez Cisneros, Institute of Engineering, Mexico
R. Johnston, WHO, Switzerland
H. Jones, Loughborough University, United Kingdom
T.T. Jorge, formerly WHO, Switzerland
C. Jørgensen, DHI, Denmark
P.S. Joshi, National Environment Agency, Singapore
T. Jung, German Federal Office for Radiation Protection, Germany
A. Kabirizi, Ministry of Water and Environment, Uganda
Mihály Kádár, formerly National Institute of Environmental Health, Hungary
S. Kalandarov, WHO, Tajikistan
N. Kalebaila, Water Research Commission, South Africa
A. Kämpfe, Federal Environment Agency, Germany
M. Kanazawa, Ministry of Health, Labour and Welfare, Japan
B.P. Kandel, Amarapuri Water Utility, Nepal
C. Kanyesigye, National Water and Sewerage Corporation (NWSC), Uganda
P. Karani, African Development Bank, Tunisia
G.Y.-H. Karina, National University of Singapore, Singapore
H. Kasan, Rand Water, South Africa
A. Kasuya, Ministry of Health Labour and Welfare, Japan
H. Katayama, University of Tokyo, Japan
D. Kay, Aberystwyth University, United Kingdom
S. Khan, The University of New South Wales, Australia
K. Khatri, WHO, Fiji
N.R. Khatri, formerly WHO, Nepal
R. Khush, Aquaya, USA
P. Kirch, Enwor-Energie & Wasser Vor Ort GmbH, Germany
N. Kishida, National Institute of Public Health, Japan
T. Kistemann, University of Bonn, Germany
S. Klitzke, Federal Environment Agency, Germany
W. Kloas, Leibniz-Institute of Freshwater Ecology and Inland Fisheries, Germany
K. Komatsu, National Institute for Environmental Studies, Japan
K. Kosaka, National Institute of Public Health, Japan
N.O. Kotei, Public Utilities Regulatory Commission, Ghana
P. Kozarsky, Centers for Disease Control and Prevention, USA
F. Kozisek, National Institute of Public Health, Czech Republic

R. Kryschi, Germany
Y. Kubo, Ministry of Health, Labour and Welfare, Japan
P. Kubon, Federal Environment Agency, Germany
Y. Kudo, Japan Water Works Association, Japan
S. Kumar, University of Malaya, Malaysia
S. Kunikane, University of Shizuoka, Japan
S. Kurebayashi, Ministry of the Environment, Japan
W. Kutane, WHO, Ethiopia
P. Labhasetwar, National Environmental Engineering Research Institute, India
J. Lafontaine, Health Canada, Canada
H. Lahav, Makhshim Chemical Works Ltd, USA
K.C. Lai, PUB, the national water agency, Singapore
D. Lantagne, Tufts University, USA
L. Laraki, Office National de l'eau Potable, Morocco
M.W. LeChevallier, American Water, USA
H.K. Lee, National University of Singapore, Singapore
J. Lee, Health Protection Agency, United Kingdom
F. Lemieux, Health Canada, Canada
P. Lennon, PATH, USA
K. Levy, Rollins School of Public Health, USA
R. Lieberman, USEPA
M.H. Lim, PUB, the national water agency, Singapore
K. Linden, University of Colorado Boulder, USA
J.-F. Loret, Centre International de Recherche Sur l'eau et l'Environnement – Suez Environnement, France
P. Lotz, MINTEK, South Africa
A. Lovell, Water Services Association of Australia, Australia
S. Luby, International Centre for Diarrhoeal Disease Research, Bangladesh
L. Lucentini, National Institute for Health, Italy
D. MacChesney, Environmental Protection Agency, USA
Y. Magara, Hokkaido University, Japan
B. Magtibay, WHO, Philippines
S.G. Mahmud, WHO, Bangladesh
D. Maison, WHO, Switzerland
H.-J. Mälzer, IWW Water Centre, Germany
D. Mara, University of Leeds, United Kingdom
K.J. Marienau, Centers for Disease Control and Prevention, USA
P. Marsden, Department for Environment, Food and Rural Affairs, United Kingdom
M.G. Martí, Sociedad General de Aguas de Barcelona (AGBAR), Spain
C. Martinho, Acquawise, Portugal
T. Matsuda, Ministry of Health, Labour and Welfare, Japan
Y. Matsui, Hokkaido University, Japan
K. Matsumoto, Ministry of Health, Labour and Welfare, Japan
A. Mavridou, Technological Educational Institute of Athens, Greece
A. May, Drinking Water Inspectorate, United Kingdom

A. McCoy, Health Canada, Canada
A. McDonald, Population Services International (PSI), USA
S. McFadyen, Health Canada, Canada
K. McHugh, Population Services International (PSI), USA
R.M. McKeown, WHO, Switzerland
C. McLaren, Drinking Water Quality Regulator for Scotland, United Kingdom
D. Medeiros, Health Canada, Canada
G. Medema, KWR Watercycle Research Institute and Delft University of Technology, the Netherlands
K. Medlicott, WHO, Switzerland
E. Medlin, Centers for Disease Control and Prevention, USA
M.E. Meek, University of Ottawa, Canada
R. Meierhofer, Eawag, Switzerland
K. Meme, Lifewater International, USA
R. Mendes, Acquawise, Portugal
D.L. Menucci, WHO, France
J. Mercer, Health Canada, Canada
B.J. Merkel, Freiberg University of Mining and Technology, Germany
W. Merkel, IWW, Germany
R. Meyerhoff, Lilly Research Laboratories, Eli Lilly and Company, USA
F. Miranda da Rocha, National Sanitary Control Agency, Brazil
R. Mitchell, WRc, United Kingdom
H.G.H. Mohammad, Ministry of Health, Kuwait
D. Moir, Health Canada, Canada
D. Mokadam, Association of Flight Attendants-CWA, USA
A. Molinari, Ente Regulador de Agua y Sanemiento (ERAS), Argentina
M. Mons, Kiwa Water Research, the Netherlands
M. Montgomery, WHO, Switzerland
A. Mooijman, Independent Consultant, the Netherlands
C. Morais, Águas do Cávado, Portugal
H. Morii, Osaka City University, Japan
V. Morisset, Health Canada, Canada
T. Morita, Japan Water Forum, Japan
N. Moritani, Ministry of Health, Labour and Welfare, Japan
R. Morris, University College London, United Kingdom
B. Mouchtouri, University of Thessal, Greece
M. Moussif, Mohamed V Airport, Morocco
F.H. Mughal, Independent Researcher, India
C. Munoz-Trochez, formerly International Water Association, United Kingdom
J. Nadeau, Health Canada, Canada
N.O. Nascimento, Federal University of Minas Gerais, Brazil
K.J. Nath, Institution of Public Health Engineers, India
M. Ncube, Johannesburg Water, South Africa
R. Neipp, Ministry of Health and Social Policy, Spain
T. Neville, Vestergaard Frandsen, Zambia

T. Ngai, Centre for Affordable Water and Sanitation Technology (CAWST), Canada
M.S. Ngon, WHO, Myanmar
A.V.F. Ngowi, Muhimbili University of Health and Allied Sciences, United Republic of Tanzania
C. Nicholson, Sydney Water, Australia
F.H. Nielsen, United States Department of Agriculture, USA
J.W. Nieves, Columbia University, USA
Y. Nijdam, Waternet, the Netherlands
C. Nokes, Environmental Science and Research Ltd, New Zealand
V.J. Novotny, Professor Emeritus, Marquette University, USA, and Northeastern University, USA
N. O'Connor, Ecos Environmental Consulting, Australia
O. Odediran, United Nations Children's Fund, USA
O. Oenema, Wageningen University and Research Center, the Netherlands
G. Offringa, formerly Water Research Commission, South Africa
M. Ogoshi, National Institute for Land and Infrastructure Management, Japan
J-E Oh, Pusan National University, Korea
E. Ohanian, Environmental Protection Agency, USA
S. Okamoto, Public Works Research Institute, Japan
S. Ólafsdóttir, Icelandic Food and Veterinary Authority, Iceland
C.N. Ong, National University of Singapore, Singapore
S.L. Ong, National University of Singapore, Singapore
L. Onyon, WHO, Switzerland
P. Osborn, 300in6 initiative, the Netherlands
W. Oswald, Rollins School of Public Health, USA
J. O'Toole, Monash University, Australia
S. Ou, Public Health South, New Zealand
M. Overmars, formerly Pacific Islands Applied Geoscience Commission, Fiji
S.R. Panthi, WHO, Nepal
A. Paoli, Atkins Limited, United Kingdom
J.M. Parra Morte, European Food Safety Authority, Italy
T. Paux, Ministère de la santé, de la jeunesse et des sports, France
Payden, WHO, India
G.L. Peralta, WHO, Philippines
S. Perry, State of Washington Office of Drinking Water, USA
S. Petterson, Water & Health Pty Ltd, Australia
C. Pickl, Federal Environment Agency, Germany
B. Pilon, International Air Transport Association, Switzerland
O. Pintos, Asociación Federal de Entes Reguladores de Agua y Saneamiento de Argentina, Argentina
W. Piyasena, formerly Ministry of Water Supply and Drainage, Sri Lanka
M. Plemp, Centre for Infectious Disease Control, the Netherlands
B. Plotkin, WHO, Switzerland
M. Podeprel, Helioz Research and Development, Austria
T. Pohle, Air Transport Association, USA

C. Pollard, Drinking Water Inspectorate, United Kingdom
S. Pollard, Cranfield University, United Kingdom
K. Pond, University of Surrey, United Kingdom
K. Porter, Environmental Protection Agency, USA
D. Poulin, Health Canada, Canada
J. Pratt, Veolia Water Central, United Kingdom
F. Properzi, WHO, Switzerland (currently UN-Water, Switzerland)
T. Pule, WHO, Republic of Congo
D. Purkiss, NSF International, USA
W. Qu, Fudan University, China
A. Queste, University of Bonn, Germany
H. Quiñones, Scientific and Technical Translator, Spain
R. Rainey, United States Agency for International Development (USAID), USA
S. Ramasamy, Environmental Protection Agency, Washington, DC, USA
V. Ramnath, National Environment Agency, Singapore
T. Rapp, Federal Environment Agency, Germany
S. Regli, Environmental Protection Agency, USA
P. Regunathan, Regunathan & Associates Inc., USA
D. Reid, Alberta Environment and Parks, Canada
B. Rickert, Federal Environment Agency, Germany
A. Rinehold, WHO, Switzerland
U. Ringelband, formerly Federal Environment Agency, Germany
J. Ringo, Bio-Cide International, Inc., USA
S. Risica, National Institute of Health, Italy
M. Rivett, University of Birmingham, United Kingdom
W. Robertson, retired (formerly Health Canada, Canada)
C. Robertson-Kellie, Drinking Water Quality Regulator for Scotland, United Kingdom
C. Rockey, South West Water, United Kingdom
G. Rodier, WHO, Switzerland
A.L.G. Rodrigues, Sabesp, Brazil
J. Rose, Michigan State University, USA
J.W. Rosenboom, Water and Sanitation Program of the World Bank (WSP), Cambodia (currently Bill & Melinda Gates Foundation)
S. Rostron, Ministry of Health, New Zealand
K. Rotert, Environmental Protection Agency, USA
R. Rowe, The Water Institute, University of North Carolina, USA
H.J. Salas, Adviser, Pan American Center for Sanitary Engineering and Environmental Sciences, Lima, Peru
M. Samwell, Women in Europe for a Common Future, the Netherlands
R. Sancho, Águas do Algarve, Portugal
H. Sanderson, Danish National Environmental Research Institute, Denmark
A. Sargaonkar, National Environmental Engineering Research Institute, India
B. Schaefer, Federal Environment Agency, Germany
S. Schaub, formerly Environmental Protection Agency, USA
J. Schijven, RIVM and Utrecht University, the Netherlands

O. Schmoll, WHO European Centre for Environment and Health, Bonn, Germany
B. Schnabel, formerly Federal Environment Agency, Germany
R. Sebastien, Health Canada, Canada
S. Seki, Ministry of the Environment, Japan
C. Sevenich, Hamburg Port Health Center, Germany
F. Shafeeqa, Live & Learn Environmental Education, Maldives
G. Shaghaghi, Ministry of Health, Islamic Republic of Iran
N. Shah, Unilever R & D Laboratory, India
F. Shannoun, WHO, Switzerland
R.K. Sharma, Rural Water Supply and Sanitation Fund Development Board, Nepal
N. Shaw, International Shipping Federation, United Kingdom
D. Sheehan, Coliban Water, Australia
M. Sheffer, Editor, Canada
E. Sheward, University of Central Lancashire, United Kingdom
P. Shodmonov, State Sanitary Epidemiological Surveillance Service, Tajikistan
K. Sholtes, Centers for Disease Control and Prevention, USA
D. Shrestha, United Nations High Commissioner for Refugees, Switzerland
L. Siegel, Safe Water International, USA
L. Simas, ERSAR, the Water and Waste Services Regulation Authority, Portugal
D. Simazaki, National Institute of Public Health, Japan
J. Simmonds, Health Protection Agency, United Kingdom
J. Sims, retired (formerly WHO, Switzerland)
M. Sinclair, Monash University, Australia
O. Sinitsyna, Ministry of Health, Russia
C. Skak, Danish Toxicology Centre, Denmark
P. Smeets, KWR Watercycle Research Institute, the Netherlands
D. Smith, Melbourne Water, Australia
J. Smith, Independent Consultant, United Kingdom
S. Smith, Wessex Water, United KingdomS. Snyder, University of Arizona, USA
S. Snyder, University of Arizona, USA
M. Sobsey, University of North Carolina, USA
J. Soller, Soller Environmental, LLC, USA
B. Sontia, University of Ottawa, Canada
T.-A. Stenstrom, Swedish Institute for Infectious Disease Control, Sweden (currently Durban University of Technology, South Africa)
M. Stevens, Melbourne Water, Australia
M. Stevenson, Cascade Designs, USA
N. Stewart, Carnival UK, United Kingdom
V. Straškrábová, Czech Academy of Sciences, Czech Republic
S. Sturm, German Technical and Scientific Association for Gas and Water – Technologiezentrum Wasser, Germany
K. Sudo, Japan International Cooperation Agency, Japan
A. Sufiev, State Sanitary Epidemiological Surveillance Service, Tajikistan
J. Suhaimi, Ranhill Utilities, Malaysia
S. Sumanaweera, National Water Supply and Drainage Board, Sri Lanka

C. Summerill, Cranfield University, United Kingdom
S. Surman-Lee, Health Protection Agency, United Kingdom
D. Susau, Live & Learn Environmental Education, Fiji
D. Sutherland, Independent Consultant, United Kingdom
A. Suzuki, Ministry of the Environment, Japan
K. Suzuki, TMWW, Japan
M. Swart, Rand Water (formerly Department of Water Affairs), South Africa
M. Takahashi, Hokkaido University, Japan
A. Tamas, Swiss Federal Institute of Environmental Science and Technology/ Department of Water and Sanitation in Developing Countries, Switzerland
H. Tanaka, Kyoto University, Japan
K Tanaka, formerly Waterworks Bureau Kawasaki City, Japan
R. Tanner, Independent Consultant, Belgium
M. Taylor, formerly Ministry of Health, New Zealand
C. Teaf, Florida State University, USA
P. Teixeira, WHO, USA
M. Templeton, Imperial College London, United Kingdom
P. Teunis, National Institute for Public Health and the Environment, the Netherlands, and Rollins School of Public Health, Emory University, USA
C. Thibeault, International Air Transport Association, Canada
T. Thompson, WHO, Philippines
S.M. Tibatemwa, International Water Association, Kenya
D. Till, Independent Consultant, New Zealand
I. Toh, PUB, the national water agency, Singapore
R. Tomisaka, Ministry of the Environment, Japan
N. Ton Tuan, WHO, Viet Nam
R. Torres, WHO, Plurinational State of Bolivia
R.M. Touyz, University of Ottawa, Canada
B. Tracy, Health Canada, Canada
A. Trevett, WHO, Bangladesh (currently United Nations Children's Fund [UNICEF], Kenya)
Y. Trihadiningrum, Institut Teknologi Sepuluh Nopember, Indonesia
D.M. Trindade, Centre for Disease Control and Prevention, Macao Special Administrative Region, China
A. Tritscher, WHO, Switzerland
S. Tuite, Health Canada, Canada
T.M. Ua-Cookson, Ministry of Health, New Zealand
T. Udagawa, Japan Water Works Association, Japan
P. Undesser, Water Quality Association, USA
S. Vajpeyee, Government Medical College and New Civil Hospital, India
K. van den Belt, Flander Environment Agency, Belgium
J.P. van der Hoek, Amsterdam Water Supply, the Netherlands
P. Van Maanen, United Nations Children's Fund, USA
J. Van Zyl, University of Cape Town, South Africa
L. Varadi, President of the Hungarian Aquaculture Association, Hungary

G. Velo, University of Verona, Italy
F. Venter, University of Pretoria, South Africa
E. Veschetti, Istituto Superiore di Sanità, Italy
E.Viau, Bioenergy Frontiers, USA
C. Vickers, WHO, Switzerland
J.M.P. Vieira, University of Minho, Portugal
L. Vijselaar, Danish Committee for Aid to Afghan Refugees (DACAAR), Afghanistan
C. Viljoen, Rand Water, South Africa
D. Viola, International Association of Plumbing and Mechanical Officials and World Plumbing Council, USA
N. Virabouth, Ministry of Public Works and Transport, Lao People's Democratic Republic
G. Vivas, WHO, Barbados
M. von Sperling, Federal University of Minas Gerais, Brazil
T. Wade, Environmental Protection Agency, USA
R. Walker, Water Corporation, Australia
C. Wallace, United Nations University, Canada
N. Wang, WHO, France
C. Weaver, Purdue University, USA
S. Webster, MWH, New Zealand
W. Weglicki, George Washington University Medical Center, USA
S. Weragoda, National Water Supply and Drainage Board, Sri Lanka
S. Westacott, Southampton City Council, United Kingdom
K. White, representing collective view from American Chemistry Council, USA
I. Wienand, University of Bonn, Germany
S. Wijesekara, United Nations Children's Fund (UNICEF), USA
A. Wiklund, DG Energy, European Commission, Luxembourg
T. Williams, International Water Association, the Netherlands
D. Wilusz, Department of State, USA
C. Witkowski, Association of Flight Attendants-CWA, USA
K.-M. Wollin, Niedersächsisches Landesgesundheitsamt, Germany
K.W. Wong, PUB, the national water agency, Singapore
M. Yadav, Rural Water Supply and Sanitation Fund Development Board, Nepal
J. Yap, National Environment Agency, Singapore
G Yasvinski, Health Canada, Canada
R. Yuen, International Water Association, Singapore
T. Zabel, WRc, United Kingdom
R. Zhang, National Center for Rural Water Supply Technical Guidance, Center for Disease Control and Prevention, China
G. Ziglio, University of Trento, Italy

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Page numbers in **bold** indicate main discussions.

This index has not been updated to reflect any new entries or changes that result from the incorporation of the first addendum into the fourth edition of the *Guidelines for Drinking-water Quality*.

This fourth edition incorporating the first addendum, of the World Health Organization's *Guidelines for Drinking-water Quality builds* on over 50 years of guidance by WHO on drinking-water quality, which has formed an authoritative basis for the setting of national regulations and standards for water safety in support of public health.

It is the product of significant revisions to clarify and elaborate on ways of implementing its recommendations of contextual hazard identification and risk management, through the establishment of health-based targets, catchment-to-consumer water safety plans and independent surveillance. It reflects the renewed focus on primary prevention.

Significant additional guidance on good practice is presented, incorporating changes introduced by the first and second addenda to the third edition. Emerging water management issues are comprehensively addressed for a range of circumstances, from household water treatment and safe storage and the bulk supply of water over long distances to the potential implications of climate change.

Additional risk assessments are presented for a number of new chemical and microbial hazards and applied to a suite of pesticides used for public health purposes. Existing reviews on chemicals and waterborne pathogens have been revised to account for new scientific information. The chapter on radiological aspects of drinking-water quality has been comprehensively updated.

Even more than the previous edition, this new edition incorporating the first addendum, emphasizes achievable practices and the formulation of sound regulations, applicable to low-income, middle-income and industrialized countries alike, that aim to prevent a potential health crisis caused by the consumption of unsafe drinking-water, against the backdrop of rapid urbanization, water scarcity and climate change.

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Examining food, water and environmental samples from healthcare environments

Microbiological guidelines

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

For queries relating to this document, please contact:
[redacted]

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Contents

Executive summary

The microbiological examination of food, water and environmental samples from the healthcare environment has a recognised role in the routine monitoring of decontamination procedures and the demonstration of a safe environment for patients, visitors and staff. Individual guidance documents covering sampling and testing requirements in a range of healthcare environments (such as endoscopy departments, pharmacy sterile suites and hydrotherapy pools) have been published. Although many of these documents are freely available on the internet, they vary in the amount of detail provided. In some cases, particularly with respect to environmental monitoring, no clear guidance has been published.

This document aims to summarise the available legislation and guidance for microbiologists and infection control nurses working within healthcare settings and to provide additional clarification and guidance on sampling and result interpretation where these are currently lacking.

Since the use of suitable procedures and equipment is essential in order to be able to carry out the appropriate microbiological analyses on a sample and provide a meaningful interpretation of test results, general procedures for collecting food, water, air and environmental samples are also described.

Introduction

In the 1980s, it was generally held that microbiological sampling of food, water and the environment in hospitals was rarely indicated, except during the investigation of outbreaks. This was, in part, due to a lack of consensus about the best way to proceed and how to interpret results once obtained. Lessons learned from subsequent outbreaks, and issues raised as a result of the increasing complexity of medical service provision have since led to the development of numerous pieces of legislation and expert guidance that address specific aspects of hospital microbiology. The overarching aim is to be able to demonstrate the provision of a safe environment for patients, visitors and staff.

Individual guidance documents covering a range of subjects such as food (Department of Health 1989), pharmacy sterile suites (Beaney, 2006) and swimming and hydrotherapy pools (Pool Water Treatment Advisory Group, 2017) have been published. Although many are freely available on the internet, they vary in the amount of detail provided and this may be confusing for those addressing a problem for the first time. In some cases, particularly with respect to environmental monitoring, no clear guidance is available and expert advice must be sought. While there is, at present, no specific requirement for formal accreditation of laboratories undertaking this type of microbiological investigation, it is advisable, where medico-legal issues may arise, to seek the assistance of a laboratory with appropriate accreditation to perform the specific test and with specialist expertise. These are often available from Official Control Laboratories: capabilities fulfilling these criteria may not always be available from a hospital microbiology laboratory.

This document aims to summarise the available legislation and guidance for microbiologists and infection control nurses working within the healthcare setting and to provide additional clarification and guidance on sampling and result interpretation where these are currently lacking. It is recognised that legislation and guidance are subject to regular review and that advice given here will eventually be superseded by future publications.

Outbreaks and incidents of infection due to food, water or environmental contamination in hospitals and healthcare establishments are of major concern. Hospitals are complex establishments, often with microbiological testing requirements originating from multiple departments and disciplines, sometimes operating independently even from within the same site. Hospital environments can present multiple challenging environmental hazards to which highly susceptible individuals (as well as visitors and staff) may be exposed. Whilst this document focuses largely on routine monitoring, the sampling procedures described apply equally to outbreak and incident investigations. However, some additional sampling techniques and targets for microbiological testing may be

relevant in these situations, and further advice and guidance should be sought from the local Public Health England (PHE) Food Water and Environmental Microbiology Laboratory as appropriate.

Sampling procedures

In order to be able to carry out the appropriate microbiological examinations on a sample and provide a meaningful interpretation of test results, it is essential that samples are collected in a suitable manner using the correct equipment. General procedures for the sampling of food, water, the air and the environment are described below. For more unusual sampling requirements, advice on procedures and sampling equipment should be sought from a specialist food, water and environmental microbiology laboratory with appropriate accreditation.

Health and safety considerations

Collection of food, water and environmental samples in hospitals may occur in a variety of locations including wards, operating theatres, equipment decontamination and preparation areas, plant rooms and cooling towers. Each location and reason for sampling will be associated with its own risks. It is important to make an assessment of these risks and put appropriate control measures in place before any sampling is carried out. Examples of hazards include:

- wet floors that present a slip hazard when sampling from swimming and hydrotherapy pools or from kitchen areas
- working at height when ladders/steps are required to reach sampling points
- manual handling when carrying large amounts of sampling equipment to and from the site of sampling
- working in confined spaces when sampling from difficult-to-reach parts of water systems
- exposure to aerosols when sampling from cooling towers and showers - appropriate precautions should be taken to minimise aerosol production, as described in BS 7592:2008 (British Standards Institution, 2008); for example, running taps gently to reduce splashing; using a sterile plastic bag with one corner cut off to enclose the shower head and to funnel the water into a sampling container; and sampling cooling towers from sampling points on the return service of the cooling water to the tower, rather than the tower itself
- lone working in isolated areas such as plant rooms

In addition, some specific safety notes have been included in the sections below.

General equipment requirements

Equipment that may be needed for sampling includes:

- sterile food-grade plastic bags/twist-seal bags/honey jars
- tamper evident tags or evidence bags
- labels
- permanent waterproof marker pens and biros
- laboratory sample submittal forms for food, water and environmental samples (usually provided by the laboratory)
- nitrile gloves
- alcohol wipes
- plastic shoe coverings
- cool box with separators, data loggers and 10% by volume of frozen cold packs (see Appendix 2 for further guidance) - cold packs should not be used for *Legionella* samples
- camera (optional)

The list is not intended to be exhaustive and not all items may be required for all types of sampling.

Food sampling

There is no requirement for routine sampling of food in healthcare settings. It is, however, essential that food providers, whether subcontracted or in-house, have robust food safety management systems in place, such as HACCP, and can demonstrate 'due diligence' (i.e. that they have done everything possible to ensure the provision of safe and wholesome food). Healthcare providers should ensure that this assurance is extended to include the whole process up to and including the point at which food is served to the patient or client. Many food manufacturers and some hospitals choose to adopt a programme of routine microbiological monitoring as an added measure of quality and this has often been of value in identifying unforeseen problems at an early stage. When catering services are contracted out, healthcare providers may require certain levels of microbiological monitoring as part of their service specification; in these situations, it is appropriate to insist that Official Control Laboratories are used for microbiological examination, with accreditation for the appropriate tests.

For in-house catering facilities, a rolling monitoring programme may be agreed locally and will depend upon the resources available and accessibility of laboratory support. It is important to recognise that levels of bacteria which may be acceptable for healthy adults may present an unacceptable risk to those with compromised immunity, and we advise that tolerances should therefore be set very low in the healthcare setting (for

example, we suggest in Table 2b that *Listeria monocytogenes* should be absent in a 25g sample of ready-to-eat food from the hospital environment, whereas up to 100 cfu/g of this organism may be acceptable in foods for general retail purposes, according to EU Regulation EC 2073/2005 [as amended]). It is always advisable to liaise closely with the local Environmental Health Department (EHD) to ensure best practice.

When sampling food, it is essential that the items reach the examining laboratory in a state that is microbiologically unchanged from the time it was sampled; in all cases this will involve the use of sterile containers and in most cases the use of refrigerated storage and transportation.

In the investigation of outbreaks, where legal proceedings may ensue, it is essential to involve the local EHD in the inspection of the premises and the food sampling process. The EHD will always have access to an Official Control Laboratory with appropriate accreditation for examination of the samples collected as part of an outbreak investigation.

Equipment required

In addition to the equipment listed in ‘General Equipment Requirements’, the following items may be required:

- hair coverings – e.g. hair nets or mob caps
- clean white coat
- sterile sampling utensils (e.g. spoons, knives, spatulas)

Procedure for sampling foods (based on Food Standards Agency, 2017)

The sampling procedure may vary depending on the type of food and the reason for sampling. If food-handling practices within a catering unit are being investigated, it may be appropriate to sample the food using the utensils that would normally be used for handling or serving the food. However, if a sub-sample of food is to be examined as supplied by the producer to the hospital catering department, the sample should be collected using sterile utensils.

i. At least 100 grams of food is usually required, unless an alternative quantity has previously been agreed with laboratory staff.
ii. Where intact foods are to be examined, the whole sample in its original wrapping is placed inside a food-grade bag.
iii. For aseptic sampling of open packs, take a portion of the food using appropriate sterile utensils. This will normally be a representative portion of all components but may be a specific portion such as a core sample, surface sample, filling etc. Place the food sample

into a sterile food-grade bag or plastic honey jar, taking care not to allow the sample to touch the outside or top edge of the container. Label the container with the location and sample details, sender's unique reference/identification code, sampling officer and date and time of sampling. When a secure chain of evidence is required, place the container into another sterile bag and seal with a tamper evident tag.

iv. Record the sender's reference code and any relevant information such as the place of sampling, temperature of storage, type of packaging and type of sample on the laboratory sample submittal form.

v. Store samples in a cool box, preferably between 1 and 8°C (taking care to keep raw foods in a separate box from ready-to-eat foods, and hot food separate from cold), and return to the laboratory as soon as possible, preferably on the same day (unless there is a particular reason for a delay such as sampling late in the evening) but always within 24 hours of collection.

If necessary, samples can be left in a cool-box overnight, provided that it is properly packed with an adequate number of cold packs (10% of the total cool box volume; see Appendix 2 for further guidance) or transferred to a secure fridge or cold-room, and submitted to the laboratory as early as possible on the following day. A calibrated datalogger should be used to monitor the temperature throughout the storage period.

Water sampling

The only statutory requirements for water quality, at present, pertain to the quality of drinking water. There are, however, several authoritative guidance documents addressing best practice in the maintenance of water systems in general (for example, the control of *Legionella*; Health and Safety Executive, 2013) and for specific purposes e.g. endoscopy rinse water (Department of Health, 2016a), swimming, hydrotherapy and birthing pools (Pool Water Treatment Advisory Group, 2017), renal dialysis water (UK Renal Association, 2016) and dental line supplies (Department of Health, 2013). Bacteria in water systems tend to be few in number due to low nutrient availability and are frequently associated with biofilms which form on the inside surfaces of pipework, valves etc. Higher counts will be found in water which is stagnant or stationary for long periods, e.g. tanked supplies, dead legs, infrequently used parts of buildings. It is therefore important to use a risk-based approach to the selection of appropriate sampling points, and to collect sufficient volumes of water to enable adequate assessment of the water quality. All available guidance documents give recommended volumes and methods for sampling. Disinfectants, such as chlorine dioxide, which are used to improve water quality, have residual effects and must be neutralised in order to give an accurate microbiological result. Therefore, appropriate sampling bottles containing neutralising agents must be used and advice on these can be obtained from the testing laboratory prior to sampling.

As with food sampling, the highest standards of water system management and maintenance are essential, including an assessment of temperature control in the water distribution system. Microbiological monitoring is much less important than achieving high engineering standards, but can be valuable during commissioning of new systems, often revealing unexpected problems or deficiencies in a system.

It is important, in any investigation of a water system, to have a thorough knowledge of the supply and the system itself. In this respect, the local estates officers should normally be involved at an early stage. It is usually necessary to sample systematically, working proximally to the problem in order to identify its source. Full temperature profiles are extremely useful in the investigation of raised counts of *Legionella*.

If all reasonable measures fail to determine the source of a microbiological problem, expert advice should be sought.

Equipment required

In addition to the equipment listed in ‘General equipment requirements’, items that may be required include:

- plastic measuring jug or wash bottle
- sodium hypochlorite solution or tablets
- disposable cleaning cloth
- water bottles (see Table 1)
- food grade plastic bags; sterile scissors and elastic bands (for taking shower samples)
- electronic thermometer with probe
- kit and appropriate consumables for measuring pH and residual disinfectant (may be colorimetric or electronic type)
- timer
- torch

Table 1: Sample bottles required for the collection of water for different microbiological and chemical analyses

Test Required	Sample Bottles
Coliform bacteria, *Escherichia coli, Pseudomonas aeruginosa*, Aerobic Colony Counts, environmental mycobacteria	1 x sterile 500 ml plastic bottle containing an appropriate neutraliser to neutralise any residual disinfectant in the water. The most commonly used neutraliser, which is appropriate for chlorinated or brominated water systems and those using ozone or hydrogen peroxide, is sodium thiosulphate. For mains water and hydrotherapy pools, 18 mg/L sodium thiosulphate should be added. However, for cooling towers, 180 mg/L (i.e. sufficient to neutralise 50 mg chlorine per litre) must be used. If alternative disinfection methods are used, the laboratory should be contacted to obtain the appropriate neutraliser, if one is available.
Legionella	1 x sterile 1 litre bottle *Or* 2 x sterile 500 ml plastic bottles (as above) (See note above regarding neutralisers)
Endotoxin	Designated “Pyrogen-free” containers
Chemical parameters	Specific bottles should be requested from laboratory depending on tests required

Procedure for sampling tap water (based on Standing Committee of Analysts, 2010)

The sampling strategy should determine the sampling technique. If the quality of water as delivered from the tap (i.e. including any bacteria that are colonising the tap) is of interest, then the tap should not be sanitised and the sample should comprise the first portion of water delivered (i.e. omit steps i – iv below), preferably immediately after a period of no, or minimal, use. If only bacteria present in the system prior to the tap are sought, the tap should be sanitised and run for 2 – 3 minutes before sampling. When attempting to ascertain the origin of contamination, it may be appropriate to take samples before and after sanitisation and flushing. The following sampling procedure should be followed:

i. If possible, ensure that the tap is in good condition, with no leaks.
ii. Remove any internal and external fittings such as hosing.

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

Safety Note: Sodium hypochlorite is highly corrosive and should be handled with care. Nitrile gloves and goggles should be worn, and if contact with skin, eyes or clothes occurs, wash the affected area immediately with copious amounts of water. Contact with clothes may result in a bleaching effect. If a wash bottle is used, this should produce a directed spray but not a fine mist.

iv. Turn on the tap gently to avoid unnecessary aerosol production and run water to waste for 2 to 3 minutes.

v. Label a sterile bottle (1 litre or 500 ml bottle containing neutraliser; see Table 1) with the location and sample details, sender's reference code, sampling officer and date and time of sampling.

vi. Aseptically open the bottle, fill almost to the brim with water, replace and tighten the lid and shake the bottle to distribute the neutraliser.

vii. Water samples (except for *Legionella* samples) should be stored between 1 and 8^{o}C. They should be submitted to the laboratory to ensure that they are examined promptly, ideally the same day, but always within 24 hours of collection.

Procedure for sampling swimming, spa and hydrotherapy pool water (based on Pool Water Treatment Advisory Group, 2017)

Normally a single sample of pool water is taken. The most appropriate site for taking a single sample from a pool is where the water velocity is likely to be at its lowest and away from fresh water inlets or outlets. Depending on the size of the pool, it may be advisable to take samples from other sites to establish whether there are "dead spots" in the water circulation. During investigations of poor water quality, it is recommended that a sample is taken from the balance tank and skimmers, and that swabs are taken from inside/behind any jets and from the lid or cover for the pool if used.

i. Outside shoes should be removed or plastic shoe coverings worn if entering swimming pool areas.

ii. Wipe the outside of a sterile bottle (500 ml bottle containing neutraliser; see Table 1) with an alcohol wipe (this is not necessary if bottles are individually packed), and label with a waterproof marker or biro (indicating the location and sample details, sender's reference code, sampling officer and date and time of sampling).

iii. Aseptically open the bottle.

iv. Immerse the bottle, keeping the long axis approximately horizontal but with the neck pointing slightly upwards to avoid loss of the neutralising agent (see Figure 1).

v. Once the bottle is immersed to about 200-400mm (8-16”) below the surface, tilt the bottle to allow it to fill, leaving a small headspace.

vi. On removal from the water, immediately replace the cap and shake the sample to disperse the neutralising agent.

vii. Water samples (except for *Legionella* samples) must be stored between 1 and 8^{o}C, and submitted to the laboratory in a timely way to ensure that they are examined on the day of collection or at least within 24 hours of the collection.

viii. If both routine testing parameters and *Legionella* are required, then separate 1 litre and 500 ml samples should be collected.

It is good practice to determine total and combined disinfectant levels and pH value from the same site as the microbiological sample. These should be determined in a separate sample collected in a bottle without any neutralising agent (e.g. a sterile plastic universal container) and the tests carried out at the pool-side. These results together with information on the number of users in the pool at the time of sampling should accompany the sample to the laboratory. It is important to also note the type of disinfectant in use in the pool.

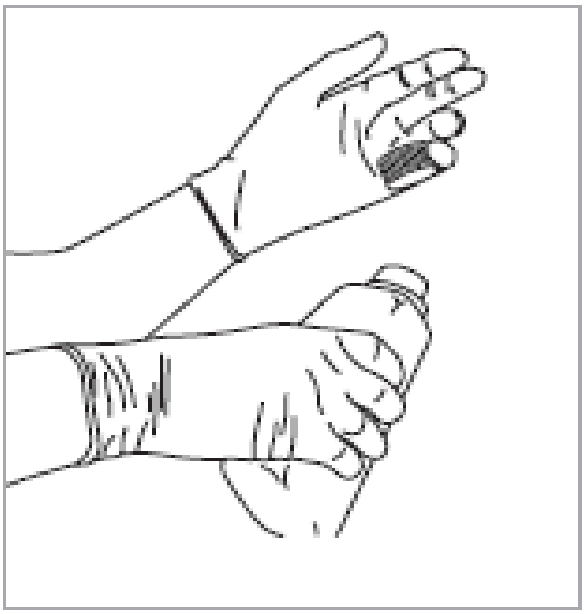
Procedure for sampling water for *Pseudomonas* testing in augmented care areas (based on Department of Health, 2013b)

The water outlets to be sampled should be those that supply water that has direct contact with patients, used to wash staff hands or used to clean equipment that will have contact with patients as determined by local risk assessment. It is recommended that water outlets are tested every 6 months or more frequently if results prove to be unsatisfactory.

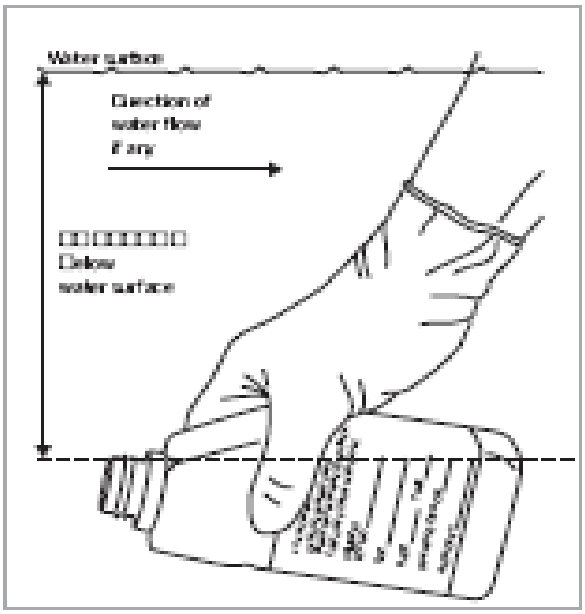
Water samples should be taken during a time of low or no use (at least 2 hours or preferably longer without use). The first water delivered from the outlet (i.e. pre-flush) should be used for routine monitoring, according to the method described in ‘Procedure for Sampling Tap Water’ (points v - vii). For follow-up samples, pre- and post-flush samples should be collected (i.e. an initial, pre-flush sample should be taken as described above; the tap should then be run for 2 minutes and a second post-flush sample taken).

Figure 1: Illustration of how to collect a swimming /spa pool sample (taken from Health Protection Agency, 2006).

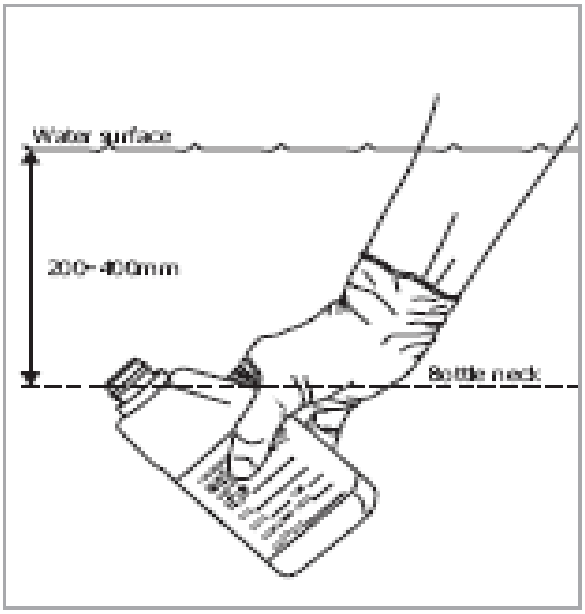
Note that cold packs are not required for collection of samples for Legionella which should be stored at ambient temperature (approximately 20°C) in the dark.



1. Aseptically removing the bottle top

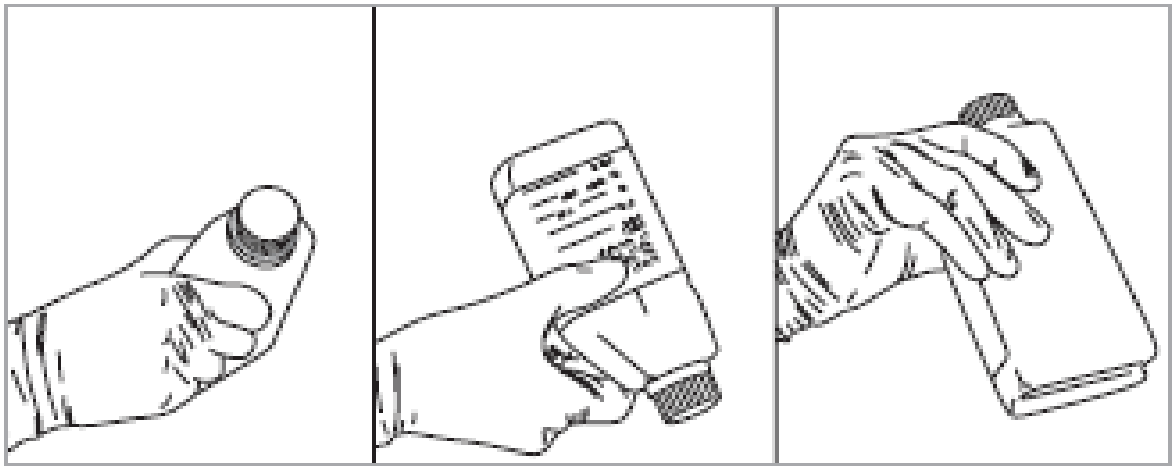


2. Immerse bottle 200–400mm below the surface, keeping bottle almost horizontal but tipped slightly to ensure neutraliser is not tipped out

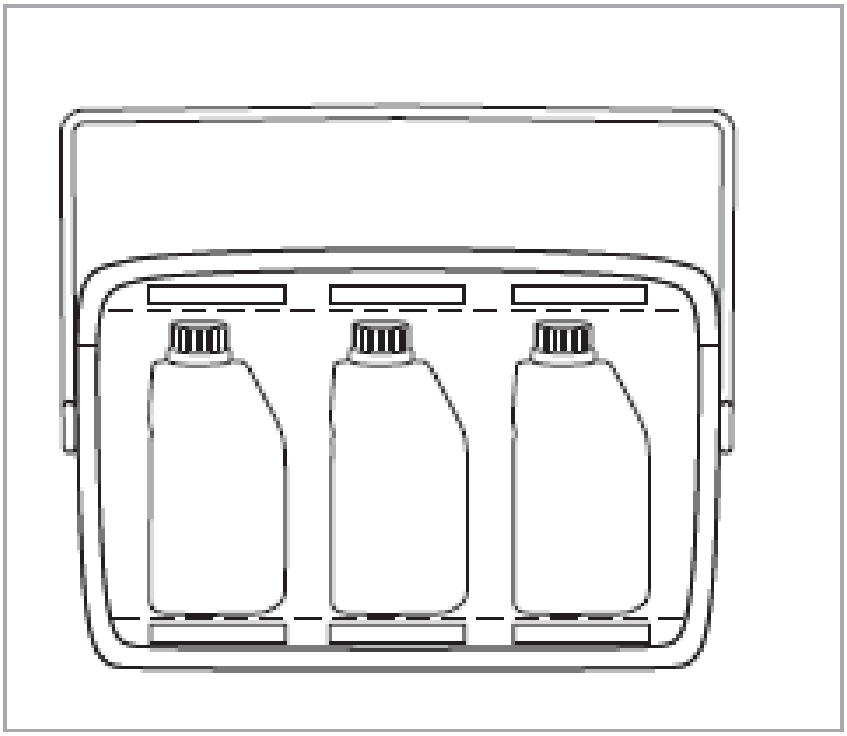


3. Tilt bottle up to approximately 45° to fill

4. Remove bottle. If the bottle is full to the brim pour off a small amount to leave 1–2cm air above the water surface. Replace the cap



5. Invert a few times to mix the contents and place the bottle in a cool box for transport



6. Transport to laboratory as soon as possible in an insulated container – process on day of collection

Procedure for sampling water for *Legionella* testing (based on British Standards Institution, 2008)

During investigations, sampling must not be carried out in isolation but should be done in conjunction with a review of the risk assessment, up-to-date schematics of the water systems, a review of previous monitoring results (both microbiological and temperature) and a review of current control measures. Sampling must be carried out based on the perceived risk. For example, water should be sampled from the areas where *Legionella* are likely to multiply, such as the warmest parts of a cold system, the coolest parts of a hot system or areas where there is low usage/ stagnation. Where there are several floors in the building under investigation, flow and return temperatures should be taken on each floor and to and from the calorifier or other heat source. Further details of appropriate sampling points are given in Approved Code of Practice and Guidance: L8 (Health and Safety Executive, 2013).

For details of appropriate sample bottles to use for *Legionella* sampling, see Table 1. For sampling from taps and swimming/spa pools, see procedures in the relevant sections above (but note that a pre-flush sample is useful from taps, as *Legionella* may flourish in any standing water in the outlet. i.e. omit steps i to iv in 'Procedure for Sampling Tap Water').

To sample from showers, proceed as described below. Normally, a 1 litre sample is taken from each shower head.

i. Label a sterile bottle with the location, sample details, sender's reference code, sampling officer and date and time of sampling.
ii. Before turning on the shower, adjust the temperature setting to the midpoint for non-thermostatic taps and the normal use temperature (35°C to 43°C) for thermostatic taps.
iii. Detach the shower head from the hose and, without changing the temperature setting of the shower, place a sample bottle under the end of the hose, turn the shower on gently and fill the bottle almost to the brim.
iv. If the shower head is fixed onto the hose, place a sterile food-grade plastic bag over the shower head and secure with a rubber band. Using sterile scissors cut off one of the bottom corners of the bag to form a funnel. Use this funnel to fill the bottle.
v. Replace and tighten the lid and shake the bottle to distribute the neutralising agent.

All water samples for *Legionella* examination should be stored at an ambient temperature (approximately 20°C), in the dark, and returned to the laboratory as soon as possible, preferably the same day but at the latest so that processing can begin within 24 hours of taking the sample.

Safety Note: When investigating a *Legionella* case or outbreak, it is *essential* that an assessment of risks associated with sampling is carried out in discussion with suitably experienced staff before samples are collected and that a sampling plan is drawn up in consultation with other experts eg. site engineers and Infection Control officers (see BS 7592-2008 section 1 parts 4- 6 for more advice)

It is good practice to establish the water temperature at the time of sampling. This is particularly important if an investigation is being carried out to determine the source of *Legionella* in a clinical case or as part of a risk monitoring process. Hot water should reach 50°C within 1 minute at outlets, whilst cold water should be 20°C or below after running the water for 2 minutes (Health and Safety Commission, 2013). A calibrated stopwatch and calibrated probe thermometer must be used to measure the temperature of the water to ensure conformity with these guidelines. This information should be recorded along with the identity of the site and whether or not the outlet was intended to be hot or cold. For taps with a thermostatic mixer valve (TMV) it will be necessary to take the temperature of the water upstream of the TMV.

Renal unit waters and dialysis fluids

Water used in the preparation of dialysis fluid is tested to determine whether it meets the minimum requirements for microbiological contamination (UK Renal Association, 2016). Samples should be taken from points expected to have the highest bacterial load, such as the end of the distribution loop or the last machine in a dead-end system (EDTNA/ERCA, 2002). If the sample is to be collected from a tap used solely for sampling, ensure that this has been appropriately sanitised as described in ‘Procedure for Sampling Tap Water’ (point iii).

i. Label a sterile bottle (usually 500 ml bottle containing neutraliser for microbiological tests or a pyrogen-free container for endotoxin; see Table 1) with the location and sample details, sender’s reference code, sampling officer and date and time of sampling.
ii. Aseptically open the bottle and fill almost to the brim with water; replace the lid.

    Note: If only small volumes of liquid are available for sampling, a smaller sterile plastic container can be used, as neutraliser is not essential for this sample type.
iii. Store the water between 1 and 8°C and return to the lab for examination, preferably on the same day but always within 24 hours of collection.

Endoscopy/washer disinfector final rinse waters

Guidance on the decontamination of flexible endoscopes is available in “Management and Decontamination of Flexible Endoscopes (HTM 01-06)” (Department of Health, 2016a). The following paragraph summarises the microbiological information contained therein:

Essentially, the user should define the standard of disinfection required in consultation with the Infection Control Doctor. For most endoscopic procedures, the final rinse water need only be of potable quality. However, rinse water for endoscopes which enter normally sterile body cavities e.g. arthroscopes will need to be of a higher standard, so it is safest to ensure that final rinse water from automated washer-disinfectors has low microbial counts and does not present a potential hazard to the patient either through infection or by leading to an erroneous diagnosis. It is essential that great care is taken to avoid introducing contamination when obtaining samples. The exact procedure will vary from one model to another, but in general, the machine should be run on a special cycle that allows the cycle to be stopped in the rinse phase and a sample collected via a sterile sampling tube. If this is not feasible, use a sampling point on the machine, disinfect the sampling point with 70% alcohol and run approximately 500 ml rinse water to waste before aseptically collecting at least 100 ml (and preferably 400 ml) in a sterile container.

The sample should be stored between 2 and 5^{o}C and processed as soon as possible, preferably within 24 hours (and always within 48 hours) of collection.

Although the Operational Management manual (Part C) of HTM 01-06, states that endoscopes that are passed into sterile body cavities should be free of endotoxins, this is, in practice, unrealistic and unsupported by evidence; sterile water for injections has allowable limits of 0.25 EU/ml. This statement is also contradicted by a different part of the same document, HTM 01-06 (Part B); Design and Installation manual, which states that ‘EWD final rinse-water should not contain more than 30 endotoxin units/ml’ and that ‘routine endotoxin testing is, therefore, not required unless there is evidence of a major water supply problem’, in which case, it would be inadvisable to continue using that supply anyway. Reverse osmosis units will reduce levels of endotoxin in the water supply but will not eliminate it.

It is essential that microbiological results are monitored sequentially in order to identify normal variation and trends so that early action may be taken if problems arise. During investigations of poor results, collection of water samples prior to the final treatment process (e.g. supply water and break tank water) should be considered. In addition, check that the correct filters are properly fitted and are included in the daily self-disinfection cycle of the washer/disinfector, and that a regular schedule of maintenance and replacement of the filters is in place.

Dental unit water lines

There is no regulation or guidance in the UK regarding the frequency of sample collection from Dental Unit Water Lines (DUWL). However, where monitoring is undertaken, the following procedure should be followed:

i. Label a sterile bottle (usually 100 ml or 500 ml bottle containing neutraliser; see Table 1) with the location and sample details, sender's reference code, sampling officer and date and time of sampling.
ii. Purge the 3:1 and/or high speed outlets of the dental unit for 2 minutes before collecting water samples.
iii. Aseptically open the bottle and collect 100 ml of water from the 3:1 and/or high speed outlets.
iv. Store the water between 1 and 8^{o}C and return to the lab for examination ideally on the same day but always within 24 hours of collection.

Heater cooler units

Heater cooler units used in cardiopulmonary bypass and ECMO procedures have been the focus of attention since 2015, due to an outbreak of *Mycobacterium chimaera* infections associated with these machines (Public Health England, 2017). Water sampling from these machines for the detection of slow-growing mycobacteria is described in a separate document (Public Health England, 2016), as summarised below:

i. The heater cooler machine should be connected and running for a minimum of 5 minutes before water sampling is performed.
ii. Ideally the water sampling should take place just prior to the machine undergoing its disinfection cycle.
iii. Bottles containing sodium thiosulphate should be used, as described in Table 1.
iv. Water should be sampled from both circuits i.e. the 'patient' circuit and the 'cardioplegia' circuit via the tubing systems. Ensure that sterile tubing/fittings are available for each machine being tested.
v. A volume of 100 ml per sample is suggested if only an environmental mycobacteria test is required. However, 500 ml is more appropriate if tests for a range of different parameters are to be undertaken.
vi. If the water is not processed immediately, it should be stored between 1°C and 8°C for up to 24 hours.

Environmental surface sampling

Cleaning of the hospital environment is essential to protect patients from hospital acquired infections and must be carried out according to current guidelines. Care facilities must carry out risk assessment of the healthcare environment, document cleaning tasks and monitor the effectiveness of cleaning. These guidelines use visual inspection only as a measure of cleanliness (British Standards Institution, 2014). Routine sampling of environmental surfaces in healthcare environments is therefore not usually indicated. It may, however, be required in order to identify an environmental source of infection/contamination, to demonstrate efficacy of disinfection or cleaning procedures or as a research tool. It is essential that careful thought is given to the

nature and purpose of the sampling and whether quantitative or qualitative results are needed. Diluents and isolation media should be appropriate for the isolation of the specific organisms sought. In some cases, it may be necessary to consider the need for controls or sampling over time to establish a baseline.

Effective sampling of surfaces requires moisture in order for the microorganisms to adhere to the sampling matrix – there may be moisture already present on the surface, or, more frequently, a sterile diluent such as saline or buffered peptone water is used. Appropriate neutralisers (such as TLTR neutralising solution; see ‘Media’ section below) must be used if disinfectant residues are likely to be present on the surface to be sampled.

Sampling may be quantitative i.e. a known area is swabbed (using a swab or sponge) in a standardised way in order to compare results from different sites, or from the same site but taken at different times. This is most often done using a sterile metal or plastic template. It is also possible to sample using an agar contact plate. These methods are only suitable for relatively flat surfaces. If uneven or complex surfaces are to be sampled, contact plates cannot be used, but if it is possible to estimate the area swabbed, this would enable reporting of a semi-quantitative result. Alternatively, qualitative sampling (to determine the presence or absence of a pathogen) is usually appropriate when investigating the source of an outbreak or a cross-contamination incident. In this case, the larger the area sampled, the better the chance of detecting the pathogen of interest.

For large areas, sponges are often found to be most convenient, while cotton-tipped swabs are often more convenient for complex surfaces or areas which are less accessible. However, it should be noted that sponges generally achieve a more efficient recovery of micro-organisms than cotton-tipped swabs, whilst contact plates give a lower recovery than either swabs or sponges.

The procedures below are suitable for the detection of bacterial contamination. Swabbing for norovirus or other viruses is not usually indicated. However, in some situations (for example, verification of cleaning procedures during norovirus outbreaks) it may be useful to carry out surface swabbing. Appropriate procedures, equipment and sample numbers should be discussed with the local PHE Food Water and Environmental Microbiology Laboratory and/or Virus Reference Laboratory before undertaking any sampling.

Equipment required

In addition to the equipment listed in 'General equipment requirements', items that may be required include:

- sterile templates of known area (usually 10 x 10 cm)
- sterile sponge swabs (with or without a handle) moistened with neutralising solution (store as indicated by the supplier)
- sterile sponge swabs on sticks with neutralising solution
- sterile cotton-tipped swabs with neutralising solution
- page's saline (for legionella swabs)

Note: The laboratory will only hold accreditation for analysis of swab types that have been validated prior to use to ensure that they do not inhibit the target organism(s). Therefore, it is advisable to use swabs that are provided by the laboratory.

Media

TLTR neutralising solution (Holah, 1999)*

Sodium thiosulphate	5 g
¼ strength Ringer tablets (Oxoid BR52) OR Thiosulphate Ringer tablets (Oxoid BR48)	2 2
Lecithin	3 g
Polysorbate 80 (Tween 80)	30g
Maximum Recovery Diluent (Oxoid CM733) (0.1% peptone, 0.85% saline)	9.5 g
Water	1 litre

pH 7.2 ± 0.2 at 25 ˚C

*Note: Maximum Recovery Diluent or sterile physiological saline can be used as an alternative to TLTR neutralising solution, but microbiological results may be affected if disinfectant residues are present on the surfaces being sampled.

Rodac (contact) plates containing selective or non-selective agar as required.

Procedure for swabbing flat surfaces

A template may be used to accurately quantify the area to be sampled. Alternatively, the area may be judged by eye, in which case stages i to iii may be omitted.

i. Aseptically open the sterile template pouch allowing access to the template handle. Do not remove the template at this stage.
ii. Wash and dry hands thoroughly.
iii. Remove the sterile template from its pouch, taking care not to touch the inside surface.

Place the template on the surface of interest.

iv. Open a sponge swab pack and aseptically take hold of the sponge, either by holding the handle or by using sterile gloves for sponges without a handle. (Refer to the manufacturer's instructions for specific guidance on different types of sponge swab). If not pre-moistened, moisten the sponge by dipping it into an appropriate liquid medium (usually 10 ml of TLTR neutralising solution, if disinfectant residues are likely to be present on the surface or if an assessment of this cannot be made) and squeezing out excess liquid against the side of the container.

v. Applying a firm pressure, and using up and down movements (taking approximately 1 second per stroke), swab the entire surface area within the template (up to the inner edge of the template).

vi. Hold the sponge at right-angles to the first movement and repeat the process.

vii. Aseptically return the sponge to its sterile container. If using a sponge with handle, **do not** insert the part of the handle you have touched with your hands into the final container; break off the handle according to the manufacturer's instructions.

viii. Seal the container and label clearly.

ix. Wipe over the area that has been swabbed with an alcohol wipe.

x. Store the sponge at between 1 and 8°C and return to the laboratory as soon as possible to ensure that it is examined on the day of collection or at least within 24 hours of collection.

Procedure for swabbing objects without a flat surface

A template cannot be used for objects such as door handles, pipework and drains, where no flat surface is available. In this case, follow the procedure described above ('Procedure for swabbing flat surfaces'; points iv – x) to swab the desired area. Ensure that a clear record is kept of the exact area swabbed. It is preferable to swab the entire surface of a handle, for example, or an entire utensil, to ensure that a repeat sample of the same surface can be taken in a comparable manner if required. Taking a photograph of the surface sampled can be useful in ensuring reproducibility if resampling is necessary.

Procedure for environmental monitoring of surfaces using contact plates

Surface contact plates are prepared in specialised plastic dishes known as Rodac plates, which are filled with a known volume of agar to provide a convex surface that is slightly raised above the top of the dish. Following appropriate quality control procedures to ensure sterility, they can be used to monitor the cleanliness of surfaces, as follows:

i. Press the agar surface onto the surface to be sampled, rock slightly from side to side then carefully remove from the surface and replace the lid.

ii. Use an alcohol wipe to remove any agar debris from the surface that has been sampled.

iii. Place the plates in a sterile plastic bag, seal and label clearly.

iv. Store the plates at between 1 and 8ºC and return to the laboratory as soon as possible to ensure that they are processed on the day of collection or at least within 24 hours of collection.

Air sampling

The microbiological quality of air varies widely and is dependent upon factors such as temperature, relative humidity and exposure to ultraviolet or electromagnetic radiation. In addition, the survival of microorganisms suspended in air will depend upon their susceptibility to these factors and the nature of the particles in which they are carried – fungal spores will remain suspended and survive much longer than vegetative bacteria contained within airborne droplets. Results of air sampling in any particular location will be subject to changes throughout the day and on a seasonal basis so that it is possible to construct a microbiological profile over time. Indoor air is, likewise, subject to the same factors, but in addition, will vary according to the number of people and activity within the room, traffic in and out of the room, basic ventilation such as windows and the performance of any air-handling systems. In order to be meaningful, air sampling must take these factors into account so that results are only compared with those of samples taken under similar, defined conditions.

Sampling is usually undertaken to assess air quality in areas such as operating theatres, pharmacy sterile units and sterile supply units. It may also be used as a continuous monitoring system e.g. in laboratories, in order to assess fluctuations in background counts which may contaminate test cultures.

Sampling may be either passive or active. Passive sampling needs no special equipment – agar plates are simply exposed in the area for a defined period of time. Several plates would usually be exposed at the same time in order to assess the average microbial count. This method is time-consuming and needs careful interpretation as air movements and activity may lead to wide fluctuations in results. Active sampling involves the use of mechanical equipment which draws in known volumes of air which then impinge on culture media or filters. Numbers of microbes present per unit volume of air can then be calculated accurately. Before performing any air sampling, special consideration should be given to whether a specific organism or all organisms are to be targeted, the volume of air to be sampled, the need for quantitative or qualitative results and what actions might be taken on the basis of the results obtained.

Equipment required

In addition to the equipment listed in ‘General equipment requirements’, items that may be required include:

- timer
- air sampler

Media

Agar plates containing selective or non-selective media as required (e.g. Blood Agar or Tryptone Soya Agar for total microbial counts and Dichloran Rose Bengal Chloramphenicol Agar (DRBC) for mould investigations). Before use, the agar plates should be subjected to appropriate quality control procedures to ensure sterility. Pre-incubation of plates is not recommended for this purpose, as it is likely to dry the agar out and potentially change the composition of the medium.

Procedure for passive air sampling using settle plates

Settle plates can be used to monitor air quality as follows:

i. Place agar plate (containing selective or non-selective agar, depending on organism(s) of interest) on a flat surface in the test location, and expose the agar surface by removing the lid.

ii. Leave the agar exposed for the agreed period of time (this may vary depending on the likely level of contamination in the test environment, but time periods of at least 30 minutes, and up to 4 hours, are usually recommended). Monitor the exposure time with a timer.

iii. Replace the lid, place the plates in a sterile plastic bag, seal and label clearly.

iv. Store the plates at between 1 and 8^{o}C and return to the laboratory as soon as possible to ensure that they are processed on the day of collection or at least within 24 hours of collection.

Active air sampling

Active air sampling of known volumes of air (as specified in Table 11) is carried out using specialist equipment, by trained staff, and should be performed according to the manufacturer’s instructions for the air sampling equipment used. Further information may be sought from the local food, water and environmental microbiology laboratory or infection control department, and guidance is also provided in HTM 03-01 (Department of Health, 2007).

Testing parameters and interpretation of microbiology results

Testing requirements and interpretations of results are provided in Tables 2 to 12 for a variety of sample types collected from the hospital environment. Wherever possible, testing should be carried out by a laboratory that is UKAS-accredited to perform a specific test. It should be noted that for laboratories performing work to the ISO 17025 standard, each test and sample type is accredited separately by UKAS, so it is important to check that the sample types and tests of interest are covered by the laboratory's scope of accreditation. Schedules of accredited tests are available on the UKAS website for each laboratory. Clinical laboratories are usually accredited through UKAS to the ISO 15189 standard, which is for the entire quality system and does not include accreditation for individual tests. As with laboratories accredited to the ISO 17025 standard, the accreditation status of a clinical laboratory accredited to ISO 15189 can be found on the UKAS website.

In addition to the tests shown in Tables 2 to 12, a range of further microbiological tests may be carried out, and advice given regarding interpretation of results through discussion with the microbiologists at the local laboratory. Advice on the interpretation of results should be sought from a microbiologist with experience of the healthcare environment. Contact details for PHE Food Water and Environmental Laboratories and the laboratory for Healthcare-Associated Infections and Antimicrobial Resistance are provided on the PHE website (www.gov.uk/phe).

Interpretation of microbiology results for water from a mains supply is covered in the Water Supply (Water Quality) Regulations 2016 (Great Britain, 2016) as amended in 2018 (Great Britain, 2018), and is not discussed further in this document. Criteria for private water supplies are covered in the Private Water Supplies Regulations 2016 (Great Britain, 2016a) as amended in 2018 (Great Britain, 2018a).

Legionella criteria in water systems, based on Approved Code of Practice and Guidance: L8 (Health and Safety Commission, 2013), are specified in Table 4. However, a *Legionella* specialist should be consulted when interpreting *Legionella* results from a hospital under investigation. More detailed guidance on actions required is available in the Approved Code of Practice: L8 (Health and Safety Commission, 2013).

Table 2a: Testing requirements and interpretation of results for cook chill food

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Minimum requirement of monthly testing of a range of products. A rolling programme of testing to cover all menu items and catering processes is recommended Approximately100g of each item of food to be sampled should be taken prior to reheating or regeneration.	≥ 100,000 /g	UNSATISFACTORY	Investigate cause and put corrective action in place	Department of Health, 1989
		< 100,000 /g	SATISFACTORY	N/A	
Salmonella species		Detected in 25 g	UNACCEPTABLE	Withdraw food from use and investigate cause immediately	
		Not detected in 25g	SATISFACTORY	N/A	
Escherichia coli		≥ 10 /g	UNSATISFACTORY	Investigate cause and put corrective action in place	
		< 10 /g	SATISFACTORY*	*Presence of this organism at lower levels may require investigation, depending on local experience and risk assessment	
Staphylococcus aureus		≥ 100/g	UNSATISFACTORY	Investigate cause and put corrective action in place	
		< 100 /g	SATISFACTORY*	*Presence of this organism at lower levels may require investigation, depending on local experience and risk assessment	
Clostridium perfringens		≥ 100/g	UNSATISFACTORY	Investigate cause and put corrective action in place	
		< 100 /g	SATISFACTORY*	*Presence of this organism at lower levels may require investigation, depending on local experience and risk assessment	
Listeria monocytogenes		Detected in 25 g	UNSATISFACTORY	Investigate cause and put corrective action in place	
		Not detected in 25g	SATISFACTORY	N/A	

Table 2b: Testing requirements and interpretation of results for ready-to-eat foods including sandwiches

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Listeria monocytogenes	As indicated by local risk assessment	Detected in 25 g	UNSATISFACTORY in foods likely to be served to vulnerable groups	Investigate cause and put corrective action in place	Health Protection Agency, 2009
		Not detected in 25g	SATISFACTORY	N/A	
Aerobic Colony Count; Enterobacteriaceae; *Escherichia coli*; *Staphylococcus aureus*; *Salmonella* species *Clostridium perfringens* (for meat products and those including gravy/stock) *Bacillus cereus* and other *Bacillus* species (for products including rice or spice ingredients)		Results should be interpreted according to HPA Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market.			

Table 2c: Testing requirements and interpretation of results for dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Bacillus cereus (presumptive)	Criteria apply at end of manufacturing process, but can be used as a guideline during investigations	> 500 /g	UNSATISFACTORY	Investigate cause and put corrective action in place	European Commission (EC 2073/2005 as amended in EC 1441/2007)
		≥ 50 - < 500 /g	BORDERLINE (unsatisfactory if present in 2 or more samples in a batch of 5 examined)		
		< 50 /g	SATISFACTORY	N/A	
Enterobacteriaceae		Presence in 10 g	UNSATISFACTORY	Investigate cause and put corrective action in place	
		Absence in 10 g	SATISFACTORY	N/A	

Table 3a: Testing requirements and interpretation of results for hydrotherapy pool water samples

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Escherichia coli	Weekly (collect sample while in use)	>0 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	Pool Water Treatment Advisory Group, 2017
		0 in 100 ml	SATISFACTORY	N/A	
Coliform bacteria (Total coliforms)		>10 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	
		1 - ≤10 in 100 ml	ACCEPTABLE*	* This level is considered acceptable provided that Aerobic Colony Count is <10/ml, *E. coli* is not detected, disinfectant & pH values are acceptable and coliforms are absent in repeat samples	
		0 in 100 ml	SATISFACTORY	N/A	
Pseudomonas aeruginosa		>50 in 100 ml	UNACCEPTABLE	Close pool and seek advice on remedial actions required	
		>10 in 100 ml	UNSATISFACTORY	Investigate and take repeat sample	
		1-10 in 100 ml	BORDERLINE	Take repeat sample	
		0 in 100 ml	SATISFACTORY	N/A	
Aerobic Colony Count		> 100 / ml	UNSATISFACTORY	Immediate investigation required	
		>10 - ≤100/ ml	BORDERLINE	Take repeat sample. Acceptable in the absence of *E.coli* or coliforms. Repeated raised counts require further investigation.	
		0 - ≤10 / ml	SATISFACTORY	N/A	
Staphylococcus aureus	As part of wider investigations only –in discussion with local microbiologist	>0 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	Pool Water Treatment Advisory Group, 2017
		0 in 100 ml	SATISFACTORY	N/A	

Legionella	Quarterly (depending on risk assessment) and before pool used for first time / after it has been shut down	> 1000 in 1 litre	UNSATISFACTORY	Close pool immediately. Shock dose then drain, clean and disinfect. Review risk assessment. Re-test before re-opening.	Pool Water Treatment Advisory Group, 2017
		20 – ≤1000 in 1 litre	BORDERLINE	Take repeat sample. Drain, clean and disinfect pool and review risk assessment and controls.	
		<20 in 1 litre	SATISFACTORY	N/A	

Table 3b: Testing requirements and interpretation of results for birthing pool water samples

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Escherichia coli	Weekly (collect sample while in use)	>0 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	Pool Water Treatment Advisory Group, 2017
		0 in 100 ml	SATISFACTORY	N/A	
Coliform bacteria (Total coliforms)		>10 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	
		1 - ≤10 in 100 ml	ACCEPTABLE*	* This level is considered acceptable provided that Aerobic Colony Count is <10/ml, *E. coli* is not detected, disinfectant & pH values are acceptable and coliforms are absent in repeat samples	
		0 in 100 ml	SATISFACTORY	N/A	
Pseudomonas aeruginosa		>50 in 100 ml	UNACCEPTABLE	Close pool and seek advice on remedial actions required	
		>10 in 100 ml	UNSATISFACTORY	Investigate and take repeat sample	
		1 - 10 in 100 ml	BORDERLINE	Take repeat sample	
		0 in 100 ml	SATISFACTORY	N/A	
Legionella	Quarterly (depending on risk assessment) and before pool used for first time / after it has been shut down	> 1000 in 1 litre	UNSATISFACTORY	Close pool immediately. Shock dose then drain, clean and disinfect. Review risk assessment. Re-test before re-opening.	
		20 – ≤1000 in 1 litre	BORDERLINE	Take repeat sample. Drain, clean and disinfect pool and review risk assessment and controls.	
		<20 in 1 litre	SATISFACTORY	N/A	

Table 4: Testing requirements and interpretation of results for hot and cold water systems

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Legionella	As indicated by risk assessment	≥1000 cfu/l	UNSATISFACTORY	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.	Health and Safety Executive, 2013
		≥100 - <1000 cfu/l	UNDESIRABLE	(a) If only one or 2 samples are positive, system should be resampled. If a similar count is found again, a review of the control measures and risk assessment should be carried out to identify any remedial actions (b) If the majority of samples are positive, the system may be colonised, albeit at a 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 action required.	
		<100 cfu/l	SATISFACTORY	No action; system under control	
*Pseudomonas aeruginosa**	In augmented care wards, as indicated by risk assessment (sample to be collected without pre-flushing)	>10 in 100 ml	UNSATISFACTORY	Investigate cause and put corrective actions in place. Re-sample after 3 weeks.	Department of Health, 2013b
		1-10 in 100 ml	UNDESIRABLE	Re-test and refer back to those responsible for the Water Safety Plan to determine what actions may be required.	
		0 in 100 ml	SATISFACTORY	No action; system under control	

*Investigation of water supplies for other *Pseudomonas* species may be required during outbreak investigations.

Table 5: Testing requirements and interpretation of results for renal dialysis fluid and water used for the preparation of dialysis fluid

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Monthly (or more frequently if necessary)	>100 / ml	UNSATISFACTORY	Take out of use until corrective action implemented	UK Renal Association, 2013
		>50 - ≤100 / ml	BORDERLINE	Investigate cause and put corrective action in place	
		0 - ≤50 / ml	SATISFACTORY	N/A	
Endotoxin /ml		>0.25 EU/ml	UNSATISFACTORY	Take out of use until corrective action implemented	
		>0.125 - ≤0.25 EU /ml	BORDERLINE	Investigate cause and put corrective action in place	
		<0.125 EU/ml	SATISFACTORY	N/A	

Note: The production of ultrapure dialysis fluid is generally achieved by the use of additional filters which form part of the dialysis machine hydraulic pathway. BS EN ISO 23500:2015 states there is no requirement to test for bacterial growth or endotoxins when the haemodialysis system is fitted with endotoxin retentive filters that are operated according to the manufacturer's instructions, unless the manufacturer requires such tests to be performed

Table 6: Testing requirements and interpretation of results for endoscopy final rinse water

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Weekly	>100 in 100 ml	UNACCEPTABLE	Discuss with Infection Control Team; complete risk assessment; consider taking washer /disinfector out of use (particularly for endoscopes used for sterile sites such as ERCP and bronchoscopes).	Department of Health, 2016a
		10 – ≤100 in 100 ml	UNSATISFACTORY	Discuss with Infection Control Team; complete risk assessment to investigate potential problems; super-chlorinate or repeat self-disinfect cycle	
		1 - 9 in 100 ml (on a regular basis)	ACCEPTABLE*	*Acceptable provided that *Pseudomonas aeruginosa* is not detected	
		<1 in 100 ml	SATISFACTORY	N/A	
Environmental mycobacteria	Quarterly	> 0 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	
		0 in 100 ml	SATISFACTORY	N/A	
Pseudomonas aeruginosa	Quarterly	> 0 in 100 ml	UNSATISFACTORY	Investigate immediately and take repeat sample	
		0 in 100 ml	SATISFACTORY	N/A	
Endotoxin	Not routinely required	≤ 30 EU/ml	SATISFACTORY	Risk low even above this level but would usually be associated with high microbial counts and subject to remedial action	Department of Health, 2016a

Table 7: Testing requirements and interpretation of results for final rinse water in surgical instrument washer disinfectors

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count (final rinse water – where products are rinsed after the disinfection stage)	Weekly	≥1 in 100 ml <1 in 100 ml	UNSATISFACTORY SATISFACTORY	Discuss with Infection Control Team; complete risk assessment; super-chlorinate or repeat self-disinfect cycle; consider taking washer /disinfector out of use. N/A	Department of Health, 2016b
Aerobic Colony Count (other water services supplied to washer/disinfector)	Not specified	≥100 in 100 ml <100 in 100 ml	UNSATISFACTORY SATISFACTORY	Discuss with Infection Control Team; complete risk assessment; super-chlorinate or repeat self-disinfect cycle. N/A	
Endotoxin (for washer disinfectors that are used for surgically invasive items or those that come into contact with parenteral solutions)	Annually	>0.25 EU/ml ≤0.25 EU/ml	UNSATISFACTORY SATISFACTORY	Investigate immediately and take repeat sample N/A	

Table 8: Testing requirements and interpretation of results for dental unit water lines

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count at 22°C	As required	>200 /ml	UNDESIRABLE	Discuss with microbiologist; investigate cause and put corrective action in place	Department of Health, 2013a
		100 – 200 /ml	ACCEPTABLE	Ensure appropriate controls are in place	
		<100 /ml	SATISFACTORY	N/A	

Table 9: Heater cooler unit waters

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Environmental mycobacteria	Quarterly	Detected in 100 ml	UNSATISFACTORY	Take out of use, disinfect and retest	Public Health England, 2017
		Not detected in 100 ml	SATISFACTORY	N/A	
Legionella	Monthly	≥1000 cfu/l	UNSATISFACTORY	*Any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment	Health and Safety Executive, 2013
		Up to 1000 cfu/l	UNDESIRABLE*		
		Not detected	SATISFACTORY	N/A	

Table 10a: Testing requirements and interpretation of results from pharmacy contact plates

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Counts	Weekly	<50	SATISFACTORY for Grade D	Area considered clean but activity should be restricted to low risk activities and an investigation into the source of contamination considered[#]	European Commission, 2008
		<25	SATISFACTORY for Grade C		
		<5	SATISFACTORY for Grade B	Area can be used for aseptic preparation and filling**	
		<1	SATISFACTORY for Grade A	Area can be used for high risk operations*	

Note: Where counts exceed the specified limits, action should be taken on the basis of trend analysis and characteristics, significance and source of isolates.

Table 10b: Testing requirements and interpretation of results from pharmacy glove prints

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Counts	Sessional (for Grade A and B areas only)	<5 cfu/glove	SATISFACTORY for Grade B	Action should be taken on the basis of trend analysis & characteristics, significance & source of isolates.	European Commission, 2008
		<1 cfu/glove	SATISFACTORY for Grade A	N/A	

Table 10c: Testing requirements and interpretation of results from pharmacy passive and active air sampling.

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Sessional, weekly and quarterly (Passive sampling using 90mm settle plate with 4hr exposure)	<100 cfu	SATISFACTORY for Grade D	Area considered clean but activity should be restricted to low risk activities and an investigation into the source of contamination considered#	European Commission, 2008
		<50 cfu	SATISFACTORY for Grade C		
		<5 cfu	SATISFACTORY for Grade B	Area can be used for aseptic preparation and filling**	
		<1 cfu	SATISFACTORY for Grade A	Area can be used for high risk operations*	
	Sessional, weekly and quarterly (Active sampling)	<200 cfu/m^3	SATISFACTORY for Grade D	Area considered clean but activity should be restricted to low risk activities and an investigation into the source of contamination considered#	
		<100 cfu/m^3	SATISFACTORY for Grade C		
		<10 cfu/m^3	SATISFACTORY for Grade B	Area can be used for aseptic preparation and filling**	
		<1 cfu/m^3	SATISFACTORY for Grade A	Area can be used for high risk operations*	

Note: Where counts exceed the specified limits, action should be taken on the basis of trend analysis and characteristics, significance and source of isolates.

Table 10d: Testing requirements and interpretation of results from broths for process validation of material transfer techniques in specialised tissue labs

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Sporadic- usually when training new staff	Growth No Growth	UNSATISFACTORY SATISFACTORY	Investigate cause and out corrective action in place N/A	Beaney, 2006

* Grade A: The local zone for high risk operations, e.g. filling zone, stopper bowls, open ampoules and vials, making aseptic connections. Normally such conditions are provided by a laminar air flow work station.

**Grade B: For aseptic preparation and filling, this is the background environment for the grade A zone.

Grade C and D: Clean areas for carrying out less critical stages in the manufacture of sterile products.

Table 11: Testing requirements and interpretation of results for operating theatre air quality (as determined by active air sampling)

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	On commissioning or following any work that may affect the nature of the air supply or its distribution (this does not include routine filter changes); in empty theatre after ventilation system has achieved steady state	> 10 cfu/m^3	UNSATISFACTORY	Do not bring theatre into use. Check that the sampling technique has not led to erroneous results. Ensure with local Estates Department that airflows and rates are as specified in guidance; ensure that air handling unit is constructed as in guidance with filters to specification and fitted such that air cannot bypass filtration. Repeat sampling. If still unsatisfactory, seek external advice.	Department of Health, 2007
		0 - $\leq$ 10 cfu/m^3	SATISFACTORY*	*If counts near or above the acceptable level contain a preponderance of fungi, check that the final filter is of adequate grade (F7 or greater) or that air is not bypassing poorly fitted or missing filters.	
	During a surgical operation	> 180 cfu/m^3 (averaged over 5-minute period)	UNSATISFACTORY	Investigate and re-test	
		0 - $\leq$ 180 cfu/m^3	SATISFACTORY	N/A	
Ultra-clean theatres:					
Microbiological testing of empty theatre is not recommended on commissioning or post maintenance					

Note: Where theatres were built before the publication of the more stringent microbiological criteria given in HTM 03-01 (Department of Health, 2007), there is no statutory requirement to meet the criteria in this document, and those specified in HTM 2025 (NHS Estates, 1994) apply. However, the criteria specified here should still be aspired to, and where these are not met, investigation into the cause should be implemented, and corrective action put in place where appropriate.

Table 12: Testing requirements and interpretation of results for bioburden testing of medical instruments

Hazard / Hygiene Indicator	Timing / Frequency of Testing	Result	Interpretation	Action	References
Aerobic Colony Count	Prior to autoclaving	Monitor trends – acceptable limits to be determined based on previously generated data		Adverse trends should prompt an investigation of the cause, and implementation of corrective actions	International Organisation for Standardisation, 2018

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Appendix 1: Useful websites and resources

British Society of Gastroenterology:
www.bsg.org.uk

Includes guidelines for decontamination of equipment for gastrointestinal endoscopy

Food Standards Agency:
www.food.gov.uk

Provides guidance on food safety and hygiene

Hospital Infection Society:
www.his.org.uk

Makes available reports and guidelines from the Society's working parties, including guidance on endoscopy rinse water and commissioning and monitoring of operating theatres.

Public Health England:

www.gov.uk/government/organisations/public-health-england

Includes contact details for testing laboratories and reference facilities, publications and information on a wide range of infectious agents

Renal Association:
www.renal.org

Provides Clinical Practice Guidelines for the renal community in the UK, including guidance on haemodialysis

Appendix 2: Guidance on refrigerated transport of food, water and environmental samples using cool boxes

Scope

This guidance relates specifically to the use of cool boxes for refrigerated transport of samples. It is the responsibility of the person collecting the samples to ensure that the cool box is clean prior to use and that it has been packed properly.

Safety considerations

Fully loaded cool boxes present a potential manual handling hazard and it is recommended that those involved in sampling and transport receive manual handling training. Cool boxes must not be over loaded and it is recommended that a maximum full weight of 15 kg be observed.

Cool box requirements

i. Good quality cool box that has been tested in accordance with EN 12546-2:2000 and has been shown to hold a temperature of between 5°C and 15°C for a minimum of 24hrs.
ii. A minimum of 10% of the total cool box volume of frozen cold packs that have been frozen at -18°C for a minimum of 24 hours e.g. 6 x 500 ml cold packs (or equivalent) in a 30-litre box. The cold packs must be evenly distributed within the cool box to achieve the necessary cooling of samples.
iii. Use of sample separators is recommended to prevent direct contact of the samples with the frozen cold packs and facilitate air circulation inside the cool box. Alternatively cover the ice packs with a non-insulating layer before adding samples. Further advice can be obtained from your laboratory.

Method for packing a cool box

a. Insert FROZEN (minimum -18°C for 24hr) cold pack(s) to cover the base (and, if possible, sides) of the cool box.
b. Ensure that the samples are not in direct contact with the cold packs by placing a separating (non-insulating) layer over the cold pack(s).
c. Place the samples inside the cool box to allow adequate air circulation between samples. Do not over load the cool box. Place the datalogger (if using) alongside the samples.

d. Place another separating layer over the samples and datalogger, and add the remaining FROZEN cold packs over the top of this layer.
e. Place sample paperwork (request forms complete with sample details) in a plastic wallet and place inside the cool box
f. Securely close the cool box.

Special considerations

- **Environmental** and **ready to eat food** samples can be transported in the same cool box
- **Water samples** must be transported in a separate cool box to food and environmental samples
- **Hot and cold samples** must be transported in separate cool boxes and increasing the volume of cold packs used to 15% should be considered when collecting hot food or water
- **Legionella water** samples should be transported at ambient temperature and protected from daylight. Cold packs should not be placed in the box

References

BS EN 12546-2:2000. Materials and articles in contact with foodstuffs. Insulated containers for domestic use. Specification for insulated bags and boxes.

Public Health England

Responding to the detection of legionella in healthcare premises

Guidance for PHE Health Protection Teams

Guidance for the PHE response to positive counts of legionella in healthcare premises, in the absence of associated cases of Legionnaires' disease

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

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Contents

1. Background and purpose

A survey was carried out across all Health Protection Teams (HPT) in England to assess their involvement and engagement with local healthcare premises in relation to legionella control. In some areas, the local HPT is informed by those responsible for healthcare premises when relatively low levels of legionella are detected, or when there are significantly elevated levels of legionella, and there are a small number of instances where the HPT is only contacted when there are clinical cases. There is also considerable variation in the level of involvement that premises request of HPTs.

This document for Public Health England HPTs aims to provide:

- public health guidance for HPTs when approached by infection, prevention and control teams and estate departments with enquiries in relation to their water systems (in conjunction with L8[1],HTM 04-01[2] and HSG274[3]) to ensure there is a consistent and appropriate response from PHE;
- information and practical guidance for HPT staff who are participating in incident control teams, or a water safety group.

This document describes situations where HPTs should be contacted, and the extent of involvement that can be expected of HPTs where legionella counts are detected in the hot and cold water systems (excludes cooling towers) of healthcare premises. **This is not a technical guidance document for water management contractors or estates departments.** For technical guidance on management of water systems, please refer to L8, HTM 04-01 and HSG274.

The guidance and accompanying algorithm (Figure 1, p.9) applies to situations where there are **no associated nosocomial cases**, although it is possible that cases may subsequently be identified.

Expert advice on environmental legionella management can be obtained from the relevant Food, Water and Environmental Microbiology laboratory (FWEM)

Click here for the contact details of the PHE FWEM services.

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[1] L8: Legionnaires' disease. The control of Legionella bacteria in water systems: Approved Code of Practice and guidance - 4th Edition. HSE 2013. http://www.hse.gov.uk/pubns/books/l8.htm
[2] Health Technical Memorandum 04-01: The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144147/HTM_04-01_Part_A.pdf
[3] HSG274 Legionnaires disease: Technical Guidance, Health Service Executive, 2014.
Part 1: The control of legionella bacteria in evaporative cooling systems
Part 2: The control of legionella bacteria in hot and cold water systems
Part 3: The control of legionella bacteria in other risk systems
http://www.hse.gov.uk/pubns/books/hsg274.htm

2. Routine water management

The vast majority of legionella outbreaks occur due to the incorrect management of water systems. The day to day management of water systems in healthcare premises is the responsibility of the organisation and is usually undertaken by Estate Departments, often in conjunction with infection control teams. There should be an established Water Safety Group that meets regularly to review management strategies, incidents, any sampling results and actions to be taken.

Composition of the Water safety Group

The water safety group should include:

- a named **responsible person** (legionella) and their deputy.
- an infection control doctor or nurse.
- consultant medical microbiologist.

A member of the local HPT staff can be nominated as a standing member of the group and invited if there are relevant issues to discuss. Regular attendance is not mandatory but may be useful to understand what frameworks are in place for the maintenance, control and monitoring of water systems in line with Approved Code of Practice (L8) and HTM 04-01, and if management issues arise.

The purpose of this *'check assurance'* is to gain an overall insight of what management systems for the control of water systems / legionella are in place. If these rudimentary measures are not in place, then this will heighten concern that the system is not being managed appropriately.

The checklist (appendix 2) can be used as a detailed assessment tool to work with the Trust on ensuring that they are aware of, and are addressing as necessary, legionella control issues on the premises.

The Water Safety Plan

The Approved Code of Practice[1] (ACOP) for the control of *Legionella* (L8) applies to any undertaking where there is a reasonably foreseeable risk of exposure to legionella bacteria. The ACOP requires a risk assessment to be carried out for the premises and plans to be developed to monitor and prevent exposure, or control the risk from exposure, to legionella.

The risk assessment allows a written scheme of controls and precautions to be created (a water safety plan) that is implemented and properly managed, and should specify the measures to be taken to ensure that it remains effective. Every healthcare setting should have a water safety plan for the management of their hot and cold (including drinking) water systems and any cooling towers.

Routine documentation

As part of the ongoing routine management of the water systems the following documentation should be available and regularly reviewed (and updated) by the Group:

- risk assessment.
- written scheme for control of risks identified.
- clear and up to date schematics of water system on site.
- schedules for flushing and descaling (sites and frequency).
- schedules for legionella sampling (sites and frequency).
- temperature control regimen.
- chemical dosing and monitoring (where appropriate).
- records of temperature monitoring data, flushing, legionella sampling and test reports.
- planned or recent building works and schedules.
- schedule and records of maintenance to chemical dosing equipment (where appropriate).
- inspection, cleaning and disinfection of water storage vessels (including tanks and calorifiers).
- organogram of management system.
- out of hour contact list/details.

3. Elevated legionella counts

Routine sampling results are the starting point of the algorithm in Figure 1; the frequency and sites for routine environmental sampling and culture for legionella in healthcare facilities should be based on a comprehensive risk assessment and should be part of an overall management strategy.

The purpose of this algorithm is to help in ascertaining the level of response required by HPTs when an elevated legionella count is reported and principally consists of two parts:

1. To assess that the trust is checking assurance.
2. Obtain further information to ascertain the degree of contamination and the risk to health; and agree with the trust infection control team on an appropriate response.

Further information outlining the two points above can be found in Appendix 1, which accompanies the algorithm.

The algorithm in this guidance begins where legionella counts are **greater than 100 cfu/l** (colony forming units per litre). It does not distinguish between different species of legionella and serogroups of *Legionella pneumophila* (e.g. sg 1 and sg 2-14) because where one is found; others are as likely to be present.

In most instances, the HPT should only be informed (and advice sought) when critical points are reached, for example, where there is a lack of legionella control after application of routine measures, an augmented care area is affected, or a suspected nosocomial case linked to the premises is identified.

4. Local health protection response

The following outlines the role of PHE HPTs in responding to enquiries related to elevated counts of legionella in healthcare premises. Expert advice is available within PHE should local teams not have sufficient expertise, and the Directory of Legionella Services provides guidance on what support is available, and who to contact. See the ‘PHE Duty Doctors Pack’ on the intranet for a copy of the directory.

In general, HPTs can be expected to (as part of a trust led incident team):

- review risk assessment and control procedures – the estates team/IPCT should already have undertaken (or contributed to) a risk assessment. This can be reviewed off-site by HPT staff with expert support as required
- provide advice on further sampling, continued monitoring and clearance results
- signpost trusts regarding laboratory support for testing and (where appropriate) typing samples and, where necessary, to coordinate typing of isolates at Respiratory and Vaccine Preventable Bacteria Reference Unit, Public Health England - Microbiology Reference Services, Colindale
- discuss emergency remedial control measures eg. pasteurisation, chlorination, and fitting filters on outlets, again with expert support as required (see below)
- support the review of the risks to vulnerable individuals on site by the IPCT
- assist with case finding among current in-patients, out-patients and staff over the previous two years using hospital and PHE case records
- if there is confirmation of a nosocomial case at the trust, to contribute to the incident team
- provide advice on defining an end point at which the initial remedial work can be judged successful eg two or three consecutive sets of samples where legionella is not detected
- support trust led public facing communications as appropriate

PHE HPTs should not:

- make recommendations for long term legionella control, operational management and water treatment processes
- advise on engineering aspects of management of the water system

5. Key documents

1. L8 Legionnaires' disease. The control of legionella bacteria in water systems. Approved Code of Practice), Health Service Executive, 2013.
http://www.hse.gov.uk/pubns/priced/l8.pdf

2. HSG274 Legionnaires disease: Technical Guidance, Health Service Executive, 2014.
   Part 1: The control of legionella bacteria in evaporative cooling systems
   Part 2: The control of legionella bacteria in hot and cold water systems
   Part 3: The control of legionella bacteria in other risk systems

   http://www.hse.gov.uk/pubns/books/hsg274.htm

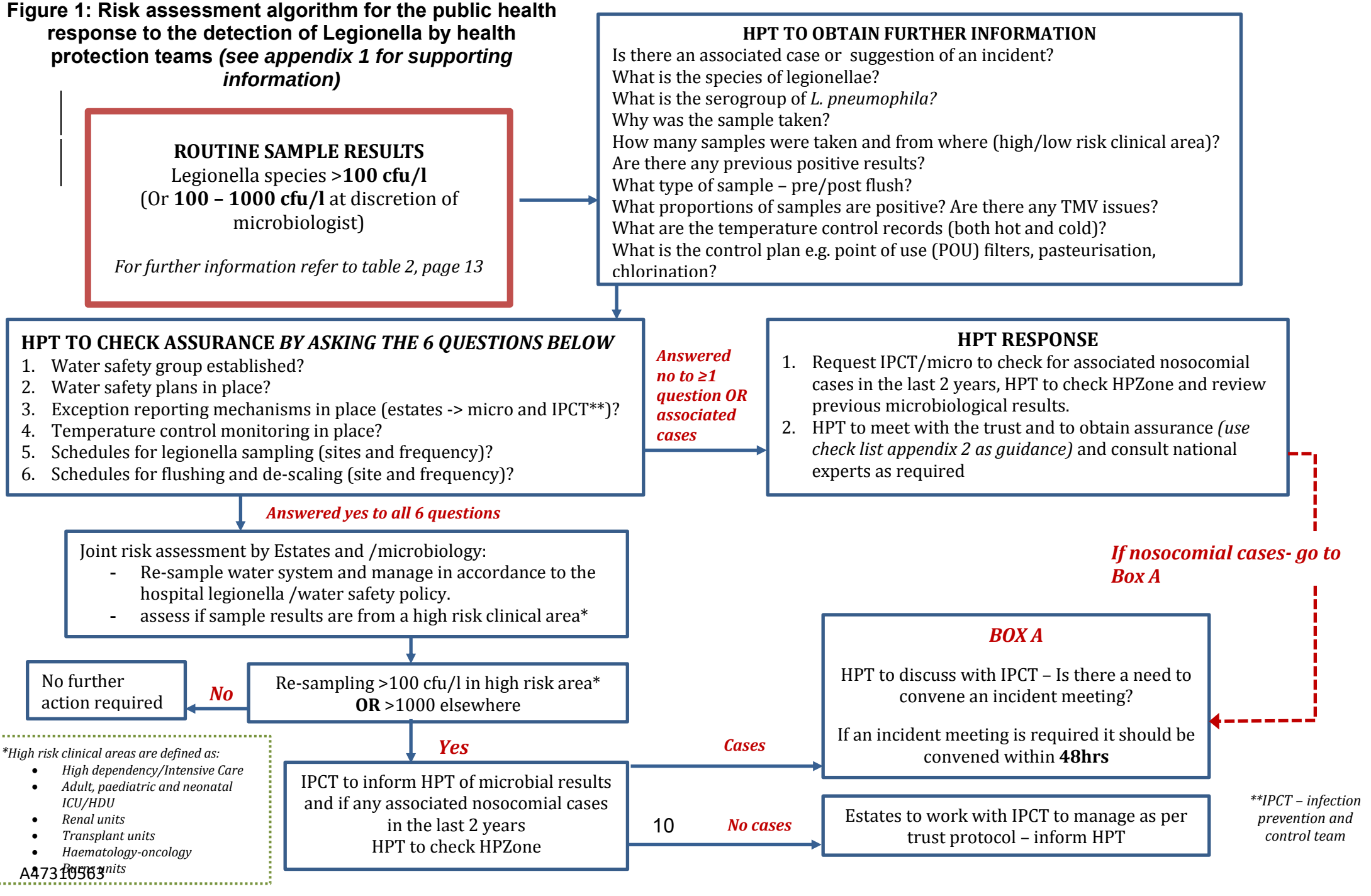
3. HTM 04-01 Part A (design, Installation and testing):
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144147/HTM_04-01_Part_A.pdf

4. HTM 04-01 Part B (operational management):
http://www.whtlimited.com/doc/lib/98/htm-04-01-part-b-20061009113435.pdf

5. HTM 04-01 Addendum (Pseudomonas aeruginosa – advice for augmented care units):
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140105/Health_Technical_Memorandum_04-01_Addendum.pdf

6. Legionella and the prevention of Legionellosis. WHO, 2007.
http://www.who.int/water_sanitation_health/emerging/legionella.pdf

Figure 1: Risk assessment algorithm for the public health response to the detection of Legionella by health protection teams *(see appendix 1 for supporting information)*



Appendix 1 – Information to support the algorithm

Assess risk - Hospitals should have a framework for the maintenance, control and monitoring of water systems in line with L8 and HTM 04-01. The vast majority of legionella outbreaks occur because the water system is not managed correctly. The purpose of the assurance check is to get an insight, albeit superficial, of what management systems for the control of water systems / legionella exist. If these rudimentary measures are not in place then this will heighten the concern that the system is not being managed appropriately.

Further information:

1. **Trying to ascertain the degree of contamination and risk to health**

Temperature control not achieved of contaminated system- the principal means of controlling legionella is to maintain water temperatures above 55°C for hot water and below 20°C for cold water.

Location of the contamination - A degree of contamination at the periphery of a water system with legionella is almost inevitable. Presence of legionella may represent poor use of an outlet or the presence of materials that promote biofilm formation. In addition, sampling through a thermostatic mixer valve (TMV) will also have an impact on the microbiological results and their interpretation. The results from pre-and post-flush samples will help identify whether the colonisation is local to the outlet or system-wide.

Table 1: Location of contamination using pre and post-flush samples*

	Presence of legionella bacteria (cfu/l)in pre-flush samples	***Presence of legionella bacteria (cfu/l) in post flush samples***	***Comments on legionella positive outlets***
Contamination of water system	Levels (cfu/l) are similar to post flush	Usually levels (cfu/l) are similar to pre flush	A high proportion of outlets may be positive but this will be dependent upon the local water system and other risk factors e.g. temperature control, flushing regimes and presence of dead legs
Contamination at the outlet	Usually higher than post flush	Usually low or absent	May be interspersed with positive and negative outlets, but this will be dependent upon the local water system and other risk factors e.g. temperature control, flushing regimes and presence of dead legs

Local interpretation must take in to account other risks e.g. temperature control, flushing regimes and presence of dead legs; and the variations in local water systems such as usage and plumbing.

Sample results, both positive and negative, should be plotted on the water schematics in order to understand their relationship and where the contamination may be located.

Serogroup of *Legionella pneumophila* – Serogroup 1 accounts for the vast majority of Legionnaires' disease cases. Other serogroups / legionella species may give rise to clinical cases and may require other tests to diagnose, as the urinary antigen test will usually only detect serogroup 1. The finding of legionella irrespective of serogroup or species indicates that conditions exist in the system which will support the growth of legionella.

Flushing records – water turnover is a pre-requisite to maintaining temperature control of the system. Water stagnation produces temperatures and conditions which promote biofilm formation and bacterial multiplication. The absence of flushing records or a risk assessment of outlets with regards to water turnover indicates the system is not being managed appropriately.

2. **Whether an appropriate response has / is going to occur.**

Is an incident meeting being held?

Who will be attending the incident control meeting/water management group – depending on size of problem should include for example: the DIPC; infection control doctor, responsible person for water, estates and infection control; representative from water treatment specialist company (if used); and communications

Are further water samples being tested and from where? Is there a policy detailing collection of water samples and have staff been trained? If not refer to PHE 'Examining food, water and environmental samples from healthcare environments Microbiological Guidelines'. Please click **here** for a copy.

What measures are being taken to reduce risk? Further sampling to monitor and validate control measures, such as point of use filters, pasteurisation, use of biocides, enhanced flushing, placing a bleed on the system, water system review and refurbishment?

If a significant risk is thought to be present what communication has occurred to medical staff ie consider in differential diagnosis of hospital acquired pneumonia, what specimens to take, should you include a macrolide in addition to standard therapy? Who else should you tell?

Table 2: Action levels following legionella sampling in hot and cold water systems in healthcare premises with susceptible patients[4]

Legionella bacteria (cfu/l)	**Recommended actions**
Not detected or up to 100 cfu/l	In healthcare, the primary concern is protecting susceptible patients, so any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment.
>100 cfu/l and up to 1000 cfu/l	Either: • if the minority of samples are positive, the system should be resampled. If similar results are found again, review the control measures and risk assessment to identify any remedial actions necessary or • if the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of control measures and a risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered.
>1000 cfu/l	The system should be resampled following an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. Retesting should take place a few days after disinfection and at frequent intervals thereafter until a satisfactory level of control is achieved.

[4] Legionnaires' disease - Part 2: The control of legionella bacteria in hot and cold water systems, p51 http://www.hse.gov.uk/pubns/priced/hsg274part2.pdf

Appendix 2 – Assurance checklist

The checklist below provides a detailed checklist to be used as a basis for establishing assurance that a Trust are aware of and are addressing legionella control appropriately. Undertaking these actions is the responsibility of the IPCT and estates department.

This checklist may also be useful for providing:

- guidance to less experienced IPCT and estate departments on investigating their systems (in conjunction with L8 and HTM 04-01)
- information and a practical tool for public health consultants who are participating in incident control teams, or a water management group .

1.0 Information about positive samples – this should reflect the sampling results
1.1 Why were the samples taken?
1.2 How many samples were taken, and from where?
1.3 What levels of *Legionella* were found (≤100 cfu/l, ≤1000 cfu/l, ≤10000 cfu/l, ≥10,000 cfu/l)?
1.4 What type of samples are these (pre-flush, post-flush or post-disinfection)?
1.5 Were any positive samples from a high-risk clinical area?
1.6 What is the proportion of positive samples (number positive/total taken x 100)?
1.7 Was the water temperature recorded (and appropriate) for each sample taken?
1.8 Were samples taken through thermostatic mixer valves (TMV)?
1.9 What serotype of legionella was recorded?
1.10 Have repeat samples been taken?
1.11 Have further areas now been sampled, or are such areas planned to be sampled?
2.0 Environmental systems – this should be available from the risk assessment
2.1 Who owns the building?
2.2 Is the building leased out?
2.3 Description of the building? e.g. age, size etc
2.3 How many floors are within the building?

2.4 How many people use, visit, or are resident in the building?
2.5 Are there any people who are vulnerable to legionella, using, visiting or resident within the premises?
2.6 What is the cold water system supply?
2.7 What are the water sources? Eg cold water tanks, mains, borehole.
2.8 What is the cold water entry temperature?
2.9 What type of hot water system is in place?
2.10 How is the water system linked between various buildings/wards/units etc?
2.11 What biocide is being used and are target levels being reached and maintained at outlets?
2.12 Is there continuous biocide dosing?
2.13 Is any other form of water treatment used eg ultraviolet light
2.14 Are there any TMVs? Has a survey of TMVs been undertaken?
2.15 Is an anti-stratification pump fitted to the calorifier? If yes, when does it operate and for how long?
2.16 Is there a water softening system in place? Is there a maintenance contract for this?
2.17 Are there any wet cooling systems present?
2.18 Are there any water features in the premises?
2.19 Are there multiple circuits to the ring main?
2.20 Are there connections between the different water systems?
3.0 Risk assessment, paperwork and maintenance
3.1 Who has the contract for legionella water management on the premises?
3.2 Where is the risk assessment? Ask for a copy.
3.3 Is the risk assessment up to date? Has it been reviewed following changes to the system?
3.4 What does the risk assessment inform the responsible person to do when legionella has been found in the system?

3.5 Do the estates team service/monitor the TMVs?
3.6 Is there a regime for checking the TMVs? Whether it gets scaled up, whether the hot water feed and the cold water feed reaches the appropriate temperature (checked with surface probe).
3.7 Are there up-to-date schematic(s) of the water system?
3.8 Is there a regime for cleaning and descaling shower heads, and are there records to show this?
3.9 What are the historical temperatures at the hot and cold outlets?
3.10 Is there documentation of temperature monitoring, flushing, descaling and disinfection, and are these signed and dated?
3.11 When were the last legionella counts performed? What were they?
3.12 Which laboratory undertakes the testing?
3.13 What is their reporting threshold eg 100 cfu/l?
3.14 Is the laboratory United Kingdom Accreditation Service (UKAS) accredited for legionella testing (they may be accredited for other testing)? What is their UKAS number?
3.15 Do they participate in the EQA scheme?
3.16 Does the responsible person have a copy of the SOP for laboratory testing including sensitivity?
4.0 Diagnostics
4.1 What are the flow temperatures – coming from the boiler? The outgoing water from the calorifier should be at least 60^{o}C.
4.2 What are the return temperatures coming back from the system? The return should be at least 55^{o}C.
4.3 What are the temperatures at the hot outlets – are they satisfactory? The hot water temperature should be at least 55^{o}C within a minute of running the water. Temperatures should be taken from outlets NOT fitted with TMVs, or where this is impractical, from the hot water feed to the TMV by means of a suitably calibrated surface probe thermometer.
4.4 What is the temperature at the cold water tank? Is there more than 2 ^{o}C gain from entry temperature?
4.5 Is the cold water tank in good condition? Well insulated, no evidence of biofilm, no significant sediment, no rust, no scum, no hot water flow entering, no dust on surface, should hold no more than 24 hours supply, should have lid to prevent ingress of air-

borne contaminant, insects, vermin etc.
4.6 What are the temperatures at the cold outlets – are they satisfactory? The HSE HSG274 part 2 document recommends that cold water should be below 20°C after running the tap for up to two minutes.
4.7 Were these temperature measurements taken after a period of non-use?
4.8 What is the surface temperature of the hot water going to TMVs? This can be measured using a suitably calibrated surface probe thermometer
4.9 Are flexible hoses used on TMVs or hand wash stations?
4.10 How frequently are the affected areas used, by whom and for what purpose?
4.11 Have any areas been identified with poor insulation of pipes or hot adjoining cold pipes?
4.12 Have any functional dead legs been identified e.g. outlets not used, shower rooms used as store cupboards?
4.13 Have any blind ends (where a facility has been removed and a length of pipe cut back) been identified?
4.14 What is the most likely cause of the problem?
5.0 Further investigation
5.1 What further sampling has been done? As a guide, sampling should be carried out from cold water tanks, hot and cold outlets, sentinel sites (eg, those most distal from the hot and cold supply and those in other 'high risk' areas – should have been identified from schematic). Particularly sample from outlets less likely to be used eg an assisted toilet. Do before chlorination/pasteurisation. Weekly samples if an area is affected.
5.2 Is there an outlet use audit planned? eg to identify functional dead legs
5.3 What further investigations are planned?
6.0 Control measures
6.1 Is the control plan being implemented as described in the risk assessment?
6.2 Have particular areas been shut or vacated? They will need to be sampled, need to consider risk of shutting – does it affect people's care?
6.3 Has a flushing regime been implemented for unused areas or outlets and are there records of this? Daily flushing in affected areas. A risk assessment will be required for the people undertaking the flushing.
6.4 Has the water been pasteurised? Note, this may not help with the cold water system,

does not get beyond the TMVs and carries a risk of scalding
6.5 Has flexible hosing been removed?
6.6 Has the water been chlorinated?
6.7 Have point of use filters been used? These are effective, but may not fit all taps or be suitable for some outlets such as showers, and need replacing every month.
6.8 Have vulnerable patients been moved?
6.9 Have any dead legs been removed?
6.10 Has the use/necessity of TMVs been reviewed? TMVs are generally not needed in kitchens, and staff areas. They are needed in areas where clients may have risk of scalding eg elderly, mental health, childrens' wards. HTM 04-01 Addendum for *Pseudomonas aeruginosa* suggests TMV outlets are not used in augmented care settings, as patients are unlikely to be using outlets and so the scalding risk is reduced.
6.11 Has case finding been initiated? Eg have staff been advised to be aware of symptoms, and provided information about legionella.
6.12 What other control measures have already been put into place?
7.0 Communications
7. 1 Who is the communications lead?
7.2 Has a press statement been drafted?
7.3 Have any staff been informed?
7.4 Have the residents/clients/users been informed?
7.5 Has the service commissioner been alerted?
7.6 Has the local authority been alerted?
7.7 Has the PHE legionella section, at Colindale, been alerted?
7.8 Has the local PHE food, water and environmental microbiology lab been alerted?
7.9 Do the Health & Safety Executive (HSE) need to be informed?
7.10 Who else knows about this issue?

Glossary

aerosol a suspension in a gaseous medium of solid particles, liquid particles or solid and liquid particles having a negligible falling velocity. In the context of this document, it is a suspension of particles which may contain legionella with a typical droplet size of <5 µm that can be inhaled deep into the lungs.

algae a small, usually aquatic, plant that requires light to grow.

bacteria (singular bacterium) a microscopic, unicellular (or more rarely multicellular) organism.

biocide a substance which kills microorganisms.

biofilm a community of bacteria and other microorganisms embedded in a protective layer with entrained debris, attached to a surface.

calorifier an apparatus used for the transfer of heat to water in a vessel, the source of heat being contained within a pipe or coil immersed in the water.

chlorine an element used as a biocide and for disinfection.

chlorine dioxide a compound used as a biocide.

cold water service installation of plant, pipes and fitting in which cold water is stored, distributed and subsequently discharged.

contact time the time a chemical is retained in the system.

corrosion inhibitors chemicals which protect metals by: passivating the metal by the promotion of a thin metal oxide film (anodic inhibitors); or physically forming a thin barrier film by controlled deposition (cathodic inhibitors).

dead end/blind end a length of pipe closed at one end through which no water passes.

dead leg a length of water system pipework leading to a fitting through which water only passes infrequently when there is draw off from the fitting, providing the potential for stagnation.

disinfection the reduction of the number of microorganisms to safe levels by either chemical or non-chemical means (eg biocides, heat or radiation).

distribution circuit pipework which distributes water from hot or cold water plant to one or more fittings/appliances.

domestic water hot and cold water intended for drinking, washing, cooking, food preparation or other domestic purposes.

fouling organic growth or other deposits on heat transfer surfaces causing loss in efficiency.

hot water service installation of plant, pipes and fittings in which water is heated, distributed and subsequently discharged (not including cold water feed tank or cistern).

legionnaires' disease a form of pneumonia caused by bacteria of the genus *Legionella*.

legionella (plural legionellae) a bacterium (or bacteria) of the genus *Legionella*.

legionellosis any illness caused by exposure to legionella.

mg/l (milligrams per litre) a measure of dissolved substances given as the number of parts there are in a million parts of solvent. It is numerically equivalent to ppm (parts per million) with respect to water.

microorganism an organism of microscopic size, including bacteria, fungi and viruses.

neonates newborn children.

nutrient a food source for microorganisms.

pasteurisation heat treatment to destroy microorganisms, usually at high temperature.

pH the logarithm of the reciprocal of the hydrogen ion concentration in water, expressed as a number between 0 and 14 to indicate how acidic or alkaline the water is. Values below 7 are increasingly acidic, 7 is neutral, and values higher than 7 are progressively alkaline. However, acidity and alkalinity are not proportional to pH.

planktonic free-floating microorganisms in an aquatic system.

point of use (POU) filters a filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow.

ppm (parts per million) a measure of dissolved substances given as the number of parts there are in a million parts of solvent. It is numerically equivalent to milligrams per litre (mg/l) with respect to water.

risk assessment identifying and assessing the risk from legionellosis from work activities and water sources on premises and determining any necessary precautionary measures.

scale inhibitors chemicals used to control scale. They function by holding up the precipitation process and/or distorting the crystal shape, thus preventing the build-up of a hard adherent scale.

sentinel taps for hot water services – the first and last taps on a recirculating system. For cold water systems (or non-recirculating HWS), the nearest and furthest taps from the storage tank. The choice of sentinel taps may also include other taps which represent parts of the recirculating system where monitoring can aid control.

sero-group a sub-group of the main species.

sessile aquatic microorganisms adhering to a surface, normally as part of a biofilm.

shunt pump a circulation pump fitted to hot water service/plant to overcome the temperature stratification of the stored water.

slime a mucus-like exudate that covers a surface produced by some microorganisms.

sludge a general term for soft mud-like deposits found on heat transfer surfaces or other important sections of a cooling system. Also found at the base of calorifiers and cold water storage tanks.

stagnation the condition where water ceases to flow and is therefore liable to microbiological growth.

strainers coarse filters usually positioned upstream of a sensitive component, such as a pump control valve or heat exchanger, to protect it from debris.

thermal disinfection heat treatment to disinfect a system.

thermostatic mixing valve (TMV) a mixing valve in which the temperature at the outlet is pre-selected and controlled automatically by the valve.

total viable counts (TVC) the total number of culturable bacteria (per volume or area) in a given sample (does not include legionella).

wholesome water water supplied for such domestic purposes as cooking, drinking, food preparation or washing; or supplied to premises in which food is produced

Pseudomonas aeruginosa routine water sampling in augmented care areas for NHSScotland

This guidance applies to the following high risk areas:

- Bone Marrow Transplant Units, Haemato-Oncology and Neonatal Units, and any other care areas where patients are severely immunosuppressed through disease or treatment.
- Critical and intensive care units (neonatal, paediatric and adult), renal units, and respiratory units (including Cystic Fibrosis patient care units). Burns units and other care areas where patients have extensive breaches in their dermal integrity.

Routine water testing in NHSScotland should be specific for *Pseudomonas aeruginosa* in augmented care areas. Water testing for *Pseudomonas* species is not advised as not all *Pseudomonas* are clinically relevant.

Note: If *Pseudomonas aeruginosa* is detected in the water supply the local Water Safety Group (WSG) must assess the risk of continuing to use the tap water in that clinical area. The Infection Control Committee should be informed.

Frequency of Water Sampling

Routine water sampling for *Pseudomonas aeruginosa* should be undertaken at least six-monthly using a pre-flush sample. This routine testing aims to support timely review of all the component parts of the water system to determine whether there is a 'niche' (area) in the system capable of supporting a *P. aeruginosa* containing biofilm; if there are 'niches' in the water system biofilm is likely to occur rapidly; (correspondence to HPS from HIS water group).

The frequency of testing should increase if any of the criteria in **Table 1** is met.

Table 1: Criteria for increased testing

1	There is an increase in clinical isolates within the care area and water borne pathogens are indicative of a source of infection/colonisation.
2	There have been changes made to the water distribution and delivery system components or water system configuration.
3	Pre-flush trend analysis demonstrates increasing cfu/100mls.

Pre- flush Classification of Results and actions

A pre-flush sample should be obtained following Appendix 2[1].

1. **Not detected:** No further action required; re-sample six-monthly (earlier if any of the criteria in Table 1 is met).
2. **Detected: Counts 1-10 cfu/100mls:** Re-test outlet using pre- and post-flush sampling until three consecutive negative samples (each subsequent sample being taken on receipt of previous sample result). Following three consecutive negative results samples should be taken weekly for four weeks; after four weeks, if the outlet remains negative commence quarterly routine sampling.
3. **Detected: Counts >10cfu/100mls:** Retest the outlet and risk assess the need to remove the outlet from service; retest using pre and post-flush sampling as explained in point 2.

Actions: Re-sampling results (pre-flush and post-flush)

Comparison of counts from pre- and post- samples can help derive the source of the *Pseudomonas aeruginosa*.

Detected: the WSG must review results and produce a risk reduction action plan considering the following thresholds for action:

1. **Result: High pre-flush >10cfu + low post-flush counts <10 cfu/100mls:** These results are indicative of a local water outlet problem; investigate cause and ensure controls are in place. The following must be considered:

[1] **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**

- Removing the outlet from use.
- Implement extended flushing time at the outlet.
- Remove and replace contaminated outlets and Thermostatic Mixer Valve (TMV) pipe-work back to the supply junction.
- Disinfect any new components and fittings before re-installation.
- Re-assess system component requirements to reduce risk i.e. no inserts. Where possible hard plumb all pipe-work.
- Installation of Point of Use (POU) filters (this should be considered a short-term control measure).
- Installation of outlets that are demountable and, auto-clavable, part of planned maintenance and compatible with POU filters.

2. **Result: High Pre- flush + post flush counts > 10 cfu/100mls:** These results are indicative of a wider problem within the water supply; investigate cause and ensure controls are in place. The following must be considered:

    - Removing the outlet from use.
    - Installation of Point of Use (POU) filters (this should be considered a short-term control measure). Requesting an engineering survey of the water system to review, to guide remedial actions alongside the water sampling results.
    - A review of the hospital water delivery system materials and the compatibility with water; BS 6920-1 sets out requirements for non-metallic materials that should not enhance microbial growth. The review should include:
        - Identifying substances that may be present in rubber compounds, and are also occasionally associated with non-metallic materials such as plasticised (softened) plastics, which can provide nutrients for *Pseudomonas aeruginosa* growth.
        - Identifying materials such as ethylene propylene diene monomer (EPDM) rubber may be susceptible to microbial colonisation often used in flexi hoses.

3. **Result: High pre-flush + post flush counts >100 cfu/100ml:** Single outlet contamination is indicated by high counts. If other nearby outlets have no or low counts, investigate cause and ensure controls are in place. The following must be considered:

    - Removing the outlet from clinical use and continue daily flushing.

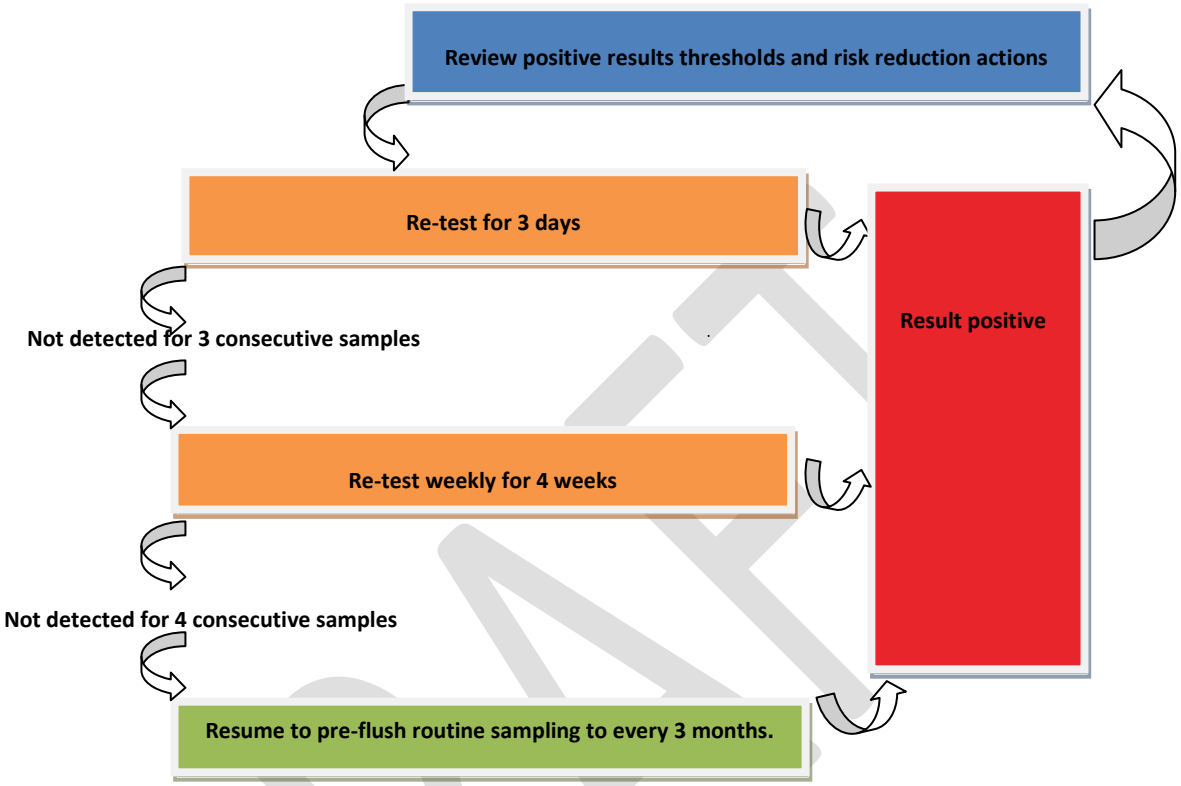
- Explore further testing dilutions (seek advice from WSG) of pre and post-flush water samples from the outlet or use an extended 5 minute flush prior to post-flush sampling.
- Alternatively, disinfect outlet and re-sample post-flush.
- Removal of flow straighteners; if not feasible clean and/or disinfect the straighteners according to the manufacturer's instructions or replace with new. Straightener replacement frequency should be confirmed via sampling results.
- Assess splash risk from the outlet; if confirmed, investigate the following:
    - Check compatibility of tap design flow profile with the clinical hand wash basin (CWHB);
    - Height compatibility between tap outlet and surface of basin;
    - Excess water pressure; and
    - Blocked or malfunctioning flow straightener(s).

4. Result: Not detected

See Figure 1 below for retesting frequencies and period of negative results required prior to re-instatement of outlets removed from use.

Figure 1

Pseudomonas aeruginosa positive result re-sampling frequencies (pre-flush and post-flush) and actions



Outlets taken out of use:

Re-samples must remain not detected for 2 weeks prior to re-instatement of outlet.

Defra

Reference: WD 0906

A REVIEW OF FUNGI IN DRINKING WATER AND THE IMPLICATIONS FOR HUMAN HEALTH

Final Report

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In association with:

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University of BRISTOL

Bio Intelligence Service - Scaling sustainable development
Industrial Ecology - Nutritional Health

Bio Intelligence Service S.A.S - biois@biois.com
20-22 Villa Deshayes - 75014 Paris - France
Tél. + 33 (0) 1 53 90 11 80 - fax + 33 (0) 156 53 99 90

Contact BIO Intelligence Service
Pierre Sonigo - Arianna De Toni - Kate Reilly
☏ + 33 (0) 1 53 90 11 80
[redacted]

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EXECUTIVE SUMMARY

Fungi are eukaryotic, heterotrophic organisms, including both single-celled yeasts and multi-cellular filamentous fungi. Many fungal species can survive in oligotrophic environments, through scavenging nutrients from the substrate which they colonise, or the air or water in which they live. Fungi also produce secondary metabolites, some of which are toxins. Some of the fungal species and the metabolites they produce are human pathogens or allergens.

Fungi can enter drinking water distribution systems through several contamination pathways, including treatment breakthrough, deficiencies in stored water facilities cross-connections, mains breaks and intrusions, and during mains installation and maintenance. Once introduced, fungal species can become established on the inner surfaces of pipes, induding interaction and reaction with sealings and coatings, and biofilms within distribution systems, or can be suspended in the water. Water companies in England and Wales have in place procedures to minimise the risk of microbial contamination.

The results of sample analysis from customer taps and other points within distribution systems often reveal higher numbers of fungi than the analysis of samples following treatment, prior to entry into the distribution system. Such increases through the distribution system could be due to two reasons: i) the fungi that remain present after treatment multiply within the system or that fungi that were only partially inactivated later recover, and ii) fungi enter the system via pathways of secondary contamination. Accumulation of fungi in stored water at the consumer end, such as in water tanks, has also been observed. For example, higher numbers of colony forming units of *Aspergillus* have been found in hospital water storage tanks than in the municipal water supply.

A number of different methods of analysing drinking water samples are used, including culture, measurement of ergosterol, quantitative PCR, gene markers and probes, protein probes, direct observation and mass spectrometry. There is currently no international standard specifically for the measurement of fungi in drinking water, and there is no widespread adoption of other relevant standards. Therefore, differences in analysis methods limit the extent to which results can be compared between studies. Furthermore, the most commonly used unit of quantification is numbers of Colony Forming Units (CFUs). However, this measure does not necessarily give an accurate representation of the number of fungi present in a sample, as not all species can be detected using culturing methods. It is also likely that one colony is formed of many different fungal structures, such as hyphae, conidia, conidiophores, from different “individuals” clumped together into one CFU.

Relatively few studies have investigated the fungi found in treated drinking water. The numbers of fungi found in the existing studies range from 1 CFU per litre to 5000 CFU per litre. Of the sixty-five genera that have been isolated in the studies analysed during this review, the majority were filamentous fungi. The most commonly isolated genera were *Penicillium*, *Cladosporium*, *Aspergillus*, *Phialophora* and *Acremonium*.

A number of factors influence the ecology of fungal taxa in drinking water distribution systems. Fungi are more likely to be isolated from surface-water derived drinking water than from that derived from groundwater. This may be related to the larger amounts of organic matter in surface water. Differences in acidity and calcium content may also account for some of the variation. Fungi were also more likely to be isolated from cold water than hot water, although this depends on the species considered and their optimum temperature range. Associations between fungi and bacteria are also relevant, in order to determine if fungal numbers correlate with commonly measured bacterial parameters of drinking water quality. However, there is no consensus in the literature of whether such a correlation exists.

Biofilms are an important habitat for fungi in drinking water. Their development is influenced by many factors including temperature, nutrient concentration, pipe material and water flow rate. However, how exactly such factors affect biofilm development and specifically the role of fungi in biofilms is not well known.

Water treatment appears to reduce the number of fungi in water, without removing all of them. Melanised species are particularly able to resist water treatment. Different treatment processes have different removal efficiencies, although it is not agreed which process is the most efficient method.

Many of the fungi that have been isolated from treated drinking water are known to be pathogenic, particularly *Aspergillus* and *Candida*. Although healthy individuals may suffer from superficial or localised fungal infections caused by these taxa, there is little evidence that their pathogenicity arises from their presence in drinking water. More severe invasive infections are limited to those with immune deficiency, due to for example HIV/AIDS, chemotherapy, immunosuppressive therapy following transplants, or other underlying health conditions, such as cystic fibrosis or diabetes mellitus. Such invasive infections carry a high mortality rate, estimated at between 50 and 100%, depending on the species involved. The extent to which infections arise from at-risk individuals is not well known. The continuing rise of *Aspergillus* infections in at-risk individuals despite hospital-based measures to control airborne fungal spores suggests that another environmental source exists. A small number of studies have linked the genotype of fungi recovered from patients to that of fungi from hospital water supplies. The significance of exposure via drinking the water, as opposed to washing with it, has not been specifically studied. Aerosolisation of fungi during showering or from running taps has received more attention; numbers of airborne fungi have been found to increase after running taps or showers. Infections caused by *Candida* species

are also significant, and while this genus has been isolated from drinking water the significance of exposure via drinking water is not known.

Fungi have also been linked to allergic disease, including worsening of asthma symptoms, hypersensitivity pneumonitis and skin irritation. Fungi known to provoke allergic responses in susceptible individuals, such as *Alternaria* spp., *Aspergillus*, spp., *Cladosporium* spp. and *Penicillium* spp., have been isolated from drinking water. Symptoms have arisen due to exposure when showering, bathing or using saunas, or from exposure to water-damaged buildings.

Some fungi, including *Penicillium* spp., *Aspergillus* spp., *Fusariam* spp. and *Claviceps* spp. are known to produce mycotoxins such as patulin, aflatoxins and zearalenone. It is thought that concentrations of mycotoxins in drinking water are low due to being diluted. No reports of disease caused by mycotoxins in drinking water have been identified.

Indirect health impacts may arise from association with other pathogens. For example, colonisation of the respiratory tract with *Candida* spp. increases the risk of ventilator-associated pneumonia from *Pseudomonas aeruginosa.* Biocorrosion of pipes by fungal species may represent a second indirect health impact. This process can lead to increased metal concentrations in drinking water and corrosion tubercles also provide habitat for fungi.

Secondary metabolites produced by fungi, particularly those growing in localised pockets near the consumer end may be responsible for altering the taste and odour of drinking water. It is thought that the threshold level for numbers of fungi that can cause such issues may be around 102-103 CFU l^{-1}. While problems with taste and odour do not necessarily imply a health risk they are often perceived as such by the consumer.

Due to the relative lack of literature on the topic of fungi in drinking water, there are a number of aspects that remain poorly understood. Research needs include a need to determine the importance of drinking water as the environmental source of fungal infection in vulnerable or at-risk population groups. Greater knowledge on the importance of ingestion as opposed to inhalation or skin contact as exposure pathways for fungi in drinking water will ensure that mitigation measures for at-risk patients are appropriate. Finally, greater understanding of the effect of the analytical method on the results obtained and development of a standard method would facilitate further research into fungi in drinking water.

- Fungi present in drinking water may cause severe fungal infections in immunosuppressed patients. In a small number of studies, drinking water supplies have been found to be the source of infection, although the pathway of infection (drinking vs. inhalation of aerosolised spores while showering) is uncertain
- Additional research would be required to further investigate the link between fungi in drinking water and infections in immunosuppressed patients, address its frequency from an epidemiological viewpoint and determine the fungal species and quantity in water that may cause such infections.
- The present risk of health impact for the general population is thought to be low based on current knowledge. Therefore current procedures for water system maintenance or water monitoring and treatment might be sufficient.
- The literature should be reviewed periodically in order to take account of potential environmental or procedural changes, such as climate change or altered water treatment processes.
- If future scientific results suggest an increase in risk, pilot epidemiological studies and surveillance may be justified.
- Further research and monitoring (if needed) would be facilitated by the use of a simpler and quicker method of fungal quantification and identification than culture.
- Greater knowledge of the associations between fungi and bacteria would help to ascertain whether commonly measured bacterial parameters of water quality correlate with fungi presence.

1. INTRODUCTION

Fungi are eukaryotic, heterotrophic organisms, including both single-celled yeasts and multi-cellular filamentous fungi. They primarily function as recyclers of organic material. Many fungal species can survive in oligotrophic environments, through scavenging nutrients from the substrate which they colonise, or the air or water in which they live. To maximise nutrient uptake, filamentous fungi form mats of fine hyphae. Dispersion is via spores. Fungi also produce secondary metabolites, some of which are toxins. Some of the fungal species and the metabolites they produce are human pathogens or allergens (Paterson and Lima, 2005).

Due to their tolerance of oligotrophic environments, some species of fungi are able to colonise drinking water distribution systems, which are typically low in nutrients. The significance of drinking water as an exposure pathway to pathogenic, allergenic or toxic fungal species or their metabolites is not well known.

Fungal infections are becoming of increasing concern due to the increasing numbers of immunocompromised patients and those with other risk-factors (Annaisie et al., 2002). Therefore, there is a need to ascertain what the exposure pathways are and whether treated drinking water has a role as a source of exposure to pathogenic fungi.

The presence of fungi in water distribution systems may cause other indirect challenges for water companies. For instance, the secondary metabolites produced by some species can alter the taste and smell of water, generating complaints from end-users. Organic acids produced by fungal metabolic processes can increase the rate of corrosion of water pipes, especially when it is difficult to maintain sufficient concentrations of water disinfectants, such as chlorine, throughout the distribution system (Grabinska-Loniewska et al., 2007).

There is a need to determine the extent of current knowledge regarding which fungal species have been reliably identified as present in treated drinking water and its distribution systems, their ecology and the extent to which they are a hazard to human health. **This report aims to synthesise and analyse the most significant recent literature regarding the occurrence and implications of fungi in treated drinking water and distribution systems.**

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2. METHODOLOGY

Literature was collected using keyword searches in Science Direct[1] and PubMed[2], focusing on publications from 2000 onwards, supplemented with older papers to provide theoretical knowledge where necessary. Several keyword combinations were used to search the title, abstract and keywords, including:

- 'fungi' AND 'drinking water'
- 'mycotoxin' AND 'drinking water'
- 'filamentous' AND 'drinking water'
- 'yeast' AND 'drinking water'
- 'biofilm' 'fungi' AND 'drinking water'
- 'fungi' AND 'water supply'
- 'fungi' AND 'water infrastructure'
- 'fungi' AND 'water network'
- 'fungal infection' AND 'water'
- 'allergy' 'fungi' AND 'drinking water'
- 'allergy' 'fungi' AND 'water'
- 'toxicity' 'fungi' AND 'water' (AND 'drinking water')
- 'taste' 'fungi' AND 'drinking water'
- 'odour' 'fungi' AND 'drinking water'
- 'drinking water treatment' AND 'fungi'
- 'drinking water purification' AND 'fungi'

The results that were obtained from each search were exported to EndNote.

The results obtained through the systematic literature search were supplemented by literature identified using broad searches using Google Scholar (for example for 'fungi' and 'protozoa') in order to include books and grey literature (i.e. unpublished reports and documents) and from the references of key papers, such as recent literature reviews. This was done in order to fill in gaps in coverage identified during the initial review of the literature collected.

[1] Available from: www.sciencedirect.com [Accessed 30/11/2010]

[2] Available from: www.ncbi.nlm.nih.gov/pubmed [Accessed 30/11/2010]

The complete list of references was then reviewed to identify any references that were not relevant to the topic of fungi in drinking water. These references were marked as such, but were retained in order to have a complete record of the search results.

Following the search on Science Direct and PubMed, 164 unique references were identified, of which 48 were found to be not relevant to this study following the initial review. Examples of those that were not relevant include papers where yeast was mentioned only as a culture medium and papers that were only focused on bacteria in drinking water. In these cases fungi may have been mentioned but not analysed sufficiently to be of use. This left 116 papers that could be of use in the literature review. The papers were prioritised according to those that provided the most useful and directly relevant information. This was determined by reading the abstract, on the basis of the following criteria:

- the study was conducted in the UK;
- the paper was focused on the ecology of fungi in treated drinking water;
- the paper was published recently (i.e. since 2000 in most cases); and
- the paper included inventories of species isolated from treated drinking water, or was a review of existing knowledge.

No papers fit all the criteria; for example there was very little information from the UK. The one paper published before 2000 (Kelley et al., 1997) was included in the list due to it including information from the UK. It was this priority list (see Annex 3) on which the analysis was based, supplemented with references on specific points where appropriate.

3. FUNGAL TAXA IN TREATED DRINKING WATER

3.1. FUNGI ENTERING THE DRINKING WATER DISTRIBUTION SYSTEM

Fungi were isolated from treated drinking water in all the studies that were analysed in-depth (see Annex 3). A summary of the full results are presented in Annex 1. As can be seen, these studies were conducted in a limited number of countries, including UK, US, Germany, and Poland. While there are a number of species that are frequently isolated from drinking water systems, the precise species composition observed in different studies varies considerably. This indicates that the specific environmental characteristics of the individual distribution systems examined influence considerably the microbial communities found. However, the culturing method used may also affect the species isolated (see sub-section 3.2.2.). The current knowledge on how particular biotic and abiotic factors affect this variation is discussed further in chapter 4.

3.1.1. PATHWAYS OF CONTAMINATION OF DRINKING WATER DISTRIBUTION SYSTEMS

Contamination pathways are the entry points that allow microorganisms and pollutants to enter the water distribution system. Pathways can be either primary, i.e. where the source water contains microorganisms which survive treatment, or secondary, i.e. where contamination occurs after water treatment. There are a number of potential pathways, which are illustrated in Table 3-1.

Table 3-1: Contamination pathways for fungi and other microorganisms (US EPA, 2006)

	Pathway	Description	Level of importance
Primary contamination	Treatment breakthrough	Water treatment and disinfection processes may fail to remove/inactivate all microorganisms of concern from source water.	Many fungal species resistant to treatment and disinfection (Doggett, 2000). Higher risk following rainfall and flood events (US EPA, 2002).
Secondary contamination	Deficiencies in treated water storage facilities	Physical openings in storage facilities, and lack of cover allow microorganisms to be introduced from the air, animals, introduction of untreated surface or groundwater, etc (US EPA, 2002).	All service reservoirs in England and Wales are covered and vents protected by gauze to prevent animals gaining access. Contamination introduced earlier in the system may be amplified in stored water (e.g. through biofilm growth) and due to particle accumulation.
	Cross	Cross connections are where	Significance as a pathway for fungal

	Pathway	Description	Level of importance
	connections	the distribution system for treated water is conencted to any other system, including waste water, industrial process systems. If connections do not have devices to prevent backflow or back siphonage, other fluids can enter the treated water distribution system, particularly when pressure in the system drops (US EPA, 2002).	introduction unknown. In England and Wales the risk of this is minimised through water company enforcement of the Water Supply (Water Fittings) Regulations.
	Mains breaks and intrusions	Mains breaks include leaking joints and adapters, cracks in pipelines and deficient seals. Low and negative pressure events can allow intrusions of contaminants through such breaks). Changes in pressure can arise from pump startup and shutdown, flushing operations, sudden changes in demans, power failure, main breaks, large changes in demand etc. (US EPA, 2002).	Breaks are more common in ageing infrastructure, and can also result from thermal contraction and expansion arising from temperature changes. Frequency of breaks is variable by size of the system (US EPA, 2002). It is estimated that 3275 Ml/day were leaked in 2009/2010 (Ofwat, 2010).. The frequency and significance of low and negative pressure events is not well known. However, this is thought to be a key pathway for the introduction of soil-borne fungi (Doggett, 2000). Water companies have procedures in place to minimise the risk of ingress during bursts and repairs.
	Water main installation and maintenance	Insufficient treatment of materials, equipment or personnel can allow microbial entry to the distribution system.	Water companies have procedures in place to manage this. These procedure should in accordance with the "Principles of Water Supply Hygiene" and the associated technical guidance notes

Fungi may enter through any of these pathways, although the relative importance of each is not fully understood, controls are in place to minimise risks. In terms of allowing entry to microbes of concern, the following risk levels have been applied (US EPA, 2002):

- **high risk:** treatment breakthrough, intrusion, cross-connections, main repair/break (note that procedures are in place in England and Wales to minimise risk of microbial introduction during treatment and throughout the distribution system);
- **medium risk:** uncovered water storage facilities (note that there are no uncovered service reservoirs in England and Wales);

- **low risk:** new mains installation, covered water storage facilities, growth and resuspension, purposeful contamination.

For example, soil-borne fungi can enter distribution systems through leaks and mains joints if the main pressure is low, or during potentially during maintenance (University of Sheffield, 2009). Airborne species can be introduced from the air in contact with stored water (Göttlich et al., 2002 and Gonçalves et al., 2006). Physical entrapment of the spores may be responsible for the introduction of hydrophobic spores in water systems (Gonçalves et al., 2006).

Once introduced, fungal species can become established on the inner surfaces of pipes, including interaction and reaction with , sealings and coatings, and biofilms (see Box 1 for a full explanation of biofilms) within distribution systems, or can be suspended in the water (Göttlich et al., 2002, Grabinska-Loniewska et al., 2007 and Gonçalves et al., 2006). Some species are found throughout water distribution networks, while others may be restricted to localised sites (Kelley et al., 1997). For example, Göttlich et al. (2002) classified *Phialophora*, *Exophiala* and *Acremonium* as widespread and resident, and *Verticillium* and *Phoma* as transients with restricted distribution. The presence of transient species indicates that either such species grow at localised points within the system or that the system is regularly breached, allowing frequent local contamination (Kelley et al., 1997).

Water with long residence times in dead ends, tidal points and oversized pipes, and stored water on the consumer side[3], i.e. in tanks and other storage facilities, is particularly vulnerable to fungal colonisation (Paterson and Lima, 2005, Hageskal et al., 2007 and International Mycological Institute, 1996). Terminal pipe ends are favoured locations for fungal colonisation as they typically do not support sufficient concentrations of residual chlorine to kill fungi (Grabinska-Loniewska et al., 2007). At the consumer side, installations such as cisterns, heating tanks, taps, and shower heads can yield large numbers of fungi (in terms of Colony Forming Units (CFUs)) (Hageskal et al., 2007). For example, Anaissie et al. (2002) found that *Aspergillus* species were significantly more likely to be isolated in significantly greater concentrations (p=0.001) from cold water storage tanks than from municipal water or water from cold taps.

[3] The term "consumer side" refers to all water piping and installations in the consumer's premises.

Box 1: Fungi in biofilms

Biofilms are communities of micro-organisms, including bacteria, fungi and protozoa, that are attached to a surface, usually at phase boundaries such as the interface between a liquid and a solid (Paterson and Lima, 2005 and Doggett, 2000). They can include organic and inorganic material which, along with the microbes, is incorporated into an organic polymer matrix produced by microbes (US EPA, 2002). While bacteria are frequently the principal component of biofilms in water distribution systems, fungi and fungal spores can also become embedded on the biofilm surface or in encrustations. Fungi can also be primary colonisers of biofilms, if exposure time to pipe surfaces is long enough. Biofilms are a significant habitat for fungi in water distribution systems (Paterson and Lima, 2005 and Doggett, 2000). For example, Grabinska-Loniewska et al. (2007) found that the number of fungal CFUs held in biofilms was 1000-5000 times greater than that in water. The density of fungi in biofilms and the species involved vary between local sites (Doggett, 2000). For example, the number of yeasts in biofilms was found by Doggett (2000) to vary between 0 and 8.9 CFU cm^{-2} and for filamentous fungi between 4.0 and 25.2 CFU cm^{-2}. Inner surfaces of pipes in water distribution systems may have a continuous biofilm or, more commonly, patchy biofilms (US EPA, 2002).

The five stages of biofilm development are illustrated in Figure 3-1. Initial attachment to a solid surface occurs when bacteria penetrate a film of organic molecules on a surface by eddy diffusion (i.e. mixing of the liquid) and attach by weak electrostatic or Van Der Waals forces. Highly specific interactions between microorganisms and with the surface, such as dipole, ionic or hydrogen bonding, or hydrophobic interactions, create irreversible attachment. Pieces of biofilm periodically break off, due to shear forces (Wimpenny, 2000). This releases fungi and other microorganisms into the water transported through the network to end users (Hageskal et al., 2007).

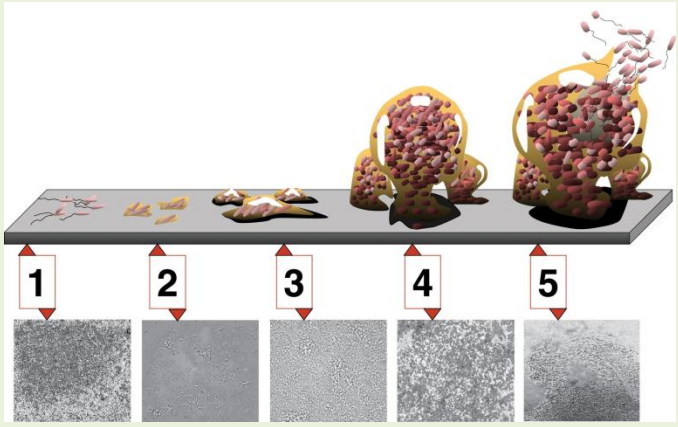

Figure 3-1: The five stages of biofilm development: 1. Initial attachment, 2. Irreversible attachment, 3. Maturation I, 4. Maturation II, 5. Dispersion (Monroe, 2007)

The organisms that make up biofilms may function as a community and thus have "emergent" properties, i.e. properties greater or different to those of the individual

components (Wimpenny, 2000). This is facilitated by the production of extracellular polymeric substances (EPS) which help to adhere the microorganisms to the surface, protect the community from environmental stresses and facilitate community interactions. Therefore, once fungi are established in biofilms they are less susceptible to water treatment or disinfection procedures (Hageskal et al., 2009 and Paterson and Lima, 2005). Fungal hyphae may also serve to strengthen the entire biofilm and make it more difficult to remove (Paramonova et al., 2009).

Interactions between fungi and bacteria, including in biofilms, are discussed in sub-section 4.2.1.

3.1.2. MULTIPLICATION AND SURVIVAL OF FUNGI WITHIN THE WATER DISTRIBUTION SYSTEM

The results of sample analysis from customer taps and other points within distribution systems often reveal higher numbers of fungi than the analysis of samples following treatment, prior to entry into the distribution system. For example, Grabinska-Loniewski et al. (2007) found a total of 200 CFU l^{-1} in newly treated water delivered to the distribution system. This increased to 5000 CFU l^{-1} in samples taken 10.3 km away from the treatment plant. Such increases through the distribution system could be due to two reasons: i) that the fungi that remain present after initial treatment/disinfection multiply within the system or are partially inactivated to later recover, and ii) that fungi enter the system via pathways of secondary contamination, or that fungi are not completely inactivated and later recover. Lack of sufficient concentrations of residual disinfectants throughout the system contributes to allowing the establishment of fungi entering the system. Accumulation in stored water at the consumer end has also been observed. For example, Anaissie et al. (2002) found higher numbers of colony forming units of *Aspergillus* in hospital water storage tanks than in the municipal water supply.

3.2. IDENTIFICATION AND CHARACTERISATION OF FUNGI IN THE DRINKING WATER DISTRIBUTION SYSTEM

3.2.1. SAMPLING METHODS

Most studies take samples of water from the tap or from various places in the distribution system, often as part of routine bacteriological monitoring. It is difficult to obtain a representative sample; fungi are often unevenly distributed through water. Many are held in biofilms, fragments of which occasionally break off. Therefore, quantities of fungi are likely to be highly variable with time with occurrences in mobile phases often for short durations and small volumes (Hageskal et al., 2009 and Paterson and Lima, 2005). Other recent distribution system quality-related research is utilising 'large volume' sampling. However, this is relatively unproven at present. Biofilms have

been collected by taking pipe coupons (i.e. longitudinal sections of the inside of the pipe), from which biofilm fragments were removed (Doggett, 2000).

3.2.2. ISOLATION, IDENTIFICATION AND QUANTIFICATION

The main methods of isolating, identifying and quantifying the fungi in the samples taken are described in Table 3-2.

Results of the quantification methods described in Table 3-2 are usually given as the number of Colony Forming Units (CFUs) of fungi in a certain volume of water. However, this measure does not necessarily give an accurate representation of the number of fungi present in a sample; it is likely to be an underestimation. For example, it is likely that one colony is formed of many different fungal structures, such as hyphae, conidia, conidiophores, from different "individuals" clumped together into one CFU (Gonçalves et al., 2006 and Paterson and Lima, 2005).

The specific protocol chosen for culturing fungi in water samples can select for particular species and hinder the growth of others. For example, incubating samples at a temperature of 25°C allows growth of mesophiles[4], but for thermotolerant species such as *Aspergillus fumigatas* incubation 30°C is needed. This point is particularly important as species which are human pathogens can withstand human body temperatures and thus may also need higher incubation temperatures (Gonçalves et al., 2006). The medium used for isolation and culturing can also select for some species and exclude others, depending on its nutritional content (Hageskal et al., 2009). When resources allow, it is recommended that samples are cultured on both a low-nutrient and a high-nutrient medium (Kinsey el al., 1999).

International standards exist concerning specific aspects of the microbiological analysis of water and food stuffs, such as ISO 6222:1999 – Water quality (enumeration of culturable micro-organisms) and ISO 11133 (preparation, production, storage and performance testing of culture media) (joint water and food standard). At national level, the American Public Health Association, the American Water Works Association and the Water Environment Federation publish "Standard Methods for the Examination of Water and Wastewater". This includes a specific standard (no. 9610) on the detection of fungi[5]. In the UK, methods for the enumeration of micro-fungi and yeasts by membrane filtration or spread plate techniques are published in the "Microbiology of Drinking Water" (Environment Agency, 2004).

[4] Mesophiles are organisms that grow best at moderate temperatures of between 20 and 50°C (Brochier-Armanet et al., 2008).

[5] Available from: www.standardmethods.org/store/ProductView.cfm?ProductID=117 [Accessed 12/1/2010]

Table 3-2: Advantages and disadvantages of main methods of sample analysis

Method	Description	Advantages	Disadvantages
Culture of samples (detection and quantification)	Fungi are cultured either from filtered water samples or direct spread of the sample on to the plate. Samples may also be centrifuged prior to culture to collect the fungi. Ideally samples are cultured on both high and low nutrient media. Plates are kept at a constant temperature and examined at regular intervals. The number of CFUs present are then counted.	-Low cost and practical. Low level of expertise needed.	-The media, time and temperature of cultivation can all influence the taxa identified. -Not all fungi can be cultured successfully in laboratory environments (producing false negatives). -Slow-growing species are likely to be under-represented in counts if insufficient time for culture is given (International Mycological Institute, 1996). -Culturing water samples can give inaccurate results due to interactions between species. For example, competition for nutrients will reduce the counts of weaker competitors, and production of mycotoxins by filamentous fungi could inhibit the growth of other species (Gonçalves et al., 2006). A fungal toxin (rose bengal) is sometimes added to prevent overgrowth of dominant species, which then leads to them being under-represented (International Mycological Institute, 1996). -Fungi can be outcompeted on culture plates if overgrowth of bacteria occurs. To avoid this, antibacterial substances are sometimes used. However, such substances have the potential to also inhibit some fungal species (International Mycological Institute, 1996). - Different volumes of water used each have different detection limits (Hageskal et al., 2009).
HPLC of ergosterol (detection and quantification)	Provides estimation of total fungal biomass as this is directly correlated with ergosterol production. The concentration of ergosterol is measured using UV spectroscopy (Kelley et al., 2003 and Paterson and Lima, 2005).	-Is more sensitive than quantification by dry weight- quantities in water samples are likely to be too low to be detectable by measuring dry weight. -Good indication of fungal surface area.	-Does not discriminate between species. -Not a particularly accurate measurement of biomass.
Quantitative PCR (detection, identification and	DNA is extracted from water samples, and is mixed with species-specific DNA primer sequences and probes. The qPCR	-Sensitive and specific. - Rapid processing times, thus allowing real time analysis.	-Difficulties of determining which species are included in or excluded from the test. -Can create false positives, i.e. where cells are dead but

Method	Description	Advantages	Disadvantages
quantification)	instrument then detects the quantity of DNA for each species in relation to known quantities of species-specific reference stocks of DNA.		still detectable.
Gene markers and probes and protein markers (detection and identification)	Gene markers used to detect mycotoxin metabolic pathways. Protein markers can also be used to detect specific proteins using the Western Blot technique.	-Useful supplements to morphological identification (Hageskal et al, 2009 and Paterson and Lima, 2005).	
Direct observation (identification)	Light or scanning election microscopy used to identify taxa based on morphology.	-Low cost.	-Morphological identification is subjective (Paterson and Lima, 2005). -Impossible for non-sporing species, or those individuals that are not sporing at the time of the sample being taken (Hageskal et al, 2009 and Paterson and Lima, 2005). -Due to limitations in morphological identification, many studies identify fungi to genus rather than species level.
Mass spectrometry (identification)	Specimens are usually mixed with a matrix that absorbs a laser beam. Ions are produced from the resulting high-energy impact, which can be extracted and detected as a mass/charge spectrum/	-High precision, sensitivity and speed.	-Requires database to be completed (Marklein et al., 2008).
Standard methods for detection and quantification of fungi	No international standards currently exist.	-Will allow standardisation of methods and comparability between studies	-No widespread adoption – considerable variation exists between studies and many state the lack of international standardised methods as a hindrance.

However, such national standards are not widely adopted and there is currently no international standard method specifically for the analysis of fungi in drinking water (Hageskal, et al., 2009). This represents the main limitation in the detection, identification and quantification of fungi in drinking water samples and makes it difficult to compare results between studies (Paterson et al., 2009). Thus it is often not possible to determine the proportion of variation between studies that is attributable to differences in methodology and the proportion attributable to environmental variation.

The total number of fungal CFUs found in treated drinking water is highly variable between studies (see Table 3-3), ranging from 1 CFU per litre to 5000 CFU l^{-1}. Colony Forming Units are not an accurate measure of fungal numbers, as discussed above, which may explain a degree of the variation between studies. However, it is the most commonly used unit of quantification and is reported here for that reason.

Table 3-3: Fungal biomass in treated drinking water

Mean total number of CFUs	Location	Study
200 - 5000 CFU l^{-1}	Poland	Grabinska, 2007
90 CFU l^{-1}	Norway	Hageskal, 2007
2800 CFU l^{-1} (mean yeasts), 1000 CFU l^{-1} (mean filamentous fungi)	Brazil	Yamaguchi et al., 2007
180 CFU l^{-1}	US	Nagy and Olson, 1982
28 CFU l^{-1}	US	Kelley et al 2003
1-20 CFU l^{-1}	Portugal	Gonçalves et al., 2006
$3.7x10^{2}$ CFU l^{-1}	Greece	Arvanitidou et al., 1999
8.9-31.8 CFU cm^{-2}	US	Doggett, 2000
100-1500 CFU l^{-1}	US	West, 1986
91 CFU l^{-1}	Austria	Kanzler et al., 2008

Of the studies that were analysed in-depth in this review (see Annex 3), 65 genera were isolated from treated drinking water. Of these, the majority were filamentous fungi. More filamentous fungi than yeasts are also identified within individual studies of the same water distribution system (Göttlich et al., 2002, Doggett, 2000 and Grabinska-Loniewska et al., 2007). It should be noted when interpreting this finding that depauperate filamentous fungi can form yeast-like cells.

It should also be noted that findings from other countries may not be directly applicable to the UK. For example, chlorine concentrations in the US are commonly

higher than in the UK, and by contrast the water in the study by Göttlich et al. (2002) was not chlorinated. Climatic differences in mean temperatures and rainfall may also influence the taxa found. Furthermore, treatment and disinfection regimes vary locally, as will the source of the drinking water.

Figure 3-2 illustrates the most frequently isolated genera by the number of studies in which they were found. *Penicillium, Cladosporium* and *Aspergillus* were the most common genera.

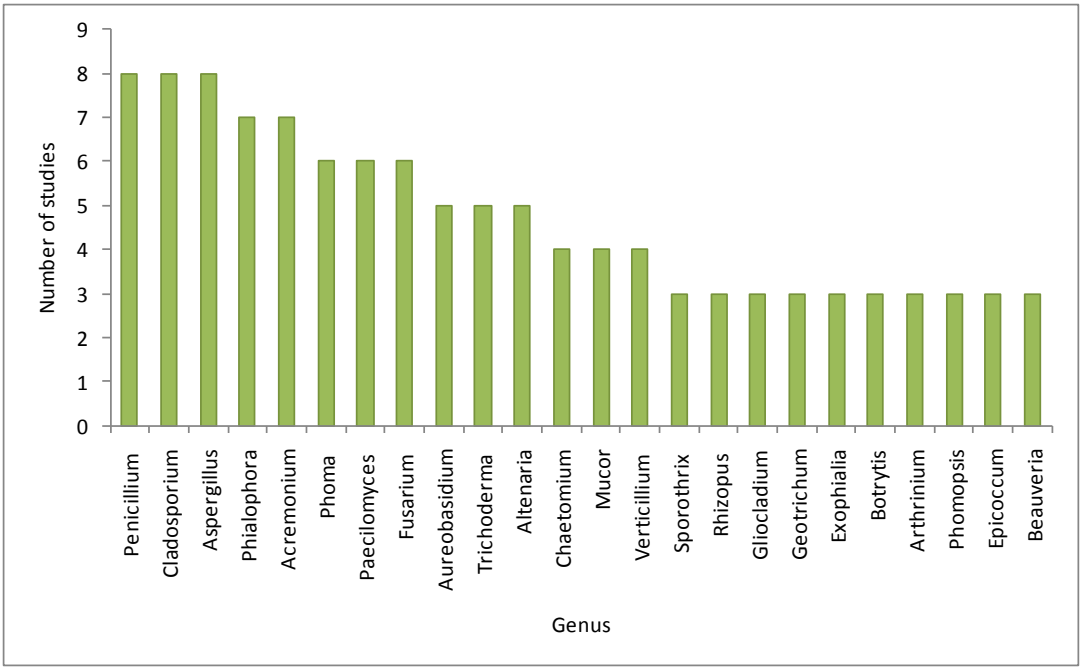

Figure 3-2: Number of studies in which most common genera were isolated from treated drinking water (those isolated by 1 or 2 studies excluded)

The temperature ranges that are tolerated by the taxa most frequently isolated from treated drinking water (see Table 3-4) affect the habitats within the water distribution system that they can inhabit. For example, some *Phialophora* species are thermotolerant (Göttlich et al., 2002), thus enabling them to colonise habitats such as hot water tanks. Differences in temperature tolerance between species may lead to seasonal variation in species composition. For example, numbers of *Acremonium* spp. isolated from drinking water samples taken in Braga, Portugal increased significantly between the months of November and February during the study period. During these months the abundance of other taxa declined to almost nothing, therefore suggesting that *Acremonium* spp. had a strong competitive advantage over winter. While this is likely to be due to the colder temperatures over winter other seasonal conditions such as rainfall may have had an effect (Gonçalves et al., 2006).

Table 3-4: Optimum temperature range of most frequently isolated taxa

Taxon	Optimum temperature range
Penicillium	Some species psychrophilic or pyschrotolerant (4-12°C), such as *P. expansum* and *P. cyclopium* (Gesheva, 2009).
Aspergillus	A. fumigatus optimum = 37-42°C (Chang et al., 2004). Other species optimum=30°C. Others psychrophilic (4-12°C) (Gesheva, 2009).
Cladosporium	Most species approximately 20-25°C. Some species psychrophilic (Feller and Gerday, 2003)
Phialophora	Some species thermotolerant e.g. *P. verrucosa*
Acremonium	Some species thermophilic, e.g. *Acremonium alabamensis* (Johri et al., 1999), some psychrophilic, e.g. *Acremonium pyschrophilum*, some psychrotolerant e.g. *Acremonium cerealis* (Margesin et al., 2008), many others are mesophilic.

Many of the taxa most frequently isolated from treated drinking water, including *Peniciullium* spp., *Aspergillus* spp. and *Cladosporium* spp., are melanised, meaning they secrete pigment called melanin. This pigment provides protection (especially for spores) against a range of stresses. Such species have a competitive advantage and greater resistance to water treatment. Melanin increases virulence in pathogenic species due to the protection it gives against host species' defences (Langfelder et al., 2003). It is possible that fungal species develop further resistance following exposure to disinfectants found throughout the distribution system. However, there is little evidence that resistance by mutation to disinfectants is acquired, and little is known about potential mechanisms by which such resistance would be acquired (McDonnell and Russell, 1999). The factors that affect the ecology of fungi in the water system will be discussed in chapter 4.

The hydrophobic property of the spores of many of these frequently-isolated genera, including *Peniciullium* spp., *Aspergillus* spp. and *Acremonium* spp. provides further protection against water disinfection. Such spores tend to aggregate due to the hydrophobic molecules associating more with each other and other particles than with water. This aggregation appears to be associated with increased resistance to water disinfection using UV and chlorine (Marmane-Gravetz and Linden, 2005).

3.2.3. PATHOGENICITY OF ISOLATED SPECIES

Many of the species that have been observed in drinking water, including all of the five most commonly isolated genera, are either known pathogens or implicated in a number of diseases (see Annex 1). The implications of such pathogenicity will be discussed further in chapter 5.

3.2.4. CURRENT REGULATIONS

At present, regulations controlling levels of fungi in drinking water are rare. For example, in the UK fungi are not required to be monitored or controlled, according to

the Water Supply (Water Quality) Regulations 2000[6]. An exception is Sweden, which limits fungal numbers under the National Food Administration Regulation (SLVFS 2001: 30) regarding drinking water (amendments/new print 2005:10). The Regulation limits microfungi to 100 CFU per 100 ml. This limitation applies at the point of water use, and therefore takes into account fungi which enter the system through pathways of secondary contamination (National Food Administration, 2001).

[6] Available from: www.legislation.gov.uk/uksi/2000/3184/contents/made [Accessed 12/1/2010]

4. FUNGAL ECOLOGY IN WATER SYSTEMS

Numerous factors, both biotic and abiotic influence the ecology of fungi in drinking water, in terms of their prevalence, likelihood of colonisation, growth rate, establishment in biofilms, and the species composition of communities. However, it is difficult to generalise as to the precise effects of such factors, particularly in terms of biofilm development. This is because biofilm communities are also regulated by the interactions between components, and therefore may develop "emergent" properties (see section 3.1.) different to those of the individual components (Hamilton, 1987).

4.1. ABIOTIC AND ANTHROPOGENIC FACTORS INFLUENCING ECOLOGY OF FUNGAL TAXA IN WATER SYSTEMS

4.1.1. RAW WATER SOURCE

Studies that included analyses of both groundwater-derived and surface water-derived drinking water found that isolation of fungi was more likely from surface water-derived drinking water (Hageskal et al., 2006 and Hageskal et al., 2007). For example, Hageskal et al. (2007) found that a greater proportion of surface water- derived drinking water samples were positive for fungi than groundwater-derived samples. However, there was not a great difference in the total mean number of CFUs obtained from all samples of surface water-derived water taken by Hageskal et al. (2007), compared to all samples of groundwater-derived water (9.5 CFU 100 ml^{-1} and 8.4 CFU 100 ml^{-1} respectively). There was one anomalous data point in the groundwater sample – sampling of one shower head produced 100 CFU 100 ml^{-1}, which increased the total number of CFUs found in groundwater-derived water samples. In a study of untreated source water, Pereira et al. (2009) found significantly higher mean levels of fungi in surface and spring water (1750 CFU 100 ml^{-1} and 1025 CFU 100 ml^{-1} respectively) than in groundwater (66 CFU 100 ml^{-1}).

The source of the raw water affects the total number of CFUs found due to biotic and abiotic differences between surface and groundwater. Surface waters tend to contain larger amounts of organic matter, which both provide nutrients and a substrate for fungal growth. Differences in acidity and calcium content may also account for some of the variation – studies in Norway and Portugal found that surface water is slightly more acidic with a lower calcium content (Hageskal et al., 2007 and Pereira et al., 2009). Furthermore, groundwater has lower levels of turbidity and total organic carbon compared to spring and surface water (Pereira et al., 2009).

It could be expected that seasonal variation in the detection frequency of fungi is more prominent in surface-water derived water supplies, given the greater exposure that surface water has to climatic influences compared to groundwater. However, this hypothesis was not supported by the results of the study conducted by Hageskal et al. (2007) which looked at the frequency of positive samples by season.

4.1.2. WATER TEMPERATURE

Temperature is an important influence on fungal counts, as it affects survival, growth rate and ability to reproduce. Species differ in their particular temperature requirements (see Table 3-4 for examples). For example, filamentous fungi were found by Gonçalves et al. (2006) to be particularly prevalent during the winter when temperatures are colder. In Norway, fungi were 14 times more likely to be isolated from cold tap water than from hot tap water, although this depended on the precise temperatures considered (Hageskal et al., 2007). Göttlich et al. (2002) noted that many of the species that they identified were known as being psychrophilic[7], thus supporting these findings.

Studies of fungi in other environments such as soil and the laboratory have also observed that fungi can grow at low temperatures (Pietkainen et al., 2005 and Pasanen et al., 1991), even as low as -20°C. Furthermore, Pietkainen et al. (2005) noted that soil fungi are better adapted to cold environments than bacteria, in terms of having a higher growth rate at lower temperatures. This would therefore result in a change in the composition of microbial communities to favour fungi.

Biofilm formation, an important location of fungal colonisation, is affected by water temperature (Lund and Ormerod, 1995). The highest rates of biofilm formation in water distribution systems have been observed to be at water temperatures of 15-25°C (Donlan et al., 1994). Once established, the water temperature influences the microbial composition of the biofilm (Rogers et al., 1994) as different temperatures will favour different species. For example, the biofilms that formed at 20°C were dominated by bacteria with 96% of microbes being *Pseudomonas*, with several protozoa also being present. At 40°C, 50°C and 60°C, *Aspergillus* spp. were a key component of the climax community, along with several bacterial species but no protozoa (see section 4.2. for further discussion of the interactions of species in biofilms).

4.1.3. WATER FLOW RATE AND SYSTEM HYDRAULICS

Flow rate of water within distribution systems varies according to many factors, including the layout of pipes, system condition, system size, level of demand, elevation and pump operation (US EPA, 2002).

Numerous factors related to biofilm formation and development are influenced by water flow rate, including likelihood of initial attachment, nutrient availability, biofilm

[7] i.e. are organisms which thrive at cold temperatures.

structure, loss of extracellular polymeric substances (EPS), and biofilm removal. The effects of water velocity on such factors are summarised in Table 4-1.

Table 4-1: Effects of water flow rate on biofilms

Stage of biofilm formation/ development	Result	Mechanism	Reference
Likelihood of initial attachment and development	Biofilm formation increases and is more rapid at higher velocities	Higher flow rates reduce the thickness of the boundary layer between the substrate and the water, and increase mixing in the water. Thus, microbial cells come into contact with the substrate surface more frequently (Donlan, 2002). Biofilms appear to be able to compress under pressure and exhibit a high resistance to shear stress.	Manuel et al. (2007) Howsam, 1995 Percival et al., 1999 Lehtola et al., 2006
	Maximum biofilm accumulation at very low flow rates	Higher flow rates increased shear stress, which reduced biofilm accumulation. Low flows also result in longer residence times and thus a loss of disinfectant residual in stagnant water (US EPA, 2002).	Lau and Liu, 1993
Nutrient availability	Higher flow rates provide higher nutrient levels, and have thus been observed to lead to higher bacterial growth. This issue has not been specifically studied for fungi, and the role of competition for nutrients between fungi and bacteria should be considered.		Lehtola et al., 2006
Biofilm structure	Streamers of EPS which attach the community to the surface and bind cells together at high velocities	Streamers improve resistance of the biofilm to shear stress and increase its surface area.	Percival et al., 1999
	Patchy biofilms at low velocities		Percival et al., 1999
	Open and 'fluffy' structures formed at low velocities (0-5m s-1). Cells aligned in the direction of flow at high velocities (2-5 m s-1).		Santos, et al., 1991
	Biofilms developed at		Santos, et

Stage of biofilm formation/ development	Result	Mechanism	Reference
	lower velocities (0-5 m s-1) are less compact and thicker than those developed at 2-5 m s-1);		al., 1991
Loss of EPS	At a relatively high velocity (0.96m s-1), the EPS matrix developed faster than at 0.32 m s-1. However, at 1.75m s-1 the EPS matrix was not present, and bacteria were attached to the surface by fibrillar structures.		Percival et al., 1999
Biofilm removal	Fluctuating cell counts at higher velocities indicates sloughing of biofilm	Biofilms are viscous, giving fluid frictional resistance. Thus, at high velocities biofilms may become more compact and stabilised.	Christen and Characklis, 1989, cited in Percival et al., 1999
	Amount of pre-existing biofilms reduced when flow velocity increased.	Large shear stresses (greater than 10-12Nm^{-2}) resulted in significant cell detachment.	Duddridge et al., 1982
	Changes in flow rate remove biofilms and resuspend the microorganisms in water		Lehtola et al., 2006

In addition to the rate of flow, the type of flow can also influence biofilm formation. The biofilm formed in laminar flow had a greater total number of cells than that formed in turbulent flow. However, the biofilm in turbulent flow had a higher number of cells per unit volume and was more stable (Pereira et al., 2002). Reversal of the direction of flow caused by backflow can remove biofilms, resulting in release of biofilm microbes. Interrupted or pounding water flows may have the same effect (US EPA, 2002).

As can be seen in Table 4-1, the effects of water flow rate on biofilm development are complex, and sometimes contradictory. To some degree, the different findings in relation to water velocity and biofilm development may reflect different structures and composition of the biofilms, which gives them different emergent properties. Furthermore, the effects of water flow rate on such factors may interact with other biotic or abiotic factors, such as pipe material, the species composition, chlorine

concentration, etc. For example, it was found that in unchlorinated or low chlorine water, biofilm growth rate increases as shear stress increases. However, in water with higher chlorine concentrations, growth rate decreased as shear stress increased (Tsai, 2006).

It should also be noted that the work examining the effects of water flow rate on biofilm formation and development is focused on bacterial biofilms. The interactions between fungi and bacteria are discussed in sub-section 4.2.1. How water flow rate affects fungal colonisation of biofilms specifically is not known, nor is whether the presence of fungi affects how biofilms respond to water velocity.

Fungi that have been observed to be able to grow in both stagnant and flowing water whether attached to surfaces or not. Indeed it has been hypothesised that the shape of spores may be an adaptation to allow anchorage to surfaces in flowing water (Kinsey et al., 2003).

4.1.4. NUTRIENT CONCENTRATION

Heterotrophic organisms such as fungi require nutrients for survival and growth, including assimilable organic carbon (AOC), phosphorus and ammonium. Such nutrients tend to concentrate at the solid-liquid interface, and can become trapped in biofilms at this interface. The level of nutrients often regulates the rate and extent of biofilm growth. Indeed, some countries such as the Netherlands prefer controlling AOC over disinfection for limiting biofilm growth. Phosphorus and ammonium concentrations may be limiting for microbial growth. Higher concentrations may facilitate the recovery of microbes that have been stressed by disinfectants (US EPA, 2002). Such studies have focused on bacteria when investigating the influence of nutrients on biofilm development, and further research is needed to determine the effect on fungi in biofilms. The overall influence of nutrient concentration on fungal establishment in water distribution systems is likely to be different from that for bacteria, given that fungi are able to grow in environments that appear to be nutrient free (Kinsey et al., 2003). Competition for nutrients between bacteria and fungi in culture is thought to occur (Gonçalves et al., 2006), but the extent to which such competition influences ecology of biofilms in water distribution systems is not known.

4.1.5. PIPE MATERIAL

The material from which the pipes in water distribution systems are made influences the deposition and presence of fungi. Grabinska-Loniewska et al. (2007) isolated fungi only in sections of the system made of iron and steel. Similarly, Doggett (2000) found fungi to be present in all samples of sections of iron piping, but not in the sample of PVC piping. However, it should be noted that this study only included one sample of PVC piping. Other studies have also found that bacterial biofilms develop more rapidly on iron pipe surfaces than PVC (Le Chevallier, 1999).

Differences between copper and polyethylene (PE) pipes in terms of biofilm formation have also been investigated. It was found that biofilm formation was more rapid in the PE pipes than the copper pipes, but after 200 days there was no difference in microbial numbers between the two materials (Lehtola et al., 2004).

Those piping materials with a high degree of surface roughness are more likely to be colonised, due to the greater surface area and the reduction in shear forces (Percival et al., 1999).

The hydrophobic/hydrophilic properties of the substrate will also influence biofilm formation (Momba et al., 2000).Theoretically, biofilms are more likely to attach to hydrophobic surfaces such as plastics, than hydrophilic ones such as metals (Donlan, 2002). However, the studies that have obtained this finding have not specifically assessed biofilm formation in drinking water distribution systems (Fletcher and Loeb, 1979, Pringle and Fletcher, 1983 and Bendinger et al., 1993). Therefore, it may be that other environmental factors in distribution systems are of greater influence than the hydrophobic/hydrophilic properties of the substrate.

The pipe material can also modify the effectiveness of water disinfectants. For example, the products of corrosion of iron pipes react with residual chlorine and prevent it from penetrating the biofilm (Le Chevallier, 1999). In a comparison of copper and PE pipes, it was found that chlorine was more effective in the PE pipes. Chlorine concentration declined more rapidly in the copper pipes, allowing microbial numbers to return to the pre-treatment level within a few days of chlorination (Lehtola et al., 2005).

Again, such studies focus on the effects of pipe material with respect to bacterial biofilms. The extent to which the pipe materials influence fungal establishment of biofilms or colonisation of existing biofilms requires further investigation.

4.1.6. PARTICLE ACCUMULATION

Organic and inorganic particles accumulate in areas of low flow within the distribution system. Water storage facilities are particularly vulnerable to particle accumulation due to the longer residence time of the water – it is usually only drawn on during periods of high demand. Such particles are important areas of microbial activity due to the nutrients and protection from disinfectants they provide, and many fungal species have been observed in particle accumulation. Furthermore, nutrients may be released from particles, leading to increased biofilm growth (US EPA, 2002). High biofilm growth may may lead to more particles being trapped, thus in turn leading to greater biofilm growth. As was discussed in sub-section, 4.1.4. further research is needed to determine the effect of nutrient concentration on fungi in biofilms specifically.

4.1.7. MAINTENANCE PROCEDURES

As introduction of fungi into water supplies during maintenance has been identified as a key secondary contamination pathway for soil species, maintenance procedures and

practices can have an influence on the species that enter the system. Personnel carrying out maintenance or repairs can be a pathway for introduction of contaminants. Any materials used, such as piping, filters, and seals, or equipment, such as tank cleaning equipment or video equipment used for inspection, can introduce contaminants if not disinfected before use. However, water companies have procedures in place to minimise the risk of introducing soil and microorganisms into the water distribution system during repairs.

4.1.8. WATER TREATMENT AND DISINFECTION

Under the Water Quality Regulations (2000 and as amended), water must not contain any microorganism, parasite, or other substance at a concentration or value which would constitute a potential danger to human health. This can be achieved through disinfection, which is defined in the Regulations as being 'a process of water treatment to remove or render harmless to human health every pathogenic micro-organism […] that would otherwise be present in the water'. This involves a number of processes carried out in a water treatment plant as well as maintaining a residual disinfection throughout the water distribution system to inactivate microorganisms introduced after the treatment plant.

- **Removal of fungi**

A number of different processes are used to remove microorganisms, including fungi. The main processes and the efficiency by which they remove fungi are provided in Table 4-2.

Table 4-2: Main removal processes and their efficiencies

Removal process	Removal efficiency	References
Filtration (sand or granular activated carbon)	90% of fungi removed.	Kelley et al., 2001
	13% of samples positive for thermophilic fungi and 100% positive for mesophilic fungi before treatment, compared to 14% and 92% positive respectively following sand filtration.	Niemi et al., 1982
Chemical coagulation – this involves adding a coagulant to remove contaminants from suspension.	56% of samples positive for thermophilic fungi and 100% positive for mesophilic fungi before treatment, compared to 0% and 46% positive respectively following treatment. The precise coagulation process used here is not known.	Niemi et al., 1982
Clarification – this involves allowing solids to separate out of the water and sink to the bottom of the tank. The term may also refer to the whole process of coagulation, flocculation and sedimentation.	70% of fungi removed. In the water treatment facility assessed in the study, the term clarification refers to 'floc blanket clarification'. In this case the blanket acts as both a coagulater and a filter.	Kelley et al., 2001

Overall, to varying degrees remove some but not all of the fungi found in the source water (Grabinska-Loniewska et al., 2007, Hageskal et al., 2007, Kelley et al., 1997, Paterson and Lima, 2005 and Kinsey et al., 2003).

However, fungal growth that is already well established within distribution systems is considerably more difficult to remove (Kinsey et al., 2003). The degree of treatment efficacy depends on a number of factors, including the particular processes used, and the species. For example, as has been discussed in section 3.1. , melanised, thick-walled species with hydrophobic spores are particularly resistant to treatment (Hageskal et al., 2009, Paterson and Lila, 2005 and Kinsey et al., 2003) .

Sand filtration has been suggested as an effective treatment method (Kinsey et al., 2003 and Paterson and Lima, 2005), and more so than clarification[8] (Kinsey et al., 2003). However, the filters can be colonised by fungi, thus increasing the biological load and reducing the effectiveness of the treatment processes (Hageskal et al., 2009 and Paterson and Lima, 2005). To remove already-established biofilms, flow jetting has been found to be the most effective method (Kinsey et al., 2003).

The efficiency of water treatment processes and the factors that influence it have not been widely studied (Hageskal et al., 2009). There is a need for greater research in this area, particularly in order to explain the discrepancies between existing studies, and to build consensus on the most effective techniques in particular sets of circumstances.

- **Inactivation of fungi**

Table 4-3: Main inactivation processes and their efficiencies

Removal process	Removal efficiency	References
UV radiation	Turbidity reduces effectiveness and no residual is provided. Pigmented spores better protected against radiation so less susceptible to UV treatment.	Betancourt and Rose, 2004. Hageskal et al., 2009
Copper and silver ionisation (not used in treatment of public drinking supplies)	29% of ionised water samples were positive for fungi compared to 77% of non-ionised water samples.	Pedro-Bodet, et al., 2007
Chlorine	99.36% inactivation of *Trichoderma harzianum* after 60 minutes, 98.11% inactivitation of *Epicoccum nigrum* after 40 minutes and 97.65% inactivation of *Aspergillus niger* after 10 minutes, all with an initial free chlorine concentration of 1.3 mg L^{-1}.	Kelley et al., 1997
Ozone	99% inactivation after 18 seconds at 0.02 mg L^{-1} ozone and after 5 seconds at 1 mg L^{-1} ozone.	Kawamura et al., 1986.
Chloramine	Not available	-

[8] Causing a precipitate to be formed in the water that can then be physically removed.

Ionisation of water with silver and copper, a well-recognised method of controlling *Legionella* in hospital water supplies, has resulted in a significantly lower prevalence of fungi compared to non-ionised water in hospital distribution systems. However, as the effectiveness of this method has only been investigated by one study, further research is needed to confirm the finding (Pedro-Bodet et al., 2007). Furthermore, it is not used as a method of treating public drinking supplies.

Chemical disinfectants are frequently also used as the last process in a water treatment plant and to maintain a residual concentration throughout the distribution system. Residual concentrations are needed to inactivate fungi that enter the system after the treatment plant and those which are initially only partially inactivated and thus can recover later in the system. The efficacy of chemical disinfectants against fungi is variable between species (Kinsey et al., 2003).

Efficacy of chlorine is the most dependent on temperature - inactivation of spores occurs less frequently at lower temperatures. The exposure time to free chlorine that is needed to inactivate fungi is longer than for other chemical disinfectants, particularly ozone and chlorine dioxide (Paterson and Lima, 2005). Spores are more resistant than hyphal cells, with some being extremely chlorine-resistant (Kelley et al., 1997). Such spores could thus allow the establishment of fungi in the water system even if treatment processes have removed the vegetative cells. Once fungi are established in the system, it can be difficult to maintain sufficient concentrations (i.e. of 0.4 to 0.5 mg l^{-1}) (Rosenzweig et al., 1983) of free chlorine to prevent colonisation and biofilm formation (Grabinska-Loniewska et al., 2007 and Lund and Ormerod, 1995). This is because the chlorine demand of fungi is high (Kelley et al., 1997 and Rosenzweig et al., 1983). Chlorine demand can also be affected by other microbes in the system and the material from which the pipes are made (Kelley et al., 1997). It has been suggested that initial free chlorine concentrations of approximately 1 mg l^{-1} are sufficient for spore inactivation and to provide sufficient residual chlorine in the system to assist in prevention of new growth (Kelley et al., 1997 and Kinsey et al., 2003) and development of biofilms (Lund and Ormerod, 1995 and Momba et al., 2000). However, concentrations of free chlorine are not always as high as 1 mg/l at UK treatment works and are likely to be much lower in distribution systems (0.3 mg l^{-1}),.Therefore, inactivation and prevention of regrowth within the UK's water distribution system is likely to be lower than suggested by these studies.

Chlorine dioxide and ozone have been found to be the most effective in studies by Kelley et al. (2001). However, chlorine dioxide is not widely used in the UK and ozone is not used in the UK to provide a residual disinfectant in the distribution system. Ozone has a lifetime of less than one hour in water due to its rapid decomposition. In most cases, i.e. apart from very short distribution systems, it does not remain long enough to provide a disinfectant residual throughout the distribution system. Therefore, it does not have an effect on biofilms and fungi present in the system after treatment.

Where water is treated with ozone it is usually replaced by chlorine or chlorine dioxide as a final step in order to maintain a disinfectant residual (Camel and Bermond, 1998).

Chloramines are another common choice of disinfectant. There are three types: monochloramine, dichloramine and nitrogen trichloride. Monochloramine is most commonly used as the other two negatively affect the taste and odour of the water (Chung et al., 2006). Monochloramine is more stable than chlorine, chlorine dioxide and ozone, and therefore may be more effective in the long-term, due to its greater persistence in distribution systems (Kelley et al., 2001). Monochloramine is a stronger fungicide than other chloramines (Arnitz et al., 2009).

Combinations of a number of removal and inactivation processes are likely to be the most effective. For example, in a Polish study, two different combinations of treatment processes were used successfully to remove all species but *A. fumigatus* and *A. niger*. The first treatment process involved filtration and aeration, including sand filters and sand filters with activated carbon, and disinfection with chlorine and chlorine dioxide. The second included chemical coagulation using aluminium sulphate, silica and pulverised carbon; alkalisation with lime; fast filtration with sand; and disinfection with chlorine and chlorine dioxide (Grabinska-Loniewska, 2007).

4.2. BIOTIC FACTORS INFLUENCING ECOLOGY OF FUNGAL TAXA IN WATER SYSTEMS

4.2.1. INTERACTIONS WITH BACTERIA

Understanding the interactions between bacteria and fungi is important in order to determine if bacterial content, a commonly measured parameter of drinking water, can be used as an indicator of fungal content (Gonçalves et al., 2006). If the absence of a correlation is common across distribution systems, it can mean that there is the potential for bacteriologically safe water to contain potentially pathogenic fungi.

As can be seen in Table 4-4, different studies have found different relationships between fungi and bacteria. These differences could arise from the different species compositions isolated from water systems, differences in methodologies, or different biological mechanisms affecting the relationship. For example, the interactions between fungi and biofilm-bacteria may explain the positive relationships (Jefferson, 2004). Fungi are often secondary colonisers of pre-established bacterial biofilms (Paterson and Lima, 2005 and Kinsey et al., 2003).

Table 4-4: Observed correlations between fungi and bacteria in drinking water

Positive correlations	Negative correlations	No correlation
A positive correlation was found between yeasts and total heterotrophic bacteria in tap water (Brazil) (Yamaguchi et	A negative correlation has been observed between fungi and bacteria in samples of high bacterial biomass (Germany)	No correlation was found between fungal and bacterial biomass in unchlorinated

Positive correlations	Negative correlations	No correlation
al., 2007)	(Göttlich et al., 2003)	groundwater-derived water in Germany (Göttlich et al., 2003) nor in treated water in Poland (Grabinska-Loniewska et al., 2007)
A significant positive correlation was observed between yeasts and total and faecal coliforms (Greece) (Aravanitidou et al., 1999)		No correlation was observed between filamentous fungi and total coliform (Brazil) (Yamaguchi et al., 2007)
A significant correlation was observed between filamentous fungi and total heterotrophic bacteria (Greece) (Aravanitidou et al., 1999)		No correlation found between levels of fungi and total coliform (untreated water) (Pereira et al., 2009).
Correlation between level of fungi and *Escherichia coli* and *Enterococcus* (untreated water) (Pereira et al., 2009).		

The different ecological requirements of the two organisms can theoretically lead to commensal relationships, in which one benefits while the other is unaffected (Jefferson, 2004). This theory suggests that negative correlations between fungi and bacteria in biofilms are unlikely. Furthermore, it has been demonstrated that fungi colonise pre-established bacterial biofilms, again indicating a positive relationship should be expected (Doggett, 2000). Negative relationships observed may be related to the culturing process, where bacteria and fungi are in direct competition for resources (Gonçalves et al., 2006).

These findings illustrate that correlations with bacteria depend on whether filamentous fungi or yeasts are being considered, and which bacteria are being assessed. Whether the remaining variation in findings between studies is due to differences in the specific composition of species, or to differences in methodology (such as the amount of time samples are cultured to allow for slow-growing fungi) is unclear. Therefore, there is a need for further research to investigate the different correlations between fungi and bacteria, and what factors influence such associations. This will allow it to be determined whether, and in which circumstances, bacterial contamination of drinking water indicates fungal contamination.

If bacteria and fungi inhabit the same location specific interactions have been observed. For example, culturing marine bacteria and fungi together has led to the production of novel compounds that are not produced by either species separately in laboratory conditions (Oh, et al., 2005 and Oh et al., 2007, in Shank and Kolter, 2009). Fungi-bacteria interactions can also inhibit secondary metabolite production. When a

bacteria (*Pseudomonas aeruginosa*) is cultured with a fungus (*Candida albicans*), farnesol, a metabolite produced by *C. albicans*, inhibits the production of secondary metabolites by *P. aeruginosa*, such as pyocyanin and Pseudomonas quinolone signal (Cugini et al., 2007, in Shank and Kolter, 2009). Farnesol also inhibits hyphal growth in *C. albicans* (Hogan, 2006). However, peptidoglycan, which forms bacterial cell walls has been shown to stimulate hyphal growth in *C. albicans* (Xu et al. 2008, Shank and Kolter, 2009).

Interactions and associations with other microorganisms are discussed in Box 2.

Box 2: Interactions and associations between fungi and other microorganisms

The importance of interactions and associations between other microorganisms and fungi in drinking water has not been well studied. Potentially important interactions that have been described in other circumstances are discussed below.

- **Interactions with protozoa**

Some species of amoebae, including *Acanthamoeba* spp., *Balamuthia mandrillaris, Naegleria fowleri* and *Sappinia diploidea* are known human pathogens (Visvesvara et al., 2007). In addition, free-living amoebae are known to be reservoirs for amoebae-resisting bacteria such as *Legionella,* which can survive and multiply within the amoeba host and exit it once environmental conditions become more favourable. The protection that the amoeba host provides the internalised bacteria allows them to avoid inactivation by water disinfection processes. It is this mechanism that is likely to explain the rapid recolonisation of some water systems immediately after a disinfection programme has stopped (Loret and Greub, 2010). An example of a fungus being phagocytosed by and replicating within an amoeba has been described in the literature. The melanisation of *Cryptococcus neoformans* is thought to be responsible for allowing it to survive within *Acanthamoeba castellanii* (Steenbergen et al., 2001).

However, associations between fungi and protozoa are also ecologically important. For example, in a study on microbial interactions in water-damaged buildings amoebae were observed to co-occur with several fungal species, including *Acremonium* spp., *Aspergillus versicolor, Chaetomium* spp. and *Trichoderma* spp. (Yli-Pirila et al., 2004). Given that amoebae have been found in treated drinking water (Singh and Coogan, 2005 and Berry and Raskin, 2006), such co-occurrences are potentially important and their significance in drinking water is not well known.

- **Interactions with viruses**

Many fungal species, including *Penicillium chrysogenum, Alternaria alternata* and *Aspergillus fumigatus*, are inhabited by viruses, forming fungi-virus complexes (Jamal et al., 2010). The effect on fungi of their infection by viruses varies depending on the species involved. Infection of *Aspergillus* species with mycoviruses has been observed to reduce mycelia growth rate, spore production and competitive ability (van Diepeningen et al., 2006).

- **Interactions with algae**

Some freshwater algae are infected with the chytrid fungus (Lopez-Llorca and Hernandez, 1996) and some other fungal genera, including *Penicillium* and *Aspergillus*, have been associated with green and red algae from marine environments Dewey et al., 1983). Marine algae also produce compounds which have been observed to have antifungal properties (de Félicio et al., 2010). Conversely, freshwater algal species have been observed to be destroyed by a fungus (*Trichaptum abietinum*) (Jia et al., 2010).

4.3. SUMMARY OF BIOTIC AND ABIOTIC FACTORS INFLUENCING FUNGAL ECOLOGY

The specific influences of the main biotic and abiotic factors on the most common taxa observed in drinking water systems are summarised in Table 4-5.

Table 4-5: Summary of biotic and abiotic factors influencing fungal ecology

Factor		Influence on fungal ecology on drinking water systems
Abiotic and anthropogenic factors	Raw water source	-Whether the raw water source is surface-water or groundwater influences the rate of fungal isolation. Surface water has more organic material and nutrients, thus leading to a greater likelihood of isolating fungi from surface-water derived systems.
	Water temperature	-Temperature affects fungal growth rate, reproduction, competition for nutrients with other elements of microbial community and survival. Studies of drinking water systems have found higher prevalence of fungi in cold water.
	Water flow rate and system hydraulics	-Flow rate affects biofilm formation, but no consensus as to the specific mechanisms by which this happens.
	Nutrient concentration	- Nutrients, particularly AOC, phosphorus and ammonium, are frequently a limiting factor for microbial growth, including in biofilms.
	Pipe material	-Pipe material influences fungal deposition and biofilm formation(e.g. iron and steel favour the colonisation).
	Particle accumulation	-Accumulated particles provide nutrients and protection from disinfectants and thus are a common habitat for fungi in distribution systems.
	Ingress and intrusion	-Introduction during maintenance procedures and intrusion during low and negative pressure events are a potentially important pathway for the introduction of soil and air-borne fungi .
	Water treatment	-Standard water treatment procedures are effective in removing most fungi from raw water. Melanised species have been found to be resistant to treatment however.

Factor		Influence on fungal ecology on drinking water systems
	Water disinfection	-Maintaining residual chlorine within the system can help to reduce biofilm formation and growth of fungi that enter the system after treatment.
Biotic	Interactions with bacteria	-Fungi colonise pre-established biofilms formed by bacteria, and may form commensal relationships with bacteria due to different ecological requirements, thus leading to positive correlations. -In culture fungi and bacteria are in competition for resources, thus leading to negative correlations being observed. This is probably true also in water distribution systems.
	Interactions with protozoa	-Some amoebae are known to attack and consume fungi. In addition, some species of amoebae can host bacteria and release them depending on the environmental conditions, thus having potential indirect impacts on fungal ecology. Although this interaction has not been sufficiently considered in drinking water systems
	Interactions with viruses	-Many fungi are inhabited by viruses.

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5. IMPACTS ON HUMAN HEALTH

A range of fungal taxa have been isolated from drinking water distribution systems, in a number of different countries (see Annex 1). Of greatest concern to consumers of drinking water is whether the presence of such fungi, some species of which are known to be pathogenic or allergenic, has negative impacts on health. The consumption of fungi-contaminated drinking water has, as far as is known, not caused acute disease, at least in immuno-competent individuals (Hageskal et al., 2009). However, there is a risk of superficial or localised infection in healthy individuals and more severe and invasive infection in immuno-compromised patients. Some species also have the potential to cause allergic reaction and disease. Furthermore, the health effects of fungal secondary metabolites should be the object of further research since some are toxic and others are thought to have caused taste and odour problems in tap water. Studies that directly assess whether fungi in drinking water are responsible for fungal infections and allergies are few. Therefore, while it is known that fungal species have been isolated from drinking water and that some fungal species cause the disease, the extent to which the two are linked is not well known.

This chapter assesses the various risks arising from fungi in drinking water for various population groups, and discusses how the risks are managed. A summary of health and taste/odour impacts is provided in Annex 2.

5.1. EXPOSURE PATHWAYS

- **Sources of pathogenic or allergenic fungi**

As has been discussed in section 5.2.1. there are a number of reasons to suggest that water should be considered as a potential transmission route for pathogenic or allergenic fungi. However, a number of other environmental sources exist, which are described in Box 3.

Determining the environmental source of a fungal infection or allergic disease requires genotyping and comparing fungal DNA taken from the affected patient and DNA taken from environmental sources. A number of different sources for a fungal infection are also possible (Menotti et al., 2005). For example, Warris et al. (2003) found that patients suffering from invasive aspergillosis were infected from either the air, water, or both. Furthermore, water was found to be the source of infections caused by *Fusarium* in a hospital in Houston, Texas, due to the molecular similarities between isolates from patients and isolates from water environments within the hospital (Anaissie et al., 2001).

Box 3: Sources of exposure to fungi

The air is thought to be a common source of pathogenic/allergenic fungi (Perlroth et al., 2007). Due to this, hospitals have implemented a number of measures to remove such fungi from the air to reduce exposure for patients at risk of fungal infection. Such measures include using high-efficiency particulate air filters and laminar airflow systems (Anaissie et al., 2002).

Fungal colonisation of food is also thought to be an important source from which patients' respiratory or digestive systems are colonised. Contaminated water used in food production processes may be a route by which fungi are introduced into food (Paterson et al., 2009 and Hageskal et al., 2006). Preventative measures include sterilising or disinfecting foods where possible, and banning some particularly contaminated foods such as soft cheeses for high-risk patients (Bouakline et al., 2000).

In some cases, such as the studies by Warris et al. (2003) and Anaissie et al. (2001), drinking water has been confirmed as at least one of the sources of fungal infections acquired in hospital. In other cases, fungal species that have been isolated from drinking water are involved, but drinking water as the infection source has not been confirmed.

Pathways of exposure

The four principal pathways by which people can be exposed to fungi in drinking water are:

- **ingestion**– drinking contaminated water directly;
- **inhalation** of aerosolised spores while showering or in the sauna;
- **skin contact** with contaminated water, such as while showering or bathing; and
- **introduction through mucous membranes**, such as the skin, eyes and oral cavity, while showering or bathing.

Aerosolisation of spores or fragments of hyphae from water has been particularly investigated as a pathway of exposure. For example, Anaissie et al. (2002) attempted to identify sources of *Aspergillus* infection in a hospital. They found that bathrooms had significantly higher numbers of airborne propagules than in patients' rooms (2.95 CFU m^{-3} and 0.78 CFU m^{-3} respectively, P=0.05). This was thought to arise from aerosolisation following running the tap or shower or flushing the toilet, allowing colonisation of damp microniches within the bathroom. Warris et al. (2001a) also found that airborne *A. fumigatus* levels increased after running the shower multiple times.

Skin contact with fungi in water while bathing can be a source of allergic skin irritation (see sub-section 5.2.2.).

5.2. DIRECT HEALTH IMPACTS OF FUNGAL INFECTIONS

5.2.1. SUPERFICIAL, SUBCUTANEOUS AND SYSTEMIC INFECTIONS

There a number of infections that are known to be caused by fungi, which can be classified according to the site of initial infection (Richardson and Warnock, 2003):

- **superficial mycoses**: infections of the skin, nails, hair and mucous membranes, such as topical candidiasis[9]. Such infections are relatively common and easily treated.
- **subcutaneous mycoses**: infections of the dermis, subcutaneous tissues and adjacent bone. These usually arise from implantation of fungi in soil or decomposing vegetation and are most common in tropical and sub-tropical regions when skin is exposed to soil (e.g. when barefoot). Disseminated infection is rare and usually only occurs in immunocompromised individuals.
- **systemic mycoses**: originate in an internal organ, often the lungs, and may spread to other organs (i.e. become invasive). These infections may be caused by true pathogens which can invade normal (i.e. immunocompetent) hosts, or by opportunistic pathogens which are less virulent and can only invade immunocompromised hosts.

A limited number of species are responsible for such diseases; it is thought that of the 50 000 to 250 000 known species of fungi, 500 have been linked to disease in humans and 100 can cause disease in otherwise healthy individuals (Richardson and Warnock, 2003). The most problematic species are *Candida* spp. (especially *C. albicans*), *Aspergillus* spp. (especially *A. fumigatus*) and *Cryptococcus neoformans* (Paterson et al., 2009 and Pfaller et al., 2006.).

The incidence rate of invasive fungal infections primarily in certain population groups, such as those that are immunosuppressed, continues to increase (Annaisie et al., 2002 and Arvantidou, et al., 1999). For example, the prevalence of invasive fungal infection at autopsy in a German hospital was found to increase 14-fold between 1978 and 1992 (Groll et al., 1996). The increase was found to continue during the follow-up study in the same hospital: 6.6% of patients autopsied in the period 1993-1996 had an invasive fungal infection, rising to 10.4% in the period 2001-2005 (Lehrnbecher et al., 2010). Several reasons for the observed increases have been suggested, including increases in incidence of HIV/AIDS; changes in medical procedures such as increased use of immunosuppressive medication, broad-spectrum antibiotics and prosthetic devices; and more invasive surgical procedures (Denning, 2006 and Enoch et al., 2006).

Immunocompetent individuals with no underlying health condition may experience superficial or localised infections but with fewer complications and a much smaller risk

[9] A general term for infections caused by Candida spp.

of disseminated or invasive disease and death (Anaissie et al., 1989, Chen et al., 2001, Walsh et al., 2004). For example, a study of both immunocompetent and immunocompromised patients with *Fusarium* infections found that skin infections in immunocompetent patients resulted from skin breakdown, were localised to this site, progressed slowly and responded well to treatment. By contrast, in immunocompromised individuals skin infections only occasionally resulted from skin breakdown. Infection progressed rapidly, was disseminated within the body including to the blood, and in some cases led to death (Nucci and Anaissie, 2002).

The following sections will discuss the taxa most frequently isolated from drinking water (Figure 3-2) and their direct health impacts. Subsequently, other taxa which are responsible for direct health impacts and which have been isolated from drinking water (although less frequently) will be discussed. It should be that noted not all species of the same genus have the same degree of toxicity, pathogenicity or allergenicity (Hageskal et al., 2009). However, the genetic boundaries between species are not well defined and can be misleading (Paterson and Lima, 2005).

In the discussion of fungal infections below, it is specified if infections are limited to a particular population sub-group or at-risk group. When such a group is not specified it indicates that the infection can occur in the general population, i.e. including healthy, immunocompetent individuals.

- ***Penicillium* spp.**

Penicillium marneffei has been identified as a pathogen endemic to south east Asia, India and China, that particularly affects HIV-infected individuals causing disseminated infection (Vanittanakom et al., 2006). However, there appear to be no reports of *P. marneffei* in drinking water or of infection being acquired via water. Invasive infection by other species is very rare, although superficial infection causing keratitis and otomycosis is more common (Lyratzopoulos, 2002). *Penicillium* is the genus that was most commonly identified in drinking water according to the studies examined (see Figure 3-2) and therefore drinking water is a source of exposure. However, whether *Penicillium* in drinking water is the source of *Penicillium* infections is not known.

- ***Cladosporium* spp.**

Fungi in the genus *Cladosporium* are not normally thought to be responsible for severe infections, although they have been isolated from skin and toenail infections (Tamiskar et al., 2006). They are allergenic, and can lead to hypersensitivity pneumonitis, sinusitis or asthma (Hayette et al., 2010) (see sub-section 5.2.2. for more details).

- ***Aspergillus* spp.**

Aspergillus spp. have been isolated from drinking water by many studies (see Figure 3-2).For example, Annaisie et al. (2002) isolated it from 33% of municipal water samples, 55% of samples from hospital water storage tanks and from 21% of samples

of water from hospital patient care areas. Infections caused by *Aspergillus* species are known as aspergillosis, a term which covers a range of invasive and non-invasive infections and allergic diseases.

Aspergillosis infections are primarily caused by inhalation of airborne spores (Annaisie et al., 2002). However, it is increasingly being recognised that water is an environmental source of *Aspergillus* spp. and has been identified as being the source of exposure. The genotype of *A. fumigatus* recovered from water was related to the genotype of isolates from three patients (Warris, 2003).There are a number of further arguments that suggest that water should be considered an important route of transmission of pathogenic *Aspergillus* spp. (Annaisie et al., 2002):

- incidence of aspergillosis continues to increase, despite measures to control fungi in air in hospital environments, such as the use of laminar air flow systems and high efficiency particulate air filters;
- there appears to be no correlation between airborne spore counts of *Aspergillus* spp. and rates of aspergillosis;
- the skin and the digestive system have been identified as points of entry for *Aspergillus* spp. (as opposed to lungs which are the point of entry for airborne fungi);
- *Aspergillus* species are similar to *Legionella* species, known water pathogens, in several aspects of their ecology, including amplification in water reservoirs, presence in biofilms in water distribution systems, and some requirements for growth; and
- invasive aspergillosis has been linked anecdotally with inhalation of contaminated surface water in patients who have suffered near drowning (Warris, 2001).

Aspergillus terreus is increasingly reported as a cause of pneumonia and disseminated infections in at-risk populations. This is an issue as *A. terreus* is relatively resistant to amphotericin B, the standard drug for treating fungal infections (Vesper et al., 2007). *Aspergillus ustus* has also been implicated as an emerging but rare opportunistic pathogen in immunocompromised individuals (Hageskal et al., 2006). An outbreak of *A. ustus* infections in a hospital in the US amongst patients that had undergone hematopoietic stem cell transplant stimulated a retrospective analysis of the likely cause. *Aspergillus ustus* infections result in onychomycosis, otitis media, primary cutaneous infection, endocarditis, pneumonia and disseminated infection. Eighty-three per cent of the patients in this outbreak had graft-versus-host disease following transplant that required immunosuppressive therapy, thus making them vulnerable to opportunistic infections (for more details see sub-section 5.2.4.). Water was not specifically tested, but a common environmental source (such as air, water, or surfaces) was thought likely. This was due to the genetic similarity of the fungal isolates

and the spatial proximity of the patients while in the hospital (Panackal et al., 2006). Hageskal et al. (2006) hypothesised that slight differences in time between infections may be a result of the biofilm theory, i.e. that sloughing of biofilm may periodically occur, leading to temporal differences in prevalence. They also suggested that the hot water tank in the hospital may have been a source as *A. ustus* is able to establish in such installations.

- ***Phialophora* spp.**

Infections caused by a number of *Phialophora* species have been observed, including rare superficial infections in healthy patients (Kimura et al., 2003). *Phialophora europaea*, a member of the *P. verrucosa* complex, has been isolated from cutaneous and nail infections in north-western Europe (de Hoog et al., 2000).

Phialophora is one of the genera that were most commonly identified in drinking water according to the studies examined (see Figure 3-2). However, whether *Phialophora* infections arise from exposure to *Phialophora* in drinking water or whether other sources such as spores or hyphae in air or food for example are the source of exposure is not known.

- ***Acremonium* spp.**

Acremonium infections have been observed in vulnerable individuals, for example pulmonary infection with *Acremonium strictum* was observed in a patient with chronic lymphocytic leukaemia (Herbrecht et al., 2002). However, *Acremonium* infections are rare, even in immunocompromised hosts (Mattei et al., 2003).

- **Other pathogenic taxa isolated from drinking water**

Candida spp. are a frequent cause of infections, which can range from superficial candidiasis infections that are common and easily treated, to systemic candidiasis. Superficial infections can occur in the skin and mucous membranes, and can arise from the overgrowth of normal yeast flora. Systemic or invasive candidiasis includes disseminated candidiasis, candidemia (i.e. the presence of *Candida* spp. in the blood), endocarditis and meningitis. It has a mortality rate of 40-50% (De Rosa et al., 2009).

The incidence of candidaemia in UK hospitals has been assessed as part of the European Confederation of Medical Mycology epidemiological survey of candidaemia. It found that there were 18.7 episodes per 100 000 finished consultant encounters or 3.0 per 100 000 bed days, with a 30 day mortality rate of 26.4%. *Candida albicans* was isolated in the majority (64.7%) of cases. The patients demonstrated a number of predisposing factors, including use of antibiotics, intensive care treatment, surgery, cancer and intravascular catheters (Tortorano et al., 2004). The mortality rate is falling over time (Kibbler et al., 2003).

Candida spp. in biofilms have been observed a cause of hospital-acquired infections via implanted catheters and other devices (Douglas, 2003). While *Candida* spp. have been

observed in drinking water (see Annex 1), it is not known whether this is a significant pathway for infection.

Infections caused by *Fusarium* spp. are increasing in frequency in immunocompromised patients. They carry a high mortality rate; 79-87% of patients die within 90 days of being diagnosed. *Fusarium* species have been isolated from drinking water, and as was discussed in section 5.1. the drinking water in one hospital in Texas has been identified of the environmental source of *Fusarium* infections.

Discussion of pathogenicity for each taxon found in drinking water can be found in Annex 1.

- **Conclusions**

Superficial or localised, easily treated fungal infections occur in healthy people without risk factors for more serious disease, but there is little evidence that such infections are caused by exposure to fungi in dinking water. Invasive disease is much rarer and limited to immunocompromised patients or those with underlying conditions. Occurrence of invasive disease per year in the US is estimated at 72-228 infections per million population for *Candida* species, 30-66 infections per million population for *Cryptococcus neoformans* and 12-34 infections per million population for *Aspergillus* species (Pfaller et al., 2006). Such invasive infections can cause severe disease and tend to have high rates of mortality associated with them (see sub-section 5.2.5.). In a small number of studies, fungi in drinking water are thought to be the source of infection in vulnerable patients (Warris et al., 2003). However, in the majority of cases it is known that the taxa involved have been isolated from drinking water, but it is not known if this is the source of infection.

Hageskal et al. (2006) concluded that the concentrations of fungi that they isolated from drinking water in Norway were unlikely to cause severe infection in healthy individuals. The concentrations that they reported were in similar ranges to concentrations reported by other studies for the same species (see Annex 1). The study conducted in the UK (Institute of Mycology, 1996) did not quote CFU numbers per species, and therefore it is difficult to determine if concentrations of individual species are in the same range. However, the total CFU numbers for all fungi reported by the Institute of Mycology were broadly within the same range as other studies (see Table 4-3).

5.2.2. ALLERGIES

Many species of fungi, including some found in drinking water (see Annex 1), are known to be potential allergens (Paterson and Lima, 2005). These include *P. richardsiae*, *A. fumigatus*, *A. niger*, *A. flavus, Penicillium* spp. and *Cladosporium* spp. Allergies are the main negative health impact for healthy individuals. Allergic symptoms may also arise in response to dead spores and other fungal debris that would not be culturable (Kauffman and van der Heide, 2003). Therefore, water that is

found to be free of fungi from testing by culture may in fact still provoke allergic disease.

Allergic respiratory disease

There is strong evidence of a correlation between fungal exposure and severity of asthma (Hogaboam et al., 2005). For example, a study of children on the Isle of Wight found that 0.5% were sensitive to *Alternaria* species and 2.9% to *Cladosporium* species. A US study of asthmatic patients found that the percentage sensitive to fungal extracts was as high as 80% (Bush and Portnoy, 2001). A small study of young people suffering a severe asthma attack and respiratory arrest found that 10 of the 11 patients were sensitive to *Alternaria* species (O'Hollaren et al., 1991). Whether this is a causal relationship has not yet been fully confirmed. Much of the evidence is related to associations between frequency of asthma attacks and numbers of airborne spores. Such spores may have been aerosolised from a water source. For example, inhabiting damp and mouldy buildings has also been linked to a worsening of asthma symptoms (Denning et al., 2006).

Allergic fungal rhinitis has also been reported, causing nasal obstruction and congestion. Symptoms are similar to allergic fungal sinusitis, which is caused by a wide range of fungal species, including *Alternaria* spp., *Aspergillus*, spp., *Cladosporium* spp. and *Penicillium* spp., many of which have been isolated from drinking water (Ponikau et al., 1999).

Hypersensitivity pneumonitis or extrinsic allergic alveolitis, is a condition where the alveoli of the lung become inflamed due to oversensitivity to inhaled particles, including microorganisms. Fungi have been implicated in incidents in Finland in which exposure was attributed to taking baths, showers and saunas (Muittari et al., 1980, in Hageskal et al., 2009). In other cases, disease has arisen from exposure to fungal spores in water-damaged buildings (Seuri et al., 2000).

Skin irritation

Outbreaks of allergic disease have in some cases been linked to presence of particular fungal species in water supplies, and have also been associated with exposure when taking baths or showers and using hot tubs or saunas (Paterson et al., 2009, Jacobs et al., 1986 and Hageskal et al., 2009). For example, this association was observed during an outbreak of skin irritation in Sweden, where the water was found to contain 77-3100 CFU 100 ml^{-1} of *Phialophora richardsiae* (Hageskal et al., 2009).

Conclusions

There is clear evidence that fungi trigger a range of allergic responses, particularly within the respiratory system and on the skin. Allergic sensitivity to fungi occurs in the general population and is particularly common in asthmatic patients. However, determining the proportion of people who are sensitive to fungi as allergens is

complicated by the fact that sensitivity may be localised. This occurs when allergic reactions in specific locations such as the nasal cavity arise but the patient does not respond to skin-prick tests, the usual test for allergies (Ponikau et al., 1999). Prevalence of allergic fungal disease is not well known. It is thought that the majority (93% in one study) of patients suffering from chronic rhinosinusitis meet the diagnostic criteria for allergic fungal sinusitis (Ponikau et al., 1999 and Schubert, 2006).

The gravity of fungal allergic disease depends on the type of reaction. In cases of hypersensitivity pneumonitis, removal of the patient from the source of exposure may be sufficient to reduce symptoms (Jacobs et al., 1986, Apostolakos et al., 2001 and Churg et al., 2006). Chronic stages may be more difficult to treat.

A number of cases, such as the outbreak of skin irritation in Sweden, imply that fungi in drinking water may be the source of exposure, particularly via skin contact when bathing or through aerosolisation of spores when showering or using saunas.

The correlation between ingestion of fungi in drinking water and allergic reactions has not been studied, and would require larger-scale epidemiological studies to confirm or reject such correlations (Hageskal et al., 2009).

5.2.3. MYCOTOXIN-MEDIATED HEALTH IMPACTS

- **Mycotoxins and mycotoxin producers**

Some fungal taxa, including *Penicillium* spp., *Aspergillus* spp., *Fusariam* spp. and *Claviceps* spp., produce mycotoxins during their metabolic processes. Of these genera, the first three have been isolated from drinking water. *Alternaria* is another potential mycotoxin producer which has been observed in drinking water (see Annex 1). Of the thousands of mycotoxins that can be produced, only about ten cause problems in food, feed and beverages. Of these, aflatoxins and zearalenone are the most relevant and have been detected in drinking water. (Paterson and Lima, 2005 and Paterson et al., 2009).

Penicillium expansum produces patulin (Paterson et al., 2009), however large amounts of *P. expansum* does not imply that there will be large amounts of patulin. Patulin is sensitive to physicochemical parameters; for example, it is sensitive to pH and becomes increasingly stable as pH decreases. In culture studies, production of patulin has been observed to occur when fungal growth rate decreases, for example because of limiting nitrogen (Paterson et al., 2007).

The concentrations of mycotoxins in drinking water are likely to be very low as they will be diluted (Hageskal et al., 2009 and Gonçalves et al., 2006). For example, only trace amounts of aflatoxins were detected by Kinsey et al., 2003 and the levels of zearalenone produced in water inoculated with *F. graminearum* by Paterson (2007) were 10^5 lower than the dietary concentration at which it mimics oestrogen (<1 mg kg^{-1} feed). Stored water, such as bottled water, and processes in which water is evaporated, such as in some food production processes, may present more of a risk as

the mycotoxins become more concentrated (Gonçalves et al., 2006, Paterson et al., 2009 and Paterson and Lima, 2005).

- **Health effects of mycotoxins**

The effects of mycotoxins can be mutagenic (induces or increases mutations), teratogenic (disturbs embryo development), oestrogenic (mimics the action of oestrogen) or carcinogenic (produces a cancer). The frequency of such impacts and their severity depends on the mycotoxin in question, its concentration, the exposure pathway and duration of exposure. They can also damage major organs or systems such as the nervous, endocrine or immune system (Paterson et al., 2009). Schütze et al. (2010) found that in an animal model chronic exposure to mycotoxins (gliotoxin and patulin) increased allergic response in asthmatic individuals by worsening chronic airway inflammation. However, no reports have been identified of disease attributed to mycotoxins produced in the water distribution system (Kelley et al., 1997 and Paterson and Lima, 2005).

- **Conclusions**

Mycotoxin-producing taxa have been identified in the drinking water system. However, while consumption of mycotoxins is known to produce health impacts, drinking water has not been identified as the source of symptoms attributable to mycotoxins.

5.2.4. AT-RISK GROUPS FOR FUNGAL INFECTIONS

As has been discussed in section 5.2. , healthy individuals may suffer from superficial or localised fungal infections, for example of the skin, nails or hair, but are not at risk of invasive infections. Individuals at greater risk of invasive or disseminated infections include:

- immunocompromised patients, arising from HIV/AIDS, chronic granulomatous disease, chemotherapy, immunosuppressive therapy, graft-versus-host disease following allogeneic bone marrow transplant, allogeneic haematopoietic stem cell transplants (HSCT), etc.;
- those with underlying health conditions, e.g. diabetes mellitus and cystic fibrosis;
- those undergoing treatment for inflammatory conditions such as rheumatoid arthritis and Crohn's disease;
- recipients of haemodialysis;
- those with reduced integrity of the skin barrier, such as following surgery or burns, or through use of indwelling medical devices such as catheters; and
- very low birth weight babies.

The degree of risk may vary between these groups and depends on the species of fungus. For example, the incidence of invasive aspergillosis in a number of at-risk groups is given in Table 5-1.

Table 5-1: Incidence of invasive aspergillosis in at-risk groups

At-risk group	Incidence of invasive aspergillosis	Reference
Acute leukaemia	5-24%	Warris et al., 2001
Chronic granulomatous disease	25-40%	Warris et al., 2001
AIDS	0-12%	Warris et al., 2001
Allogeneic stem cell transplant	12.8%	Cornet et al., 2002
Autologous stem cell transplant	1.1%	Cornet et al., 2002
Bone marrow stem cell transplant	6%	Cornet et al., 2002
Peripheral stem cell transplant	1.6%	Cornet et al., 2002
Heart-lung transplant	11.1%	Cornet et al., 2002
Small bowel/liver-small bowel transplant	10.7%	Cornet et al., 2002
Lung transplant	2%	Cornet et al., 2002
Liver transplant	1.9%	Cornet et al., 2002
Heart transplant	1.3%	Cornet et al., 2002
Kidney transplant	0.4%	Cornet et al., 2002
Kidney-pancreas transplant	0%	Cornet et al., 2002

- **Immunocompromised patients**

The number of cases of invasive infections caused by filamentous fungi has increased significantly recently, which is thought to be due to increases in the number of immunocompromised patients (Paterson et al., 2009, Hageskal et al., 2006 and Denning, 2006). The increase is linked to growing elderly populations, increased incidence of cancer and increased numbers of transplantations (Perlroth et al., 2007). Furthermore, modern treatment regimes, for example for cancer or following organ transplant, often result in more intensive immunosuppression for longer periods of time (Richardson, 2005). By contrast, the use of highly active antiretroviral therapy (HAART) has reduced the rate of fungal infections in HIV-positive individuals (Richardson, 2005).

Box 4 illustrates an example of a group of immunocompromised patients and how their immune deficiency affects the risk of developing fungal infections.

The risk of fungal infection for immunocompromised patients is predominantly in hospitals, where patients are being treated for diseases that reduce immunocompetency or are undergoing immunosuppressive therapies. Awareness of the risk of infection from water in hospitals is high, and guidelines exist for reducing the risk for immunocompromised patients (see sub-section 5.2.6. for more details). For example, it is recommended that such patients use sterile water during their stay in hospital (Anaissie et al., 2002a).

Box 4: Acute leukaemia: Immunodeficiency and risk of fungal infection

Patients with acute leukaemia are at increased risk of fungal infections due to neutropenia, a disorder caused by the leukaemia where the patient does not produce enough neutrophils (a type of white blood cell). Therapy to remove cancerous bone marrow prolongs the state of neutropenia. In such patients, incidence of invasive aspergillosis was 6.3-8% in a prospective study in the Paris area. Invasive pulmonary fungal infection is more common in patients with blood cancers than disseminated disease (i.e. where disease spreads from the initial site of infection to other body organs and systems), which is more common following haematopoietic stem cell transplants (Richardson, 2005).

- **Underlying conditions**

Those with underlying health problems, such as pulmonary disorders, cystic fibrosis and diabetes mellitus, are more at risk of invasive or systemic fungal infections than the general population (Denning, 2006). For example, patients with cystic fibrosis (CF) are at risk of allergic bronchopulmonary aspergillosis as their respiratory tracts are often colonised by *Aspergillus fumigatus*. Pulmonary aspergillosis (i.e. deeper in the lungs than bronchopulmonary aspergillosis) is a complication of lung transplants in CF patients due to colonisation of their airways prior to transplant. In one study, 53% of lung transplant recipients with CF were already colonised by *Aspergillus* spp. before the transplant (Helmi et al., 2003).

Treatment of systemic inflammatory diseases, such as Crohn's disease and rheumatoid arthritis, using agents that neutralise macrophage inflammatory cytokines also increases the risk of opportunistic fungal infections (Richardson, 2005).

- **Haemodialysis**

Contaminated dialysate is a potential source of fungal infection in dialysis patients when machinery malfunctions. A study in Greece found that fungi and yeasts were recovered from 77.7% and 12.9% of dialysate samples respectively from 85 haemodialysis units in Greece (Arvanitidou et al., 2000). Similar results were found in an analysis in Brazil, with filamentous fungi being found in tap water samples and yeasts found in dialysate samples (Pires-Gonçalves et al., 2008). Occasionally this contamination can lead to disease. For example, two patients who had dialysis from the same machine at a centre in Illinois, US, developed infections caused by *Phialemonium curvatum*. The fungus was isolated from both blood samples of the affected patients and the water used for dialysis. The problem arose due to malfunction and improper maintenance of the machine (Rao et al., 2009).

- **Very low birth weight babies and children**

Premature or very low birth weight (VLBW) babies are also at risk of fungal infections. For example, the incidence of such infections is estimated at 2-4% in VLBW infants and can rise to 10% in those babies with the smallest birth weight (McCrossan et al., 2007). This is because newborns tend to have weaker immune systems, and VLBW or premature babies may have indwelling catheters or be receiving broad-spectrum antibiotics. Other risk factors for infections in these babies include a gestational age of less than 32 weeks, an Apgar score of less than 5 at 5 minutes after birth, shock, presence of central venous catheters and a stay in intensive care of longer than 7 days before infection (Clark and Hajjeh, 2002). Mortality from systemic candidiasis is around 30% (Richardson, 2005).

Paediatric cancer patients can also experience invasive fungal infections. A retrospective study of the incidence of candidaemia in cancer patients found a variety of species were responsible for episodes of candidaemia. The rate of mortality from the infection was 21%, with *C. albicans* and *C. tropicalis* responsible for most of the deaths (Mullen et al., 2003).

Babies and infants are also more susceptible to mycotoxins (Paterson et al., 2009).

5.2.5. MORTALITY

Invasive systemic infections have high mortality rates, depending on the causal species; the characteristics of the host, such as the degree of immunocompetency; the timing of diagnosis; and the timing and effectiveness of therapy. Estimates of mortality differ and range from 50 to 100% (Warris, 2001); examples are provided in Table 5-2.

Table 5-2: Mortality rates from main systemic fungal infections (Pfaller et al., 2006)

Disease	Mortality rate
Invasive candidiasis	10 - 49% (excess attributable mortality rate)
Invasive aspergillosis	62 - >85%
Fusariosis	79-87%

5.2.6. MANAGING NEGATIVE HEALTH IMPACTS

The implications of fungi in drinking water for the general healthy public have not been thoroughly assessed (Hageskal et al., 2009). However, invasive fungal infections are rare in such individuals (Peter et al., 2002 and Pfaller et al., 2006).

Preventing individuals in at-risk groups from being exposed to fungi in water, particularly in hospitals, is important (Paterson et al., 2009). Various guidelines exist for this purpose. For example, in the UK the NICE guidelines (2003) recommend using cooled freshly boiled water or sterile water for mixing feeds or cleaning feeding tubes when caring for immunocompromised patients. Procedures for protective isolation, particularly of patients with immune deficiency, can also help to limit exposure to fungi. Specific policies vary slightly between hospitals. They may prohibit showering if

the water is thought to be contaminated or require sterile water for drinking[10]. Providing separate bathrooms for at-risk patients and thoroughly cleaning the walls and floor of showers before use is also recommended; this measure has been found to be effective in reducing exposure to fungi (Hayette et al., 2010). Point of use water filtration devices could also be added to taps and showers to prevent aerosolisation of fungi (Hageskal et al., 2009). However, this measure is relatively costly, due to the need to frequently replace the filters. An alternative would be to apply a thermal shock to water entering the hospital to remove heat-sensitive fungi (Hayette et al., 2010).

Amphotericin B is the standard therapy for invasive fungal infections, and has a success rate of between 25 and 34% (Warris, 2001). However, resistance to antifungal medication is increasing (Paterson et al., 2009); in particular, resistance to amphotericin B is common in many pathogenic species (Richardson, 2005), such as *Aspergillus* species (Pfaller et al., 2006). Resistance of *Candida* species has in some instances been associated with prophylactic use of fluconazole, an anti-fungal medication, although this has not been found in all hospitals in which prophylactic medication is used (McCrossan et al., 2007). However, in general, *Candida* species continue to be sensitive to common antifungal medication (Kibbler et al., 2003).

Managing risk of allergic disease in sensitive patients who are experiencing long stays in hospitals is also important, in order to avoid further complications to their condition (Hayette et al., 2010).

5.3. FACTORS THAT COULD INFLUENCE SOME INDIRECT HEALTH IMPACTS

5.3.1. BIOCORROSION

Fungal species that have the potential to corrode pipes in the water distribution system include those species that are iron reducing, such as *Penicillium*, *Aspergillus* and *Rhizopus* (Emde et al., 1992).

Corrosion of pipes can lead to metal concentrations in the water rising above those recommended by drinking water quality guidelines, potentially leading to health implications and changes in water taste (Dietrich et al., 2004). The element vanadium is found in iron corrosion by-products, which can be released into drinking water when the by-products are disturbed. Vanadium has the potential to cause negative health impacts (Gerke et al., 2010). Furthermore, corrosion tubercles may provide a habitat for fungal species in treated water (Emde et al;, 1992).

[10] See for example Royal United Hospital Bath NHS Trust Isolation Policy. Available from: www.ruh.nhs.uk/about/policies/documents/clinical_policies/yellow_infection_control/Yellow_627_Isolation_Policy.pdf [Accessed 26/1/2011]

Corrosion inhibitors are applied to the water to minimise the release of corrosion by-products into the water and resultant health risks. However, the health risks arising from fungi-induced corrosion has not been well studied.

5.3.2. INTERACTIONS WITH OTHER PATHOGENS AND DISEASES

Both the ecology and virulence of pathogenic organisms can be affected by the presence of other microbes. For example, fungi and bacteria influence each other directly and indirectly through physical interactions and chemical exchanges, and via metabolic by-products, changes in the environment (e.g. pH) and alteration of the host's immune response. See section 4.2.1. for further discussions of the interactions between fungi and bacteria. In some cases, such as bacterial biofilms on the surfaces of fungal hyphae, the interactions reduce fungal viability. In other circumstances, interactions can be mutually beneficial. For example, mixed-species biofilms may infer greater protection against antimicrobial substances or host immune defences (Peleg et al., 2010).

Mixed-species infections have clinical implications. For example, colonisation of the respiratory tract with *Candida* spp. increases the risk of ventilator-associated pneumonia from *Pseudomonas aeruginosa* (Azoulay et al., 2006). Whether this is related to drinking water depends on the source of the fungi colonising the respiratory tract. Assessing the significance of mixed-species infections in humans is difficult. However, it has been observed that bloodstream infections of both *Candida* spp. and a bacterial species have a higher mortality rate than *Candida* spp. infection alone. In animal models it has been found that simultaneous infection with *C. albicans* and *Escherichia coli* killed the host more frequently than infection with either species alone. These species are frequent causes of hospital-acquired bloodstream infections (Peleg et al., 2010) and *C. albicans* has been found in drinking water (see Annex 1).

5.4. TASTE AND ODOUR ISSUES

Taste and odours are common water quality problems in many countries. The common problem includes i) chlorine taste and odour ii) rust and metallic tastes iii) musty, earthy and fishy tastes and odours and iv) rotten egg smells. Odour compounds may originate from industrial effluents or from the biological activities of the algae, cyanobacteria and heterotrophic microorganisms (Cees et al. 1974). The major odour compounds include naphthalene, 2-methylbenzthiazol, chlorinated organics such as bis(2-chloroisopropyl) ether, o-chlorophenol, dichlorobenzes and hexachlorobutadiene (Cees et al. 1974).

5.4.1. DETERMINING THE SOURCE OF TASTE AND ODOUR ISSUES

Occasionally, problems with the taste and odour of water arise due to contaminants within the water distribution system. Investigations of the source of such problems

usually happen on a case-by-case basis in response to a problem and in many earlier investigations, fungi were not the main focus of analysis. The source of the problem can be terrestrial or from microbial activity in biofilms, with the compounds then being washed into the water supply. In both cases, the microbes responsible will not necessarily be isolated from samples of the affected water. Conversely, detection of fungi in such samples cannot be taken to imply causality (Hageskal et al., 2009).

5.4.2. COMPOUNDS AND FUNGAL TAXA RESPONSIBLE FOR TASTE AND ODOUR ISSUES

The Actinomycetes have been found to be associated with the musty and earthy odours in water (Zaitlina and Watson, 2006). Musty/earthy odours are the second problems encountered by the water utilities besides chlorine (Suffett et al. 1996). The filamentous fungi and the actinomycetes in the water can produce volatile compounds like geosmin (Paterson et al. 2007). Many of the taste and odour compounds produced by bacteria are also found to be produced by filamentous fungi and significantly affect the effectiveness of chemicals used for disinfecting drinking water (Paterson et al. 2009). Fungi also produce their own compounds with distinctive off-odours and tastes. Some of the fungal isolates are capable of transforming 2,4,6-tricholorophenol to 2,4,6-trichloroanisol and that causes taste and odour problems in the distribution system (Paterson et al. 2009). Several of the fungi that have been isolated from drinking water are known to produce such compounds during their metabolism (see Annex 1), including Aspergillus spp., Acremonium spp., Phialophora and Penicillium spp. which produce geosmin (Kelley et al., 1997 and Hageskal et al., 2006).

During investigations of bad tasting water, the quantities of fungi present were found to be in the region of 102-103 CFU l^{-1}, which may represent a threshold level (Gonçalves et al., 2006). Fungi growing in localised pockets near the consumer end may be at the origin of taste and odour problems (Kelley et al., 1997).

5.4.3. PUBLIC PERCEPTION OF TASTE AND ODOUR ISSUES

Problems with the taste and odour of drinking water are frequently perceived by the consumer as being an indication that the water presents a health risk (Rogers, 2001). There is unlikely to be a strong link between health risk and off-tastes (Jardine et al., 1999), and perception of risk is modulated by a variety of other factors including external information (such as from water companies or the media), trust in water suppliers and previous experiences, particularly previous health problems (de França Doria et al., 2009). Reassurance from water companies may not be effective (Jardine et al., 1999 and McGuire, 1995). Therefore, minimising taste and odour problems, such as those arising from fungi, is important to maintain consumer confidence in high-quality drinking water (Rogers, 2001).

6. CONCLUSIONS

Fungi are a common component of the microflora in water distribution systems and in treated tap water. The specific community of fungal species found varies between systems, and may also vary over time. Some species are resident in the system while others are transient and do not become established. A number of species have been regularly isolated from different systems, including some that are known human pathogens. However, there are numerous issues with the methods used to sample, isolate, identify and quantify fungal species in water samples. Fungi are unevenly distributed in water due to being filamentous nature or held in biofilms. Therefore, it is difficult to obtain a representative sample. The species isolated is influenced by the method used for isolation and identification, which can itself select for some individual species. No international standard methodology is widely in use, which presents a significant hindrance to progressing in this field of research as it is not possible to compare results between studies (Kelley et al., 1997 and Paterson and Lima, 2005).

Water treatment and disinfection processes are effective in reducing the number and diversity of species found in the raw source water, although fungi are not completely removed and may be only partially inactivated. Secondary contamination via mains breaks, maintenance and low/negative pressure events is a potentially significant but poorly understood contamination pathway. A number of procedures are already in place to reduce the risk of secondary introduction of contaminants, although their effectiveness in reducing fungal contamination is not well known. Residuals of chemical disinfectants are maintained in distribution systems to maintain the microbiological quality of the water, which will also inactivate fungi within the system.

Once in the distribution system, fungi are capable of establishing and multiplying, particularly in biofilms, particles, and water with a long residence time in dead ends, tidal points and oversized pipes. A number of biotic and abiotic factors influence the ecology of fungi in drinking water distribution systems, including water temperature and flow rate, material of pipes and interactions with bacteria and protozoa. Knowledge on some specific aspects of the ecology of fungi in these environments is lacking. For example, the relationship between bacteria and fungi in drinking water is not well understood, as indicated by the lack of agreement between studies regarding correlations between them. Further work is needed to characterise this relationship in order to determine if and how the bacterial content of water is associated with its fungal content.

Fungi are responsible for a range of infections and allergies. In healthy populations, superficial or localised fungal infections, for example of the skin, are relatively common and can be treated. Allergic disease caused by fungi may also be of relevance in this

population. More severe invasive fungal infection is limited to at-risk individuals, such as those with immune deficiency or underlying conditions such as cystic fibrosis.

Measures are in place in high-risk locations, such as hospitals, to manage risk of fungal infection via airborne spores or hyphal fragments. Despite such measures, however, incidence of infection in at-risk individuals is continuing to increase. This has led researchers to investigate alternative sources of infection. Species known to be pathogenic, such as *Aspergillus* spp., have been isolated from drinking water, and therefore the potential exists for patients to be exposed to fungi via drinking water. In a small number of cases, water has been confirmed as the source of fungi following genotyping of isolates from the patient and from the environment. Monitoring of fungi in drinking water linked to an alert system for outbreaks of fungal infection would help in identifying the environmental source of infection. Pathways of exposure to fungi in drinking water include ingestion of drinking water, inhalation of spores that have become aerosolised from running the shower or tap or using saunas, skin contact with fungi in water, or introduction via wounds or the conjunctiva when bathing or showering. A significant knowledge gap concerns the quantity of fungi in water acceptable and the threshold level for infection or allergic response (Hageskal et al., 2007). However, this may depend on individual host factors.

Opinions among researchers as to whether fungi in drinking water are a significant source of fungal infections in vulnerable patients are contradictory, leading to debate about whether further information is required before action taken (Hageskal et al., 2009). However, risk of severe invasive fungal infections for healthy individuals is low, regardless of the environmental source of the pathogenic fungi (Anaissie et al., 1989, Chen et al., 2001, Walsh et al., 2004). Therefore, precautionary measures beyond normal water treatment and disinfection may not be needed for this group, particularly given the need to avoid causing alarm amongst the public (Hageskal et al, 2009). Further studies to more precisely evaluate this risk would be helpful.

Applying the precautionary principle and given the high mortality rate from invasive fungal infections amongst high-risk patients, preventative measures for this group would be warranted. A number of measures are already in place in hospitals, such as preventing vulnerable patients from showering. Evidence of which exposure pathways are most significant for such patients would enable appropriate mitigation measures to be put in place. Furthermore, more studies that investigate the environmental source of hospital-based fungal infections would be beneficial to determine the degree of risk from water relative to other sources.

6.1. FUTURE PERSPECTIVES

The number of people in at-risk groups continues to increase due to HIV/AIDS, advances in medical treatment of conditions such as cancer that prolong immunosuppression, increases in transplant numbers and medical advances in keeping

extremely low birth weight babies alive. Therefore, monitoring and control of fungi in the hospital environment, including in water, is vital to avoid greater numbers of severe infections with a high mortality rate.

Climate change should also be considered in its potential to alter the abundance and species composition of fungi in water supplies. For those taxa that exhibit seasonal variation, it would be important to assess how warmer and wetter weather in the UK alters their numbers and habitats. For example, O'Gorman and Fuller (2008) found that levels of airborne spores of *Cladosporium* were positively correlated to temperature and that spores of *Penicillium* and *Aspergillus* were positively correlated with relative humidity. Climate change may also increase exposure to fungi. For example, floods are expected to increase in frequency in the future, leading to increased numbers of people inhabiting water-damaged buildings. Therefore, risk of being exposed to aerosolised fungi can increase, as was found following the New Orleans flooding (Ahikari et al., 2009).

6.2. POTENTIAL IMPROVEMENTS TO THE WATER SYSTEM

Standard treatment procedures for drinking water have been shown to be effective in removing many of the species and reducing the number of fungal CFUs (Kinsey et al., 2003).

A number of other measures in addition to treatment have been identified to control microbial growth, particularly in biofilms, within water distribution systems. These are presented in Table 6-1. It should be noted that these measures are intended to control microorganisms in the distribution system and not specifically fungi, and represent normal good practice for water suppliers in the UK.

Table 6-1: Measures for controlling microbes in drinking water distribution systems

Measure	Description
Mains flushing and cleaning	Biofilms, particles and tuberculation (deposits of corrosion products on inner surfaces of pipes) affect the systems hydraulics. Regular flushing and cleaning removes such deposits, enabling water to flow better through the system. Maintaining positive pressure throughout the system is also important. Storage facilities should also be flushed or cleaned and then disinfected at regular intervals.
Maintenance of disinfectant residuals	Ensuring sufficient concentrations of disinfectants throughout the distribution system reduces the contamination of treated water for example by microbes in biofilms in the system. It also can inactivate pathogens and suppress microbial and biofilm growth.
Mains repair and replacement	Sections of the distribution system with frequent leaks or contamination problems are sometimes replaced rather than repairing the problem or flushing the system. Other devices such as valves may also be replaced when they fail.
Flow management and	There should be sufficient turnover of water in storage

Measure	Description
minimising dead ends	facilities and areas of low flow to avoid long residence times and particle accumulation. This can be done by exercising valves and avoiding excess storage. Proper network design should also minimise the number of dead ends.
Corrosion control	Controlling corrosion can reduce biofilm development as corrosion inhibitors also inhibit biofilm formation and prevent biofilms from sloughing off by coating the inner surface of the pipe.
Control of nutrient concentrations	Control of nutrients, particularly carbon, occurs during treatment through techniques such as coagulation, membrane filtration, granular activated carbon and biological treatment (microbial activity at the point of treatment).
Reduction of cross-connections and backflow	Installing and inspecting backflow prevention devices reduce the intrusion of microbes from cross-connections.
Control of contamination from materials and equipment	Disinfection and high pressure washing of tools can reduce the microbes found thereon. Following maintenance procedures, it is important to thoroughly disinfect and flush the system (in one direction to avoid removing biofilms) before the system becomes operational. Repairing mains breaks involves isolating the affected system before carrying out disinfection and flushing.

Other options to reduce the fungal contamination of drinking water are to implement control measures at the point of use. Such measures include installing filters on taps and showers, and using treatment/disinfection methods such as copper and silver ionisation in hospitals and other high-risk locations (Hageskal et al., 2009).

6.3. RESEARCH NEEDS

There are a number of aspects regarding fungi in drinking water that have not been well studied, or for which considerable uncertainty or contradiction still exists. Once the risk posed by fungi in drinking water has been has been better established, the costs and benefits of additional treatment and control measures should be determined. Specific research needs to achieve this are presented in Table 6-2 by priority level.

Table 6-2: Research needs

Research need	Significance
Medium priority	
Importance of drinking water as an environmental source of fungal infections in at-risk patients	A small number of studies have genotyped fungal isolates from infected patients and various environmental sources of fungi. The importance of *Candida* species in drinking water is particularly unknown, and pertinent given the relative importance of *Candida* as a pathogen.

Research need	Significance
Relative importance of ingestion as an exposure pathway for fungi in drinking water (compared to inhalation or skin contact).	To determine whether control measures for at-risk individuals should include drinking sterilised water, reducing risk of aerosolised spores, avoiding bathing in unsterilised water, etc. Knowing the most common pathways of exposure will ensure that mitigation methods are targeted appropriately.
Effects of analytical methods on results regarding fungal species and quantities	Greater understanding of how the method chosen can affect the results and development of a standard methodology will allow facilitate many of the other research needs.
Low priority	
Interactions with bacteria	To determine if numbers of pathogenic fungi correlate with standard parameters of drinking water or whether additional monitoring is needed for locations with high-risk people such as hospitals.
Relative proportions of fungi and biofilms in distribution systems compared to in consumer-side installations	To determine if measures to reduce fungi in the distribution system are needed or whether consumers, particularly hospitals and individuals in at-risk groups, should be provided with information on how to reduce fungal prevalence. A better understanding of fungal regrowth within distribution systems will also allow assessment of the relative effectiveness of water treatment and disinfection procedures.
Risks associated with secondary contamination pathways	To better understand and quantify the risks from secondary contamination pathways. However, control measures are already in place for reducing secondary contamination with other microbes and pollutants.

There are a number of other aspects of the ecology of fungi in drinking water that are not fully understood or have not been well researched. A greater understanding of these issues will not affect assessment of the level of risk but may be beneficial for a greater academic knowledge of the subject. These are presented in Table 7-3.

Table 6-3: Areas for potential future research

Research area	Description
Effects of nutrient levels on fungal ecology in distribution systems and competition between fungi and bacteria	Nutrient levels likely to be less influential for fungi than bacteria, given that many fungi can grow in low-nutrient environments. Determining the nature of competition for nutrients may help to better understand fungi-bacteria interactions.
Interactions with viruses	Infection of *Aspergillus* with mycoviruses appears to reduce fungal viability, and hence such interactions may reduce rather than raise risk of fungal infection from drinking water. This hypothesis should be tested however.
Interactions with algae	Interactions have only been studied in marine environments but appear to have little relevance for risk of fungal infection.

Research area	Description
Fungi-induced corrosion of pipes	The importance of fungi in microbially-induced corrosion is not well known. However, corrosion inhibitors are applied when appropriate to reduce release of corrosion by-products and health impacts.
Effect of pipe material on establishment of fungal biofilms or fungal colonisation of existing biofilms and rate of detachment	May be an important consideration for future pipe replacement. However, impacts of material on pathogenic bacteria, by-products, etc. may be more important than effects on fungi and many other factors will affect the decision of pipe material.
Clarification of effect of water flow rate on biofilms and fungi in biofilms, and biofilm detachment	May be a consideration in designing future water distribution networks although generic guidance already exists.
Interactions with protozoa	Fungal replication inside protozoa has occurred but the significance of this as a means by which fungi are protected from treatment and disinfection is not known. Co-associations between pathogenic protozoa and fungi may also be significant.
Impacts of climate change on fungal numbers and ecology in drinking water	Changing fungal numbers or ecology may increase risks for certain population groups and therefore require different control measures.
Adequate monitoring plans and methods	In response to potential future risk (e.g. from climate change) research into optimal monitoring plans, combined with monitoring for other pathogens, would ensure that changing risk can be ascertained.
Concentrations of mycotoxins in drinking water and significance of drinking water as an exposure pathway	While it is not thought that mycotoxins have caused acute disease in the UK or US, it would be useful to determine the concentrations of mycotoxins in drinking water, particularly in relation to chronic exposure.

Box 5: Summary of conclusions

- Fungi present in drinking water may cause severe fungal infections in immunosuppressed patients. In a small number of studies, drinking water supplies have been found to be the source of infection, although the pathway of infection (drinking vs. inhalation of aerosolised spores while showering) is uncertain
- Additional research would be required to further investigate the link between fungi in drinking water and infections in immunosuppressed patients, address its frequency from an epidemiological viewpoint and determine the fungal species and quantity in water to cause such infections.
- The present risk of health impact for the general population is thought to be low based on current knowledge. Therefore current procedures for water system maintenance or water monitoring and treatment might be sufficient.
- The literature should be reviewed periodically in order to take account of potential environmental or procedural changes, such as climate change or altered water treatment processes.
- If future scientific works suggests an increase in risk, pilot epidemiological studies and surveillance may be justified.
- Further research and monitoring (if needed) would be facilitated by the use of a simpler and quicker method of fungal quantification and identification than culture.
- Greater knowledge of the associations between fungi and bacteria would help to ascertain whether commonly measured bacterial parameters of water quality correlate with fungi presence.

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7. GLOSSARY

Biofilm: microbial populations enclosed in a matrix which are adherent to each other and/or surface, i.e. biofilms are not single cells dispersed in a fluid (Stoodley et al., 1997).

Conidia: asexual fungal spores produced by mitosis, non-motile.

Eutrophic: aquatic habitats with high concentration of organic compounds (nutrients) and low dissolved oxygen content.

Filamentous fungi: fungi that grow in multi-cellular colonies.

Heterotrophic: organisms that do not produce their own food, and hence require organic carbon from external sources for growth.

Invasive infection: an infection that spreads from the initial site of infection to the surrounding tissues.

Melanised fungi: fungal species which are encapsulated in a layer of melanin pigment. This is thought to protect them from particular stressors, including the immune system of the hosts of pathogenic fungi (Mednick et al., 2005, and others).

Mycotoxin: a toxic secondary metabolite produced by a fungus.

Oligotroph: organisms that live in low-nutrient environments.

Oligotrophic: aquatic habitats with low concentration of organic compounds (nutrients) and high dissolved oxygen content.

Opportunistic infection: an infection caused by a microorganism in an immunocompromised host that is not normally pathogenic in a healthy host.

Psychrophile: organism that thrives at cold temperatures (i.e. close to 0°C), does not have temperature regulation mechanisms, and cannot develop at warmer temperatures (Feller and Gerday, 2003).

Secondary metabolites: Products of metabolic processes that are not directly associated with universal biochemical processes (i.e. protein formation, DNA replication, etc.) (Paterson and Lima, 2005).

Yeast: primarily single-celled fungi the vegetative growth of which is by budding or fission. Their sexual states are not enclosed in fruiting bodies (Furtzman and Fell, 1998).

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9. ANNEXES

ANNEX 1: FUNGAL TAXA IDENTIFIED IN TREATED DRINKING WATER AND IN WATER DISTRIBUTION AND STORAGE SYSTEMS

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
Absidia spp. (ff)	4 CFU/100 ml[11]	Surface		Norway[12]	*A. corymbifera:* An infrequent opportunistic pathogen (Larone, 2002)	Hageskal, 2006
	-			UK, US		Kinsey, et al., 1997
Acremonium spp. (ff)	1.4 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Many spp. opportunistic pathogens (Guarro et al., 1997, and others). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	132 CFU	Unknown	Water from the tap (treated)	Portugal		Gonçalves et al., 2006
	12.1%	Groundwater	Raw water, waterworks, water networks, house installation, newly laid pipes (unchlorinated)	Germany		Göttlich et al., 2002
	3-40 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006

[11] In cases where species were listed separately in the minimum CFU count per 100 ml for each of the species of the same genus was summed, and then the maximum count was summed to give a range. In cases where the minimum and maximum counts were the same, only one figure is given.

[12] Both treated and untreated water was investigated in this study, and the results do not differentiate between those species found in each water type. However, it is stated that a similar species diversity was found in both treated and untreated water, and therefore all species isolated in this study are considered as being likely to occur in treated water.

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	25.6% of samples positive	Groundwater	Tap water/ groundwater	Austria		Kanzler et al., 2007[13]
Altenaria spp.(ff)	3.8 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Can cause upper respiratory tract infections and asthma (Salo et al., 2006), some species opportunistic pathogens (Vermeire et al., 2010). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	1 CFU	Unknown	Water from the tap (treated)	Portugal		Gonçalves et al., 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	2.6% samples positive	Groundwater	Groundwater/ tap water	Austria		Kanzler et al.,2007
Arthrinium spp. (ff)	2 CFU/100 ml	Surface		Norway	Produce mycotoxins (Magan and Olson, 2004)	Hageskal, 2006
	-			UK, US		Kinsey, et al., 1997
Ascochyta spp. (ff)	-			UK	No reports of pathogenicity in humans. Can produce	International Mycological Institute, 1996

[13] Samples from this study were taken from both groundwater and tap water, the taxa found in each source were not differentiated.

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
					mycotoxins (Betina, 1993).	
Aspergillus spp. (ff)	3.9-7.1 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Some species causes invasive aspergillosis (Larone, 2002) and some are allergens (Banerjee and Kurup, 1998). Mycotoxins are also produced (Fox et al., 2004). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	1 CFU	Unknown	Water from the tap (treated)	Portugal		Gonçalves et al., 2006
	2%	Groundwater	Raw water, waterworks, newly laid pipes unchlorinated)	Germany		Göttlich et al., 2002
	-	Surface water	Surface source waters, after different treatment stages, water pumped to supply network	Poland		Grabinska-Loniewska et al., 2007
	5-20 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-					International Mycological Institute, 1996
	15.4% samples positive, 5.1% positive for *A. terreus*	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Aureobasidium spp. (yeast)	1.3-3.1 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	*A. pullulans* is a: rare pathogen – causes phaeo-hyphomycosis (Larone, 2002).	Doggett, 2000
	1-3 CFU/100 ml	Surface water		Norway		Hageskal, 2006.

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	5.10% samples positive	Groundwater	Groundwater/ tap water	Austria		Kanzler et al., 2007
Beauveria spp. (ff)	2-15 CFU/100 ml	Surface water		Norway	Reported pathogenicity (Henke et al., 2002)	Hageskal, 2006.
	-			UK, US		Kinsey, et al., 1997
	2.6% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Botrytis spp. (ff)	2-3 CFU/100 ml	Surface water		Norway	No reports of pathogenicity in humans	Hageskal, 2006.
	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Byssochlamys spp. (ff)	1-2 CFU/100 ml	Surface water		Norway	Produces a mycotoxin (patiulin) (Moulé and Hatey, 1977). No reports of pathogenicity in humans.	Kinsey, et al., 1997
Candida spp. (yeast)	4.8-6.3 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Pathogenic (Calderone and Fonzi, 2001).	Doggett, 2000

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	-		Treated tap water	Brazil	Produce compounds causing off tastes (Kelley et al., 1997).	Yamaguchi, 2007
Ceratocystis spp. (ff)	1-3 CFU/100 ml	Surface water		Norway	No reports of pathogenicity in humans. Can produce mycotoxins (Betina, 1993).	Hageskal, 2006
Chaetomium spp. (ff)	2 CFU	Unknown	Water from the tap (treated)	Portugal	Pathogenic (Guppy et al., 1998)	Gonçalves et al., 2006
	2-6 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Chrysonilia spp. (ff)	1 CFU/100 ml	Surface and groundwater		Norway	Reports of allergenicity (Francuz et al., 2010). Not reported as being pathogenic.	Hageskal, 2006
Chrysosporium spp. (ff)	1 CFU/100 ml	Surface water		Norway	Produces a mycotoxin (Betina, 1993). A rare pathogen (Chabasse et al., 1989 and Roilides et al., 1999)	Hageskal, 2006
Cistella spp.	2.6% samples positive	Groundwater	Groundwater/tap water	Austria	Not reported as being pathogenic in humans.	Kanzler et al., 2007
Cladosporium spp. (ff)	1.5 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Skin and toenail infections, sinusitis, pulmonary infections (Tamiska et al., 2006).	Doggett, 2000
	12 CFU	Unknown	Water from the tap (treated)	Portugal	Produce compounds causing off tastes (Kelley et al., 1997).	Gonçalves et al., 2006

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	2%	Groundwater	Waterworks, house installation, newly laid pipes (unchlorinated)	Germany		Göttlich et al., 2002
	-	Surface water	Source water from river	Poland		Grabinska-Loniewska et al., 2007
	3-17 CFU/100 ml	Surface water		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
				UK		International Mycological Institute, 1996
				Austria		Kanzler et al., 2007
Cordyceps spp.	2.6% samples positive	Groundwater	Groundwater/tap water	Austria	Not reported as being pathogenic in humans.	Kanzler et al., 2007
Cryptococcus spp. (yeast)	7.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	*C. neoformans:* opportunistic infections (Walsh and Groll, 1999). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	-			US		Kinsey, et al., 1997
Dactylaria spp.	2.6% samples positive	Groundwater	Groundwater/ tap water	Austria	*D. constricta* has caused subcutaneous and disseminated infections in immunocompromised patients (Larone, 2002).	Kanzler et al., 2007
Dendryphion spp.	1.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Not reported as pathogenic	Doggett, 2000

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
Doratomyces spp. (ff)	1.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Allergen (Fischer and Dott, 2003)	Doggett, 2000
Epicoccum spp. (ff)	1-2 CFU/100 ml	Surface and groundwater		Norway	Not reported as pathogenic (Lorone, 2002).	Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	5.1% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Eupenicillium spp. (ff)	1 CFU/100 ml	Surface water		Norway		Hageskal, 2006
	-			UK		Kinsey, et al., 1997
Exophialia spp. (yeast-like)	9.5%	Groundwater	Raw water, waterworks, water networks, house installation, newly laid pipes (unchlorinated)	Germany	Some species pathogenic (Lorone, 2002).	Göttlich et al., 2002
	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Fusarium spp. (ff)	3.5%	Groundwater	House installation, newly laid pipes (unchlorinated)	Germany	Some species produce mycotoxins such as fumonisins and trichothecenes (Betina, 1993), some opportunistic pathogens, causing eye infections and disseminated systemic infections (Lorone, 2002).	Göttlich et al., 2002
	-	Surface water	After different stages of treatment of river water, river water sedimentation basin source water	Poland		Grabinska-Loniewska et al., 2007
	102-107 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	-		Treated water	UK, US	Produce compounds causing off tastes (Kelley et al., 1997).	Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	2.6% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Geotrichum spp. (ff)	-	Surface water	Source water from river water sedimentation basin, after different stages of treatment of this water	Poland	Pathogenic (Sfakianakis, et al., 2007 and Kelley et al., 1997). Produce compounds causing off tastes (Kelley et al., 1997).	Grabinska-Loniewska et al., 2007
	1-2 CFU/100 ml	Surface water		Norway		Hageskal, 2006
	-			UK, US		Kinsey, et al., 1997
Gliocladium spp. (ff)	1.0 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Not been reported as being pathogenic. Produces mycotoxins (Betina, 1993).	Doggett, 2000
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Graphium spp.	2.6% samples positive	Groundwater	Groundwater/tap water	Austria	*G. basitruncatum* very rare pathogen – observed once in patient with acute leukaemia (Kumar et al., 2007).	Kanzler et al., 2007
Lecythophora spp. (ff)	1-3 CFU/100 ml	Surface and groundwater		Norway	Rare pathogen (Marriott et al., 1997)	Hageskal, 2006

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	12.8% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Leptodontidium spp. (ff)	-		Treated water	UK, US	Not been reported as being pathogenic.	Kinsey, et al., 1997
Leptosphaeria spp.	25.6% samples positive	Groundwater	Groundwater/tap water	Austria	Not been reported as being pathogenic.	Kanzler et al., 2007
Leucostoma spp. (ff)	1-4 CFU/1OO ml			Norway	Not been reported as being pathogenic.	Hageskal, 2006
Mauginiella spp. (ff)	-		Treated water	UK	Not been reported as being pathogenic.	Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Microdochium spp. (ff)	-		Treated water	US	Not been reported as being pathogenic.	Kinsey, et al., 1997
	2.6% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Microsphaeropsis spp. (ff)	-		Treated water	UK, US	Pathogenic (Shah et al., 2001)	Kinsey, 2003
Monascus spp. (ff)	1-5 CFU/1OO ml	Surface water		Norway	Produces mycotoxins (Betina, 1993)	Hageskal, 2006
Mortierella spp. (ff)	-		Treated water	UK, US	Not been reported as being pathogenic.	Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Mucor spp. (ff)	2.7-3.5 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after	US	Pathogenic: occasionally	Doggett, 2000

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
			treatment		causes zygomycosis (Lorone, 2002).	
	4-9 CFU/100 ml	Surface water		Norway	Allergen (Corey et al., 1990). Produce compounds causing off tastes (Kelley et al., 1997).	Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Nectria spp. (ff)	2.8 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Unknown	Doggett, 2000
	-			US		Kinsey, et al., 1997
Paecilomyces spp. (ff)	2.0 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Some species pathogenic (Walsh and Groll, 1999). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	2%	Groundwater	Raw water, newly laid pipes (unchlorinated)	Germany		Göttlich et al., 2002
	--	Surface water	After different stages of treatment of infiltration intake of river water	Poland		Grabinska-Loniewska et al., 2007
	7-16 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-			UK, US		Kinsey, et al., 1997
	5.1% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
Papulaspora spp. (ff)	0.84-1.1 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US		Doggett, 2000
Penicillium spp. (ff)	6.5-12.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Implicated in a range of diseases but causal significance unknown (Lorone, 2002). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	138 CFU	Unknown	Water from the tap (treated)	Portugal		Gonçalves et al., 2006
	7%	Groundwater	Raw water, waterworks, house installation, newly laid pipes (unchlorinated)	Germany		Göttlich et al., 2002
	-	Surface water	Infiltration intake of river water and after different treatment stages of this water	Poland		Grabinska-Loniewska et al., 2007
	48-136 CFU/1OO ml	Surface and groundwater		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	48.7% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Pestalotiopsis spp. (ff)	-		Treated water	US		Kinsey, et al., 1997
Phaeosphaeria spp.	2.6% samples positive	Groundwater	Groundwater/tap water	Austria	Not reported as being pathogenic in humans.	Kanzler et al., 2007
Phialophora spp. (ff)	14 CFU	Unknown	Water from the tap (treated)	Portugal	Some species pathogenic (chromoblastomycosis,	Gonçalves et al., 2006

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	32.7%	Groundwater	Raw water, waterworks, water networks, house installation, newly laid pipes (unchlorinated)	Germany	phaeohypthomycosis, cutaneous and nail infections) (Lorone, 2002). Produce compounds causing off tastes (Kelley et al., 1997).	Göttlich et al., 2002
	-	Surface water	After different treatment stages of infiltration intake of river water	Poland		Grabinska-Loniewska et al., 2007
	10-19 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	20.5% samples positive *P. malorum*, 2.6% positive *P.* spp.	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Phoma spp. (ff)	4.3 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Occasionally causes phaeo-hypthomycosis (Lorone, 2002). Allergen, subcutaneous and respiratory infections. Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	2.5%	Groundwater	Networks, newlylaid pipes (unchlorinated)	Germany		Göttlich et al., 2002
	2-18 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
	7.7% samples positive	Groundwater	Groundwater/ tap water	Austria		Kanzler et al., 2007
Phomopsis spp. (ff)	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	2.6% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al.,2007
Pithomyces spp. (ff)	-		Treated water	UK, US		Kinsey, et al., 1997
Pseudogym-noascus spp. (ff)	1 CFU/100 ml	Surface water		Norway		Hageskal, 2006
Rhizoctonia spp. (ff)	2.8 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Unknown	Doggett, 2000
Rhizopus spp. (ff)	10 CFU	Unknown	Water from the tap (treated)	Portugal	*Rhizopus spp.* pathogenic: commonly cause zygomycosis (Lorone, 2002).	Gonçalves et al., 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Rhodotorula spp. (yeast)	6.1-8.2 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Opportunistic pathogen (Lanzafame et al., 2001 and Neofytos et al., 2007). Produce compounds causing off tastes (Kelley et al., 1997).	Doggett, 2000
	10.3% samples positive	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
Scopulariopsis spp. (ff)	4 CFU/100 ml	Surface water		Norway	Pathogenic: causes nail infections and occasionally subcutaneous and invasive infection (Lorone, 2002).	Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
Sesquicillium spp. (ff)	-	Surface water	After different stages of treatment of infiltration intake of river water	Poland		Grabinska-Loniewska et al., 2007
	-		Treated water	UK		Kinsey, et al., 1997
Sporotrichum spp. (dimorphous)	2.0-2.8 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Has been associated with respiratory disorders (Lorone, 2002). Some/all species pathogenic e.g. *S. schenckii*	Doggett, 2000
	-			UK		Kinsey, et al., 1997
Sporothrix spp. (dimorphous)	1.0-1.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Some/all species pathogenic e.g. *S. schenckii*	Doggett, 2000
	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Stachybotrys chartarum (ff)	2.8-4.8 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Produces mycotoxins, potentially pathogenic (Lorone, 2002).	Doggett, 2000
	-	Surface water	Source water from infiltration intake and sedimentation basin from river	Poland		Grabinska-Loniewska et al., 2007

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
Staphylotrichum spp. (ff)	2 CFU/100 ml	Surface water		Norway		Hageskal, 2006
Stereum spp. (ff)	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
Stysanus spp. (ff)	2.9-4.7 CFU cm^{-2}	Groundwater	Biofilms on iron pipe surfaces of water distribution system after treatment	US	Unknown	Doggett, 2000
Trametes spp.	5.1% of samples positive	Groundwater	Groundwater/tap water	Austria	Not reported as being pathogenic in humans.	Kanzler et al., 2007
Trichoderma spp. (ff)	-	Surface water	Source river water sedimentation basin and after different stages of treatment of this basin	Poland	Produce compounds causing off tastes (Kelley et al., 1997).	Grabinska-Loniewska et al., 2007
	1-12 CFU/100 ml	Surface water		Norway		Hageskal, 2006
	-		Treated water	UK, US		Kinsey, et al., 1997
	-			UK		International Mycological Institute, 1996
	2.6% samples positive *T.viride*, 2.6% positive *T.* sp,	Groundwater	Groundwater/tap water	Austria		Kanzler et al., 2007
Truncatella spp.	-		Treated water	UK		Kinsey, et al., 1997
	-			UK		International Mycological

Taxon	Prevalence	Raw source water (ground/ surface)	Where in the distribution and storage systems it has been isolated	Where it has been isolated	Known pathogenicity/ risk	References
						Institute, 1996
Verticillium spp. (ff)	4%	Groundwater	Raw water, newly laid pipes (unchlorinated)	Germany	Reported as a possible cause of keratitis (Sutton et al., 1998) Produce compounds causing off tastes (Kelley et al., 1997).	Göttlich et al., 2002
	-	Surface water	Source infiltration intake river water and after different treatment stages of this water.	Poland		Grabinska-Loniewska et al., 2007
	1-2 CFU/100 ml	Surface and groundwater		Norway		Hageskal, 2006
	-			UK, US		Kinsey, et al., 1997

ANNEX 2: DIRECT AND INDIRECT HEALTH EFFECTS AND TASTE/ODOUR IMPACTS

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
Pathogenic moulds in hospital water distribution systems – clinical implications for patients with hematologic malignancies	Water, water surfaces, air and other environmental sources from bone marrow trans-plantation unit	Moulds (*Aspergillus* and other fungal species) were recovered in 70% of the water samples , 22% of the swabs from plumbing structures and environmental surfaces and 83% of the air samples	Direct impact – aerosolisation of fungal spores and potential exposure to patients. Hospital water systems serve as a potential reservoir of *Aspergillus* and other fungal species.	USA	Anaissie et al. (2003), Blood 101: 2542-2546.
High level of recovery of fungi from water and dialysate in haemodialysis units (Yeasts and filamentous fungi were investigated)	Municipal water (feed water) supplies of haemodialysis centres, treated water and dialysate.	Out of 255 samples, 209 (82.0%) samples were positive for filamentous fungi and 21 (8.2%) for yeasts. Filamentous fungi and yeasts were isolated from 69 (81.2%) and 3 (3.5%) of feed water samples, from 74 (87.1%) and 7 (8.2%) of treated water samples, 66 (77%) and 11 (12.9%) dialysate samples, respectively.	Direct impact – The occurrence of high percentage of filamentous fungi and yeasts from haemodialysis aqueous environments indicates a potential risks for haemodialysis patients.	Greece	Arvanitidou et al. (2000), Journal of Hospital Infection 45: 225-230.
Possible linkages between lignite aquifers, pathogenic microbes, and renal pelvic cancer (RPC)	Residential drinking water wells and dewatering well of lignite mine; surface waters of coal mine.	Samples were tested for presence of fungi, for metal, trace metal and other physic-chemical parameters. Significant associations were observed between cancer rates and the presence of fungi	Direct impact – the presence of pathogenic microbes are associated with high risks of renal pelvic cancer (RPC)	USA	Bunnell et al. (2006). Environmental Geochemistry and Health 28:577-587.

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
		Zygomycetes, organic compounds, some nutrients and chemical elements. Human pathogenic leptospires was detected in 50% of the surface water sites sampled.			
Occurrence and hygienic relevance of fungi in drinking water	Drinking water and ground water samples (Wells, water tanks and tap water)	Highest fungal concentrations in elevated water storage tanks and the lowest after UV-disinfection. 32 different taxa of fungi were found and isolated in all samples tested. *Cladosporium* spp. (74.6%), Basidiomycetes (56.4%) and *Penicillium* spp. (48.7%) were observed more frequently. Pathogenic fungi like *Aspergillus* spp. or *Fusarium* spp. were found.	Direct impact: Drinking water serves as a reservoir for opportunistic infections in hospitals because of the increasing number of immune-suppressed patients. Aerosolisation during showering is a major problem as compared to drinking of the water.	Austria	Kanzler et al. (2007) Mycoses 51, 165–169.
Occurrence of fungi in water used at a haemodialysis centre	Samples in the hydraulic circuit for the distribution of the water, dialysate samples and samples of sterilisation solution from dialysers.	116 isolates of fungi were recovered from 89% of all water samples collected. Prevalence of moulds in tap water samples and yeasts in dialysate samples. *Fusarium* spp. was the most abundant genus found. *Candida parapsilosis* was	Direct impact: Recovery of fungi from aqueous haemodialysis environments implies a potential risk for haemodialysis patients.	Brazil	Pires-Goncalves (2008), Lett Appl Micro 46: 542-547.

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
		the predominant yeast species found.			
Contaminated product water as the source of *Phialemonium curvatum* bloodstream infection (BSI) among patients undergoing hemodialysis	Bloods samples of person who underwent dialysis were tested positive for *Phialemonium curvatum* on culture. Water, surface, and dialysate samples were also tested by culture.	Two patients with BSI due to *P. curvatum* was identified. *P. curvatum* was identified from the product water used for dialysis at 2 of 19 treatment stations, one of which was the implicated station.	Direct impact: First report of patients acquiring a mould BSI from contaminated product water. The source of *P. curvatum* was likely the water distribution system.	USA	Rao et al. (2009) Infect Control Hosp Epidemiol 30: 840-847
Diversity and significance of mold species in Norwegian drinking water	Samples of raw water, treated water, and water from private homes and hospital installations were collected and the total fungal count and diversity was determined.	94 mould species belonging to 30 genera were identified. Species of *Penicillium*, *Trichoderma*, and *Aspergillus* were dominated and some of them found throughout the drinking water system.	Direct impact/ taste & odour problems: Many species isolated from water may have the potential to cause allergic reactions or disease in humans. Some species are contaminants of food and beverages. Some may cause unwanted changes in the taste or smell of water.	Norway	Hageskal et al. (2006) AEM, 72:7586–7593.
Enhancement of formation of the esophageal carcinogen benzylmethylnitrosamine from its precursors by *Candida albicans*	Pure culture of *Candida albicans* was used to study the formation of the carcinogen benzylmethylnitrosamine (NBMA; N-nitroso-N-methylbenzylamine).	Significant increase in the amount of NBMA formed in the cultures, compared to precursors-only controls. Exponentially growing cultures were also able to cause NBMA formation.	Indirect impact: Formation of nitrosamine could result in a concentration sufficient to initiate tumourigenesis. It may also cause hygiene related cancers, such as those of the penis and	China	Hsia et al. (1981) PNAS, 78:1878-881.

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
	Stationary *C. albicans* cultures were incubated with the precursors.		uterine cervix.		
Initial investigation of microbially influenced corrosion (MIC) in a low temperature water distribution system	Treated and untreated water samples were collected and analyzed for chemical and microbial constituents. A section of corroded pipe, carrying treated water was removed and included for microbial analysis.	Results showed that potentially corrosive microorganisms were present in untreated supply water, treated water and corrosion tubercles. Besides bacteria (Sulfite-reducers, sulphate-reducers, iron-reducers, sulphur-oxidizers), sulfate-reducing actinomycetes and iron-reducing fungi *(Penicillium. Rhizopus, Aspergillus)* were found in the samples.	Indirect impact/ taste & odour problems: Corrosion tubercles may serve as a habitat for certain taste and odour-producing actinomycetes and fungi in treated water supplies.	Canada	Emde et al. (1992). Wat Res: 26:169-175.
Health and immunology study following exposure to toxigenic fungi *(Stachybotrys chartarum)* in a water-damaged office environment	The health status of office workers after exposure to fungal bio-aerosols and its toxigenic metabolites (satratoxins) was studied. Exposure characterization and quantification were performed using microscopic, culture, and	Widespread fungal contamination of water-damaged, primarily cellulose material with *Stachybotrys chartarum* was found. *S. chartarum* produced macrocyclic trichothecene, satratoxin H, and spirocyclic	Direct Impact: The prolonged exposure to toxigenic *S chartarum* and other fungi was associated with reported disorders of the respiratory and central nervous, mucus membranes and immune system.	USA	Johanning et al. (1996) Int Arch Occup Environ Health 68:207-218

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
	chemical techniques.	lactones. Strong association with exposure indicators and employees/controls were found for respiratory, dermatological, eye and other chronic symptoms.			
Culturable mould in indoor air and its association with moisture related problems and asthma and allergy among Swedish children	Case control study: Relationship between mould spore exposure indoor and mouldy odour, visible signs of dampness and diagnosed asthma and allergy was studied with 198 children with asthmatic and allergic cases and 202 healthy controls.	No association was found between the indoor fungal spore concentration and mouldy odour and visible dampness in the homes. No association was found between the fungal spore concentration in indoor air and asthma/allergy in the children.	No impact?: The study suggests that, there is no reason for on-time air sampling of mould CFU in indoor air to identify the risk factors for asthma/allergy in children living in Scandinavian countries.	Norway	Holme et al. (2010). Indoor Air 20: 329–340.
Indoor airborne fungal spores, house dampness and associations with environmental factors and respiratory health in children	Case study: Airborne samples of total and viable fungal spores were collected from bedrooms, living rooms, kitchens and outdoors. 80 households with 148 children between 7 and	The fungal concentration was more associated with musty odour, water intrusion and high indoor humidity. *Penicillium* – risk factor for asthma *Aspergillus* – risk factor for atopy.	Direct impact/risk: The exposure to certain fungal spores is found to be risk factor for asthma, atopy, respiratory symptoms in children. However, no association was observed between total/viable fungal spores and child health.	Australia	Garrett et al. Clinical and Experimental Allergy 28: 459-467.

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
	14 yrs involved in the study.	Fungal allergy is more common among children's exposed to *Cladosporium* / *Penicillium* and respiratory symptoms were common with exposure to *Cladosporium*.			
Growth and metabolites production by *Penicillium brevicompactum* in yoghurt	The growth study and the production of volatile organic compounds (VOC) and mycophenolic (MPA) was conducted using the fungus *P. brevicompactum*, which was previously isolated from contaminated yoghurt.	*P. brevicompactum* produced different metabolites in yoghurts. Sweetened yoghurts are considered an excellent medium for fungal growth. The occurrence of mycophenolic acid production under refrigeration temperatures has been found.	Indirect effect: Yoghurt may serve as a potential vehicle for production of toxic compounds by fungi growing at low temperature.	Italy	Ndagijimana et al. (2008) Int. J Food Micro 127: 276–283

Topic/Title	Type of samples Examined	Main findings from the study	Health impacts / risks	Country	Reference
Zearalenone (ZEN) production and growth in drinking water inoculated with *Fusarium graminearum*	The production of the mycotoxin ZEN was examined in drinking water inoculated with *F. graminearum*. This strain was isolated from a drinking water distribution system in US.	The results showed that the extracellular yield of ZEN was 15.0 ng per litre. Ergosterol was obtained an average of 6.2 µg per litre.	Indirect impact/toxin production: ZEN was produced readily in water by *F. graminearum*. It is recommended to monitor mycotoxin level in water as a standard method.	Portugal	Russell and Paterson (2007). Mycol Progress 6:109–113

ANNEX 3: PRIORITY PAPERS

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Perspective

Fungal Contaminants in Drinking Water Regulation? A Tale of Ecology, Exposure, Purification and Clinical Relevance

Monika Novak Babič [1,*], Nina Gunde-Cimerman [1], Márta Vargha [2], Zsófia Tischner [3], Donát Magyar [4], Cristina Veríssimo [5], Raquel Sabino [5,6], Carla Viegas [6], Wieland Meyer [7] and João Brandão [8,*]

1 Department of Biology, Biotechnical Faculty, University of Ljubljana, Jamnikarjeva 101, 1000 Ljubljana, Slovenia; nina.gunde-cimerman@bf.uni-lj.si
2 Department of Water Hygiene, National Public Health Center, Albert Flórián út 2-6, H-1097 Budapest, Hungary; vargha.marta@oki.antsz.hu
3 Department of Biology, University of Veterinary Medicine, István utca 2, H-1078 Budapest, Hungary; zsofi.tischner@gmail.com
4 Department of Air Hygiene and Aerobiology, National Public Health Center, Albert Flórián út 2-6, H-1097 Budapest, Hungary; magyar.donat@gmail.com
5 Department of Infectious Diseases, National Institute of Health Doutor Ricardo Jorge, Av. Padre Cruz, 1649-016 Lisboa, Portugal; cristina.verissimo@insa.min-saude.pt (C.V.); raquel.sabino@insa.min-saude.pt (R.S.)
6 GIAS, ESTeSL—Escola Superior de Tecnologia da Saúde de Lisboa, Instituto Politécnico de Lisboa, 1990-096 Lisbon, Portugal; carla.viegas@estesl.ipl.pt
7 Molecular Mycology Research Laboratory, Centre for Infectious Disease and Microbiology, Sydney Medical School, Westmead Hospital, Marie Bashir Institute for Emerging Infectious Diseases and Biosecurity, Westmead Institute for Medical Research, The University of Sydney, Level 4, Room 0.4.04, 176 Hawkesbury Road, Westmead, NSW 2145, Australia; wieland.meyer@sydney.edu.au
8 Department of Environmental Health, National Institute of Health Doutor Ricardo Jorge, Av. Padre Cruz, 1649-016 Lisboa, Portugal
* Correspondence: Monika.NovakBabic@bf.uni-lj.si (M.N.B.); joao.brandao@insa.min-saude.pt (J.B.)

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Abstract: Microbiological drinking water safety is traditionally monitored mainly by bacterial parameters that indicate faecal contamination. These parameters correlate with gastro-intestinal illness, despite the fact that viral agents, resulting from faecal contamination, are usually the cause. This leaves behind microbes that can cause illness other than gastro-intestinal and several emerging pathogens, disregarding non-endemic microbial contaminants and those with recent pathogenic activity reported. This white paper focuses on one group of contaminants known to cause allergies, opportunistic infections and intoxications: Fungi. It presents a review on their occurrence, ecology and physiology. Additionally, factors contributing to their presence in water distribution systems, as well as their effect on water quality are discussed. Presence of opportunistic and pathogenic fungi in drinking water can pose a health risk to consumers due to daily contact with water, via several exposure points, such as drinking and showering. The clinical relevance and influence on human health of the most common fungal contaminants in drinking water is discussed. Our goal with this paper is to place fungal contaminants on the roadmap of evidence based and emerging threats for drinking water quality safety regulations.

Keywords: drinking water; fungi; fungal contaminants; *Aspergillus*; in water; Candida; moulds; molds; mycotoxins

1. Introduction

Fungi are ubiquitous, heterotrophic organisms present in oceans, fresh water and drinking water. They can be divided based on the ability to colonize different environments into three groups: as mesophilic fungi, generalists and specialists [1,2]. Mesophilic species inhabit niches with moderate physicochemical parameters, while generalists grow under changing life conditions, but with growth optimum under moderate conditions. Specialists inhabit extreme habitats and are unable to grow under moderate conditions [1]. Ecologically, fungi are saprophytes, degrading organic matter, with some species acting also as parasites or symbionts [3,4]. Due to their diverse life cycle, ability to form large hyphal networks and produce spores, or growing as single yeast-cells, they maximize nutrients uptake and can survive under various life conditions, one of them being oligotrophic water systems [2]. In the last 30 years, the presence of a high variety of fungi was reported from European water, including surface-, ground- and tap water intended for human consumption [2]. It is thus imperative that we regard fungi as nature's resilient recycling machines, when we supply drinking water to users who may lack standard natural abilities to fight back.

Using cultivation techniques, ascomycetous filamentous fungi were those mainly detected, classified as members of the genera *Acremonium*, *Alternaria*, *Aspergillus*, *Cladosporium*, *Fusarium*, *Penicillium* and *Trichoderma*. The second most cultivated group were fungi from the subphylum Mucormycotina (former phylum Zygomycota) [5–19]. The presence of yeasts from surface-, ground- and tap water was rarely reported, probably due to the cultivation bias [19]. Numbers and diversity of fungi were reported to be higher in surface water in comparison to ground- and tap water; environmental factors, such as high contents of organic nutrients, varying temperature, pH, and water flow being the main reason why [15,20,21]. During the production of tap water, cleaning processes including techniques for removing large particles from raw water, and addition of chlorine contribute to a lower load of fungi. Yet, some species remain present in tap water, later establishing biofilms that persist in water distribution systems [22,23]. Reservoirs before elevation stations, positive pressures in building distribution designs, preventive maintenance, permanent running water in the system and adequate residual disinfectant are examples of how the distribution system should be operating [24,25].

Presence of fungi in biofilms and their interactions with other microorganisms remain poorly understood, even though in recent years the use of metagenomic approaches brought more detailed insight to this field [23,26,27]. Fungi growing in biofilms inside taps and in tap water affect the taste and odour, interfering with the chlorination process, due to the release of a large scale of products known as secondary metabolites. These may be very diverse and specific for different fungal species [28]. While the role of secondary metabolites in the ecology of fungi is to defend their habitat, and suppress the growth of competitors [29], some of them are toxic to animals, and may present a risk for human health in higher concentrations or under prolonged time of exposure [30]. Not only secondary metabolites, but also fungal cell wall components and the fungal load itself may contribute to the emergence of allergies and other opportunistic and systemic infections, mainly in immunocompromised individuals [31,32]. Although in the last few decades fungi are becoming frequently recognized as causative agents of respiratory, mucosal, rhinocerebral, cutaneous and subcutaneous infections [32], they remain largely overlooked in the regulations of water quality and consumption [2]. Possible reasons may be the lack of knowledge of the fungal load in water, divergent cultivation methods, heterogeneous mechanisms of fungal pathogenicity and consequently the low number of reports connecting fungal presence in tap water and the occurrence of diseases in humans [21]. Also, unlike obvious outbreaks, low prevalence afflictions are handled discretely, and rarely explored as to how they originate.

The present paper represents a joint review on the presence of fungi in surface water, groundwater and tap water from European countries reported in the last 30 years. It includes known ecological and anthropogenic factors contributing to the presence of fungi in water, together with the mostly used methods for their cultivation and detection, followed by a sustained clarification of the possible relevance of these organisms in drinking water and a recommendation concurred by the authoring team.

2. Fungi and Water—Background Information

2.1. Regulations

Though the presence of fungi in water distribution system and the associated health risks are well documented in the scientific literature, inclusion of fungi in the drinking water regulations is scarce. Most national and international guideline documents (including the World Health Organization) list fungi among the "nuisance organisms" causing odour problems, and do not deem dedicated monitoring necessary [33,34]. The U.S. EPA considered the inclusion of microsporidia in drinking water regulations earlier, but it was withdrawn from the list of "Contaminant Candidate List" in a later phase [35,36]. The European Union drinking water directive does not address fungi explicitly either. However, the directive states that wholesome drinking water should be "free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health" [37]. This definition implies that the presence of pathogenic or allergenic fungi in the drinking water is not acceptable either. The obligatory microbial drinking water parameters (*E. coli*, *Enterococci*, coliforms or clostridia) have no indicative value of fungal contamination. The indicator parameter heterotrophic plate count (HPC), however, may include fungi as well. HPC is widely used to indicate changes in microbial concentration (i.e., ingress or regrowth in the drinking water distribution system [38]. Regulatory value is generally not rendered to HPC. The EU directive does not give a parametric value; compliance is defined as "no abnormal change".

Only a limited number of member states have additional, more specific regulation. The Czech drinking water legislation requires light microscopic analysis of drinking water samples concentrated by centrifugation. It gives a collective parametric value of 50 individuals/mL for all "microscopic organisms" [39] including all eukaryotes and cyanobacteria, which are visible under the microscope. Analysis extends to the visual identification of the observed microorganisms, e.g., the filaments and spores of micromycetes. The Hungarian drinking water act takes a similar approach. Samples are concentrated by membrane filtration and analysed by light microscopy. However, parametric values are given by groups of organisms separately (for fungi, 0 individuals/L) [40]. The Swedish legislation is the only one that requires the direct detection of fungi by culture. It lists "microfungi" (including moulds and yeasts) as an indicator parameter, with a parametric value of 100 CFU/100 mL [41]. All three of the above requirements apply for drinking water samples at the point of compliance (i.e., the consumer's tap). National standards are used for detection and enumeration (CSN 75 7712, MSZ 448-36:1985 and SS 028192, respectively).

2.2. Ecology of Fungi in Water

Fresh water available for human consumption represents only 0.6% of global water supplies stored in glaciers, running surface water and groundwater [4]. Depending on geological features of the area, either groundwater or surface water is used as a primary source to produce tap water [2,42]. In other regions of the world, rainwater is also a relevant source. Therefore, the presence, colonization and growth of fungi in tap water depends on several factors, such as location of primary water source, sun irradiation, temperature, ion composition and pH, presence of organic material, dissolved oxygen concentration, water treatment, use of materials for water distribution systems and consequently the possibility of biofilm formation [2,4,12,19,43–46].

2.3. Aqueous Geochemistry Processes Affect the Presence of Fungi in Water and Vice-Versa

Locations of aquifers and primary water sources are naturally determined by geological features, not only influencing water availability from the main water bodies, but also their physico-chemical properties [4,19]. Water in predominantly rocky areas, with low solubility, have less diverse ion composition, and are more likely present on the surface or as a groundwater close to the surface [47]. On the other hand, geological structures, such as limestone composed from calcium carbonate, have

a significant effect on the formation of specific areas, known as karst systems [48]. Water in such areas dissolves the ground faster, thus water bodies are frequently absent from the surface and are more likely present in form of carbonate-rich groundwater inside the cave systems [47,48]. Chemical properties of water influence fungal presence in water systems, and vice-versa. Fungi were proven to be actively involved in aqueous geochemistry processes, such as dissolution and corrosion of rocks and precipitation of minerals [46,48]. In general, rocks with alkaline pH proved to be more susceptible to fungal colonization than rocks with acidic pH [49]. Besides limestone also the presence of other rock types, such as andesite, amphibolite, basalt, dolerite, gneiss, granite, marble, sandstone, soapstone and quartz, positively influence the growth of fungi, like *Aschersonia* spp., *Aspergillus niger*, *Penicillium expansum*, *P. simplicissimum*, *Scopulariopsis brevicaulis*, and a wide range of melanized, meristematic fungi, known under the umbrella-term "black yeasts" [48,50,51]. The latter include species of the genera *Aureobasidium*, *Exophiala*, *Phaeotheca* and *Trimmatostroma*, and were globally isolated from different rocks exposed to sun irradiation, salty and fresh water, and from statues of cultural heritage in urban cities [51]. Fungi are influencing biological weathering of rocks and together with chemical weathering they are contributing to changes in pH and ion composition of water [50].

The pH of water has shown to have an important role on fungal presence, their growth and bioremediation processes. Positive correlation was observed between the growth of aquatic hyphomycetes and pH between 5 and 7 [20,52], and confirmed recently in a study of deep groundwater reporting the highest diversity in mixed fungal communities at slightly lower pH [47]. Acidic pH has a positive influence on binding of heavy metals like manganese and cadmium to the fungal cell wall components [53], which can be beneficial for some fungal species. For instance, species of plant- and water-related fungi *Paraconiothyrium* and *Phoma* stabilize and oxidize manganese ions by organic acids and use them in degradation of phenolic structures [54]. Metal-binding onto or around fungal hyphae, under acidic conditions, represents sink for heavy metals (e.g., aluminium, copper and zinc) in environment and high bioremediation potential of aquatic fungi [50,55]. Changes in pH in the environment are related also with the polymorphic growth of certain fungi, with low pH inducing growth of round, swollen hyphal cells or yeast-like cells, as observed for *Alternaria*, *Fusarium* and *Mucor* species [52,56,57]. Some species of black yeasts, like *Exophiala dermatitidis* were reported to form thick cell walled muriform clumps [56,58]. Changes in growth form lower the pH-induced stress allowing fungi a more efficient intake of nutrients and the survival under extreme conditions. The pH-induced stress could be additionally lowered with the intake of certain ions, like calcium. This has been shown for *E. dermatitidis* [56,57]. A recent study conducted by Novak Babič et al. [19] showed a positive correlation between higher concentrations of calcium and magnesium ions, contributing to the water hardness, and the presence of fungi in water [19]. Not only inorganic ions, also carbon availability, nitrate, phosphate and sulphate positively correlated with the presence and diversity of fungi in water systems; suggesting an important role of fungi in geochemical cycles of metals, carbon, nitrogen and sulphur in water habitats [4,19,46,47,50]. Additionally, the presence of nitrate and phosphate in water has been shown to be important for fungal growth and the effective breakdown of long-chained components of plant material and other organic matter [59].

2.4. Number and Diversity of Fungi Depends on Organic Matter Originating from Natural and Anthropogenic Sources

The concentration of organic matter in water depends on the location and the surface area of water bodies [4,43–45]. Small surface water bodies or water with low flow receive the most of organic matter due to the plant vegetation, and larger water bodies and streams on high altitude are mainly supplied with organic matter due to the algal primary producers [4]. Surface water with slow flow close to the stream mouth are rich on nitrate, nitrite, phosphate and other products of organic material degradation, such as plant debris, lignin, hemicelluloses and cellulose [4,60]. Besides these, also human habitation may contribute to the water pollution with organic substances via fertilizers or industrial and household waste [61,62]. Consequently, surface water contains high biomass and rich

diversity of plant degrading filamentous fungi [63]. In Europe, the majority of the isolated fungal species from surface-, ground- and tap water belong to the ascomycetous genera *Alternaria*, *Aspergillus*, *Cladosporium*, *Fusarium*, *Gibberella*, *Penicillium*, *Phoma*, *Sarocladium*, *Scopulariopsis*, *Sporothrix*, *Talaromyces* and *Trichoderma*, but also fungi from subphylum Mucormycotina, such as *Absidia*, *Mortierella*, *Mucor*, *Rhizopus* and *Umbelopsis* were regularly isolated (Table 1). The presence of yeasts has been reported sporadically. Reports have been limited mainly to the genera of basidiomycetous yeasts *Cystobasidium*, *Naganishia* (former *Cryptococcus*) and *Rhodotorula* (Table 1) [8,20,64]. The presence of the human pathogen *Candida albicans* (Ascomycota) in surface water has been reported only once [17]. Among black yeast-like fungi only the plant-related species *Aureobasidium pullulans* has been isolated directly from surface water [20], while *Cyphellophora catalaunica*, *Exophiala aquamarina*, *E. lacus*, *E. oligosperma*, and *Rhinocladiella similis* were associated with river sediments [65].

In comparison to surface water, groundwater contains more inorganic ions, but usually lacks organic nutrients provided by plants and algae. Low amounts of organic nutrients are present mainly in the form of mono- or polysaccharides derived from the remains of bacterial biofilms [47,50]. Thus, the presence of fungi in groundwater associated with degradation of plant debris is limited or reported less often. On the other hand, oligotrophic conditions support growth of melanised fungi, such as *Aureobasidium melanogenum*, high diversity of *Exophiala* species and *Rhinocladiella similis* (Table 1) [9,11,19,23,26,66,67]. These species were regularly reported from different European countries from both ground- and tap water, but were rarely reported in a relation to surface water, pointing toward groundwater as the main source of contamination of tap water with these opportunistic pathogenic fungi (Table 1) [19].

Environmental water in areas with dense human population do not only contain high amounts of organic waste, but contain compounds of anthropogenic origin, such as organohalogens, pesticides, xenobiotics and long-chained aromatic hydrocarbons (benzene, toluene, ethylbenzene and xylene, known as BTEX) [68]. The later derive from crude oil and fuels, and are released in the environment by partial combustion of coal and other fuels, or accidental spills [68,69]. Although their presence may be toxic for most organisms, certain fungi assimilate them as a sole source of carbon [70,71]. Breaking down long-chained pollutants is a well documented feature of the black yeasts *Aureobasidium pullulans*, *Cladophialophora* spp., *Exophiala dermatitidis*, *E. jeanselmei*, *E. mesophila*, *E. oligosperma*, *E. xenobiotica*, *Graphium* sp., and *Rhinocladiella similis* [68]. Table 1 displayes also a wide range of filamentous fungi from the genera *Acremonium*, *Alternaria*, *Aspergillus*, *Beauveria*, *Chrysosporium*, *Cladosporium*, *Fusarium*, *Geomyces*, *Geotrichum*, *Gliocladium*, *Graphium*, *Paecilomyces*, *Penicillium*, *Scedosporium*, *Scopulariopsis*, *Sepedonium*, *Stachybotrys*, *Trichoderma*, and *Verticillium* [4,52,72,73] that exhibit the same ability (and have been detected in both, surface- and groundwater).

Particularly in closed surface water bodies with low flow rates the high concentration of organic nutrients and pollutants leads to an overgrowth of algae and bacteria, lowering the amount of oxygen [4]. Oxygen concentration decreases also with the depth in both, surface- and groundwater [52]. Since fungi are in general aerobic microorganisms, depletion of oxygen can negatively affect fungal biomass production in water systems with low oxygen concentrations [45]. However, some fungi do not only sustain the lack of oxygen, but also grow under anaerobic conditions by adaptation of their metabolism and growth form [4,74,75]. Species from the genera *Aspergillus*, *Nectria*, *Fusarium* and *Penicillium* growing as facultative anaerobes, using nitrate or nitrite as alternative terminal electron acceptors in the absence of oxygen, falling under this category [76,77]. Some *Mucor* species, for example, grow in hyphal networks in the presence of oxygen, but change to a yeast-like form under anaerobic conditions [78]. Similar situations were observed for species from the genera *Aureobasidium* and *Candida* [4,52]. Besides these, another important adaptation at low level of water and oxygen is the formation of buoyant conidia occurring in many water-related fungal species [4].

Table 1. Fungal genera and species isolated from groundwater, surface water, tap water and non-mineral bottled water reported in studies conducted in Europe during the last 30 years.

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Acremonium psammosporum	1	+	–	+	–	Germany	[11]
Acremonium spp.	1/2	+	+	+	–	Germany, Greece, Slovakia, France, Austria, Portugal, Norway, Belgium, Serbia, UK, Sweden, Hungary	[5–14,16,18,79]
Acrostalagmus luteoalbus	1	+	+	+	–	Germany, Serbia	[11,12]
Alternaria alternata	1	+	+	+	–	Austria, Portugal, Ukraine, Serbia, Slovenia, UK, Hungary	[9,12,14,15,17,79,80]
Alternaria atra	1	–	+	–	–	UK	[9]
Alternaria botrytis	1	–	–	+	–	UK	[9]
Alternaria infectoria	1	–	+	–	–	Portugal, UK	[9,15]
Alternaria spp.	1	+	–	+	–	Greece, Slovakia, Portugal, Norway, Hungary, Belgium, Spain, Germany, UK	[7–10,13,16,18,23,81,82]
Alternaria tenuissima	1	–	–	+	–	Hungary	[79]
Arthrinium phaeospermum	1	–	+	+	–	Norway, UK	[9,20]
Arthrobotrys spp.	1	+	–	–	–	Slovakia	[7]
Arthrographis spp.	1/2	–	–	+	–	Poland, Norway, UK	[9,10,66]
Ascochyta spp.	1	–	–	+	–	UK	[9]
Aspergillus aculeatus	1	–	+	–	–	UK	[9]
Aspergillus alliaceus	1	–	+	–	–	Portugal	[15]
Aspergillus brasiliensis	1	–	+	–	–	Portugal	[15]
Aspergillus calidoustus	1	–	+	+	–	Portugal, Norway	[18,20]
Aspergillus candidus	1	–	+	–	–	Serbia	[12]
Aspergillus carbonarius	1	–	–	+	–	Greece	[8]
Aspergillus chevalieri	1	–	+	–	–	Portugal	[15]
Aspergillus clavatus	1	+	+	+	–	Norway, UK	[9,20]
Aspergillus fischeri	1	–	–	+	–	Slovenia	[80]
Aspergillus flavus	2	+	+	+	–	Germany, Greece, Belgium, Serbia, UK	[8,9,11,12,16]
Aspergillus fumigatus	2	+	+	+	+	Germany, Greece, Poland, Hungary, Norway, Portugal, The Netherlands, Finland, Belgium, Serbia, UK	[8–12,15,16,18,20,28,66,83–85]
Aspergillus glaucus	1	–	–	+	–	Greece	[8]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Aspergillus inflatus	1	–	+	–	–	Norway	[20]
Aspergillus insuetus	1	+	–	–	–	Portugal	[18]
Aspergillus japonicus	1	–	+	–	–	UK	[9]
Aspergillus nidulans	1	–	–	+	–	Greece, Belgium	[8,16]
Aspergillus niger	1	+	+	+	–	Germany, Greece, Poland, Norway, Belgium, Ukraine, Serbia, UK, Portugal	[8–12,16–18,20,28]
Aspergillus ochraceus	1	–	–	+	–	Greece	[8]
Aspergillus ostianus	1	–	–	+	–	Greece	[8]
Aspergillus parasiticus	1	–	–	+	–	Greece, Poland	[8,28]
Aspergillus parvulus	1	–	–	+	–	UK	[9]
Aspergillus repens	1	+	–	–	–	Portugal	[18]
Aspergillus restrictus	1	+	–	+	–	Greece, The Netherlands	[8,85]
Aspergillus sydowii	1	–	+	+	–	Norway, Belgium	[16,20]
Aspergillus terreus	1	+	+	+	–	Greece, Austria, Portugal, Norway, UK	[8–10,14,15,18]
Aspergillus tubingensis	1	–	+	–	–	Portugal	[15]
Aspergillus ustus	1	+	+	+	–	Poland, Norway, Portugal, Serbia	[12,15,20,28]
Aspergillus versicolor	1	+	+	+	+	Germany, Poland, Serbia, Slovenia, UK	[9,11,12,28,80]
Aspergillus viridinutans	1	–	+	–	–	Portugal	[18]
Aspergillus spp.	1/2	+	–	+	–	Slovakia, France, Austria, Portugal, Norway, Spain, Slovenia, Hungary	[5,7,10,13,14,19,79,81]
Asteroma sp.	1	–	+	–	–	UK	[9]
Asteromella sp.	1	–	–	+	–	UK	[9]
Aureobasidium melanogenum	1	+	–	+	–	Slovenia	[19,67,80]
Aureobasidium pullulans	1	+	+	+	+	Greece, Norway, Austria, Ukraine, Serbia	[8,12,14,17,20,86]
Aureobasidium spp.	1	+	+	+	–	Slovakia, UK, Portugal, Hungary	[7,9,18,79]
Beauveria bassiana	1	+	+	+	–	Norway, Austria, UK, Portugal	[9,14,18,20]
Beauveria brongniartii	1	–	+	–	–	Norway, UK	[9,20]
Beauveria spp.	1	+	–	–	–	Slovakia	[7]
Bionectria ochroleuca	1	+	–	–	–	Portugal	[18]
Bionectria sp.	No data	+	–	–	–	Portugal	[18]
Bipolaris spp.	1/2	–	–	+	–	Greece	[8]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Biscogniauxia sp.	No data	–	+	–	–	Portugal	[18]
Bisifusarium dimerum	1	+	–	+	–	Norway, Slovenia	[19,20,67]
Boeremia exigua	1	–	–	+	–	UK	[9]
Botryotrichum spp.	1	+	–	–	–	Slovakia	[7]
Botrytis cinerea	1	–	+	+	–	Norway, Portugal, Serbia, UK	[9,12,15,20]
Botrytis elliptica	1	–	+	–	–	Norway	[20]
Byssochlamys lagunculariae	1	–	+	–	–	Norway	[20]
Cadophora luteo-olivacea	1	+	–	–	–	Germany	[23]
Cadophora malorum	1	+	+	+	–	Germany, Poland, Norway, Austria	[14,20,23,28]
Cadophora melinii	1	–	+	–	–	Norway	[20]
Candida albicans	2	–	+	–	–	Ukraine	[17]
Candida glaebosa	1	–	–	+	–	Slovenia	[67]
Candida intermedia	1	–	–	+	–	Poland, Slovenia	[66,67]
Candida orthopsilosis	2	–	–	+	–	Slovenia	[19]
Candida parapsilosis	2	+	–	+	–	Poland, Slovenia	[19,66,67]
Candida pararugosa	1	–	–	+	–	Slovenia	[19,67]
Candida pseudointermedia	1	–	–	+	–	Slovenia	[19]
Candida saitoana	1	–	–	+	–	Slovenia	[19]
Candida sake	1	–	+	–	–	Portugal	[15]
Candida sp.	No data	+	–	+	–	Portugal, Greece	[8,15]
Candida tropicalis	2	–	–	+	–	Greece	[8]
Candida versatilis	1	–	–	+	–	Poland	[66]
Capronia munkii	1	–	+	–	–	Portugal	[18]
Capronia pilosella	1	–	–	+	–	Germany	[23]
Capronia sp.	No data	–	–	+	–	Slovenia	[67]
Cephalosporium spp.	1/2	+	+	+	–	Slovakia, Portugal	[7,18]
Ceratocystis fimbriata	1	–	+	–	–	Norway	[20]
Chaetomium globosum	1	–	+	–	–	Norway, Serbia, UK	[9,12,20]
Chaetomium spp.	1	+	–	+	–	Greece, Norway, Portugal	[8,13,20]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Chalara sp.	No data	+	–	+	–	Germany	[11]
Chalaropsis spp.	1	+	–	–	–	Slovakia	[7]
Chrysosporium spp.	1	–	–	+	–	Greece	[8]
Chrysonilia sp.	No data	+	+	–	–	Norway	[20]
Cistella acuum	1	+	–	+	–	Austria	[14]
Cladosporium cladosporioides	1	+	+	+	–	Germany, Greece, Poland, Norway, Portugal, The Netherlands, Serbia, Slovenia, UK, Hungary	[8,9,11,12,15,18,20,23,28,79,80,85]
Cladosporium cucumerinum	1	–	+	–	–	Serbia	[12]
Cladosporium diaphanum	1	–	+	–	–	Serbia	[12]
Cladosporium halotolerans	1	+	+	+	–	Portugal, Germany	[15,18,23]
Cladosporium herbarum	1	+	+	+	–	Germany, Norway, Portugal, Serbia, UK	[9,11,12,15,20]
Cladosporium macrocarpum	1	–	+	–	–	Portugal	[18]
Cladosporium oxysporum	1	–	+	–	–	Serbia	[12]
Cladosporium pseudocladosporioides	1	–	–	+	–	Slovenia	[80]
Cladosporium sphaerospermum	1	–	+	+	–	Poland, Norway, UK	[9,20,28]
Cladosporium spp.	1	+	+	+	+	Greece, Slovakia, France, Austria, Portugal, Norway, Hungary, Belgium, Ukraine, Spain, UK	[5,7–10,13–18,81–84,87]
Cladosporium tenuissimum	1	–	+	–	–	Portugal	[15]
Cladosporium variabile	1	–	+	–	–	Serbia	[12]
Clavispora lusitaniae	1	–	–	+	–	Slovenia	[19]
Clethridium corticola	1	–	–	+	–	UK	[9]
Clonostachys candelabrum	1	–	+	+	–	Poland	[28]
Coniochaeta hoffmannii	1	+	+	+	–	Norway, Austria, Portugal	[14,18,20]
Coniochaeta velutina	1	–	+	–	–	Portugal	[18]
Coniothyrium olivaceum	1	–	+	+	–	UK	[9]
Cordyceps bassiana	1	+	–	+	–	Austria	[14]
Cosmospora arxii	1	+	–	+	–	Germany	[11]
Cosmospora berkeleyana	1	+	–	+	–	Germany	[11]
Cosmospora butyri	1	+	+	–	–	Norway	[20]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Cosmospora sp.	No data	–	+	–	–	Portugal	[15]
Curvularia spp.	1/2	+	–	+	–	Greece, Slovakia	[7,8]
Cyclothyrium sp.	No data	–	–	+	–	UK	[9]
Cylindrocarpon spp.	1/2	+	+	–	–	Slovakia, UK	[7,9]
Cyphellophora europaea	2	–	–	+	–	Germany	[23]
Cyphellophora reptans	1	+	–	+	–	Germany	[23]
Cyphellophora sessilis	1	+	–	+	–	Germany	[11,23]
Cytospora sp.	No data	–	+	+	–	UK	[9]
Dactylaria spp.	1/2	+	–	+	–	Slovakia, Austria	[7,14]
Dactylella spp.	1	+	–	+	–	Slovakia	[7]
Debaryomyces hansenii	1	–	–	+	+	Poland, Slovenia, France	[5,19,66]
Didymella molleriana	1	+	+	+	–	Norway, Austria, Portugal	[14,15,18,20]
Didymella musae	1	–	+	+	–	UK	[9]
Diplocladium spp.	No data	+	–	–	–	Slovakia	[7]
Discosporium sp.	No data	–	–	+	–	UK	[9]
Doratomyces spp.	1	–	–	+	–	Greece	[8]
Embellisia sp.	No data	–	+	–	–	UK	[9]
Emmonsia spp.	1/2	–	–	+	–	Greece	[8]
Epicoccum nigrum	1	+	+	+	–	Norway, Austria, UK, Serbia	[9,12,14,20]
Epicoccum spp.	1	–	–	+	–	Greece	[8]
Eupenicillium sp.	No data	–	–	+	–	UK	[9]
Eurotium spp.	1	–	–	+	–	Greece	[8]
Exophiala alcalophila	1	–	–	+	–	Slovenia, Germany	[19,23,67]
Exophiala angulospora	1	+	–	+	–	Germany	[11,23]
Exophiala cancerae	1	–	–	+	–	Germany	[23]
Exophiala castellanii	2	+	–	+	–	Germany, Poland	[11,23,66]
Exophiala dermatitidis	2	+	–	+	–	Slovenia	[19,67]
Exophiala equina	1	+	–	+	–	Germany	[23]
Exophiala jeanselmei	2	–	–	+	–	Poland, UK	[9,66]
Exophiala lecanii-corni	1	–	–	+	–	Slovenia, Germany	[19,23,67]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Exophiala mesophila	1	+	–	+	–	Slovenia, Germany	[19,23]
Exophiala oligosperma	2	+	–	+	–	Slovenia, Germany	[19,23]
Exophiala opportunistica	1	–	–	+	–	Germany	[23]
Exophiala phaeomuriformis	2	–	–	+	–	Slovenia, Germany	[19,23,67]
Exophiala pisciphila	1	+	–	+	–	Germany	[11]
Exophiala psychrophila	1	+	–	+	–	Germany	[23]
Exophiala salmonis	1	+	–	+	–	Germany	[23]
Exophiala spinifera	2	–	–	+	+	Poland	[66]
Exophiala spp.	1/2	+	–	+	–	Germany, Greece	[8,11]
Exophiala xenobiotica	1	+	–	+	–	Slovenia, Germany	[19,23]
Fusarium begoniae	1	–	+	–	–	Portugal	[15]
Fusarium culmorum	1	–	+	+	–	Serbia, UK	[9,12]
Fusarium flocciferum	1	–	+	–	–	UK	[9]
Fusarium foetens	1	–	+	–	–	Portugal	[18]
Fusarium incarnatum	1	–	+	–	–	Serbia	[12]
Fusarium oxysporum	2	+	+	+	–	Norway, Serbia, UK	[9,12,20]
Fusarium solani	2	+	+	+	–	Germany, Greece, Poland, Serbia, UK	[8,9,11,12,28]
Fusarium sporotrichioides	1	–	+	–	–	Serbia	[12]
Fusarium spp.	1/2	+	+	+	+	Germany, Slovakia, Austria, Portugal, Norway, Belgium, Ukraine, Spain, Hungary, UK	[7,9–11,14–18,79,81,84,87]
Fusarium torulosum	1	–	+	–	–	UK	[9]
Fusicolla aquaeductuum	1	–	–	+	–	UK	[9]
Fusicolla merismoides	1	+	–	+	–	Germany	[11]
Galactomyces geotrichum	1	–	+	+	–	Slovenia, Portugal, Poland, Serbia, UK	[9,12,18,19,28,67]
Geomyces sp.	No data	+	–	+	–	Germany	[11]
Geotrichum spp.	1/2	+	+	+	–	Slovakia, Norway, Hungary	[7,20,79]
Gibberella avenacea	1	–	+	+	–	UK	[9]
Gibberella fujikuroi	1	–	+	–	–	UK	[9]
Gibberella gordonii	1	–	+	–	–	Serbia	[12]
Gibberella intricans	1	–	+	–	–	UK	[9]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Gliocladium spp.	1	+	+	+	–	Greece, Slovakia, UK, Hungary	[7–9,79]
Graphium silanum	1	+	–	+	–	Austria	[14]
Hormiscium spp.	1/2	+	–	+	–	Slovakia	[7]
Hyphopichia burtonii	1	–	+	–	–	Portugal	[15]
Humicola grisea	1	–	–	+	–	Hungary	[79]
Isaria farinosa	1	+	+	+	–	Germany, Norway, Serbia	[11,12,20]
Issatchenkia orientalis	1	–	–	+	–	Poland	[66]
Kloeckera spp.	1	+	–	+	–	Greece, Portugal	[8,15]
Kluyveromyces lactis	1	–	–	+	–	Poland	[66]
Kluyveromyces marxianus	1	–	–	+	–	Poland	[66]
Lecanicillium lecanii	1	+	+	+	–	Germany, Poland, Norway	[11,20,28]
Leptodontidium sp.	No data	–	–	+	–	UK	[9]
Leptosphaeria sp.	No data	+	+	+	–	Austria, UK	[9,14]
Leucostoma persoonii	1	–	+	–	–	Norway	[20]
Mauginiella sp.	No data	–	–	+	–	UK	[9]
Melanospora simplex	1	–	+	+	–	Poland	[28]
Metarhizium carneum	1	+	+	–	–	Norway	[20]
Meyerozyma caribbica	1	–	–	+	–	Slovenia	[19,67]
Meyerozyma guilliermondii	1	–	–	+	–	Slovenia	[19]
Microdochium sp.	No data	+	–	+	–	Austria	[14]
Microsphaeropsis sp.	No data	–	+	–	–	UK	[9]
Microsporum spp.	1/2	–	–	+	–	Slovakia	[7]
Monascus ruber	1	–	+	–	–	Norway	[20]
Monilia spp.	1/2	+	–	+	–	Slovakia, Belgium	[7,16]
Nakazawaea holstii	1	–	+	–	–	Portugal	[15]
Neurospora sp.	No data	–	+	–	–	UK	[9]
Ochroconis musae	1	–	–	+	–	Germany	[23]
Ochroconis sp.	1	+	–	+	–	Germany	[11]
Oosporidium margaritiferum	1	–	–	+	–	Poland	[66]
Paecilomyces spp.	1	+	–	+	+	Slovakia, Austria, Norway, Belgium, Spain, Poland	[7,10,14,16,66,81]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Paecilomyces variotii	1	+	+	+	–	Norway, Austria, Greece	[8,14,20]
Papulaspora sp.	No data	+	–	+	–	Slovakia	[7]
Paraconiothyrium sp.	No data	–	+	–	–	Portugal	[15]
Paraphaeosphaeria minitans	1	–	+	–	–	Potugal	[18]
Paraphaeosphaeria sporulosa	1	–	+	–	–	Portugal	[15]
Paraphoma fimeti	1	+	–	+	–	Germany	[23]
Paspalomyces sp.	No data	+	–	+	–	Slovakia	[7]
Penicillium atrofulvum	1	–	+	–	–	Portugal	[18]
Penicillium aurantiogriseum	1	–	+	+	–	UK, Portugal	[9,15]
Penicillium brevicompactum	1	+	+	+	–	Germany, Norway, Portugal, UK	[9,11,13,18,20]
Penicillium canescens	1	–	+	–	–	Norway, Portugal, Serbia	[12,15,18,20]
Penicillium chrysogenum	1	+	+	+	+	Germany, Norway, Serbia, Slovenia, UK, Hungary	[9,11,12,20,80,84]
Penicillium citrinum	1	–	+	+	–	Norway, Portugal, UK	[9,15,18,20]
Penicillium corylophilum	1	+	+	+	–	Portugal, UK	[9,13,18]
Penicillium dierckxii	1	–	+	–	–	Portugal, Norway	[15,18,20]
Penicillium digitatum	1	–	+	–	–	Portugal	[18]
Penicillium echinulatum	1	–	+	–	–	UK	[9]
Penicillium expansum	1	–	+	+	–	Norway, Portugal, UK	[9,13,18,20]
Penicillium glabrum	1	+	+	+	+	Germany, Norway, Portugal, UK, France, Poland	[9,11,13,15,18,20,28,88]
Penicillium griseofulvum	1	–	+	+	–	Portugal, Serbia, UK	[9,12,13,15,18]
Penicillium hirsutum	1	–	–	+	–	UK	[9]
Penicillium implicatum	1	–	+	–	–	Norway, Portugal	[15,20]
Penicillium janczewskii	1	–	+	+	–	Norway, UK	[9,20]
Penicillium jensenii	1	–	+	–	–	Norway	[20]
Penicillium lanosum	1	–	+	–	–	Norway	[20]
Penicillium megasporum	1	–	+	–	–	Norway	[20]
Penicillium melanoconidium	1	–	+	–	–	Portugal	[15]
Penicillium melinii	1	–	+	–	–	Norway	[20]
Penicillium miczynskii	1	–	+	–	–	Norway	[20]
Penicillium montanense	1	+	+	–	–	Norway	[20]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Penicillium novae-zeelandiae	1	–	+	–	–	Portugal	[18]
Penicillium ochrochloron	1	–	+	–	–	Portugal	[15]
Penicillium ochrosalmoneum	1	–	–	+	–	UK	[9]
Penicillium olsonii	1	–	+	–	–	Norway, Portugal	[18,20]
Penicillium oxalicum	1	–	+	–	–	Norway	[20]
Penicillium pancosmium	1	–	+	–	–	Portugal	[18]
Penicillium paxilli	1	–	+	–	–	Norway	[20]
Penicillium phoeniceum	1	–	+	–	–	Norway	[20]
Penicillium purpurogenum	1	–	+	+	–	Norway, UK	[9,20]
Penicillium raistrickii	1	–	+	+	–	Norway, Portugal, UK	[9,13,15,20]
Penicillium resedanum	1	–	+	–	–	Serbia	[12]
Penicillium restrictum	1	–	+	–	–	Norway, Portugal	[15,18,20]
Penicillium roseopurpureum	1	–	+	–	–	Norway	[20]
Penicillium sanguifluum	1	–	+	–	–	Portugal	[18]
Penicillium scabrosum	1	–	+	–	–	Portugal	[15]
Penicillium simplicissimum	1	–	+	–	–	Norway, UK, Portugal	[9,18,20]
Penicillium solitum	1	–	+	+	–	Norway, UK, Portugal	[9,13,15,18,20]
Penicillium spinulosum	1	+	+	+	–	Norway, UK	[9,20]
Penicillium spp.	1/2	+	+	+	+	Germany, Greece, Slovakia, France, Austria, Norway, Belgium, Ukraine, Spain, Sweden, Portugal, Hungary	[5–8,10,11,14,16,17,79,81,87]
Penicillium thomii	1	–	+	–	–	Norway, Portugal, Serbia	[12,15,20]
Penicillium verrucosum	1	+	+	–	–	Norway, Serbia	[12,20]
Penicillium virgatum	1	–	+	–	–	Portugal	[18]
Penicillium waksmanii	1	–	+	+	–	Portugal, UK	[9,13]
Penicillium westlingii	1	–	+	–	–	Norway	[20]
Phaeosphaeria juncophila	1	+	–	+	–	Austria	[14]
Phialemonium sp.	No data	–	+	–	–	Portugal	[18]
Phialocephala dimorphospora	1	–	–	+	–	Germany	[23]
Phialophora cyclaminis	1	–	+	–	–	Norway	[20]
Phialophora fastigiata	1	+	+	+	–	Italy, Germany, Norway, UK	[9,20,23,89]
Phialophora spp.	1/2	+	–	+	–	Germany, Greece, Slovakia, Austria, Portugal, Sweden	[6–8,11,13,14]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Phialophora verrucosa	2	–	+	–	–	Norway	[20]
Phoma herbarum	1	+	+	+	–	Germany, Serbia	[11,12]
Phoma leveillei	1	+	+	+	–	Germany, Italy, UK	[9,11,89]
Phoma macrostoma	1	–	+	+	–	UK	[9]
Phoma medicaginis	1	–	+	+	–	Serbia, UK	[9,12]
Phoma sp.	No data	+	+	+	–	Poland, Norway, Portugal, Serbia	[10,12,15,20,28]
Phomatodes nebulosa	1	–	–	+	–	UK	[9]
Phomopsis spp.	1	+	–	+	–	Austria, UK	[9,14]
Pichia fermentans	1	–	–	+	–	Slovenia	[19]
Pichia membranifaciens	1	–	–	+	–	France, Greece	[5,8]
Pilidium concavum	1	+	+	+	–	UK, Portugal	[9,18]
Priceomyces carsonii	1	–	–	+	–	Poland	[66]
Prosthecium pyriforme	1	+	–	–	–	Portugal	[18]
Pseudeurotium hygrophilum	1	–	+	–	–	UK	[9]
Pseudogymnoascus pannorum	1	–	+	–	–	Norway	[20]
Pseudogymnoascus roseus	1	–	+	–	–	Norway	[20]
Pseudopithomyces sacchari	1	–	+	–	–	UK	[9]
Purpureocillium lilacinum	1	+	+	+	–	UK, Portugal, Poland, Norway, Italy	[9,18,20,28,89]
Pyrenochaeta spp.	1/2	–	+	+	–	Greece, Italy, UK	[8,9,89]
Pyrenochaeta unguis-hominis	2	–	–	+	–	Germany	[23]
Rhinocladiella similis	2	+	–	+	–	Slovenia, Germany	[19,23,67]
Saccharomycopsis capsularis	1	–	–	+	–	Poland	[66]
Saprochaete suaveolens	1	–	–	+	–	Poland	[66]
Sarocladium kiliense	2	–	+	+	–	Poland, UK	[9,66]
Sarocladium strictum	1	+	+	+	–	Germany, Italy, Norway, Serbia	[11,12,20,89]
Sarocladium terricola	1	–	+	+	–	Serbia, Poland	[12,28]
Sclerotinia sclerotiorum	1	–	–	+	–	Poland	[28]
Scopulariopsis acremonium	1	–	+	–	–	UK	[9]
Scopulariopsis brevicaulis	2	–	+	+	–	Greece, Norway, UK	[8,9,20]
Scopulariopsis fusca	1	–	+	+	–	Poland	[20,66]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Scopulariopsis spp.	1/2	–	–	+	–	Greece	[8]
Sepedonium spp.	1	–	–	+	–	Greece, Norway	[8,10]
Sporothrix spp.	1/2	–	+	+	–	UK	[9]
Stachybotrys chartarum	1	+	+	+	–	Poland, Portugal	[18,28]
Stachybotrys spp.	1	+	–	+	–	Greece, Slovakia	[7,8]
Staphylotrichum sp.	No data	–	+	–	–	Norway	[20]
Stemphylium sp.	No data	+	–	+	–	Slovakia	[7]
Stephanoma strigosum	1	–	–	+	–	Hungary	[79]
Sydowia polyspora	1	–	–	+	–	UK	[9]
Talaromyces funiculosus	1	–	+	–	–	Serbia	[12]
Talaromyces minioluteus	1	–	–	+	–	UK	[9]
Talaromyces pinophilus	1	–	–	+	–	UK	[9]
Talaromyces ruber	1	–	+	+	–	Poland	[28]
Talaromyces rugulosus	1	–	–	–	+	Poland	[66]
Talaromyces verruculosus	1	–	–	+	–	Slovenia	[67]
Trichoderma asperellum	1	–	+	–	–	Portugal	[18]
Trichoderma citrinoviride	1	–	+	+	–	Slovenia, Portugal	[18,80]
Trichoderma harzianum	1	+	+	+	–	Portugal, UK	[9,15,18]
Trichoderma koningii	1	–	+	+	–	Serbia, UK, Portugal	[9,12,18]
Trichoderma longibrachiatum	1	–	–	–	+	Poland	[66]
Trichoderma pleuroticola	1	–	+	–	–	Portugal	[18]
Trichoderma polysporum	1	–	+	+	–	UK	[9]
Trichoderma pseudokoningii	1	–	+	+	–	UK	[9]
Trichoderma spp.	1	+	+	+	–	Greece, Slovakia, Norway, France, Austria, Belgium, Spain, Serbia, Hungary	[5,7,8,10,12,14,16,20,79,81]
Trichoderma viride	1	+	+	+	–	Poland, Austria, Ukraine, Serbia	[12,14,17,28]
Trichomonascus ciferrii	1	–	–	+	–	Greece	[8]
Trichothecium sp.	No data	+	–	+	–	Greece, Slovakia, Hungary	[7,8,79]
Trichophyton sp.	No data	+	–	+	–	Slovakia	[7]
Tritirachium sp.	No data	+	–	+	–	Slovakia	[7]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Ascomycota (phylum)							
Truncatella angustata	1	–	+	–	–	UK	[9]
Varicosporium spp.	1	+	–	–	–	Slovakia	[7]
Verticillium spp.	1	+	–	+	–	Greece, Slovakia, UK, Hungary	[7–9,79]
Volutella sp.	No data	+	–	+	–	Germany	[11]
Westerdykella dispersa	1	–	+	–	–	UK	[9]
Wickerhamomyces anomalus	1	–	–	+	–	Poland	[66]
Yarrowia lipolytica	1	–	–	+	–	Slovenia	[19]
Basidiomycota (phylum)							
Apiotrichum montevideense	1	–	–	+	–	Slovenia	[19,67]
Cryptococcus sp.	No data	–	+	–	–	Portugal	[15]
Cystobasidiopsis lactophilus	1	–	–	+	–	Poland	[66]
Cystobasidium minuta	1	–	+	+	–	France, Portugal	[5,15]
Cystobasidium slooffiae	1	–	–	+	–	Slovenia	[19,67]
Cystofilobasidium lari-marini	1	–	–	+	–	Poland	[66]
Filobasidium magnum	1	–	–	–	+	Norway	[86]
Naganishia albida	1	–	+	–	–	Portugal	[15]
Rhizoctonia spp.	1	+	–	–	–	Slovakia	[7]
Rhodotorula glutinis	1	–	+	+	–	France, Ukraine	[5,17]
Rhodotorula mucilaginosa	1	+	–	+	–	Slovenia	[19,67]
Rhodotorula spp.	1	+	+	+	–	Germany, Greece, Poland, Austria, Portugal	[8,11,14,15,66]
Schizophyllum commune	1	–	–	+	–	Slovenia	[67]
Sporidiobolus salmonicolor	1	+	–	–	–	Slovenia	[19]
Sporobolomyces japonicus	1	–	–	+	–	Poland	[66]
Sporobolomyces ruberrimus	1	–	–	+	–	Slovenia	[80]
Sporotrichum spp.	1/2	+	+	–	–	Slovakia, UK	[7,9]
Stereum sp.	No data	–	–	+	–	UK	[9]
Tilletiopsis sp.	No data	+	–	+	–	Germany	[11]
Trametes versicolor	1	+	–	+	–	Austria	[14]
Trichosporon coremiiforme	1	+	–	–	–	Slovenia	[19]
Triodiomyces crassus	1	–	–	+	–	Slovenia	[19,67]

Table 1. *Cont.*

Fungal Species	BSL *	Water Type				Country	Reference
		Ground Water	Surface Water	Tap Water	Non-Mineral Bottled Water		
Mucoromycotina (subphylum)							
Absidia cylindrospora	1	–	+	+	–	Norway, UK	[9,20]
Absidia glauca	1	–	+	+	–	Norway, UK	[9,20]
Absidia spp.	1/2	+	–	+	–	Slovakia, Spain	[7,81]
Chaetocladium brefeldii	1	–	+	–	–	UK	[9]
Cunninghamella elegans	1	–	+	–	–	Portugal	[18]
Gongronella butleri	1	–	+	–	–	UK	[9]
Lichtheimia corymbifera	2	–	+	–	–	Norway	[20]
Mortierella alpina	1	–	+	–	–	UK	[9]
Mortierella elongata	1	–	+	–	–	UK	[9]
Mortierella zychae	1	–	–	+	–	UK	[9]
Mucor azygosporus	1	–	+	–	–	Norway	[20]
Mucor circinelloides	1	–	+	+	–	Norway, UK	[9,20]
Mucor fuscus	1	–	+	–	–	UK	[9]
Mucor hiemalis	1	–	+	+	–	Norway, Serbia, UK	[9,12,20]
Mucor moelleri	1	–	+	–	–	UK, Portugal	[9,18]
Mucor mucedo	1	–	–	+	–	Greece	[8]
Mucor plumbeus	1	–	+	+	–	Norway, UK	[9,20]
Mucor racemosus	1	–	+	+	–	Portugal, UK	[9,15,18]
Mucor spp.	1/2	+	+	+	–	Germany, Slovakia, France, Norway, Spain, Serbia, Hungary	[5,7,10–12,18,79,81]
Mucor strictus	1	–	+	+	–	UK	[9]
Rhizomucor spp.	1/2	–	–	+	–	Norway	[10]
Rhizopus arrhizus	1	–	+	–	–	Ukraine	[17]
Rhizopus spp.	1/2	–	–	+	–	Greece, Slovakia, France, Norway, Spain	[5,7,8,10,81]
Rhizopus stolonifer	1	–	+	+	–	Portugal, UK, Serbia	[9,12,13]
Syncephalastrum racemosum	1	–	–	+	–	UK	[9]
Umbelopsis isabellina	1	–	+	–	–	UK	[9]
Umbelopsis ramanniana	1	–	+	+	–	UK	[9]

Legend: * BSL: Biosafety level; +: fungi were present in the water samples; –: fungi were absent from the water samples. Taxonomical data and data on Biosafety level were obtained from Centraalbureau voor Schimelcultures, Utrecht, The Netherlands (CBS), Index Fungorum and MycoBank databases.

2.5. Effect of Sunlight and Water Temperature on Fungi in the Natural Environment

Not only chemical processes, but also physical factors contribute to fungal presence in raw water sources. The most important may be the effect of sun irradiation and consequently changes in the water temperature. The effect of sunlight irradiation is stronger in high altitude areas and in low flow surface water [2]. It consists of infra-red, ultra-violet (UV) and visible spectre of the light; among those, the effect of the UV-radiation causes the highest damage of cell mechanisms and is thus the most studied [90]. Natural solar disinfection is a proven technique for generating safer drinking water, particularly by inactivation of faecal bacteria [91,92]. However, the effect on fungi is not well documented. Tests with simulated solar disinfection successfully lowered the number of the species *Alternaria alternata*, *Fusarium equiseti*, *F. oxysporum*, *F. solani*, *F. verticillioides* and *Candida albicans* in water samples [92–95], while fungi with melanised cell walls were less susceptible [2]. The effect of solar UV-radiation varies with the time of the day, is lower during cloudy days, in large volumes of water, and in water with high contents of organic matter with increased turbidity [95,96]. Together with the DNA-damaging effect of UV-radiation, solar disinfection contributes also to the thermal disinfection with raising the water temperature [92]. The water temperature depends also on the depth, volume, and flow rate (higher effect in shallow waters with low flow rates) [95]. Normally, temperatures of running surface water in temperate climate are below optimal growth temperatures of most water-related fungi, with growth peaks between 15 °C and 25 °C, but may vary over the seasons [97]. Also the structure of fungal communities in surface water is not stable [52], with a higher content of thermotolerant *Aspergillus* and *Phialophora* species and yeasts [11] during the summer, being replaced by filamentous fungi from the genera *Acremonium*, *Cladosporium* and *Penicillium* during the cold seasons [13,98,99].

Abiotic and biotic conditions in natural water habitats play an important role for the presence and diversity of fungi. Although being still largely unexplored, the above-described factors have an influence on the water quality in natural environments and as such, they need to be taken into consideration during the processes of tap water production (Figure 1).

2.6. Effect of Drinking Water Treatment Processes on Fungal Contaminants

Until the end of the 19th century, water for human consumption was derived to the public either from groundwater, or rivers and springs upstream of habitation [42]. With the concentration of growing populations in large areas and cities, supplying clean water became a problem, resulting in major cholera outbreaks in Europe [42]. After the expanding knowledge in microbiology, contaminated water became connected with water-borne and faecal-borne diseases, and the first water treatment practices (first mechanical sand filtration, then coagulation-sedimentation processes) were implemented [42]. Shortly after, Robert Koch showed for the first time that chlorine is effective against *Vibrio cholerae* and other waterborne bacteria [100]. Today, the water industry is using a combination of techniques to provide pathogen-free drinking water (Figure 1). Chlorine, introduced with the beginning of the 20th century, is still the most common disinfectant [42].

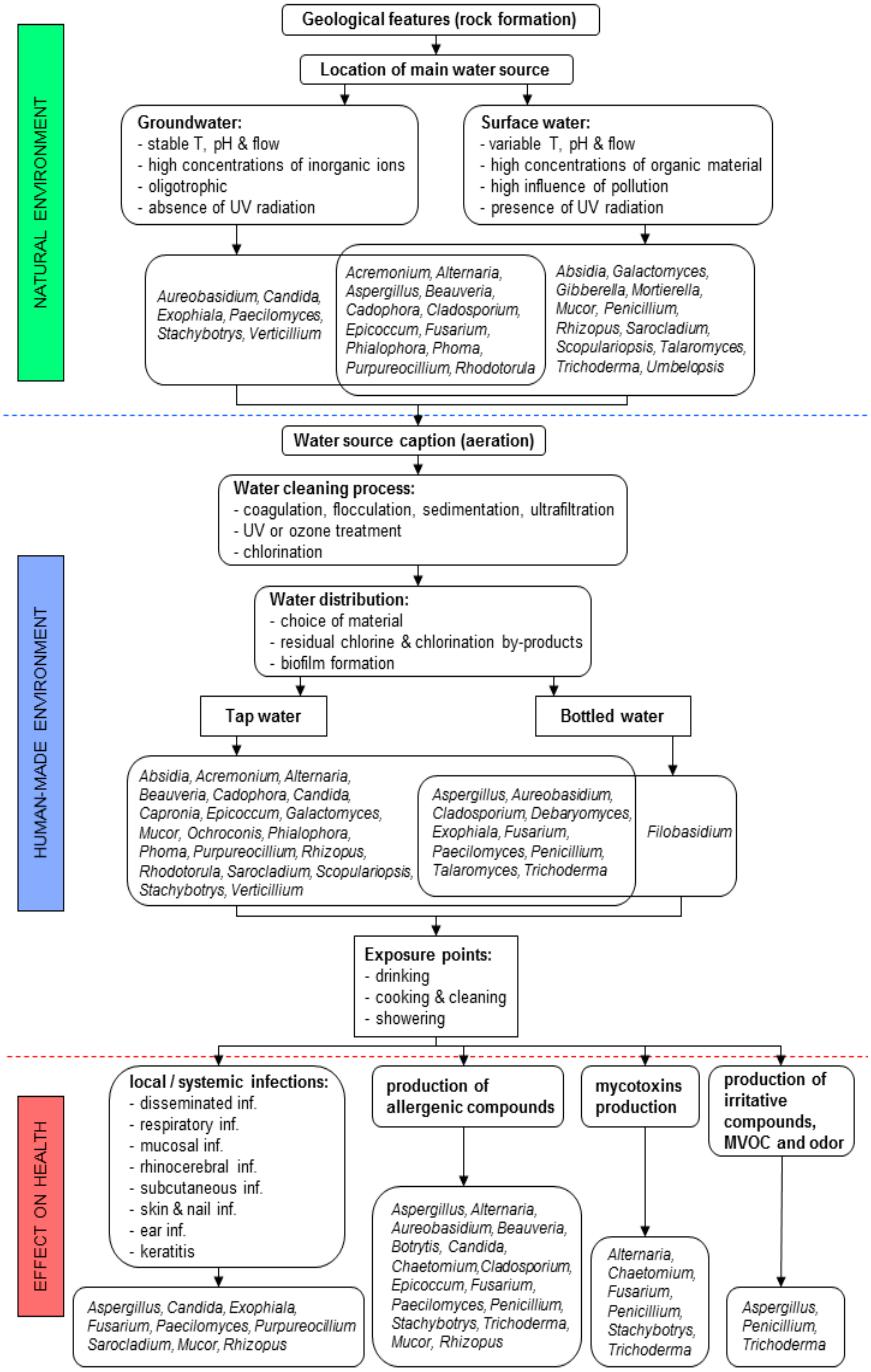

Figure 1. Abiotic, biotic and anthropogenic factors influencing fungal presence in groundwater, surface water, tap water and non-mineral bottled water, with possible effect of fungi on human health via different exposure points. The most common factors having an influence on the fungal presence and diversity in different water sources divided into factors influencing fungal presence, mainly in raw water sources in the natural environment (indicated with green colour), anthropogenic factors influencing fungal presence during production of tap and non-mineral bottled water, and exposure points of fungi via water-related activities (indicated with blue colour). Red colour indicates the most frequently detected fungal genera from tap and bottled water with their possible effects on human health.

Figure 1. Abiotic, biotic and anthropogenic factors influencing fungal presence in groundwater, surface water, tap water and non-mineral bottled water, with possible effect of fungi on human health via different exposure points. The most common factors having an influence on the fungal presence and diversity in different water sources divided into factors influencing fungal presence, mainly in raw water sources in the natural environment (indicated with green colour), anthropogenic factors influencing fungal presence during production of tap and non-mineral bottled water, and exposure points of fungi via water related activities (indicated with blue colour). Red colour indicates the most frequently detected fungal genera from tap and bottled water with their possible effects on human health.

The first step in the process of raw water purification starts with aeration in reservoirs for the removal of volatile compounds and gases from raw water sources [22]. The most commonly

used technique is cascade aeration. During the process, air is blown and mixed into the water [22]. An alternative technique is the use of compressed air, introduced into water through a system of perforated pipes, which is generally used for the removal of iron and manganese [22]. However, air based treatment steps are one of the possible contamination sources by airborne fungal particles. The nest step is usually coagulation of the suspended particles by adding chemical agents (coagulants) [22]. After adding coagulants both the visible particles and microorganisms combine into larger flocks, which sediment and are then removed by filtration [22]. The process usually removes cysts of protozoa (e.g., *Giardia* spp.), as well as most other microorganisms and some viruses [101]. The most commonly used coagulants are aluminium and iron salts (aluminium sulphate, ferric sulphate, ferric chloride), which act primarily by changing the pH of water to less alkaline values. They may be used together with positively charged polymers, or alternatively be replaced by negatively charged organic polymers, often used in a combination with metal coagulants [102]. Larger flocks sediment whereas smaller flocks are removed by filtration, with cellulose, sand, charcoal or fabrics filters [22,103]. Primary filtration may be replaced or followed by ultrafiltration or microfiltration [22]. The process can be combined with active carbon for the adsorption and removal of dissolved small organic molecules, such as trihalomethanes and pesticides [22,103]. These methods have different effects on microorganisms, and can be used against them with different degrees of efficiency. Data available generally cover various microorganisms causing enteric diseases but no fungi. Coagulation, flocculation and sedimentation may remove approximately 30% of bacteria, 30–70% of viruses and 30–99.99% of protozoa. The efficacy depends on the coagulants used, pH, temperature and turbidity of water [22]. Efficacy of filtration depends on the pre-treatment and the used membranes, thus the removal may vary between 30% and 99.99% for bacteria, 50–99.99% for protozoa and 20–99% for viruses [22]. The WHO does not report any values for fungi, however, it has been shown that sand filtration may remove between 8% and 90% of fungi, coagulation process 54%, and the sedimentation process 70% [83,104]; none remove 100%. Not all treatment steps are used always; the quality of the saource water will determine the process.

Water after filtration is usually still not suitable for human consumption, thus additional disinfection is needed. Disinfection is, depending on the site of action, divided into primary and secondary. Primary disinfection destroys microorganisms in the raw water stored in reservoirs. Secondary or residual disinfection inhibits the growth of microorganisms in the water supply network [105]. The choice of disinfection methods depends on the water quality after treatment, availability of materials and cost. UV-radiation is commonly used in smaller facilities [2,22]. UV disinfection is carried out without addition of any substances to the water, and therefore does not leave toxic by-products. Its biocidal effect is reached between 180 nm and 320 nm and is also highly dependent on the water turbidity (dissolved organic particles), water flow, and on pigmentation of the cells and spores [2,22,106,107]. According to WHO a 99% reduction may be achieved under a dosage of 7 mJ/cm^2 for bacteria, between 5 mJ/cm^2 and 10 mJ/cm^2 for protozoa and 59 mJ/cm^2 for viruses [22]. A fungicidal effect on single strains of yeasts, such as *Candida albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis* and *C. tropicalis*, was achieved after 10–45 min at the wavelength of 254 nm. To achieve the effect with the same wavelength for filamentous fungi, such as *Aspergillus fumigatus*, *A. niger*, *Microsporum canis* and *Trichophyton rubrum*, 75 min of exposure were required [90,106].

Primary disinfection of water may also be achieved also with the ozonation. Ozone, as a strong oxidizing agent has many advantages, such as oxidation of inorganic and organic chemicals increasing their biodegradability and removing the colour, smell and taste from water [2,22]. Under proper dosage and contact time it does not leave any by-products, though under some conditions, mutagenic and carcinogenic by-products may be generated (e.g., bromate) [108]. Ozone-enriched air is introduced directly into water in contractor tanks, providing between 10 min and 20 min of contact time [22]. Effect of ozonation against viruses, bacteria and protozoa is better at slightly acidic pH (6–7) and temperatures between 15 °C and 20 °C [22]. Ozonation proved to be effective against different fungi and their spores. Tested species included single strains of *Aspergillus brasiliensis*, *A. flavus*, *A. fumigatus*,

A. niger, *Candida albicans*, *C. parapsilosis* and *Fusarium oxysporum* complex [109–115]. Although used as an alternative for chemical disinfection, UV and ozone disinfection do not provide residual effect and are usually combined with a chlorination process.

Chlorination is used for primary and secondary microbial disinfection of water. The most widely used forms of chlorine for water disinfection are chlorine gas or hypochlorite in the form of powder as calcium hypochlorite ($Ca(OCl)_2$) or as liquid sodium hypochlorite (NaOCl). Both are suitable for the disinfection of water with a low content of organic substances. Chlorine dioxide is used when better penetration into the biofilms formed on the walls of pipelines and tanks is needed [42,116]. Optimal disinfection with chlorine and its derivatives is usually achieved at temperatures between 15–20 °C and pH between 7.0 and 7.5. Additionally, water should contain the least possible amount organic material, iron, manganese and ammonia, due to chlorine reactions with these agents, lowering its residual effect [22,42]. The free chlorine concentration in chlorination tanks must reach >0.5 ppm, with the contact time being at least 30 min to inactivate bacteria and protozoa [42]. For the proper residual effect, final concentrations of free chlorine in the water supply network must be between 0.3 mg/L and 0.5 mg/L [42]. During the chlorination process, aqueous chlorine reacts with ammonia and forms chloramines. These exist in the form of mono-, di- and trichloramines, but only monochloramine has useful disinfection effect. Although it is less effective against microbes than free chlorine, it is persistent and provides a stable residual effect through the water supply network [22,42]. While both free chlorine and monochloramine have a known effect on viruses, bacteria and protozoa [22], little is known about their effect on fungi. A variety of fungal species belonging to the genera *Acremonium*, *Alternaria*, *Aspergillus*, *Aureobasidium*, *Beauveria*, *Botrytis*, *Candida*, *Chaetomium*, *Cladosporium*, *Epicoccum*, *Exophiala*, *Fusarium*, *Geotrichum*, *Gliocladium*, *Mortierella*, *Mucor*, *Naganishia*, *Ochroconis*, *Paecilomyces*, *Penicillium*, *Phoma*, *Rhizopus*, *Rhodotorula*, *Sarocladium*, *Sporotrichum*, *Sporothrix*, *Stachybotrys* and *Trichoderma* have been cultivated from chlorinated water, pointing out possible resistance to the regular chlorination process (Table 1) [2]. However, tested free-chlorine concentrations between 1 ppm and 2 ppm in 97–99% inactivated single strains of *Trichoderma harzianum*, *Epicoccum nigrum* and *Aspergillus niger* after the exposure time of 60, 40 and 10 min, respectively [117]. A recent study, conducted by Pereira et al. [118] showed that single strains of the filamentous fungi *Aspergillus fumigatus*, *A. terreus*, *Cladosporium cladosporioides*, *C. tenuissimum*, *Penicillium citrinum*, *P. griseofulvum* and *Phoma glomerata* were more resistant to chlorination than viruses and bacteria and less resistant than protozoan oocysts. The study also confirmed slightly acidic pH and temperatures ~20 °C as the best chlorination conditions for fungal inactivation [118].

2.7. Materials Used for Building Water Supply Networks and Their Effect on Biofilm Formation

Following chemical disinfection, the quality of water is checked, and if suitable for drinking, it is delivered to consumers via water supply networks. The network pipe systems are built of different materials and they may interact with residual chlorine and chlorination by-products. They may influence microbiological quality of water as well, due to possible biofilm formation [2]. The European Union (EU) does not have a unified approach for materials and products in contact with drinking water. Thus, in 2011, four member states (4 MS; France, Germany, The Netherlands and the United Kingdom) standardized procedures for the approval of materials and products for water supply systems [119,120]. In 2012 Belgium also issued independently a document for acceptance of materials in contact with drinking water [121], while some countries like Portugal and Slovenia mainly follow the requirements set by 4MS [120]. They include lists of allowed composition for cement and its additives, organic materials (e.g., polyethylene (PE) and its derivates—PEX, GFRP, and rubber) and metals (e.g., copper and its alloys; Cu-Zn, Cu-Zn-As, Cu-Zn-Pb, Cu-Zn-Pb-As, etc.). The document recommends also standard procedures for testing the materials adequacy in contact with water, to avoid possible corrosion and microbial growth promotion. Materials more prone to corrosion negatively affect residual chlorination and can be thus used only for water with pH $\geq$ 7.5, concentration of Ca^{2+} $\geq$ 0.5 mmol/L and free CO_2 $\leq$ 0.25 mmol/L, and conductivity $\leq$600 µS/cm (measured at

25 °C) [119,120]. Materials should not promote the growth of planktonic cells of total coliforms at 37 °C and total microbial count at 22 °C and the establishment of biofilms should be limited under test conditions [120]. Studies conducted in the last decades have shown a certain correlation between used materials and the establishment of biofilms [2]. Although biofilms occur independently of the hydrophobicity or hydrophilicity of the material [122], it was noted that both bacteria and fungi were more likely present in pipe systems made of steel or iron, in comparison to PVC [28,123–125]. One of the reasons has been the chemical interaction between metals and free-chlorine leading to corrosion and the loss of residual effect of free-chlorine [2,28]. Subsequently, surfaces of such materials become rough, inducing changes in water flow and causing the reduction in shear forces, enabling easy attachment of microorganisms [126].

Microbial biofilms are formed in 3 stages, starting with initial colonizers irreversibly attaching on inorganic and organic surface molecules. In the second stage, secondary microbial colonizers attach to the initial colonizers and synergistically form the mature biofilm [127]. Only ~15% of a biofilm is represented by microorganisms, while the rest of the biofilm is composed of extracellular polysaccharides (EPS), water, proteins, nucleic acids and lipids [124]. During the last stage of the maturation process, microorganisms from the upper part of biofilm are released into water [128]. While initial colonizers are mainly bacterial species, secondary colonizers also include protozoa and fungi. The role of fungi in biofilms is still poorly investigated; however, it was suggested that they may provide bacteria with intermediate decomposition products that they cannot produce on their own [129]. Fungi are also involved in building up the extracellular polymeric substances of a biofilm, such as humic acids and aliphatic constituents (carbohydrates and peptides) [130]. Fungal hyphae and pseudo-hyphae, formed during the biofilm maturation, cross-link the biofilm structure, making the latter more difficult to remove and present a scaffold for the attachment of bacteria [124,131]. The number of fungal cells inside biofilms may be up to 5000 times higher than in running water, with filamentous fungi being more likely present than yeasts [28]. Experimentally, the formation of fungal biofilms was studied with single strains for the yeast genera *Candida*, *Saccharomyces*, *Naganishia* (former *Cryptococcus*) and *Aureobasidium*, and filamentous fungal genera *Aspergillus*, *Penicillium*, *Coriolus* and *Trichoderma*; many of which are frequently present in drinking water (Table 1) [21,31,131]. Fungal biofilms were fully formed within 48 h from the beginning of an experiment mimicking real conditions in tap systems [132]. The presence of fungi in in vivo biofilms from tap systems in private homes, hospitals or industrial network was confirmed for opportunistic and pathogenic species from the genera *Aspergillus*, *Candida*, *Exophiala*, *Fusarium*, *Malassezia*, *Ochroconis*, *Penicillium*, *Phialophora*, *Phoma* and *Rhinocladiella* [23,26,27,31,133,134]. Once established, biofilms are difficult to be fully removed from the pipe system, which on the long-term leads to altered taste and odour of water, production of allergenic or irritating compounds, and mycotoxins with an effect on human health (Figure 1) [2,21].

2.8. Commonly Used Methods for Isolation and Detection of Fungi in Water and Biofilms

Results for fungi obtained from water habitats may vary among different studies; reason being the lack of a uniform approach for detection or isolation of fungi. Isolation methods for fungi from water are generally based on water filtration followed by either conventional microbiology cultures or molecular approaches [21].

The first step includes sampling of water in sterile plastic or glass containers, with different studies using different volumes of water for filtration. In our review of published reports, volumes for sampling drinking water ranged from 50 mL to up to 1 L [8,13,19,135,136]. Filtration was usually performed with the use of sterile cellulose filters, with porosity between 0.2 µm and 0.45 µm; 0.45 µm diameter being recognised as the most efficient one [21,133]. Filters were then placed onto solid agar media, frequently supplemented with an antibiotic to prevent the bacterial growth. Since the choice of media is not defined, they may vary from oligotrophic to nutrient-rich; some authors used also selective media supporting the growth of targeted fungal genera. Most commonly reported media were Sabouraud dextrose agar (SDA), Sabouraud glucose agar

(SGA), Sabouraud gentamicin-chloramphenicol agar (SGCA), malt extract agar (MEA), corn meal agar (half-strength) (CMA/2), Czapek Dox agar (CZ), potato dextrose agar (PDA), Dichloran Rose Bengal chloramphenicol agar (DRBC), Neopeptone glucose Rose Bengal aureomycin agar (NGRBA), Dichloran 18% glycerol agar (DG18), erythritol-chloramphenicol agar (ECA), tap water agar and oomycete selective medium [8,13,19,21,26,133,134]. Most of these support growth of filamentous fungi, whereas DRBC, DG18 and ECA were used to obtain yeasts and black yeasts from both, water and biofilm samples [19,21,26,64,133]. Incubation was also reported at different temperatures (20, 25, 30 or 37 °C), for 3 days to up to 4 weeks. The broadest spectrum of fungi was reported at 30 °C after 14 days [21]. Pure fungal cultures were obtained and identified per macro- and micromorphological features. Some studies conducted during the last decade also used molecular approaches (polymerase-chain reaction and sequencing). The generally recommended genetic marker for basic fungal identification is the whole internal transcribed spacer (ITS) region (the official fungal DNA barcode) [137,138], which has already been used in most studies [2,19,26,67,134]. Considering the limitations of the ITS in separating all fungal species, when used on its own as primary fungal DNA barcoding region, more recently the elongation factor 1 alpha has been added as secondary [139].

Sampling of biofilms has usually been performed with scraping or swabbing surfaces; with a generally recommended surface area of 1 cm^2 [21,26,27,67]. Obtained biofilm material was then either plated onto solid media directly from a swab, or firstly resuspended in sterile buffer or saline solution, followed by 100 µL of the suspension being plated onto the medium using the spread plate technique [21,26,27,67]. Some authors successfully obtained fungi after putting pieces of pipe material together with the biofilm directly onto media. However, the disadvantage of the method is its difficulty in repeating the experiment, since that part of the pipe isreplaced after sampling [133]. For this reason, Siqueira et al. [133] recommended the use of "sampler devices" instead—PVC pipes within polyethylene or acetate coupons that can be placed in the pipe network allowing biofilms to grow inside the device, without removing the original pipe [133]. Media used, incubation conditions and identification of pure fungal cultures from biofilms were usually the same as described above for planktonic fungi in water samples [19,21,26,67,133].

Culture-dependent methods may give a general overview over the presence of cultivable fungi from water and biofilms. However, results vary significantly and are usually limited by the choice of growth media, temperature and incubation time [21,133]. Culture-independent methods have thus gained relevance, either as a support to the classical methods, or to detect and quantify fungal DNA directly in water; e.g., Real Time Quantitative PCR [140,141]. Few studies used a metagenomic pyrosequencing approach for the detection of fungi in tap water or biofilm samples [19,23,27,67]. Since all of them used different kits for DNA extraction, different oligonucleotide pairs and different sequencing techniques (TEFAP, 454 Platform), their results are hard to compare. However, authors reported differences in the results obtained via metagenomic analyses in comparison to culture-based techniques. Metagenomic approaches usually yield higher fungal diversity, but also reveal different percentages of single species in biofilms [19,23,27,67]. Further investigation on metagenomic approaches should be conducted to select the best fungal detection in water and biofilm; including optimization of environmental DNA extraction, choice of primers and sequencing techniques used (e.g., TEFAP, 454 Platform, Illumina, Ion Torrent, etc.)

3. Exposure to Fungi from Water in Indoor Environments and Their Medical Relevance

Although the number of fungal cells may significantly vary, and is not necessarily high in running drinking water, water is still a vector for fungal particles to reach human-made indoor habitats; where fungi are exposed to environmental pressure, leading towards the selection of opportunistic human pathogens [19,21]. People may come across them on a daily basis at different exposure points; directly while using water for drinking, bathing and showering, or indirectly due to the use of appliances connected to the water supply, for instance dishwashers and washing machines (Figure 1) [19,27,67,80].

Over the last two decades, the increasing number of immunocompromised patients led to an increase in the incidence of nosocomial and community-acquired infections by opportunistic fungal pathogens. Fungi can enter the hospital environment and may survive and proliferate, especially in humid and unsterile areas. Of special concern is direct or indirect exposure of immunocompromised individuals to water-borne fungi from the environment, to single fungal propagules, as well as to fungi in biofilms potentially formed in catheters, dental units, haemodialysis units and intensive care units [21,31,136,142,143]. Severe invasive fungal infections have a high mortality rate, currently estimated at between 50% and 100%; depending on the species involved [2,144].

Table 2 intends to summarize the most common fungal genera/species isolated from different water sources in Europe, recognised as causative agents of opportunistic infections and their effect on human health. The following paragraphs describe some of these fungal genera, their occurrence in water supplies and possible health effects.

Table 2. The list of the most common fungi isolated from different water sources in Europe, recognised as causative agents of opportunistic infections and other health effects on human health.

Fungal Species	Local or Systemic Infections	Allergenic Compounds	Mycotoxins Production	Irritative Compounds, MVOC, Odor	References
Alternaria: *A. alternata*	respiratory infections, skin and nail infections, keratitis	X	X	No data	[32,145]
Aspergillus: *A. flavus* *A. fumigatus* *A. niger* *A. terreus* *A. ustus* *A. versicolor*	disseminated infections, respiratory infections, subcutaneous infections, rhinocerebral infections, skin and nail infections, ear infections, keratitis	X	X	X	[32,146–154]
Aureobasidium: *A. pullulans* *A. melanogenum*	skin and nail infections, keratitis	X	No data	No data	[32,155]
Beauveria: *B. bassiana*	disseminated infections, keratitis	X	No data	No data	[32,156]
Botrytis: *B. cinerea*	No data	X	No data	No data	[157]
Candida: *C. albicans* *C. parapsilosis species complex*	disseminated infections, mucosal infections	X	No data	No data	[32,158,159]
Chaetomium: *C. globosum*	respiratory infections, rhinocerebral infections, skin and nail infections	X	X	No data	[32,160]
Cladosporium: *C. cladosporioides* *C. herbarum* *C. sphaerospermum*	respiratory infections, skin and nail infections, keratitis	X	No data	No data	[32,161–163]

Table 2. *Cont.*

Fungal Species	Local or Systemic Infections	Allergenic Compounds	Mycotoxins Production	Irritative Compounds, MVOC, Odor	References
Epicoccum: *E. nigrum*	No data	X	No data	No data	[164]
Exophiala: *E. dermatitidis* *E. jeanselmei*	disseminated infections, respiratory infections, skin and nail infections	No data	No data	No data	[32]
Fusarium: *F. oxysporum* *F. solani*	disseminated infections, keratitis, skin and nail infections	X	X	No data	[32,165,166]
Paecilomyces: *P. variotii*	disseminated infections, respiratory infections, keratitis, skin and nail infections	X	No data	No data	[32,167]
Penicillium: *P. brevicompactum* *P. chrysogenum* *P. citrinum* *P. expansum* *P. glabrum* *P. simplicissimum*	respiratory infections, endocarditis, rhinocerebral infections, keratitis	X	X	X	[32,151,168–172]
Purpureocillium: *P. lilacinum*	disseminated infections, respiratory infections, keratitis, subcutaneous infections, skin and nail infections	No data	No data	No data	[32]
Sarocladium: *S. kiliense* *S. strictum*	disseminated infections, respiratory infections, keratitis, subcutaneous infections, skin and nail infections	No data	No data	No data	[32]
Scopulariopsis: *S. brevicaulis*	skin and nail infections, keratitis, endocarditis	X	No data	No data	[32,173]
Stachybotrys: *S. chartarum*	respiratory infections	X	X	No data	[174]
Trichoderma: *T. harzianum* *T. viride*	disseminated infections, respiratory infections	X	X	X	[32,151,160,175]
Rhodotorula: *R. mucilaginosa*	catheter-related fungemia	X	No data	No data	[32,176]

Table 2. *Cont.*

Fungal Species	Local or Systemic Infections	Allergenic Compounds	Mycotoxins Production	Irritative Compounds, MVOC, Odor	References
Mucor: *M. circinelloides* *M. hiemalis* *M. racemosus*	disseminated infections, keratitis, rhinocerebral infections, skin and nail infections, subcutaneous infections	X	No data	No data	[32,177,178]
Rhizopus: *R. arrhizus* *R. stolonifer*	disseminated infections, keratitis, subcutaneous infections, skin and nail infections	X	No data	No data	[32,179,180]

Legend: X; indicating the ability of fungi to produce allergenic compounds, mycotoxins, irritative compounds, MVOC and odor.

3.1. Direct Contact with Fungi

People come in direct contact with fungi from water via skin and mucosa when bathing and showering. Indoor surfaces in regular contact with tap water (e.g., bathrooms) are colonised mainly with opportunistic pathogens. Among these the most frequently isolated filamentous fungi belong to the genera *Cladosporium*, *Fusarium*, *Ochroconis*, *Phoma* and *Scedosporium*, yeasts of the genera *Candida*, *Cryptococcus* and *Rhodotorula*, and black yeast from the genera *Aureobasidium*, *Cladophialophora*, *Exophiala* and *Rhinocladiella* [181–184]. The origin of their spores could be the tap water but they are also common in the air. After deposited, spores start to germinate. Spores of species adapted to high water activity can colonize surfaces covered by water (bathroom surfaces, sink, etc.), while those adapted to low water activity thrive on hydrophilic surfaces (i.e., in between ceramic tiles). Organic materials found in bathrooms and kitchens (dust, building materials) serve as nutrient supply—some of those fungi can degrade and utilize detergents and soaps [185].

Recent research conducted on shower hose biofilms revealed the presence of the following opportunistic pathogens: *Aspergillus glaucus*, *Cladosporium* spp., *Exophiala mesophila*, *Fusarium fujikuroi* species complex, *Malassezia restricta*, *Penicillium* spp. and *Schizophyllum commune* [27]. During showering people are exposed to fungal propagules also via watery aerosols released into the environment (Figure 1) [21]. Their inhalation is the most relevant route of systemic infection for susceptible patients. Any situation that enhances the air-borne dispersion of mould propagules increases the exposure of patients to such pathogens [142]. Thus, special attention should be paid to aerosols released in bathrooms in hospital environments. Anaissie et al. [181] reported a change in the microbial community in the air and on surfaces between and immediately after showering. Showering increased the presence of filamentous fungi from the genera *Alternaria*, *Acremonium*, *Aspergillus*, *Cladosporium*, *Fusarium*, *Paecilomyces*, and *Penicillium*, regularly involved in worsening of asthma symptoms, hypersensitivity pneumonitis and skin irritation [31,181]. Molds were recovered in 70% of 398 water samples. The authors found that hospital water distribution systems may serve as a potential indoor reservoir of *Aspergillus* and other molds, leading to aerosolization of fungal spores and potential exposure for patients. In a study performed by Warris et al. [186], water was identified as the source of exposure in a nosocomial outbreak. In fact, the genotype of *A. fumigatus* recovered from water was related to the genotype of isolates collected from three patients. Environmental *A. fumigatus* isolates resistant to azoles have been described in recent years especially in Europe [187]. The exposure of immunocompromised patients or persons with a hyper-reactive immune system to these resistant

strains may lead to serious invasive fungal infections, difficult to manage due to the lack of response to the available antifungals. Patients inhale both susceptible and resistant conidia, but the resistant conidia may have a selective advantage, thus allowing their germination in the lungs and subsequently causing an invasive disease.

Some fungi like *Fusarium* are particularly adapted to an aquatic environment and are present in water worldwide as part of biofilms. *Fusarium* species cause a broad spectrum of infections in humans, including superficial and locally invasive diseases. The principal portal of entry for *Fusarium* spp. are the airways, followed by the skin at the site of tissue breakdown and possibly the mucosal membranes [188]. The clinical form of fusariosis depends largely on the immune status of the host and the portal of entry, with superficial and localized disease occurring mostly in immunocompetent patients and invasive and disseminated disease affecting immunocompromised patients. Further, and on a global scale, *Fusarium* is also one of the most common etiological agents of fungal corneal ulcers [189–191].

Like Fusarium, *Scedosporium* spp., especially *S. apiospermum*, *S. aurantiacum* and *L. prolificans* (former *S. prolificans*), are also saprophytic fungi isolated worldwide from soil, plant residues and polluted waters. These species usually cause localized disease after penetrating trauma or aspiration of polluted water. However, in immunocompromised patients they may cause severe pulmonary or disseminated infections. Recently, *S. apiospermum* has been isolated from patients with chronic lung disease, receiving chronic corticosteroid therapy, in particular in cystic fibrosis patients [192].

3.2. Indirect Contact with Fungi

Indirectly, people are exposed to fungi from water via everyday use of home appliances, using water for their operation (Figure 1). Examples of such are dishwashers and washing machines, where fungi from water are exposed to extreme life conditions like elevated temperatures, use of detergents and drastic pH changes [58,80]. Environmental pressure inside the appliances leads to the selection of polyextremotolerant water-related fungi, with many of them being recognised as opportunistic pathogens [58]. Recent discoveries of fungal colonization of domestic dishwashers showed great consistence in fungal biota. Globally, dishwasher rubber seals were colonized with muriform black yeasts *Exophiala dermatitidis* and *E. phaeomuriformis*, *Candida parapsilosis*, *Rhodotorula mucilaginosa*, and filamentous *Magnusiomyces capitatus*, *Fusarium dimerum*, *F. oxysporum* and the *F. solani* species complexes [58,67]. Except *M. capitatus* the above listed fungi colonizing dishwashers originated from water sources. While tap water contained between 1–130 fungal CFU/L, the number inside dishwasher biofilms increased to 10^2–10^6 CFU/cm^2 [19,67]. Enrichment of water-related fungi inside dishwashers may represent a risk for human health due to the use of contaminated dishes and via aerosols released after completed washing cycles. As proven, dishes were rarely colonised with fungi, but aerosols released from dishwashers contained fungi of the core mycobiota—*C. parapsilosis*, *R. mucilaginosa* and *E. dermatitidis*, as well as water- and air-related filamentous fungi from the genera *Aspergillus*, *Cladosporium*, *Penicillium* and *Trichoderma* [67]. Aerosols from dishwashers contributed to contamination of kitchen surfaces when kitchens with dishwasher were compared to kitchens without them [67].

Similar to dishwashers, selection of certain water-related fungi happens also in washing machines. Recent ecological trends support washing at lower temperatures, 40 °C being the choice of most consumers [80]. Besides, use of biodegradable detergents and softeners leads to the formation of slimy film on plastic and rubber parts of washing machines, offering an ideal environment for biofilms [80,193]. Water-related fungi representing the core mycobiota of washing machines differed from those colonising dishwashers. Washing machine mycobiota consisted primarily of *F. oxysporum* species complex, followed by *C. parapsilosis*, *R. mucilaginosa* and black yeast *E. phaeomuriformis* [80,194]. In comparison to dishwashers, washing machines favoured colonisation of mesophilic water-related fungi *E. mesophila*, *E. lecanii-corni*, *Ochroconis* spp. and *Penicillium* spp., together with previously reported *Mucor* spp. and *Trichophyton mentagrophytes* [80,193]. Besides causing odour in washing

machines and clothing, enrichment of water borne fungi may pose a health risk due to the contact of contaminated clothes with skin [193].

Members of the genus *Exophiala* are dematiaceous fungi widely distributed in the environment, especially in the soil, wood, polluted water, and sewage. Humid indoor environments lead to the selection of only few mesophilic and thermotolerant opportunistic species, such as *E. dermatitidis*, *E. phaeomuriformis*, *E. mesophila*, and *E. lecanii-corni* [67,80]. Besides dishwashers and washing machines, also steam baths provide optimal growth conditions for *E. dermatitidis* and *E. phaeomuriformis* [195]. *Exophiala* can cause post-traumatic cutaneous infections, keratitis, onychomycosis, otitis externa, it can infect lungs of patients with cystic fibrosis, and cause disseminated mycosis in immunocompromised patients, even involving the brain [32].

Candida was the second most common fungal genus, isolated from the above mentioned indoor habitats. *C. albicans* and *C. parapsilosis* currently show up in the first ranks of the list of potential hospitalization threats on a worldwide scale [196,197]. Both are associated with biofilm formation and are commonly found in water collected from hospitals and private homes [19,67,80], indicating that water may be one of the means of propagation and a possible cause of nosocomial infections.

3.3. Fungal Metabolites—Mycotoxins, Allergens, Microbial Volatile Organic Compounds (MVOCs)

Not only fungi can cause adverse health effects, but also their secondary products are involved in those effects. Exposures include also those to allergens, airborne cell wall components and metabolites such as MVOCs, and mycotoxins (Figure 1). Many metabolites are candidates for causal agents that exhibit allergenic, cytotoxic, irritant, immuno-modulatory and psychosomatic effects [198–200]. A significant number of allergenic fungi have been reported from water (Table 2), but to our knowledge, there are no reports on allergic symptoms caused by fungi in tap water. Exposure of humans or animals to mycotoxins can cause severe health problems. Some mycotoxins are considered to be carcinogenic [201]. They have been shown to exacerbate airway hyper-reactivity, inflammation, and remodelling by both ingestion, and inhalation in a murine asthma model [30,202]. However, recent findings implicate that increased exposure to secondary fungal metabolites does not explain the elevated risk of asthma development in homes in association with moisture damage [203].

Exposure to mycotoxins is likely to occur from food, water or beverages made with water. Mycotoxins may be aerosolized and further inhaled [30,202]; if present in water and as proved in several occupational environments [204–208]. In addition, Boonen et al. [209] reported that aflatoxin B1 can penetrate into and through skin, thus the contact with liquids containing this mycotoxin should be avoided [209]. The estimated values of secondary fungal metabolites through ingestion are considerably higher than by inhalation, but compared to the exposure to secondary metabolites through foods, these total amounts are marginal [203]. Kelley et al. [104] showed that mycotoxins can be produced during submerged growth in water, but normally the levels of mycotoxins would be low. There is a lack of information about the effect on health of fungi being ingested directly with drinking water from the tap [21]. However, possible threats may be presented by taps that supply water not used on a daily basis; or contaminated bottled water stored for longer time in plastic bottles (Figure 1) [66,87]. A few studies conducted in Europe on bottled water reported the presence of fungi, with the genera *Aspergillus*, *Aureobasidium*, *Cladosporium*, *Debaryomyces*, *Exophiala*, *Fusarium*, *Paecilomyces*, *Penicillium*, *Talaromyces*, and *Trichoderma* being the most commonly detected (Table 1). These genera are known to form biofilms on plastic and can use plastic material as the sole source of carbon [182]. Their growth inside bottled water may lead to mycotoxin production affecting human health (Table 2) [87]. Therefore, the existence of fungal species in drinking water that potentially can produce mycotoxins is an issue of concern and needs further studies [203].

4. Discussion

Drinking water in European countries originates either from surface water or groundwater [2,4,42]. At the beginning of 19th century drinking water in urban areas was available with little or no

purification needed, but growing industrialization and urbanization led to increased pollution and occurrence of faecal-borne diseases [42]. Recent knowledge of ecology and transmission routes of faecal microorganisms promoted the development of water cleaning processes, such as filtration and chlorination [42]. The process of water cleaning evolved throughout time, including new techniques such as aeration and ultra-filtration [22]; chlorine remains the most used agent for chemical disinfection providing also the residual effect [42].

Based on past knowledge, countries worldwide still use faecal-borne microorganisms as indicators for water pollution [37], but considering the hygiene standards and conditions in developed countries changed considerably along time, quality assessment parameters for drinking water safety should be updated to reflect the present situation. While during the 19th and beginning of the 20th century water consumption was low and more or less limited to drinking and food preparation [42], it is today used in larger volumes also for daily hygiene, including showering, dishwashing and laundry [27,67,80]. Urbanisation, dense population in cities and especially the development of new daily routines (also the use of new, human-made materials, such as plastic, rubber, and metal coats) [58,71]. In parallel with higher hygiene standards and ecological concerns, the use of low water temperatures and biodegradable cleaning agents created specific niches which select and support the enrichment of stress tolerant microbial species, able to form biofilms and degrade new materials [58,67,80]. Among them, fungi showed remarkable adaptability to changes in living conditions and are becoming regularly detected in the metropolitan environments associated to higher density populations, man-made materials and complex chemical compounds [58,67,71,80].

Due to high adaptability at a physiological level, fungi may colonise environments with extreme growth conditions, one of them being also oligotrophic water systems [2]. Presence of fungi in natural raw water sources was investigated mainly in the relation with plant diseases and microbial blooms [44,60]; and connected to diverse conditions supporting their growth, such as presence of certain ions, changes of pH, temperature, sunlight and organic material [2,4,12,19,43,45].

Despite well-developed raw water cleaning processes, fungi were discovered in tap water systems in single-cell form and as a part of biofilms [2]. During the last 30 years, researchers from 19 European countries investigated and reported the presence of fungi in a relation to surface water, groundwater and tap drinking water (Table 1). A variety of fungal genera, with more than 400 different species, was found to inhabit different water sources. The most commonly detected fungi belonged to the genus *Aspergillus*, reported from 17 out of 19 countries (89.5%), followed by *Cladosporium* and *Penicillium* species (both were reported from 84.2% of countries), *Trichoderma* (73.7%), *Alternaria* and *Fusarium* (both 68.4%) and *Aureobasidium* and *Mucor* (both 52.6%) (Table 1). The majority of the listed genera were isolated from both raw water sources (surface- and groundwater) and tap water, while species from the genera *Mucor*, *Trichoderma*, and *Penicillium* were more related to surface water samples (Table 1). This research was conducted mainly using traditional cultivation techniques and may thus not be exhaustive [21].

Culture-based methods are often biased by the selection of culture media [210]. Moreover, dead microorganisms are not culturable even though they may retain activity linked to allergenic proteins or toxic secondary metabolites [211]. On the contrary, DNA-based techniques can detect also unculturable, dead and dormant microorganisms. Polymerase chain reaction (PCR) amplifies DNA markers of interest and is highly sensitive to detect down to one fungal spore from an environmental sample [212]. In the last decade, also high-throughput sequencing (HTS) methods have been introduced to analyse fungal communities in the environments [213]. These are not quantitative, but can be combined with quantitative PCR (qPCR) to provide taxon-specific concentrations of fungi [214], and thus be used for taxon-specific measurements of water-borne fungi. This is of crucial importance for fast detection of species of interest, particularly in hospital environment, where the above listed fungal genera are not only the most frequently reported in drinking water, but are also often being recognised as causative agents of diseases (Table 2) [215–218].

Since the European population is becoming on average older and the ratio of immuno-compromised people is increasing, also fungal infections are becoming regularly present, not only in hospitals, but also in private homes [219]. Human immune impairment may be transient (acute) or permanent (chronic), and is not always deriving from immune-suppression. Hyper-reactivity of the immune system also potentiates fungal colonization and pathogenesis [220,221]. Under this category fall the people who suffer from chronic bronchitis and asthmatic disorders [222]. Some conditions may even be triggered or sustained by fungal colonisation (i.e., allergic bronchopulmonary mycosis), be it caused by the usually overlooked *Candida* spp. [223], *Aspergillus* spp. or by quite a few other fungal agents (Table 2) [219]. Populations prone to fungal infections, include also individuals with transient conditions or situations (e.g., pregnancy), chronic illnesses, such as diabetes mellitus, or circulatory system impairments (which mitigate a good blood circulation in lower body extremities and peripheral tissues e.g., skin and toe or fingernails). The latter group also includes individuals suffering from chronic pulmonary obstructive disease (COPD), cystic fibrosis, uncontrolled (un-medicated) HIV, cancer and those who use immunosuppressive drugs and therapies [219,224]. All these individuals do not inhabit hospitals only, but are in fact more likely present in their private homes due to patient and bed management policies and costs, and most definitely to avoid exposure to nosocomial infection agents and multi-drug resistant microbes [224]. Should then fungal contaminants in drinking water supply be of concern as a general concept? How cost effective would this activity be?

Drinking water quality management is shifting towards a risk-based approach worldwide. The 4th Edition of the WHO Guidelines on Drinking Water Quality [34] considers end-point testing in itself "too little-too late" as it only gives information on the quality of water, which was already consumed, and only focuses on known or regulated contaminants. Therefore, relying solely on monitoring provides limited protection for human health. The water safety plan approach, on the other hand, calls for the identification of all hazards throughout the water supply system and the management of associated risks before they reach the consumers. Fungi, as previously unrecognized risk factors, fit very well in this concept, and should be considered in water safety planning on both the water supply and the building water system level; especially in high-risk settings. Guidelines exist in many European countries to develop water safety plan for health-care facilities as a tool in the prevention of nosocomial infections [225]. Hazard identification should extend to fungi by considering how can they enter to and colonize the water system. For raw water derived fungi, the efficiency of treatment technologies in their removal is the key issue, as described above. Certain technological steps, such as aeration, may also contribute to the fungal load. Regrowth of fungi may occur in the water distribution system, especially in premise plumbing, where the above listed factors favouring biofilm formation, such as ambient temperature and low flow, are most likely to be present. Risk management interventions, which were demonstrated to be efficient against other pathogens residing in water system biofilms, such as *Legionella*, may also provide some protection against fungi, but further data is necessary to support this assumption.

5. Conclusions

Recent discoveries on fungi requiring special attention include the presence of opportunistic and emerging pathogens in raw water sources. Many environmental species (particularly of the genus *Aspergillus*) recently display resistance to azoles, being the target of many studies as a serious health risk. In addition, many water-borne fungi showed resistance to the usual water disinfection procedures, allowing them to enter water distribution systems; where they form mixed biofilm communities with bacteria, algae and protozoa. Biofilms increase ability to survive heat- and chlorination-shocks. Consequently, fungal presence in tap water distribution systems leads to the enrichment of the sturdiest fungi tolerating 37 °C, in certain water-related indoor environments (e.g., dishwashers, washing machines, bathrooms and showers). Enrichment of fungi in indoor environments may affect human health via direct exposure, such as inhaling of aerosols, contact or through drinking; and indirectly by exposure to contaminated surfaces, dishes or clothes. Thus, the present knowledge of ecology and

pathogenesis of fungal contaminants in water reveals the need to measure and regulate their presence in drinking water at least in the environment with high numbers of immunocompromised people.

The authors of this white paper conclude that the herein gathered reports of fungal contaminants in drinking water, as many other possible inlays and invasive activities, illustrate and justify a recommendation to consider fungi in risk assessment and risk management of drinking water, including monitoring in relevant settings.

5.1. Future Scientific Research Needs

During the production of this white paper, knowledge gaps were identified on the following items:

1. Development of a consensus standard operating analytical procedure for the assessment of fungal contaminants in drinking water;
2. Establishment of a geographically broad report on fungal contaminants in water (enumeration and variety) using a standardized analytical procedure.
3. Development of sampling techniques necessary to detect sporadic particles released by biofilms.
4. Large scale assessment of the presence and quantification of mycotoxins and MVOCs in drinking water.
5. Generating agent specific epidemiological assessments of the health effects resulting from drinking-waterborne fungi.

5.2. Recommendations

1 Surveillance of drinking water in relevant contexts.
2 Adoption of the current Swedish legislation with an update of its fungal parameters to levels compatible with current knowledge.
3 Special attention to be paid to hospitals and other open-to-public buildings, where immunocompromised people circulate or stay for a longer time and where molecular typing may be required in order to track sources or link infections together.

5.3. Afterword

The Swedish drinking water regulation [226] determines:

- Filtration: use of filters with a pore diameter of 0.45 µm and a filtration volume of 100 mL
- Media: Rose Bengal Chloramphenicol and Chlortetracycline Agar (RBCC) for filamentous fungi and for yeasts
- Incubation temperature: 25 °C.
- Incubation time: 7 days
- Results: maximum allowed number of moulds + yeasts = 100 CFU/100 mL [41]

The consensus modified version and justification:

- Filtration: use of filters with a pore diameter of 0.45 µm and a filtration volume 100 mL
- Media: Sabouraud agar for filamentous fungi and Dichloran Rose Bengal Chloramphenicol Agar (DRBC) for yeasts
- Incubation temperature: 30 °C yields the highest diversity as reported by different authors
- Incubation time: 7 days
- Results: maximum allowed number (Unchanged due to the lack of epidemiological data that could support alterations) of moulds + yeasts = 100 CFU/100 mL
- Detection and quantification of clinically relevant species/genera (culture-based + PCR-based in hospitals and other open-to-public buildings)

Quantitative analysis of the fungal agents listed in Table 2 would be the ideal solution, but ultimately, rather labour-intensive and costly. It is, however, not unprecedented: In 1996, a recommendation from the American Industrial Hygiene Association states that "the presence of the species *Stachybotrys chartarum*, *Aspergillus versicolor*, *Aspergillus flavus*, *Aspergillus fumigatus* and *Fusarium moniliforme* in different settings requires the implementation of corrective measures" [227].

Certain areas of hospitals, for which a strict surveillance is recommended, are units where the most susceptible patients are temporary residents: Intensive care units (due to open wounds and burns), infectious diseases wards, haematology, oncology and transplant units. Patients must not be exposed to fungal contaminants in drinking water in these units. Molecular methods may be considered for species identification, but they carry the usual issue of looking into genetic material instead of at viable organisms. When combined with classical identification methods, they can support source tracking of any relevant colonies by typing. This is of great importance in a hospital in order to promote the mitigation of nosocomial infections. Therefore, as a future research, authors emphasize the necessity of the development of DNA-based, routine test(s) for waterborne fungi.

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Sample Number	Test Date	Date of Receipt	Completion Date	Sample Type	Sample Name	Suites	Details 1	Details 2	Details5	W001 Legionella spp cfu/l	W001 Legionella spp in 1l	* Yeast @ 25oC DRBC cfu/100ml	* Mould @ 25oC DRBC cfu/100ml	M042 Aerobic Colony Count @ 22?C 68hrs cfu/ml	M043 Aerobic Colony Count @ 37oC 44h cfu/ml	W003* Mycobacteria	M044 Confirmed E.coli cfu/100ml	M044 Confirmed Total Coliforms cfu/100ml	M047 Pseudomonas aeruginosa cfu/100ml
WS10638360	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 1	Trough Sink Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	0	0	-	0	0	0
WS10638361	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 2	Trough Sink Hot Tap Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	0	0	-	0	0	0
WS10638362	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 3	Trough Sink Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	20	80	-	0	0	0
WS10638363	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 4	Trough Sink Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	0	0	-	0	0	0
WS10638364	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 5	WHB opp Nurses Station Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	400	268	-	0	0	0
WS10638365	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 6	WHB opp Nurses Station Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	0	30	-	0	0	0
WS10638366	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 7	Infant Feed Room 1 B1-068 Small Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	3	0	30	-	0	0	0
WS10638367	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 8	Infant Feed Room 1 B1-068 Small Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	0	0	0	-	0	0	0
WS10638368	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 9	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	8	0	210	-	0	0	0
WS10638369	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	BACTI	Sample 10	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	0	4	0	0	-	0	0	0
WS10638370	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Critical Care	BACTI	Sample 11	018-021 Beds WHB Mixer (window) 1-B1-063 Pre	The Royal Hospital for Children and Young People Edinburgh Critical Care	-	-	0	0	100	230	-	0	0	0
WS10638371	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 12	018-021 Beds WHB Mixer (window) 1-B1-063 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	10	-	0	0	0
WS10638372	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 13	016 Gowning Room WHB Mixer 1-B1-033 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	440	400	-	0	0	0
WS10638373	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 14	016 Gowning Room WHB Mixer 1-B1-033 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638374	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 15	011-015 WHB Mixer (next to printer) 1-B1-031 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	1	200	300	-	0	0	0
WS10638375	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 16	011-015 WHB Mixer (next to printer) 1-B1-031 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	24	0	-	0	0	0
WS10638376	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 17	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	290	180	-	0	0	0
WS10638377	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 18	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638378	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 19	Trough Sink Outside 001-004 Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	330	277	-	0	0	0
WS10638379	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 20	Trough Sink Outside 001-004 Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638380	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 21	006 1-B1-017 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	294	296	-	0	0	0
WS10638381	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 22	006 1-B1-017 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638382	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 23	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	30	67	-	0	0	0
WS10638383	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 24	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	30	35	-	0	0	0
WS10638384	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 25	001 Bed 001 (ES) 1-L1-002 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	55	100	960	-	0	0	0
WS10638385	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 26	001 Bed 001 (ES) 1-L1-002 Shower Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	6	0	12	-	0	0	0
WS10638386	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 27	006 Bed 1-L1-021 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	1	0	0	-	0	0	0
WS10638387	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 28	006 Bed 1-L1-021 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638388	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 29	Dirty Utility 1-L1-061 Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638389	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 30	Dirty Utility 1-L1-061 Hot Tap Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638390	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 31	Dirty Utility 1-L1-061 Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	20	0	-	0	0	0
WS10638391	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 32	Dirty Utility 1-L1-061 Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638392	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 33	Bed 009-012 WHB Mixer 1-L1-097 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	100	400	-	0	0	0
WS10638393	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 34	Bed 009-012 WHB Mixer 1-L1-097 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	4	0	0	-	0	0	0
WS10638394	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 35	Bed 018 WHB Mixer 1-L1-093 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	77	-	0	0	0
WS10638395	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 36	Bed 018 WHB Mixer 1-L1-093 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	20	-	0	0	0
WS10638396	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 37	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	57	88	-	0	0	0
WS10638397	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 38	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638398	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 39	Treatment Room 1 L1-103 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	350	300	-	0	0	0
WS10638399	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 40	Treatment Room 1 L1-103 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	30	0	-	0	0	0
WS10638400	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 41	Dirty Utility Hot Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638401	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 42	Dirty Utility Hot Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638402	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 43	Dirty Utility Cold Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	200	60	-	0	0	0
WS10638403	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 44	Dirty Utility HoCold Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638404	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 45	Ward 230/025 WHB Mixer 2L2-087 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	350	220	-	0	0	0
WS10638405	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 46	Ward 230/025 WHB Mixer 2L2-087 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	30	-	0	0	0
WS10638406	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 47	Ward 230/025 2-L2-088 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	10	40	-	0	0	0
WS10638407	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 48	Ward 230/025 2-L2-088 Shower Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	30	20	-	0	0	0
WS10638408	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 49	Loch Ranza Ward Kitchen SS Hot Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	340	770	-	0	0	0
WS10638409	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 50	Loch Ranza Ward Kitchen SS Hot Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638410	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 51	Loch Ranza Ward Kitchen SS Cold Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638411	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 52	Loch Ranza Ward Kitchen SS Cold Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638412	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 53	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	1	-	0	0	0
WS10638413	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 54	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	0	0	-	0	0	0
WS10638414	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 55	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	0	86	0	250	-	0	0	0
WS10638415	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 56	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	-	-	0	3	0	260	-	0	0	0
WS10638416	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 57	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	0	8	2.2x10^3	960	-	0	0	0
WS10638417	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 58	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Post Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	0	0	90	40	-	0	0	0
WS10638418	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 59	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	0	> 101	300	225	-	0	0	0
WS10638419	26-07-2019	26-07-2019	30-07-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	BACTI	Sample 60	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	0	45	213	74	-	0	0	0
WS10638420	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 1	Trough Sink Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-

WS10638421	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 2	Trough Sink Hot Tap Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638422	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 3	Trough Sink Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638423	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 4	Trough Sink Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638424	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 5	WHB opp Nurses Station Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638425	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 6	WHB opp Nurses Station Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638426	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 7	Infant Feed Room 1-B1-068 Small Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638427	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 8	Infant Feed Room 1-B1-068 Small Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638428	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 9	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638429	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	LEG	Sample 10	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638430	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Critical Care	LEG	Sample 11	018-021 Beds WHB Mixer (window) 1-B1-063 Pre	The Royal Hospital for Children and Young People Edinburgh Critical Care	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638431	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 12	018-021 Beds WHB Mixer (window) 1-B1-063 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638432	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 13	016 Gowning Room WHB Mixer 1-B1-033 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638433	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 14	016 Gowning Room WHB Mixer 1-B1-033 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638434	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 15	011-015 WHB Mixer (next to printer) 1-B1-031 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638435	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 16	011-015 WHB Mixer (next to printer) 1-B1-031 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638436	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 17	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638437	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People v	LEG	Sample 18	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People v	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638438	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 19	Trough Sink Outside 001-004 Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638439	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 20	Trough Sink Outside 001-004 Mixer Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638440	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 21	006 1-B1-017 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638441	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 22	006 1-B1-017 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638442	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 23	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638443	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 24	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638444	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 25	001 Bed 001 (ES) 1-L1-002 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638445	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 26	001 Bed 001 (ES) 1-L1-002 Shower Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638446	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 27	006 Bed 1-L1-021 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638447	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 28	006 Bed 1-L1-021 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638448	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 29	Dirty Utility 1-L1-061 Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638449	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 30	Dirty Utility 1-L1-061 Hot Tap Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638450	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 31	Dirty Utility 1-L1-061 Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638451	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 32	Dirty Utility 1-L1-061 Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638452	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 33	Bed 009-012 WHB Mixer 1-L1-097 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638453	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 34	Bed 009-012 WHB Mixer 1-L1-097 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638454	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 35	Bed 018 WHB Mixer 1-L1-093 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638455	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 36	Bed 018 WHB Mixer 1-L1-093 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638456	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 37	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638457	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 38	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638458	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 39	Treatment Room 1-L1-103 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638459	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 40	Treatment Room 1-L1-103 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638460	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 41	Dirty Utility Hot Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638461	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 42	Dirty Utility Hot Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638462	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 43	Dirty Utility Cold Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638463	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 44	Dirty Utility HoCold Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638464	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 45	Ward 230/025 WHB Mixer 2L2-087 Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638465	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 46	Ward 230/025 WHB Mixer 2L2-087 Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638466	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 47	Ward 230/025 2-L2-088 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638467	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 48	Ward 230/025 2-L2-088 Shower Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638468	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 49	Loch Ranza Ward Kitchen SS Hot Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638469	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 50	Loch Ranza Ward Kitchen SS Hot Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638470	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 51	Loch Ranza Ward Kitchen SS Cold Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638471	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 52	Loch Ranza Ward Kitchen SS Cold Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638472	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 53	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638473	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 54	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638474	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 55	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638475	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 56	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638476	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 57	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638477	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 58	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Post Bed 012	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638478	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 59	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638479	26-07-2019	26-07-2019	05-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	LEG	Sample 60	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	< 50	Not Detected	-	-	-	-	-	-	-	-	-
WS10638480	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 1	Trough Sink Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-
WS10638481	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People EdinburghNeonatal	MYCO	Sample 2	Trough Sink Hot Tap Post	The Royal Hospital for Children and Young People EdinburghNeonatal	-	-	-	-	-	-	-	0	-	-	-
WS10638482	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 3	Trough Sink Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-

WS10638483	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 4	Trough Sink Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638484	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 5	WHB opp Nurses Station Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638485	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 6	WHB opp Nurses Station Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638486	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 7	Infant Feed Room 1-B1-068 Small Mixer Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638487	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 8	Infant Feed Room 1-B1-068 Small Mixer Post	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638488	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 9	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638489	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Neonatal	MYCO	Sample 10	Relative Room en-suite Shower 1-B3-083 Pre	The Royal Hospital for Children and Young People Edinburgh Neonatal	-	-	-	-	-	-	-	0	-	-	-	-
WS10638490	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh Critical Care	MYCO	Sample 11	018-021 Beds WHB Mixer (window) 1-B1-063 Pre	The Royal Hospital for Children and Young People Edinburgh Critical Care	-	-	-	-	-	-	-	0	-	-	-	-
WS10638491	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 12	018-021 Beds WHB Mixer (window) 1-B1-063 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638492	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 13	016 Gowning Room WHB Mixer 1-B1-033 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638493	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 14	016 Gowning Room WHB Mixer 1-B1-033 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638494	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 15	011-015 WHB Mixer (next to printer) 1-B1-031 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638495	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 16	011-015 WHB Mixer (next to printer) 1-B1-031 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638496	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 17	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638497	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 18	009 WHB Mixer 1-B1-021 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638498	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 19	Trough Sink Outside 001-004 Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638499	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 20	Trough Sink Outside 001-004 Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638500	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 21	006 1-B1-017 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638501	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 22	006 1-B1-017 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638502	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 23	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638503	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 24	001-004 4 Bed Bay 1-B1-009 WHB RHS Door Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638504	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 25	001 Bed 001 (ES) 1-L1-002 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638505	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 26	001 Bed 001 (ES) 1-L1-002 Shower Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638506	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 27	006 Bed 1-L1-021 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638507	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 28	006 Bed 1-L1-021 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638508	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 29	Dirty Utility 1-L1-061 Hot Tap Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638509	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 30	Dirty Utility 1-L1-061 Hot Tap Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638510	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 31	Dirty Utility 1-L1-061 Cold Tap Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638511	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 32	Dirty Utility 1-L1-061 Cold Tap Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638512	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 33	Bed 009-012 WHB Mixer 1-L1-097 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638513	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 34	Bed 009-012 WHB Mixer 1-L1-097 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638514	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 35	Bed 018 WHB Mixer 1-L1-093 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638515	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 36	Bed 018 WHB Mixer 1-L1-093 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638516	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 37	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638517	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 38	Bed 018 1-L1-094 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638518	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 39	Treatment Room 1-L1-103 WHB Mixer Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638519	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 40	Treatment Room 1-L1-103 WHB Mixer Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638520	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 41	Dirty Utility Hot Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638521	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 42	Dirty Utility Hot Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638522	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 43	Dirty Utility Cold Tap G-A2-084 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638523	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 44	Dirty Utility HoCold Tap G-A2-084 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638524	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 45	Ward 230/025 WHB Mixer 2L2-087 Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638525	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 46	Ward 230/025 WHB Mixer 2L2-087 Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638526	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 47	Ward 230/025 2-L2-088 Shower Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638527	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 48	Ward 230/025 2-L2-088 Shower Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638528	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 49	Loch Ranza Ward Kitchen SS Hot Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638529	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 50	Loch Ranza Ward Kitchen SS Hot Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638530	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 51	Loch Ranza Ward Kitchen SS Cold Pre 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638531	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 52	Loch Ranza Ward Kitchen SS Cold Post 3-C1-4-063	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638532	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 53	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638533	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 54	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638534	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 55	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Pre	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638535	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 56	Dunvegan Ward 3-C1-8-035 Bathroom Arjo Shower Main Fill Post	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638536	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 57	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638537	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 58	Dunvegan Ward 3-C1-8-035 Bathroom WHB Mixer Post Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638538	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 59	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-
WS10638539	26-07-2019	26-07-2019	23-08-2019	TVC	The Royal Hospital for Children and Young People Edinburgh	MYCO	Sample 60	3-C1-8-31 Shower Pre Bed 012	The Royal Hospital for Children and Young People Edinburgh	-	-	-	-	-	-	-	0	-	-	-	-

180	Samples Total
0	Samples OOS
0.00%	OOS Percentage
0	Samples WARN
0.00%	WARN Percentage

Accessable version: https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html

Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30329

2003
Updated: July 2019

⚠ **Ebola Virus Disease Update [August 2014]:** The recommendations in this guideline for Ebola has been superseded by these CDC documents:

- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals (https://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html)
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus (https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/hospitals.html)

See CDC's Ebola Virus Disease website (https://www.cdc.gov/vhf/ebola/index.html) for current information on how Ebola virus is transmitted.

⚠ **New Categorization Scheme for Recommendations [November 2018]**
In November 2018, HICPAC voted to approve an updated recommendation scheme. The category **Recommendation** means that we are confident that the benefits of the recommended approach clearly exceed the harms (or, in the case of a negative recommendation, that the harms clearly exceed the benefits). In general, Recommendations should be supported by high- to moderate-quality evidence. In some circumstances, however, Recommendations may be made based on lesser evidence or even expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms or when then Recommendation is required by federal law. For more information, see November 2018 HICPAC Meeting Minutes [PDF - 126 pages] (http://www.cdc.gov/hicpac/pdf/2018-Nov-HICPAC-Meeting-508.pdf).

⚠ ***C. difficile* Update [April 2019]:** Recommendations E.VI.G. and E.VI.H. and the supporting text were updated to reflect changes in Federal regulatory approvals: LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).

⚠ **Interim Measles Infection Control [July 2019]**
See Interim Infection Prevention and Control Recommendations for Measles in Healthcare Settings (https://www.cdc.gov/infectioncontrol/guidelines/measles)

Suggested Citations:

Available from the CDC Internet Site:

The full-text version of the guidelines appears as a web-based document at the CDC's Division of Healthcare Quality Promotion's Infection Control website (https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html).

The full-text version of the guidelines should be cited when reference is made primarily to material in Parts I and IV. The print version of the guidelines appears as:

Sehulster LM, Chinn RYW, Arduino MJ, Carpenter J, Donlan R, Ashford D, Besser R, Fields B, McNeil MM, Whitney C, Wong S, Juranek D, Cleveland J. 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.

Part II of these guidelines appeared in the CDC's "Morbidity and Mortality Weekly Report:"

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 2003; 52 (No. RR-10): 1–48.

Updates to the Part II recommendations also appeared in the MMWR in 2003 as "Errata: Vol. 52 (No. RR-10)" (MMWR Vol. 52 [42]: 1025–6) on October 24, 2003 and as a "Notice to Readers" scheduled to appear in February 2004. The full-text version of these guidelines (this document) incorporates these updates.

Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee (HICPAC)

Guidelines for Environmental Infection Control in Health-Care Facilities

Abstract

Background:
Although the environment serves as a reservoir for a variety of microorganisms, it is rarely implicated in disease transmission except in the immunocompromised population. Inadvertent exposures to environmental opportunistic pathogens (e.g., *Aspergillus* spp. and *Legionella* spp.) or airborne pathogens (e.g., *Mycobacterium tuberculosis* and varicella-zoster virus) may result in infections with significant morbidity and/or mortality. Lack of adherence to established standards and guidance (e.g., water quality in dialysis, proper ventilation for specialized care areas such as operating rooms, and proper use of disinfectants) can result in adverse patient outcomes in health-care facilities.

Objective:
The objective is to develop an environmental infection-control guideline that reviews and reaffirms strategies for the prevention of environmentally-mediated infections, particularly among health-care workers and immunocompromised patients. The recommendations are evidence-based whenever possible.

Search Strategies:
The contributors to this guideline reviewed predominantly English-language articles identified from MEDLINE literature searches, bibliographies from published articles, and infection-control textbooks.

Criteria for Selecting Citations and Studies for This Review:
Articles dealing with outbreaks of infection due to environmental opportunistic microorganisms and epidemiological- or laboratory experimental studies were reviewed. Current editions of guidelines and standards from organizations (i.e., American Institute of Architects [AIA], Association for the Advancement of Medical Instrumentation [AAMI], and American Society of Heating, Refrigeration, and Air-Conditioning Engineers [ASHRAE]) were consulted. Relevant regulations from federal agencies (i.e., U.S. Food and Drug Administration [FDA]; U.S. Department of Labor, Occupational Safety and Health Administration [OSHA]; U.S. Environmental Protection Agency [EPA]; and U.S. Department of Justice) were reviewed. Some topics did not have well-designed, prospective studies nor reports of outbreak investigations. Expert opinions and experience were consulted in these instances.

Types of Studies:
Reports of outbreak investigations, epidemiological assessment of outbreak investigations with control strategies, and *in vitro* environmental studies were assessed. Many of the recommendations are derived from empiric engineering concepts and reflect industry standards. A few of the infection-control measures proposed cannot be rigorously studied for ethical or logistical reasons.

Outcome Measures:

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 healthcare 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 airborne infection isolation rooms (AII) and positive airflow in protective environment rooms (PE), 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, 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 materials within 72 hours, or removal of the wet material if drying is unlikely within 72 hours.

Main Results:

Infection-control strategies and engineering controls, when consistently implemented, are effective in preventing opportunistic, environmentally-related infections in immunocompromised populations. Adherence to proper use of disinfectants, proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors and hydrotherapy equipment), water-quality standards for hemodialysis, and proper ventilation standards for specialized care environments (i.e., airborne infection isolation [AII], protective environment [PE], and operating rooms [ORs]), and prompt management of water intrusion into facility structural elements will minimize health-care associated infection risks and reduce the frequency of pseudo-outbreaks. Routine environmental sampling is not advised except in the few situations where sampling is directed by epidemiologic principles and results can be applied directly to infection control decisions, and for water quality determinations in hemodialysis.

Reviewers' Conclusions:

Continued compliance with existing environmental infection control measures will decrease the risk of health-care associated infections among patients, especially the immunocompromised, and health-care workers.

Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee (HICPAC)

Guidelines for Environmental Infection Control in Health-Care Facilities

Table of Contents

List of Abbreviations Used in This Publication

Abbreviation	Meaning
AAA	animal-assisted activity
AAMI	Association for the Advancement of Medical Instrumentation
AAT	animal-assisted therapy
ACGIH	American Council of Governmental Industrial Hygienists
ACH	air changes per hour
ADA	Americans with Disabilities Act
AER	automated endoscope reprocessor
AFB	acid-fast bacilli
AHA	American Hospital Association
AHJ	authorities having jurisdiction
AIA	American Institute of Architects
AII	airborne infection isolation
AmB	amphotericin B
ANC	absolute neutrophil count
ANSI	American National Standards Institute
AORN	Association of periOperative Registered Nurses
ASHE	American Society for Healthcare Engineering
ASHRAE	American Society of Heating, Refirgeration, and Air-Conditioning Engineers
BCG	Bacille Calmette-Guérin
BCYE	buffered charcoal yeast extract medium
BHI	brain-heart infusion
BMBL	CDC/NIH publication “Biosafety in Microbiological and Biomedical Laboratories”
BOD	biological oxygen demand
BSE	bovine spongiform encephalopathy
BSL	biosafety level
C	Centigrade
CAPD	continuous ambulatory peritoneal dialysis
CCPD	continual cycling peritoneal dialysis
CMAD	count median aerodynamic diameter
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CFU	colony-forming unit
CJD	Creutzfeldt-Jakob disease
cm	centimeter
CMS	U.S. Centers for Medicare and Medicaid Services
CPL	compliance document (OSHA)
CT/EC	cooling tower/evaporative condenser
DFA	direct fluorescence assay; direct fluorescent antibody
DHHS	U.S. Department of Health and Human Services
DHBV	duck hepatitis B virus
DNA	deoxyribonucleic acid
DOP	dioctylphthalate
DOT	U.S. Department of Transportation
EC	environment of care (JCAHO)
ELISA	enzyme-linked immunosorbent assay
EPA	U.S. Environmental Protection Agency
ESRD	end-stage renal disease
EU	endotoxin unit
F	Fahrenheit

Abbreviation	Meaning
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FRC	free residual chlorine
ft	foot (feet)
FTC	U.S. Federal Trade Commission
GISA	glycopeptide intermediate resistant *Staphylococcus aureus*
HBV	hepatitis B virus
HCV	hepatitis C virus
HEPA	high efficiency particulate air
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	human immunodeficiency virus
HPV	human papilloma virus
HSCT	hematopoietic stem cell transplant
HVAC	heating, ventilation, air conditioning
ICRA	infection control risk assessment
ICU	intensive care unit
ID 50	50% median infectious dose
IPD	intermittent peritoneal dialysis
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
kg	kilogram
L	liter
MAC	*Mycobacterium avium* complex; also used to denote MacConkey agar
MDRO	multiple-drug resistant organism
MIC	minimum inhibitory concentration
µm	micrometer; micron
mL	milliliter
min	minute
mg	milligram
MMAD	mass median aerodynamic diameter
MMWR	"Morbidity and Mortality Weekly Report"
MRSA	methicillin-resistant *Staphylococcus aureus*
MSDS	material safety data sheet
N	Normal
NaCl	sodium chloride
NaOH	sodium hydroxide
NCID	National Center for Infectious Diseases
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCCLS	National Committee for Clinical Laboratory Standards
ng	nanogram
NICU	neonatal intensive care unit
NIH	U.S. National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
nm	nanometer
NNIS	National Nosocomial Infection Surveillance
NTM	nontuberculous mycobacteria
OPL	on-premises laundry
OSHA	U.S. Occupational Safety and Health Administration
Pa	Pascal
PCP	Pneumocystis carinii pneumonia
PCR	polymerase chain reaction
PD	peritoneal dialysis

Abbreviation	Meaning
PE	protective environment
PEL	permissible exposure limit
PPE	personal protective equipment
ppm	parts per million
PVC	polyvinylchloride
RAPD	randomly amplified polymorphic DNA
RODAC	replicate organism direct agar contact
RSV	respiratory syncytial virus
RO	reverse osmosis
SARS	severe acute respiratory syndrome
SARS-CoV	SARS coronavirus
sec	second
spp	species
SSI	surgical site infection
TB	tuberculosis
TLV®-TWA	threshold limit value-time weighted average
TSA	tryptic soy agar
TSB	tryptic soy broth
TSE	transmissible spongiform encephalopathy
U.S.	United States
USC	United States Code
USDA	U.S. Department of Agriculture
USPS	U.S. Postal Service
UV	ultraviolet
UVGI	ultraviolet germicidal irradiation
VAV	variable air ventilation
vCJD	variant Creutzfeldt-Jakob disease
VISA	vancomycin intermediate resistant *Staphylococcus aureus*
VRE	vancomycin-resistant *Enterococcus*
VRSA	vancomycin-resistant Staphylococcus aureus
v/v	volume/volume
VZV	varicella-zoster virus

Note: Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services. References to non-CDC sites on the Internet are provided as a service to the reader and does not constitute or imply endorsement of these organization s or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites.

The following CDC staff member and HICPAC member prepared this report:

Lynne Sehulster, PhD
Division of Healthcare Quality Promotion
National Center for Infectious Diseases

Raymond Y.W. Chinn, MD
HICPAC Advisor
Sharp Memorial Hospital
San Diego, California

Disclosure of Relationship: Raymond Y.W. Chinn is a private-practice physician and salaried employee of Sharp Memorial Hospital in San Diego, California. Dr. Chinn received no research funds from commercial sources either directly, or indirectly through awards made to the hospital, before or during the development of these guidelines.

Contributions were made by the following CDC staff members:

Matthew Arduino, DrPH
Joe Carpenter, PE
Rodney Donlan, PhD
Lynne Sehulster, PhD
Division of Healthcare Quality Promotion
National Center for Infectious Diseases

David Ashford, DVM, Dsc, MPH
Richard Besser, MD
Barry Fields, PhD
Michael M. McNeil, MBBS, MPH
Cynthia Whitney, MD, MPH
Stephanie Wong, DMV, MPH
Division of Bacterial and Mycotic Diseases
National Center for Infectious Diseases

Dennis Juranek, DVM, MSC
Division of Parasitic Diseases
National Center for Infectious Diseases

Jennifer Cleveland, DDS, MPH
Division of Oral Health
National Center for Chronic Disease Prevention and Health Promotion

In collaboration with the Healthcare Infection Control Practices Advisory Committee (HICPAC)

HICPAC Members, February 2002

Robert A. Weinstein, MD
Chair
Cook County Hospital
Chicago, IL

Michele L. Pearson, MD
Executive Secretary
Centers for Disease Control and Prevention
Atlanta, GA

Alfred DeMaria, Jr., MD
Massachusetts Department of Public Health
Jamaica Plain, MA

James T. Lee, MD, PhD
University of Minnesota
VA Medical Center

William A. Rutala, PhD, MPH, CIC
University of North Carolina School of Medicine
Chapel Hill, NC

Beth H. Stover, RN, CIC
Kosair Children's Hospital
Louisville, KY

Jane D. Siegel, MD
Co-Chair
University of Texas Southwestern Medical Center
Dallas, TX

Raymond Y.W. Chinn, MD
Sharp Memorial Hospital
San Diego, CA

Elaine L. Larson, RN, PhD
Columbia University School of Nursing
New York, NY

Ramon E. Moncada, MD
Coronado Physician's Medical Center
Coronado, CA St. Paul, MN

William E. Scheckler, MD
University of Wisconsin Medical School
Madison, WI

Marjorie A. Underwood, RN, BSN, CIC
Mt. Diablo Medical Center
Concord, CA

Liaison Members

Loretta L. Fauerbach, MS, CIC
Association for Professionals in Infection Control and Epidemiology (APIC)
Washington, DC

Dorothy M. Fogg, RN, BSN, MA
Association of periOperative Registered Nurses (AORN)
Denver, CO

Chiu S. Lin, PhD
U.S. Food and Drug Administration
Rockville, MD

Sandra L. Fitzler, RN
American Health Care Association
Washington, DC

Stephen F. Jencks, MD, MPH
U.S. Centers for Medicare and Medicaid Services
Baltimore, MD

James P. Steinberg, MD
Society for Healthcare Epidemiology of America, Inc. (SHEA)
Atlanta, GA

Liaison Members (continued)

Michael L. Tapper, MD
Advisory Committee for the Elimination of Tuberculosis (ACET)
New York, NY

Expert Reviewers

Trisha Barrett, RN, MBA, CIC
Alta Bates Medical Center
Berkeley, CA

Judene Bartley, MS, MPH, CIC
Epidemiology Consulting Services, Inc.
Beverly Hills, MI

Michael Berry
University of North Carolina
Chapel Hill, NC

Col. Nancy Bjerke, BSN, MA, MEd, MPH, CIC (USAF, Retired)
Infection Control Associates (ICA)
San Antonio, TX

Walter W. Bond, MS
RCSA, Inc.
Lawrenceville, GA

Cheryl Carter, RN
University of Iowa Health Center
Iowa City, IA

Douglas Erickson, FASHE
American Society for Healthcare Engineering (ASHE)
Park Ridge, IL

Martin S. Favero, PhD
Advanced Sterilization Products, Johnson and Johnson
Irvine, CA

Richard Miller, MD
University of Louisville School of Medicine
Louisville, KY

Col. Shannon E. Mills, DDS
HQ USAF / Surgeon General Detail
Bolin AFB, DC

Gina Pugliese, RN, MS
Premier Safety Institute
Oak Brook, IL

Craig E. Rubens, MD, PhD
Children's Hospital and Medical Center
Seattle, WA

James D. Scott, PE
Michigan Department of Consumer and Industry Services
Lansing, MI

Andrew J. Streifel, MPH, REHS
University of Minnesota
Minneapolis, MN

Dale Woodin
American Society for Healthcare Engineering (ASHE)
Chicago, IL

Executive Summary

The *Guidelines for Environmental Infection Control in Health-Care Facilities* is a compilation of recommendations for the prevention and control of infectious diseases that are associated with healthcare environments. This document

a. revises multiple sections from previous editions of the Centers for Disease Control and Prevention [CDC] document titled *Guideline for Handwashing and Hospital Environmental Control*;[1, 2]
b. incorporates discussions of air and water environmental concerns from CDC's *Guideline for the Prevention of Nosocomial Pneumonia*;[3]
c. consolidates relevant environmental infection-control measures from other CDC guidelines;[4–9] and
d. 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.

Part I of this report, *Background Information: Environmental Infection Control in Health-Care Facilities*, provides a comprehensive review of the scientific literature. Attention is given to engineering and infection-control concerns during construction, demolition, renovation, and repairs 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, and disruption of the water supply) and the limited effects of environmental surfaces, laundry, plants, animals, medical wastes, cloth furnishings, and carpeting on disease transmission in healthcare facilities.

Part II of this guideline, *Recommendations for Environmental Infection Control in Health-Care Facilities*, outlines environmental infection control in health-care facilities, describing measures for preventing infections associated with air, water, and other elements of the environment. These recommendations represent the views of different divisions within CDC's National Center for Infectious Diseases (NCID) (e.g., the Division of Healthcare Quality Promotion [DHQP] and the Division of Bacterial and Mycotic Diseases [DBMD]) and the consensus of 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. healthcare facilities.10 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 guideline are applicable to the majority of health-care venues in the United States. This document is intended for use primarily by infection-control professionals (ICPs), epidemiologists, employee health and safety personnel, information system specialists, administrators, engineers, facility managers, environmental service professionals, and architects for health-care facilities.

Key recommendations include

a. infection-control impact of ventilation system and water system performance;
b. establishment of a multidisciplinary team to conduct infection-control risk assessment;
c. use of dust-control procedures and barriers during construction, repair, renovation, or demolition;
d. environmental infection-control measures for special care areas with patients at high risk;
e. use of airborne particle sampling to monitor the effectiveness of air filtration and dust-control measures;
f. procedures to prevent airborne contamination in operating rooms when infectious tuberculosis [TB] patients require surgery
g. guidance regarding appropriate indications for routine culturing of water as part of a comprehensive control program for legionellae;
h. guidance for recovering from water system disruptions, water leaks, and natural disasters [e.g., flooding];
i. infection-control concepts for equipment that uses water from main lines [e.g., water systems for hemodialysis, ice machines, hydrotherapy equipment, dental unit water lines, and automated endoscope reprocessors]);
j. environmental surface cleaning and disinfection strategies with respect to antibiotic-resistant microorganisms;
k. infection-control procedures for health-care laundry;

l. use of animals in health care for activities and therapy;
m. managing the presence of service animals in health-care facilities;
n. infection-control strategies for when animals receive treatment in human health-care facilities; and
o. a call to reinstate the practice of inactivating amplified cultures and stocks of microorganisms on-site during medical waste treatment.

Whenever possible, the recommendations in Part II are based on data from well-designed scientific studies. However, certain of these studies were conducted by using narrowly defined patient populations or for specific health-care settings (e.g., hospitals versus long-term care facilities), making generalization of findings potentially problematic. Construction standards for hospitals or other healthcare 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 are derived from empiric engineering concepts and may reflect an industry standard rather than an evidence-based conclusion. Where recommendations refer to guidance from the American Institute of Architects (AIA), (AIA guidance has been superseded by the Facilities Guidelines Institute [FGI]) the statements reflect standards intended for new construction or renovation. Existing structures and engineered systems are expected to be in continued compliance with the 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 a strong theoretical rationale and suggestive evidence. Finally, certain recommendations are derived from existing federal regulations. The references and the appendices comprise Parts III and IV of this document, respectively.

Infections caused by the microorganisms described in these guidelines 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 (Box 1):

Box 1. Environmental infection control: performance measures

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 airborne infection isolation (AII) rooms and positive airflow in protective environment (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 with 72 hours.

Topics outside the scope of this document include
a. noninfectious adverse events (e.g., sick building syndrome);
b. environmental concerns in the home;
c. home health care;
d. bioterrorism; and
e. healthcare-associated foodborne illness.

This document includes only limited discussion of
a. handwashing/hand hygiene;
b. standard precautions; and
c. infection-control measures used to prevent instrument or equipment contamination during patient care (e.g., preventing waterborne contamination of nebulizers or ventilator humidifiers).

These topics are mentioned only if they are important in minimizing the transfer of pathogens to and from persons or equipment and the environment. Although the document discusses principles of cleaning and disinfection as they are applied to maintenance of environmental surfaces, the full discussion of sterilization and disinfection of medical instruments and direct patient-care devices is deferred for inclusion in the *Guideline for Disinfection and Sterilization in Health-Care Facilities*, a document currently under development. Similarly, the full discussion of hand hygiene is available as the *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*. Where applicable, the *Guidelines for Environmental Infection Control in Health-Care Facilities* are consistent in content to the drafts available as of October 2002 of both the revised *Guideline for Prevention of Health-care Associated Pneumonia* and *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities*.

This guideline was prepared by CDC staff members from NCID and the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and the designated HICPAC advisor. Contributors to this document reviewed predominantly English-language manuscripts identified from reference searches using the National Library of Medicine's MEDLINE, bibliographies of published articles, and infection-control textbooks. Working drafts of the guideline were reviewed by CDC scientists, HICPAC committee members, and experts in infection control, engineering, internal medicine, infectious diseases, epidemiology, and microbiology. All recommendations in this guideline may not reflect the opinions of all reviewers.

Part I. Background Information: Environmental Infection Control in Health-Care Facilities

A. Introduction

The health-care environment contains a diverse population of microorganisms, but only a few are significant pathogens for susceptible humans. Microorganisms are present in great numbers in moist, organic environments, but some also can persist under dry conditions. Although pathogenic microorganisms can be detected in air and water and on fomites, assessing their role in causing infection and disease is difficult.[11] Only a few reports clearly delineate a "cause and effect" with respect to the environment and in particular, housekeeping surfaces.

Eight criteria are used to evaluate the strength of evidence for an environmental source or means of transmission of infectious agents (Box 2).[11, 12] Applying these criteria to disease investigations allows scientists to assess the contribution of the environment to disease transmission. An example of this application is the identification of a pathogen (e.g., vancomycin-resistant enterococci [VRE]) on an environmental surface during an outbreak. The presence of the pathogen does not establish its causal role; its transmission from source to host could be through indirect means (e.g., via hand transferral).[11] The

surface, therefore, would be considered one of a number of potential reservoirs for the pathogen, but not the "de facto" source of exposure. An understanding of how infection occurs after exposure, based on the principles of the "chain of infection," is also important in evaluating the contribution of the environment to health-care associated disease.[13] All of the components of the "chain" must be operational for infection to occur (Box 3).

Box 2. Eight criteria for evaluating the strength of evidence for environmental sources of infection*+

1. The organism can survive after inoculation onto the fomite.
2. The organism can be cultured from in-use fomites.
3. The organism can proliferate in or on the fomite.
4. Some measure of acquisition of infection cannot be explained by other recognized modes of transmission.
5. Retrospective case-control studies show an association between exposure to the fomite and infection.
6. Prospective case-control studies may be possible when more than one similar type of fomite is in use.
7. Prospective studies allocating exposure to the fomite to a subset of patients show an association between exposure and infection.
8. Decontamination of the fomite results in the elimination of infection transmission.

* These criteria are listed in order of strength of evidence.
\+ Adapted from references 11 and 12.

Box 3. Chain of infection components*

1. Adequate number of pathogenic organisms (dose)
2. Pathogenic organisms of sufficient virulence
3. A susceptible host
4. An appropriate mode of transmission or transferal of the organism in sufficient number from source to host
5. The correct portal of entry into the host

* Adapted from reference 13.

The presence of the susceptible host is one of these components that underscores the importance of the health-care environment and opportunistic pathogens on fomites and in air and water. As a result of advances in medical technology and therapies (e.g., cytotoxic chemotherapy and transplantation medicine), more patients are becoming immunocompromised in the course of treatment and are therefore at increased risk for acquiring health-care associated opportunistic infections. Trends in health-care delivery (e.g., early discharge of patients from acute care facilities) also are changing the distribution of patient populations and increasing the number of immunocompromised persons in nonacute-care hospitals. According to the American Hospital Association (AHA), in 1998, the number of hospitals in the United States totaled 6,021; these hospitals had a total of 1,013,000 beds,[14] representing a 5.5% decrease in the number of acute-care facilities and a 10.2% decrease in the number of beds over the 5-year period 1994–1998.[14] In addition, the total average daily number of patients receiving care in U.S. acute-care hospitals in 1998 was 662,000 (65.4%) – 36.5% less than the 1978 average of 1,042,000.[14] As the number of acute-care hospitals declines, the length of stay in these facilities is concurrently decreasing, particularly for immunocompetent patients. Those patients remaining in acute-care facilities are likely to be those requiring extensive medical interventions who therefore at high risk for opportunistic infection. The growing population of severely immunocompromised patients is at odds with demands on the health-care industry to remain viable in the marketplace; to incorporate modern equipment, new diagnostic procedures, and new treatments; and to construct new facilities. Increasing

numbers of health-care facilities are likely to be faced with construction in the near future as hospitals consolidate to reduce costs, defer care to ambulatory centers and satellite clinics, and try to create more "home-like" acute-care settings. In 1998, approximately 75% of health-care associated construction projects focused on renovation of existing outpatient facilities or the building of such facilities;[15] the number of projects associated with outpatient health care rose by 17% from 1998 through 1999.[16] An aging population is also creating increasing demand for assisted-living facilities and skilled nursing centers. Construction of assisted-living facilities in 1998 increased 49% from the previous year, with 138 projects completed at a cost of $703 million.[16] Overall, from 1998 to 1999, health-care associated construction costs increased by 28.5%, from $11.56 billion to $14.86 billion.[16]

Environmental disturbances associated with construction activities near health-care facilities pose airborne and waterborne disease threats risks for the substantial number of patients who are at risk for health-care associated opportunistic infections. The increasing age of hospitals and other health-care facilities is also generating ongoing need for repair and remediation work (e.g., installing wiring for new information systems, removing old sinks, and repairing elevator shafts) that can introduce or increase contamination of the air and water in patient-care environments. Aging equipment, deferred maintenance, and natural disasters provide additional mechanisms for the entry of environmental pathogens into high-risk patient-care areas.

Architects, engineers, construction contractors, environmental health scientists, and industrial hygienists historically have directed the design and function of hospitals' physical plants. Increasingly, however, because of the growth in the number of susceptible patients and the increase in construction projects, the involvement of hospital epidemiologists and infection-control professionals is required. These experts help make plans for building, maintaining, and renovating health-care facilities to ensure that the adverse impact of the environment on the incidence of health-care associated infections is minimal. The following are examples of adverse outcomes that could have been prevented had such experts been involved in the planning process:

a. transmission of infections caused by *Mycobacterium tuberculosis*, varicella-zoster virus (VZV), and measles (i.e., rubeola) facilitated by inappropriate air-handling systems in health-care facilities;[6]
b. disease outbreaks caused by *Aspergillus* spp., [17-19] *Mucoraceae*, [20] and *Penicillium* spp. associated with the absence of environmental controls during periods of health-care facility-associated construction;[21]
c. infections and/or colonizations of patients and staff with vancomycin-resistant *Enterococcus faecium* [VRE] and *Clostridium difficile* acquired indirectly from contact with organisms present on environmental surfaces in health-care facilities;[22–25] and
d. outbreaks and pseudoepidemics of legionellae,[26, 27] *Pseudomonas aeruginosa*, 28-30 and the nontuberculous mycobacteria (NTM)[31, 32] linked to water and aqueous solutions used in health-care facilities.

The purpose of this guideline is to provide useful information for both health-care professionals and engineers in efforts to provide a safe environment in which quality health care may be provided to patients. The recommendations herein provide guidance to minimize the risk for and prevent transmission of pathogens in the indoor environment.

B. Key Terms Used in this Guideline

Although Appendix A provides definitions for terms discussed in Part I, several terms that pertain to specific patient-care areas and patients who are at risk for health-care associated opportunistic infections are presented here. Specific engineering parameters for these care areas are discussed more fully in the text. **Airborne Infection Isolation (AII)** refers to the isolation of patients infected with organisms spread via airborne droplet nuclei <5 μm 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 airflow is from the outside adjacent space (e.g., 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.

Protective Environment (PE) is a specialized patient-care area, usually in a hospital, with a positive airflow 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, congenital immune deficiency syndrome, chronic diseases [such as diabetes, cancer, emphysema, and cardiac failure]) or immunosuppressive therapy (e.g., radiation, cytotoxic chemotherapy, anti-rejection medication, and 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 those 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 intensive chemotherapy (e.g., childhood acute myelogenous leukemia patients).

C. Air

1. Modes of Transmission of Airborne Diseases

A variety of airborne infections in susceptible hosts can result from exposures to clinically significant microorganisms released into the air when environmental reservoirs (i.e., soil, water, dust, and decaying organic matter) are disturbed. Once these materials are brought indoors into a health-care facility by any of a number of vehicles (e.g., people, air currents, water, construction materials, and equipment), the attendant microorganisms can proliferate in various indoor ecological niches and, if subsequently disbursed into the air, serve as a source for airborne health-care associated infections.

Respiratory infections can be acquired from exposure to pathogens contained either in droplets or droplet nuclei. Exposure to microorganisms in droplets (e.g., through aerosolized oral and nasal secretions from infected patients[33]) constitutes a form of direct contact transmission. When droplets are produced during a sneeze or cough, a cloud of infectious particles >5 μm in size is expelled, resulting in the potential exposure of susceptible persons within 3 feet of the source person.[6] Examples of pathogens spread in this manner are influenza virus, rhinoviruses, adenoviruses, and respiratory syncytial virus (RSV). Because these agents primarily are transmitted directly and because the droplets tend to fall out of the air quickly, measures to control air flow in a health-care facility (e.g., use of negative pressure rooms) generally are not indicated for preventing the spread of diseases caused by these agents. Strategies to control the spread of these diseases are outlined in another guideline.[3]

The spread of airborne infectious diseases via droplet nuclei is a form of indirect transmission.[34] Droplet nuclei are the residuals of droplets that, when suspended in air, subsequently dry and produce particles ranging in size from 1–5 μm. These particles can

a. contain potentially viable microorganisms,
b. be protected by a coat of dry secretions,
c. remain suspended indefinitely in air, and
d. be transported over long distances.

The microorganisms in droplet nuclei persist in favorable conditions (e.g., a dry, cool atmosphere with little or no direct exposure to sunlight or other sources of radiation). Pathogenic microorganisms that can be spread via droplet nuclei include *Mycobacterium tuberculosis*, VZV, measles virus (i.e., rubeola), and smallpox virus (i.e., variola major).[6] Several environmental pathogens have life-cycle forms that are similar in size to droplet nuclei and may exhibit similar behavior in the air. The spores of *Aspergillus fumigatus* have a diameter of 2–3.5 μm, with a settling velocity estimated at 0.03 cm/second (or about 1

meter/hour) in still air. With this enhanced buoyancy, the spores, which resist desiccation, can remain airborne indefinitely in air currents and travel far from their source.[35]

2. Airborne Infectious Diseases in Health-Care Facilities

a. Aspergillosis and Other Fungal Diseases

Aspergillosis is caused by molds belonging to the genus *Aspergillus*. *Aspergillus* spp. are prototype health-care acquired pathogens associated with dusty or moist environmental conditions. Clinical and epidemiologic aspects of aspergillosis (Table 1) are discussed extensively in another guideline.[3]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 1. Clinical and epidemiologic characteristics of aspergillosis

Modes of transmission	Airborne transmission of fungal spores; direct inhalation; direct inoculation from environmental sources (rare) [37]
Causative agents	*Aspergillus fumigatus* (90%–95% of *Aspergillus* infections among hematopoietic stem cell transplant (HSCT) patients; *A. flavus, A. niger, A. terreus, A. nidulans* [36–43]
Activities associated with infection	Construction, renovation, remodeling, repairs, building demolition; rare episodes associated with fomites [44–51]
Clinical syndromes and diseases	*Acute invasive:* pneumonia; ulcerative tracheobronchitis; osteomyelitis; abscesses (aspergillomas) of the lungs, brain, liver, spleen, and kidneys; thrombosis of deep blood vessels; necrotizing skin ulcers; endophthalmitis; and sinusitis *Chronic invasive*: chronic pneumonitis *Hypersensity*: allergic bronchopulmonary aspergillosis *Cutaneous*: primary skin and burn-wound infections [44, 45, 52–58]
Patient populations at greatest risk	Hematopoietic stem cell transplant patients (HSCT): immunocompromised patients (ie, those with underlying disease), patients undergoing chemotherapy, organ transplant recipients, preterm neonates, hemodialysis patients, patients with identifiable immune system deficiencies who receive care in general intensive care units (ICUs), and cystic fibrosis patients (may be colonized, occasionally become infected) [3 6, 59–78]
Factors affecting severity and outcomes	The immune status of the patient and the duration of severe neutropenia [79, 80]
Occurrence	Rare and sporadic, but increasing as proportion of immunocompromised patients increases; 5% of HSCT patients infected, <5% of solid organ transplant recipients infected [36, 37, 81–88]
Mortality rate	Rate can be as high as 100% if severe neutropenia persists; 13%–80% mortality among leukemia patients [5, 8, 83, 89, 90]

Aspergillus spp. are ubiquitous, aerobic fungi that occur in soil, water, and decaying vegetation; the organism also survives well in air, dust, and moisture present in health-care facilities.[91–93] The presence of aspergilli in the health-care facility environment is a substantial extrinsic risk factor for opportunistic invasive aspergillosis (invasive aspergillosis being the most serious form of the disease).[69, 94] Site renovation and construction can disturb *Aspergillus*-contaminated dust and produce bursts of airborne fungal spores. Increased levels of atmospheric dust and fungal spores have been associated with clusters of health-care acquired infections in immunocompromised patients.[17, 20, 44, 47, 49, 50, 95–98] Absorbent building materials (e.g., wallboard) serve as an ideal substrate for the proliferation of this organism if they become and remain wet, thereby increasing the numbers of fungal spores in the area. Patient-care items, devices,

and equipment can become contaminated with *Aspergillus* spp. spores and serve as sources of infection if stored in such areas.[57]

Most cases of aspergillosis are caused by *Aspergillus fumigatus*, a thermotolerant/thermophilic fungus capable of growing over a temperature range from 53.6°F–127.4°F (12°C–53°C); optimal growth occurs at approximately 104°F (40°C), a temperature inhibitory to most other saprophytic fungi.[99] It can use cellulose or sugars as carbon sources; because its respiratory process requires an ample supply of carbon, decomposing organic matter is an ideal substrate. (For AIA guidance on *Aspergillus* spp. see Table 2.)

Other opportunistic fungi that have been occasionally linked with health-care associated infections are members of the order *Mucorales* (e.g., *Rhizopus* spp.) and miscellaneous moniliaceous molds (e.g., *Fusarium* spp. and *Penicillium* spp.) (Table 2). Many of these fungi can proliferate in moist environments (e.g., water-damaged wood and building materials). Some fungi (e.g., *Fusarium* spp. and *Pseudoallescheria* spp.) also can be airborne pathogens.[100] As with aspergillosis, a major risk factor for disease caused by any of these pathogens is the host's severe immunosuppression from either underlying disease or immunosuppressive therapy.[101, 102]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 2. Environmental fungal pathogens: entry into and contamination of the healthcare facility

Fungal pathogen	Implicated environmental vehicle
***Aspergillus* spp.**	• Improperly functioning ventilation systems [20, 46, 47, 97, 98, 103, 104] • Air filters+ [17, 18, 105–107] Pigeons, their droppings and roosts are associated with spread of *Aspergillus, Cryptococcus,* and *Histoplasma* spp. There have been at least three outbreaks linked to contamination of the filtering systems from bird droppings[98, 103, 104] Pigeon mites may gain access into a health-care facility through the ventilation system.[119] • Air filter frames [17, 18] • Window air conditioners [96] • Backflow of contaminated air [107] • Air exhaust contamination+ [104] • False ceilings [48, 57, 97, 108] • Fibrous insulation and perforated metal ceilings [66] • Acoustic ceiling tiles, plasterboard [18, 109] • Fireproofing material [48, 49] • Damp wood building materials [49] • Opening doors to construction site [110] • Construction [69] • Open windows [20, 108, 111] • Disposal conduit door [68] • Hospital vacuum cleaner [68] • Elevator [112] • Arm boards [57] • Walls [113] • Unit kitchen [114] • Food [21] • Ornamental plants [21]
***Mucorales* / *Rhizopus* spp.**	• Air filter [20, 115] • False ceilings [97] • Heliport [115]
***Scedosporium* spp.**	• Construction [116]
***Penicillium* spp.**	• Rotting cabinet wood, pipe leak [21] • Ventilation duct fiberglass insulation [112] • Air filters [105] • Topical anesthetic [117]
***Acremonium* spp.**	• Air filters [105]
***Cladosporium* spp.**	• Air filters [105]
Sporothrix	• Construction (pseudoepidemic) [118]

+ The American Institute of Architects (AIA) standards stipulate that for new or renovated construction
  - exhaust outlets are to be placed >25 feet from air intake systems,
  - the bottom of outdoor air intakes for HVAC systems should be 6 feet above ground or 3 feet above roof level, and
  - exhaust outlets from contaminated areas are situated above the roof level and arranged to minimize the recirculation of exhausted air back into the building.[120]

Infections due *Cryptococcus neoformans*, *Histoplasma capsulatum*, or *Coccidioides immitis* can occur in health-care settings if nearby ground is disturbed and a malfunction of the facility's air-intake components allows these pathogens to enter the ventilation system. *C. neoformans* is a yeast usually 4– 8 μm in size. However, viable particles of <2 μm diameter (and thus permissive to alveolar deposition) have been found in soil contaminated with bird droppings, particularly from pigeons.[98, 103, 104, 121] *H. capsulatum*, with the infectious microconidia ranging in size from 2–5 μm, is endemic in the soil of the central river valleys of the United States. Substantial numbers of these infectious particles have been associated with chicken coops and the roosts of blackbirds.[98, 103, 104, 122] Several outbreaks of histoplasmosis have been associated with disruption of the environment; construction activities in an endemic area may be a potential risk factor for health-care acquired airborne infection.[123, 124] *C. immitis*, with arthrospores of 3–5 μm diameter, has similar potential, especially in the endemic southwestern United States and during seasons of drought followed by heavy rainfall. After the 1994 earthquake centered near Northridge, California, the incidence of coccidioidomycosis in the surrounding area exceeded the historical norm.[125]

Emerging evidence suggests that *Pneumocystis carinii*, now classified as a fungus, may be spread via airborne, person-to-person transmission.[126] Controlled studies in animals first demonstrated that *P. carinii* could be spread through the air.[127] More recent studies in health-care settings have detected nucleic acids of *P. carinii* in air samples from areas frequented or occupied by *P. carinii*-infected patients but not in control areas that are not occupied by these patients.[128, 129] Clusters of cases have been identified among immunocompromised patients who had contact with a source patient and with each other. Recent studies have examined the presence of *P. carinii* DNA in oropharyngeal washings and the nares of infected patients, their direct contacts, and persons with no direct contact.[130, 131] Molecular analysis of the DNA by polymerase chain reaction (PCR) provides evidence for airborne transmission of *P. carinii* from infected patients to direct contacts, but immunocompetent contacts tend to become transiently colonized rather than infected.[131] The role of colonized persons in the spread of *P. carinii* pneumonia (PCP) remains to be determined. At present, specific modifications to ventilation systems to control spread of PCP in a health-care facility are not indicated. Current recommendations outline isolation procedures to minimize or eliminate contact of immunocompromised patients not on PCP prophylaxis with PCP-infected patients.[6, 132]

b. Tuberculosis and Other Bacterial Diseases

The bacterium most commonly associated with airborne transmission is *Mycobacterium tuberculosis*. A comprehensive review of the microbiology and epidemiology of *M. tuberculosis* and guidelines for tuberculosis (TB) infection control have been published.[4, 133, 134] A summary of the clinical and epidemiologic information from these materials is provided in this guideline (Table 3).

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 3. Clinical and epidemiologic characteristics of tuberculosis (TB)*

Modes of transmission
- Airborne transmission via droplet nuclei 1–5 μm in diameter

Causative agents
- Mycobacterium tuberculosis, M. bovis, M. africanum

Patient factors associated with infectivity and transmission
- Disease of the lungs, airways, or larynx
- Presence of cough or other forceful expiratory measures
- Presence of acid-fast bacilli (AFB) in the sputum
- Failure of the patient to cover the mouth and nose when coughing or sneezing
- Presence of cavitation on chest radiograph
- Inappropriate or shortened duration of chemotherapy

Activities associated with infections
- Exposures in relatively small, enclosed spaces
- Inadequate ventilation resulting in insufficient removal of droplet nuclei
- Cough-producing procedures done in areas without proper environmental controls
- Recirculation of air containing infectious droplet nuclei
- Failure to use respiratory protection when managing open lesions for patients with suspected extrapulmonary TB135

Clinical syndromes and disease
- Pulmonary TB
- Extrapulmonary TB can affect any organ system or tissue
- Laryngeal TB is highly contagious

Patient populations at greatest risk
- Immunocompromised persons (eg, HIV-infected persons)
- Medically underserved persons, urban poor, homeless persons, elderly persons, migrant farm workers, close contacts of known patients
- Substance abusers, present and former prison inmates
- Foreign-born persons from areas with high prevalence of TB
- Health-care workers

Factors affecting severity and outcomes
- Concentration of droplet nuclei in air, duration of exposure
- Age at infection
- Immunosuppression due to therapy or disease, underlying chronic medical conditions, history of malignancies or lesions or the lungs

Occurrence
- Worldwide; incidence in the United States is 56 cases/100,000 population (2001)[136]

Mortality rate
- 930 deaths in the United States (1999)[136]

Chemoprophylaxis / treatment
- Treatment of latent infection includes isoniazid (INH) or rifampin (RIF)[4, 134, 137–139]
- Directly observed therapy (DOT) for active cases as indicated: INH, RIF, pyrazinamide (PZA), ethambutol (EMB), streptomycin (SM) in various combinations determined by prevalent levels of specific resistance[4, 134, 137–139]
- Consult therapy guidelines for specific treatment indications[139]

* Material in this table is compiled from references 4, 133–141.

M. tuberculosis is carried by droplet nuclei generated when persons (primarily adults and adolescents) who have pulmonary or laryngeal TB sneeze, cough, speak, or sing;[139] normal air currents can keep these particles airborne for prolonged periods and spread them throughout a room or building.[142] However, transmission of

TB has occurred from mycobacteria aerosolized during provision of care (e.g., wound/lesion care or during handling of infectious peritoneal dialysis fluid) for extrapulmonary TB patients.[135, 140]

Gram-positive cocci (i.e., *Staphylococcus aureus*, group A beta-hemolytic streptococci), also important health-care associated pathogens, are resistant to inactivation by drying and can persist in the environment and on environmental surfaces for extended periods. These organisms can be shed from heavily colonized persons and discharged into the air. Airborne dispersal of *S. aureus* is directly associated with the concentration of the bacterium in the anterior nares.[143] Approximately 10% of healthy carriers will disseminate *S. aureus* into the air, and some persons become more effective disseminators of *S. aureus* than others.[144–148] The dispersal of *S. aureus* into air can be exacerbated by concurrent viral upper respiratory infection, thereby turning a carrier into a "cloud shedder."[149] Outbreaks of surgical site infections (SSIs) caused by group A beta-hemolytic streptococci have been traced to airborne transmission from colonized operating-room personnel to patients.[150–153] In these situations, the strain causing the outbreak was recovered from the air in the operating room[150, 151, 154] or on settle plates in a room in which the carrier exercised.[151–153] *S. aureus* and group A streptococci have not been linked to airborne transmission outside of operating rooms, burn units, and neonatal nurseries.[155, 156] Transmission of these agents occurs primarily via contact and droplets.

Other gram-positive bacteria linked to airborne transmission include *Bacillus* spp. which are capable of sporulation as environmental conditions become less favorable to support their growth. Outbreaks and pseudo-outbreaks have been attributed to *Bacillus cereus* in maternity, pediatric, intensive care, and bronchoscopy units; many of these episodes were secondary to environmental contamination.[157–160]

Gram-negative bacteria rarely are associated with episodes of airborne transmission because they generally require moist environments for persistence and growth. The main exception is *Acinetobacter* spp., which can withstand the inactivating effects of drying. In one epidemiologic investigation of bloodstream infections among pediatric patients, identical *Acinetobacter* spp. were cultured from the patients, air, and room air conditioners in a nursery.[161]

Aerosols generated from showers and faucets may potentially contain legionellae and other gram-negative waterborne bacteria (e.g., *Pseudomonas aeruginosa*). Exposure to these organisms is through direct inhalation. However, because water is the source of the organisms and exposure occurs in the vicinity of the aerosol, the discussion of the diseases associated with such aerosols and the prevention measures used to curtail their spread is discussed in another section of the Guideline (see Part I: Water).

c. Airborne Viral Diseases

Some human viruses are transmitted from person to person via droplet aerosols, but very few viruses are consistently airborne in transmission (i.e., are routinely suspended in an infective state in air and capable of spreading great distances), and health-care associated outbreaks of airborne viral disease are limited to a few agents. Consequently, infection-control measures used to prevent spread of these viral diseases in health-care facilities primarily involve patient isolation, vaccination of susceptible persons, and antiviral therapy as appropriate rather than measures to control air flow or quality.[6] Infections caused by VZV frequently are described in health-care facilities. Health-care associated airborne outbreaks of VZV infections from patients with primary infection and disseminated zoster have been documented; patients with localized zoster have, on rare occasions, also served as source patients for outbreaks in health-care facilities.[162–166] VZV infection can be prevented by vaccination, although patients who develop a rash within 6 weeks of receiving varicella vaccine or who develop breakthrough varicella following exposure should be considered contagious.[167]

Viruses whose major mode of transmission is via droplet contact rarely have caused clusters of infections in group settings through airborne routes. The factors facilitating airborne distribution of these viruses in an infective state are unknown, but a presumed requirement is a source patient in the early stage of infection who is shedding large numbers of viral particles into the air. Airborne transmission of measles has been documented in health-care facilities.[168–171] In addition, institutional outbreaks of influenza virus infections have occurred predominantly in nursing homes,[172–176] and less frequently in medical and neonatal intensive care units, chronic-care areas, HSCT units, and pediatric wards.[177–180] Some evidence supports airborne

transmission of influenza viruses by droplet nuclei,[181, 182] and case clusters in pediatric wards suggest that droplet nuclei may play a role in transmitting certain respiratory pathogens (e.g., adenoviruses and respiratory syncytial virus [RSV]).[177, 183, 184] Some evidence also supports airborne transmission of enteric viruses. An outbreak of a Norwalk-like virus infection involving more than 600 staff personnel over a 3-week period was investigated in a Toronto, Ontario hospital in 1985; common sources (e.g., food and water) were ruled out during the investigation, leaving airborne spread as the most likely mode of transmission.[185]

Smallpox virus, a potential agent of bioterrorism, is spread predominantly via direct contact with infectious droplets, but it also can be associated with airborne transmission.[186, 187] A German hospital study from 1970 documented the ability of this virus to spread over considerable distances and cause infection at low doses in a well-vaccinated population; factors potentially facilitating transmission in this situation included a patient with cough and an extensive rash, indoor air with low relative humidity, and faulty ventilation patterns resulting from hospital design (e.g., open windows).[188] Smallpox patients with extensive rash are more likely to have lesions present on mucous membranes and therefore have greater potential to disseminate virus into the air.[188] In addition to the smallpox transmission in Germany, two cases of laboratory-acquired smallpox virus infection in the United Kingdom in 1978 also were thought to be caused by airborne transmission.[189]

⚠ **Ebola Virus Disease Update [August 2014]:** The recommendations in this guideline for Ebola has been superseded by these CDC documents:

- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals (https://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html)
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus (https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/hospitals.html)

See CDC's Ebola Virus Disease website (https://www.cdc.gov/vhf/ebola/index.html) for current information on how Ebola virus is transmitted.

Airborne transmission may play a role in the natural spread of hantaviruses and certain hemorrhagic fever viruses (e.g., Ebola, Marburg, and Lassa), but evidence for airborne spread of these agents in health-care facilities is inconclusive.[190] Although hantaviruses can be transmitted when aerosolized from rodent excreta,[191, 192] person-to-person spread of hantavirus infection from source patients has not occurred in health-care facilities.[193–195] Nevertheless, health-care workers are advised to contain potentially infectious aerosols and wear National Institute of Occupational Safety and Health (NIOSH) approved respiratory protection when working with this agent in laboratories or autopsy suites.[196] Lassa virus transmission via aerosols has been demonstrated in the laboratory and incriminated in health-care associated infections in Africa,[197–199] but airborne spread of this agent in hospitals in developed nations likely is inefficient.[200, 201] Yellow fever is considered to be a viral hemorrhagic fever agent with high aerosol infectivity potential, but health-care associated transmission of this virus has not been described.[202] Viral hemorrhagic fever diseases primarily occur after direct exposure to infected blood and body fluids, and the use of standard and droplet precautions prevents transmission early in the course of these illnesses.[203, 204] However, whether these viruses can persist in droplet nuclei that might remain after droplet production from coughs or vomiting in the latter stages of illness is unknown.[205] Although the use of a negative-pressure room is not required during the early stages of illness, its use might be prudent at the time of hospitalization to avoid the need for subsequent patient transfer. Current CDC guidelines recommend negative-pressure rooms with anterooms for patients with hemorrhagic fever and use of HEPA respirators by persons entering these rooms when the patient has prominent cough, vomiting, diarrhea, or hemorrhage.[6, 203] Face shields or goggles will help to prevent mucous-membrane exposure to potentially-aerosolized infectious material in these situations. If an anteroom is not available, portable, industrial-grade high efficiency particulate air (HEPA) filter units can be used to provide the equivalent of additional air changes per hour (ACH).

Table 4. Microorganisms associated with airborne transmission*

Evidence for airborne transmission	Fungi	Bacteria	Viruses
Numerous reports in health-care facilities	*Aspergillus* spp.+ *Mucorales* (*Rhizopus* spp.)[97, 115]	*Mycobacterium tuberculosis*+	Measles (rubeola) virus[168-170] Varicella-zoster virus[162-166]
Occasional reports in health-care facilities (atypical)	*Acremonium spp.*[105, 206] *Fusarium spp.*[102] *Pseudoallescheria boydii*[100] *Scedosporium spp.*[116] *Sporothrix cyanescens*¶[118]	*Acinetobacter spp.*[161] *Bacillus spp.*¶[160, 207] *Brucella spp.***[208-211] *Staphylococcus aureus*[148, 156] Group A *Streptococcus*[151]	Smallpox virus (variola)§[188, 189] Influenza viruses[181, 182] Respiratory syncytial virus[183] Adenoviruses[184] Norwalk-like virus[185]
No reports in health-care facilities; known to be airborne outside.	*Coccidioides immitis*[125] *Cryptococcus* spp.[121] *Histoplasma capsulatum*[124]	*Coxiella burnetii* (Q fever)[212]	Hantaviruses[193, 195] Lassa virus[205] Marburg virus[205] Ebola virus†[205] Crimean-Congo virus[205]
Under investigation	*Pneumocystis carinii*[131]	n/a	n/a

* This list excludes microorganisms transmitted from aerosols derived from water.
\+ Refer to the text for references for these disease agents.
§ Airborne transmission of smallpox is infrequent. Potential for airborne transmission increases with patients who are effective disseminators present in facilities with low relative humidity in the air and faulty ventilation.
¶ Documentation of pseudoepidemic during construction.
** Airborne transmission documented in the laboratory but not in patient-care areas
† **Ebola Virus Disease Update [August 2014]:** The recommendations in this guideline for Ebola has been superseded by these CDC documents:
- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals (https://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html)
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus (https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/hospitals.html)

See CDC's Ebola Virus Disease website (https://www.cdc.gov/vhf/ebola/index.html) for current information on how Ebola virus is transmitted.

3. Heating, Ventilation, and Air Conditioning Systems in Health-Care Facilities

a. Basic Components and Operations

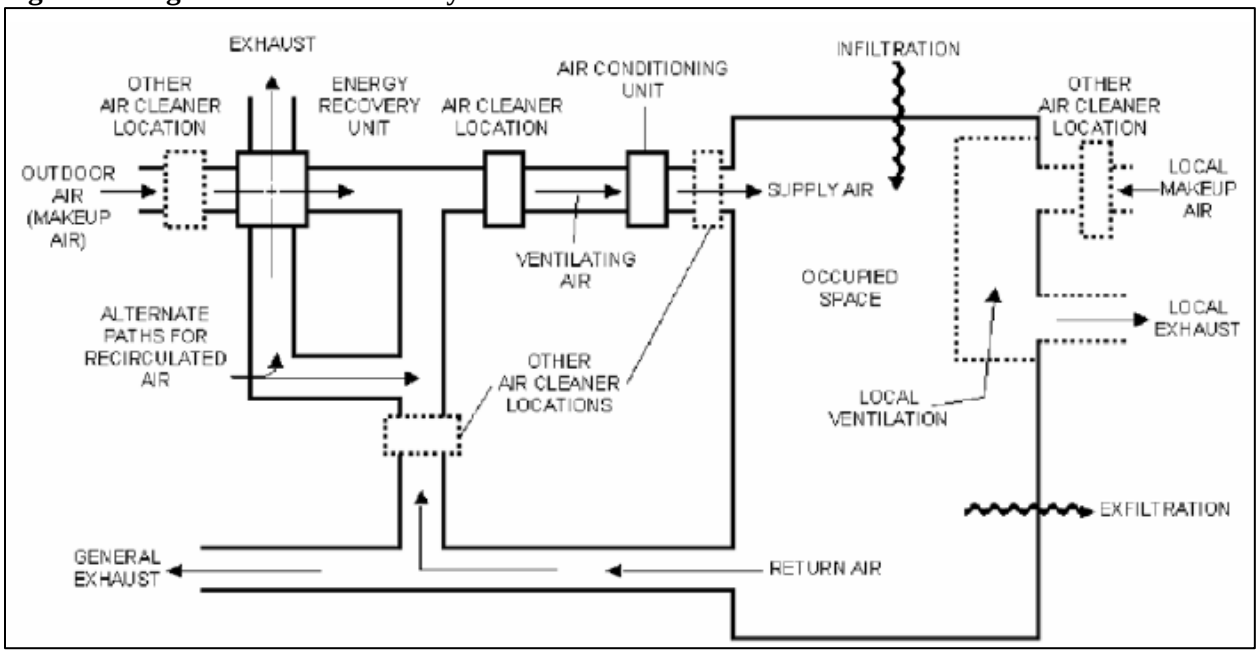
Heating, ventilation, and air conditioning (HVAC) systems in health-care facilities are designed to
a. maintain the indoor air temperature and humidity at comfortable levels for staff, patients, and visitors
b. control odors;
c. remove contaminated air;
d. facilitate air-handling requirements to protect susceptible staff and patients from airborne health-care associated pathogens; and
e. minimize the risk for transmission of airborne pathogens from infected patients.[35, 120]

An HVAC system includes an outside air inlet or intake; filters; humidity modification mechanisms (i.e., humidity control in summer, humidification in winter); heating and cooling equipment; fans; ductwork; air exhaust or out-takes; and registers, diffusers, or grilles for proper distribution of the air (Figure 1).[213, 214] Decreased performance of healthcare facility HVAC systems, filter inefficiencies, improper installation, and poor maintenance can contribute to the spread of health-care associated airborne infections.

The American Institute of Architects (AIA) has published guidelines for the design and construction of new health-care facilities and for renovation of existing facilities. These AIA guidelines address indoor

air-quality standards (e.g., ventilation rates, temperature levels, humidity levels, pressure relationships, and minimum air changes per hour [ACH]) specific to each zone or area in health-care facilities (e.g., operating rooms, laboratories, diagnostic areas, patient-care areas, and support departments).[120] These guidelines represent a consensus document among authorities having jurisdiction (AHJ), governmental regulatory agencies (i.e., Department of Health and Human Services [DHHS]; Department of Labor, Occupational Safety and Health Administration [OSHA]), health-care professionals, professional organizations (e.g., American Society of Heating, Refrigeration, and Air-Conditioning Engineers [ASHRAE], American Society for Healthcare Engineering [ASHE]), and accrediting organizations (i.e., Joint Commission on Accreditation of Healthcare Organizations [JCAHO]). More than 40 state agencies that license health-care facilities have either incorporated or adopted by reference these guidelines into their state standards. JCAHO, through its surveys, ensures that facilities are in compliance with the ventilation guidelines of this standard for new construction and renovation.

Figure 1. Diagram of a ventilation system*



Outdoor air and recirculated air pass through air cleaners (e.g., filter banks) designed to reduce the concentration of airborne contaminants. Air is conditioned for temperature and humidity before it enters the occupied space as supply air. Infiltration is air leakage inward through cracks and interstitial spaces of walls, floors, and ceilings. Exfiltration is air leakage outward through these same cracks and spaces. Return air is largely exhausted from the system, but a portion is recirculated with fresh, incoming air.

* Used with permission of the publisher of reference 214 (ASHRAE)

Engineering controls to contain or prevent the spread of airborne contaminants center on
a. local exhaust ventilation [i.e., source control],
b. general ventilation, and
c. air cleaning.[4]

General ventilation encompasses
a. dilution and removal of contaminants via well-mixed air distribution of filtered air,
b. directing contaminants toward exhaust registers and grilles via uniform, non-mixed airflow patterns,
c. pressurization of individual spaces relative to all other spaces, and
d. pressurization of buildings relative to the outdoors and other attached buildings.

A centralized HVAC system operates as follows. Outdoor air enters the system, where low-efficiency or "roughing" filters remove large particulate matter and many microorganisms. The air enters the distribution system for conditioning to appropriate temperature and humidity levels, passes through an additional bank of filters for further cleaning, and is delivered to each zone of the building. After the conditioned air is distributed to the designated space, it is withdrawn through a return duct system and delivered back to the HVAC unit. A portion of this "return air" is exhausted to the outside while the remainder is mixed with outdoor air for dilution and filtered for removal of contaminants.[215] Air from toilet rooms or other soiled areas is usually exhausted directly to the atmosphere through a separate duct exhaust system. Air from rooms housing tuberculosis patients is exhausted to the outside if possible, or passed through a HEPA filter before recirculation. Ultraviolet germicidal irradiation (UVGI) can be used as an adjunct air-cleaning measure, but it cannot replace HEPA filtration. [15]

b. Filtration

i. Filter Types and Methods of Filtration

Filtration, the physical removal of particulates from air, is the first step in achieving acceptable indoor air quality. Filtration is the primary means of cleaning the air. Five methods of filtration can be used (Table 5). During filtration, outdoor air passes through two filter beds or banks (with efficiencies of 20%–40% and ≥90%, respectively) for effective removal of particles 1–5 μm in diameter.[35, 120] The low-to-medium efficiency filters in the first bank have low resistance to airflow, but this feature allows some small particulates to pass onto heating and air conditioning coils and into the indoor environment.[35] Incoming air is mixed with recirculated air and reconditioned for temperature and humidity before being filtered by the second bank of filters. The performance of filters with ≤90% efficiency is measured using either the dust-spot test or the weight-arrestance test.[35, 216]

Table 5. Filtration methods*

Basic method	Principle of performance	Filtering efficiency
Straining	Particles in the air are larger than the openings between the filter fibers, resulting in gross removal of large particles.	Low
Impingement	Particles collide with filter fibers and remain attached to the filter. Fibers may be coated with adhesive.	Low
Interception	Particles enter into the filter and become entrapped and attached to the filter fibers.	Medium
Diffusion	Small particles, moving in erratic motion, collide with filter fibers and remain attached.	High
Electrostatic	Particles bearing negative electrostatic charge are attracted to the filter with positively charged fibers.	High

* Material in this table was compiled from information in reference 217.

The second filter bank usually consists of high-efficiency filters. This filtration system is adequate for most patient-care areas in ambulatory-care facilities and hospitals, including the operating room environment and areas providing central services.[120] Nursing facilities use 90% dust-spot efficient filters as the second bank of filters,[120] whereas a HEPA filter bank may be indicated for special-care areas of hospitals. HEPA filters are at least 99.97% efficient for removing particles ≥0.3 μm in diameter. (As a reference, *Aspergillus* spores are 2.5–3.0 μm in diameter.) Examples of care areas where HEPA filters are used include PE rooms and those operating rooms designated for orthopedic implant procedures.[35]

Maintenance costs associated with HEPA filters are high compared with other types of filters, but use of in-line disposable prefilters can increase the life of a HEPA filter by approximately 25%. Alternatively, if a disposable prefilter is followed by a filter that is 90% efficient, the life of the HEPA filter can be extended ninefold. This concept, called progressive filtration, allows HEPA filters in special care areas to be used for 10 years.[213] Although progressive filtering will extend the mechanical ability of the HEPA

filter, these filters may absorb chemicals in the environment and later desorb those chemicals, thereby necessitating a more frequent replacement program. HEPA filter efficiency is monitored with the dioctylphthalate (DOP) particle test using particles that are 0.3 μm in diameter.[218]

HEPA filters are usually framed with metal, although some older versions have wood frames. A metal frame has no advantage over a properly fitted wood frame with respect to performance, but wood can compromise the air quality if it becomes and remains wet, allowing the growth of fungi and bacteria. Hospitals are therefore advised to phase out water-damaged or spent wood-framed filter units and replace them with metal-framed HEPA filters.

HEPA filters are usually fixed into the HVAC system; however, portable, industrial grade HEPA units are available that can filter air at the rate of 300–800 ft^3/min. Portable HEPA filters are used to
a. temporarily recirculate air in rooms with no general ventilation,
b. augment systems that cannot provide adequate airflow, and
c. provide increased effectiveness in airflow.[4]

Portable HEPA units are useful engineering controls that help clean the air when the central HVAC system is undergoing repairs[219] but these units do not satisfy fresh-air requirements.[214]

The effectiveness of the portable unit for particle removal is dependent on
a. the configuration of the room,
b. the furniture and persons in the room,
c. the placement of the units relative to the contents and layout of the room, and
d. the location of the supply and exhaust registers or grilles.

If portable, industrial-grade units are used, they should be capable of recirculating all or nearly all of the room air through the HEPA filter, and the unit should be designed to achieve the equivalent of ≥12 ACH.[4] (An average room has approximately 1,600 ft^3 of airspace.) The hospital engineering department should be contacted to provide ACH information in the event that a portable HEPA filter unit is necessary to augment the existing fixed HVAC system for air cleaning.

ii. Filter Maintenance
Efficiency of the filtration system is dependent on the density of the filters, which can create a drop in pressure unless compensated by stronger and more efficient fans, thus maintaining air flow. For optimal performance, filters require monitoring and replacement in accordance with the manufacturer's recommendations and standard preventive maintenance practices.[220] Upon removal, spent filters can be bagged and discarded with the routine solid waste, regardless of their patient-care area location.[221] Excess accumulation of dust and particulates increases filter efficiency, requiring more pressure to push the air through. The pressure differential across filters is measured by use of manometers or other gauges. A pressure reading that exceeds specifications indicates the need to change the filter. Filters also require regular inspection for other potential causes of decreased performance. Gaps in and around filter banks and heavy soil and debris upstream of poorly maintained filters have been implicated in health-care associated outbreaks of aspergillosis, especially when accompanied by construction activities at the facility.[17, 18, 106, 222]

c. Ultraviolet Germicidal Irradiation (UVGI)

As a supplemental air-cleaning measure, UVGI is effective in reducing the transmission of airborne bacterial and viral infections in hospitals, military housing, and classrooms, but it has only a minimal inactivating effect on fungal spores.[223–228] UVGI is also used in air handling units to prevent or limit the growth of vegetative bacteria and fungi. Most commercially available UV lamps used for germicidal purposes are low-pressure mercury vapor lamps that emit radiant energy predominantly at a wave-length of 253.7 nm.[229, 230] Two systems of UVGI have been used in health-care settings – duct irradiation and upper-room air irradiation. In duct irradiation systems, UV lamps are placed inside ducts that remove air from rooms to disinfect the air before it is recirculated. When properly designed, installed, and maintained, high levels of UVGI can be attained in the ducts with little or no exposure of persons in the rooms.[231, 232] In upper-room air irradiation, UV lamps are either suspended from the ceiling or mounted on the wall.[4] Upper

air UVGI units have two basic designs:
a. a "pan" fixture with UVGI unshielded above the unit to direct the irradiation upward and
b. a fixture with a series of parallel plates to columnize the irradiation outward while preventing the light from getting to the eyes of the room's occupants.

The germicidal effect is dependent on air mixing via convection between the room's irradiated upper zone and the lower patient-care zones.[233, 234]

Bacterial inactivation studies using BCG mycobacteria and *Serratia marcescens* have estimated the effect of UVGI as equivalent to 10 ACH–39 ACH.[235, 236] Another study, however, suggests that UVGI may result in fewer equivalent ACH in the patient-care zone, especially if the mixing of air between zones is insufficient.[234] The use of fans or HVAC systems to generate air movement may increase the effectiveness of UVGI if airborne microorganisms are exposed to the light energy for a sufficient length of time.[233, 235, 237–239] The optimal relationship between ventilation and UVGI is not known.

Because the clinical effectiveness of UV systems may vary, UVGI is not recommended for air management prior to air recirculation from airborne isolation rooms. It is also not recommended as a substitute for HEPA filtration, local exhaust of air to the outside, or negative pressure.[4] The use of UV lamps and HEPA filtration in a single unit offers only minimal infection-control benefits over those provided by the use of a HEPA filter alone.[240] Duct systems with UVGI are not recommended as a substitute for HEPA filters if the air from isolation rooms must be recirculated to other areas of the facility.[4] Regular maintenance of UVGI systems is crucial and usually consists of keeping the bulbs free of dust and replacing old bulbs as necessary. Safety issues associated with the use of UVGI systems are described in other guidelines.[4]

d. Conditioned Air in Occupied Spaces

Temperature and humidity are two essential components of conditioned air. After outside air passes through a low- or medium-efficiency filter, the air undergoes conditioning for temperature and humidity control before it passes through high-efficiency or HEPA filtration.

i. Temperature
HVAC systems in health-care facilities are often single-duct or dual-duct systems.[35, 241] A single-duct system distributes cooled air (55°F [12.8°C]) throughout the building and uses thermostatically controlled reheat boxes located in the terminal ductwork to warm the air for individual or multiple rooms. The dual-duct system consists of parallel ducts, one with a cold air stream and the other with a hot air stream. A mixing box in each room or group of rooms mixes the two air streams to achieve the desired temperature. Temperature standards are given as either a single temperature or a range, depending on the specific health-care zone. Cool temperature standards (68°F–73°F [20°C–23°C]) usually are associated with operating rooms, clean workrooms, and endoscopy suites.[120] A warmer temperature (75°F [24°C]) is needed in areas requiring greater degrees of patient comfort. Most other zones use a temperature range of 70°F–75°F (21°C–24°C).[120] Temperatures outside of these ranges may be needed occasionally in limited areas depending on individual circumstances during patient care (e.g., cooler temperatures in operating rooms during specialized operations).

ii. Humidity
Four measures of humidity are used to quantify different physical properties of the mixture of water vapor and air. The most common of these is relative humidity, which is the ratio of the amount of water vapor in the air to the amount of water vapor air can hold at that temperature.[242] The other measures of humidity are specific humidity, dew point, and vapor pressure.[242]

Relative humidity measures the percentage of saturation. At 100% relative humidity, the air is saturated. For most areas within health-care facilities, the designated comfort range is 30%–60% relative humidity.[120, 214] Relative humidity levels >60%, in addition to being perceived as uncomfortable, promote fungal growth.[243] Humidity levels can be manipulated by either of two mechanisms.[244] In a water-wash unit, water is sprayed and drops are taken up by the filtered air; additional heating or cooling of this air sets the humidity levels. The second mechanism is by means of water vapor created from steam and added to filtered air in humidifying boxes. Reservoir-type humidifiers are not allowed in health-care facilities as per AIA guidelines and many state codes.[120] Cool-mist humidifiers should be avoided, because they can disseminate aerosols containing allergens and microorganisms.[245] Additionally, the small, personal-use versions of this equipment can be difficult to clean.

iii. Ventilation

The control of air pollutants (e.g., microorganisms, dust, chemicals, and smoke) at the source is the most effective way to maintain clean air. The second most effective means of controlling indoor air pollution is through ventilation. Ventilation rates are voluntary unless a state or local government specifies a standard in health-care licensing or health department requirements. These standards typically apply to only the design of a facility, rather than its operation.[220, 246] Health-care facilities without specific ventilation standards should follow the AIA guideline specific to the year in which the building was 120, 214, 241 built or the ANSI/ASHRAE Standard 62, *Ventilation for Acceptable Indoor Air Quality*.

Ventilation guidelines are defined in terms of air volume per minute per occupant and are based on the assumption that occupants and their activities are responsible for most of the contaminants in the conditioned space.[215] Most ventilation rates for health-care facilities are expressed as room ACH. Peak efficiency for particle removal in the air space occurs between 12 ACH–15 ACH.[35, 247, 248] Ventilation rates vary among the different patient-care areas of a health-care facility (Appendix B).[120]

Health-care facilities generally use recirculated air.[35, 120, 241, 249, 250] Fans create sufficient positive pressure to force air through the building duct work and adequate negative pressure to evacuate air from the conditioned space into the return duct work and/or exhaust, thereby completing the circuit in a sealed system (Figure 1). However, because gaseous contaminants tend to accumulate as the air recirculates, a percentage of the recirculated air is exhausted to the outside and replaced by fresh outdoor air. In hospitals, the delivery of filtered air to an occupied space is an engineered system design issue, the full discussion of which is beyond the scope of this document.

Hospitals with areas not served by central HVAC systems often use through-the-wall or fan coil air conditioning units as the sole source of room ventilation. AIA guidelines for newly installed systems stipulate that through-the-wall fan-coil units be equipped with permanent (i.e., cleanable) or replaceable filters with a minimum efficiency of 68% weight arrestance.[120] These units may be used only as recirculating units; all outdoor air requirements must be met by a separate central air handling system with proper filtration, with a minimum of two outside air changes in general patient rooms (D. Erickson, ASHE, 2000).[120] If a patient room is equipped with an individual through-the-wall fan coil unit, the room should not be used as either AII or as PE.[120] These requirements, although directed to new HVAC installations also are appropriate for existing settings. Non-central air-handling systems are prone to problems associated with excess condensation accumulating in drip pans and improper filter maintenance; health-care facilities should clean or replace the filters in these units on a regular basis while the patient is out of the room.

Laminar airflow ventilation systems are designed to move air in a single pass, usually through a bank of HEPA filters either along a wall or in the ceiling, in a one-way direction through a clean zone with parallel streamlines. Laminar airflow can be directed vertically or horizontally; the unidirectional

system optimizes airflow and minimizes air turbulence.[63, 241] Delivery of air at a rate of 0.5 meters per second (90 ± 20 ft/min) helps to minimize opportunities for microorganism proliferation.[63, 251, 252] Laminar airflow systems have been used in PE to help reduce the risk for health-care associated airborne infections (e.g., aspergillosis) in high-risk patients.[63, 93, 253, 254] However, data that demonstrate a survival benefit for patients in PE with laminar airflow are lacking. Given the high cost of installation and apparent lack of benefit, the value of laminar airflow in this setting is questionable.[9, 37] Few data support the use of laminar airflow systems elsewhere in a hospital.[255]

iv. Pressurization

Positive and negative pressures refer to a pressure differential between two adjacent air spaces (e.g., rooms and hallways). Air flows away from areas or rooms with positive pressure (pressurized), while air flows into areas with negative pressure (depressurized). AII rooms are set at negative pressure to prevent airborne microorganisms in the room from entering hallways and corridors. PE rooms housing severely neutropenic patients are set at positive pressure to keep airborne pathogens in adjacent spaces or corridors from coming into and contaminating the airspace occupied by such high-risk patients. Self-closing doors are mandatory for both of these areas to help maintain the correct pressure differential.[4, 6, 120] Older health-care facilities may have variable pressure rooms (i.e., rooms in which the ventilation can be manually switched between positive and negative pressure). These rooms are no longer permitted in the construction of new facilities or in renovated areas of the facility,[120] and their use in existing facilities has been discouraged because of difficulties in assuring the proper pressure differential, especially for the negative pressure setting, and because of the potential for error associated with switching the pressure differentials for the room. Continued use of existing variable pressure rooms depends on a partnership between engineering and infection control. Both positive- and negative-pressure rooms should be maintained according to specific engineering specifications (Table 6).

Table 6. Engineered specifications for positive- and negative pressure rooms*

Engineering characteristics	Positive pressure areas (e.g., protective environments [PE])	Negative pressure areas (e.g., airborne infection isolation [AII])
Pressure differentials	> +2.5 Pa§ (0.01″ water gauge)	> −2.5 Pa (0.01″ water gauge)
Air changes per hour (ACH)	>12	≥12 (for renovation or new construction)
Filtration efficiency	Supply: 99.97% @ 0.3 µm DOP (dioctylphthalate particles of 0.3 µm diameter) Return: none required (If the patient requires both PE and AII, return air should be HEPA-filtered or otherwise exhausted to the outside)	Supply: 90% (dust spot test) Return: 99.97% @ 0.3 µm DOP (dioctylphthalate particles of 0.3 µm diameter); HEPA filtration of exhaust air from AII rooms should not be required, providing that the exhaust is properly located to prevent re-entry into the building.
Room airflow direction	Out to the adjacent area	In to the room
Clean-to-dirty airflow in room	Away from the patient (high-risk patient, immunosuppressed patient)	Towards the patient (airborne disease patient)
Ideal pressure differential	> + 8 Pa	> −2.5 Pa

* Material in this table was compiled from references 35 and 120. Table adapted from and used with permission of the publisher of reference [35] (Lippincott Williams and Wilkins).

§ Pa is the abbreviation for Pascal, a metric unit of measurement for pressure based on air velocity; 250 Pa equals 1.0 inch water gauge.

Health-care professionals (e.g., infection control, hospital epidemiologists) must perform a risk assessment to determine the appropriate number of AII rooms (negative pressure) and/or PE rooms (positive pressure) to serve the patient population. The AIA guidelines require a certain number of AII rooms as a minimum, and it is important to refer to the edition under which the building was built for appropriate guidance.[120]

In large health-care facilities with central HVAC systems, sealed windows help to ensure the efficient operation of the system, especially with respect to creating and maintaining pressure differentials. Sealing

the windows in PE areas helps minimize the risk of airborne contamination from the outside. One outbreak of aspergillosis among immunosuppressed patients in a hospital was attributed in part to an open window in the unit during a time when both construction and a fire happened nearby; sealing the window prevented further entry of fungal spores into the unit from the outside air.[111] Additionally, all emergency exits (e.g., fire escapes and emergency doors) in PE wards should be kept closed (except during emergencies) and equipped with alarms.

e. Infection Control Impact of HVAC System Maintenance and Repair

A failure or malfunction of any component of the HVAC system may subject patients and staff to discomfort and exposure to airborne contaminants. Only limited information is available from formal studies on the infection-control implications of a complete air-handling system failure or shutdown for maintenance. Most experience has been derived from infectious disease outbreaks and adverse outcomes among high-risk patients when HVAC systems are poorly maintained. (See Table 7 for potential ventilation hazards, consequences, and correction measures.)

AIA guidelines prohibit U.S. hospitals and surgical centers from shutting down their HVAC systems for purposes other than required maintenance, filter changes, and construction.[120] Airflow can be reduced; however, sufficient supply, return, and exhaust must be provided to maintain required pressure relationships when the space is not occupied. Maintaining these relationships can be accomplished with special drives on the air-handling units (i.e., a variable air ventilation [VAV] system).

Microorganisms proliferate in environments wherever air, dust, and water are present, and air-handling systems can be ideal environments for microbial growth.[35] Properly engineered HVAC systems require routine maintenance and monitoring to provide acceptable indoor air quality efficiently and to minimize conditions that favor the proliferation of health-care associated pathogens.[35, 249] Performance monitoring of the system includes determining pressure differentials across filters, regular inspection of system filters, DOP testing of HEPA filters, testing of low- or medium efficiency filters, and manometer tests for positive- and negative-pressure areas in accordance with nationally recognized standards, guidelines, and manufacturers' recommendations. The use of hand-held, calibrated equipment that can provide a numerical reading on a daily basis is preferred for engineering purposes (A.Streifel, University of Minnesota, 2000).[256] Several methods that provide a visual, qualitative measure of pressure differentials (i.e., airflow direction) include smoke-tube tests or placing flutter strips, ping-pong balls, or tissue in the air stream.

Preventive filter and duct maintenance (e.g., cleaning ductwork vents, replacing filters as needed, and properly disposing spent filters into plastic bags immediately upon removal) is important to prevent potential exposures of patients and staff during HVAC system shut-down. The frequency of filter inspection and the parameters of this inspection are established by each facility to meet their unique needs. Ductwork in older health-care facilities may have insulation on the interior surfaces that can trap contaminants. This insulation material tends to break down over time to be discharged from the HVAC system. Additionally, a malfunction of the air-intake system can overburden the filtering system and permit aerosolization of fungal pathogens. Keeping the intakes free from bird droppings, especially those from pigeons, helps to minimize the concentration of fungal spores entering from the outside.[98]

Accumulation of dust and moisture within HVAC systems increases the risk for spread of health-care–associated environmental fungi and bacteria. Clusters of infections caused by *Aspergillus* spp., *P. aeruginosa, S. aureus,* and *Acinetobacter* spp. have been linked to poorly maintained and/or malfunctioning air conditioning systems.[68, 161, 257, 258] Efforts to limit excess humidity and moisture in the infrastructure and on air-stream surfaces in the HVAC system can minimize the proliferation and dispersion of fungal spores and waterborne bacteria throughout indoor air.[259–262] Within the HVAC system, water is present in water-wash units, humidifying boxes, or cooling units. The dual-duct system

may also create conditions of high humidity and excess moisture that favor fungal growth in drain pans as well as in fibrous insulation material that becomes damp as a result of the humid air passing over the hot stream and condensing.

If moisture is present in the HVAC system, periods of stagnation should be avoided. Bursts of organisms can be released upon system start-up, increasing the risk of airborne infection.[206] Proper engineering of the HVAC system is critical to preventing dispersal of airborne organisms. In one hospital, endophthalmitis caused by *Acremonium kiliense* infection following cataract extraction in an ambulatory surgical center was traced to aerosols derived from the humidifier water in the ventilation system.[206] The organism proliferated because the ventilation system was turned off routinely when the center was not in operation; the air was filtered before humidification, but not afterwards.

Most health-care facilities have contingency plans in case of disruption of HVAC services. These plans include back-up power generators that maintain the ventilation system in high-risk areas (e.g., operating rooms, intensive-care units, negative- and positive-pressure rooms, transplantation units, and oncology units). Alternative generators are required to engage within 10 seconds of a loss of main power. If the ventilation system is out of service, rendering indoor air stagnant, sufficient time must be allowed to clean the air and re-establish the appropriate number of ACH once the HVAC system begins to function again. Air filters may also need to be changed, because reactivation of the system can dislodge substantial amounts of dust and create a transient burst of fungal spores.

Duct cleaning in health-care facilities has benefits in terms of system performance, but its usefulness for infection control has not been conclusively determined. Duct cleaning typically involves using specialized tools to dislodge dirt and a high-powered vacuum cleaner to clean out debris.[263] Some duct-cleaning services also apply chemical biocides or sealants to the inside surfaces of ducts to minimize fungal growth and prevent the release of particulate matter. The U.S. Environmental Protection Agency (EPA), however, has concerns with the use of sanitizers and/or disinfectants to treat the surfaces of ductwork, because the label indications for most of these products may not specifically include the use of the product in HVAC systems.[264] Further, EPA has not evaluated the potency of disinfectants in such applications, nor has the agency examined the potential attendant health and safety risks. The EPA recommends that companies use only those chemical biocides that are registered for use in HVAC systems.[264] Although infrequent cleaning of the exhaust ducts in AII areas has been documented as a cause of diminishing negative pressure and a decrease in the air exchange rates,[214] no data indicate that duct cleaning, beyond what is recommended for optimal performance, improves indoor air quality or reduces the risk of infection. Exhaust return systems should be cleaned as part of routine system maintenance. Duct cleaning has not been shown to prevent any health problems,[265] and EPA studies indicate that airborne particulate levels do not increase as a result of dirty air ducts, nor do they diminish after cleaning, presumably because much of the dirt inside air ducts adheres to duct surfaces and does not enter the conditioned space.[265] Additional research is needed to determine if air-duct contamination can significantly increase the airborne infection risk in general areas of health-care facilities.

4. Construction, Renovation, Remediation, Repair, and Demolition

a. General Information

Environmental disturbances caused by construction and/or renovation and repair activities (e.g., disruption of the above-ceiling area, running cables through the ceiling, and structural repairs) in and near health-care facilities markedly increase the airborne *Aspergillus* spp. spore counts in the indoor air of such facilities, thereby increasing the risk for health-care associated aspergillosis among high-risk patients. Although one case of health-care associated aspergillosis is often difficult to link to a specific environmental exposure, the occurrence of temporarily clustered cases increase the likelihood that an environmental source within the facility may be identified and corrected.

Table 7. Ventilation hazards in health-care facilities that may be associated with increased potential of airborne disease transmission*

Problem§	Consequences	Possible solutions
Water-damaged building materials (18, 266)	Water leaks can soak wood, wall board, insulation, wall coverings, ceiling tiles, and carpeting. All of these materials can provide microbial habitat when wet. This is especially true for fungi growing on gypsum board.	1. Replace water-damaged materials. 2. Incorporate fungistatic compounds into building materials in areas at risk for moisture problems. 3. Test for all moisture and dry in less than 72 hours. Replace if the material cannot dry within 72 hours.
Filter bypasses (17)	Rigorous air filtration requires air flow resistance. Air stream will elude filtration if openings are present because of filter damage or poor fit.	1. Use pressure gauges to ensure that filters are performing at proper static pressure. 2. Make ease of installation and maintenance criteria for filter selection. 3. Properly train maintenance personnel in HVAC concerns. 4. Design system with filters down- stream from fans. 5. Avoid water on filters or insulation.
Improper fan setting (267)	Air must be delivered at design volume to maintain pressure balances. Air flow in special vent rooms reverses.	1. Routinely monitor air flow and pressure balances throughout critical parts of HVAC system. 2. Minimize or avoid using rooms that switch between positive and negative pressure.
Ductwork disconnections (268)	Dislodged or leaky supply duct runs can spill into and leaky returns may draw from hidden areas. Pressure balance will be interrupted, and infectious material may be disturbed and entrained into hospital air supply.	1. Design a ductwork system that is easy to access, maintain, and repair. 2. Train maintenance personnel to regularly monitor air flow volumes and pressure balances throughout the system. 3. Test critical areas for appropriate air flow
Air flow impedance (213)	Debris, structural failure, or improperly adjusted dampers can block duct work and prevent designed air flow.	1. Design and budget for a duct system that is easy to inspect, maintain, and repair. 2. Alert contractors to use caution when working around HVAC systems during the construction phase. 3. Regularly clean exhaust grilles. 4. Provide monitoring for special ventilation areas.
Open windows (96, 247)	Open windows can alter fan-induced pressure balance and allow dirty-to clean air flow.	1. Use sealed windows. 2. Design HVAC systems to deliver sufficient outdoor dilution ventilation. 3. Ensure that OSHA indoor air quality standards are met.
Dirty window air conditioners (96, 269)	Dirt, moisture, and bird droppings can contaminate window air conditioners, which can then introduce infectious material into hospital rooms.	1. Eliminate such devices in plans for new construction. 2. Where they must be used, make sure that they are routinely cleaned and inspected.
Inadequate filtration (270)	Infectious particles may pass through filters into vulnerable patient areas.	1. Specify appropriate filters during new construction design phase. 2. Make sure that HVAC fans are sized to overcome pressure demands of filter system. 3. Inspect and test filters for proper installation.

Problem§	Consequences	Possible solutions
Maintenance disruptions (271)	Fan shut-offs, dislodged filter cake material contaminates downstream air supply and drain pans. This may compromise air flow in special ventilation areas.	1. Budget for a rigorous maintenance schedule when designing a facility. 2. Design system for easy maintenance. 3. Ensure communication between engineering and maintenance personnel. 4. Institute an ongoing training program for all involved staff members.
Excessive moisture in the HVAC system (120)	Chronically damp internal lining of the HVAC system, excessive condensate, and drip pans with stagnant water may result from this problem.	1. Locate duct humidifiers upstream of the final filters. 2. Identify a means to remove water from the system. 3. Monitor humidity; all duct take-offs should be downstream of the humidifiers so that moisture is absorbed completely. 4. Use steam humidifiers in the HVAC system.
Duct contamination (18, 272)	Debris is released during maintenance or cleaning.	1. Provide point-of-use filtration in the critical areas. 2. Design air-handling systems with insulation of the exterior of the ducts. 3. Do not use fibrous sound attenuators. 4. Decontaminate or encapsulate contamination.

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§ Numbers in parentheses are reference citations.

Construction, renovation, repair, and demolition activities in health-care facilities require substantial planning and coordination to minimize the risk for airborne infection both during projects and after their completion. Several organizations and experts have endorsed a multi-disciplinary team approach (Box 4) to coordinate the various stages of construction activities (e.g., project inception, project implementation, final walk-through, and completion).[120, 249, 250, 273–276] Environmental services, employee health, engineering, and infection control must be represented in construction planning and design meetings should be convened with architects and design engineers. The number of members and disciplines represented is a function of the complexity of a project. Smaller, less complex projects and maintenance may require a minimal number of members beyond the core representation from engineering, infection control, environmental services, and the directors of the specialized departments.

Box 4. Suggested members and functions of a multi-disciplinary coordination team for construction, renovation, repair, and demolition projects

Members

- Infection-control personnel, including hospital epidemiologists
- Laboratory personnel
- Facility administrators or their designated representatives, facility managers
- Director of engineering
- Risk-management personnel
- Directors of specialized programs (e.g., transplantation, oncology and ICU [intensive care unit] programs)
- Employee safety personnel, industrial hygienists, and regulatory affairs personnel
- Environmental services personnel Information systems personnel
- Construction administrators or their designated representatives
- Architects, design engineers, project managers, and contractors

Functions and responsibilities

- Coordinate members' input in developing a comprehensive project management plan.
- Conduct a risk assessment of the project to determine potential hazards to susceptible patients.
- Prevent unnecessary exposures of patients, visitors, and staff to infectious agents.
- Oversee all infection-control aspects of construction activities.
- Establish site-specific infection-control protocols for specialized areas.
- Provide education about the infection-control impact of construction to staff and construction workers.
- Ensure compliance with technical standards, contract provisions, and regulations.
- Establish a mechanism to address and correct problems quickly.
- Develop contingency plans for emergency response to power failures, water supply disruptions, and fires.
- Provide a water-damage management plan (including drying protocols) for handling water intrusion from floods, leaks, and condensation.
- Develop a plan for structural maintenance.

Education of maintenance and construction workers, health-care staff caring for high-risk patients, and persons responsible for controlling indoor air quality heightens awareness that minimizing dust and moisture intrusion from construction sites into high-risk patient-care areas helps to maintain a safe environment.[120, 250, 271, 275–278] Visual and printed educational materials should be provided in the language spoken by the workers. Staff and construction workers also need to be aware of the potentially catastrophic consequences of dust and moisture intrusion when an HVAC system or water system fails during construction or repair; action plans to deal quickly with these emergencies should be developed in advance and kept on file. Incorporation of specific standards into construction contracts may help to prevent departures from recommended practices as projects progress. Establishing specific lines of communication is important to address problems (e.g., dust control, indoor air quality, noise levels, and vibrations), resolve complaints, and keep projects moving toward completion. Health-care facility staff should develop a mechanism to monitor worker adherence to infection-control guidelines on a daily basis in and around the construction site for the duration of the project.

b. Preliminary Considerations

The three major topics to consider before initiating any construction or repair activity are as follows:

a. design and function of the new structure or area,
b. assessment of environmental risks for airborne disease and opportunities for prevention, and
c. measures to contain dust and moisture during construction or repairs.

A checklist of design and function considerations can help to ensure that a planned structure or area can be easily serviced and maintained for environmental infection control (Box 5) .[17, 250, 273, 275–277]

Specifications for the construction, renovation, remodeling, and maintenance of health-care facilities are outlined in the AIA document, *Guidelines for Design and Construction of Hospitals and Health Care Facilities*. [120, 275]

Box 5. Construction design and function considerations for environmental infection control

- Location of sinks and dispensers for handwashing products and hand hygiene products
- Types of faucets (e.g., aerated vs. non-aerated)
- Air-handling systems engineered for optimal performance, easy maintenance, and repair
- ACH and pressure differentials to accommodate special patient-care areas
- Location of fixed sharps containers
- Types of surface finishes (e.g., porous vs. non-porous)
- Well-caulked walls with minimal seams
- Location of adequate storage and supply areas
- Appropriate location of medicine preparations areas (e.g., >3 ft. from a sink)
- Appropriate location and type of ice machines (e.g., preferably ice dispensers rather than ice bins)
- Appropriate materials for sinks and wall coverings
- Appropriate traffic flow (e.g., no "dirty" movement through "clean" areas)
- Isolation rooms with anterooms as appropriate
- Appropriate flooring (e.g., seamless floors in dialysis units)
- Sensible use carpeting (e.g., avoiding use of carpeting in special care areas or areas likely to become wet)*
- Convenient location of soiled utility areas
- Properly engineered areas for linen services and solid waste management
- Location of main generator to minimize the risk of system failure from flooding or other emergency
- Installation guidelines for sheetrock

* Use of carpet cleaning methods (e.g., "bonneting") that disperse microorganisms into the air may increase the risk of airborne infection among at-risk patients, especially if they are in the vicinity of the cleaning activity.[111]

Proactive strategies can help prevent environmentally mediated airborne infections in health-care facilities during demolition, construction, and renovation. The potential presence of dust and moisture and their contribution to health-care associated infections must be critically evaluated early in the planning of any demolition, construction, renovation, and repairs.[120, 250, 251, 273, 274, 276–279] Consideration must extend beyond dust generated by major projects to include dust that can become airborne if disturbed during routine maintenance and minor renovation activities (e.g., exposure of ceiling spaces for inspection; installation of conduits, cable, or sprinkler systems; rewiring; and structural repairs or replacement).[273, 276, 277] Other projects that can compromise indoor air quality include construction and repair jobs that inadvertently allow substantial amounts of raw, unfiltered outdoor air to enter the facility (e.g., repair of elevators and elevator shafts) and activities that dampen any structure, area, or item made of porous materials or characterized by cracks and crevices (e.g., sink cabinets in need of repair, carpets, ceilings, floors, walls, vinyl wall coverings, upholstery, drapes, and countertops).[18, 273, 277] Molds grow and proliferate on these surfaces when they become and remain wet.[21, 120, 250, 266, 270, 272, 280] Scrubbable materials are preferred for use in patient-care areas.

Containment measures for dust and/or moisture control are dictated by the location of the construction site. Outdoor demolition and construction require actions to keep dust and moisture out of the facility (e.g., sealing windows and vents and keeping doors closed or sealed). Containment of dust and moisture generated from construction inside a facility requires barrier structures (either pre-fabricated or constructed of more durable materials as needed) and engineering controls to clean the air in and around the construction or repair site.

c. Infection-Control Risk Assessment

An infection-control risk assessment (ICRA) conducted before initiating repairs, demolition, construction, or renovation activities can identify potential exposures of susceptible patients to dust and moisture and determine the need for dust and moisture containment measures. This assessment centers on the type and extent of the construction or repairs in the work area but may also need to include adjacent patient-care areas, supply storage, and areas on levels above and below the proposed project. An example of designing an ICRA as a matrix, the policy for performing an ICRA and implementing its results, and a sample permit form that streamlines the communication process are available.[281] Knowledge of the air flow patterns and pressure differentials helps minimize or eliminate the inadvertent dispersion of dust that could contaminate air space, patient-care items, and surfaces.[57, 282, 283] A recent aspergillosis outbreak among oncology patients was attributed to depressurization of the building housing the HSCT unit while construction was underway in an adjacent building. Pressure readings in the affected building (including 12 of 25 HSCT-patient rooms) ranged from 0.1 Pa–5.8 Pa. Unfiltered outdoor air flowed into the building through doors and windows, exposing patients in the HSCT unit to fungal spores.[283] During long-term projects, providing temporary essential services (e.g., toilet facilities) and conveniences (e.g., vending machines) to construction workers within the site will help to minimize traffic in and out of the area. The type of barrier systems necessary for the scope of the project must be defined.[12, 120, 250, 279, 284]

Depending on the location and extent of the construction, patients may need to be relocated to other areas in the facility not affected by construction dust.[51, 285] Such relocation might be especially prudent when construction takes place within units housing immunocompromised patients (e.g., severely neutropenic patients and patients on corticosteroid therapy). Advance assessment of high-risk locations and planning for the possible transport of patients to other departments can minimize delays and waiting time in hallways.[51] Although hospitals have provided immunocompromised patients with some form of respiratory protection for use outside their rooms, the issue is complex and remains unresolved until more research can be done. Previous guidance on this issue has been inconsistent.[9] Protective respirators (i.e., N95) were well tolerated by patients when used to prevent further cases of construction-related aspergillosis in a recent outbreak.[283] The routine use of the N95 respirator by patients, however, has not been evaluated for preventing exposure to fungal spores during periods of non-construction. Although health-care workers who would be using the N95 respirator for personal respiratory protect must be fit-tested, there is no indication that either patients or visitors should undergo fit-testing.

Surveillance activities should augment preventive strategies during construction projects.[3, 4, 20, 110, 286, 287] By determining baseline levels of health-care acquired airborne and waterborne infections, infection-control staff can monitor changes in infection rates and patterns during and immediately after construction, renovations, or repairs.[3]

d. Air Sampling

Air sampling in health-care facilities may be conducted both during periods of construction and on a periodic basis to determine indoor air quality, efficacy of dust-control measures, or air-handling system performance via parametric monitoring. Parametric monitoring consists of measuring the physical periodic assessment of the system (e.g., air flow direction and pressure, ACH, and filter efficiency) can give assurance of proper ventilation, especially for special care areas and operating rooms.[288]

Air sampling is used to detect aerosols (i.e., particles or microorganisms). Particulate sampling (i.e., total numbers and size range of particulates) is a practical method for evaluating the infection-control performance of the HVAC system, with an emphasis on filter efficiency in removing respirable particles (<5 μm in diameter) or larger particles from the air. Particle size is reported in terms of the mass median aerodynamic diameter (MMAD), whereas count median aerodynamic diameter (CMAD) is useful with respect to particle concentrations.

Particle counts in a given air space within the health-care facility should be evaluated against counts obtained in a comparison area. Particle counts indoors are commonly compared with the particulate levels of the outdoor air. This approach determines the "rank order" air quality from "dirty" (i.e., the outdoor air) to "clean" (i.e., air filtered through high-efficiency filters [90%–95% filtration]) to "cleanest" (i.e., HEPA-filtered air).[288] Comparisons from one indoor area to another may also provide useful information about the magnitude of an indoor air-quality problem. Making rank-order comparisons between clean, highly-filtered areas and dirty areas and/or outdoors is one way to interpret sampling results in the absence of air quality and action level standards.[35, 289]

In addition to verifying filter performance, particle counts can help determine if barriers and efforts to control dust dispersion from construction are effective. This type of monitoring is helpful when performed at various times and barrier perimeter locations during the project. Gaps or breaks in the barriers' joints or seals can then be identified and repaired. The American Conference of Governmental Industrial Hygienists (ACGIH) has set a threshold limit value-time weighted average (TLV®-TWA) of 10 mg/m^3 for nuisance dust that contains no asbestos and <1% crystalline silica.[290] Alternatively, OSHA has set permissible exposure limits (PELs) for inert or nuisance dust as follows: respirable fraction at 5 mg/m^3 and total dust at 15 mg/m^3 .[291] Although these standards are not measures of a bioaerosol, they are used for indoor air quality assessment in occupational settings and may be useful criteria in construction areas. Application of ACGIH guidance to health-care settings has not been standardized, but particulate counts in health-care facilities are likely to be well below this threshold value and approaching clean-room standards in certain care areas (e.g., operating rooms).[100]

Particle counters and anemometers are used in particulate evaluation. The anemometer measures air flow velocity, which can be used to determine sample volumes. Particulate sampling usually does not require microbiology laboratory services for the reporting of results.

Microbiologic sampling of air in health-care facilities remains controversial because of currently unresolved technical limitations and the need for substantial laboratory support (Box 6). 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.[35, 289] Microbiologic air sampling should be limited to assays for airborne fungi; of those, the thermotolerant fungi (i.e., those capable of growing at 95°F–98.6°F [35°C–37°C]) are of particular concern because of their pathogenicity in immunocompromised hosts.[35] Use of selective media (e.g., Sabouraud dextrose agar and inhibitory mold agar) helps with the initial identification of recovered organisms.

Microbiologic sampling for fungal spores performed as part of various airborne disease outbreak investigations has also been problematic.[18, 49, 106, 111, 112, 289] The precise source of a fungus is often difficult to trace with certainty, and sampling conducted after exposure may neither reflect the circumstances that were linked to infection nor distinguish between health-care acquired and community-acquired infections. Because fungal strains may fluctuate rapidly in the environment, health-care acquired *Aspergillus* spp. infection cannot be confirmed or excluded if the infecting strain is not found in the health-care setting.[287] Sensitive molecular typing methods (e.g., randomly amplified polymorphic DNA (RAPD) techniques and a more recent DNA fingerprinting technique that detects restriction fragment length polymorphisms in fungal genomic DNA) to identify strain differences among *Aspergillus* spp., however, are becoming increasingly used in epidemiologic investigations of health-care acquired fungal infection (A.Streifel, University of Minnesota, 2000).[68, 110, 286, 287, 292–296] During case cluster evaluation, microbiologic sampling may provide an isolate from the environment for molecular typing and comparison with patient isolates.

Therefore, it may be prudent for the clinical laboratory to save *Aspergillus* spp. isolated from colonizations and invasive disease cases among patients in PE, oncology, and transplant services for these purposes.

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 *Aspergillus* 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 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)

* Material in this box is compiled from references 35, 100, 222, 289, 297.

Sedimentation methods using settle plates and volumetric sampling methods using solid impactors are commonly employed when sampling air for bacteria and fungi. Settle plates have been used by numerous investigators to detect airborne bacteria or to measure air quality during medical procedures (e.g., surgery).[17, 60, 97, 151, 161, 287] 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.[35, 289, 298–301] Settle plates, however, may detect fungi aerosolized during medical procedures (e.g., during wound dressing changes), as described in a recent outbreak of aspergillosis among liver transplant patients.[302]

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.[35, 289] 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/m^3) of air.[18, 94] 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 m^3) should be considered when sampling highly filtered areas.[283] Investigators have also suggested limits of 15 CFU/m^3 for gross colony counts of fungal organisms and <0.1 CFU/m^3 for *Aspergillus fumigatus* and other potentially opportunistic fungi in heavily filtered areas (≥12 ACH and filtration of ≥99.97% efficiency).[120] No correlation of these values with the incidence of health-care– associated fungal infection rates has been reported.

Air sampling in health-care facilities, whether used to monitor air quality during construction, to verify filter efficiency, or to commission new space prior to occupancy, requires careful notation of the

circumstances of sampling. Most air sampling is performed under undisturbed conditions. However, when the air is sampled during or after human activity (e.g., walking and vacuuming), a higher number of airborne microorganisms likely is detected.[297] The contribution of human activity to the significance of air sampling and its impact on health-care associated infection rates remain to be defined. Comparing microbiologic sampling results from a target area (e.g., an area of construction) to those from an unaffected location in the facility can provide information about distribution and concentration of potential airborne pathogens. A comparison of microbial species densities in outdoor air versus indoor air has been used to help pinpoint fungal spore bursts. Fungal spore densities in outdoor air are variable, although the degree of variation with the seasons appears to be more dramatic in the United States than in Europe.[92, 287, 303]

Particulate and microbiologic air sampling have been used when commissioning new HVAC system installations; however, such sampling is particularly important for newly constructed or renovated PE or operating rooms. Particulate sampling is used as part of a battery of tests to determine if a new HVAC system is performing to specifications for filtration and the proper number of ACH.[268, 288, 304] Microbiologic air sampling, however, remains controversial in this application, because no standards for comparison purposes have been determined. If performed, sampling should be limited to determining the density of fungal spores per unit volume of air space. High numbers of spores may indicate contamination of air-handling system components prior to installation or a system deficiency when culture results are compared with known filter efficiencies and rates of air exchange.

e. External Demolition and Construction

External demolition, planned building implosions, and dirt excavation generate considerable dust and debris that can contain airborne microorganisms. In one study, peak concentrations in outdoor air at grade level and HVAC intakes during site excavation averaged 20,000 CFU/m^3 for all fungi and 500 CFU/m^3 for *Aspergillus fumigatus*, compared with 19 CFU/m^3 and 4 CFU/m^3, respectively, in the absence of construction.[280] Many health-care institutions are located in large, urban areas; building implosions are becoming a more frequent concern. Infection-control risk assessment teams, particularly those in facilities located in urban renewal areas, would benefit by developing risk management strategies for external demolition and construction as a standing policy. In light of the events of 11 September 2001, it may be necessary for the team to identify those dust exclusion measures that can be implemented rapidly in response to emergency situations (Table 8). Issues to be reviewed prior to demolition include

a. proximity of the air intake system to the work site,
b. adequacy of window seals and door seals,
c. proximity of areas frequented by immunocompromised patients, and
d. location of the underground utilities (D. Erickson, ASHE, 2000).[120, 250, 273, 276, 277, 280, 305]

Table 8. Strategies to reduce dust and moisture intrusion during external demolition and construction

Item	Recommendation
Demolition site	• Shroud the site if possible to reduce environmental contamination.
Dust-generating equipment	• Prior to placing dust-generating equipment, evaluate the location to ensure that dust produced by the equipment will not enter the building through open doorways or windows, or through ventilation air intakes.
Construction materials storage	• Locate this storage away from the facility and ventilation air intakes.
Adjacent air intakes	• Seal off affected intakes, if possible, or move if funds permit.
HVAC system	• Consult with the facility engineer about pressure differentials and air recirculation options; keep facility air pressure positive to outside air.
Filters	• Ensure that filters are properly installed; change roughing filters frequently to prevent dust build-up on high-efficiency filters.
Windows	• Seal and caulk to prevent entry of airborne fungal spores.
Doors	• Keep closed as much as possible; do not prop open; seal and caulk unused doors (i.e., those that are not designated as emergency exits); use mats with tacky surfaces at outside entrances.
Water utilities	• Note location relative to construction area to prevent intrusion of dust into water systems. (Contamination of water pipes during demolition activities has been associated with health-care associated transmission of *Legionella* spp.[305])
Medical gas piping	• Ensure that these lines/pipes are insulated during periods of vibration.
Rooftops	• Temporarily close off during active demolition/construction those rooftop areas that are normally open to the public (e.g., rooftop atrium).
Dust generation	• Provide methods (e.g., misting the area with water) to minimize dust.
Immunocompromised patients	• Use walk-ways protected from demolition/construction sites; avoid outside areas close to these sites; avoid rooftops.
Pedestrian traffic	• Close off entry ways as needed to minimize dust intrusion.
Truck traffic	• Reroute if possible, or arrange for frequent street cleaning.
Education and awareness+	• Encourage reporting of hazardous or unsafe incidents associated with construction.

+ When health-care facilities have immunosuppressed patients in their census, telephoning the city building department each month to find out if buildings are scheduled for demolition is prudent.

Minimizing the entry of outside dust into the HVAC system is crucial in reducing the risk for airborne contaminants. Facility engineers should be consulted about the potential impact of shutting down the system or increasing the filtration. Selected air handlers, especially those located close to excavation sites, may have to be shut off temporarily to keep from overloading the system with dust and debris. Care is needed to avoid significant facility-wide reductions in pressure differentials that may cause the building to become negatively pressured relative to the outside. To prevent excessive particulate overload and subsequent reductions in effectiveness of intake air systems that cannot be shut off temporarily, air filters must be inspected frequently for proper installation and function. Excessive dust penetration can be avoided if recirculated air is maximally utilized while outdoor air intakes are shut down. Scheduling demolition and

excavation during the winter, when *Aspergillus* spp. spores may be present in lower numbers, can help, although seasonal variations in spore density differ around the world.[92, 287, 303]

Dust control can be managed by misting the dirt and debris during heavy dust-generating activities. To decrease the amount of aerosols from excavation and demolition projects, nearby windows, especially in areas housing immunocompromised patients, can be sealed and window and door frames caulked or weather-stripped to prevent dust intrusion.[50, 301, 306] Monitoring for adherence to these control measures throughout demolition or excavation is crucial. Diverting pedestrian traffic away from the construction sites decreases the amount of dust tracked back into the health-care facility and minimizes exposure of high-risk patients to environmental pathogens. Additionally, closing entrances near construction or demolition sites might be beneficial; if this is not practical, creating an air lock (i.e., pressurizing the entry way) is another option.

f. Internal Demolition, Construction, Renovations, and Repairs

The focus of a properly implemented infection-control program during interior construction and repairs is containment of dust and moisture. This objective is achieved by

a. educating construction workers about the importance of control measures
b. preparing the site;
c. notifying and issuing advisories for staff, patients, and visitors;
d. moving staff and patients and relocating patients as needed;
e. issuing standards of practice and precautions during activities and maintenance;
f. monitoring for adherence to control measures during construction and providing prompt feedback about lapses in control
g. monitoring HVAC performance;
h. implementing daily clean-up, terminal cleaning and removal of debris upon completion; and
i. ensuring the integrity of the water system during and after construction.

These activities should be coordinated with engineering staff and infection-control professionals.

Physical barriers capable of containing smoke and dust will confine dispersed fungal spores to the construction zone.[279, 284, 307, 308] The specific type of physical barrier required depends on the project's scope and duration and on local fire codes. Short-term projects that result in minimal dust dispersion (e.g., installation of new cables or wiring above ceiling tiles) require only portable plastic enclosures with negative pressure and HEPA filtration of the exhaust air from the enclosed work area. The placement of a portable industrial-grade HEPA filter device capable of filtration rate of 300–800 ft^3/min. adjacent to the work area will help to remove fungal spores, but its efficacy is dependent on the supplied ACH and size of the area. If the project is extensive but short-term, dust-abatement, fire-resistant plastic curtains (e.g., Visqueen®) may be adequate. These should be completely airtight and sealed from ceiling to floor with overlapping curtains;[276, 277, 309] holes, tears, or other perforations should be repaired promptly with tape. A portable, industrial-grade HEPA filter unit on continuous operation is needed within the contained area, with the filtered air exhausted to the outside of the work zone. Patients should not remain in the room when dust-generating activities are performed. Tools to assist the decision-making process regarding selection of barriers based on an ICRA approach are available.[281]

More elaborate barriers are indicated for long-term projects that generate moderate to large amounts of dust. These barrier structures typically consist of rigid, noncombustible walls constructed from sheet rock, drywall, plywood, or plaster board and covered with sheet plastic (e.g., Visqueen®). Barrier requirements to prevent the intrusion of dust into patient-care areas include

a. installing a plastic dust abatement curtain before construction of the rigid barrier
b. sealing and taping all joint edges including the top and bottom;
c. extending the barrier from floor to floor, which takes into account the space [approximately 2–8 ft.] above the finished, lay-down ceiling; and
d. fitting or sealing any temporary doors connecting the construction zone to the adjacent area. (See Box 7 for a list of the various construction and repair activities that require the use of some type of barrier.)

Box 7. Construction/repair projects that require barrier structures*

- Demolition of walls, wallboard, plaster, ceramic tiles, ceiling tiles, and ceilings
- Removal of flooring and carpeting, windows and doors, and casework
- Working with sinks and plumbing that could result in aerosolization of water in high-risk areas
- Exposure of ceiling spaces for demolition and for installation or rerouting of utility services (e.g., rewiring, electrical conduction installation, HVAC ductwork, and piping)
- Crawling into ceiling spaces for inspection in a manner that may dislodge dust
- Demolition, repair, or construction of elevator shafts
- Repairing water damage

* Material for this box was compiled from references 120, 250, 273, 276, 277.

Dust and moisture abatement and control rely primarily on the impermeable barrier containment approach; as construction continues, numerous opportunities can lead to dispersion of dust to other areas of the health-care facility. Infection-control measures that augment the use of barrier containment should be undertaken (Table 9).

Dust-control measures for clinical laboratories are an essential part of the infection-control strategy during hospital construction or renovation. Use of plastic or solid barriers may be needed if the ICRA determines that air flow from construction areas may introduce airborne contaminants into the laboratory space. In one facility, pseudofungemia clusters attributed to *Aspergillus* spp. and *Penicillium* spp. were linked to improper air flow patterns and construction projects adjacent to the laboratory; intrusion of dust and spores into a biological safety cabinet from construction activity immediately next to the cabinet resulted in a cluster of cultures contaminated with *Aspergillus niger*. [310, 311] Reportedly, no barrier containment was used and the HEPA filtration system was overloaded with dust. In addition, an outbreak of pseudobacteremia caused by *Bacillus* spp. occurred in another hospital during construction above a storage area for blood culture bottles.[207] Airborne spread of *Bacillus* spp. spores resulted in contamination of the bottles' plastic lids, which were not disinfected or handled with proper aseptic technique prior to collection of blood samples.

Table 9. Infection-control measures for internal construction and repair projects*+

Infection-control measure	Steps for implementation
Prepare for the project.	1. Use a multi-disciplinary team approach to incorporate infection control into the project. 2. Conduct the risk assessment and a preliminary walk-through with project managers and staff.
Educate staff and construction workers.	1. Educate staff and construction workers about the importance of adhering to infection-control measures during the project. 2. Provide educational materials in the language of the workers. 3. Include language in the construction contract requiring construction workers and subcontractors to participate in infection-control training.
Issue hazard and warning notices.	1. Post signs to identify construction areas and potential hazards. 2. Mark detours requiring pedestrians to avoid the work area.
Relocate high-risk patients as needed, especially if the construction is in or adjacent to a PE area.	1. Identify target patient populations for relocation based on the risk assessment. 2. Arrange for the transfer in advance to avoid delays. 3. At-risk patients should wear protective respiratory equipment (e.g., a high- efficiency mask) when outside their PE rooms.

Infection-control measure	Steps for implementation
Establish alternative traffic patterns for staff, patients, visitors, and construction workers.	1. Determine appropriate alternate routes from the risk assessment. 2. Designate areas (e.g., hallways, elevators, and entrances/exits) for construction-worker use. 3. Do not transport patients on the same elevator with construction materials and debris.
Erect appropriate barrier containment.	1. Use prefabricated plastic units or plastic sheeting for short-term projects that will generate minimal dust. 2. Use durable rigid barriers for ongoing, long-term projects.
Establish proper ventilation.	1. Shut off return air vents in the construction zone, if possible, and seal around grilles. 2. Exhaust air and dust to the outside, if possible. 3. If recirculated air from the construction zone is unavoidable, use a pre-filter and a HEPA filter before the air returns to the HVAC system. 4. When vibration-related work is being done that may dislodge dust in the ventilation system or when modifications are made to ductwork serving occupied spaces, install filters on the supply air grilles temporarily. 5. Set pressure differentials so that the contained work area is under negative pressure. 6. Use air flow monitoring devices to verify the direction of the air pattern. 7. Exhaust air and dust to the outside, if possible. 8. Monitor temperature, air changes per hour (ACH), and humidity levels (humidity levels should be <65%). 9. Use portable, industrial grade HEPA filters in the adjacent area and/or the construction zone for additional ACH. 10. Keep windows closed, if possible.
Control solid debris.	1. When replacing filters, place the old filter in a bag prior to transport and dispose as a routine solid waste. 2. Clean the construction zone daily or more often as needed. 3. Designate a removal route for small quantities of solid debris. 4. Mist debris and cover disposal carts before transport (i.e., leaving the construction zone). 5. Designate an elevator for construction crew use. 6. Use window chutes and negative pressure equipment for removal of larger pieces of debris while maintaining pressure differentials in the construction zone. 7. Schedule debris removal to periods when patient exposures to dust is minimal.
Control water damage.	1. Make provisions for dry storage of building materials. 2. Do not install wet, porous building materials (i.e., sheet rock). 3. Replace water-damaged porous building materials if they cannot be completely dried out within 72 hours.
Control dust in air and on surfaces.	1. Monitor the construction area daily for compliance with the infection-control plan. 2. Protective outer clothing for construction workers should be removed before entering clean areas. 3. Use mats with tacky surfaces within the construction zone at the entry; cover sufficient area so that both feet make contact with the mat while walking through the entry. 4. Construct an anteroom as needed where coveralls can be donned and removed. 5. Clean the construction zone and all areas used by construction workers with a wet mop. 6. If the area is carpeted, vacuum daily with a HEPA-filtered–equipped vacuum. 7. Provide temporary essential services (e.g., toilets) and worker conveniences (e.g, vending machines) in the construction zone as appropriate. 8. Damp-wipe tools if removed from the construction zone or left in the area. 9. Ensure that construction barriers remain well sealed; use particle sampling as needed. 10. Ensure that the clinical laboratory is free from dust contamination.

Infection-control measure	Steps for implementation
Complete the project.	1. Flush the main water system to clear dust-contaminated lines. 2. Terminally clean the construction zone before the construction barriers are removed. 3. Check for visible mold and mildew and eliminate (i.e., decontaminate and remove), if present. 4. Verify appropriate ventilation parameters for the new area as needed. 5. Do not accept ventilation deficiencies, especially in special care areas. 6. Clean or replace HVAC filters using proper dust-containment procedures. 7. Remove the barriers and clean the area of any dust generated during this work. 8. Ensure that the designated air balances in the operating rooms (OR) and protective environments (PE) are achieved before occupancy. 9. Commission the space as indicated, especially in the OR and PE, ensuring that the room's required engineering specifications are met.

* Material in this table includes information from D. Erickson, ASHE, 2000.

+ Material in this table was compiled from references 19, 51, 67, 80, 106, 120, 250, 266, 273, 276–278, 280, 285, 309, 312–315.

5. Environmental Infection-Control Measures for Special Health-Care Settings

Areas in health-care facilities that require special ventilation include

a. operating rooms
b. PE rooms used by high-risk, immunocompromised patients; and
c. AII rooms for isolation of patients with airborne infections (e.g., those caused by *M. tuberculosis*, VZV, or measles virus).

Interim Measles Infection Control [July 2019]
See Interim Infection Prevention and Control Recommendations for Measles in Healthcare Settings (https://www.cdc.gov/infectioncontrol/guidelines/measles)

The number of rooms required for PE and AII are determined by a risk assessment of the health-care facility.[6] Continuous, visual monitoring of air flow direction is required for new or renovated pressurized rooms. [120, 256]

a. Protective Environments (PE)

Although the exact configuration and specifications of PEs might differ among hospitals, these care areas for high-risk, immunocompromised patients are designed to minimize fungal spore counts in air by maintaining

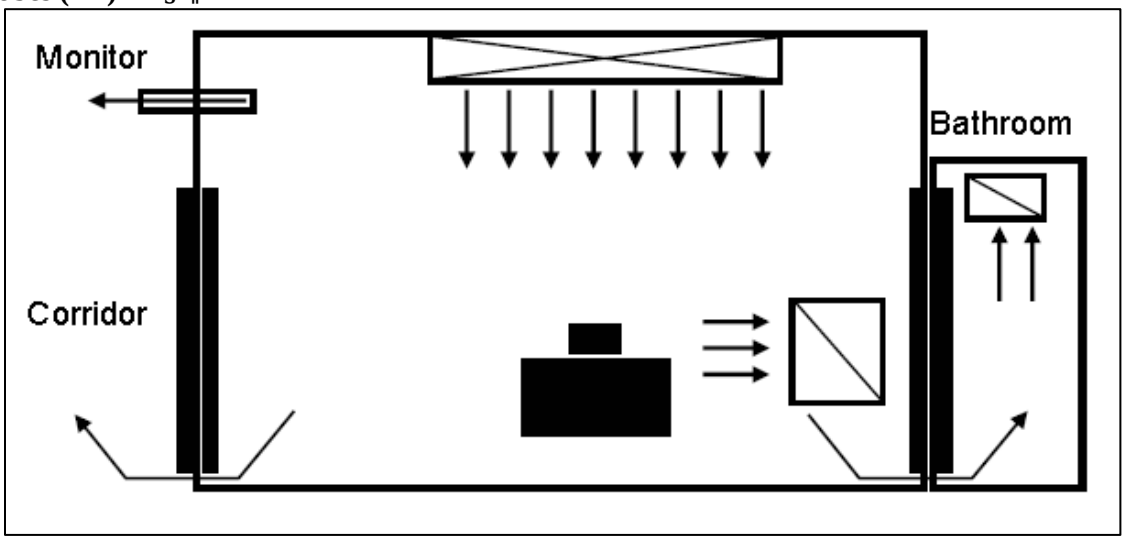
a. filtration of incoming air by using central or point-of-use HEPA filters
b. directed room air flow [i.e., from supply on one side of the room, across the patient, and out through the exhaust on the opposite side of the room];
c. positive room air pressure of 2.5 Pa [0.01" water gauge] relative to the corridor;
d. well-sealed rooms; and
e. ≥12 ACH.[44, 120, 251, 254, 316–319]

Air flow rates must be adjusted accordingly to ensure sufficient ACH, and these rates vary depending on certain factors (e.g., room air leakage area). For example, to provide ≥12 ACH in a typical patient room with 0.5 sq. ft. air leakage, the air flow rate will be minimally 125 cubic feet/min (cfm).[320, 321] Higher air flow rates may be needed. A general ventilation diagram for a positive-pressure room is given in Figure 2. Directed room air flow in PE rooms is not laminar; parallel air streams are not generated. Studies attempting to demonstrate patient benefit from laminar air flow in a PE setting are equivocal.[316, 318, 319, 322 - 327]

Air flow direction at the entrances to these areas should be maintained and verified, preferably on a daily basis, using either a visual means of indication (e.g., smoke tubes and flutter strips) or manometers. Permanent installation of a visual monitoring device is indicated for new PE construction and renovation.[120] Facility service structures can interfere with the proper unidirectional air flow from the

patients' rooms to the adjacent corridor. In one outbreak investigation, *Aspergillus* spp. infections in a critical care unit may have been associated with a pneumatic specimen transport system, a textile disposal duct system, and central vacuum lines for housekeeping, all of which disrupted proper air flow from the patients' rooms to the outside and allowed entry of fungal spores into the unit (M.McNeil, CDC, 2000).

Figure 2. Example of positive-pressure room control for protection from airborne environmental microbes (PE)* + § ¶



* 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 air flow.

\+ 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; air flow volume differential >125-cfm supply versus exhaust; sealed room, approximately 0.5-sq. ft. leakage; clean to dirty air flow; monitoring; ≥12 air changes per hour (ACH); and return air if refiltered.

¶ This diagram is a generic illustration of air flow in a typical installation. Alternative air flow arrangements are recognized. Adapted and used with permission from A. Streifel and the publisher of reference 328 (Penton Media, Inc.)

The use of surface fungicide treatments is becoming more common, especially for building materials.[329] Copper-based compounds have demonstrated anti-fungal activity and are often applied to wood or paint. Copper-8-quinolinolate was used on environmental surfaces contaminated with *Aspergillus* spp. to control one reported outbreak of aspergillosis.310 The compound was also incorporated into the fireproofing material of a newly constructed hospital to help decrease the environmental spore burden.[316]

b. Airborne Infection Isolation (AII)

Acute-care inpatient facilities need at least one room equipped to house patients with airborne infectious disease. Every health-care facility, including ambulatory and long-term care facilities, should undertake an ICRA to identify the need for AII areas. Once the need is established, the appropriate ventilation equipment can be identified. Air handling systems for this purpose need not be restricted to central systems. Guidelines for the prevention of health-care acquired TB have been published in response to multiple reports of health-care associated transmission of multi-drug resistant strains.[4, 330] In reports documenting health-care acquired TB, investigators have noted a failure to comply fully with prevention

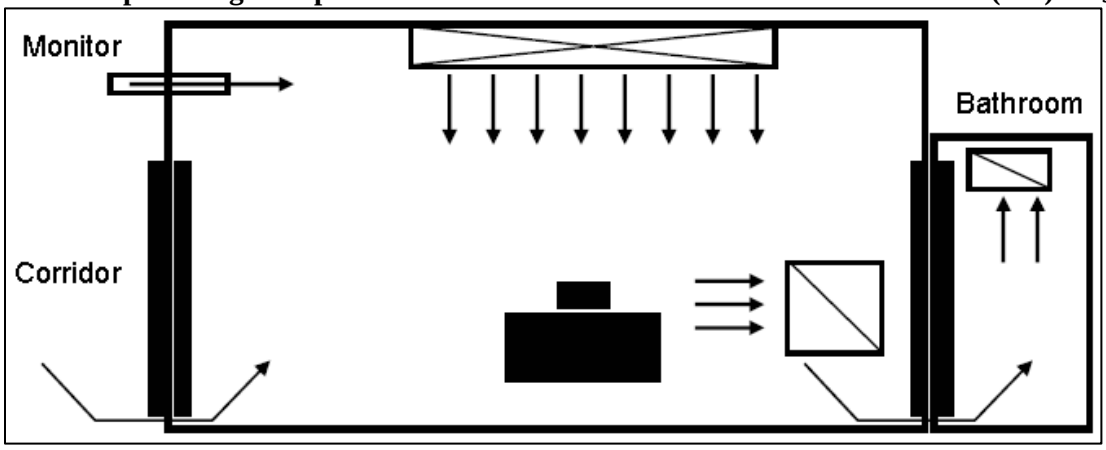
measures in established guidelines.[331 - 345] These gaps highlight the importance of prompt recognition of the disease, isolation of patients, proper treatment, and engineering controls. AII rooms are also appropriate for the care and management of smallpox patients.[6] Environmental infection control with respect to smallpox is currently being revisited (see Appendix E).

Salient features of engineering controls for AII areas include

a. use of negative pressure rooms with close monitoring of air flow direction using manometers or temporary or installed visual indicators [e.g., smoke tubes and flutter strips] placed in the room with the door closed
b. minimum 6 ACH for existing facilities, ≥12 ACH for areas under renovation or for new construction; and
c. air from negative pressure rooms and treatment rooms exhausted directly to the outside if possible.[4, 120, 248]

As with PE, airflow rates need to be determined to ensure the proper numbers of ACH.[320, 321] AII rooms can be constructed either with (Figure 3) or without (Figure 4) an anteroom. When the recirculation of air from AII rooms is unavoidable, HEPA filters should be installed in the exhaust duct leading from the room to the general ventilation system. In addition to UVGI fixtures in the room, UVGI can be placed in the ducts as an adjunct measure to HEPA filtration, but it can not replace the HEPA filter.[4, 346] A UVGI fixture placed in the upper room, coupled with a minimum of 6 ACH, also provides adequate air cleaning.[248]

Figure 3. Example of negative-pressure room control for airborne infection isolation (AII)* + §¶



* 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 air flow.

\+ 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); air flow volume differential >125-cfm exhaust versus supply; sealed room, approximately 0.5-sq. ft. leakage; clean to dirty air flow; monitoring; ≥12 air changes per hour (ACH) new or renovation, 6 ACH existing; and exhaust to outside or HEPA-filtered if recirculated.

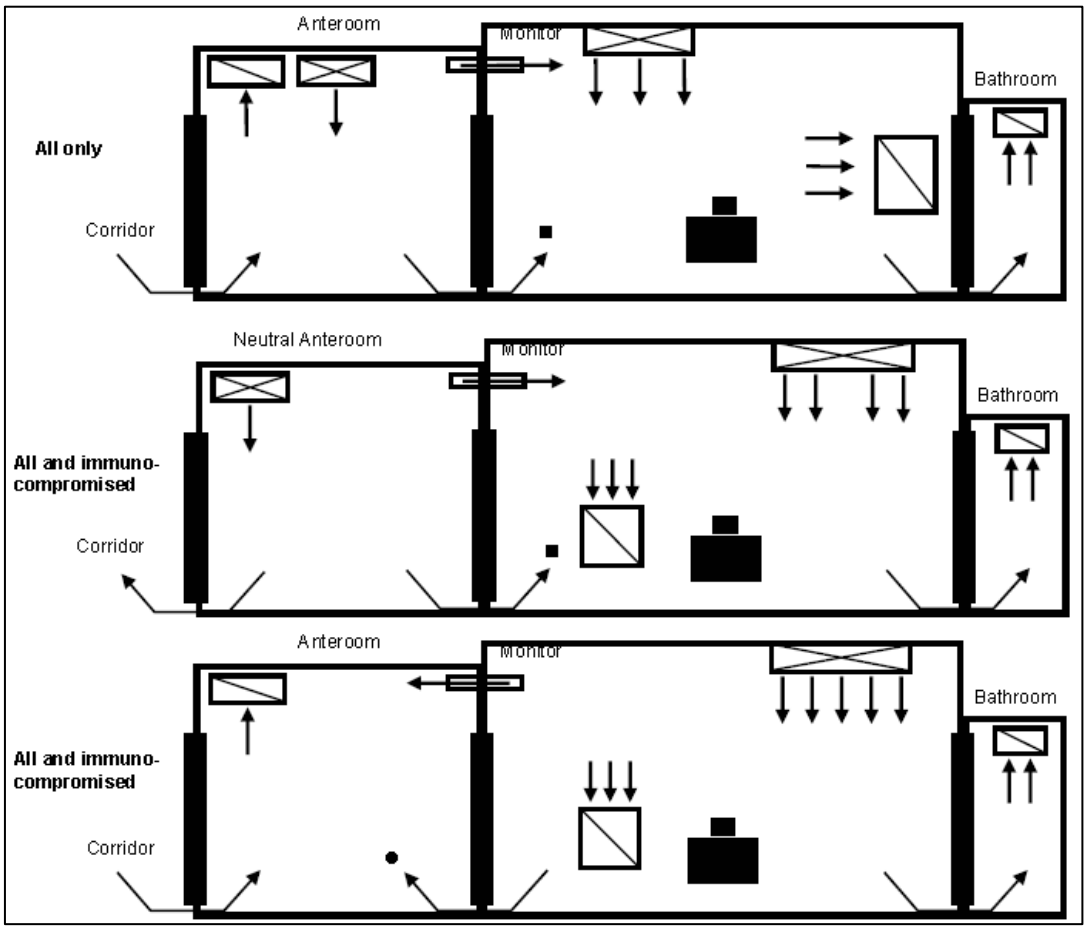
¶ This diagram is a generic illustration of air flow in a typical installation. Alternative air flow arrangements are recognized. Adapted and used with permission from A. Streifel and the publisher of reference 328 (Penton Media, Inc.)

One of the components of airborne infection isolation is respiratory protection for health-care workers and visitors when entering AII rooms.[4, 6, 347] Recommendations of the type of respiratory protection are dependent on the patient's airborne infection (indicating the need for AII) and the risk of infection to

persons entering the AII room. A more in-depth discussion of respiratory protection in this instance is presented in the current isolation guideline;[6] a revision of this guideline is in development. Cough-inducing procedures (e.g., endotracheal intubation and suctioning of known or suspected TB patients, diagnostic sputum induction, aerosol treatments, and bronchoscopy) require similar precautions.[348–350]

Additional engineering measures are necessary for the management of patients requiring PE (i.e., allogeneic HSCT patients) who concurrently have airborne infection. For this type of patient treatment, an anteroom (Figure 4) is required in new construction and renovation as per AIA guidelines.[120]

Figure 4. Example of airborne infection isolation (AII) room with anteroom and neutral anteroom* + §



* The top diagram indicates air flow patterns when patient with only airborne infectious disease occupies room. Middle and bottom diagrams indicate recommended air flow 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 air flow.

\+ AII isolation room with anteroom engineering features include

- pressure differential of 2.5 Pa (0.01-in. water gauge) measured at the door between patient room and anteroom;
- air flow volume differential >125-cfm. depending on anteroom air flow direction (pressurized versus depressurized);
- 38 sealed room with approximately 0.5-sq. ft. leakage;
- clean to dirty air flow
- monitoring;
- ≥12 air changes per hour (ACH) new or renovation, 6 ACH existing; and
- anteroom air flow patterns. The small ■ in panels 1 and 2 indicate the anteroom is pressurized

(supply versus exhaust), while the small • in panel 3 indicates the anteroom is depressurized (exhaust versus supply).

§ Used with permission of A. Streifel, University of Minnesota

The pressure differential of an anteroom can be positive or negative relative to the patient in the room.[120] An anteroom can act as an airlock (Figure 4). If the anteroom is positive relative to the air space in the patient's room, staff members do not have to mask prior to entry into the anteroom if air is directly exhausted to the outside and a minimum of 10 ACH (Figure 4, top diagram).[120] When an anteroom is negative relative to both the AII room and the corridor, health-care workers must mask prior to entering the anteroom (Figure 4, bottom diagram). If an AII room with an anteroom is not available, use of a portable, industrial-grade HEPA filter unit may help to increase the number of ACHs while facilitating the removal of fungal spores; however, a fresh air source must be present to achieve the proper air exchange rate. Incoming ambient air should receive HEPA filtration.

c. Operating Rooms

Operating room air may contain microorganisms, dust, aerosol, lint, skin squamous epithelial cells, and respiratory droplets. The microbial level in operating room air is directly proportional to the number of people moving in the room.[351] One study documented lower infection rates with coagulase-negative staphylococci among patients when operating room traffic during the surgical procedure was limited.[352] Therefore, efforts should be made to minimize personnel traffic during operations. Outbreaks of SSIs caused by group A beta-hemolytic streptococci have been traced to airborne transmission from colonized operating-room personnel to patients.[150–154] Several potential health-care associated pathogens (e.g., *Staphylococcus aureus* and *Staphylococcus epidermidis*) and drug-resistant organisms have also been recovered from areas adjacent to the surgical field,[353] but the extent to which the presence of bacteria near the surgical field influences the development of postoperative SSIs is not clear.[354]

Proper ventilation, humidity (<68%), and temperature control in the operating room is important for the comfort of surgical personnel and patients, but also in preventing environmental conditions that encourage growth and transmission of microorganisms.[355] Operating rooms should be maintained at positive pressure with respect to corridors and adjacent areas.[356] Operating rooms typically do not have a variable air handling system. Variable air handling systems are permitted for use in operating rooms only if they continue to provide a positive pressure with respect to the corridors and adjacent areas and the proper ACHs are maintained when the room is occupied. Conventional operating-room ventilation systems produce a minimum of about 15 ACH of filtered air for thermal control, three (20%) of which must be fresh air.[120, 357, 358] Air should be introduced at the ceiling and exhausted near the floor.[357, 359]

Laminar airflow and UVGI have been suggested as adjunct measures to reduce SSI risk for certain operations. Laminar airflow is designed to move particle-free air over the aseptic operating field at a uniform velocity (0.3–0.5 m/sec), sweeping away particles in its path. This air flow can be directed vertically or horizontally, and recirculated air is passed through a HEPA filter.[360–363] Neither laminar airflow nor UV light, however, has been conclusively shown to decrease overall SSI risk.[356, 364–370]

Elective surgery on infectious TB patients should be postponed until such patients have received adequate drug therapy. The use of general anesthesia in TB patients poses infection-control challenges because intubation can induce coughing, and the anesthesia breathing circuit apparatus potentially can become contaminated.[371] Although operating room suites at 15 ACH exceed the air exchanges required transmission of TB to operating-room personnel. If feasible, intubation and extubation of the TB surgical patient should be performed in AII. AIA currently does not recommend changing pressure from positive to negative or setting it to neutral; most facilities lack the capability to do so.[120] When

emergency surgery is indicated for a suspected/diagnosed infectious TB patient, taking specific infection-control measures is prudent (Box 8).

Box 8. Strategy for managing TB patients and preventing airborne transmission in operating rooms*

1. If emergency surgery is indicated for a patient with active TB, schedule the TB patient as the last surgical case to provide maximum time for adequate ACH.
2. Operating room personnel should use NIOSH-approved N95 respirators without exhalation valves.[347]
3. Keep the operating room door closed after the patient is intubated, and allow adequate time for sufficient ACH to remove 99% of airborne particles (Appendix B, Table B.1.):
   a. after the patient is intubated and particularly if intubation produces coughing
   b. if the door to the operating suite must be opened, and intubation induces coughing in the patient; or
   c. after the patient is extubated and suctioned [unless a closed suctioning system is present].
4. Extubate the patient in the operating room or allow the patient to recover in AII rather than in the regular open recovery facilities.
5. Temporary use of a portable, industrial grade HEPA filter may expedite removal of airborne contaminants (fresh-air exchange requirements for proper ventilation must still be met).+
6. Breathing circuit filters with 0.1–0.2 μm pore size can be used as an adjunct infection-control measure.[373, 374]

* Material in this table was compiled from references 4, 347, and 372–374.

\+ The placement of portable HEPA filter units in the operating room must be carefully evaluated for potential disruptions in normal air flow. The portable unit should be turned off while the surgical procedure is underway and turned on following extubation. Portable HEPA filter units previously placed in construction areas may be used in subsequent patient care, provided that all internal and external surfaces are cleaned and the filter's performance is verified with appropriate particle testing and is changed, if needed.

Table 10. Summary of ventilation specifications in selected areas of health-care facilities*

Specifications	AII room (includes bronchoscopy suites)	PE room	Critical care room§	Isolation anteroom	Operating room
Air pressure¶	Negative	Positive	Positive, negative, or neutral	Positive or negative	Positive
Room air changes	≥6 ACH (for existing rooms); ≥12 ACH (for renovation or new construction)	≥12 ACH	≥6 ACH	≥10 ACH	≥15 ACH
Sealed**	Yes	Yes	No	Yes	Yes
Filtration supply	90% (dust-spot ASHRAE 52.1 1992)	99.97% (Fungal spore filter at point of use (HEPA at 99.97% of 0.3 μm particles))	>90%	>90%	90%
Recirculation	No (Recirculated air may be used if the exhaust air is first processed through a HEPA filter.)	Yes	Yes	No	Yes

* Material in this table is compiled from references 35 and 120. Table used with permission of the publisher of reference 35 (Lippincott Williams and Wilkins).

§ Positive pressure and HEPA filters may be preferred in some rooms in intensive care units (ICUs) caring for large numbers of immunocompromised patients.
¶ Clean-to-dirty: negative to an infectious patient, positive away from an immunocompromised patient.
** Minimized infiltration for ventilation control; pertains to windows, closed doors, and surface joints.
¶¶ Table used with permission of the publisher of reference 35 (Lippincott Williams and Wilkins).

6. Other Aerosol Hazards in Health-Care Facilities

In addition to infectious bioaerosols, several crucial non-infectious, indoor air-quality issues must be addressed by health-care facilities. The presence of sensitizing and allergenic agents and irritants in the workplace (e.g., ethylene oxide, glutaraldehyde, formaldehyde, hexachlorophene, and latex allergens[375]) is increasing. Asthma and dermatologic and systemic reactions often result with exposure to these chemicals. Anesthetic gases and aerosolized medications (e.g., ribavirin, pentamidine, and aminoglycosides) represent some of the emerging potentially hazardous exposures to health-care workers. Containment of the aerosol at the source is the first level of engineering control, but personal protective equipment (e.g., masks, respirators, and glove liners) that distances the worker from the hazard also may be needed.

Laser plumes and surgical smoke represent another potential risk for health-care workers.[376–378] Lasers transfer electromagnetic energy into tissues, resulting in the release of a heated plume that includes particles, gases, tissue debris, and offensive smells. One concern is that aerosolized infectious material in the laser plume might reach the nasal mucosa of surgeons and adjacent personnel. Although some viruses (i.e., varicella-zoster virus, pseudorabies virus, and herpes simplex virus) do not aerosolize efficiently,[379, 380] other viruses and bacteria (e.g., human papilloma virus [HPV], HIV, coagulasenegative *Staphylococcus, Corynebacterium* spp., *and Neisseria* spp.) have been detected in laser plumes.[381–387] The presence of an infectious agent in a laser plume may not, however, be sufficient to cause disease from airborne exposure, especially if the normal mode of transmission for the agent is not airborne. No evidence indicated that HIV or hepatitis B virus (HBV) has been transmitted via aerosolization and inhalation.[388]

Although continuing studies are needed to fully evaluate the risk of laser plumes to surgical personnel, the prevention measures in these other guidelines should be followed:
a. NIOSH recommendations,[378]
b. the *Recommended Practices for Laser Safety in Practice Settings* developed by the Association of periOperative Registered Nurses [AORN],[389]
c. the assessments of ECRI,[390–392] and
d. the ANSI standard.[393]

These guidelines recommend the use of
a. respirators (N95 or N100) or full face shields and masks,[260]
b. central wall-suction units with in-line filters to collect particulate matter from minimal plumes, and
c. dedicated mechanical smoke exhaust systems with a high-efficiency filter to remove large amounts of laser plume.

Although transmission of TB has occurred as a result of abscess management practices that lacked airborne particulate control measures and respiratory protection, use of a smoke evacuator or needle aspirator and a high degree of clinical awareness can help protect healthcare workers when excising and draining an extrapulmonary TB abscess.[137]

D. Water

1. Modes of Transmission of Waterborne Diseases

Moist environments and aqueous solutions in health-care settings have the potential to serve as reservoirs for waterborne microorganisms. Under favorable environmental circumstances (e.g., warm temperature and the presence of a source of nutrition), many bacterial and some protozoal microorganisms can either

proliferate in active growth or remain for long periods in highly stable, environmentally resistant (yet infectious) forms. Modes of transmission for waterborne infections include

a. direct contact [e.g., that required for hydrotherapy];
b. ingestion of water [e.g., through consuming contaminated ice];
c. indirect-contact transmission [e.g., from an improperly reprocessed medical device];[6]
d. inhalation of aerosols dispersed from water sources;[3] and
e. aspiration of contaminated water.

The first three modes of transmission are commonly associated with infections caused by gram-negative bacteria and nontuberculous mycobacteria (NTM). Aerosols generated from water sources contaminated with *Legionella* spp. often serve as the vehicle for introducing legionellae to the respiratory tract.[394]

2. Waterborne Infectious Diseases in Health-Care Facilities

a. Legionellosis

Legionellosis is a collective term describing infection produced by *Legionella* spp., whereas Legionnaires disease is a multi-system illness with pneumonia.[395] The clinical and epidemiologic aspects of these diseases (Table 11) are discussed extensively in another guideline.[3] Although Legionnaires disease is a respiratory infection, infection-control measures intended to prevent healthcare-associated cases center on the quality of water—the principal reservoir for *Legionella* spp.

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 11. Clinical and epidemiologic characteristics of legionellosis/Legionnaires disease

Modes of transmission
- Aspiration of water, direct inhalation or water aerosols. [3, 394–398, 400]

Causative agent
- Legionella pneumophila (90% of infections); L. micdadei, L. bozemanii, L. dumoffii, L. longbeachii, (14 additional species can cause infection in humans). [395–399]

Source of exposure
- Exposure to environmental sources of *Legionella* spp. (i.e., water or water aerosols). [31, 33, 401–414]

Clinical syndromes and diseases

Two distinct illnesses: [397–399, 415–422]
- Pontiac fever [a milder, influenza-like illness]; and
- progressive pneumonia that may be accompanied by cardiac, renal, and gastrointestinal involvement [3]

Patient populations at greatest risk
- Immunosuppressed patients (e.g., transplant patients, cancer patients, and patients receiving corticosteroid therapy);
- Immunocompromised patients (e.g., surgical patients, patients with underlying chronic lung disease, and dialysis patients);
- Elderly persons; and
- Patients who smoke. [395–397, 423–433]

Occurrence
- Proportion of community-acquired pneumonia caused by *Legionella* spp. ranges from 1%–5%; estimated annual incidence among the general population is 8,000–18,000 cases in the United States; the incidence of healthcare-associated pneumonia (0%–14%) may be underestimated if appropriate laboratory diagnostic methods are unavailable. [396, 397, 434–444]

Mortality rate

- Mortality declined markedly during 1980–1998, from 34% to 12% for all cases; the mortality rate is higher among persons with health-care associated pneumonia compared with the rate among community-acquired pneumonia patients (14% for health-care associated pneumonia versus 10% for community-acquired pneumonia [1998 data]). [395–397, 445]

Legionella spp. are commonly found in various natural and man-made aquatic environments[446, 447] and can enter health-care facility water systems in low or undetectable numbers.[448, 449] Cooling towers, evaporative condensers, heated potable water distribution systems, and locally-produced distilled water can provide environments for multiplication of legionellae.[450–454] In several hospital outbreaks, patients have been infected through exposure to contaminated aerosols generated by cooling towers, showers, faucets, respiratory therapy equipment, and room-air humidifiers.[401–410, 455] Factors that enhance colonization and amplification of legionellae in man-made water environments include

a. temperatures of 77°F–107.6°F [25°C–42°C],[456–460]
b. stagnation,[461]
c. scale and sediment, [462] and
d. presence of certain free-living aquatic amoebae that can support intracellular growth of legionellae.[462, 463]

The bacteria multiply within single-cell protozoa in the environment and within alveolar macrophages in humans.

b. Other Gram-Negative Bacterial Infections

Other gram-negative bacteria present in potable water also can cause health-care associated infections. Clinically important, opportunistic organisms in tap water include *Pseudomonas aeruginosa, Pseudomonas* spp., *Burkholderia cepacia, Ralstonia pickettii, Stenotrophomonas maltophilia*, and *Sphingomonas* spp. (Tables 12 and 13). Immunocompromised patients are at greatest risk of developing infection. Medical conditions associated with these bacterial agents range from colonization of the respiratory and urinary tracts to deep, disseminated infections that can result in pneumonia and bloodstream bacteremia. Colonization by any of these organisms often precedes the development of infection. The use of tap water in medical care (e.g., in direct patient care, as a diluent for solutions, as a water source for medical instruments and equipment, and during the final stages of instrument disinfection) therefore presents a potential risk for exposure. Colonized patients also can serve as a source of contamination, particularly for moist environments of medical equipment (e.g., ventilators).

In addition to *Legionella* spp., *Pseudomonas aeruginosa* and *Pseudomonas* spp. are among the most clinically relevant, gram-negative, health-care associated pathogens identified from water. These and other gram-negative, non-fermentative bacteria have minimal nutritional requirements (i.e., these organisms can grow in distilled water) and can tolerate a variety of physical conditions. These attributes are critical to the success of these organisms as health-care associated pathogens. Measures to prevent the spread of these organisms and other waterborne, gram-negative bacteria include hand hygiene, glove use, barrier precautions, and eliminating potentially contaminated environmental reservoirs.[464, 465]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 12. *Pseudomonas aeruginosa* infections

Modes of transmission

- Direct contact with water, aerosols; aspiration of water and inhalation of water aerosols; and indirect transfer from moist environmental surfaces via hands of health-care workers. [28, 502–506]

Clinical syndromes and diseases

- Septicemia, pneumonia (particularly ventilator-associated), chronic respiratory infections among cystic fibrosis patients, urinary tract infections, skin and soft-tissue infections (e.g., tissue necrosis and hemorrhage), burn-wound infections, folliculitis, endocarditis, central nervous system infections (e.g., meningitis and abscess), eye infections, and bone and joint infections. [466–503]

Environmental sources of pseudomonads in healthcare settings

- Potable (tap) water, distilled water, antiseptic solutions contaminated with tap water, sinks, hydrotherapy pools, whirlpools and whirlpool spas, water baths, lithotripsy therapy tanks, dialysis water, eyewash stations, flower vases, and endoscopes with residual moisture in the channels. [28, 29, 466, 468, 507–520]

Environmental sources of pseudomonads in the community

- Fomites (e.g., drug injection equipment stored in contaminated water). [494, 495]

Patient populations at greatest risk

- Intensive care unit (ICU) patients (including neonatal ICU), transplant patients (organ and hematopoietic stem cell), neutropenic patients, burn therapy and hydrotherapy patients, patients with malignancies, cystic fibrosis patients, patients with underlying medical conditions, and dialysis patients.[28, 466, 467, 472, 477, 493, 506–508, 511, 512, 521–526]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 13. Other gram-negative bacteria associated with water and moist environments

Bacteria	Implicated contaminated environmental vehicle
Burkholderia cepacia	• Distilled water [527] • Contaminated solutions and disinfectants [528, 529] • Dialysis machines [527] • Nebulizers [530–532] • Water baths [533] • Intrinsically-contaminated mouthwash [534] (This report describes contamination occurring during manufacture prior to use by the health-care facility staff. All other entries reflect extrinsic sources of contamination.) • Ventilator temperature probes [535]
***Stenotrophomonas maltophlia, Sphingomonas* spp.**	• Distilled water [536, 537] • Contaminated solutions and disinfectants [529] • Dialysis machines [527] • Nebulizers [530–532] • Water [538] • Ventilator temperature probes [539]
Ralstonia pickettii	• Fentanyl solutions [540] • Chlorhexidine [541] • Distilled water [541] • Contaminated respiratory therapy solution [541, 542]
Serratia marcescens	• Potable water [543] • Contaminated antiseptics (i.e., benzalkonium chloride and chlorhexidine) [544–546] • Contaminated disinfectants (i.e., quaternary ammonium compounds and glutaraldehyde) [547, 548]
***Acinetobacter* spp.**	• Medical equipment that collects moisture (e.g., mechanical ventilators, cool mist humidifiers, vaporizers, and mist tents) [549–556] • Room humidifiers [553, 555] • Environmental surfaces [557–564]
***Enterobacter* spp.**	• Humidifier water [565] • Intravenous fluids [566–578] • Unsterilized cotton swabs [573] • Ventilators [565, 569] • Rubber piping on a suctioning machine [565, 569] • Blood gas analyzers [570]

Two additional gram-negative bacterial pathogens that can proliferate in moist environments are *Acinetobacter* spp. and *Enterobacter* spp. [571, 572] Members of both genera are responsible for healthcare–

associated episodes of colonization, bloodstream infections, pneumonia, and urinary tract infections among medically compromised patients, especially those in ICUs and burn therapy units.[566, 572–583]

Infections caused by *Acinetobacter* spp. represent a significant clinical problem. Average infection rates are higher from July through October compared with rates from November through June.[584] Mortality rates associated with *Acinetobacter* bacteremia are 17%–52%, and rates as high as 71% have been reported for pneumonia caused by infection with either *Acinetobacter* spp. or *Pseudomonas* spp.Multi-drug resistance, especially in third generation cephalosporins for *Enterobacter* spp., contributes to increased morbidity and mortality.[569, 572]

Patients and health-care workers contribute significantly to the environmental contamination of surfaces and equipment with *Acinetobacter* spp. and *Enterobacter* spp., especially in intensive care areas, because of the nature of the medical equipment (e.g., ventilators) and the moisture associated with this equipment.[549, 571, 572, 585]

Hand carriage and hand transfer are commonly associated with health-care– associated transmission of these organisms and for *S. marcescens*. [586] *Enterobacter* spp. are primarily spread in this manner among patients by the hands of health-care workers.[567, 587] *Acinetobacter* spp. have been isolated from the hands of 4%–33% of health-care workers in some studies,[585–590] and transfer of an epidemic strain of *Acinetobacter* from patients' skin to health-care workers' hands has been demonstrated experimentally.[591] *Acinetobacter* infections and outbreaks have also been attributed to medical equipment and materials (e.g., ventilators, cool mist humidifiers, vaporizers, and mist tents) that may have contact with water of uncertain quality (e.g., rinsing a ventilator circuit in tap water).[549– 556] Strict adherence to hand hygiene helps prevent the spread of both *Acinetobacter* spp. and *Enterobacter* spp.[577, 592]

Acinetobacter spp. have also been detected on dry environmental surfaces (e.g., bed rails, counters, sinks, bed cupboards, bedding, floors, telephones, and medical charts) in the vicinity of colonized or infected patients; such contamination is especially problematic for surfaces that are frequently touched.[557–564] In two studies, the survival periods of *Acinetobacter baumannii* and *Acinetobacter calcoaceticus* on dry surfaces approximated that for *S. aureus* (e.g., 26–27 days).[593, 594] Because *Acinetobacter* spp. may come from numerous sources at any given time, laboratory investigation of health-care associated *Acinetobacter* infections should involve techniques to determine biotype, antibiotype, plasmid profile, and genomic fingerprinting (i.e., macrorestriction analysis) to accurately identify sources and modes of transmission of the organism(s).[595]

c. Infections and Pseudo-Infections Due to Nontuberculous Mycobacteria

NTM are acid-fast bacilli (AFB) commonly found in potable water. NTM include both saprophytic and opportunistic organisms. Many NTM are of low pathogenicity, and some measure of host impairment is necessary to enhance clinical disease.[596] The four most common forms of human disease associated with NTM are

a. pulmonary disease in adults;
b. cervical lymph node disease in children;
c. skin, soft tissue, and bone infections; and
d. disseminated disease in immunocompromised patients.[596, 597]

Person-to-person acquisition of NTM infection, especially among immunocompetent persons, does not appear to occur, and close contacts of patients are not readily infected, despite the high numbers of organisms harbored by such patients.[596, 598–600] NTM are spread via all modes of transmission associated with water. In addition to health-care associated outbreaks of clinical disease, NTM can colonize patients in health-care facilities through consumption of contaminated water or ice or through inhalation of aerosols.[601–605] Colonization following NTM exposure, particularly of the respiratory tract, occurs when a patient's local defense mechanisms are impaired; overt clinical disease does not develop.[606] Patients may have positive sputum cultures in the absence of clinical disease.

Using tap water during patient procedures and specimen collection and in the final steps of instrument reprocessing can result in pseudo-outbreaks of NTM contamination.[607– 609] NTM pseudo-outbreaks of *Mycobacterium chelonae, M. gordonae,* and *M. xenopi* have been associated with both bronchoscopy and gastrointestinal endoscopy when

a. tap water is used to provide irrigation to the site or to rinse off the viewing tip *in situ* or
b. the instruments are inappropriately reprocessed with tap water in the final steps.[610– 612]

Table 14. Nontuberculous mycobacteria—environmental vehicles

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 14a. Infections or colonizations

Pathogen	Vehicles associated with infections or colonizations
Mycobacterium abscessus	• Inadequately sterilized medical instruments [613]
***Mycobacterium avium* complex (MAC)**	• Potable water [614–616]
Mycobacterium chelonae	• Dialysis, reprocessed dialyzers [31, 32] • Inadequately-sterilized medical instruments, jet injectors [617, 618] • Contaminated solutions [619, 620] • Hydrotherapy tanks [621]
Mycobacterium fortuitum	• Aerosols from showers or other water sources [605, 606] • Ice [602] • Inadequately sterilized medical instruments [603] • Hydrotherapy tanks [622]
Mycobacterium marinum	• Hydrotherapy tanks [623]
Mycobacterium ulcerans	• Potable water [624]

Table 14b. Pseudo-outbreaks

Pathogen	Vehicles associated with pseudo-outbreaks
Mycobacterium chelonae	• Potable water used during bronchoscopy and instrument reprocessing [610]
Mycobacterium fortuitum	• Ice [607]
Mycobacterium gordonae	• Deionized water [611] • Ice [603] • Laboratory solution (intrinsically contaminated [625] • Potable water ingestion prior to sputum specimen collection [626]
Mycobacterium kansasii	• Potable water [627]
Mycobacterium terrae	• Potable water [608]
Mycobacterium xenopi	• Potable water [609, 612, 627]

NTM can be isolated from both natural and man-made environments. Numerous studies have identified [632] Some NTM species (e.g., *Mycobacterium xenopi*) can survive in water at 113°F (45°C), and can be isolated from hot water taps, which can pose a problem for hospitals that lower the temperature of their hot water systems.[627] Other NTM (e.g., *Mycobacterium kansasii, M. gordonae, M. fortuitum*, and *M. chelonae*) cannot tolerate high temperatures and are associated more often with cold water lines and taps.[629]

NTM have a high resistance to chlorine; they can tolerate free chlorine concentrations of 0.05–0.2 mg/L (0.05–0.2 ppm) found at the tap.[598, 633, 634] They are 20–100 times more resistant to chlorine compared with coliforms; slow-growing strains of NTM (e.g., *Mycobacterium avium* and *M. kanasii*) appear to be

more resistant to chorine inactivation compared to fast-growing NTM.[635] Slow-growing NTM species have also demonstrated some resistance to formaldehyde and glutaraldehyde, which has posed problems for reuse of hemodialyzers.[31] The ability of NTM to form biofilms at fluid-surface interfaces (e.g., interior surfaces of water pipes) contributes to the organisms' resistance to chemical inactivation and provides a microenvironment for growth and proliferation.[636, 637]

d. Cryptosporidiosis

Cryptosporidium parvum is a protozoan parasite that causes self-limiting gastroenteritis in normal hosts but can cause severe, life-threatening disease in immunocompromised patients. First recognized as a human pathogen in 1976, *C. parvum* can be present in natural and finished waters after fecal contamination from either human or animal sources.[638–641]

The health risks associated with drinking potable water contaminated with minimal numbers of *C. parvum* oocysts are unknown.[642] It remains to be determined if immunosuppressed persons are more susceptible to lower doses of oocysts than are immunocompetent persons. One study demonstrated that a median 50% infectious dose (ID50) of 132 oocysts of calf origin was sufficient to cause infection among healthy volunteers.[643] In a second study, the same researchers found that oocysts obtained from infected foals (newborn horses) were infectious for human volunteers at median ID50 of 10 oocysts, indicating that different strains or species of *Cryptosporidium* may vary in their infectivity for humans.[644] In a small study population of 17 healthy adults with pre-existing antibody to *C. parvum*, the ID50 was determined to be 1,880 oocysts, more than 20-fold higher than in seronegative persons.[645] These data suggest that pre-existing immunity derived from previous exposures to *Cryptosporidium* offers some protection from infection and illness that ordinarily would result from exposure to low numbers of oocysts.[645, 646]

Oocysts, particularly those with thick walls, are environmentally resistant, but their survival under natural water conditions is poorly understood. Under laboratory conditions, some oocysts remain viable and infectious in cold (41°F [5°C]) for months.[641] The prevalence of *Cryptosporidium* in the U.S. drinking water supply is notable. Two surveys of approximately 300 surface water supplies revealed that 55%–77% of the water samples contained *Cryptosporidium* oocysts.[647, 648] Because the oocysts are highly resistant to common disinfectants (e.g., chlorine) used to treat drinking water, filtration of the water is important in reducing the risk of waterborne transmission. Coagulation-floculation and sedimentation, when used with filtration, can collectively achieve approximately a 2.5 log10 reduction in the number of oocysts.[649] However, outbreaks have been associated with both filtered and unfiltered drinking water systems (e.g., the 1993 outbreak in Milwaukee, Wisconsin that affected 400,000 people).[641, 650–652] The presence of oocysts in the water is not an absolute indicator that infection will occur when the water is consumed, nor does the absence of detectable oocysts guarantee that infection will not occur. Health-care associated outbreaks of cryptosporidiosis primarily have been described among groups of elderly patients and immunocompromised persons.[653]

3. Water Systems in Health-Care Facilities

a. Basic Components and Point-of-Use Fixtures

Treated municipal water enters a health-care facility via the water mains and is distributed throughout the building(s) by a network of pipes constructed of galvanized iron, copper, and polyvinylchloride (PVC). The pipe runs should be as short as is practical. Where recirculation is employed, the pipe runs should be insulated and long dead legs avoided in efforts to minimize the potential for water stagnation, which favors the proliferation of *Legionella* spp. and NTM. In high-risk applications (e.g., PE areas for severely immunosuppressed patients), insulated recirculation loops should be incorporated as a design minimal loss.

Each water service main, branch main, riser, and branch (to a group of fixtures) has a valve and a means to reach the valves via an access panel.[120] Each fixture has a stop valve. Valves permit the isolation of a portion of the water system within a facility during repairs or maintenance. Vacuum breakers and other similar devices in the lines prevent water from back-flowing into the system. All systems that supply water should be evaluated to determine risk for potential back siphonage and cross connections.

Health-care facilities generate hot water from municipal water using a boiler system. Hot water heaters and storage vessels for such systems should have a drainage facility at the lowest point, and the heating element should be located as close as possible to the bottom of the vessel to facilitate mixing and to prevent water temperature stratification. Those hot or cold water systems that incorporate an elevated holding tank should be inspected and cleaned annually. Lids should fit securely to exclude foreign materials.

The most common point-of-use fixtures for water in patient-care areas are sinks, faucets, aerators, showers, and toilets; eye-wash stations are found primarily in laboratories. The potential for these fixtures to serve as a reservoir for pathogenic microorganisms has long been recognized (Table 15).[509, 654–656]

Wet surfaces and the production of aerosols facilitate the multiplication and dispersion of microbes. The level of risk associated with aerosol production from point-of-use fixtures varies. Aerosols from shower heads and aerators have been linked to a limited number of clusters of gram-negative bacterial colonizations and infections, including Legionnaires disease, especially in areas where immunocompromised patients are present (e.g., surgical ICUs, transplant units, and oncology units).[412, 415, 656–659]

In one report, clinical infection was not evident among immunocompetent persons (e.g., hospital staff) who used hospital showers when *Legionella pneumophila* was present in the water system.[660] Given the infrequency of reported outbreaks associated with faucet aerators, consensus has not been reached regarding the disinfection of or removal of these devices from general use. If additional clusters of infections or colonizations occur in high-risk patient-care areas, it may be prudent to clean and decontaminate the aerators or to remove them.[658, 659] ASHRAE recommends cleaning and monthly disinfection of aerators in high-risk patient-care areas as part of *Legionella* control measures.[661] Although aerosols are produced with toilet flushing,[662, 663] no epidemiologic evidence suggests that these aerosols pose a direct infection hazard.

Although not considered a standard point-of-use fixture, decorative fountains are being installed in increasing numbers in health-care facilities and other public buildings. Aerosols from a decorative fountain have been associated with transmission of *Legionella pneumophila* serogroup 1 infection to a small cluster of older adults.[664] This hotel lobby fountain had been irregularly maintained, and water in the fountain may have been heated by submersed lighting, all of which favored the proliferation of *Legionella* in the system.[664] Because of the potential for generations of infectious aerosols, a prudent prevention measure is to avoid locating these fixtures in or near high-risk patient-care areas and to adhere to written policies for routine fountain maintenance.[120]

Table 15. Water and point-of-use fixtures as sources and reservoirs of waterborne pathogens*

Reservoir	Associated pathogens	Transmission	Strength of evidence+	Prevention and control	References
Potable water	*Pseudomonas*, gram-negative bacteria, NTM	Contact	**Moderate:** occasional well-described outbreaks.	Follow public health guidelines.	(See Tables 12–14)
Potable water	Legionella	Aerosol inhalation	**Moderate:** occasional well-described outbreaks.	Provide supplemental treatment for water.	(See Table 11)

Reservoir	Associated pathogens	Transmission	Strength of evidence+	Prevention and control	References
Holy water	Gram-negative bacteria	Contact	**Low:** few well-described outbreaks	Avoid contact with severe burn injuries. Minimize use among immunocompromised patients.	665
Dialysis water	Gram-negative bacteria	Contact	**Moderate:** occasional well-described outbreaks.	Dialysate should be ≤2,000 cfu/mL; water should be ≤200 cfu/mL.	2, 527, 666– 668
Automated endoscope reprocessors and rinse water	Gram-negative bacteria	Contact	**Moderate:** occasional well-described outbreaks.	Use and maintain equipment according to instructions; eliminate residual moisture by drying the channels (e.g., through alcohol rinse and forced air drying).	669–675
Water baths	Pseudomonas, Burkholderia, Acinetobacter	Contact	**Moderate:** occasional well-described outbreaks.	Add germicide to the water; wrap transfusion products in protective plastic wrap if using the bath to modulate the temperature of these products.	29, 533, 676, 677
Tub immersion	Pseudomonas, Enterobacter, Acinetobacter	Contact	**Moderate:** occasional well-described outbreaks.	Drain and disinfect tub after each use; consider adding germicide to the water; water in large hydrotherapy pools should be properly disinfected and filtered.	678–683
Ice and ice machines	NTM, Enterobacter, Pseudomonas, Cryptosporidium Legionella	Ingestion, contact	**Moderate:** occasional well-described outbreaks. **Low:** few well-described outbreaks	Clean periodically; use automatic dispenser (avoid open chest storage compartments in patient areas).	601, 684–687
Faucet aerators	Legionella	Aerosol inhalation	**Moderate:** occasional well-described outbreaks.	Clean and disinfect monthly in high-risk patient areas; consider removing if additional infections occur.	415, 661
Faucet aerators	Pseudomonas, Acinetobacter, Stenotrophomonas, Chryseobacterium	Contact, droplet	**Low:** few well-described outbreaks	No precautions are necessary at present in immunocompetent patient-care areas.	658, 659, 688, 689
Sinks	Pseudomonas	Contact, droplet	**Moderate:** occasional well-described outbreaks.	Use separate sinks for handwashing and disposal of contaminated fluids.	509, 653, 685–693
Showers	Legionella	Aerosol inhalation	**Low:** few well-described outbreaks	Provide sponge baths for hematopoietic stem cell transplant patients; avoid shower use for immunocompromised patients when Legionella is detected in facility water.	656
Dental unit water lines	Pseudomonas, Legionella, Sphingomonas, Acinetobacter	Contact	**Low:** few well-described outbreaks	Clean water systems according to system manufacturer's instructions.	636, 694–696

Reservoir	Associated pathogens	Transmission	Strength of evidence+	Prevention and control	References
Ice baths for thermodilution catheters	Ewingella, Staphylococcus	Contact	**Low:** few well-described outbreaks	Use sterile water.	697, 698
Decorative fountains	Legionella	Aerosol inhalation	**Low:** few well-described outbreaks	Perform regular maintenance, including water disinfection; avoid use in or near high-risk patient-care areas.	664
Eyewash stations	Pseudomonas, amoebae, Legionella	Contact	**Low:** few well-described outbreaks **Minimal:** actual infections not demonstrated.	Flush eyewash stations weekly; have sterile water available for eye flushes.	518, 699, 700
Toilets	Gram-negative bacteria	n/a	**Minimal:** actual infections not demonstrated.	Clean regularly; use good hand hygiene.	662
Flowers	Gram-negative bacteria, Aspergillus	n/a	**Minimal:** actual infections not demonstrated.	Avoid use in intensive care units and in immunocompromised patient-care settings.	515, 701, 702

* Modified from reference 654 and used with permission of the publisher (Slack, Inc.)

b. Water Temperature and Pressure

Hot water temperature is usually measured at the point of use or at the point at which the water line enters equipment requiring hot water for proper operation.[120] Generally, the hot water temperature in hospital patient-care areas is no greater than a temperature within the range of 105°F–120°F (40.6°C– 49°C), depending on the AIA guidance issued at the year in which the facility was built.[120] Hot water temperature in patient-care areas of skilled nursing-care facilities is set within a slightly lower range of 95°F–110°F (35°C–43.3°C) depending on the AIA guidance at the time of facility construction.[120] Many states have adopted a temperature setting in these ranges into their health-care regulations and building codes. ASHRAE, however, has recommended higher settings.[661] Steam jets or booster heaters are usually needed to meet the hot water temperature requirements in certain service areas of the hospital (e.g., the kitchen [120°F (49°C)] or the laundry [160°F (71°C)]).[120] Additionally, water lines may need to be heated to a particular temperature specified by manufacturers of specific hospital equipment. Hot-water distribution systems serving patient-care areas are generally operated under constant recirculation to provide continuous hot water at each hot-water outlet.[120] If a facility is or has a hemodialysis unit, then continuously circulated, cold treated water is provided to that unit.[120]

To minimize the growth and persistence of gram-negative waterborne bacteria (e.g., thermophilic NTM and *Legionella* spp.),[627, 703–709] cold water in health-care facilities should be stored and distributed at temperatures below 68°F (20°C); hot water should be stored above 140°F (60°C) and circulated with a minimum return temperature of 124°F (51°C),[661] or the highest temperature specified in state regulations and building codes. If the return temperature setting of 124°F (51°C) is permitted, then installation of preset thermostatic mixing valves near the point-of-use can help to prevent scalding. Valve maintenance is especially important in preventing valve failure, which can result in scalding. New shower systems in large buildings, hospitals, and nursing homes should be designed to permit mixing of hot and cold water near the shower head. The warm water section of pipe between the control valve and shower head should be self-draining. Where buildings can not be retrofitted, other approaches to minimize the growth of *Legionella* spp. include

a. periodically increasing the temperature to at least 150°F [66°C] at the point of use [i.e., faucets] and
b. adding additional chlorine and flushing the water. [661, 710, 711]

Systems should be inspected annually to ensure that thermostats are functioning properly.

Adequate water pressure ensures sufficient water supplies for
a. direct patient care;
b. operation of water-cooled instruments and equipment [e.g., lasers, computer systems, telecommunications systems, and automated endoscope reprocessors[712]];
c. proper function of vacuum suctioning systems;
d. indoor climate control; and
e. fire-protection systems.

Maintaining adequate pressure also helps to ensure the integrity of the piping system.

c. Infection-Control Impact of Water System Maintenance and Repair

Corrective measures for water-system failures have not been studied in well-designed experiments; these measures are instead based on empiric engineering and infection-control principles. Health-care facilities can occasionally sustain both intentional cut-offs by the municipal water authority to permit new construction project tie-ins and unintentional disruptions in service when a water main breaks as a result of aging infrastructure or a construction accident. Vacuum breakers or other similar devices can prevent backflow of water in the facility's distribution system during water-disruption emergencies.[11] To be prepared for such an emergency, all health-care facilities need contingency plans that identify
a. the total demand for potable water,
b. the quantity of replacement water [e.g., bottled water] required for a minimum of 24 hours when the water system is down,
c. mechanisms for emergency water distribution, and
d. procedures for correcting drops in water pressure that affect operation of essential devices and equipment that are driven or cooled by a water system [Table 16].[713]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 16. Water demand in health-care facilities during water disruption emergencies

Potable water use	Bottled, sterile water use
• Drinking water • Handwashing • Cafeteria services • Ice • Manual flushing of toilets • Patient baths, hygiene • Hemodialysis • Hydrotherapy • Fire prevention (e.g., sprinkler systems) • Surgery and critical care areas • Laboratory services • Laundry and central sterile services (Arrange to have a contingency provision of these services from another resource, if possible (e.g., another health-care facility or contractor).) • Cooling towers (Some cooling towers may use a potable water source, but most units use non-potable water.) • Steam generation	• Surgical scrub • Emergency surgical procedures • Pharmaceutical preparations • Patient-care equipment (e.g., ventilators) (This item is included in the table under the assumption that electrical power is available during the water emergency.)

Detailed, up-to-date plans for hot and cold water piping systems should be readily available for maintenance and repair purposes in case of system problems. Opening potable water systems for repair or construction and subjecting systems to water-pressure changes can result in water discoloration and dramatic increases in the concentrations of *Legionella* spp. and other gram-negative bacteria. The maintenance of a chlorine residual at all points within the piping system also offers some protection from entry of contamination to the pipes in the event of inadvertent cross-connection between potable and non-potable water lines. As a minimum preventive measure, ASHRAE recommends a thorough flushing of

the system.[661] High-temperature flushing or hyperchlorination may also be appropriate strategies to decrease potentially high concentrations of waterborne organisms. The decision to pursue either of these remediation strategies, however, should be made on a case-by-case basis. If only a portion of the system is involved, high temperature flushing or chlorination can be used on only that portion of the system.[661]

When shock decontamination of hot water systems is necessary (e.g., after disruption caused by construction and after cross-connections), the hot water temperature should be raised to 160°F–170°F (71°C–77°C) and maintained at that level while each outlet around the system is progressively flushed. A minimum flush time of 5 minutes has been recommended;[3] the optimal flush time is not known, however, and longer flush times may be necessary.[714] The number of outlets that can be flushed simultaneously depends on the capacity of the water heater and the flow capability of the system. Appropriate safety procedures to prevent scalding are essential. When possible, flushing should be performed when the fewest building occupants are present (e.g., during nights and weekends).

When thermal shock treatment is not possible, shock chlorination may serve as an alternative method.[661] Experience with this method of decontamination is limited, however, and high levels of free chlorine can corrode metals. Chlorine should be added, preferably overnight, to achieve a free chlorine residual of at least 2 mg/L (2 ppm) throughout the system.[661] This may require chlorination of the water heater or tank to levels of 20–50 mg/L (20–50 ppm). The pH of the water should be maintained at 7.0–8.0.[661] After completion of the decontamination, recolonization of the hot water system is likely to occur unless proper temperatures are maintained or a procedure such as continuous supplemental chlorination is continued.

Interruptions of the water supply and sewage spills are situations that require immediate recovery and remediation measures to ensure the health and safety of patients and staff.[715] When delivery of potable water through the municipal distribution system has been disrupted, the public water supplier must issue a "boil water" advisory if microbial contamination presents an immediate public health risk to customers. The hospital engineer should oversee the restoration of the water system in the facility and clear it for use when appropriate. Hospitals must maintain a high level of surveillance for waterborne disease among patients and staff after the advisory is lifted.[642]

Flooding from either external (e.g., from a hurricane) or internal sources (e.g., a water system break) usually results in property damage and a temporary loss of water and sanitation.[716–718] JCAHO requires all hospitals to have plans that address facility response for recovery from both internal and external disasters.[713, 719] The plans are required to discuss

a. general emergency preparedness,
b. staffing,
c. regional planning among area hospitals,
d. emergency supply of potable water,
e. infection control and medical services needs,
f. climate control, and
g. remediation.

The basic principles of structural recovery from flooding are similar to those for recovery from sewage contamination (Box 9 and 10). Following a major event (e.g., flooding), facilities may elect to conduct microbial sampling of water after the system is restored to verify that water quality has been returned to safe levels (<500 CFU/mL, heterotrophic plate count). This approach may help identify point-of-use fixtures that may harbor contamination as a result of design or engineering features.[720] Medical records should be allowed to dry and then either photocopied or placed in plastic covers before returning them to the record.

Moisture meters can be used to assess water-damaged structural materials. If porous structural materials for walls have a moisture content of >20% after 72 hours, the affected material should be removed.[266, 278, 313] The management of water-damaged structural materials is not strictly limited to major water catastrophes (e.g., flooding and sewage intrusions); the same principles are used to evaluate the damage

from leaking roofs, point-of-use fixtures, and equipment. Additional sources of moisture include condensate on walls from boilers and poorly engineered humidification in HVAC systems.

Box 9. Recovery and remediation measures for water-related emergencies*

Potable water disruptions

- **Contingency plan items**
  - Ensure access to plumbing network so that repairs can be easily made.
  - Provide sufficient potable water, either from bottled sources or truck delivery.
  - Post advisory notices against consuming tap water, ice, or beverages made with water.
  - Rope off or bag drinking fountains to designate these as being "out of service" until further notice.
  - Rinse raw foods as needed in disinfected water.
  - Disconnect ice machines whenever possible. (Ice machines should always be disconnected from the water source in advance of planned water disruptions.)
  - Postpone laundry services until after the water system is restored.
- **Water treatment**
  - Heat water to a rolling boil for ≥1 minute.
- **Remediation of the water system after the "boil water" advisory is rescinded**
  - Flush fixtures (e.g., faucets and drinking fountains) and equipment for several minutes and restart.
  - Run water softeners through a regeneration cycle.
  - Drain, disinfect, and refill water storage tanks, if needed.
  - Change pretreatment filters and disinfect the dialysis water system.

Sewage spills/malfunction

- **Overall strategy**
  - Move patients and clean/sterile supplies out of the area.
  - Redirect traffic away from the area.
  - Close the doors or use plastic sheeting to isolate the area prior to clean-up.
  - Restore sewage system function first, then the potable water system (if both are malfunctioning).
  - Remove sewage solids, drain the area, and let dry.
- **Remediation of the structure**
  - Hard surfaces: clean with detergent/disinfectant after the area has been drained.
  - Carpeting, loose tiles, buckled flooring: remove and allow the support surface to dry; replace the items; wet down carpeting with a low-level disinfectant or sanitizer prior to removal to minimize dust dispersion to the air.
  - Wallboard and other porous structural materials: remove and replace if they cannot be cleaned and dried within 72 hours. (Moisture meter readings should be <20% moisture content.)
- **Furniture**
  - Hard surface furniture (e.g., metal or plastic furniture): clean and allow to dry.
  - Wood furniture: let dry, sand the wood surface, and reapply varnish.
  - Cloth furniture: replace.
- **Electrical equipment**
  - Replace if the item cannot be easily dismantled, cleaned, and reassembled.

* Material in this box is compiled from references 266, 278, 315, 713, 716–719, 721–729.

An exception to these recommendations is made for hemodialysis units where water is further treated either by portable water treatment or large-scale water treatment systems usually involving reverse osmosis (RO). In the United States, >97% of dialysis facilities use RO treatment for their water.[721] However, changing pre-treatment filters and disinfecting the system to prevent colonization of the RO membrane and microbial contamination down-stream of the pre-treatment filter are prudent measures.

Box 10. Contingency planning for flooding

General emergency preparedness

- Ensure that emergency electrical generators are not located in flood-prone areas of the facility.
- Develop alternative strategies for moving patients, water containers, medical records, equipment, and supplies in the event that the elevators are inoperable.
- Establish in advance a centralized base of operations with batteries, flashlights, and cellular phones.
- Ensure sufficient supplies of sandbags to place at the entrances and the area around boilers, incinerators, and generators.
- Establish alternative strategies for bringing core employees to the facility if high water prevents travel.

Staffing Patterns

- Temporarily reassign licensed staff as needed to critical care areas to provide manual ventilation and to perform vital assessments on patients.
- Designate a core group of employees to remain on site to keep all services operational if the facility remains open.
- Train all employees in emergency preparedness procedures.

Regional planning among are facilities for disaster management

- Incorporate community support and involvement (e.g., media alerts, news, and transportation).
- Develop in advance strategies for transferring patients, as needed.
- Develop strategies for sharing supplies and providing essential services among participating facilities (e.g., central sterile department services, and laundry services).
- Identify sources for emergency provisions (e.g., blood, emergency vehicles, and bottled water).

Medical services and infection control

- Use alcohol-based hand rubs in general patient-care areas.
- Postpone elective surgeries until full services are restored, or transfer these patients to other facilities.
- Consider using portable dialysis machines. (Portable dialysis machines require less water compared to the larger units situated in dialysis settings.)
- Provide an adequate supply of tetanus and hepatitis A immunizations for patients and staff.

Climate control

- Provide adequate water for cooling towers. (Water for cooling towers may need to be trucked in, especially if the tower uses a potable water source.)

* Material in this box was compiled from references 713, 716–719.

4. Strategies for Controlling Waterborne Microbial Contamination

a. Supplemental Treatment of Water with Heat and/or Chemicals

In addition to using supplemental treatment methods as remediation measures after inadvertent contamination of water systems, health-care facilities sometimes use special measures to control waterborne microorganisms on a sustained basis. This decision is most often associated with outbreaks of legionellosis and subsequent efforts to control legionellae,[722] although some facilities have tried supplemental measures to better control thermophilic NTM.[627]

The primary disinfectant for both cold and hot water systems is chlorine. However, chlorine residuals are expected to be low, and possibly nonexistent, in hot water tanks because of extended retention time in the tank and elevated water temperature. Flushing, especially that which removes sludge from the bottom of the tank, probably provides the most effective treatment of water systems. Unlike the situation for disinfecting cooling towers, no equivalent recommendations have been made for potable water systems, although specific intervention strategies have been published.[403, 723] The principal approaches to disinfection of potable systems are heat flushing using temperatures 160°F–170°F (71°– 77°C), hyperchlorination, and physical cleaning of hot-water tanks.[3, 403, 661] Potable systems are easily recolonized and may require continuous intervention (e.g., raising of hot water temperatures or continuous

chlorination).[403, 711] Chlorine solutions lose potency over time, thereby rendering the stocking of large quantities of chlorine impractical.

Some hospitals with hot water systems identified as the source of *Legionella* spp. have performed emergency decontamination of their systems by pulse (i.e., one-time) thermal disinfection/superheating or hyperchlorination.[711, 714, 724, 725] After either of these procedures, hospitals either maintain their heated water with a minimum return temperature of 124°F (51°C) and cold water at <68°F (<20°C) or chlorinate their hot water to achieve 1–2 mg/L (1–2 ppm) of free residual chlorine at the tap.[26, 437, 709–711, 726, 727]

Additional measures (e.g., physical cleaning or replacement of hot-water storage tanks, water heaters, faucets, and shower heads) may be required to help eliminate accumulations of scale and sediment that protect organisms from the biocidal effects of heat and chlorine.[457, 711] Alternative methods for controlling and eradicating legionellae in water systems (e.g., treating water with chlorine dioxide, heavy metal ions [i.e., copper/silver ions], ozone, and UV light) have limited the growth of legionellae under laboratory and operating conditions.[728–742] Further studies on the long-term efficacy of these treatments are needed before these methods can be considered standard applications.

Renewed interest in the use of chloramines stems from concerns about adverse health effects associated with disinfectants and disinfection by-products.[743] Monochloramine usage minimizes the formation of disinfection by-products, including trihalomethanes and haloacetic acids. Monochloramine can also reach distal points in a water system and can penetrate into bacterial biofilms more effectively than free chlorine.[744] However, monochloramine use is limited to municipal water treatment plants and is currently not available to health-care facilities as a supplemental water-treatment approach. A recent study indicated that 90% of Legionnaires disease outbreaks associated with drinking water could have been prevented if monochloramine rather than free chlorine has been used for residual disinfection.[745] In a retrospective comparison of health-care associated Legionnaires disease incidence in central Texas hospitals, the same research group documented an absence of cases in facilities located in communities with monochloramine-treated municipal water.[746] Additional data are needed regarding the effectiveness of using monochloramine before its routine use as a disinfectant in water systems can be recommended. No data have been published regarding the effectiveness of monochloramine installed at the level of the health-care facility.

Additional filtration of potable water systems is not routinely necessary. Filters are used in water lines in dialysis units, however, and may be inserted into the lines for specific equipment (e.g., endoscope washers and disinfectors) for the purpose of providing bacteria-free water for instrument reprocessing. Additionally, an RO unit is usually added to the distribution system leading to PE areas.

b. Primary Prevention of Legionnaires Disease (No Cases Identified)

The primary and secondary environmental infection-control strategies described in this section on the guideline pertain to health-care facilities without transplant units. Infection-control measures specific to PE or transplant units (i.e., patient-care areas housing patients at the highest risk for morbidity and mortality from *Legionella* spp. infection) are described in the subsection titled *Preventing Legionnaires Disease in Protective Environments*.

Health-care facilities use at least two general strategies to prevent health-care associated legionellosis when no cases or only sporadic cases have been detected. The first is an environmental surveillance approach involving periodic culturing of water samples from the hospital's potable water system to monitor for *Legionella* spp. [747–750] If any sample is culture-positive, diagnostic testing is recommended for all patients with health-care associated pneumonia.[748, 749] In-house testing is recommended for facilities with transplant programs as part of a comprehensive treatment/management program. If ≥30% of the samples are culture-positive for *Legionella* spp., decontamination of the facility's potable water system is warranted.[748] The premise for this approach is that no cases of health-care associated legionellosis can occur if *Legionella* spp. are not present in the potable water system, and, conversely, cases of health-care associated legionellosis could potentially occur if *Legionella* spp. are cultured from the water.[26, 751]

Physicians who are informed that the hospital's potable water system is culture-positive for *Legionella* spp. are more likely to order diagnostic tests for legionellosis.

A potential advantage of the environmental surveillance approach is that periodic culturing of water is less costly than routine laboratory diagnostic testing for all patients who have health-care associated pneumonia. The primary argument against this approach is that, in the absence of cases, the relationship between water-culture results and legionellosis risk remains undefined.[3] *Legionnella* spp. can be present in the water systems of buildings[752] without being associated with known cases of disease.[437, 707, 753] In a study of 84 hospitals in Québec, 68% of the water systems were found to be colonized with *Legionella* spp., and 26% were colonized at >30% of sites sampled; cases of Legionnaires disease, however, were infrequently reported from these hospitals.[707]

Other factors also argue against environmental surveillance. Interpretation of results from periodic water culturing might be confounded by differing results among the sites sampled in a single water system and by fluctuations in the concentration of *Legionella* spp. at the same site.[709, 754] In addition, the risk for illness after exposure to a given source might be influenced by several factors other than the presence or concentration of organisms, including

a. the degree to which contaminated water is aerosolized into respirable droplets,
b. the proximity of the infectious aerosol to the potential host,
c. the susceptibility of the host, and
d. the virulence properties of the contaminating strain.[755–757]

Thus, data are insufficient to assign a level of disease risk even on the basis of the number of colony-forming units detected in samples from areas for immunocompetent patients. Conducting environmental surveillance would obligate hospital administrators to initiate water-decontamination programs if *Legionella* spp. are identified. Therefore, periodic monitoring of water from the hospital's potable water system and from aerosol-producing devices is not widely recommended in facilities that have not experienced cases of health-care associated legionellosis.[661, 758]

The second strategy to prevent and control health-care associated legionellosis is a clinical approach, in which providers maintain a high index of suspicion for legionellosis and order appropriate diagnostic tests (i.e., culture, urine antigen, and direct fluorescent antibody [DFA] serology) for patients with health-care associated pneumonia who are at high risk for legionellosis and its complications.[437, 759, 760] The testing of autopsy specimens can be included in this strategy should a death resulting from healthcare–associated pneumonia occur. Identification of one case of definite or two cases of possible healthcare–associated Legionnaires disease should prompt an epidemiologic investigation for a hospital source of *Legionella* spp., which may involve culturing the facility's water for *Legionella*. Routine maintenance of cooling towers, and use of sterile water for the filling and terminal rinsing of nebulization devices and ventilation equipment can help to minimize potential sources of contamination. Circulating potable water temperatures should match those outlined in the subsection titled *Water Temperature and Pressure*, as permitted by state code.

c. Secondary Prevention of Legionnaires Disease (With Identified Cases)

The indications for a full-scale environmental investigation to search for and subsequently decontaminate identified sources of *Legionella* spp. in health-care facilities without transplant units have not been clarified; these indications would likely differ depending on the facility. Case categories for health-care associated Legionnaires disease in facilities without transplant units include definite cases (i.e., laboratory-confirmed cases of legionellosis that occur in patients who have been hospitalized continuously for ≥10 days before the onset of illness) and possible cases (i.e., laboratory-confirmed infections that occur 2–9 days after hospital admission).[3] In settings in which as few as one to three health-care associated cases are recognized over several months, intensified surveillance for Legionnaires disease has frequently identified numerous additional cases.[405, 408, 432, 453, 739, 759, 760] This finding suggests the need for a low threshold for initiating an investigation after laboratory confirmation of cases of health-care associated legionellosis. When developing a strategy for responding to such a finding, however,

infection-control personnel should consider the level of risk for health-care– associated acquisition of, and mortality from, *Legionella* spp. infection at their particular facility.

An epidemiologic investigation conducted to determine the source of *Legionella* spp. involves several important steps (Box 11). Laboratory assessment is crucial in supporting epidemiologic evidence of a link between human illness and a specific environmental source.[761] Strain determination from subtype analysis is most frequently used in these investigations.[410, 762–764] Once the environmental source is established and confirmed with laboratory support, supplemental water treatment strategies can be initiated as appropriate.

Box 11. Steps in an epidemiologic investigation for legionellosis

- Review medical and microbiologic records.
- Initiate active surveillance to identify all recent or ongoing cases.
- Develop a line listing of cases by time, place, and person.
- Determine the type of epidemiologic investigation needed for assessing risk factors:
    - Case-control study,
    - Cohort study.
- Gather and analyze epidemiologic information:
    - Evaluate risk factors associated with potential environmental exposures (e.g., showers, cooling towers, and respiratory-therapy equipment).
- Collect water samples:
    - Sample environmental sources implicated by epidemiologic investigation,
    - Sample other potential source of water aerosols.
- Subtype strains of *Legionella* spp. cultured from both patients and environmental sources.
- Review autopsy records and include autopsy specimens in diagnostic testing.

The decision to search for hospital environmental sources of *Legionella* spp. and the choice of procedures to eradicate such contamination are based on several considerations, as follows:

a. the hospital's patient population
b. the cost of an environmental investigation and institution of control measures to eradicate *Legionella* spp. from the water supply;[765–768] and
c. the differential risk, based on host factors, for acquiring health-care associated legionellosis and developing severe and fatal infection.

d. Preventing Legionnaires Disease in Protective Environments

This subsection outlines infection-control measures applicable to those health-care facilities providing care to severely immunocompromised patients. Indigenous microorganisms in the tap water of these facilities may pose problems for such patients. These measures are designed to prevent the generation of potentially infectious aerosols from water and the subsequent exposure of PE patients or other immunocompromised patients (e.g., transplant patients) (Table 17). Infection-control measures that address the use of water with medical equipment (e.g., ventilators, nebulizers, and equipment humidifiers) are described in other guidelines and publications.[3, 455]

If one case of laboratory-confirmed, health-care associated Legionnaires disease is identified in a patient in a solid-organ transplant program or in PE (i.e., an inpatient in PE for all or part of the 2–10 days prior to onset of illness) or if two or more laboratory-confirmed cases occur among patients who had visited an outpatient PE setting, the hospital should report the cases to the local and state health departments. The hospital should then initiate a thorough epidemiologic and environmental investigation to determine the likely environmental sources of *Legionella* spp.[9] The source of *Legionella* should be decontaminated or removed. Isolated cases may be difficult to investigate. Because transplant recipients are at substantially

higher risk for disease and death from legionellosis compared with other hospitalized patients, periodic culturing for *Legionella* spp. in water samples from the potable water in the solid-organ transplant and/or PE unit can be performed as part of an overall strategy to prevent Legionnaires disease in PE units.[9, 431, 710, 769] The optimal methodology (i.e., frequency and number of sites) for environmental surveillance cultures in PE units has not been determined, and the cost-effectiveness of this strategy has not been evaluated. Because transplant recipients are at high risk for Legionnaires disease and because no data are available to determine a safe concentration of legionellae organisms in potable water, the goal of environmental surveillance for *Legionella* spp. should be to maintain water systems with no detectable organisms.[9, 431] Culturing for legionellae may be used to assess the effectiveness of water treatment or decontamination methods, a practice that provides benefits to both patients and health-care workers.[767, 770]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 17. Additional infection-control measures to prevent exposure of high-risk patients to waterborne pathogens

- Restrict patients from taking showers if the water is contaminated with *Legionella* spp. [407, 412, 654, 655, 658]
- Use water that is not contaminated with *Legionella* spp. for patients' sponge baths. [9]
- Provide sterile water for drinking, tooth brushing, or for flushing nasogastric tubes. [9, 412]
- Perform supplemental treatment of the water for the unit. [732]
- Consider periodic monitoring (i.e., culturing) of the unit water supply for *Legionella* spp. [9, 431]
- Remove shower heads and faucet aerators monthly for cleaning. (These measures can be considered in settings where legionellosis cases have occurred. These measures are not generally recommended in routine patient-care setting.) [661]
- Use a 500–600 ppm (1:100 v/v dilution) solution of sodium hypochlorite to disinfect shower heads and faucet aerators. (These measures can be considered in settings where legionellosis cases have occurred. These measures are not generally recommended in routine patient-care setting.) [661]
- Do not use large-volume room air humidifiers that create aerosols unless these are subjected to cleaning and high-level disinfection daily and filled with distilled water. [3]
- Eliminate water-containing bath toys. (These items have been associated with outbreaks of *Pseudomonas*.) [30]

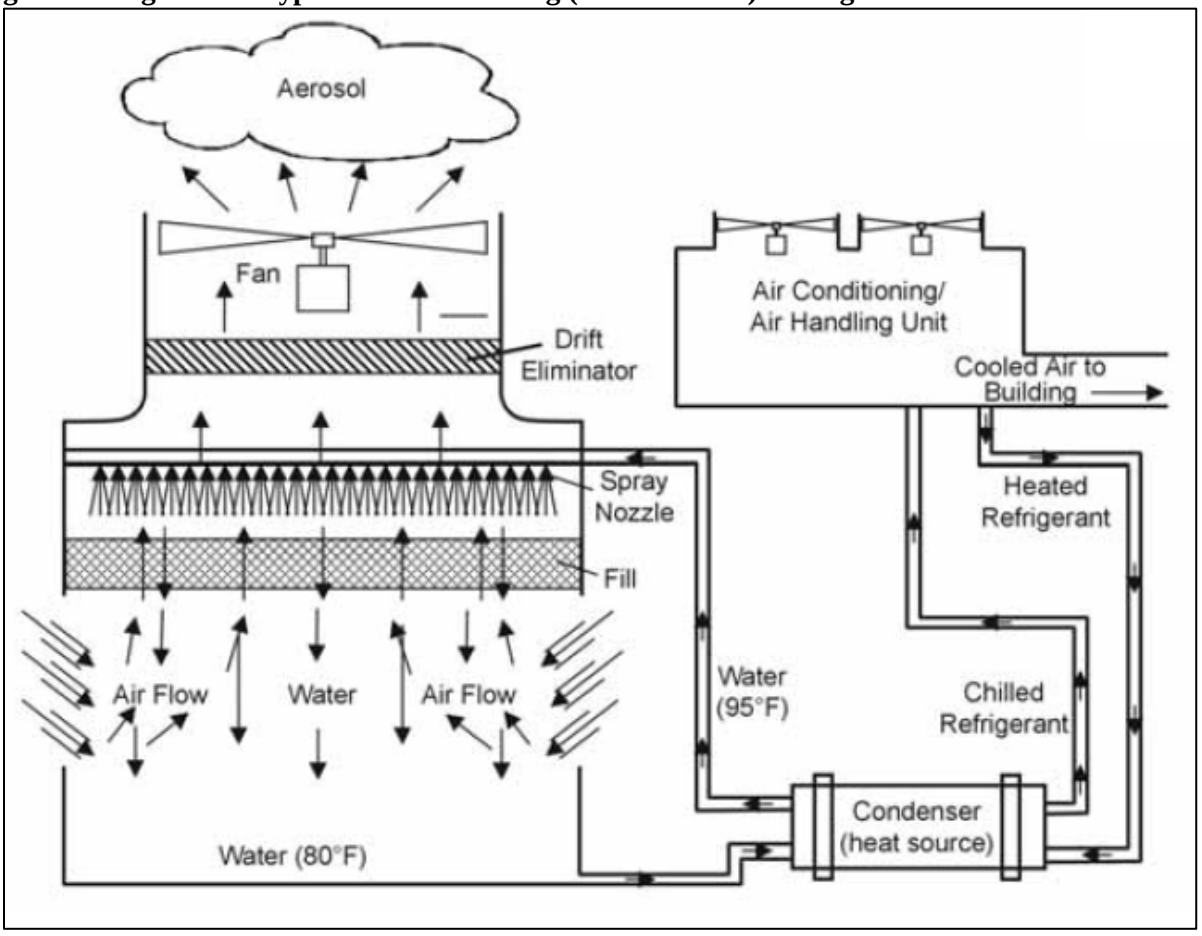
Protecting patient-care devices and instruments from inadvertent tap water contamination during room cleaning procedures is also important in any immunocompromised patient-care area. In a recent outbreak of gram-negative bacteremias among open-heart-surgery patients, pressure-monitoring equipment that was assembled and left uncovered overnight prior to the next day's surgeries was inadvertently contaminated with mists and splashing water from a hose-disinfectant system used for cleaning.[771]

5. Cooling Towers and Evaporative Condensers

Modern health-care facilities maintain indoor climate control during warm weather by use of cooling towers (large facilities) or evaporative condensers (smaller buildings). A cooling tower is a wet-type, evaporative heat transfer device used to discharge to the atmosphere waste heat from a building's air conditioning condensers (Figure 5).[772, 773] Warm water from air-conditioning condensers is piped to the cooling tower where it is sprayed downward into a counter- or cross-current air flow. To accelerate heat transfer to the air, the water passes over the fill, which either breaks water into droplets or causes it to spread into a thin film.[772, 773] Most systems use fans to move air through the tower, although some large industrial cooling towers rely on natural draft circulation of air. The cooled water from the tower is piped back to the condenser, where it again picks up heat generated during the process of chilling the system's refrigerant. The water is cycled back to the cooling tower to be cooled. Closed-circuit cooling towers and evaporative condensers are also evaporative heat-transfer devices. In these systems, the process fluid

(e.g., water, ethylene glycol/water mixture, oil, or a condensing refrigerant) does not directly contact the cooling air, but is contained inside a coil assembly.[661]

Figure 5. Diagram of a typical air conditioning (induced draft) cooling tower*



* This figure is reprinted with permission of the publisher of reference 773 (Plenum Medical).

Water temperatures are approximate and may differ substantially according to system use and design. Warm water from the condenser (or chiller) is sprayed downward into a counter- or cross-current air flow. Water passes over the fill (a component of the system designed to increase the surface area of the water exposed to air), and heat from the water is transferred to the air. Some of the water becomes aerosolized during this process, although the volume of aerosol discharged to the air can be reduced by the placement of a drift eliminator. Water cooled in the tower returns to the heat source to cool refrigerant from the air conditioning unit.

Cooling towers and evaporative condensers incorporate inertial stripping devices called drift eliminators to remove water droplets generated within the unit. Although the effectiveness of these eliminators varies substantially depending on design and condition, some water droplets in the size range of <5 μm will likely leave the unit, and some larger droplets leaving the unit may be reduced to ≤5 μm by evaporation. Thus, even with proper operation, a cooling tower or evaporative condenser can generate and expel respirable water aerosols. If either the water in the unit's basin or the make-up water (added to replace water lost to evaporation) contains *Legionella* spp. or other waterborne microorganisms, these organisms can be aerosolized and dispersed from the unit.[774] Clusters of both Legionnaires disease and Pontiac fever have been traced to exposure to infectious water aerosols originating from cooling towers and evaporative condensers contaminated with *Legionella* spp. Although most of these outbreaks have been community-

acquired episodes of pneumonia,[775–782] health-care associated Legionnaires disease has been linked to cooling tower aerosol exposure.[404, 405] Contaminated aerosols from cooling towers on hospital premises gained entry to the buildings either through open windows or via air handling system intakes located near the tower equipment.

Cooling towers and evaporative condensers provide ideal ecological niches for *Legionella* spp. The typical temperature of the water in cooling towers ranges from 85°F–95°F (29°C–35°C), although temperatures can be above 120°F (49°C) and below 70°F (21°C) depending on system heat load, ambient temperature, and operating strategy.[661] An Australian study of cooling towers found that legionellae colonized or multiplied in towers with basin temperatures above 60.8°F (16°C), and multiplication became explosive at temperatures above 73.4°F (23°C).[783] Water temperature in closed-circuit cooling towers and evaporative condensers is similar to that in cooling towers. Considerable variation in the piping arrangement occurs. In addition, stagnant areas or dead legs may be difficult to clean or penetrate with biocides.

Several documents address the routine maintenance of cooling towers, evaporative condensers, and whirlpool spas.[661, 784–787] They suggest following manufacturer's recommendations for cleaning and biocide treatment of these devices; all health-care facilities should ensure proper maintenance for their cooling towers and evaporative condensers, even in the absence of *Legionella* spp (Appendix C). Because cooling towers and evaporative condensers can be shut down during periods when air conditioning is not needed, this maintenance cleaning and treatment should be performed before starting up the system for the first time in the warm season.[782] Emergency decontamination protocols describing cleaning procedures and hyperchlorination for cooling towers have been developed for towers implicated in the transmission of legionellosis.[786, 787]

6. Dialysis Water Quality and Dialysate

a. Rationale for Water Treatment in Hemodialysis

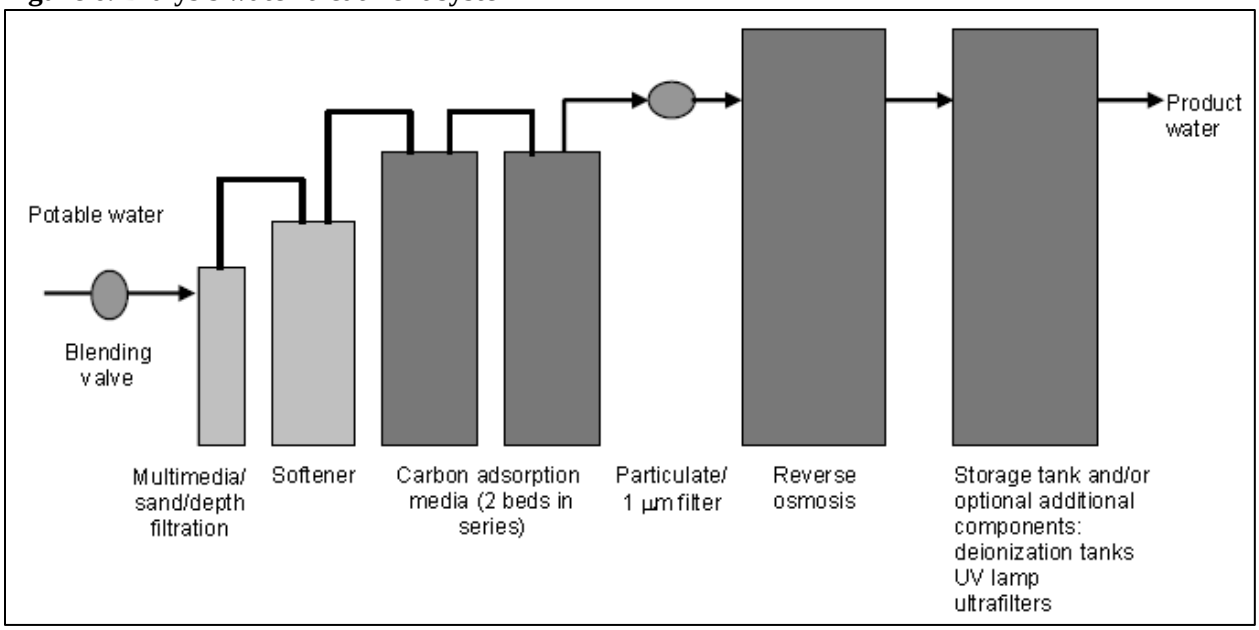
Hemodialysis, hemofiltration, and hemodiafiltration require special water-treatment processes to prevent adverse patient outcomes of dialysis therapy resulting from improper formulation of dialysate with water containing high levels of certain chemical or biological contaminants. The Association for the Advancement of Medical Instrumentation (AAMI) has established chemical and microbiologic standards for the water used to prepare dialysate, substitution fluid, or to reprocess hemodialyzers for renal replacement therapy.[788–792] The AAMI standards address:

a. equipment and processes used to purify water for the preparation of concentrates and dialysate and the reprocessing of dialyzers for multiple use and
b. the devices used to store and distribute this water. Future revisions to these standards may include hemofiltration and hemodiafiltration.

Water treatment systems used in hemodialysis employ several physical and/or chemical processes either singly or in combination (Figure 6). These systems may be portable units or large systems that feed several rooms. In the United States, >97% of maintenance hemodialysis facilities use RO alone or in combination with deionization.[793] Many acute-care facilities use portable hemodialysis machines with attached portable water treatment systems that use either deionization or RO. These machines were exempted from earlier versions of AAMI recommendations, but given current knowledge about toxic exposures to and inflammatory processes in patients new to dialysis, these machines should now come into compliance with current AAMI recommendations for hemodialysis water and dialysate quality.[788, 789] Previous recommendations were based on the assumption that acute-care patients did not experience the same degree of adverse effects from short-term, cumulative exposures to either chemicals or microbiologic agents present in hemodialysis fluids compared with the effects encountered by patients during chronic, maintenance dialysis.[788, 789] Additionally, JCAHO is reviewing inpatient practices and

record-keeping for dialysis (acute and maintenance) for adherence to AAMI standards and recommended practices.

Figure 6. Dialysis water treatment system*



* See text for description of the placement and function of these components.

Neither the water used to prepare dialysate nor the dialysate itself needs to be sterile, but tap water can not be used without additional treatment. Infections caused by rapid-growing NTM (e.g., *Mycobacterium chelonae* and *M. abscessus*) present a potential risk to hemodialysis patients (especially those in hemodialyzer reuse programs) if disinfection procedures to inactivate mycobacteria in the water (low-level disinfection) and the hemodialyzers (high-level disinfection) are inadequate.[31, 32, 633] Other factors associated with microbial contamination in dialysis systems could involve the water treatment system, the water and dialysate distribution systems, and the type of hemodialyzer.[666, 667, 794–799] Understanding the various factors and their influence on contamination levels is the key to preventing high levels of microbial contamination in dialysis therapy.

In several studies, pyrogenic reactions were demonstrated to have been caused by lipopolysaccharide or endotoxin associated with gram-negative bacteria.[794, 800–803] Early studies demonstrated that parenteral exposure to endotoxin at a concentration of 1 ng/kg body weight/hour was the threshold dose for producing pyrogenic reactions in humans, and that the relative potencies of endotoxin differ by bacterial species.[804, 805] Gram-negative water bacteria (e.g., *Pseudomonas* spp.) have been shown to multiply rapidly in a variety of hospital-associated fluids that can be used as supply water for hemodialysis (e.g., distilled water, deionized water, RO water, and softened water) and in dialysate (a balanced salt solution made with this water).[806] Several studies have demonstrated that the attack rates of pyrogenic reactions are directly associated with the number of bacteria in dialysate.[666, 667, 807] These studies provided the rationale for setting the heterotrophic bacteria standards in the first AAMI hemodialysis guideline at ≤2,000 CFU/mL in dialysate and one log lower (≤200 CFU/mL) for the water used to prepare dialysate.[668, 788] If the level of bacterial contamination exceeded 200 CFU/mL in water, this level could be amplified in the system and effectively constitute a high inoculum for dialysate at the start of a dialysis treatment.[807, 808] Pyrogenic reactions did not appear to occur when the level of contamination was below 2,000 CFU/mL in dialysate unless the source of the endotoxin was exogenous to the dialysis system (i.e., present in the community water supply). Endotoxins in a community water supply have been linked to the development of pyrogenic reactions among dialysis patients.[794]

Whether endotoxin actually crosses the dialyzer membrane is controversial. Several investigators have shown that bacteria growing in dialysate-generated products that could cross the dialyzer membrane.[809, 810] Gram-negative bacteria growing in dialysate have produced endotoxins that in turn stimulated the production of anti-endotoxin antibodies in hemodialysis patients;[801, 811] these data suggest that bacterial endotoxins, although large molecules, cross dialyzer membranes either intact or as fragments. The use of the very permeable membranes known as high-flux membranes (which allow large molecules [e.g., β2 microglobulin] to traverse the membrane) increases the potential for passage of endotoxins into the blood path. Several studies support this contention. In one such study, an increase in plasma endotoxin concentrations during dialysis was observed when patients were dialyzed against dialysate containing 10^3–10^4 CFU/mL *Pseudomonas* spp.[812] *In vitro* studies using both radiolabeled lipopolysaccharide and biologic assays have demonstrated that biologically active substances derived from bacteria found in dialysate can cross a variety of dialyzer membranes.[802, 813–816] Patients treated with high-flux membranes have had higher levels of anti-endotoxin antibodies than subjects or patients treated with conventional membranes.[817] Finally, since 1989, 19%–22% of dialysis centers have reported pyrogenic reactions in the absence of septicemia.[818, 819]

Investigations of adverse outcomes among patients using reprocessed dialyzers have demonstrated a greater risk for developing pyrogenic reactions when the water used to reprocess these devices contained >6 ng/mL endotoxin and $>10^4$ CFU/mL bacteria.[820] In addition to the variability in endotoxin assays, host factors also are involved in determining whether a patient will mount a response to endotoxin.[803] Outbreak investigations of pyrogenic reactions and bacteremias associated with hemodialyzer reuse have demonstrated that pyrogenic reactions are prevented once the endotoxin level in the water used to reprocess the dialyzers is returned to below the AAMI standard level.[821]

Reuse of dialyzers and use of bicarbonate dialysate, high-flux dialyzer membranes, or high-flux dialysis may increase the potential for pyrogenic reactions if the water in the dialysis setting does not meet standards.[796–798] Although investigators have been unable to demonstrate endotoxin transfer across dialyzer membranes,[803, 822, 823] the preponderance of reports now supports the ability of endotoxin to transfer across at least some high-flux membranes under some operating conditions. In addition to the acute risk of pyrogenic reactions, indirect evidence in increasingly demonstrating that chronic exposure to low amounts of endotoxin may play a role in some of the long-term complications of hemodialysis therapy. Patients treated with ultrafiltered dialysate for 5–6 months have demonstrated a decrease in serum β2 microglobulin concentrations and a decrease in markers of an inflammatory response.[824–826] In studies of longer duration, use of microbiologically ultrapure dialysate has been associated with a decreased incidence of β2 microglobulin-associated amyloidosis.[827, 828]

Although patient benefit likely is associated with the use of ultrapure dialysate, no consensus has been reached regarding the potential adoption of this as standard in the United States. Debate continues regarding the bacterial and endotoxin limits for dialysate. As advances in water treatment and hemodialysis processes occur, efforts are underway to move improved technology from the manufacturer out into the user community. Cost-benefit studies, however, have not been done, and substantially increased costs to implement newer water treatment modalities are anticipated.

To reconcile AAMI documents with current International Organization for Standardization (ISO) format, AAMI has determined that its hemodialysis standards will be discussed in the following four installments: RD 5 for hemodialysis equipment, RD 62 for product water quality, RD 47 for dialyzer reprocessing, and RD 52 for dialysate quality. The Renal Diseases and Dialysis Committee of AAMI is expected to finalize and promulgated the dialysate standard pertinent to the user community (RD 52), adopting by reference the bacterial and endotoxin limits in product water as currently outlined in the AAMI standard that applies to systems manufacturers (RD 62). At present, the user community should continue to observe water quality and dialysate standards as outlined in AAMI RD 5 (Hemodialysis Systems, 1992) and AAMI RD 47 (Reuse of Hemodialyzers, 1993) until the new RD 52 standard becomes available (Table 18).[789, 791]

Table 18. Microbiologic limits for hemodialysis fluids*

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 18a. Present standard

Hemodialysis fluid	Maximum total heterotrophs (CFU/mL) (colony forming units per milliliter)	Maximum endotoxin level (EU/mL) (endotoxin units per milliliter)
Product water - Used to prepare dialysate	200	No standard
Product water - Used to reprocess dialyzers	200	5
Dialysate	2,000	No standard

Product water presently includes water used to prepare dialysate and water used to reprocess dialyzers

Table 18b. Proposed standard**

Hemodialysis fluid	Maximum total heterotrophs (CFU/mL) (colony forming units per milliliter)	Maximum endotoxin level (EU/mL) (endotoxin units per milliliter)
Product water	200	2
Dialysate	200	2

** Dialysate for hemodialysis, RD 52, under development, American National Standards Institute, Association for the Advancement of Medical Instrumentation (AAMI).

* The material in this table was compiled from references 789 and 791 (ANSI/AAMI standards RD 5-1992 and ANSI/AAMI RD 47-1993).

The current AAMI standard directed at systems manufacturers (RD 62 [Water Treatment Equipment for Hemodialysis Applications, 2001]) now specifies that all product water used to prepare dialysate or to reprocess dialyzers for multiple use should contain <2 endotoxin units per milliliter (EU/mL).[792] A level of 2 EU/mL was chosen as the upper limit for endotoxin because this level is easily achieved with contemporary water treatment systems using RO and/or ultrafiltration. CDC has advocated monthly endotoxin testing along with microbiologic assays of water, because endotoxin activity may not correspond to the total heterotrophic plate counts.[829] Additionally, the current AAMI standard RD 62 for manufacturers includes action levels for product water. Because 48 hours can elapse between the time of sampling water for microbial contamination and the time when results are received, and because bacterial proliferation can be rapid, action levels for microbial counts and endotoxin concentrations are reported as 50 CFU/mL and 1 EU/mL, respectively, in this revision of the standard.[792] These recommendations will allow users to initiate corrective action before levels exceed the maximum levels established by the standard.

In hemodialysis, the net movement of water is from the blood to the dialysate, although within the dialyzer, local movement of water from the dialysate to the blood through the phenomenon of back-filtration may occur, particularly in dialyzers with highly permeable membranes.[830] In contrast, hemofiltration and hemodiaflltration feature infusion of large volumes of electrolyte solution (20–70 L) into the blood. Increasingly, this electrolyte solution is being prepared on-line from water and concentrate. Because of the large volumes of fluid infused, AAMI considered the necessity of setting more stringent requirements for water to be used in this application, but this organization has not yet established these because of lack of expert consensus and insufficient experience with on-line therapies in the United States. On-line hemofiltration and hemodiafiltration systems use sequential ultrafiltration as the final step in the preparation of infusion fluid. Several experts from AAMI concur that these point-of-use ultrafiltration systems should be capable of further reducing the bacteria and endotoxin burden of solutions prepared from water meeting the requirements of the AAMI standard to a safe level for infusion.

b. Microbial Control Strategies

The strategy for controlling massive accumulations of gram-negative water bacteria and NTM in dialysis systems primarily involves preventing their growth through proper disinfection of water-treatment systems and hemodialysis machines. Gram-negative water bacteria, their associated lipopolysaccharides (bacterial

endotoxins), and NTM ultimately come from the community water supply, and levels of these bacteria can be amplified depending on the water treatment system, dialysate distribution system, type of dialysis machine, and method of disinfection (Table 19).[634, 794, 831] Control strategies are designed to reduce levels of microbial contamination in water and dialysis fluid to relatively low levels but not to completely eradicate it.

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 19. Factors influencing microbial contamination in hemodialysis systems

Water supply—Source of community water

- **Ground water**
  Contains endotoxin and bacteria
- **Surface water**
  Contains high levels of endotoxin and bacteria

Water treatment at the dialysis center

- **None**
  Not recommended
- **Filtration: Prefilter**
  Particulate filter to protect equipment; does not remove microorganisms
- **Filtration:Absolute filter (depth or membrane filter)**
  Removes bacteria, however, unless the filter is changed frequently or disinfected, bacteria will accumulate and grow through the filter; acts as a significant reservoir of bacteria and endotoxin
- **Filtration:Activated carbon filter**
  Removes organics and available chlorine or chloramines; acts as a significant reservoir of bacteria and endotoxin

Water treatment devices

- **Deionization/ion-exchange softener**
  Both softeners and deionizers are significant reservoirs of bacteria and do not remove endotoxin.
- **Reverse osmosis (RO)**
  Removes bacteria and endotoxin, but must be disinfected; operates at high water pressure
- **Ultraviolet light**
  Kills some bacteria, but there is no residual; ultraviolet-resistant bacteria can develop if the unit is not properly maintained
- **Ultrafilter**
  Removes bacteria and endotoxin; operates on normal line pressure; can be positioned distal to deionizer; must be disinfected

Water and dialysate distribution system (Distribution pipes)

- **Size**
  Oversized diameter and length decrease fluid flow and increase bacterial reservoir for both treated water and centrally-prepared dialysate.
- **Construction**
  Rough joints, dead ends, unused branches, and polyvinyl chloride (PVC) piping can act as bacterial reservoirs.
- **Elevation**
  Outlet taps should be located at the highest elevation to prevent loss of disinfectant; keep a recirculation loop in the system; flush unused ports routinely.
- **Storage tanks**
  Tanks are undesirable because they act as a reservoir for water bacteria; if tanks are present, they must be routinely scrubbed and disinfected.

Dialysis machines

- **Single-pass**
  Disinfectant should have contact with all parts of the machine that are exposed to water or dialysis fluid.
- **Recirculating single-pass or recirculating (batch)**
  Recirculating pumps and machine design allow for massive contamination levels if not properly disinfected; overnight chemical germicide treatment is recommended.

Two components of hemodialysis water distribution systems – pipes (particularly those made of polyvinyl chloride [PVC]) and storage tanks – can serve as reservoirs of microbial contamination. Hemodialysis systems frequently use pipes that are wider and longer than are needed to handle the required flow, which slows the fluid velocity and increases both the total fluid volume and the wetted surface area of the system. Gram-negative bacteria in fluids remaining in pipes overnight multiply rapidly and colonize the wet surfaces, producing bacterial populations and endotoxin quantities in proportion to the volume and surface area. Such colonization results in formation of protective biofilm that is difficult to remove and protects the bacteria from disinfection.[832] Routine (i.e., monthly), low-level disinfection of the pipes can help to control bacterial contamination of the distribution system. Additional measures to protect pipes from contaminations include

a. situating all outlet taps at equal elevation and at the highest point of the system so that the disinfectant cannot drain from pipes by gravity before adequate contact time has elapsed and
b. eliminating rough joints, dead-end pipes, and unused branches and taps that can trap fluid and serve as reservoirs of bacteria capable of continuously inoculating the entire volume of the system.[800]

Maintain a flow velocity of 3–5 ft/sec.

A storage tank in the distribution system greatly increases the volume of fluid and surface area available and can serve as a niche for water bacteria. Storage tanks are therefore not recommended for use in dialysis systems unless they are frequently drained and adequately disinfected, including scrubbing the sides of the tank to remove bacterial biofilm. An ultrafilter should be used distal to the storage tank.[808, 833]

Microbiologic sampling of dialysis fluids is recommended because gram-negative bacteria can proliferate rapidly in water and dialysate in hemodialysis systems; high levels of these organisms place patients at risk for pyrogenic reactions or health-care associated infection.[667, 668, 808]

Health-care facilities are advised to sample dialysis fluids at least monthly using standard microbiologic assay methods for waterborne microorganisms.[788, 793, 799, 834–836] Product water used to prepare dialysate and to reprocess hemodialyzers for reuse on the same patient should also be tested for bacterial endotoxin on a monthly basis.[792, 829, 837] (See Appendix C for information about water sampling methods for dialysis.)

Cross-contamination of dialysis machines and inadequate disinfection measures can facilitate the spread of waterborne organisms to patients. Steps should be taken to ensure that dialysis equipment is performing correctly and that all connectors, lines, and other components are specific for the equipment, in good repair, and properly in place. A recent outbreak of gram-negative bacteremias among dialysis patients was attributed to faulty valves in a drain port of the machine that allowed backflow of saline used to flush the dialyzer before patient use.[838, 839] This backflow contaminated the drain priming connectors, which contaminated the blood lines and exposed the patients to high concentrations of gram-negative bacteria. Environmental infection control in dialysis settings also includes low-level disinfection of housekeeping surfaces and spot decontamination of spills of blood (see Environmental Services in Part I of this guideline for further information).

c. Infection-Control Issues in Peritoneal Dialysis

Peritoneal dialysis (PD), most commonly administered as continuous ambulatory peritoneal dialysis (CAPD) and continual cycling peritoneal dialysis (CCPD), is the third most common treatment for end-stage renal disease (ESRD) in the United States, accounting for 12% of all dialysis patients.[840] Peritonitis is the primary complication of CAPD, with coagulase-negative staphylococci the most clinically significant causative organisms.[841] Other organisms that have been found to produce peritonitis include *Staphylococcus aureus, Mycobacterium fortuitum, M. mucogenicum, Stenotrophomonas maltophilia, Burkholderia cepacia, Corynebacterium jeikeium, Candida* spp., and other fungi.[842–850] Substantial morbidity is associated with peritoneal dialysis infections. Removal of peritoneal dialysis catheters usually is required for treatment of peritonitis caused by fungi, NTM, or other bacteria that are not cleared within the first several days of effective antimicrobial treatment. Furthermore, recurrent episodes of peritonitis may lead to fibrosis and loss of the dialysis membrane.

Many reported episodes of peritonitis are associated with exit-site or tunneled catheter infections. Risk factors for the development of peritonitis in PD patients include

1. under dialysis,
2. immune suppression,
3. prolonged antimicrobial treatment,
4. patient age [more infections occur in younger patients and older hospitalized patients],
5. length of hospital stay, and
6. hypoalbuminemia.[844, 851, 852]

Concern has been raised about infection risk associated with the use of automated cyclers in both inpatient and outpatient settings; however, studies suggest that PD patients who use automated cyclers have much lower infection rates.[853] One study noted that a closed-drainage system reduced the incidence of system-related peritonitis among intermittent peritoneal dialysis (IPD) patients from 3.6 to 1.5 cases/100 patient days.[854] The association of peritonitis with management of spent dialysate fluids requires additional study. Therefore, ensuring that the tip of the waste line is not submerged beneath the water level in a toilet or in a drain is prudent.

7. Ice Machines and Ice

Microorganisms may be present in ice, ice-storage chests, and ice-making machines. The two main sources of microorganisms in ice are the potable water from which it is made and a transferral of organisms from hands (Table 20). Ice from contaminated ice machines has been associated with patient colonization, blood stream infections, pulmonary and gastrointestinal illnesses, and pseudoinfections.[602, 603, 683, 684, 854, 855]

Microorganisms in ice can secondarily contaminate clinical specimens and medical solutions that require cold temperatures for either transport or holding.[601, 620] An outbreak of surgical-site infections was interrupted when sterile ice was used in place of tap water ice to cool cardioplegia solutions.[601]

⚠ **Format Change [November 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table 20. Microorganisms and their sources in ice and ice machines

From potable water

- *Legionella* spp. [684, 685, 857, 858]
- Nontuberculous mycobacteria (NTM) [602, 603, 859]
- *Pseudomonas aeruginosa* [859]
- *Burkholderia cepacia* [859, 860]
- *Stenotrophomonas maltophilia* [860]
- *Flavobacterium* spp. [860]

From fecally-contaminated water

- Norwalk virus [861–863]
- *Giardia lamblia* [864]
- *Cryptosporidium parvum* [685]

From hand-transfer of organisms

- *Acinetobacter* spp. [859]
- Coagulase-negative staphylococci [859]
- *Salmonella enteriditis* [865]
- *Cryptosporidium parvum* [685]

In a study comparing the microbial populations of hospital ice machines with organisms recovered from ice samples gathered from the community, samples from 27 hospital ice machines yielded low numbers (<10 CFU/mL) of several potentially opportunistic microorganisms, mainly gram-negative bacilli.[859] During the survey period, no health-care associated infections were attributed to the use of ice. Ice from community sources had higher levels of microbial contamination (75%–95% of 194 samples had total heterotrophic plate counts <500 CFU/mL, with the proportion of positive cultures dependent on the incubation temperature) and showed evidence of fecal contamination from the source water.[859] Thus, ice machines in

health-care settings are no more heavily contaminated compared with ice machines in the community. If the source water for ice in a health-care facility is not fecally contaminated, then ice from clean ice machines and chests should pose no increased hazard for immunocompetent patients. Some waterborne bacteria found in ice could potentially be a risk to immunocompromised patients if they consume ice or drink beverages with ice. For example, *Burkholderia cepacia* in ice could present an infection risk for cystic fibrosis patients.[859, 860] Therefore, protecting immunosuppressed and otherwise medically at-risk patients from exposure to tap water and ice potentially contaminated with opportunistic pathogens is prudent.[9]

No microbiologic standards for ice, ice-making machines, or ice storage equipment have been established, although several investigators have suggested the need for such standards.[859, 866] Culturing of ice machines is not routinely recommended, but it may be useful as part of an epidemiologic investigation.[867–869] Sampling might also help determine the best schedule for cleaning open ice-storage chests. Recommendations for a regular program of maintenance and disinfection have been published.[866–869] Health-care facilities are advised to clean ice-storage chests on a regular basis. Open ice chests may require a more frequent cleaning schedule compared with chests that have covers. Portable ice chests and containers require cleaning and low-level disinfection before the addition of ice intended for consumption. Ice-making machines may require less frequent cleaning, but their maintenance is important to proper performance. The manufacturer's instructions for both the proper method of cleaning and/or maintenance should be followed. These instructions may also recommend an EPA-registered disinfectant to ensure chemical potency, materials compatibility, and safety. In the event that instructions and suitable EPA-registered disinfectants are not available for this process, then a generic approach to cleaning, disinfecting, and maintaining ice machines and dispensers can be used (Box 12).

Ice and ice-making machines also may be contaminated via improper storage or handling of ice by patients and/or staff.[684–686, 855–858, 870] Suggested steps to avoid this means of contamination include

a. minimizing or avoiding direct hand contact with ice intended for consumption,
b. using a hard-surface scoop to dispense ice, and
c. installing machines that dispense ice directly into portable containers at the touch of a control.[687, 869]

Box 12. 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 solutions and flush with fresh tap water.
15. Allow all surfaces of equipment to dry before returning to service.

* Material in this box is adapted from reference 869.

\+ These general guidelines should be used only where manufacturer-recommended methods and EPA-registered disinfectants are not available.

8. Hydrotherapy Tanks and Pools

a. General Information

Hydrotherapy equipment (e.g., pools, whirlpools, whirlpool spas, hot tubs, and physiotherapy tanks) traditionally has been used to treat patients with certain medical conditions (e.g., burns,[871, 872] septic ulcers, lesions, amputations,[873] orthopedic impairments and injuries, arthritis,[874] and kidney lithotripsy).[654] Wound-care medicine is increasingly moving away from hydrotherapy, however, in favor of bedside pulsed-lavage therapy using sterile solutions for cleaning and irrigation.[492, 875–878] Several episodes of health-care associated infections have been linked to use of hydrotherapy equipment (Table 21). Potential routes of infection include incidental ingestion of the water, sprays and aerosols, and direct contact with wounds and intact skin (folliculitis). Risk factors for infection include

a. age and sex of the patient,
b. underlying medical conditions,
c. length of time spent in the hydrotherapy water, and
d. portals of entry.[879]

Table 21. Infections associated with use of hydrotherapy equipment

Microorganisms	Medical conditions	References
Acinetobacter baumanii	Sepsis	572
Citrobacter freundii	Cellulitis	880
Enterobacter cloacae	Sepsis	881
Legionella spp.	Legionellosis	882
Mycobacterium abscessus, Mycobacterium fortuitum, Mycobacterium marinum	Skin ulcers and soft tissue infections	621–623, 883
Pseudomonas aeruginosa	Sepsis, soft tissue infections, folliculitis, and wound infections	492, 493, 506, 679, 884–888
Adenovirus, adeno-associated virus	Conjunctivitis	889

Infection control for hydrotherapy tanks, pools, or birthing tanks presents unique challenges because indigenous microorganisms are always present in the water during treatments. In addition, some studies have found free living amoebae (i.e., *Naegleria lovaniensis*), which are commonly found in association with *Naegleria fowleri,* in hospital hydrotherapy pools.[890] Although hydrotherapy is at times appropriate for patients with wounds, burns, or other types of non-intact skin conditions (determined on a case-by-case basis), this equipment should not be considered "semi-critical" in accordance with the Spaulding classification.[891] Microbial data to evaluate the risk of infection to patients using hydrotherapy pools and birthing tanks are insufficient. Nevertheless, health-care facilities should maintain stringent cleaning and disinfection practices in accordance with the manufacturer's instructions and with relevant scientific literature until data supporting more rigorous infection-control measures become available. Factors that should be considered in therapy decisions in this situation would include

a. availability of alternative aseptic techniques for wound management and
b. a risk-benefit analysis of using traditional hydrotherapy.

b. Hydrotherapy Tanks

Hydrotherapy tanks (e.g., whirlpools, Hubbard tanks and whirlpool bath tubs) are shallow tanks constructed of stainless steel, plexiglass, or tile. They are closed-cycle water systems with hydrojets to circulate, aerate, and agitate the water. The maximum water temperature range is 50°F–104°F (10°C–40°C). The warm water temperature, constant agitation and aeration, and design of the hydrotherapy tanks provide ideal conditions for bacterial proliferation if the equipment is not properly maintained, cleaned, and disinfected. The design of the hydrotherapy equipment should be evaluated for potential infection-

control problems that can be associated with inaccessible surfaces that can be difficult to clean and/or remain wet in between uses (i.e., recessed drain plates with fixed grill plates).[887] Associated equipment (e.g., parallel bars, plinths, Hoyer lifts, and wheelchairs) can also be potential reservoirs of microorganisms, depending on the materials used in these items (i.e., porous vs. non-porous materials) and the surfaces that may become wet during use. Patients with active skin colonizations and wound infections can serve as sources of contamination for the equipment and the water. Contamination from spilled tub water can extend to drains, floors, and walls.[680–683] Health-care associated colonization or infection can result from exposure to endogenous sources of microorganisms (autoinoculation) or exogenous sources (via cross-contamination from other patients previously receiving treatment in the unit).

Although some facilities have used tub liners to minimize environmental contamination of the tanks, the use of a tub liner does not eliminate the need for cleaning and disinfection. Draining these small pools and tanks after each patient use, thoroughly cleaning with a detergent, and disinfecting according to manufacturers' instructions have reduced bacterial contamination levels in the water from 10^4 CFU/mL to <10 CFU/mL.[892] A chlorine residual of 15 ppm in the water should be obtained prior to the patient's therapy session (e.g., by adding 15 grams of calcium hypochlorite 70% [e.g., HTH®] per 100 gallons of water).[892] A study of commercial and residential whirlpools found that superchlorination or draining, cleaning, disinfection, and refilling of whirlpools markedly reduced densities of *Pseudomonas aeruginosa* in whirlpool water.[893] The bacterial populations were rapidly replenished, however, when disinfectant concentrations dropped below recommended levels for recreational use (i.e., chlorine at 3.0 ppm or bromine at 6.0 ppm). When using chlorine, however, knowing whether the community drinking-water system is disinfected with chloramine is important, because municipal utilities adjust the pH of the water to the basic side to enhance chloramine formation. Because chlorine is not very effective at pH levels above 8, it may be necessary to re-adjust the pH of the water to a more acidic level.[894]

A few reports describe the addition of antiseptic chemicals to hydrotherapy tank water, especially for burn patient therapy.[895–897] One study involving a minimal number of participants demonstrated a reduction in the number of *Pseudomonas* spp. and other gram-negative bacteria from both patients and equipment surfaces when chloramine-T ("chlorazene") was added to the water.[898] Chloramine-T has not, however, been approved for water treatment in the United States.

c. Hydrotherapy Pools

Hydrotherapy pools typically serve large numbers of patients and are usually heated to 91.4°F–98.6°F (31°C–37°C). The temperature range is more narrow (94°F–96.8°F [35°C–36°C]) for pediatric and geriatric patient use.[899] Because the size of hydrotherapy pools precludes draining after patient use, proper management is required to maintain the proper balance of water conditioning (i.e., alkalinity, hardness, and temperature) and disinfection. The most widely used chemicals for disinfection of pools are chlorine and chlorine compounds – calcium hypochlorite, sodium hypochlorite, lithium hypochlorite, chloroisocyanurates, and chlorine gas. Solid and liquid formulations of chlorine chemicals are the easiest and safest to use.[900] Other halogenated compounds have also been used for pool-water disinfection, albeit on a limited scale. Bromine, which forms bactericidal bromamines in the presence of ammonia, has limited use because of its association with contact dermatitis.[901] Iodine does not bleach hair, swim suits, or cause eye irritation, but when introduced at proper concentrations, it gives water a greenish-yellowish cast.[892]

In practical terms, maintenance of large hydrotherapy pools (e.g., those used for exercise) is similar to that for indoor public pools (i.e., continuous filtration, chlorine residuals no less than 0.4 ppm, and pH of 7.2–7.6).[902, 903] Supply pipes and pumps also need to be maintained to eliminate the possibility of this equipment serving as a reservoir for waterborne organisms.[904] Specific standards for chlorine residual and pH of the water are addressed in local and state regulations. Patients who are fecally incontinent or who have draining wounds should refrain from using these pools until their condition improves.

d. Birthing Tanks and Other Equipment

The use of birthing tanks, whirlpool spas, and whirlpools is a recent addition to obstetrical practice.[905] Few studies on the potential risks associated with these pieces of equipment have been conducted. In one study of 32 women, a newborn contracted a *Pseudomonas* infection after being birthed in such a tank, the strain of which was identical to the organism isolated from the tank water.[906] Another report documented identical strains of *P. aeruginosa* isolates from a newborn with sepsis and on the environmental surfaces of a tub that the mother used for relaxation while in labor.[907] Other studies have shown no significant increases in the rates of post-immersion infections among mothers and infants.[908, 909]

Because the water and the tub surfaces routinely become contaminated with the mother's skin flora and blood during labor and delivery, birthing tanks and other tub equipment must be drained after each patient use and the surfaces thoroughly cleaned and disinfected. Health-care facilities are advised to follow the manufacturer's instructions for selection of disinfection method and chemical germicide. The range of chlorine residuals for public whirlpools and whirlpool spas is 2–5 ppm.[910] Use of an inflatable tub is an alternative solution, but this item must be cleaned and disinfected between patients if it is not considered a single-use unit.

Recreational tanks and whirlpool spas are increasingly being used as hydrotherapy equipment. Although such home equipment appears to be suitable for hydrotherapy, they are neither designed nor constructed to function in this capacity. Additionally, manufacturers generally are not obligated to provide the health-care facility with cleaning and disinfecting instructions appropriate for medical equipment use, and the U.S. Food and Drug Administration (FDA) does not evaluate recreational equipment. Health-care facilities should therefore carefully evaluate this "off-label" use of home equipment before proceeding with a purchase.

9. Miscellaneous Medical/Dental Equipment Connected to Main Water Systems

a. Automated Endoscope Reprocessors

The automated endoscopic reprocessor (AER) is classified by the FDA as an accessory for the flexible endoscope.[654] A properly operating AER can provide a more consistent, reliable method of decontaminating and terminal reprocessing for endoscopes between patient procedures than manual reprocessing methods alone.[911] An endoscope is generally subjected to high-level disinfection using a liquid chemical sterilant or a high-level disinfectant. Because the instrument is a semi-critical device, the optimal rinse fluid for a disinfected endoscope would be sterile water.[3] Sterile water, however, is expensive and difficult to produce in sufficient quantities and with adequate quality assurance for instrument rinsing in an AER.[912, 913] Therefore, one option to be used for AERs is rinse water that has been passed through filters with a pore size of 0.1–0.2 μm to render the water "bacteria-free." These filters usually are located in the water line at or near the port where the mains water enters the equipment. The product water (i.e., tap water passing through these filters) in these applications is not considered equivalent in microbial quality to that for membrane-filtered water as produced by pharmaceutical firms. Membrane filtration in pharmaceutical applications is intended to ensure the microbial quality of polished product water.

Water has been linked to the contamination of flexible fiberoptic endoscopes in the following two scenarios:

a. rinsing a disinfected endoscope with unfiltered tap water, followed by storage of the instrument without drying out the internal channels and
b. contamination of AERs from tap water inadvertently introduced into the equipment.

In the latter instance, the machine's water reservoirs and fluid circuitry become contaminated with waterborne, heterotrophic bacteria (e.g., *Pseudomonas aeruginosa* and NTM), which can survive and persist in biofilms attached to these components.[914–917] Colonization of the reservoirs and water lines of the AER becomes problematic if the required cleaning, disinfection, and maintenance are not performed on the equipment as recommended by the manufacturer.[669, 916, 917] Use of the 0.1–0.2-µm filter in the water line helps to keep bacterial contamination to a minimum,[670, 911, 917] but filters may fail and allow bacteria to pass through to the equipment and then to the instrument undergoing reprocessing.[671–674, 913, 918] Filters also require maintenance for proper performance.[670, 911, 912, 918, 919] Heightened awareness of the proper disinfection of the connectors that hook the instrument to the AER may help to further reduce the potential for contaminating endoscopes during reprocessing.[920] An emerging issue in the field of endoscopy is that of the possible role of rinse water monitoring and its potential to help reduce endoscopy/bronchoscopyassociated infections.[918]

Studies have linked deficiencies in endoscope cleaning and/or disinfecting processes to the incidence of post-endoscopic adverse outcomes.[921–924] Several clusters have been traced to AERs of older designs and these were associated with water quality.[675, 914–916] Regardless of whether manual or automated terminal reprocessing is used for endoscopes, the internal channels of the instrument should be dried before storage.[925] The presence of residual moisture in the internal channels encourages the proliferation of waterborne microorganisms, some of which may be pathogenic. One of the most frequently used methods employs 70% isopropyl alcohol to flush the internal channels, followed by forced air drying of these channels and hanging the endoscope vertically in a protected cabinet; this method ensures internal drying of the endoscope, lessens the potential for proliferation of waterborne microorganisms,[669, 913, 917, 922, 926, 927] and is consistent with professional organization guidance for endoscope reprocessing.[928]

An additional problem with waterborne microbial contamination of AERs centers on increased microbial resistance to alkaline glutaraldehyde, a widely used liquid chemical sterilant/high-level disinfectant.[669, 929] Opportunistic waterborne microorganisms (e.g., *Mycobacterium chelonae*, *Methylobacterium* spp.) have been associated with pseudo-outbreaks and colonization; infection caused by these organisms has been associated with procedures conducted in clinical settings (e.g., bronchoscopy).[669, 913, 929–931] Increasing microbial resistance to glutaraldehyde has been attributed to improper use of the disinfectant in the equipment, allowing the dilution of glutaraldehyde to fall below the manufacturer's recommended minimal use concentration.[929]

b. Dental Unit Water Lines

Dental unit water lines (DUWLs) consist of small-bore plastic tubing that delivers water used for general, non-surgical irrigation and as a coolant to dental handpieces, sonic and ultrasonic scalers, and air-water syringes; municipal tap water is the source water for these lines. The presence of biofilms of waterborne bacteria and fungi (e.g., *Legionella* spp., *Pseudomonas aeruginosa,* and NTM) in DUWLs has been established.[636, 637, 694, 695, 932– 934] Biofilms continually release planktonic microorganisms into the water, the titers of which can exceed $1H10^6$ CFU/mL.[694] However, scientific evidence indicates that immunocompetent persons are only at minimal risk for substantial adverse health effects after contact with water from a dental unit. Nonetheless, exposing patients or dental personnel to water of uncertain microbiological quality is not consistent with universally accepted infection-control principles.[935]

In 1993, CDC issued guidelines relative to water quality in a dental setting. These guidelines recommend that all dental instruments that use water (including high-speed handpieces) should be run to discharge water for 20–30 seconds after each patient and for several minutes before the start of each clinic day.[936] This practice can help to flush out any patient materials that many have entered the turbine, air, or waterlines.[937, 938] The 1993 guidance also indicated that waterlines be flushed at the beginning of the clinic day. Although

these guidelines are designed to help reduce the number of microorganisms present in treatment water, they do not address the issue of reducing or preventing biofilm formation in the waterlines. Research published subsequent to the 1993 dental infection control guideline suggests that flushing the lines at the beginning of the day has only minimal effect on the status of the biofilm in the lines and does not reliably improve the quality of water during dental treatment.[939–941] Updated recommendations on infection-control practices for water line use in dentistry will be available in late 2003.[942]

The numbers of microorganisms in water used as coolant or irrigant for non-surgical dental treatment should be as low as reasonably achievable and, at a minimum, should meet nationally recognized standards for safe drinking water.[935, 943] Only minimal evidence suggests that water meeting drinking water standards poses a health hazard for immunocompetent persons. The EPA, the American Public Health Association (APHA), and the American Water Works Association (AWWA) have set a maximum limit of 500 CFU/mL for aerobic, heterotrophic, mesophilic bacteria in drinking water in municipal distribution systems.[944, 945] This standard is achievable, given improvements in water-line technology. Dentists should consult with the manufacturer of their dental unit to determine the best equipment and method for maintaining and monitoring good water quality.[935, 946]

E. Environmental Services

1. Principles of Cleaning and Disinfecting Environmental Surfaces

Although microbiologically contaminated surfaces can serve as reservoirs of potential pathogens, these surfaces generally are not directly associated with transmission of infections to either staff or patients. The transferral of microorganisms from environmental surfaces to patients is largely via hand contact with the surface.[947, 948] Although hand hygiene is important to minimize the impact of this transfer, cleaning and disinfecting environmental surfaces as appropriate is fundamental in reducing their potential contribution to the incidence of healthcare-associated infections.

The principles of cleaning and disinfecting environmental surfaces take into account the intended use of the surface or item in patient care. CDC retains the Spaulding classification for medical and surgical instruments, which outlines three categories based on the potential for the instrument to transmit infection if the instrument is microbiologically contaminated before use.[949, 950] These categories are “critical,” “semicritical,” and “noncritical.” In 1991, CDC proposed an additional category designated “environmental surfaces” to Spaulding’s original classification[951] to represent surfaces that generally do not come into direct contact with patients during care. Environmental surfaces carry the least risk of disease transmission and can be safely decontaminated using less rigorous methods than those used on medical instruments and devices. Environmental surfaces can be further divided into medical equipment surfaces (e.g., knobs or handles on hemodialysis machines, x-ray machines, instrument carts, and dental units) and housekeeping surfaces (e.g., floors, walls, and tabletops).[951]

The following factors influence the choice of disinfection procedure for environmental surfaces:
a. the nature of the item to be disinfected,
b. the number of microorganisms present,
c. the innate resistance of those microorganisms to the inactivating effects of the germicide,
d. the amount of organic soil present,
e. the type and concentration of germicide used,
f. duration and temperature of germicide contact, and
g. if using a proprietary product, other specific indications and directions for use.[952, 953]

Cleaning is the necessary first step of any sterilization or disinfection process. Cleaning is a form of decontamination that renders the environmental surface safe to handle or use by removing organic matter, salts, and visible soils, all of which interfere with microbial inactivation.[954–960] The physical action of

scrubbing with detergents and surfactants and rinsing with water removes large numbers of microorganisms from surfaces.[957] If the surface is not cleaned before the terminal reprocessing procedures are started, the success of the sterilization or disinfection process is compromised.

Spaulding proposed three levels of disinfection for the treatment of devices and surfaces that do not require sterility for safe use. These disinfection levels are "high-level," "intermediate-level," and "low level." [949, 950]

The basis for these levels is that microorganisms can usually be grouped according to their innate resistance to a spectrum of physical or chemical germicidal agents (Table 22). This information, coupled with the instrument/surface classification, determines the appropriate level of terminal disinfection for an instrument or surface.

Table 22. Levels of disinfection by type of microorganism*

Disinfection level	Bacteria (vegetative)	Bacteria (Tubercle bacillus)	Bacteria (spores)	Fungi†	Viruses (lipid and medium size)	Viruses (nonlipid and small size)
High	+	+	+ High-level disinfectant chemicals possess sporicidal activity—only with extended exposure time are high level disinfections capable of killing high numbers of bacterial spores in laboratory tests.	+	+	+
Intermediate	+	+	– Some intermediate-level disinfectants (e.g., hypochlorites) can exhibit some sporicidal activity; others (e.g., alcohols and phenolics) have no demonstrable sporicidal activity.	+	+	± Variable killing effect Some intermediate-level disinfectants, although they are tuberculocidal, may have limited virucidal activity.
Low	+	–	–	Variable killing effect	+	± Variable killing effect

+ indicates that a killing effect can be expected when the normal use-concentrations of chemical disinfectants or pasteurization are properly employed

- indicates little or no killing effect

* Material in this table compiled from references 2, 951.

† This class of microorganisms includes asexual spores but not necessarily chlamydospores or sexual spores.

The process of high-level disinfection, an appropriate standard of treatment for heat-sensitive, semi-critical medical instruments (e.g., flexible, fiberoptic endoscopes), inactivates all vegetative bacteria, mycobacteria, viruses, fungi, and some bacterial spores. High-level disinfection is accomplished with powerful, sporicidal chemicals (e.g., glutaraldehyde, peracetic acid, and hydrogen peroxide) that are not appropriate for use on housekeeping surfaces. These liquid chemical sterilants/high-level disinfectants are highly toxic.[961–963] Use of these chemicals for applications other than those indicated in their label instructions (i.e., as immersion chemicals for treating heat-sensitive medical instruments) is not appropriate.[964] Intermediate-level disinfection does not necessarily kill bacterial spores, but it does inactivate *Mycobacterium tuberculosis* var. *bovis*, which is substantially more resistant to chemical germicides than ordinary vegetative bacteria, fungi, and medium to small viruses (with or without lipid envelopes). Chemical germicides with sufficient potency to achieve intermediate-level disinfection include chlorine-containing compounds (e.g., sodium hypochlorite), alcohols, some phenolics, and some iodophors. Low-level disinfection inactivates vegetative bacteria, fungi, enveloped viruses (e.g., human immunodeficiency virus [HIV], and influenza viruses), and some non-enveloped viruses (e.g., adenoviruses). Low-level disinfectants include quaternary ammonium compounds, some phenolics, and

some iodophors. Sanitizers are agents that reduce the numbers of bacterial contaminants to safe levels as judged by public health requirements, and are used in cleaning operations, particularly in food service and dairy applications. Germicidal chemicals that have been approved by FDA as skin antiseptics are not appropriate for use as environmental surface disinfectants.[951]

The selection and use of chemical germicides are largely matters of judgment, guided by product label instructions, information, and regulations. Liquid sterilant chemicals and high-level disinfectants intended for use on critical and semi-critical medical/dental devices and instruments are regulated exclusively by the FDA as a result of recent memoranda of understanding between FDA and the EPA that delineates agency authority for chemical germicide regulation.[965, 966] Environmental surface germicides (i.e., primarily intermediate- and low-level disinfectants) are regulated by the EPA and labeled with EPA registration numbers. The labels and technical data or product literature of these germicides specify indications for product use and provide claims for the range of antimicrobial activity. The EPA requires certain pre-registration laboratory potency tests for these products to support product label claims. EPA verifies (through laboratory testing) manufacturers' claims to inactivate microorganisms for selected products and organisms. Germicides labeled as "hospital disinfectant" have passed the potency tests for activity against three representative microorganisms – *Pseudomonas aeruginosa, Staphylococcus aureus,* and *Salmonella cholerae suis*. Low-level disinfectants are often labeled "hospital disinfectant" without a tuberculocidal claim, because they lack the potency to inactivate mycobacteria. Hospital disinfectants with demonstrated potency against mycobacteria (i.e., intermediate-level disinfectants) may list "tuberculocidal" on the label as well. Other claims (e.g., "fungicidal," "pseudomonicidal," and "virucidal") may appear on labels of environmental surface germicides, but the designations of "tuberculocidal hospital disinfectant" and "hospital disinfectant" correlate directly to Spaulding's assessment of intermediate-level disinfectants and low-level disinfectants, respectively.[951]

A common misconception in the use of surface disinfectants in health-care settings relates to the underlying purpose for use of proprietary products labeled as a "tuberculocidal" germicide. Such products will not interrupt and prevent the transmission of TB 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 a broad spectrum of pathogens, including much less resistant organisms such the bloodborne pathogens (e.g., hepatitis B virus [HBV], hepatitis C virus [HCV], and HIV). It is this broad spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and OSHA regulations indicating the appropriateness of using tuberculocidal chemicals for surface disinfection.[967]

2. General Cleaning Strategies for Patient-Care Areas

The number and types of microorganisms present on environmental surfaces are influenced by the following factors:

a. number of people in the environment,
b. amount of activity,
c. amount of moisture,
d. presence of material capable of supporting microbial growth,
e. rate at which organisms suspended in the air are removed, and
f. type of surface and orientation [i.e., horizontal or vertical].[968]

Strategies for cleaning and disinfecting surfaces in patient-care areas take into account

a. potential for direct patient contact,
b. degree and frequency of hand contact, and
c. potential contamination of the surface with body substances or environmental sources of microorganisms (e.g., soil, dust, and water).

a. Cleaning of Medical Equipment

Manufacturers of medical equipment should provide care and maintenance instructions specific to their equipment. These instructions should include information about

a. the equipments' compatibility with chemical germicides,
b. whether the equipment is water-resistant or can be safely immersed for cleaning, and
c. how the equipment should be decontaminated if servicing is required.[967]

In the absence of manufacturers' instructions, non-critical medical equipment (e.g., stethoscopes, blood pressure cuffs, dialysis machines, and equipment knobs and controls) usually only require cleansing followed by low- to intermediate-level disinfection, depending on the nature and degree of contamination. Ethyl alcohol or isopropyl alcohol in concentrations of 60%–90% (v/v) is often used to disinfect small surfaces (e.g., rubber stoppers of multiple-dose medication vials, and thermometers)[952, 969] and occasionally external surfaces of equipment (e.g., stethoscopes and ventilators). However, alcohol evaporates rapidly, which makes extended contact times difficult to achieve unless items are immersed, a factor that precludes its practical use as a large-surface disinfectant.[951] Alcohol may cause discoloration, swelling, hardening, and cracking of rubber and certain plastics after prolonged and repeated use and may damage the shellac mounting of lenses in medical equipment.[970]

Barrier protection of surfaces and equipment is useful, especially if these surfaces are

a. touched frequently by gloved hands during the delivery of patient care,
b. likely to become contaminated with body substances, or
c. difficult to clean. Impervious-backed paper, aluminum foil, and plastic or fluid-resistant covers are suitable for use as barrier protection.

An example of this approach is the use of plastic wrapping to cover the handle of the operatory light in dental-care settings.[936, 942] Coverings should be removed and discarded while the health-care worker is still gloved.[936, 942] The health-care worker, after ungloving and performing hand hygiene, must cover these surfaces with clean materials before the next patient encounter.

b. Cleaning Housekeeping Surfaces

Housekeeping surfaces require regular cleaning and removal of soil and dust. Dry conditions favor the persistence of gram-positive cocci (e.g., coagulase-negative *Staphylococcus* spp.) in dust and on surfaces, whereas moist, soiled environments favor the growth and persistence of gram-negative bacilli.[948, 971, 972] Fungi are also present on dust and proliferate in moist, fibrous material.

Most, if not all, housekeeping surfaces need to be cleaned only with soap and water or a detergent/disinfectant, depending on the nature of the surface and the type and degree of contamination. Cleaning and disinfection schedules and methods vary according to the area of the health-care facility, type of surface to be cleaned, and the amount and type of soil present. Disinfectant/detergent formulations registered by EPA are used for environmental surface cleaning, but the actual physical removal of microorganisms and soil by wiping or scrubbing is probably as important, if not more so, than any antimicrobial effect of the cleaning agent used.[973] Therefore, cost, safety, product-surface compatibility, and acceptability by housekeepers can be the main criteria for selecting a registered agent. If using a proprietary detergent/disinfectant, the manufacturers' instructions for appropriate use of the product should be followed.[974] Consult the products' material safety data sheets (MSDS) to determine appropriate precautions to prevent hazardous conditions during product application. Personal protective equipment (PPE) used during cleaning and housekeeping procedures should be appropriate to the task.

Housekeeping surfaces can be divided into two groups – those with minimal hand-contact (e.g., floors, and ceilings) and those with frequent hand-contact ("high touch surfaces"). The methods, thoroughness, and frequency of cleaning and the products used are determined by health-care facility policy.[6] However, high-touch housekeeping surfaces in patient-care areas (e.g., doorknobs, bedrails, light switches, wall areas around the toilet in the patient's room, and the edges of privacy curtains) should be cleaned and/or disinfected more frequently than surfaces with minimal hand contact. Infection-control practitioners

typically use a risk-assessment approach to identify high-touch surfaces and then coordinate an appropriate cleaning and disinfecting strategy and schedule with the housekeeping staff.

Horizontal surfaces with infrequent hand contact (e.g., window sills and hard-surface flooring) in routine patient-care areas require cleaning on a regular basis, when soiling or spills occur, and when a patient is discharged from the facility.[6] Regular cleaning of surfaces and decontamination, as needed, is also advocated to protect potentially exposed workers.[967] Cleaning of walls, blinds, and window curtains is recommended when they are visibly soiled.[972, 973, 975] Disinfectant fogging is not recommended for general infection control in routine patient-care areas.[2, 976] Further, paraformaldehyde, which was once used in this application, is no longer registered by EPA for this purpose. Use of paraformaldehyde in these circumstances requires either registration or an exemption issued by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Infection control, industrial hygienists, and environmental services supervisors should assess the cleaning procedures, chemicals used, and the safety issues to determine if a temporary relocation of the patient is needed when cleaning in the room.

Extraordinary cleaning and decontamination of floors in health-care settings is unwarranted. Studies have demonstrated that disinfection of floors offers no advantage over regular detergent/water cleaning and has minimal or no impact on the occurrence of health-care associated infections.[947, 948, 977–980] Additionally, newly cleaned floors become rapidly recontaminated from airborne microorganisms and those transferred from shoes, equipment wheels, and body substances.[971, 975, 981] Nevertheless, healthcare institutions or contracted cleaning companies may choose to use an EPA-registered detergent/disinfectant for cleaning low-touch surfaces (e.g., floors) in patient-care areas because of the difficulty that personnel may have in determining if a spill contains blood or body fluids (requiring a detergent/disinfectant for clean-up) or when a multi-drug resistant organism is likely to be in the environment. Methods for cleaning non-porous floors include wet mopping and wet vacuuming, dry dusting with electrostatic materials, and spray buffing.[973, 982–984] Methods that produce minimal mists and aerosols or dispersion of dust in patient-care areas are preferred.[9, 20, 109, 272]

Part of the cleaning strategy is to minimize contamination of cleaning solutions and cleaning tools. Bucket solutions become contaminated almost immediately during cleaning, and continued use of the solution transfers increasing numbers of microorganisms to each subsequent surface to be cleaned.[971, 981, 985] Cleaning solutions should be replaced frequently. A variety of "bucket" methods have been devised to address the frequency with which cleaning solutions are replaced.[986, 987] Another source of contamination in the cleaning process is the cleaning cloth or mop head, especially if left soaking in dirty cleaning solutions.[971, 988–990] Laundering of cloths and mop heads after use and allowing them to dry before re-use can help to minimize the degree of contamination.[990] A simplified approach to cleaning involves replacing soiled cloths and mop heads with clean items each time a bucket of detergent/disinfectant is emptied and replaced with fresh, clean solution (B. Stover, Kosair Children's Hospital, 2000). Disposable cleaning cloths and mop heads are an alternative option, if costs permit.

Another reservoir for microorganisms in the cleaning process may be dilute solutions of the detergents or disinfectants, especially if the working solution is prepared in a dirty container, stored for long periods of time, or prepared incorrectly.[547] Gram-negative bacilli (e.g., *Pseudomonas* spp. and *Serratia marcescens*) have been detected in solutions of some disinfectants (e.g., phenolics and quaternary ammonium compounds).[547, 991] Contemporary EPA registration regulations have helped to minimize this problem by asking manufacturers to provide potency data to support label claims for detergent/disinfectant properties under real- use conditions (e.g., diluting the product with tap water instead of distilled water). Application of contaminated cleaning solutions, particularly from small-quantity aerosol spray bottles or with equipment that might generate aerosols during operation, should be avoided, especially in high-risk patient areas.[992, 993] Making sufficient fresh cleaning solution for daily cleaning, discarding any remaining solution, and drying out the container will help to minimize the degree of bacterial contamination. Containers that dispense liquid as opposed to spray-nozzle dispensers (e.g., quart-sized dishwashing liquid bottles) can be used to apply detergent/disinfectants to surfaces and then to cleaning cloths with minimal aerosol generation. A pre-mixed, "ready-to-use" detergent/disinfectant solution may be used if available.

c. Cleaning Special Care Areas

Guidelines have been published regarding cleaning strategies for isolation areas and operating rooms.[6, 7] The basic strategies for areas housing immunosuppressed patients include

a. wet dusting horizontal surfaces daily with cleaning cloths pre-moistened with detergent or an EPA-registered hospital disinfectant or disinfectant wipes;[94, 98463]
b. using care when wet dusting equipment and surfaces above the patient to avoid patient contact with the detergent/disinfectant;
c. avoiding the use of cleaning equipment that produces mists or aerosols;
d. equipping vacuums with HEPA filters, especially for the exhaust, when used in any patient-care area housing immunosuppressed patients;[9, 94, 986] and
e. regular cleaning and maintenance of equipment to ensure efficient particle removal.

When preparing the cleaning cloths for wet-dusting, freshly prepared solutions of detergents or disinfectants should be used rather than cloths that have soaked in such solutions for long periods of time. Dispersal of microorganisms in the air from dust or aerosols is more problematic in these settings than elsewhere in health-care facilities. Vacuum cleaners can serve as dust disseminators if they are not operating properly.[994] Doors to immunosuppressed patients' rooms should be closed when nearby areas are being vacuumed.[9] Bacterial and fungal contamination of filters in cleaning equipment is inevitable, and these filters should be cleaned regularly or replaced as per equipment manufacturer instructions.

Mats with tacky surfaces placed in operating rooms and other patient-care areas only slightly minimize the overall degree of contamination of floors and have little impact on the incidence rate of health-care–associated infection in general.[351, 971, 983] An exception, however, is the use of tacky mats inside the entry ways of cordoned-off construction areas inside the health-care facility; these mats help to minimize the intrusion of dust into patient-care areas.

Special precautions for cleaning incubators, mattresses, and other nursery surfaces have been recommended to address reports of hyperbilirubinemia in newborns linked to inadequately diluted solutions of phenolics and poor ventilation.[995–997] These medical conditions have not, however, been associated with the use of properly prepared solutions of phenolics. Non-porous housekeeping surfaces in neonatal units can be disinfected with properly diluted or pre-mixed phenolics, followed by rinsing with clean water.[997] However, phenolics are not recommended for cleaning infant bassinets and incubators during the stay of the infant. Infants who remain in the nursery for an extended period should be moved periodically to freshly cleaned and disinfected bassinets and incubators.[997] If phenolics are used for cleaning bassinets and incubators after they have been vacated, the surfaces should be rinsed thoroughly with water and dried before either piece of equipment is reused. Cleaning and disinfecting protocols should allow for the full contact time specified for the product used. Bassinet mattresses should be replaced, however, if the mattress cover surface is broken.[997]

3. Cleaning Strategies for Spills of Blood and Body Substances

Neither HBV, HCV, nor HIV has ever been transmitted from a housekeeping surface (i.e., floors, walls, or countertops). Nonetheless, prompt removal and surface disinfection of an area contaminated by either blood or body substances are sound infection-control practices and OSHA requirements.[967]

Studies have demonstrated that HIV is inactivated rapidly after being exposed to commonly used chemical germicides at concentrations that are much lower than those used in practice.[998–1003] HBV is readily inactivated with a variety of germicides, including quaternary ammonium compounds.[1004] Embalming fluids (e.g., formaldehyde) are also capable of completely inactivating HIV and HBV.[1005, 1006] OSHA has revised its regulation for disinfecting spills of blood or other potentially infectious material to include proprietary products whose label includes inactivation claims for HBV and HIV, provided that such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which a higher level of disinfection is recommended.[1007] These registered products are listed in EPA's

List D – *Registered Antimicrobials Effective Against Hepatitis B Virus and Human HIV-1*, which may include products tested against duck hepatitis B virus (DHBV) as a surrogate for HBV.[1008, 1009] Additional lists of interest include EPA's List C –*Registered Antimicrobials Effective Against Human HIV-1* and EPA's List E – *Registered Antimicrobials Effective Against Mycobacterium spp., Hepatitis B Virus, and Human HIV-1*.

Sodium hypochlorite solutions are inexpensive and effective broad-spectrum germicidal solutions.[1010, 1011] Generic sources of sodium hypochlorite include household chlorine bleach or reagent grade chemical. Concentrations of sodium hypochlorite solutions with a range of 5,000–6,150 ppm (1:10 v/v dilution of household bleaches marketed in the United States) to 500–615 ppm (1:100 v/v dilution) free chlorine are effective depending on the amount of organic material (e.g., blood, mucus, and urine) present on the surface to be cleaned and disinfected.[1010, 1011] EPA-registered chemical germicides may be more compatible with certain materials that could be corroded by repeated exposure to sodium hypochlorite, especially the 1:10 dilution. Appropriate personal protective equipment (e.g., gloves and goggles) should be worn when preparing and using hypochlorite solutions or other chemical germicides.[967]

Despite laboratory evidence demonstrating adequate potency against bloodborne pathogens (e.g., HIV and HBV), many chlorine bleach products available in grocery and chemical-supply stores are not registered by the EPA for use as surface disinfectants. Use of these chlorine products as surface disinfectants is considered by the EPA to be an "unregistered use." EPA encourages the use of registered products because the agency reviews them for safety and performance when the product is used according to label instructions. When unregistered products are used for surface disinfection, users do so at their own risk.

Strategies for decontaminating spills of blood and other body fluids differ based on the setting in which they occur and the volume of the spill.[1010] In patient-care areas, workers can manage small spills with cleaning and then disinfecting using an intermediate-level germicide or an EPA-registered germicide from the EPA List D or E.[967, 1007] For spills containing large amounts of blood or other body substances, workers should first remove visible organic matter with absorbent material (e.g., disposable paper towels discarded into leak-proof, properly labeled containment) and then clean and decontaminate the area.[1002, 1003, 1012] If the surface is nonporous and a generic form of a sodium hypochlorite solution is used (e.g., household bleach), a 1:100 dilution is appropriate for decontamination assuming that

a. the worker assigned to clean the spill is wearing gloves and other personal protective equipment appropriate to the task,
b. most of the organic matter of the spill has been removed with absorbent material, and
c. the surface has been cleaned to remove residual organic matter.

A recent study demonstrated that even strong chlorine solutions (i.e., 1:10 dilution of chlorine bleach) may fail to totally inactivate high titers of virus in large quantities of blood, but in the absence of blood these disinfectants can achieve complete viral inactivation.[1011] This evidence supports the need to remove most organic matter from a large spill before final disinfection of the surface. Additionally, EPA-registered proprietary disinfectant label claims are based on use on a pre-cleaned surface.[951, 954]

Managing spills of blood, body fluids, or other infectious materials in clinical, public health, and research laboratories requires more stringent measures because of

a. the higher potential risk of disease transmission associated with large volumes of blood and body fluids and
b. high numbers of microorganisms associated with diagnostic cultures.

The use of an intermediate-level germicide for routine decontamination in the laboratory is prudent.[954] Recommended practices for managing large spills of concentrated infectious agents in the laboratory include

a. confining the contaminated area,
b. flooding the area with a liquid chemical germicide before cleaning, and
c. decontaminating with fresh germicidal chemical of at least intermediate-level disinfectant potency.[1010]

A suggested technique when flooding the spill with germicide is to lay absorbent material down on the spill and apply sufficient germicide to thoroughly wet both the spill and the absorbent material.[1013] If using a solution of household chlorine bleach, a 1:10 dilution is recommended for this purpose. EPA-registered germicides should be used according to the manufacturers' instructions for use dilution and contact time. Gloves should be worn during the cleaning and decontamination procedures in both clinical and laboratory settings. PPE in such a situation may include the use of respiratory protection (e.g., an N95 respirator) if clean-up procedures are expected to generate infectious aerosols. Protocols for cleaning spills should be developed and made available on record as part of good laboratory practice.[1013] Workers in laboratories and in patient-care areas of the facility should receive periodic training in environmental-surface infection-control strategies and procedures as part of an overall infection-control and safety curriculum.

4. Carpeting and Cloth Furnishings

a. Carpeting

Carpeting has been used for more than 30 years in both public and patient-care areas of health-care facilities. Advantages of carpeting in patient-care areas include

a. its noise-limiting characteristics
b. the "humanizing" effect on health care; and
c. its contribution to reductions in falls and resultant injuries, particularly for the elderly.[1014–1016]

Compared to hard-surface flooring, however, carpeting is harder to keep clean, especially after spills of blood and body substances. It is also harder to push equipment with wheels (e.g., wheelchairs, carts, and gurneys) on carpeting.

Several studies have documented the presence of diverse microbial populations, primarily bacteria and fungi, in carpeting;[111, 1017–1024] the variety and number of microorganisms tend to stabilize over time. New carpeting quickly becomes colonized, with bacterial growth plateauing after about 4 weeks.[1019] Vacuuming and cleaning the carpeting can temporarily reduce the numbers of bacteria, but these populations soon rebound and return to pre-cleaning levels.[1019, 1020, 1023] Bacterial contamination tends to increase with higher levels of activity.[1018–1020, 1025] Soiled carpeting that is or remains damp or wet provides an ideal setting for the proliferation and persistence of gram-negative bacteria and fungi.[1026] Carpeting that remains damp should be removed, ideally within 72 hours.

Despite the evidence of bacterial growth and persistence in carpeting, only limited epidemiologic evidence demonstrates that carpets influence health-care associated infection rates in areas housing immunocompetent patients.[1023, 1025, 1027] This guideline, therefore, includes no recommendations against the use of carpeting in these areas. Nonetheless, avoiding the use of carpeting is prudent in areas where spills are likely to occur (e.g., laboratories, areas around sinks, and janitor closets) and where patients may be at greater risk of infection from airborne environmental pathogens (e.g., HSCT units, burn units, ICUs, and ORs).[111, 1028] An outbreak of aspergillosis in an HSCT unit was recently attributed to carpet contamination and a particular method of carpet cleaning.[111] A window in the unit had been opened repeatedly during the time of a nearby building fire, which allowed fungal spore intrusion into the unit. After the window was sealed, the carpeting was cleaned using a "bonnet buffing" machine, which dispersed *Aspergillus* spores into the air.[111] Wet vacuuming was instituted, replacing the dry cleaning method used previously; no additional cases of invasive aspergillosis were identified.

The care setting and the method of carpet cleaning are important factors to consider when attempting to minimize or prevent production of aerosols and dispersal of carpet microorganisms into the air.[94, 111] Both vacuuming and shampooing or wet cleaning with equipment can disperse microorganisms to the air.[111, 994] Vacuum cleaners should be maintained to minimize dust dispersal in general, and be equipped with HEPA filters, especially for use in high-risk patient-care areas.[9, 94, 986] Some formulations of carpet-cleaning chemicals, if applied or used improperly, can be dispersed into the air as a fine dust capable of

causing respiratory irritation in patients and staff.[1029] Cleaning equipment, especially those that engage in wet cleaning and extraction, can become contaminated with waterborne organisms (e.g., *Pseudomonas aeruginosa*) and serve as a reservoir for these organisms if this equipment is not properly maintained. Substantial numbers of bacteria can then be transferred to carpeting during the cleaning process.[1030] Therefore, keeping the carpet cleaning equipment in good repair and allowing such equipment to dry between uses is prudent.

Carpet cleaning should be performed on a regular basis determined by internal policy. Although spills of blood and body substances on non-porous surfaces require prompt spot cleaning using standard cleaning procedures and application of chemical germicides,[967] similar decontamination approaches to blood and body substance spills on carpeting can be problematic from a regulatory perspective.[1031] Most, if not all, modern carpet brands suitable for public facilities can tolerate the activity of a variety of liquid chemical germicides. However, according to OSHA, carpeting contaminated with blood or other potentially infectious materials cannot be fully decontaminated.[1032] Therefore, facilities electing to use carpeting for high-activity patient-care areas may choose carpet tiles in areas at high risk for spills.[967, 1032] In the event of contamination with blood or other body substances, carpet tiles can be removed, discarded, and replaced. OSHA also acknowledges that only minimal direct skin contact occurs with carpeting, and therefore, employers are expected to make reasonable efforts to clean and sanitize carpeting using carpet detergent/cleaner products.[1032]

Over the last few years, some carpet manufacturers have treated their products with fungicidal and/or bactericidal chemicals. Although these chemicals may help to reduce the overall numbers of bacteria or fungi present in carpet, their use does not preclude the routine care and maintenance of the carpeting. Limited evidence suggests that chemically treated carpet may have helped to keep health-care– associated aspergillosis rates low in one HSCT unit, [111] but overall, treated carpeting has not been shown to prevent the incidence of health-care associated infections in care areas for immunocompetent patients.

b. Cloth Furnishings

Upholstered furniture and furnishings are becoming increasingly common in patient-care areas. These furnishings range from simple cloth chairs in patients' rooms to a complete decorating scheme that gives the interior of the facility more the look of an elegant hotel.[1033] Even though pathogenic microorganisms have been isolated from the surfaces of cloth chairs, no epidemiologic evidence suggests that general patient-care areas with cloth furniture pose increased risks of health-care associated infection compared with areas that contain hard-surfaced furniture.[1034, 1035] Allergens (e.g., dog and cat dander) have been detected in or on cloth furniture in clinics and elsewhere in hospitals in concentrations higher than those found on bed linens.[1034, 1035] These allergens presumably are transferred from the clothing of visitors. Researchers have therefore suggested that cloth chairs should be vacuumed regularly to keep the dust and allergen levels to a minimum. This recommendation, however, has generated concerns that aerosols created from vacuuming could place immunocompromised patients or patients with preexisting lung disease (e.g., asthma) at risk for development of health-care associated, environmental airborne disease.[9, 20, 109, 988] Recovering worn, upholstered furniture (especially the seat cushion) with covers that are easily cleaned (e.g., vinyl), or replacing the item is prudent; minimizing the use of upholstered furniture and furnishings in any patient-care areas where immunosuppressed patients are located (e.g., HSCT units) reduces the likelihood of disease.[9]

5. Flowers and Plants in Patient-Care Areas

Fresh flowers, dried flowers, and potted plants are common items in health-care facilities. In 1974, clinicians isolated an *Erwinia* sp. post mortem from a neonate diagnosed with fulminant septicemia, meningitis, and respiratory distress syndrome.[1038] Because *Erwinia* spp. are plant pathogens, plants brought into the delivery room were suspected to be the source of the bacteria, although the case report

did not definitively establish a direct link. Several subsequent studies evaluated the numbers and diversity of microorganisms in the vase water of cut flowers. These studies revealed that high concentrations of bacteria, ranging from 10^4–10^{10} CFU/mL, were often present, especially if the water was changed infrequently.[515, 702, 1039] The major group of microorganisms in flower vase water was gram-negative bacteria, with *Pseudomonas aeruginosa* the most frequently isolated organism.[515, 702, 1039, 1040] *P. aeruginosa* was also the primary organism directly isolated from chrysanthemums and other potted plants.[1041, 1042] However, flowers in hospitals were not significantly more contaminated with bacteria compared with flowers in restaurants or in the home.[702] Additionally, no differences in the diversity and degree of antibiotic resistance of bacteria have been observed in samples isolated from hospital flowers versus those obtained from flowers elsewhere.[702]

Despite the diversity and large numbers of bacteria associated with flower-vase water and potted plants, minimal or no evidence indicates that the presence of plants in immunocompetent patient-care areas poses an increased risk of health-care associated infection.[515] In one study involving a limited number of surgical patients, no correlation was observed between bacterial isolates from flowers in the area and the incidence and etiology of postoperative infections among the patients.[1040] Similar conclusions were reached in a study that examined the bacteria found in potted plants.[1042] Nonetheless, some precautions for general patient-care settings should be implemented, including

a. limiting flower and plant care to staff with no direct patient contact,
b. advising health-care staff to wear gloves when handling plants,
c. washing hands after handling plants,
d. changing vase water every 2 days and discharging the water into a sink outside the immediate patient environment, and
e. cleaning and disinfecting vases after use.[702]

Some researchers have examined the possibility of adding a chemical germicide to vase water to control bacterial populations. Certain chemicals (e.g., hydrogen peroxide and chlorhexidine) are well tolerated by plants.[1040, 1043, 1044] Use of these chemicals, however, was not evaluated in studies to assess impact on health-care associated infection rates. Modern florists now have a variety of products available to add to vase water to extend the life of cut flowers and to minimize bacterial clouding of the water.

Flowers (fresh and dried) and ornamental plants, however, may serve as a reservoir of *Aspergillus* spp., and dispersal of conidiospores into the air from this source can occur.[109] Health-care associated outbreaks of invasive aspergillosis reinforce the importance of maintaining an environment as free of *Aspergillus* spp. spores as possible for patients with severe, prolonged neutropenia. Potted plants, fresh-cut flowers, and dried flower arrangements may provide a reservoir for these fungi as well as other fungal species (e.g., *Fusarium* spp.).[109, 1045, 1046] Researchers in one study of bacteria and flowers suggested that flowers and vase water should be avoided in areas providing care to medically at-risk patients (e.g., oncology patients and transplant patients), although this study did not attempt to correlate the observations of bacterial populations in the vase water with the incidence of health-care associated infections.[515] Another study using molecular epidemiology techniques demonstrated identical *Aspergillus terreus* types among environmental and clinical specimens isolated from infected patients with hematological malignancies.[1046] Therefore, attempts should be made to exclude flowers and plants from areas where immunosuppressed patients are be located (e.g., HSCT units).[9, 1046]

6. Pest Control

Cockroaches, flies and maggots, ants, mosquitoes, spiders, mites, midges, and mice are among the typical arthropod and vertebrate pest populations found in health-care facilities. Insects can serve as agents for the mechanical transmission of microorganisms, or as active participants in the disease transmission process by serving as a vector.[1047–1049] Arthropods recovered from health-care facilities have been shown to carry a wide variety of pathogenic microorganisms.[1050–1056] Studies have suggested that the diversity of microorganisms associated with insects reflects the microbial populations present in the indoor health-care

environment; some pathogens encountered in insects from hospitals were either absent from or present to a lesser degree in insects trapped from residential settings.[1057–1060] Some of the microbial populations associated with insects in hospitals have demonstrated resistance to antibiotics.[1048, 1059, 1061–1063]

Insect habitats are characterized by warmth, moisture, and availability of food.[1064] Insects forage in and feed on substrates, including but not limited to food scraps from kitchens/cafeteria, foods in vending machines, discharges on dressings either in use or discarded, other forms of human detritis, medical wastes, human wastes, and routine solid waste.[1057–1061] Cockroaches, in particular, have been known to feed on fixed sputum smears in laboratories.[1065, 1066] Both cockroaches and ants are frequently found in the laundry, central sterile supply departments, and anywhere in the facility where water or moisture is present (e.g., sink traps, drains and janitor closets). Ants will often find their way into sterile packs of items as they forage in a warm, moist environment.[1057] Cockroaches and other insects frequent loading docks and other areas with direct access to the outdoors.

Although insects carry a wide variety of pathogenic microorganisms on their surfaces and in their gut, the direct association of insects with disease transmission (apart from vector transmission) is limited, especially in health-care settings; the presence of insects in itself likely does not contribute substantially to health-care associated disease transmission in developed countries. However, outbreaks of infection attributed to microorganisms carried by insects may occur because of infestation coupled with breaks in standard infection-control practices.[1063] Studies have been conducted to examine the role of houseflies as possible vectors for shigellosis and other forms of diarrheal disease in non-health–care settings.[1046, 1067] When control measures aimed at reducing the fly population density were implemented, a concomitant reduction in the incidence of diarrheal infections, carriage of *Shigella* organisms, and mortality caused by diarrhea among infants and young children was observed.

Myiasis is defined as a parasitosis in which the larvae of any of a variety of flies use living or necrotic tissue or body substances of the host as a nutritional source.[1068] Larvae from health-care acquired myiasis have been observed in nares, wounds, eyes, ears, sinuses, and the external urogenital structures.[1069–1071] Patients with this rare condition are typically older adults with underlying medical conditions (e.g., diabetes, chronic wounds, and alcoholism) who have a decreased capacity to ward off the flies. Persons with underlying conditions who live or travel to tropical regions of the world are especially at risk.[1070, 1071] Cases occur in the summer and early fall months in temperate climates when flies are most active.[1071] An environmental assessment and review of the patient's history are necessary to verify that the source of the myiasis is health-care acquired and to identify corrective measures.[1069, 1072] Simple prevention measures (e.g., installing screens on windows) are important in reducing the incidence of myiasis.[1072]

From a public health and hygiene perspective, arthropod and vertebrate pests should be eradicated from all indoor environments, including health-care facilities.[1073, 1074] Modern approaches to institutional pest management usually focus on

a. eliminating food sources, indoor habitats, and other conditions that attract pests
b. excluding pests from the indoor environments; and
c. applying pesticides as needed.[1075]

Sealing windows in modern health-care facilities helps to minimize insect intrusion. When windows need to be opened for ventilation, ensuring that screens are in good repair and closing doors to the outside can help with pest control. Insects should be kept out of all areas of the health-care facility, especially ORs and any area where immunosuppressed patients are located. A pest-control specialist with appropriate credentials can provide a regular insect-control program that is tailored to the needs of the facility and uses approved chemicals and/or physical methods. Industrial hygienists can provide information on possible adverse reactions of patients and staff to pesticides and suggest alternative methods for pest control, as needed.

7. Special Pathogen Concerns

a. Antibiotic-Resistant Gram-Positive Cocci

Vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA), and *S. aureus* with intermediate levels of resistance to glycopeptide antibiotics (vancomycin intermediate resistant *S. aureus* [VISA] or glycopeptide intermediate resistant *S. aureus* [GISA]) represent crucial and growing concerns for infection control. Although the term GISA is technically a more accurate description of the strains isolated to date (most of which are classified as having intermediate resistance to both vancomycin and teicoplanin), the term "glycopeptide" may not be recognized by many clinicians. Thus, the label of VISA, which emphasizes a change in minimum inhibitory concentration (MICs) to vancomycin, is similar to that of VRE and is more meaningful to clinicians.[1076] According to National Nosocomial Infection Surveillance (NNIS) statistics for infections acquired among ICU patients in the United States in 1999, 52.3% of infections resulting from *S. aureus* were identified as MRSA infections, and 25.2% of enterococcal infections were attributed to VRE. These figures reflect a 37% and a 43% increase, respectively, since 1994–1998.[1077]

People represent the primary reservoir of *S. aureus*. [1078] Although *S. aureus* has been isolated from a variety of environmental surfaces (e.g., stethoscopes, floors, charts, furniture, dry mops, and hydrotherapy tanks), the role of environmental contamination in transmission of this organism in health care appears to be minimal.[1079–1082] *S. aureus* contamination of surfaces and tanks within burn therapy units, however, may be a major factor in the transmission of infection among burn patients.[1083]

Colonized patients are the principal reservoir of VRE, and patients who are immunosuppressed (e.g., transplant patients) or otherwise medically at-risk (e.g., ICU patients, cardio-thoracic surgical patients, patients previously hospitalized for extended periods, and those having received multi-antimicrobial or vancomycin therapy) are at greatest risk for VRE colonization.[1084–1087] The mechanisms by which cross-colonization take place are not well defined, although recent studies have indicated that both MRSA and VRE may be transmitted either

a. directly from patient to patient,
b. indirectly by transient carriage on the hands of health-care workers,[1088–1091] or
c. by hand transfer of these gram-positive organisms from contaminated environmental surfaces and patient-care equipment.[1084, 1087, 1092–1097]

In one survey, hand carriage of VRE in workers in a long-term care facility ranged from 13%–41%.[1098] Many of the environmental surfaces found to be contaminated with VRE in outbreak investigations have been those that are touched frequently by the patient or the health-care worker.[1099] Such high-touch surfaces include bedrails, doorknobs, bed linens, gowns, overbed tables, blood pressure cuffs, computer table, bedside tables, and various medical equipment.[22, 1087, 1094, 1095, 1100–1102] Contamination of environmental surfaces with VRE generally occurs in clinical laboratories and areas where colonized patients are present,[1087, 1092, 1094, 1095, 1103] but the potential for contamination increases when such patients have diarrhea[1087] or have multiple body-site colonization.[1104] Additional factors that can be important in the dispersion of these pathogens to environmental surfaces are misuse of glove techniques by healthcare workers (especially when cleaning fecal contamination from surfaces) and patient, family, and visitor hygiene.

Interest in the importance of environmental reservoirs of VRE increased when laboratory studies demonstrated that enterococci can persist in a viable state on dry environmental surfaces for extended periods of time (7 days to 4 months)[1099, 1105] and multiple strains can be identified during extensive periods of surveillance.[1104] VRE can be recovered from inoculated hands of health-care workers (with or without gloves) for up to 60 minutes.[22] The presence of either MRSA, VISA, or VRE on environmental surfaces, however, does not mean that patients in the contaminated areas will become colonized. Strict adherence to hand hygiene/handwashing and the proper use of barrier precautions help to minimize the potential for spread of these pathogens. Published recommendations for preventing the spread of vancomycin resistance address isolation measures, including patient cohorting and management of patient-care items.[5]

Direct patient-care items (e.g., blood pressure cuffs) should be disposable whenever possible when used in contact isolation settings for patients with multiply resistant microorganisms.[1102]

Careful cleaning of patient rooms and medical equipment contributes substantially to the overall control of MRSA, VISA, or VRE transmission. The major focus of a control program for either VRE or MRSA should be the prevention of hand transfer of these organisms. Routine cleaning and disinfection of the housekeeping surfaces (e.g., floors and walls) and patient-care surfaces (e.g., bedrails) should be adequate for inactivation of these organisms. Both MRSA and VRE are susceptible to several EPA-registered low- and intermediate-level disinfectants (e.g., alcohols, sodium hypochlorite, quaternary ammonium compounds, phenolics, and iodophors) at recommended use dilutions for environmental surface disinfection.[1103, 1106–1109] Additionally, both VRE and vancomycin-sensitive enterococci are equally sensitive to inactivation by chemical germicides,[1106, 1107, 1109] and similar observations have been made when comparing the germicidal resistance of MRSA to that of either methicillin-sensitive *S. aureus* (MSSA) or VISA.[1110] The use of stronger solutions of disinfectants for inactivation of either VRE, MRSA, or VISA is not recommended based on the organisms' resistance to antibiotics.[1110–1112] VRE from clinical specimens have exhibited some measure of increased tolerance to heat inactivation in temperature ranges <212°F (<100°C);[1106, 1113] however, the clinical significance of these observations is unclear because the role of cleaning the surface or item prior to heat treatment was not evaluated. Although routine environmental sampling is not recommended, laboratory surveillance of environmental surfaces during episodes when VRE contamination is suspected can help determine the effectiveness of the cleaning and disinfecting procedures. Environmental culturing should be approved and supervised by the infection-control program in collaboration with the clinical laboratory.[1084, 1087, 1088, 1092, 1096]

Two cases of wound infections associated with vancomycin-resistant *Staphylococcus aureus* (VRSA) determined to be resistant by NCCLS standards for sensitivity/resistance testing were identified in Michigan and Pennsylvania in 2002.[1114, 1115] These represented isolated cases, and neither the family members nor the health-care providers of these case-patients had evidence of colonization or infection with VRSA. Conventional environmental infection-control measures (i.e., cleaning and then disinfecting surfaces using EPA-registered disinfectants with label claims for *S. aureus*) were used during the environmental investigation of these two cases;[1110–1112] however, studies have yet to evaluate the potential intrinsic resistance of these VRSA strains to surface disinfectants.

Standard procedures during terminal cleaning and disinfection of surfaces, if performed incorrectly, may be inadequate for the elimination of VRE from patient rooms.[1113, 1116–1118] Given the sensitivity of VRE to hospital disinfectants, current disinfecting protocols should be effective if they are diligently carried out and properly performed. Health-care facilities should be sure that housekeeping staff use correct procedures for cleaning and disinfecting surfaces in VRE-contaminated areas, which include using sufficient amounts of germicide at proper use dilution and allowing adequate contact time.[1118]

b. Clostridium difficile

Clostridium difficile is the most frequent etiologic agent for health-care associated diarrhea.[1119, 1120] In one hospital, 30% of adults who developed health-care associated diarrhea were positive for *C. difficile*.[1121] One recent study employing PCR-ribotyping techniques demonstrated that cases of *C. difiicile*-acquired diarrhea occurring in the hospital included patients whose infections were attributed to endogenous *C. difficile* strains and patients whose illnesses were considered to be health-care– associated infections.[1122] Most patients remain asymptomatic after infection, but the organism continues to be shed in their stools. Risk factors for acquiring *C. difficile*-associated infection include

a. exposure to antibiotic therapy, particularly with beta-lactam agents;[1123]
b. gastrointestinal procedures and surgery;[1124]
c. advanced age; and
d. indiscriminate use of antibiotics.[1125–1128]

Of all the measures that have been used to prevent the spread of *C. difficile*-associated diarrhea, the most successful has been the restriction of the use of antimicrobial agents.[1129, 1130]

C. difficile is an anaerobic, gram-positive bacterium. Normally fastidious in its vegetative state, it is capable of sporulating when environmental conditions no longer support its continued growth. The capacity to form spores enables the organism to persist in the environment (e.g., in soil and on dry surfaces) for extended periods of time. Environmental contamination by this microorganism is well known, especially in places where fecal contamination may occur.[1131] The environment (especially housekeeping surfaces) rarely serves as a direct source of infection for patients.[1024, 1132–1136] However, direct exposure to contaminated patient-care items (e.g., rectal thermometers) and high-touch surfaces in patients' bathrooms (e.g., light switches) have been implicated as sources of infection.[1130, 1135, 1136, 1138]

Transfer of the pathogen to the patient via the hands of health-care workers is thought to be the most likely mechanism of exposure.[24, 1133, 1139] Standard isolation techniques intended to minimize enteric contamination of patients, health-care–workers' hands, patient-care items, and environmental surfaces have been published.[1140] Handwashing remains the most effective means of reducing hand contamination. Proper use of gloves is an ancillary measure that helps to further minimize transfer of these pathogens from one surface to another.

The degree to which the environment becomes contaminated with *C. difficile* spores is proportional to the number of patients with *C. difficile*-associated diarrhea,[24, 1132, 1135] although asymptomatic, colonized patients may also serve as a source of contamination. Few studies have examined the use of specific chemical germicides for the inactivation of *C. difficile* spores, and no well-controlled trials have been conducted to determine efficacy of surface disinfection and its impact on health-care associated diarrhea. Some investigators have evaluated the use of chlorine-containing chemicals (e.g., 1,000 ppm hypochlorite at recommended use-dilution, 5,000 ppm sodium hypochlorite [1:10 v/v dilution], 1:100 v/v dilutions of unbuffered hypochlorite, and phosphate-buffered hypochlorite [1,600 ppm]). One of the studies demonstrated that the number of contaminated environmental sites was reduced by half,[1135] whereas another two studies demonstrated declines in health-care associated *C. difficile* infections in a HSCT unit[1141] and in two geriatric medical units[1142] during a period of hypochlorite use. The presence of confounding factors, however, was acknowledged in one of these studies.[1142]

***C. difficile* Update [April 2019]**

Recommendations E.VI.G. and E.VI.H. were updated to reflect changes in Federal regulatory approvals: LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).

The recommended approach to environmental infection control with respect to *C. difficile* is meticulous cleaning followed by disinfection using EPA-registered products specific for inactivating *C. difficile* spores as appropirate. Thus, combined use of appropriate hand hygiene, barrier precautions, and meticulous environmental cleaning, and use of an EPA-registered product that is appropriate for the level of risk, should effectively prevent spread of the organism. [LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium)].

c. Respiratory and Enteric Viruses in Pediatric-Care Settings

Although the viruses mentioned in this guideline are not unique to the pediatric-care setting in healthcare facilities, their prevalence in these areas, especially during the winter months, is substantial. Children

(particularly neonates) are more likely to develop infection and substantial clinical disease from these agents compared with adults and therefore are more likely to require supportive care during their illness.

Common respiratory viruses in pediatric-care areas include rhinoviruses, respiratory syncytial virus (RSV), adenoviruses, influenza viruses, and parainfluenza viruses. Transmission of these viruses occurs primarily via direct contact with small-particle aerosols or via hand contamination with respiratory secretions that are then transferred to the nose or eyes. Because transmission primarily requires close personal contact, contact precautions are appropriate to interrupt transmission.[6] Hand contamination can occur from direct contact with secretions or indirectly from touching high-touch environmental surfaces that have become contaminated with virus from large droplets. The indirect transfer of virus from one persion to other via hand contact with frequently-touched fomites was demonstrated in a study using a bacteriophage whose environmental stability approximated that of human viral pathogens (e.g., poliovirus and parvovirus).[1144] The impact of this mode of transmission with respect to human respiratory- and enteric viruses is dependent on the ability of these agents to survive on environmental surfaces. Infectious RSV has been recovered from skin, porous surfaces, and non-porous surfaces after 30 minutes, 1 hour, and 7 hours, respectively.[1145] Parainfluenza viruses are known to persist for up to 4 hours on porous surfaces and up to 10 hours on non-porous surfaces.[1146] Rhinoviruses can persist on porous surfaces and non-porous surfaces for approximately 1 and 3 hours respectively; study participants in a controlled environment became infected with rhinoviruses after first touching a surface with dried secretions and then touching their nasal or conjunctival mucosa.[1147] Although the efficiency of direct transmission of these viruses from surfaces in uncontrolled settings remains to be defined, these data underscore the basis for maintaining regular protocols for cleaning and disinfecting of high-touch surfaces.

The clinically important enteric viruses encountered in pediatric care settings include enteric adenovirus, astroviruses, caliciviruses, and rotavirus. Group A rotavirus is the most common cause of infectious diarrhea in infants and children. Transmission of this virus is primarily fecal-oral, however, the role of fecally contaminated surfaces and fomites in rotavirus transmission is unclear. During one epidemiologic investigation of enteric disease among children attending day care, rotavirus contamination was detected on 19% of inanimate objects in the center.[1148, 1149] In an outbreak in a pediatric unit, secondary cases of rotavirus infection clustered in areas where children with rotaviral diarrhea were located.[1150] Astroviruses cause gastroenteritis and diarrhea in newborns and young children and can persist on fecally contaminated surfaces for several months during periods of relatively low humidity.[1151, 1152] Outbreaks of small round-structured viruses (i.e., caliciviruses [Norwalk virus and Norwalk-like viruses]) can affect both patients and staff, with attack rates of ≥50%.[1153] Routes of person-to-person transmission include fecal-oral spread and aerosols generated from vomiting.[1154–1156] Fecal contamination of surfaces in care settings can spread large amounts of virus to the environment. Studies that have attempted to use low- and intermediate-level disinfectants to inactivate rotavirus suspended in feces have demonstrated a protective effect of high concentrations of organic matter.[1157, 1158] Intermediate-level disinfectants (e.g., alcoholic quaternary ammonium compounds, and chlorine solutions) can be effective in inactivating enteric viruses provided that a cleaning step to remove most of the organic matter precedes terminal disinfection.[1158] These findings underscore the need for proper cleaning and disinfecting procedures where contamination of environmental surfaces with body substances is likely. EPA-registered surface disinfectants with label claims for these viral agents should be used in these settings. Using disposable, protective barrier coverings may help to minimize the degree of surface contamination.[936]

d. Severe Acute Respiratory Syndrome (SARS) Virus

In November 2002 an atypical pneumonia of unknown etiology emerged in Asia and subsequently developed into an international outbreak of respiratory illness among persons in 29 countries during the

first six months of 2003. “Severe acute respiratory syndrome” (SARS) is a viral upper respiratory infection associated with a newly described coronavirus (SARS-associated Co-V [SARS-CoV]). SARS-CoV is an enveloped RNA virus. It is present in high titers in respiratory secretions, stool, and blood of infected persons. The modes of transmission determined from epidemiologic investigations were primarily forms of direct contact (i.e., large droplet aerosolization and person-to-person contact). Respiratory secretions were presumed to be the major source of virus in these situations; airborne transmission of virus has not been completely ruled out. Little is known about the impact of fecal-oral transmission and SARS.

The epidemiology of SARS-CoV infection is not completely understood, and therefore recommended infection control and prevention measures to contain the spread of SARS will evolve as new information becomes available.[1159] At present there is no indication that established strategies for cleaning (i.e., to remove the majority of bioburden) and disinfecting equipment and environmental surfaces need to be changed for the environmental infection control of SARS. In-patient rooms housing SARS patients should be cleaned and disinfected at least daily and at the time of patient transfer or discharge. More frequent cleaning and disinfection may be indicated for high-touch surfaces and following aerosol-producing procedures (e.g., intubation, bronchoscopy, and sputum production). While there are presently no disinfectant products registered by EPA specifically for inactivation of SARS-CoV, EPA-registered hospital disinfectants that are equivalent to low- and intermediate-level germicides may be used on pre-cleaned, hard, non-porous surfaces in accordance with manufacturer’s instructions for environmental surface disinfection. Monitoring adherence to guidelines established for cleaning and disinfection is an important component of environmental infection control to contain the spread of SARS.

e. Creutzfeldt-Jakob Disease (CJD) in Patient-Care Areas

Creutzfeldt-Jakob disease (CJD) is a rare, invariably fatal, transmissible spongiform encephalopathy (TSE) that occurs worldwide with an average annual incidence of 1 case per million population.[1160–1162] CJD is one of several TSEs affecting humans; other diseases in this group include kuru, fatal familial insomnia, and Gerstmann-Sträussler-Scheinker syndrome. A TSE that affects a younger population (compared to the age range of CJD cases) has been described primarily in the United Kingdom since 1996.[1163] This variant form of CJD (vCJD) is clinically and neuropathologically distinguishable from classic CJD; epidemiologic and laboratory evidence suggests a causal association for bovine spongiform encephalopathy (BSE [Mad Cow disease]) and vCJD.[1163–1166]

The agent associated with CJD is a prion, which is an abnormal isoform of a normal protein constituent of the central nervous system.[1167–1169] The mechanism by which the normal form of the protein is converted to the abnormal, disease-causing prion is unknown. The tertiary conformation of the abnormal prion protein appears to confer a heightened degree of resistance to conventional methods of sterilization and disinfection.[1170, 1171]

Although about 90% of CJD cases occur sporadically, a limited number of cases are the result of a direct exposure to prion-containing material (usually central nervous system tissue or pituitary hormones) acquired as a result of health care (iatrogenic cases). These cases have been linked to

a. pituitary hormone therapy [from human sources as opposed to hormones prepared through the use of recombinant technology],[1170–1174]
b. transplants of either dura mater or corneas,[1175–1181] and
c. neurosurgical instruments and depth electrodes.[1182–1185]

In the cases involving instruments and depth electrodes, conventional cleaning and terminal reprocessing methods of the day failed to fully inactivate the contaminating prions and are considered inadequate by today’s standards.

Prion inactivation studies involving whole tissues and tissue homogenates have been conducted to determine the parameters of physical and chemical methods of sterilization or disinfection necessary for complete inactivation;[1170, 1186–1191] however, the application of these findings to environmental infection control in health-care settings is problematic. No studies have evaluated the effectiveness of medical instrument reprocessing in inactivating prions. Despite a consensus that abnormal prions display some extreme measure of resistance to inactivation by either physical or chemical methods, scientists disagree about the exact conditions needed for sterilization. Inactivation studies utilizing whole tissues present extraordinary challenges to any sterilizing method.[1192] Additionally, the experimental designs of these studies preclude the evaluation of surface cleaning as a part of the total approach to pathogen inactivation.[951, 1192]

Some researchers have recommended the use of either a 1:2 v/v dilution of sodium hypochorite (approximately 20,000 ppm), full-strength sodium hypochlorite (50,000–60,000 ppm), or 1–2 N sodium hydroxide (NaOH) for the inactivation of prions on certain surfaces (e.g., those found in the pathology laboratory).[1170, 1188] Although these chemicals may be appropriate for the decontamination of laboratory, operating-room, or autopsy-room surfaces that come into contact with central nervous system tissue from a known or suspected patient, this approach is not indicated for routine or terminal cleaning of a room previously occupied by a CJD patient. Both chemicals pose hazards for the healthcare worker doing the decontamination. NaOH is caustic and should not make contact with the skin. Sodium hypochlorite solutions (i.e., chlorine bleach) can corrode metals (e.g., aluminum). MSDS information should be consulted when attempting to work with concentrated solutions of either chemical. Currently, no EPA-registered products have label claims for prion inactivation; therefore, this guidance is based on the best available evidence from the scientific literature.

Environmental infection-control strategies must based on the principles of the “chain of infection,” regardless of the disease of concern.[13] Although CJD is transmissible, it is not highly contagious. All iatrogenic cases of CJD have been linked to a direct exposure to prion-contaminated central nervous system tissue or pituitary hormones. The six documented iatrogenic cases associated with instruments and devices involved neurosurgical instruments and devices that introduced residual contamination directly to the recipient’s brain. No evidence suggests that vCJD has been transmitted iatrogenically or that either CJD or vCJD has been transmitted from environmental surfaces (e.g., housekeeping surfaces). Therefore, routine procedures are adequate for terminal cleaning and disinfection of a CJD patient’s room. Additionally, in epidemiologic studies involving highly transfused patients, blood was not identified as a source for prion transmission.[1193–1198] Routine procedures for containing, decontaminating, and disinfecting surfaces with blood spills should be adequate for proper infection control in these situations.[951, 1199]

Guidance for environmental infection control in ORs and autopsy areas has been published.[1197, 1199] Hospitals should develop risk-assessment procedures to identify patients with known or suspected CJD in efforts to implement prion-specific infection-control measures for the OR and for instrument reprocessing.[1200] This assessment also should be conducted for older patients undergoing non-lesionous neurosurgery when such procedures are being done for diagnosis. Disposable, impermeable coverings should be used during these autopsies and neurosurgeries to minimize surface contamination. Surfaces that have become contaminated with central nervous system tissue or cerebral spinal fluid should be cleaned and decontaminated by

a. removing most of the tissue or body substance with absorbent materials,
b. wetting the surface with a sodium hypochlorite solution containing ≥5,000 ppm or a 1 N NaOH solution, and
c. rinsing thoroughly.[951, 1197–1199, 1201]

The optimum duration of contact exposure in these instances is unclear. Some researchers recommend a 1-hour contact time on the basis of tissue-inactivation studies,[1197, 1198, 1201] whereas other reviewers of the subject draw no conclusions from this research.[1199] Factors to consider before cleaning a potentially contaminated surface are

a. the degree to which gross tissue/body substance contamination can be effectively removed and
b. the ease with which the surface can be cleaned.

F. Environmental Sampling

This portion of Part I addresses the basic principles and methods of sampling environmental surfaces and other environmental sources for microorganisms. The applied strategies of sampling with respect to environmental infection control have been discussed in the appropriate preceding subsections.

1. General Principles: Microbiologic Sampling of the Environment

Before 1970, U.S. hospitals conducted regularly scheduled culturing of the air and environmental surfaces (e.g., floors, walls, and table tops).[1202] By 1970, CDC and the American Hospital Association (AHA) were advocating the discontinuation of routine environmental culturing because rates of healthcare–associated infection had not been associated with levels of general microbial contamination of air or environmental surfaces, and because meaningful standards for permissible levels of microbial contamination of environmental surfaces or air did not exist.[1203–1205] During 1970–1975, 25% of U.S. hospitals reduced the extent of such routine environmental culturing — a trend that has continued.[1206, 1207]

Random, undirected sampling (referred to as "routine" in previous guidelines) differs from the current practice of targeted sampling for defined purposes.[2, 1204] Previous recommendations against routine sampling were not intended to discourage the use of sampling in which sample collection, culture, and interpretation are conducted in accordance with defined protocols.[2] In this guideline, targeted microbiologic sampling connotes a monitoring process that includes

a. a written, defined, multidisciplinary protocol for sample collection and culturing
b. analysis and interpretation of results using scientifically determined or anticipatory baseline values for comparison; and
c. expected actions based on the results obtained.

Infection control, in conjunction with laboratorians, should assess the health-care facility's capability to conduct sampling and determine when expert consultation and/or services are needed.

Microbiologic sampling of air, water, and inanimate surfaces (i.e., environmental sampling) is an expensive and time-consuming process that is complicated by many variables in protocol, analysis, and interpretation. It is therefore indicated for only four situations.[1208] The first is to support an investigation of an outbreak of disease or infections when environmental reservoirs or fomites are implicated epidemiologically in disease transmission.[161, 1209, 1210] It is important that such culturing be supported by epidemiologic data. Environmental sampling, as with all laboratory testing, should not be conducted if there is no plan for interpreting and acting on the results obtained.[11, 1211, 1212] Linking microorganisms from environmental samples with clinical isolates by molecular epidemiology is crucial whenever it is possible to do so.

The second situation for which environmental sampling may be warranted is in research. Well-designed and controlled experimental methods and approaches can provide new information about the spread of health-care associated diseases.[126, 129] A classic example is the study of environmental microbial contamination that compared health-care associated infection rates in an old hospital and a new facility before and shortly after occupancy.[947]

The third indication for sampling is to monitor a potentially hazardous environmental condition, confirm the presence of a hazardous chemical or biological agent, and validate the successful abatement of the hazard. This type of sampling can be used to:

a. detect bioaerosols released from the operation of health-care equipment (e.g., an ultrasonic cleaner) and determine the success of repairs in containing the hazard,[1213]
b. detect the release of an agent of bioterrorism in an indoor environmental setting and determine its successful removal or inactivation, and

c. sample for industrial hygiene or safety purposes (e.g., monitoring a “sick building”).

The fourth indication is for quality assurance to evaluate the effects of a change in infection-control practice or to ensure that equipment or systems perform according to specifications and expected outcomes. Any sampling for quality-assurance purposes must follow sound sampling protocols and address confounding factors through the use of properly selected controls. Results from a single environmental sample are difficult to interpret in the absence of a frame of reference or perspective. Evaluations of a change in infection-control practice are based on the assumption that the effect will be measured over a finite period, usually of short duration. Conducting quality-assurance sampling on an extended basis, especially in the absence of an adverse outcome, is usually unjustified. A possible exception might be the use of air sampling during major construction periods to qualitatively detect breaks in environmental infection-control measures. In one study, which began as part of an investigation of an outbreak of health-care associated aspergillosis, airborne concentrations of *Aspergillus* spores were measured in efforts to evaluate the effectiveness of sealing hospital doors and windows during a period of construction of a nearby building.[50] Other examples of sampling for quality-assurance purposes may include commissioning newly constructed space in special care areas (i.e., ORs and units for immunosuppressed patients) or assessing a change in housekeeping practice. However, the only types of routine environmental microbiologic sampling recommended as part of a quality-assurance program are

a. the biological monitoring of sterilization processes by using bacterial spores[1214] and
b. the monthly culturing of water used in hemodialysis applications and for the final dialysate use dilution.

Some experts also advocate periodic environmental sampling to evaluate the microbial/particulate quality for regular maintenance of the air handling system (e.g., filters) and to verify that the components of the system meet manufacturer’s specifications (A. Streifel, University of Minnesota, 2000). Certain equipment in health-care settings (e.g., biological safety cabinets) may also be monitored with air flow and particulate sampling to determine performance or as part of adherence to a certification program; results can then be compared with a predetermined standard of performance. These measurements, however, usually do not require microbiologic testing.

2. Air Sampling

Biological contaminants occur in the air as aerosols and may include bacteria, fungi, viruses, and pollens.[1215, 1216] Aerosols are characterized as solid or liquid particles suspended in air. Talking for 5 minutes and coughing each can produce 3,000 droplet nuclei; sneezing can generate approximately 40,000 droplets which then evaporate to particles in the size range of 0.5–12 μm.[137, 1217] Particles in a biological aerosol usually vary in size from <1 μm to ≥50 μm. These particles may consist of a single, unattached organism or may occur in the form of clumps composed of a number of bacteria. Clumps can also include dust and dried organic or inorganic material. Vegetative forms of bacterial cells and viruses may be present in the air in a lesser number than bacterial spores or fungal spores. Factors that determine the survival of microorganisms within a bioaerosol include

a. the suspending medium,
b. temperature,
c. relative humidity,
d. oxygen sensitivity, and
e. exposure to UV or electromagnetic radiation.[1215]

Many vegetative cells will not survive for lengthy periods of time in the air unless the protective cover (e.g., dried organic or inorganic matter).[1216] Pathogens that resist drying (e.g., *Staphylococcus* spp., *Streptococcus* spp., and fungal spores) can survive for long periods and can be carried considerable distances via air and still remain viable. They may also settle on surfaces and become airborne again as secondary aerosols during certain activities (e.g., sweeping and bed making).[1216, 1218]

Microbiologic air sampling is used as needed to determine the numbers and types of microorganisms, or particulates, in indoor air.[289] Air sampling for quality control is, however, problematic because of lack of uniform air-quality standards. Although airborne spores of *Aspergillus* spp. can pose a risk for

neutropenic patients, the critical number (i.e., action level) of these spores above which outbreaks of aspergillosis would be expected to occur has not been defined. Health-care professionals considering the use of air sampling should keep in mind that the results represent indoor air quality at singular points in time, and these may be affected by a variety of factors, including

a. indoor traffic,
b. visitors entering the facility,
c. temperature,
d. time of day or year,
e. relative humidity,
f. relative concentration of particles or organisms, and g) the performance of the air-handling system components.

To be meaningful, air-sampling results must be compared with those obtained from other defined areas, conditions, or time periods.

Several preliminary concerns must be addressed when designing a microbiologic air sampling strategy (Box 13). Because the amount of particulate material and bacteria retained in the respiratory system is largely dependent on the size of the inhaled particles, particle size should be determined when studying airborne microorganisms and their relation to respiratory infections. Particles >5 μm are efficiently trapped in the upper respiratory tract and are removed primarily by ciliary action.[1219] Particles ≤5 μm in diameter reach the lung, but the greatest retention in the alveoli is of particles 1–2 μm in diameter.[1220–1222]

Box 13. Preliminary concerns for conducting air sampling

- Consider the possible characteristics and conditions of the aerosol, including size range of particles, relative amount of inert material, concentration of microorganisms, and environmental factors.
- Determine the type of sampling instruments, sampling time, and duration of the sampling program.
- Determine the number of samples to be taken.
- Ensure that adequate equipment and supplies are available.
- Determine the method of assay that will ensure optimal recovery of microorganisms.
- Select a laboratory that will provide proper microbiologic support.
- Ensure that samples can be refrigerated if they cannot be assayed in the laboratory promptly.

Bacteria, fungi, and particulates in air can be identified and quantified with the same methods and equipment (Table 23). The basic methods include

a. impingement in liquids,
b. impaction on solid surfaces,
c. sedimentation,
d. filtration,
e. centrifugation,
f. electrostatic precipitation, and
g. thermal precipitation.[1218]

Of these, impingement in liquids, impaction on solid surfaces, and sedimentation (on settle plates) have been used for various air-sampling purposes in health-care settings.[289]

Several instruments are available for sampling airborne bacteria and fungi (Box 14). Some of the samplers are self-contained units requiring only a power supply and the appropriate collecting medium, but most require additional auxiliary equipment (e.g., a vacuum pump and an airflow measuring device [i.e., a flowmeter or anemometer]). Sedimentation or depositional methods use settle plates and therefore need no special instruments or equipment. Selection of an instrument for air sampling requires a clear understanding of the type of information desired and the particular determinations that must be made

(Box 14). Information may be needed regarding
a. one particular organism or all organisms that may be present in the air,
b. the concentration of viable particles or of viable organisms,
c. the change in concentration with time, and
d. the size distribution of the collected particles.

Before sampling begins, decisions should be made regarding whether the results are to be qualitative or quantitative. Comparing quantities of airborne microorganisms to those of outdoor air is also standard operating procedure. Infection-control professionals, hospital epidemiologists, industrial hygienists, and laboratory supervisors, as part of a multidisciplinary team, should discuss the potential need for microbial air sampling to determine if the capacity and expertise to conduct such sampling exists within the facility and when it is appropriate to enlist the services of an environmental microbiologist consultant.

Table 23. Air sampling methods and examples of equipment*

Method	Principle	Suitable for measuring:	Collection media or surface	Rate of collection (L/min.)	Auxilliary equipment needed+	Points to consider	Prototype samplers§
Impingement in liquids	Air drawn through a small jet and directed against a liquid surface	Viable organisms, and concentration over time. Example use: sampling water aerosols to *Legionella* spp.	Buffered gelatin, tryptose saline, peptone, nutrient broth	12.5	Yes	Antifoaming agent may be needed. Ambient temperature and humidity will influence length of collection time	Chemical Corps. All Glass Impinger (AGI)
Impaction on solid surfaces	Air drawn into the sampler; particles deposited on a dry surface	Viable particles; viable organisms (on non-nutrient surfaces, limited to organisms that resist drying and spores); size measurement, and concentration over time. Example use: sampling air for *Aspergillus* spp., fungal spores	Dry surface, coated surfaces, and agar	28 (sieve) 30–800 (slit)	Yes	Available as sieve impactors or slit impactors. Sieve impactors can be set up to measure particle size. Slit impactors have a rotating support stage for agar plates to allow for measurement of concentration over time.	Andersen Air Sampler (sieve impactor); TDL, Cassella MK-2 (slit impactors)
Sedimentation	Particles and micro-organisms settle onto surfaces via gravity	Viable particles. Example uses: sampling air for bacteria in the vicinity of and during a medical procedure; general measurements of microbial air quality.	Nutrient media (agars) on plates or slides	n/a	No	Simple and inexpensive; best suited for qualitative sampling; significant airborne fungal spores are too buoyant to settle efficiently for collection using this method.	Settle plates
Filtration	Air drawn through a filter unit; particles trapped; 0.2 µm pore size	Viable particles; viable organisms (on non-nutrient surfaces, limited to spores and organisms that resist drying);	Paper, cellulose, glass wool, gelatin foam, and membrane filters	1–50	Yes	Filter must be agitated first in rinse fluid to remove and disperse trapped micro- organisms; rinse fluid is	–

Method	Principle	Suitable for measuring:	Collection media or surface	Rate of collection (L/min.)	Auxilliary equipment needed+	Points to consider	Prototype samplers§
		concentration over time. Example use: air sampling for *Aspergillus* spp., fungal spores, and dust				assayed; used more for sampling dust and chemicals.	
Centrifugation	Aerosols subjected to centrifugal force; particles impacted onto a solid surface	Viable particles; viable organisms (on non-nutrient surfaces, limited to spores and organisms that resist drying); concentration over time. Example use: air sampling for *Aspergillus* spp., and fungal spores	Coated glass or plastic slides, and agar surfaces	40–50	Yes	Calibration is difficult and is done only by the factory; relative comparison of airborne contamination is its general use.	Biotest RCS Plus
Electrostatic precipitation	Air drawn over an electro-statically charged surface; particles become charged	Viable particles; viable organisms (on non-nutrient surfaces, limited to spores and organisms that resist drying); concentration over time	Solid collecting surfaces (glass, and agar)	85	Yes	High volume sampling rate, but equipment is complex and must be handled carefully; not practical for use in health- care settings.	–
Thermal precipitation	Air drawn over a thermal gradient; particles repelled from hot surfaces, settle on colder surfaces	Size measurements	Glass coverslip, and electron microscope grid	0.003–0.4	Yes	Determine particle size by direct observation; not frequently used because of complex adjustments and low sampling rates.	–

* Material in this table is compiled from references 289, 1218, 1223, and 1224.

\+ Most samplers require a flow meter or anemometer and a vacuum source as auxiliary equipment.

§ Trade names listed are for identification purposes only and are not intended as endorsements by the U.S. Public Health Service.

Box 14. Selecting an air sampling device*

The following factors must be considered when choosing an air sampling instrument:

- Viability and type of the organism to be sampled
- Compatibility with the selected method of analysis
- Sensitivity of particles to sampling
- Assumed concentrations and particle size
- Whether airborne clumps must be broken (i.e., total viable organism count vs. particle count)
- Volume of air to be sampled and length of time sampler is to be continuously operated
- Background contamination
- Ambient conditions
- Sampler collection efficiency
- Effort and skill required to operate sampler
- Availability and cost of sampler, plus back-up samplers in case of equipment malfunction
- Availability of auxiliary equipment and utilities (e.g., vacuum pumps, electricity, and water)

* Material in this box is compiled from reference 1218.

Liquid impinger and solid impactor samplers are the most practical for sampling bacteria, particles, and fungal spores, because they can sample large volumes of air in relatively short periods of time.[289] Solid impactor units are available as either "slit" or "sieve" designs. Slit impactors use a rotating disc as support for the collecting surface, which allows determinations of concentration over time. Sieve impactors commonly use stages with calibrated holes of different diameters. Some impactor-type samplers use centrifugal force to impact particles onto agar surfaces. The interior of either device must be made sterile to avoid inadvertent contamination from the sampler. Results obtained from either sampling device can be expressed as organisms or particles per unit volume of air (CFU/m^3).

Sampling for bacteria requires special attention, because bacteria may be present as individual organisms, as clumps, or mixed with or adhering to dust or covered with a protective coating of dried organic or inorganic substances. Reports of bacterial concentrations determined by air sampling therefore must indicate whether the results represent individual organisms or particles bearing multiple cells. Certain types of samplers (e.g., liquid impingers) will completely or partially disintegrate clumps and large particles; the sampling result will therefore reflect the total number of individual organisms present in the air.

The task of sizing a bioaerosol is simplified through the use of sieves or slit impactors because these samplers will separate the particles and microorganisms into size ranges as the sample is collected. These samplers must, however, be calibrated first by sampling aerosols under similar use conditions.[1225]

The use of settle plates (i.e., the sedimentation or depositional method) is not recommended when sampling air for fungal spores, because single spores can remain suspended in air indefinitely.[289] Settle plates have been used mainly to sample for particulates and bacteria either in research studies or during epidemiologic investigations.[161, 1226–1229] Results of sedimentation sampling are typically expressed as numbers of viable particles or viable bacteria per unit area per the duration of sampling time (i.e., CFU/area/time); this method can not quantify the volume of air sampled. Because the survival of microorganisms during air sampling is inversely proportional to the velocity at which the air is taken into the sampler,[1215] one advantage of using a settle plate is its reliance on gravity to bring organisms and particles into contact with its surface, thus enhancing the potential for optimal survival of collected organisms. This process, however, takes several hours to complete and may be impractical for some situations.

Air samplers are designed to meet differing measurement requirements. Some samplers are better suited for one form of measurement than others. No one type of sampler and assay procedure can be used to collect and enumerate 100% of airborne organisms. The sampler and/or sampling method chosen should, however, have an adequate sampling rate to collect a sufficient number of particles in a reasonable time period so that a representative sample of air is obtained for biological analysis. Newer analytical techniques for assaying air samples include PCR methods and enzyme-linked immunosorbent assays (ELISAs).

3. Water Sampling

A detailed discussion of the principles and practices of water sampling has been published.[945] Water sampling in health-care settings is used detect waterborne pathogens of clinical significance or to determine the quality of finished water in a facility's distribution system. Routine testing of the water in a health-care facility is usually not indicated, but sampling in support of outbreak investigations can help determine appropriate infection-control measures. Water-quality assessments in dialysis settings have been discussed in this guideline (see Water, Dialysis Water Quality and Dialysate, and Appendix C).

Health-care facilities that conduct water sampling should have their samples assayed in a laboratory that uses established methods and quality-assurance protocols. Water specimens are not "static specimens" at ambient temperature; potential changes in both numbers and types of microbial populations can occur during transport. Consequently, water samples should be sent to the testing laboratory cold (i.e., at approximately 39.2°F [4°C]) and testing should be done as soon as practical after collection (preferably within 24 hours).

Because most water sampling in health-care facilities involves the testing of finished water from the facility's distribution system, a reducing agent (i.e., sodium thiosulfate [Na2S2O3]) needs to be added to neutralize residual chlorine or other halogen in the collected sample. If the water contains elevated levels of heavy metals, then a chelating agent should be added to the specimen. The minimum volume of water to be collected should be sufficient to complete any and all assays indicated; 100 mL is considered a suitable minimum volume. Sterile collection equipment should always be used.

Sampling from a tap requires flushing of the water line before sample collection. If the tap is a mixing faucet, attachments (e.g., screens and aerators) must be removed, and hot and then cold water must be run through the tap before collecting the sample.[945] If the cleanliness of the tap is questionable, disinfection with 500–600 ppm sodium hypochlorite (1:100 v/v dilution of chlorine bleach) and flushing the tap should precede sample collection.

Microorganisms in finished or treated water often are physically damaged ("stressed") to the point that growth is limited when assayed under standard conditions. Such situations lead to false-negative readings and misleading assessments of water quality. Appropriate neutralization of halogens and chelation of heavy metals are crucial to the recovery of these organisms. The choice of recovery media and incubation conditions will also affect the assay. Incubation temperatures should be closer to the ambient temperature of the water rather than at 98.6°F (37°C), and recovery media should be formulated to provide appropriate concentrations of nutrients to support organisms exhibiting less than rigorous growth.[945] High-nutrient content media (e.g., blood agar and tryptic soy agar [TSA]) may actually inhibit the growth of these damaged organisms. Reduced nutrient media (e.g., diluted peptone and R2A) are preferable for recovery of these organisms.[945]

Use of aerobic, heterotrophic plate counts allows both a qualitative and quantitative measurement for water quality. If bacterial counts in water are expected to be high in number (e.g., during waterborne outbreak investigations), assaying small quantities using pour plates or spread plates is appropriate.[945] Membrane filtration is used when low-count specimens are expected and larger sampling volumes are

required (≥100 mL). The sample is filtered through the membrane, and the filter is applied directly face-up onto the surface of the agar plate and incubated.

Unlike the testing of potable water supplies for coliforms (which uses standardized test and specimen collection parameters and conditions), water sampling to support epidemiologic investigations of disease outbreaks may be subjected to modifications dictated by the circumstances present in the facility. Assay methods for waterborne pathogens may also not be standardized. Therefore, control or comparison samples should be included in the experimental design. Any departure from a standard method should be fully documented and should be considered when interpreting results and developing strategies. Assay methods specific for clinically significant waterborne pathogens (e.g., *Legionella* spp., *Aeromonas* spp., *Pseudomonas* spp., and *Acinetobacter* spp.) are more complicated and costly compared with both methods used to detect coliforms and other standard indicators of water quality.

4. Environmental Surface Sampling

Routine environmental-surface sampling (e.g., surveillance cultures) in health-care settings is neither cost-effective nor warranted.[951, 1225] When indicated, surface sampling should be conducted with multidisciplinary approval in adherence to carefully considered plans of action and policy (Box 15).

Box 15. Undertaking environmental-surface sampling*

The following factors should be considered before engaging in environmental-surface sampling:

- Background information from the literature and present activities (i.e., preliminary results from an epidemiologic investigation)
- Location of surfaces to be sampled
- Method of sample collection and the appropriate equipment for this task
- Number of replicate samples needed and which control or comparison samples are required
- Parameters of the sample assay method and whether the sampling will be qualitative, quantitative, or both
- An estimate of the maximum allowable microbial numbers or types on the surface(s) sampled (refer to the Spaulding classification for devices and surfaces)
- Some anticipation of a corrective action plan

* The material in this box is compiled from reference 1214.

Surface sampling is used currently for research, as part of an epidemiologic investigation, or as part of a comprehensive approach for specific quality assurance purposes. As a research tool, surface sampling has been used to determine

a. potential environmental reservoirs of pathogens,[564, 1230–1232]
b. survival of microorganisms on surfaces,[1232, 1233] and
c. the sources of the environmental contamination.[1023]

Some or all of these approaches can also be used during outbreak investigations.[1232] Discussion of surface sampling of medical devices and instruments is beyond the scope of this document and is deferred to future guidelines on sterilization and disinfection issues.

Meaningful results depend on the selection of appropriate sampling and assay techniques.[1214] The media, reagents, and equipment required for surface sampling are available from any well-equipped microbiology laboratory and laboratory supplier. For quantitative assessment of surface organisms, non-selective, nutrient-rich agar media and broth (e.g., TSA and brain-heart infusion broth [BHI] with or

without 5% sheep or rabbit blood supplement) are used for the recovery of aerobic bacteria. Broth media are used with membrane-filtration techniques. Further sample work-up may require the use of selective media for the isolation and enumeration of specific groups of microorganisms. Examples of selective media are MacConkey agar (MAC [selects for gram-negative bacteria]), Cetrimide agar (selects for *Pseudomonas aeruginosa*), or Sabouraud dextrose- and malt extract agars and broths (select for fungi). Qualitative determinations of organisms from surfaces require only the use of selective or non-selective broth media.

Effective sampling of surfaces requires moisture, either already present on the surface to be sampled or via moistened swabs, sponges, wipes, agar surfaces, or membrane filters.[1214, 1234–1236] Dilution fluids and rinse fluids include various buffers or general purpose broth media (Table 24). If disinfectant residuals are expected on surfaces being sampled, specific neutralizer chemicals should be used in both the growth media and the dilution or rinse fluids. Lists of the neutralizers, the target disinfectant active ingredients, and the use concentrations have been published.[1214, 1237] Alternatively, instead of adding neutralizing chemicals to existing culture media (or if the chemical nature of the disinfectant residuals is unknown), the use of either

a. commercially available media including a variety of specific and nonspecific neutralizers or
b. double-strength broth media will facilitate optimal recovery of microorganisms.

The inclusion of appropriate control specimens should be included to rule out both residual antimicrobial activity from surface disinfectants and potential toxicity caused by the presence of neutralizer chemicals carried over into the assay system.[1214]

Table 24. Examples of eluents and diluents for environmental-surface sampling* +

Solutions	Concentration in water
Ringer	1⁄4 strength
Peptone water	0.1%–1.0%
Buffered peptone water	0.067 M phosphate, 0.43% NaCl, 0.1% peptone
Phosphate-buffered saline	0.02 M phosphate, 0.9% NaCl
Sodium chloride (NaCl)	0.25%–0.9%
Calgon Ringer (This solution is used for dissolution of calcium alginate swabs.)	1⁄4 strength
Thiosulfate Ringer (This solution is used for neutralization of residual chlorine.)	1⁄4 strength
Water	n/a
Tryptic soy broth (TSB)	n/a
Brain-heart infusion broth (BHI) supplemented with 0.5% beef extract	n/a

* Material in this table is compiled from references 1214 and 1238.

\+ A surfactant (e.g., polysorbate [i.e., Tween® 80]) may be added to eluents and diluents. A concentration ranging from 0.01%–0.1% is generally used, depending on the specific application. Foaming may occur during use.

Several methods can be used for collecting environmental surface samples (Table 25). Specific step-bystep discussions of each of the methods have been published.[1214, 1239] For best results, all methods should incorporate aseptic techniques, sterile equipment, and sterile recovery media.

Table 25. Methods of environmental-surface sampling

Method	Suitable for appropriate surface(s)	Assay technique	Procedural notes	Points of interpretation	Available standards	References
Sample/rinse (Moistened swab/rinse)	Non-absorbent surfaces, corners, crevices, devices, and instruments	Dilutions; qualitative or quantitative assays	Assay multiple measures areas or devices with separate swabs	Report results per measured areas or if assaying an object, per the entire sample site	**YES**: food industry; **NO**: heath care	1214, 1239–1242
Sample/rinse (Moistened sponge/rinse)	Large areas and housekeeping surfaces (e.g., floors or walls)	Dilutions; qualitative or quantitative assays	Vigorously rub a sterile sponge over the surface	Report results per measured area	**YES**: food industry; **NO**: health care	1214, 1239–1242
Sample/rinse (Moistened wipe/rinse)	Large areas and housekeeping surfaces (e.g., countertops)	Dilutions; qualitative or quantitative assays	Use a sterile wipe	Report results per measured area	**YES**: food industry; **NO**: health care	1214, 1239–1242
Direct immersion	Small items capable of being immersed	Dilutions; qualitative or quantitative assays	Use membrane filtration if rinse volume is large and anticipated microbiological concentration is low	Report results per item	**NO**	1214
Containment	Interior surfaces of containers, tubes, or bottles	Dilutions; qualitative or quantitative assays	Use membrane filtration if rinse volume is large	Evaluate both the types and numbers of microorganisms	**YES**: food and industrial applications for containers prior to fill	1214
RODAC (Replicate Organism Direct Agar Contact)	Previously cleaned and sanitized flat, non-absorbent surfaces; not suitable for irregular surfaces	Direct assay	Overgrowth occurs if used on heavily contaminated surfaces; use neutralizers in the agar if surface disinfectant residuals are present	Provides direct, quantitative results; use a minimum of 15 plates per an average hospital room	**NO**	1214, 1237, 1239, 1243, 1244

Sample/rinse methods are frequently chosen because of their versatility. However, these sampling methods are the most prone to errors caused by manipulation of the swab, gauze pad, or sponge.[1238] Additionally, no microbiocidal or microbiostatic agents should be present in any of these items when used for sampling.[1238] Each of the rinse methods requires effective elution of microorganisms from the item used to sample the surface. Thorough mixing of the rinse fluids after elution (e.g., via manual or mechanical mixing using a vortex mixer, shaking with or without glass beads, and ultrasonic bath) will help to remove and suspend material from the sampling device and break up clumps of organisms for a more accurate count.[1238] In some instances, the item used to sample the surface (e.g., gauze pad and sponge) may be immersed in the rinse fluids in a sterile bag and subjected to stomaching.[1238] This technique, however, is suitable only for soft or absorbent items that will not puncture the bag during the elution process.

If sampling is conducted as part of an epidemiologic investigation of a disease outbreak, identification of isolates to species level is mandatory, and characterization beyond the species level is preferred.[1214] When interpreting the results of the sampling, the expected degree of microbial contamination associated with the various categories of surfaces in the Spaulding classification must be considered. Environmental surfaces should be visibly clean; recognized pathogens in numbers sufficient to result in secondary transfer to other animate or inanimate surfaces should be absent from the surface being sampled.[1214] Although the interpretation of a sample with positive microbial growth is self-evident, an environmental surface sample, especially that obtained from housekeeping surfaces, that shows no growth does not represent a "sterile" surface. Sensitivities of the sampling and assay methods (i.e., level of detection) must be taken into account when no-growth samples are encountered. Properly collected control samples will help rule out extraneous contamination of the surface sample.

G. Laundry and Bedding

1. General Information

Laundry in a health-care facility may include bed sheets and blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes for surgical procedures.[1245] Although contaminated textiles and fabrics in health-care facilities can be a source of substantial numbers of pathogenic microorganisms, reports of health-care associated diseases linked to contaminated fabrics are so few in number that the overall risk of disease transmission during the laundry process likely is negligible. When the incidence of such events are evaluated in the context of the volume of items laundered in health-care settings (estimated to be 5 billion pounds annually in the United States),[1246] existing control measures (e.g., standard precautions) are effective in reducing the risk of disease transmission to patients and staff. Therefore, use of current control measures should be continued to minimize the contribution of contaminated laundry to the incidence of health-care associated infections. The control measures described in this section of the guideline are based on principles of hygiene, common sense, and consensus guidance; they pertain to laundry services utilized by health-care facilities, either inhouse or contract, rather than to laundry done in the home.

2. Epidemiology and General Aspects of Infection Control

Contaminated textiles and fabrics often contain high numbers of microorganisms from body substances, including blood, skin, stool, urine, vomitus, and other body tissues and fluids. When textiles are heavily contaminated with potentially infective body substances, they can contain bacterial loads of 10^6–10^8 CFU/100 cm^2 of fabric.[1247] Disease transmission attributed to health-care laundry has involved contaminated fabrics that were handled inappropriately (i.e., the shaking of soiled linens). Bacteria (*Salmonella* spp., *Bacillus cereus*), viruses (hepatitis B virus [HBV]), fungi (*Microsporum canis*), and ectoparasites (scabies) presumably have been transmitted from contaminated textiles and fabrics to workers via

a. direct contact or
b. aerosols of contaminated lint generated from sorting and handling contaminated textiles.[1248–1252]

In these events, however, investigations could not rule out the possibility that some of these reported infections were acquired from community sources. Through a combination of soil removal, pathogen removal, and pathogen inactivation, contaminated laundry can be rendered hygienically clean. Hygienically clean laundry carries negligible risk to health-care workers and patients, provided that the clean textiles, fabric, and clothing are not inadvertently contaminated before use.

OSHA defines contaminated laundry as "laundry which has been soiled with blood or other potentially infectious materials or may contain sharps."[967] The purpose of the laundry portion of the standard is to

protect the worker from exposure to potentially infectious materials during collection, handling, and sorting of contaminated textiles through the use of personal protective equipment, proper work practices, containment, labeling, hazard communication, and ergonomics.

Experts are divided regarding the practice of transporting clothes worn at the workplace to the healthcare worker's home for laundering. Although OSHA regulations prohibit home laundering of items that are considered personal protective apparel or equipment (e.g., laboratory coats),[967] experts disagree about whether this regulation extends to uniforms and scrub suits that are not contaminated with blood or other potentially infectious material. Health-care facility policies on this matter vary and may be inconsistent with recommendations of professional organizations.[1253, 1254] Uniforms without blood or body substance contamination presumably do not differ appreciably from street clothes in the degree and microbial nature of soilage. Home laundering would be expected to remove this level of soil adequately. However, if health-care facilities require the use of uniforms, they should either make provisions to launder them or provide information to the employee regarding infection control and cleaning guidelines for the item based on the tasks being performed at the facility. Health-care facilities should address the need to provide this service and should determine the frequency for laundering these items. In a recent study examining the microbial contamination of medical students' white coats, the students perceived the coats as "clean" as long as the garments were not visibly contaminated with body substances, even after wearing the coats for several weeks.[1255] The heaviest bacterial load was found on the sleeves and the pockets of these garments; the organisms most frequently isolated were *Staphylococcus aureus*, diphtheroids, and *Acinetobacter* spp.[1255] Presumably, the sleeves of the coat may make contact with a patient and potentially serve to transfer environmentally stable microorganisms among patients. In this study, however, surveillance was not conducted among patients to detect new infections or colonizations. The students did, however, report that they would likely replace their coats more frequently and regularly if clean coats were provided.[1255] Apart from this study, which documents the presence of pathogenic bacteria on health-care facility clothing, reports of infections attributed to either the contact with such apparel or with home laundering have been rare. [1256, 1257]

Laundry services for health-care facilities are provided either in-house (i.e., on-premise laundry [OPL]), co-operatives (i.e., those entities owned and operated by a group of facilities), or by off-site commercial laundries. In the latter, the textiles may be owned by the health-care facility, in which case the processor is paid for laundering only. Alternatively, the textiles may be owned by the processor who is paid for every piece laundered on a "rental" fee. The laundry facility in a health-care setting should be designed for efficiency in providing hygienically clean textiles, fabrics, and apparel for patients and staff. Guidelines for laundry construction and operation for health-care facilities, including nursing facilities, have been published.[120, 1258] The design and engineering standards for existing facilities are those cited in the AIA edition in effect during the time of the facility's construction.[120] A laundry facility is usually partitioned into two separate areas - a "dirty" area for receiving and handling the soiled laundry and a "clean" area for processing the washed items.[1259] To minimize the potential for recontaminating cleaned laundry with aerosolized contaminated lint, areas receiving contaminated textiles should be at negative air pressure relative to the clean areas.[1260–1262] Laundry areas should have handwashing facilities readily available to workers. Laundry workers should wear appropriate personal protective equipment (e.g., gloves and protective garments) while sorting soiled fabrics and textiles.[967] Laundry equipment should be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system.[1250, 1263] Damp textiles should not be left in machines overnight.[1250]

3. Collecting, Transporting, and Sorting Contaminated Textiles and Fabrics

The laundry process starts with the removal of used or contaminated textiles, fabrics, and/or clothing from the areas where such contamination occurred, including but not limited to patients' rooms, surgical/operating areas, and laboratories. Handling contaminated laundry with a minimum of agitation can help prevent the generation of potentially contaminated lint aerosols in patient-care areas.[967, 1259]

Sorting or rinsing contaminated laundry at the location where contamination occurred is prohibited by OSHA.[967] Contaminated textiles and fabrics are placed into bags or other appropriate containment in this location; these bags are then securely tied or otherwise closed to prevent leakage.[967] Single bags of sufficient tensile strength are adequate for containing laundry, but leak-resistant containment is needed if the laundry is wet and capable of soaking through a cloth bag.[1264] Bags containing contaminated laundry must be clearly identified with labels, color-coding, or other methods so that health-care workers handle these items safely, regardless of whether the laundry is transported within the facility or destined for transport to an off-site laundry service.[967]

Typically, contaminated laundry originating in isolation areas of the hospital is segregated and handled with special practices; however, few, if any, cases of health-care associated infection have been linked to this source.[1265] Single-blinded studies have demonstrated that laundry from isolation areas is no more heavily contaminated with microorganisms than laundry from elsewhere in the hospital.[1266] Therefore, adherence to standard precautions when handling contaminated laundry in isolation areas and minimizing agitation of the contaminated items are considered sufficient to prevent the dispersal of potentially infectious aerosols.[6]

Contaminated textiles and fabrics in bags can be transported by cart or chute.[1258, 1262] Laundry chutes require proper design, maintenance, and use, because the piston-like action of a laundry bag traveling in the chute can propel airborne microbial contaminants throughout the facility.[1267–1269] Laundry chutes should be maintained under negative air pressure to prevent the spread of microorganisms from floor to floor. Loose, contaminated pieces of laundry should not be tossed into chutes, and laundry bags should be closed or otherwise secured to prevent the contents from falling out into the chute.[1270] Health-care facilities should determine the point in the laundry process at which textiles and fabrics should be sorted. Sorting after washing minimizes the exposure of laundry workers to infective material in soiled fabrics, reduces airborne microbial contamination in the laundry area, and helps to prevent potential percutaneous injuries to personnel.[1271] Sorting laundry before washing protects both the machinery and fabrics from hard objects (e.g., needles, syringes, and patients' property) and reduces the potential for recontamination of clean textiles.[1272] Sorting laundry before washing also allows for customization of laundry formulas based on the mix of products in the system and types of soils encountered. Additionally, if work flow allows, increasing the amount of segregation by specific product types will usually yield the greatest amount of work efficiency during inspection, folding, and pack-making operations.[1253] Protective apparel for the workers and appropriate ventilation can minimize these exposures. [967, 1258–1260] Gloves used for the task of sorting laundry should be of sufficient thickness to minimize sharps injuries.[967] Employee safety personnel and industrial hygienists can help to determine the appropriate glove choice.

4. Parameters of the Laundry Process

Fabrics, textiles, and clothing used in health-care settings are disinfected during laundering and generally rendered free of vegetative pathogens (i.e., hygienically clean), but they are not sterile.[1273] Laundering cycles consist of flush, main wash, bleaching, rinsing, and souring.[1274] Cleaned wet textiles, fabrics, and clothing are then dried, pressed as needed, and prepared (e.g., folded and packaged) for distribution back to the facility. Clean linens provided by an off-site laundry must be packaged prior to transport to prevent inadvertent contamination from dust and dirt during loading, delivery, and unloading. Functional packaging of laundry can be achieved in several ways, including

a. placing clean linen in a hamper lined with a previously unused liner, which is then closed or covered
b. placing clean linen in a properly cleaned cart and covering the cart with disposable material or a properly cleaned reusable textile material that can be secured to the cart; and

c. wrapping individual bundles of clean textiles in plastic or other suitable material and sealing or taping the bundles.

The antimicrobial action of the laundering process results from a combination of mechanical, thermal, and chemical factors.[1271, 1275, 1276] Dilution and agitation in water remove substantial quantities of microorganisms. Soaps and detergents function to suspend soils and also exhibit some microbiocidal properties. Hot water provides an effective means of destroying microorganisms.[1277] A temperature of at least 160°F (71°C) for a minimum of 25 minutes is commonly recommended for hot-water washing.[2] Water of this temperature can be provided by steam jet or separate booster heater.[120] The use of chlorine bleach assures an extra margin of safety.[1278, 1279] A total available chlorine residual of 50–150 ppm is usually achieved during the bleach cycle.[1277] Chlorine bleach becomes activated at water temperatures of 135°F–145°F (57.2°C–62.7°C). The last of the series of rinse cycles is the addition of a mild acid (i.e., sour) to neutralize any alkalinity in the water supply, soap, or detergent. The rapid shift in pH from approximately 12 to 5 is an effective means to inactivate some microorganisms.[1247] Effective removal of residual alkali from fabrics is an important measure in reducing the risk for skin reactions among patients.

Chlorine bleach is an economical, broad-spectrum chemical germicide that enhances the effectiveness of the laundering process. Chlorine bleach is not, however, an appropriate laundry additive for all fabrics. Traditionally, bleach was not recommended for laundering flame-retardant fabrics, linens, and clothing because its use diminished the flame-retardant properties of the treated fabric.[1273] However, some modern-day flame retardant fabrics can now tolerate chlorine bleach. Flame-retardant fabrics, whether topically treated or inherently flame retardant, should be thoroughly rinsed during the rinse cycles, because detergent residues are capable of supporting combustion. Chlorine alternatives (e.g., activated oxygen-based laundry detergents) provide added benefits for fabric and color safety in addition to antimicrobial activity. Studies comparing the antimicrobial potencies of chlorine bleach and oxygen-based bleach are needed. Oxygen-based bleach and detergents used in health-care settings should be registered by EPA to ensure adequate disinfection of laundry. Health-care workers should note the cleaning instructions of textiles, fabrics, drapes, and clothing to identify special laundering requirements and appropriate hygienic cleaning options.[1278]

Although hot-water washing is an effective laundry disinfection method, the cost can be substantial. Laundries are typically the largest users of hot water in hospitals. They consume 50%–75% of the total hot water,[1280] representing an average of 10%–15% of the energy used by a hospital. Several studies have demonstrated that lower water temperatures of 71°F–77°F (22°C–25°C) can reduce microbial contamination when the cycling of the washer, the wash detergent, and the amount of laundry additive are carefully monitored and controlled.[1247, 1281–1285] Low-temperature laundry cycles rely heavily on the presence of chlorine- or oxygen-activated bleach to reduce the levels of microbial contamination. The selection of hot- or cold-water laundry cycles may be dictated by state health-care facility licensing standards or by other regulation. Regardless of whether hot or cold water is used for washing, the temperatures reached in drying and especially during ironing provide additional significant microbiocidal action.[1247] Dryer temperatures and cycle times are dictated by the materials in the fabrics. Man-made fibers (i.e., polyester and polyester blends) require shorter times and lower temperatures.

After washing, cleaned and dried textiles, fabrics, and clothing are pressed, folded, and packaged for transport, distribution, and storage by methods that ensure their cleanliness until use.[2] State regulations and/or accrediting standards may dictate the procedures for this activity. Clean/sterile and contaminated textiles should be transported from the laundry to the health-care facility in vehicles (e.g., trucks, vans, and carts) that allow for separation of clean/sterile and contaminated items. Clean/sterile textiles and contaminated textiles may be transported in the same vehicle, provided that the use of physical barriers and/or space separation can be verified to be effective in protecting the clean/sterile items from contamination. Clean, uncovered/unwrapped textiles stored in a clean location for short periods of time (e.g., uncovered and used within a few hours) have not been demonstrated to contribute to increased levels of health-care acquired infection. Such textiles can be stored in convenient places for use during the

provision of care, provided that the textiles can be maintained dry and free from soil and body-substance contamination.

In the absence of microbiologic standards for laundered textiles, no rationale exists for routine microbiologic sampling of cleaned health-care textiles and fabrics.[1286] Sampling may be used as part of an outbreak investigation if epidemiologic evidence suggests that textiles, fabrics, or clothing are a suspected vehicle for disease transmission. Sampling techniques include aseptically macerating the fabric into pieces and adding these to broth media or using contact plates (RODAC plates) for direct surface sampling.[1271, 1286] When evaluating the disinfecting properties of the laundering process specifically, placing pieces of fabric between two membrane filters may help to minimize the contribution of the physical removal of microorganisms.[1287]

Washing machines and dryers in residential-care settings are more likely to be consumer items rather than the commercial, heavy-duty, large volume units typically found in hospitals and other institutional health-care settings. Although all washing machines and dryers in health-care settings must be properly maintained for performance according to the manufacturer's instructions, questions have been raised about the need to disinfect washers and dryers in residential-care settings. Disinfection of the tubs and tumblers of these machines is unnecessary when proper laundry procedures are followed; these procedures involve

a. the physical removal of bulk solids (e.g., feces) before the wash/dry cycle and
b. proper use of temperature, detergent, and laundry additives.

Infection has not been linked to laundry procedures in residential-care facilities, even when consumer versions of detergents and laundry additives are used.

5. Special Laundry Situations

Some textile items (e.g., surgical drapes and reusable gowns) must be sterilized before use and therefore require steam autoclaving after laundering.[7] Although the American Academy of Pediatrics in previous guidelines recommended autoclaving for linens in neonatal intensive care units (NICUs), studies on the microbial quality of routinely cleaned NICU linen have not identified any increased risk for infection among the neonates receiving care.[1288] Consequently, hygienically clean linens are suitable for use in this setting.[997] The use of sterile linens in burn therapy units remains unresolved.

Coated or laminated fabrics are often used in the manufacture of PPE. When these items become contaminated with blood or other body substances, the manufacturer's instructions for decontamination and cleaning take into account the compatibility of the rubber backing with the chemical germicides or detergents used in the process. The directions for decontaminating these items should be followed as indicated; the item should be discarded when the backing develops surface cracks.

Dry cleaning, a cleaning process that utilizes organic solvents (e.g., perchloroethylene) for soil removal, is an alternative means of cleaning fabrics that might be damaged in conventional laundering and detergent washing. Several studies, however, have shown that dry cleaning alone is relatively ineffective in reducing the numbers of bacteria and viruses on contaminated linens;[1289, 1290] microbial populations are significantly reduced only when dry-cleaned articles are heat pressed. Dry cleaning should therefore not be considered a routine option for health-care facility laundry and should be reserved for those circumstances in which fabrics can not be safely cleaned with water and detergent.[1291]

6. Surgical Gowns, Drapes, and Disposable Fabrics

An issue of recent concern involves the use of disposable (i.e., single use) versus reusable (i.e., multiple use) surgical attire and fabrics in health-care settings.[1292] Regardless of the material used to manufacture gowns and drapes, these items must be resistant to liquid and microbial penetration.[7, 1293– 1297] Surgical gowns and drapes must be registered with FDA to demonstrate their safety and effectiveness. Repellency and pore size of the fabric contribute to gown performance, but performance capability can be influenced by the item's design and construction.[1298, 1299] Reinforced gowns (i.e., gowns with double-layered fabric) generally are more resistant to liquid strike-through.[1300, 1301] Reinforced gowns may, however, be less comfortable. Guidelines for selection and use of barrier materials for surgical gowns and drapes have been published.[1302] When selecting a barrier product, repellency level and type of barrier should be compatible for the exposure expected.[967] However, data are limited regarding the association between gown or drape characteristics and risk for surgical site infections.[7, 1303] Health-care facilities must ensure optimal protection of patients and health-care workers. Not all fabric items in health care lend themselves to single-use. Facilities exploring options for gowns and drapes should consider the expense of disposable items and the impact on the facility's waste-management costs once these items are discarded. Costs associated with the use of durable goods involve the fabric or textile items; staff expenses to collect, sort, clean, and package the laundry; and energy costs to operate the laundry if on-site or the costs to contract with an outside service.[1304, 1305]

7. Antimicrobial-Impregnated Articles and Consumer Items Bearing Antimicrobial Labeling

Manufacturers are increasingly incorporating antibacterial or antimicrobial chemicals into consumer and health-care items. Some consumer products bearing labels that indicate treatment with antimicrobial chemicals have included pens, cutting boards, toys, household cleaners, hand lotions, cat litter, soaps, cotton swabs, toothbrushes, and cosmetics. The "antibacterial" label on household cleaning products, in particular, gives consumers the impression that the products perform "better" than comparable products without this labeling, when in fact all household cleaners have antibacterial properties.

In the health-care setting, treated items may include children's pajamas, mattresses, and bed linens with label claims of antimicrobial properties. These claims require careful evaluation to determine whether they pertain to the use of antimicrobial chemicals as preservatives for the fabric or other components or whether they imply a health claim.[1306, 1307] No evidence is available to suggest that use of these products will make consumers and patients healthier or prevent disease. No data support the use of these items as part of a sound infection-control strategy, and therefore, the additional expense of replacing a facility's bedding and sheets with these treated products is unwarranted.

EPA has reaffirmed its position that manufacturers who make public health claims for articles containing antimicrobial chemicals must provide evidence to support those claims as part of the registration process.[1308] Current EPA regulations outlined in the Treated Articles Exemption of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) require manufacturers to register both the antimicrobial chemical used in or on the product and the finished product itself if a public health claim is maintained for the item. The exemption applies to the use of antimicrobial chemicals for the purpose of preserving the integrity of the product's raw material(s). The U.S. Federal Trade Commission (FTC) is evaluating manufacturer advertising of products with antimicrobial claims.[1309]

8. Standard Mattresses, Pillows, and Air-Fluidized Beds

Standard mattresses and pillows can become contaminated with body substances during patient care if the integrity of the covers of these items is compromised. The practice of sticking needles into the mattress

should be avoided. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. Mattress covers should be replaced when torn; the mattress should be replaced if it is visibly stained. Wet mattresses, in particular, can be a substantial environmental source of microorganisms. Infections and colonizations caused by *Acinetobacter* spp., MRSA, and *Pseudomonas aeruginosa* have been described, especially among burn patients.[1310–1315] In these reports, the removal of wet mattresses was an effective infection-control measure. Efforts were made to ensure that pads and covers were cleaned and disinfected between patients using disinfectant products compatible with mattress-cover materials to ensure that these covers remained impermeable to fluids.[1310–1314] Pillows and their covers should be easily cleanable, preferably in a hot water laundry cycle.[1315] These should be laundered between patients or if contaminated with body substances.

Air-fluidized beds are used for the care of patients immobilized for extended periods of time because of therapy or injury (e.g., pain, decubitus ulcers, and burns).[1316] These specialized beds consist of a base unit filled with microsphere beads fluidized by warm, dry air flowing upward from a diffuser located at the bottom of the unit. A porous, polyester filter sheet separates the patient from direct contact with the beads but allows body fluids to pass through to the beads. Moist beads aggregate into clumps which settle to the bottom where they are removed as part of routine bed maintenance.

Because the beads become contaminated with the patient's body substances, concerns have been raised about the potential for these beds to serve as an environmental source of pathogens. Certain pathogens (e.g., *Enterococcus* spp., *Serratia marcescens, Staphylococcus aureus*, and *Streptococcus fecalis*) have been recovered either from the microsphere beads or the polyester sheet after cleaning.[1317, 1318] Reports of cross-contamination of patients, however, are few.[1318] Nevertheless, routine maintenance and between-patient decontamination procedures can minimize potential risks to patients. Regular removal of bead clumps, coupled with the warm, dry air of the bed, can help to minimize bacterial growth in the unit.[1319–1321]

Beads are decontaminated between patients by high heat (113°F–194°F [45°C–90°C], depending on the manufacturer's specifications) for at least 1 hour; this procedure is particularly important for the inactivation of *Enterococcus* spp. which are relatively resistant to heat.[1322, 1323] The polyester filter sheet requires regular changing and thorough cleaning and disinfection, especially between patients.[1317, 1318, 1322, 1323]

Microbial contamination of the air space in the immediate vicinity of a properly maintained air-fluidized bed is similar to that found in air around conventional bedding, despite the air flow out of the base unit and around the patient.[1320, 1324, 1325] An operational air-fluidized bed can, however, interfere with proper pressure differentials, especially in negative-pressure rooms;[1326] the effect varies with the location of the bed relative to the room's configuration and supply and exhaust vent locations. Use of an air-fluidized bed in a negative-pressure room requires consultation with a facility engineer to determine appropriate placement of the bed.

H. Animals in Health-Care Facilities

1. General Information

Animals in health-care facilities traditionally have been limited to laboratories and research areas. However, their presence in patient-care areas is now more frequent, both in acute-care and long-term care settings, prompting consideration for the potential transmission of zoonotic pathogens from animals to humans in these settings. Although dogs and cats may be commonly encountered in health-care settings, other animals (e.g., fish, birds, non-human primates, rabbits, rodents, and reptiles) also can be present as research, resident, or service animals. These animals can serve as sources of zoonotic pathogens that could potentially infect patients and health-care workers (Table 26).[1327–1340] Animals potentially can serve as reservoirs for antibiotic-resistant microorganisms, which can be introduced to the health-care setting while the animal is present. VRE have been isolated from both farm animals and pets,[1341] and a cat in a geriatric care center was found to be colonized with MRSA.[1342]

Table 26. Examples of diseases associated with zoonotic transmission* (This table does not include vectorborne diseases.)

Table 26A. Virus

Infectious disease	Cats	Dogs	Fish	Birds	Rabbits	Reptiles§	Primates	Rodents§
Lymphocytic choriomeningitis	n/a	n/a	n/a	n/a	n/a	n/a	n/a	+¶
Rabies	+	+	n/a	n/a	n/a	n/a	n/a	n/a

Table 26B. Bacteria

Infectious disease	Cats	Dogs	Fish	Birds	Rabbits	Reptiles§	Primates	Rodents§
Campylobacteriosis	+	+	n/a	n/a	n/a	+	+	+
Capnocytophaga canimorsus infection	+	+	n/a	n/a	n/a	n/a	n/a	n/a
Cat scratch disease (*Bartonella henselae*)	+	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Leptospirosis	+	n/a	n/a	n/a	n/a	n/a	+	+
Mycobacteriosis		n/a	+	+	n/a	n/a	n/a	n/a
Pasteurellosis	+	+	n/a		+		n/a	n/a
Plague	+	n/a	n/a	+			+	+
Psittacosis	n/a	n/a	n/a	+	n/a	n/a	n/a	n/a
Q fever (*Coxiella burnetti*)	+	n/a	n/a	n/a			n/a	n/a
Rat bite fever (*Spirrillum minus, Streptobacillus monliformis*)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	+
Salmonellosis	+	+	n/a	+	+	+	+	+
Tularemia	+	n/a	n/a	n/a	+	n/a	n/a	+
Yersiniosis	n/a	n/a	n/a	n/a	+	+	+	+

Table 26C. Parasites

Infectious disease	Cats	Dogs	Fish	Birds	Rabbits	Reptiles§	Primates	Rodents§
Ancylostomiasis	+	+	n/a	n/a	n/a	n/a	+	n/a
Cryptosporidiosis	+	n/a	n/a	n/a	n/a	n/a		n/a
Giardiasis	+	+	n/a	n/a	n/a	n/a	+	n/a
Toxocariasis	+	+	n/a	n/a	n/a	n/a	+	n/a
Toxoplasmosis	+	+	n/a	n/a	n/a	n/a	+	n/a

Table 26D. Fungi

Infectious disease	Cats	Dogs	Fish	Birds	Rabbits	Reptiles§	Primates	Rodents§
Blastomycosis	n/a	+	n/a	n/a	n/a	n/a	n/a	n/a
Dermatophytosis	n/a	+	n/a	n/a	+	n/a	+	+

* Material in this table is adapted from reference 1331 and used with permission of the publisher (Lippincott Williams and Wilkins).

§ Reptiles include lizards, snakes, and turtles. Rodents include hamsters, mice, and rats.

\+ Indicates that the pathogen associated with the infection has been isolated from animals and is considered to pose potential risk to humans.

Zoonoses can be transmitted from animals to humans either directly or indirectly via bites, scratches, aerosols, ectoparasites, accidental ingestion, or contact with contaminated soil, food, water, or unpasteurized milk.[1331, 1332, 1343–1345] Colonization and hand transferral of pathogens acquired from pets in health-care workers' homes represent potential sources and modes of transmission of zoonotic pathogens in health-care settings. An outbreak of infections caused by a yeast (*Malassezia pachydermatis*) among newborns was traced to transfer of the yeast from the hands of health-care workers with pet dogs at home.[1346] In addition, an outbreak of ringworm in a NICU caused by *Microsporum canis* was associated with a nurse and her cat,[1347] and an outbreak of *Rhodococcus (Gordona) bronchialis* sternal SSIs after coronary-artery bypass surgery was traced to a colonized nurse whose dogs were culture-positive for the organism.[1348] In the latter outbreak, whether the dogs were the sole source of the organism and whether other environmental reservoirs contributed to the outbreak are unknown. Nonetheless, limited data indicate that outbreaks of infectious disease have occurred as a result of contact with animals in areas housing immunocompetent patients. However, the low frequency of outbreaks may result from

a. the relatively limited presence of the animals in health-care facilities and
b. the immunocompetency of the patients involved in the encounters.

Formal scientific studies to evaluate potential risks of transmission of zoonoses in health-care settings outside of the laboratory are lacking.

2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals

Animal-Assisted Activities (AAA) are those programs that enhance the patients' quality of life. These programs allow patients to visit animals in either a common, central location in the facility or in individual patient rooms. A group session with the animals enhances opportunities for ambulatory patients and facility residents to interact with caregivers, family members, and volunteers.[1349–1351] Alternatively, allowing the animals access to individual rooms provides the same opportunity to non-ambulatory patients and patients for whom privacy or dignity issues are a consideration. The decision to allow this access to patients' rooms should be made on a case-by-case basis, with the consultation and consent of the attending physician and nursing staff.

Animal-Assisted Therapy (AAT) is a goal-directed intervention that incorporates an animal into the treatment process provided by a credentialed therapist.[1330, 1331] The concept for AAT arose from the observation that some patients with pets at home recover from surgical and medical procedures more rapidly than patients without pets.[1352, 1353] Contact with animals is considered beneficial for enhancing wellness in certain patient populations (e.g., children, the elderly, and extended-care hospitalized patients).[1349, 1354–1357] However, evidence supporting this benefit is largely derived from anecdotal reports and observations of patient/animal interactions.[1357–1359] Guidelines for establishing AAT programs are available for facilities considering this option.[1360]

The incorporation of non-human primates into an AAA or AAT program is not encouraged because of concerns regarding potential disease transmission from and unpredictable behavior of these animals.[1361, 1362] Animals participating in either AAA or AAT sessions should be in good health and up-to-date with recommended immunizations and prophylactic medications (e.g., heartworm prevention) as determined by a licensed veterinarian based on local needs and recommendations. Regular re-evaluation of the animal's health and behavior status is essential.[1360] Animals should be routinely screened for enteric parasites and/or have evidence of a recently completed antihelminthic regimen.[1363] They should also be free of ectoparasites (e.g., fleas and ticks) and should have no sutures, open wounds, or obvious dermatologic lesions that could be associated with bacterial, fungal, or viral infections or parasitic infestations. Incorporating young animals (i.e., those aged <1 year) into these programs is not encouraged because of issues regarding unpredictable behavior and elimination control. Additionally, health of these animals at risk. Animals should be clean and well-groomed. The visits must be supervised by persons who know the animals and their behavior. Animal handlers should be trained in these activities and

receive site-specific orientation to ensure that they work efficiently with the staff in the specific health-care environment.[1360] Additionally, animal handlers should be in good health.[1360]

The most important infection-control measure to prevent potential disease transmission is strict enforcement of hand-hygiene measures (e.g., using either soap and water or an alcohol-based hand rub) for all patients, staff, and residents after handling the animals.[1355, 1364] Care should also be taken to avoid direct contact with animal urine or feces. Clean-up of these substances from environmental surfaces requires gloves and the use of leak-resistant plastic bags to discard absorbent material used in the process.[2] The area must be cleaned after visits according to standard cleaning procedures.

The American Academy of Allergy, Asthma, and Immunology estimates that dog or cat allergies occur in approximately 15% of the population.[1365] Minimizing contact with animal saliva, dander, and/or urine helps to mitigate allergic responses.[1365–1367] Some facilities may not allow animal visitation for patients with

a. underlying asthma,
b. known allergies to cat or dog hair,
c. respiratory allergies of unknown etiology, and
d. immunosuppressive disorders.

Hair shedding can be minimized by processes that remove dead hair (e.g., grooming) and that prevent the shedding of dead hair (e.g., therapy capes for dogs). Allergens can be minimized by bathing therapy animals within 24 hours of a visit.[1333, 1368]

Animal therapists and handlers must take precautions to prevent animal bites. Common pathogens associated with animal bites include *Capnocytophaga canimorsus, Pasteurella* spp., *Staphylococcus* spp., and *Streptococcus* spp. Selecting well-behaved and well-trained animals for these programs greatly decreases the incidence of bites. Rodents, exotic species, wild/domestic animals (i.e., wolf-dog hybrids), and wild animals whose behavior is unpredictable should be excluded from AAA or AAT programs. A well-trained animal handler should be able to recognize stress in the animal and to determine when to terminate a session to minimize risk. When an animal bites a person during AAA or AAT, the animal is to be permanently removed from the program. If a bite does occur, the wound must be cleansed immediately and monitored for subsequent infection. Most infections can be treated with antibiotics, and antibiotics often are prescribed prophylactically in these situations.

The health-care facility's infection-control staff should participate actively in planning for and coordinating AAA and AAT sessions. Many facilities do not offer AAA or AAT programs for severely immunocompromised patients (e.g., HSCT patients and patients on corticosteroid therapy).[1339] The question of whether family pets or companion animals can visit terminally-ill HSCT patients or other severely immunosuppressed patients is best handled on a case-by-case basis, although animals should not be brought into the HSCT unit or any other unit housing severely immunosuppressed patients. An in-depth discussion of this issue is presented elsewhere.[1366]

Immunocompromised patients who have been discharged from a health-care facility may be at higher risk for acquiring some pet-related zoonoses. Although guidelines have been developed to minimize the risk of disease transmission to HIV-infected patients,[8] these recommendations may be applicable for patients with other immunosuppressive disorders. In addition to handwashing or hand hygiene, these recommendations include avoiding contact with

a. animal feces and soiled litter box materials,
b. animals with diarrhea,
c. very young animals (i.e., dogs <6 months of age and cats <1 year of age), and
d. exotic animals and reptiles.[8]

Pets or companion animals with diarrhea should receive veterinary care to resolve their condition.

Many health-care facilities are adopting more home-like environments for residential-care or extended-stay patients in acute-care settings, and resident animals are one element of this approach.[1369] One

concept, the "Eden Alternative," incorporates children, plants, and animals (e.g., dogs, cats, fish, birds, rabbits, and rodents) into the daily care setting.[1370, 1371] The concept of working with resident animals has not been scientifically evaluated. Several issues beyond the benefits of therapy must be considered before embarking on such a program, including

a. whether the animals will come into direct contact with patients and/or be allowed to roam freely in the facility
b. how the staff will provide care for the animals;
c. the management of patients' or residents' allergies, asthma, and phobias;
d. precautionary measures to prevent bites and scratches; and
e. measures to properly manage the disposal of animal feces and urine, thereby preventing environmental contamination by zoonotic microorganisms (e.g., *Toxoplasma* spp., *Toxocara* spp., and *Ancylostoma* spp.).[1372, 1373]

Few data document a link between health-care acquired infection rates and frequency of cleaning fish tanks or rodent cages. Skin infections caused by *Mycobacterium marinum* have been described among persons who have fish aquariums at home.[1374, 1375] Nevertheless, immunocompromised patients should avoid direct contact with fish tanks and cages and the aerosols that these items produce. Further, fish tanks should be kept clean on a regular basis as determined by facility policy, and this task should be performed by gloved staff members who are not responsible for patient care. The use of the infection-control risk assessment can help determine whether a fish tank poses a risk for patient or resident safety and health in these situations. No evidence, however, links the incidence of health-care acquired infections among immunocompetent patients or residents with the presence of a properly cleaned and maintained fish tank, even in dining areas. As a general preventive measure, resident animal programs are advised to restrict animals from

a. food preparation kitchens,
b. laundries,
c. central sterile supply and any storage areas for clean supplies, and
d. medication preparation areas.

Resident-animal programs in acute-care facilities should not allow the animals into the isolation areas, protective environments, ORs, or any area where immunocompromised patients are housed. Patients and staff routinely should wash their hands or use waterless, alcohol-based hand-hygiene products after contact with animals.

3. Service Animals

Although this section provides an overview about service animals in health-care settings, it cannot address every situation or question that may arise (see Appendix E - Information Resources). A service animal is any animal individually trained to do work or perform tasks for the benefit of a person with a disability.[1366, 1376] A service animal is not considered a pet but rather an animal trained to provide assistance to a person because of a disability. Title III of the "Americans with Disabilities Act" (ADA) of 1990 mandates that persons with disabilities accompanied by service animals be allowed access with their service animals into places of public accommodation, including restaurants, public transportation, schools, and health-care facilities.[1366, 1376] In health-care facilities, a person with a disability requiring a service animal may be an employee, a visitor, or a patient.

An overview of the subject of service animals and their presence in health-care facilities has been published.[1366] No evidence suggests that animals pose a more significant risk of transmitting infection than people; therefore, service animals should not be excluded from such areas, unless an individual patient's situation or a particular animal poses greater risk that cannot be mitigated through reasonable measures. If health-care personnel, visitors, and patients are permitted to enter care areas (e.g., inpatient rooms, some ICUs, and public areas) without taking additional precautions to prevent transmission of infectious agents (e.g., donning gloves, gowns, or masks), a clean, healthy, well-behaved service animal should be allowed access with its handler.[1366] Similarly, if immunocompromised patients are able to

receive visitors without using protective garments or equipment, an exclusion of service animals from this area would not be justified.[1366]

Because health-care facilities are covered by the ADA or the Rehabilitation Act, a person with a disability may be accompanied by a service animal within the facility unless the animal's presence or behavior creates a fundamental alteration in the nature of a facility's services in a particular area or a direct threat to other persons in a particular area.[1366] A "direct threat" is defined as a significant risk to the health or safety of others that cannot be mitigated or eliminated by modifying policies, practices, or procedures.[1376] The determination that a service animal poses a direct threat in any particular healthcare setting must be based on an individualized assessment of the service animal, the patient, and the health-care situation. When evaluating risk in such situations, health-care personnel should consider the nature of the risk (including duration and severity); the probability that injury will occur; and whether reasonable modifications of policies, practices, or procedures will mitigate the risk (J. Wodatch, U.S. Department of Justice, 2000). The person with a disability should contribute to the risk-assessment process as part of a pre-procedure health-care provider/patient conference.

Excluding a service animal from an OR or similar special care areas (e.g., burn units, some ICUs, PE units, and any other area containing equipment critical for life support) is appropriate if these areas are considered to have "restricted access" with regards to the general public. General infection-control measures that dictate such limited access include

a. the area is required to meet environmental criteria to minimize the risk of disease transmission,
b. strict attention to hand hygiene and absence of dermatologic conditions, and
c. barrier protective measures [e.g., using gloves, wearing gowns and masks] are indicated for persons in the affected space.

No infection-control measures regarding the use of barrier precautions could be reasonably imposed on the service animal. Excluding a service animal that becomes threatening because of a perceived danger to its handler during treatment also is appropriate; however, exclusion of such an animal must be based on the actual behavior of the particular animal, not on speculation about how the animal might behave.

Another issue regarding service animals is whether to permit persons with disabilities to be accompanied by their service animals during all phases of their stay in the health-care facility. Healthcare personnel should discuss all aspects of anticipatory care with the patient who uses a service animal. Health-care personnel may not exclude a service animal because health-care staff may be able to perform the same services that the service animal does (e.g., retrieving dropped items and guiding an otherwise ambulatory person to the restroom). Similarly, health-care personnel can not exclude service animals because the health-care staff perceive a lack of need for the service animal during the person's stay in the health-care facility. A person with a disability is entitled to independent access (i.e., to be accompanied by a service animal unless the animal poses a direct threat or a fundamental alteration in the nature of services); "need" for the animal is not a valid factor in either analysis. For some forms of care (e.g., ambulation as physical therapy following total hip replacement or knee replacement), the service animal should not be used in place of a credentialed health-care worker who directly provides therapy. However, service animals need not be restricted from being in the presence of its handler during this time; in addition, rehabilitation and discharge planning should incorporate the patient's future use of the animal. The health-care personnel and the patient with a disability should discuss both the possible need for the service animal to be separated from its handler for a period of time during non-emergency care and an alternate plan of care for the service animal in the event the patient is unable or unwilling to provide that care. This plan might include family members taking the animal out of the facility several times a day for exercise and elimination, the animal staying with relatives, or boarding off-site. Care of the service animal, however, remains the obligation of the person with the disability, not the health-care staff.

Although animals potentially carry zoonotic pathogens transmissible to man, the risk is minimal with a healthy, clean, vaccinated, well-behaved, and well-trained service animal, the most common of which are dogs and cats. No reports have been published regarding infectious disease that affects humans originating in service dogs. Standard cleaning procedures are sufficient following occupation of an area

by a service animal.[1366] Clean-up of spills of animal urine, feces, or other body substances can be accomplished with blood/body substance procedures outlined in the Environmental Services section of this guideline. No special bathing procedures are required prior to a service animal accompanying its handler into a health-care facility.

Providing access to exotic animals (e.g., reptiles and non-human primates) that are used as service animals is problematic. Concerns about these animals are discussed in two published reviews.[1331, 1366] Because some of these animals exhibit high-risk behaviors that may increase the potential for zoonotic disease transmission (e.g., herpes B infection), providing health-care facility access to nonhuman primates used as service animals is discouraged, especially if these animals might come into contact with the general public.[1361, 1362] Health-care administrators should consult the Americans with Disabilities Act for guidance when developing policies about service animals in their facilities.[1366, 1376]

Requiring documentation for access of a service animal to an area generally accessible to the public would impose a burden on a person with a disability. When health-care workers are not certain that an animal is a service animal, they may ask the person who has the animal if it is a service animal required because of a disability; however, no certification or other documentation of service animal status can be required.[1377]

4. Animals as Patients in Human Health-Care Facilities

The potential for direct and indirect transmission of zoonoses must be considered when rooms and equipment in human health-care facilities are used for the medical or surgical treatment or diagnosis of animals.[1378] Inquiries should be made to veterinary medical professionals to determine an appropriate facility and equipment to care for an animal.

The central issue associated with providing medical or surgical care to animals in human health-care facilities is whether cross-contamination occurs between the animal patient and the human health-care workers and/or human patients. The fundamental principles of infection control and aseptic practice should differ only minimally, if at all, between veterinary medicine and human medicine. Health-care–associated infections can and have occurred in both patients and workers in veterinary medical facilities when lapses in infection-control procedures are evident.[1379–1384] Further, veterinary patients can be at risk for acquiring infection from veterinary health-care workers if proper precautions are not taken.[1385]

The issue of providing care to veterinary patients in human health-care facilities can be divided into the following three areas of infection-control concerns:

a. whether the room/area used for animal care can be made safe for human patients,
b. whether the medical/surgical instruments used on animals can be subsequently used on human patients, and
c. which disinfecting or sterilizing procedures need to be done for these purposes.

Studies addressing these concerns are lacking. However, with respect to disinfection or sterilization in veterinary settings, only minimal evidence suggests that zoonotic microbial pathogens are unusually resistant to inactivation by chemical or physical agents (with the exception of prions). Ample evidence supports the contrary observation (i.e., that pathogens from human- and animal sources are similar in their relative instrinsic resistance to inactivation).[1386–1391] Further, no evidence suggests that zoonotic pathogens behave differently from human pathogens with respect to ventilation. Despite this knowledge, an aesthetic and sociologic perception that animal care must remain separate from human care persists. Health-care facilities, however, are increasingly faced with requests from the veterinary medical community for access to human health-care facilities for reasons that are largely economical (e.g., costs of acquiring sophisticated diagnostic technology and complex medical instruments). If hospital guidelines allow treatment of animals, alternate veterinary resources (including veterinary hospitals, clinics, and universities) should be exhausted before using human health-care settings. Additionally, the hospital's public/media relations should be notified of the situation. The goal is to develop policies and procedures to proactively and positively discuss and disclose this activity to the general public.

An infection-control risk assessment (ICRA) must be undertaken to evaluate the circumstances specific to providing care to animals in a human health-care facility. Individual hospital policies and guidelines should be reviewed before any animal treatment is considered in such facilities. Animals treated in human health-care facilities should be under the direct care and supervision of a licensed veterinarian; they also should be free of known infectious diseases, ectoparasites, and other external contaminants (e.g., soil, urine, and feces). Measures should be taken to avoid treating animals with a known or suspected zoonotic disease in a human health-care setting (e.g., lambs being treated for Q fever).

If human health-care facilities must be used for animal treatment or diagnostics, the following general infection-control actions are suggested:

a. whenever possible, the use of ORs or other rooms used for invasive procedures should be avoided [e.g., cardiac catheterization labs and invasive nuclear medicine areas]
b. when all other space options are exhausted and use of the aforementioned rooms is unavoidable, the procedure should be scheduled late in the day as the last procedure for that particular area such that patients are not present in the department/unit/area;
c. environmental surfaces should be thoroughly cleaned and disinfected using procedures discussed in the Environmental Services portion of this guideline after the animal is removed from the care area;
d. sufficient time should be allowed for ACH to help prevent allergic reactions by human patients [Table B.1. in Appendix B];
e. only disposable equipment or equipment that can be thoroughly and easily cleaned, disinfected, or sterilized should be used;
f. when medical or surgical instruments, especially those invasive instruments that are difficult to clean [e.g., endoscopes], are used on animals, these instruments should be reserved for future use only on animals; and g) standard precautions should be followed.

5. Research Animals in Health-Care Facilities

The risk of acquiring a zoonotic infection from research animals has decreased in recent years because many small laboratory animals (e.g., mice, rats, and rabbits) come from quality stock and have defined microbiologic profiles.[1392] Larger animals (e.g., nonhuman primates) are still obtained frequently from the wild and may harbor pathogens transmissible to humans. Primates, in particular, benefit from vaccinations to protect their health during the research period provided the vaccination does not interfere with the study of the particular agent. Animals serving as models for human disease studies pose some risk for transmission of infection to laboratory or health-care workers from percutaneous or mucosal exposure. Exposures can occur either through

a. direct contact with an infected animal or its body substances and secretions or
b. indirect contact with infectious material on equipment, instruments, surfaces, or supplies.[1392]

Uncontained aerosols generated during laboratory procedures can also transmit infection.

Infection-control measures to prevent transmission of zoonotic infections from research animals are largely derived from the following basic laboratory safety principles:

a. purchasing pathogen-free animals,
b. quarantining incoming animals to detect any zoonotic pathogens,
c. treating infected animals or removing them from the facility,
d. vaccinating animal carriers and high-risk contacts if possible,
e. using specialized containment caging or facilities, and
f. using protective clothing and equipment [e.g., gloves, face shields, gowns, and masks].[1392]

An excellent resource for detailed discussion of these safety measures has been published.[1013]

The animal research unit within a health-care facility should be engineered to provide

a. adequate containment of animals and pathogens;
b. daily decontamination and transport of equipment and waste;

c. proper ventilation and air filtration, which prevents recirculation of the air in the unit to other areas of the facility; and
d. negative air pressure in the animal rooms relative to the corridors.

To ensure adequate security and containment, no through traffic to other areas of the health-care facility should flow through this unit; access should be restricted to animal-care staff, researchers, environmental services, maintenance, and security personnel.

Occupational health programs for animal-care staff, researchers, and maintenance staff should take into consideration the animals' natural pathogens and research pathogens. Components of such programs include
a. prophylactic vaccines,
b. TB skin testing when primates are used,
c. baseline serums, and
d. hearing and respiratory testing.

Work practices, PPE, and engineering controls specific for each of the four animal biosafety levels have been published.[1013, 1393] The facility's occupational or employee health clinic should be aware of the appropriate post-exposure procedures involving zoonoses and have available the appropriate post-exposure biologicals and medications.

Animal-research-area staff should also develop standard operating procedures for
a. daily animal husbandry [e.g., protection of the employee while facilitating animal welfare]
b. pathogen containment and decontamination;
c. management, cleaning, disinfecting and/or sterilizing equipment and instruments; and
d. employee training for laboratory safety and safety procedures specific to animal research worksites.[1013]

The federal Animal Welfare Act of 1966 and its amendments serve as the regulatory basis for ensuring animal welfare in research.[1394, 1395]

I. Regulated Medical Waste

1. Epidemiology

No epidemiologic evidence suggests that most of the solid- or liquid wastes from hospitals, other healthcare facilities, or clinical/research laboratories is any more infective than residential waste. Several studies have compared the microbial load and the diversity of microorganisms in residential wastes and wastes obtained from a variety of health-care settings.[1399–1402] Although hospital wastes had a greater number of different bacterial species compared with residential waste, wastes from residences were more heavily contaminated.[1397, 1398] Moreover, no epidemiologic evidence suggests that traditional waste-disposal practices of health-care facilities (whereby clinical and microbiological wastes were decontaminated on site before leaving the facility) have caused disease in either the health-care setting or the general community.[1400, 1401] This statement excludes, however, sharps injuries sustained during or immediately after the delivery of patient care before the sharp is "discarded." Therefore, identifying wastes for which handling and disposal precautions are indicated is largely a matter of judgment about the relative risk of disease transmission, because no reasonable standards on which to base these determinations have been developed. Aesthetic and emotional considerations (originating during the early years of the HIV epidemic) have, however, figured into the development of treatment and disposal policies, particularly for pathology and anatomy wastes and sharps.[1402–1405] Public concerns have resulted in the promulgation of federal, state, and local rules and regulations regarding medical waste management and disposal.[1406–1414]

2. Categories of Medical Waste

Precisely defining medical waste on the basis of quantity and type of etiologic agents present is virtually impossible. The most practical approach to medical waste management is to identify wastes that represent a sufficient potential risk of causing infection during handling and disposal and for which some precautions likely are prudent.[2] Health-care facility medical wastes targeted for handling and disposal precautions include microbiology laboratory waste (e.g., microbiologic cultures and stocks of microorganisms), pathology and anatomy waste, blood specimens from clinics and laboratories, blood products, and other body-fluid specimens.[2] Moreover, the risk of either injury or infection from certain sharp items (e.g., needles and scalpel blades) contaminated with blood also must be considered. Although any item that has had contact with blood, exudates, or secretions may be potentially infective, treating all such waste as infective is neither practical nor necessary. Federal, state, and local guidelines and regulations specify the categories of medical waste that are subject to regulation and outline the requirements associated with treatment and disposal. The categorization of these wastes has generated the term "regulated medical waste." This term emphasizes the role of regulation in defining the actual material and as an alternative to "infectious waste," given the lack of evidence of this type of waste's infectivity. State regulations also address the degree or amount of contamination (e.g., blood-soaked gauze) that defines the discarded item as a regulated medical waste. The EPA's *Manual for Infectious Waste Management* identifies and categorizes other specific types of waste generated in health-care facilities with research laboratories that also require handling precautions.[1406]

3. Management of Regulated Medical Waste in Health-Care Facilities

Medical wastes require careful disposal and containment before collection and consolidation for treatment. OSHA has dictated initial measures for discarding regulated medical-waste items. These measures are designed to protect the workers who generate medical wastes and who manage the wastes from point of generation to disposal.[967] A single, leak-resistant biohazard bag is usually adequate for containment of regulated medical wastes, provided the bag is sturdy and the waste can be discarded without contaminating the bag's exterior. The contamination or puncturing of the bag requires placement into a second biohazard bag. All bags should be securely closed for disposal. Puncture-resistant containers located at the point of use (e.g., sharps containers) are used as containment for discarded slides or tubes with small amounts of blood, scalpel blades, needles and syringes, and unused sterile sharps.[967] To prevent needlestick injuries, needles and other contaminated sharps should not be recapped, purposefully bent, or broken by hand. CDC has published general guidelines for handling sharps.[6, 1415] Health-care facilities may need additional precautions to prevent the production of aerosols during the handling of blood-contaminated items for certain rare diseases or conditions (e.g., Lassa fever and Ebola virus infection).[203]

Transporting and storing regulated medical wastes within the health-care facility prior to terminal treatment is often necessary. Both federal and state regulations address the safe transport and storage of on- and off-site regulated medical wastes.[1406–1408] Health-care facilities are instructed to dispose medical wastes regularly to avoid accumulation. Medical wastes requiring storage should be kept in labeled, leak-proof, puncture-resistant containers under conditions that minimize or prevent foul odors. The storage area should be well ventilated and be inaccessible to pests. Any facility that generates regulated medical wastes should have a regulated medical waste management plan to ensure health and environmental safety as per federal, state, and local regulations.

4. Treatment of Regulated Medical Waste

Regulated medical wastes are treated or decontaminated to reduce the microbial load in or on the waste and to render the by-products safe for further handling and disposal. From a microbiologic standpoint, waste need not be rendered "sterile" because the treated waste will not be deposited in a sterile site. In addition, waste need not be subjected to the same reprocessing standards as are surgical instruments. Historically, treatment methods involved steam-sterilization (i.e., autoclaving), incineration, or interment

(for anatomy wastes). Alternative treatment methods developed in recent years include chemical disinfection, grinding/shredding/disinfection methods, energy-based technologies (e.g., microwave or radiowave treatments), and disinfection/encapsulation methods.[1409] State medical waste regulations specify appropriate treatment methods for each category of regulated medical waste.

Of all the categories comprising regulated medical waste, microbiologic wastes (e.g., untreated cultures, stocks, and amplified microbial populations) pose the greatest potential for infectious disease transmission, and sharps pose the greatest risk for injuries. Untreated stocks and cultures of microorganisms are subsets of the clinical laboratory or microbiologic waste stream. If the microorganism must be grown and amplified in culture to high concentration to permit work with the specimen, this item should be considered for on-site decontamination, preferably within the laboratory unit. Historically, this was accomplished effectively by either autoclaving (steam sterilization) or incineration. If steam sterilization in the health-care facility is used for waste treatment, exposure of the waste for up to 90 minutes at 250°F (121°C) in a autoclave (depending on the size of the load and type container) may be necessary to ensure an adequate decontamination cycle.[1416–1418] After steam sterilization, the residue can be safely handled and discarded with all other nonhazardous solid waste in accordance with state solid-waste disposal regulations. On-site incineration is another treatment option for microbiologic, pathologic, and anatomic waste, provided the incinerator is engineered to burn these wastes completely and stay within EPA emissions standards.[1410] Improper incineration of waste with high moisture and low energy content (e.g., pathology waste) can lead to emission problems. State medical-waste regulatory programs identify acceptable methods for inactivating amplified stocks and cultures of microorganisms, some of which may employ technology rather than steam sterilization or incineration.

Concerns have been raised about the ability of modern health-care facilities to inactivate microbiologic wastes on-site, given that many of these institutions have decommissioned their laboratory autoclaves. Current laboratory guidelines for working with infectious microorganisms at biosafety level (BSL) 3 recommend that all laboratory waste be decontaminated before disposal by an approved method, preferably within the laboratory.[1013] These same guidelines recommend that all materials removed from a BSL 4 laboratory (unless they are biological materials that are to remain viable) are to be decontaminated before they leave the laboratory.[1013] Recent federal regulations for laboratories that handle certain biological agents known as “select agents” (i.e., those that have the potential to pose a severe threat to public health and safety) require these agents (and those obtained from a clinical specimen intended for diagnostic, reference, or verification purposes) to be destroyed on-site before disposal.[1412] Although recommendations for laboratory waste disposal from BSL 1 or 2 laboratories (e.g., most health-care clinical and diagnostic laboratories) allow for these materials to be decontaminated off-site before disposal, on-site decontamination by a known effective method is preferred to reduce the potential of exposure during the handling of infectious material.

A recent outbreak of TB among workers in a regional medical-waste treatment facility in the United States demonstrated the hazards associated with aerosolized microbiologic wastes.[1419, 1420] The facility received diagnostic cultures of *Mycobacterium tuberculosis* from several different health-care facilities before these cultures were chemically disinfected; this facility treated this waste with a grinding/shredding process that generated aerosols from the material. [1419, 1420] Several operational deficiencies facilitated the release of aerosols and exposed workers to airborne *M. tuberculosis*. Among the suggested control measures was that health-care facilities perform on-site decontamination of laboratory waste containing live cultures of microorganisms before release of the waste to a waste management company.[1419, 1420] This measure is supported by recommendations found in the CDC/NIH guideline for laboratory workers.[1013] This outbreak demonstrates the need to avoid the use of any medical-waste treatment method or technology that can aerosolize pathogens from live cultures and stocks (especially those of airborne microorganisms) unless aerosols can be effectively contained and workers can be equipped with proper PPE.[1419–1421] Safe laboratory practices, including those addressing waste management, have been published.[1013, 1422]

In an era when local, state, and federal health-care facilities and laboratories are developing bioterrorism response strategies and capabilities, the need to reinstate in-laboratory capacity to destroy cultures and stocks of microorganisms becomes a relevant issue.[1423] Recent federal regulations require health-care

facility laboratories to maintain the capability of destroying discarded cultures and stocks on-site if these laboratories isolate from a clinical specimen any microorganism or toxin identified as a "select agent" from a clinical specimen (Table 27).[1412, 1413] As an alternative, isolated cultures of select agents can be transferred to a facility registered to accept these agents in accordance with federal regulations.[1412] State medical waste regulations can, however, complicate or completely prevent this transfer if these cultures are determined to be medical waste, because most states regulate the inter-facility transfer of untreated medical wastes.

Table 27. Microorganisms and biologicals identified as select agents*+

Table 27 A. HHS Non-overlap select agents and toxins (42 CFR Part 73 §73.4)

Pathogen type	Select agents
Viruses	Crimean-Congo hemorrhagic fever virus; Ebola viruses; Cercopithecine herpesvirus 1 (herpes B virus); Lassa fever virus; Marburg virus; monkeypox virus; South American hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito); tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis [Russian spring and summer encephalitis, Kyasnaur Forest disease, Omsk hemorrhagic fever]); variola major virus (smallpox virus); and variola minor virus (alastrim) **Exclusions:** ¶ Vaccine strain of Junin virus (Candid. #1)
Bacteria	Rickettsia prowazekii, R. rickettsii, Yersinia pestis
Fungi	Coccidioides posadasii
Toxins	Abrin; conotoxins; diacetoxyscirpenol; ricin; saxitoxin; Shiga-like ribosome inactivating proteins; tetrodotoxin **Exclusions:** ¶ The following toxins (in purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of abrin; 100 mg of conotoxins; 1,000 mg of diacetoxyscirpenol; 100 mg of ricin; 100 mg of saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of tetrodotoxin
Genetic elements, recombinant nucleic acids, and recombinant organisms¶	• Select agent viral nucleic acids (synthetic or naturally-derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses; • Nucleic acids (synthetic or naturally-derived) that encode for the functional form(s) of any of the toxins listed in this table if the nucleic acids: a. are in a vector or host chromosome; b. can be expressed *in vivo* or *in vitro*; or c. are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*; • Viruses, bacteria, fungi, and toxins listed in this table that have been genetically modified.

Table 27 B. High consequence livestock pathogens and toxins/select agents (overlap agents) (42 CFR Part 73 §73.5 and USDA regulation 9 CFR Part 121)

Pathogen type	Select agents
Viruses	Eastern equine encephalitis virus; Nipah and Hendra complex viruses; Rift Valley fever virus; Venezuelan equine encephalitis virus **Exclusions:** ¶ MP-12 vaccine strain of Rift Valley fever virus; TC-83 vaccine strain of Venezuelan equine encephalitis virus
Bacteria	Bacillus anthracis; Brucella abortus, B. melitensis, B. suis; Burkholderia mallei (formerly Pseudomonas mallei), B. pseudomallei (formerly P. pseudomallei); botulinum neurotoxin-producing species of Clostridium; Coxiella burnetii; Francisella tularensis
Fungi	Coccidioides immitis
Toxins	Botulinum neurotoxins; *Clostridium perfringens* epsilon toxin; Shigatoxin; staphylococcal enterotoxins; T-2 toxin **Exclusions:** ¶The following toxins (in purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 0.5 mg of botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; 5 mg of staphylococcal enterotoxins; or 1,000 mg of T-2 toxin

Pathogen type	Select agents
Genetic elements, recombinant nucleic acids, and recombinant organisms¶	• Select agent viral nuclei acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) thatcan encode infectious and/or replication competent forms of any of the select agent viruses; • Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in this table if the nucleic acids: a. are in a vector or host chromosome; b. can be expressed *in vivo* or *in vitro*; or c. are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*; • Viruses, bacteria, fungi, and toxins listed in this table that have been genetically modified

* Material in this table is compiled from references 1412, 1413, 1424. Reference 1424 also contains lists of select agents that include plant pathogens and pathogens affecting livestock.

\+ 42 CFR 73 §§73.4 and 73.5 do not include any select agent or toxin that is in its naturally-occurring environment, provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. These sections also do not include non-viable select agent organisms or nonfunctional toxins. This list of select agents is current as of 3 October 2003 and is subject to change pending the final adoption of 42 CFR Part 73.

¶ These table entries are listed in reference 1412 and 1413, but were not included in reference 1424.

5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks

The contents of all vessels that contain more than a few milliliters of blood remaining after laboratory procedures, suction fluids, or bulk blood can either be inactivated in accordance with state-approved treatment technologies or carefully poured down a utility sink drain or toilet.[1414] State regulations may dictate the maximum volume allowable for discharge of blood/body fluids to the sanitary sewer. No evidence indicates that bloodborne diseases have been transmitted from contact with raw or treated sewage. Many bloodborne pathogens, particularly bloodborne viruses, are not stable in the environment for long periods of time;[1425, 1426] therefore, the discharge of small quantities of blood and other body fluids to the sanitary sewer is considered a safe method of disposing of these waste materials.[1414] The following factors increase the likelihood that bloodborne pathogens will be inactivated in the disposal process:

a. dilution of the discharged materials with water
b. inactivation of pathogens resulting from exposure to cleaning chemicals, disinfectants, and other chemicals in raw sewage; and
c. effectiveness of sewage treatment in inactivating any residual bloodborne pathogens that reach the treatment facility.

Small amounts of blood and other body fluids should not affect the functioning of a municipal sewer system. However, large quantities of these fluids, with their high protein content, might interfere with the biological oxygen demand (BOD) of the system. Local municipal sewage treatment restrictions may dictate that an alternative method of bulk fluid disposal be selected. State regulations may dictate what quantity constitutes a small amount of blood or body fluids.

Although concerns have been raised about the discharge of blood and other body fluids to a septic tank system, no evidence suggests that septic tanks have transmitted bloodborne infections. A properly functioning septic system is adequate for inactivating bloodborne pathogens. System manufacturers' instructions specify what materials may be discharged to the septic tank without jeopardizing its proper operation.

6. Medical Waste and CJD

Concerns also have been raised about the need for special handling and treatment procedures for wastes generated during the care of patients with CJD or other transmissible spongiform encephalopathies (TSEs). Prions, the agents that cause TSEs, have significant resistance to inactivation by a variety of physical, chemical, or gaseous methods.[1427] No epidemiologic evidence, however, links acquisition of CJD with medical-waste disposal practices. Although handling neurologic tissue for pathologic examination and autopsy materials with care, using barrier precautions, and following specific procedures for the autopsy are prudent measures,[1197] employing extraordinary measures once the materials are

discarded is unnecessary. Regulated medical wastes generated during the care of the CJD patient can be managed using the same strategies as wastes generated during the care of other patients. After decontamination, these wastes may then be disposed in a sanitary landfill or discharged to the sanitary sewer, as appropriate.

Part II. Recommendations for Environmental Infection Control in Health-Care Facilities

A. 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 benefit. 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 American Institute of Architects (AIA), American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), and the Association for the Advancement in 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.

B. 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 theoretical 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 standard).
- **Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.
- **Unresolved Issue.** No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.

C. Recommendations—Air

C.I. Air-Handling Systems in Health-Care Facilities

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

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.[120] ***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.[18, 35, 106, 120, 220, 222, 333, 336] ***Category IB, IC*** (AIA: 7.2, 7.31.D, 8.31.D, 9.31.D, 10.31.D, 11.31.D, EPA guidance)
   1. Ensure that heating, ventilation, air conditioning (HVAC) filters are properly installed and maintained to prevent air leakages and dust overloads.[17, 18, 106, 222] ***Category IB***
   2. Monitor areas with special ventilation requirements (e.g., AII or PE) for ACH, filtration, and pressure differentials.[21, 120, 249, 250, 273–275, 277, 333–344] ***Category IB, IC*** (AIA: 7.2.C7, 7.2.D6)
      - * Develop and implement a maintenance schedule for ACH, pressure differentials, and filtration efficiencies using facility-specific data as part of the multidisciplinary risk assessment. Take into account the age and reliability of the system.
      - * Document these parameters, especially the pressure differentials.
   3. Engineer humidity controls into the HVAC system and monitor the controls to ensure proper moisture removal.[120] ***Category IC*** (AIA: 7.31.D9)
      - * Locate duct humidifiers upstream from the final filters.
      - * Incorporate a water-removal mechanism into the system.
      - * Locate all duct takeoffs sufficiently down-stream 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.[3, 120] ***Category IC*** (AIA: 7.31.D3, 8.31.D3, 9.31.D3, 10.31.D3, 11.31.D3)
      - * Locate exhaust outlets >25 ft. from air-intake systems.
      - * Locate outdoor air intakes ≥6 ft. above ground or ≥3 ft. above roof level.
      - * 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.[3, 120, 249, 250, 273–275, 277] ***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.[106, 221] ***Category IB***
      - * Seal or close the bag containing the discarded filter.
      - * Discard spent filters as regular solid waste, regardless of the area from which they were removed.[221]
   8. Remove bird roosts and nests near air intakes to prevent mites and fungal spores from entering the ventilation system.[3, 98, 119] ***Category IB***
   9. Prevent dust accumulation by cleaning air-duct grilles in accordance with facility-specific procedures and schedules when rooms are not occupied by patients.[21, 120, 249, 250, 273–275, 277] ***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.[120, 263, 264] ***Category II*** (AIA: 7.31.D10)

C. Use portable, industrial-grade HEPA filter units capable of filtration rates in the range of 300–800 ft^3/min. to augment removal of respirable particles as needed.[219] ***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.[4] ***Category II***
2. Portable HEPA filter units previously placed in construction zones can be used later in patient-care areas, provided all internal and external surfaces are cleaned, and the filter's 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.[4] ***Category II***
4. Ensure that fresh-air requirements for the area are met.[214, 219] ***Category II***

D. Follow appropriate procedures for use of areas with through-the-wall ventilation units.[120] ***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.[120] ***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 required are met.[4, 120] ***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.[4, 6, 9, 18, 19, 69, 94, 120, 142, 331–334, 336–338] ***Category IA, IC*** (AIA: 7.2.C, 7.2.D)

F. When UVGI is used as a supplemental engineering control, install fixtures:
   - * on the wall near the ceiling or suspended from the ceiling as an upper air unit;
   - * in the air-return duct of an AII room; or
   - * in designated enclosed areas or booths for sputum induction.[4] ***Category II***

G. Seal windows in buildings with centralized HVAC systems and especially with PE areas.[35, 111, 120] ***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.[713] ***Category IC*** (Joint Commission on Accreditation of Healthcare Organizations [JCAHO]: Environment of Care [EC] 1.4)
   1. Emphasize restoration of proper air quality and ventilation conditions in AII rooms, PE rooms, operating rooms, emergency departments, and intensive care units.[120, 713] ***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.[6, 120, 713] ***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.[120, 206] ***Category IB, IC*** (AIA: 5.1, 5.2.B, C)
   1. Coordinate HVAC system maintenance with infection-control staff to allow for relocation of immunocompromised patients if necessary.[120] ***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, AII rooms, operating rooms, and other critical-care areas.[9, 120, 278] ***Category IC*** (AIA: 1.5, 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.[219] ***Category II***
   4. Coordinate system startups with infection-control staff to protect patients in PE rooms from bursts of fungal spores.[9, 35, 120, 278] ***Category IC*** (AIA: 5.1, 5.2) 120
   5. Allow sufficient time for ACH to clean the air once the system is operational (Appendix B, Table B.1).[4, 120] ***Category IC*** (AIA: 5.1, 5.2)

K. HVAC systems serving offices and administration 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, AII rooms, operating rooms). ***Category II***

L. Whenever possible, avoid inactivating or shutting down the entire HVAC system at one time, especially in acute-care facilities. ***Category II***

M. Whenever feasible, design and install fixed backup ventilation systems for new or renovated construction for PE rooms, AII rooms, operating rooms, and other critical care areas identified by ICRA.[120] ***Category IC*** (AIA: 1.5.A1)

C.II. Construction, Renovation, Remediation, Repair, and Demolition

⚠ **Edit [February 2017]:** These recommendations contain minor edits in order to clarify the meaning. The edits do not constitute any change to the intent of the recommendations.
* Indicates a change to the numbering system.
~ Indicates a text change.

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.[17, 19, 20, 97, 109, 120, 249, 250, 273–277] ***Category IB, IC*** (AIA: 5.1)

B. Educate both the construction team and the 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.[3, 249, 250, 273–277, 1428–1432] ***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.[3, 120, 249, 273–277] ***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.[3, 64, 65, 79] ***Category IB***
   1. Using active surveillance, monitor for airborne fungal infections in immunocompromised patients.[3, 9, 64, 65] ***Category IB***
   2. Periodically review the facility's microbiologic, histopathologic, and postmortem data to identify additional cases.[3, 9, 64, 65] ***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.[3, 64, 65, 79, 249, 273–277] ***Category IB***

E. Implement infection-control measures relevant to construction, renovation, maintenance, demolition, and repair.[96, 97, 120, 276, 277] ***Category IB, IC*** (AIA: 5.1, 5.2)
   1. Before the project gets underway, perform an ICRA to define the scope of the project and the need for barrier measures.[96, 97, 120, 249, 273–277]
      - * Determine if immunocompromised patients may be at risk for exposure to fungal spores from dust generated during the project.[20, 109, 273–275, 277]
      - * Develop a contingency plan to prevent such exposures.[20, 109, 273–275, 277] ***Category IB, IC*** (AIA: 5.1)
   2. Implement infection-control measures for external demolition and construction activities.[50, 249, 273–277, 283]
      - * Determine if the facility can operate temporarily on recirculated air; if feasible, seal off adjacent air intakes.
      - * If this is not possible or practical, check the low-efficiency (roughing) filter banks frequently and replace as needed to avoid buildup of particulates.
      - * Seal windows and reduce wherever possible other sources of outside air intrusion (e.g., open doors in stairwells and corridors), especially in PE areas. ***Category IB***
   3. Avoid damaging the underground water distribution system (i.e., buried pipes) to prevent soil and dust contamination of the water.[120, 305] ***Category IB, IC*** (AIA: 5.1) 121
   4. Implement infection-control measures for internal construction activities.[20, 49, 97, 120, 249, 273–277]
      - * 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.[20, 49, 97, 120, 284, 312, 713, 1431]

- * Block and seal off return air vents if rigid barriers are used for containment.[120, 276, 277]
- * Implement dust control measures on surfaces and by diverting pedestrian traffic away from work zones.[20, 49, 97, 120]
- * Relocate patients whose rooms are adjacent to work zones, depending upon 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.[49, 120, 281] ***Category IB, IC*** (AIA: 5.1, 5.2)

5. Perform those engineering and work-site related infection-control measures as needed for internal construction, repairs, and renovations:[20, 49, 97, 109, 120, 312] ***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.[49, 69, 276, 278] ***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.[20, 49, 97, 109, 120, 132] ***~ Category IB***
   c. Monitor negative air flow inside rigid barriers.[120, 281] ***~ Category IC***
   d. Monitor barriers and ensure the integrity of the construction barriers; repair gaps or breaks in barrier joints.[120, 284, 307, 312] ***~ Category IC***
   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.[20, 120, 273] ***~ Category IC***
   f. Direct pedestrian traffic from construction zones away from patient-care areas to minimize the dispersion of dust.[20, 49, 97, 109, 111, 120, 273–277] ***~ Category IB***
   g. Provide construction crews with
      - * designated entrances, corridors, and elevators whenever practical;
      - * essential services [e.g., toilet facilities], and convenience services [e.g., vending machines];
      - * protective clothing [e.g., coveralls, footgear, and headgear] for travel to patient-care areas; and
      - * a space or anteroom for changing clothing and storing equipment.[120, 249, 273–277] ***~ Category IB***
   h. Clean work zones and their entrances daily by
      - wet-wiping tools and tool carts before their removal from the work zone;
      - placing mats with tacky surfaces inside the entrance; and
      - covering debris and securing this covering before removing debris from the work zone.[120, 249, 273–277] ***~ Category IB***
   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 ranging from 300–800 ft^3/min., or exhaust air directly to the outside.[49, 276, 277, 281, 309] ***~ Category IB***
   j. Upon completion of the project, clean the work zone according to facility procedures, and install barrier curtains to contain dust and debris before removal of rigid barriers.[20, 97, 120, 249, 273–277] ***~ Category IB***
   k. Flush the water system to clear sediment from pipes to minimize waterborne microorganism proliferation.[120, 305] ***~ Category IB***
   l. Restore appropriate ACH, humidity, and pressure differential; clean or replace air filters; dispose of spent filters.[35, 106, 221, 278] ***~ Category IC***

F. Use airborne-particle sampling as a tool to evaluate barrier integrity.[35, 100] ***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.[100, 120, 288, 304] ***Category IC*** (AIA: 5.1; ASHRAE: 11996)
H. **No recommendation is offered** on routine microbiologic air sampling before, during, or after construction or before or during occupancy of areas housing immunocompromised patients.[17, 20, 49, 97, 109, 272, 1433] ***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.[20, 55, 62, 77, 94, 95] ***Category IB***
   1. Review pressure differential monitoring documentation to verify that pressure differentials in the construction zone and in PE rooms were appropriate for their settings.[94, 95, 120] ***Category IB, IC*** (AIA: 5.1)
   2. Implement corrective engineering measures to restore proper pressure differentials as needed.[94, 95, 120] ***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.[3, 20, 62, 63, 104] ***Category IB***
   4. If there is no evidence of ongoing transmission, continue routine maintenance in the area to prevent health-care acquired fungal disease.[3, 55] ***Category IB***

J. If there is epidemiologic evidence of ongoing transmission of fungal disease, conduct an environmental assessment to determine and eliminate the source.[3, 96, 97, 109, 111, 115, 249, 273–277] ***Category IB***
   1. Collect environmental samples from potential sources of airborne fungal spores, preferably using a high-volume air sampler rather than settle plates.[3, 18, 44, 48, 49, 97, 106, 111, 112, 115, 249, 254, 273–277, 292, 312] ***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.[96, 97] ***Category IB***
   3. Use an EPA-registered anti-fungal biocide (e.g., copper-8-quinolinolate) for decontaminating structural materials.[50, 277, 312, 329] ***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.[73, 117] ***Category IB***
   5. If possible, perform molecular subtyping of *Aspergillus* spp. isolated from patients and the environment to establish strain identities.[252, 293–296] ***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.[3, 120, 273–277] ***Category II***

C.III. Infection-Control and Ventilation Requirements for PE Rooms

⚠ **Edit [February 2017]:** These recommendations contain minor edits in order to clarify the meaning. The edits do not constitute any change to the intent of the recommendations.
* Indicates a change to the numbering system.
~ Indicates a text change.

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).[9, 20, 109, 272] ***Category IB***

B. Minimize the length of time that immunocompromised patients in PE are outside their rooms for diagnostic procedures and other activities.[9, 283] ***Category IB***

C. Provide respiratory protection for severely immunocompromised patients when they must leave PE for diagnostic studies and other activities; consult the most recent revision of CDC's *Guidelines for Prevention of Health-Care Associated Pneumonia* for information regarding the appropriate type of respiratory protection.[3, 9] ***Category II***

D. Incorporate ventilation engineering specifications and dust-controlling processes into the planning and construction of new PE units. ***Category IB, IC***
   1. Install central or point-of-use HEPA filters for supply (incoming) air.[3, 18, 20, 44, 99–104, 120, 254, 316–318, 1432, 1434] ***Category IB, IC*** (AIA: 5.1, 5.2, 7.2.D)
   2. Ensure that rooms are well sealed by
      - * properly constructing windows, doors, and intake and exhaust ports;
      - * maintaining ceilings that are smooth and free of fissures, open joints, and crevices;
      - * sealing walls above and below the ceiling, and

- * monitoring for leakage and making necessary repairs.[3, 111, 120, 317, 318] ***Category IB, IC*** (AIA: 7.2.D3)

3. Ventilate the room to maintain ≥12 ACH.[3, 9, 120, 241, 317, 318] ***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. [3, 120, 317, 318] ***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.[3, 35, 120, 317, 318] ***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 using other visual methods (e.g., flutter strips, or smoke tubes) in existing PE units. Document the monitoring results.[120, 273] ***Category IC*** (AIA: 7.2.D6)
7. Install self-closing devices on all room exit doors in protective environments.[120] ***Category IC*** (AIA: 7.2.D4)

E. Do not use laminar air flow systems in newly constructed PE rooms.[316, 318] ***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. ~ ***Category IC***
   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.[120, 317] ***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.[219] ***Category II***
G. Maintain backup ventilation equipment (e.g., portable units for fans or filters) for emergency provision of ventilation requirements for PE areas and take immediate steps to restore the fixed ventilation system function.[9, 120, 278] ***Category IC*** (AIA: 5.1)

C.IV. Infection-Control and Ventilation Requirements for All Rooms

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

A. Incorporate certain specifications into the planning, and construction or renovation of AII units.[4, 107, 120, 317, 318] ***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.[120, 317, 318] ***Category IB, 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.[120, 317, 318] ***Category IB, IC*** (AIA: 7.2.C3)
   3. Install self-closing devices on all AII room exit doors.[120] ***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.[4, 107, 120] ***Category 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.[4, 120] ***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.[4] ***Category II***
C. Implement environmental infection-control measures for persons with known 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

- * ≥12 ACH;
- * 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 ft^3/min.; and
- * air exhausted directly outside away from air intakes and traffic or exhausted after HEPA filtration prior to recirculation.[4, 120, 348–350] ***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.[202–204]
   - * 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.
   - * 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.[203] ***Category II***

   ⚠ **Ebola Virus Disease [August 2014]:** The recommendations in this guideline for Ebola has been superseded by these CDC documents:
   - Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals (https://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html)
   - Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus (https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/hospitals.html)

   See CDC's Ebola Virus Disease website (https://www.cdc.gov/vhf/ebola/index.html) for current information on how Ebola virus is transmitted.

3. Place smallpox patients in negative pressure rooms at the onset of their illness, preferably using a room with an anteroom if available.[6] ***Category II***

D. **No recommendation is offered** regarding negative pressure or isolation rooms for patients with *Pneumocystis carinii* pneumonia.[126, 131, 132] ***Unresolved issue***

E. Maintain back-up 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 function.[4, 120, 278] ***Category IC*** (AIA: 5.1)

C.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.[7, 120, 356] ***Category IB, IC*** (AIA: Table 7.2)
   2. Maintain ≥15 ACH, of which ≥3 ACH should be fresh air.[120, 357, 358] ***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.[120, 362] ***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.[120, 357, 359] ***Category IC*** (AIA: 7.31.D4)
   5. Do not use UV lights to prevent surgical-site infections.[356, 364–370] ***Category IB***
   6. Keep operating room doors closed except for the passage of equipment, personnel, and patients, and limit entry to essential personnel.[351, 352] ***Category IB***

B. Follow precautionary procedures for TB patients who also require emergency surgery.[4, 347, 371] ***Category IB, IC***
   1. Use an N95 respirator approved by the National Institute for Occupational Safety and Health (NIOSH) without exhalation valves in the operating room.[347, 372] ***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 (Appendix B, Table B.1).[4, 358] ***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.[371, 373] ***Category IB***
4. Extubate and allow the patient to recover in an AII room.[4, 358] ***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 (Appendix B, Table B.1) because extubation is a cough-producing procedure.[4, 358] ***Category IB***

C. Use portable, industrial-grade HEPA filters temporarily for supplemental air cleaning during intubation and extubation for infectious TB patients who require surgery.[4, 219, 358] ***Category II***
1. Position the units appropriately so that all room air passes through the filter; obtain engineering consultation to determine the appropriate placement of the unit.[4] ***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.[120, 215, 219] ***Category II***

D. If possible, schedule infectious 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.[362, 364] ***Unresolved issue***

F. Maintain backup ventilation equipment (e.g., portable units for fans or filters) for emergency provision of ventilation requirements for operating rooms, and take immediate steps to restore the fixed ventilation system function.[68, 120, 278,372] ***Category IB, IC*** (AIA: 5.1)

C.VI. Other Potential Infectious Aerosol Hazards in Health-Care Facilities

A. In settings where surgical lasers are used, wear appropriate personal protective equipment, including N95 or N100 respirators, to minimize exposure to laser plumes.[347, 378, 389] ***Category IC*** (OSHA; 29 CFR 1910.134,139)

B. Use central wall suction units with in-line filters to evacuate minimal laser plumes.[378, 382, 386, 389] ***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.[4, 382, 389– 392] ***Category II***

D. Recommendations—Water

D.I. Controlling the Spread of Waterborne Microoganisms

A. Practice hand hygiene to prevent the hand transfer of waterborne pathogens, and use barrier precautions (e.g., gloves) as defined by other guidelines.[6, 464, 577, 586, 592, 1364] ***Category IA***

B. Eliminate contaminated water or fluid environmental reservoirs (e.g., in equipment or solutions) wherever possible.[464, 465] ***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 post-procedural, colonization occurs after use of tap water in patient care).[607, 610–612] ***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 the public areas of the healthcare facility.[664] ***Category IB***

D.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 ≥124°F (≥51°C), and maintain cold water temperature at <68°F (<20°C).[3, 661] ***Category IC*** (States; ASHRAE: 12:2000)
B. If the hot water temperature can be maintained at ≥124°F (≥51°C), explore engineering options (e.g., install preset thermostatic valves in point-of-use fixtures) to help minimize the risk of scalding.[661] ***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 ≥150°F (≥66°C) at the point of use.[661] ***Category II***
    2. Alternatively, chlorinate the water and then flush it through the system.[661, 710, 711] ***Category II***
D. Maintain constant recirculation in hot-water distribution systems serving patient-care areas. [120] ***Category IC*** (AIA: 7.31.E.3)

D.III. Remediation Strategies for Distribution System Repair or Emergencies

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

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.[713, 719] ***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.[642] ***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).[642] ***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.[642, 661] ***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).[3, 661] ***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.[3, 661] ***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.[661]
        - * Flush each outlet until chlorine odor is detected.
        - * Maintain the elevated chlorine concentration in the system for ≥2 hrs (but ≤24 hrs).
    4. Use a very 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 manufacturers' 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.[721] ***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 management 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 upon release.[713, 719] ***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
        - * before performing invasive procedures;
        - * before and after each patient contact; and
        - * whenever hand hygiene is indicated.[1364] ***Category II***
    3. If hands are visibly soiled or contaminated with proteinaceous material, use soap and bottled water for handwashing.[1364] ***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-surface 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: II G 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 ≤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.[18, 266, 278, 1026] ***Category IB***

D.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]).[661, 711, 714, 724, 764, 766] ***Category IB*** (ASHRAE: 12:2000)
B. After a pulse treatment, maintain both the heated water temperature at the return and the cold water temperature as per the recommendation (Water: IIA) 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 using a chlorine-based product registered by the EPA for water treatment (e.g., sodium hypochlorite [bleach]).[26, 437, 661, 709, 726, 727] ***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), monochloramine, ozone, or UV light.[728–746] ***Unresolved issue***

D.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.[3, 431, 432] ***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).[3, 431, 432] ***Category IB***
   1. Establish a surveillance process to detect health-care associated Legionnaires disease.[3, 431, 432] ***Category IB***
   2. Inform health-care personnel (e.g., infection control, physicians, patient-care staff, and engineering) regarding the potential for Legionnaires disease to occur and measures to prevent and control health-care associated legionellosis.[437, 759] ***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.[3, 431] ***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]).[3, 395, 417, 423–425, 432, 435, 437, 453] ***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).[453] ***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.[405, 408, 431, 453, 739, 759] ***Category IB***
   1. Report the cases to the 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 healthcare–associated Legionnaires disease, and begin intensive prospective surveillance for additional cases.[3, 405, 408, 431, 453, 739, 759] ***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.[3, 405, 408, 431, 453, 739, 759] ***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.[403–410, 455] ***Category IB***
   1. Collect water samples from potential aerosolized water sources (Appendix C).[1209] ***Category IB***
   2. Save and subtype isolates of *Legionella* spp. obtained from patients and the environment.[403–410, 453, 763, 764] ***Category IB***
   3. If a source is identified, promptly institute water system decontamination measures per recommendations (see Water IV).[766, 767] ***Category IB***
   4. If *Legionella* spp. are detected in ≥1cultures (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 for initial decontamination, or a combination of superheating and hyperchlorination.[3, 767, 768] ***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. [26, 453, 707, 709, 714, 747, 753] ***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***

D.VI. Preventing Legionnaires Disease in Protective Environments and Transplant Units

A. When implementing strategies for preventing Legionnaires disease among severely immunosuppressed patients housed in facilities with HSCT or solid-organ transplant programs, incorporate these specific surveillance and epidemiologic measures in addition to the steps previously outlined (Water: V and Appendix C).
   1. Maintain a high index of suspicion for legionellosis in transplant patients even when environmental surveillance cultures do not yield legionellae.[430, 431] ***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. [431, 767] ***Category IB***

B. Implement culture strategies and potable water and fixture treatment measures in addition to those previously outlined (Water: V). ***Category II***
   1. Depending on state regulations on potable water temperature in public buildings,[725] hospitals housing patients at risk for health-care associated legionellosis should either maintain heated water with a minimum return temperature of ≥124°F [≥51°C] and cold water at <68°F [<20°C]), or chlorinate heated water to achieve 1–2 mg/L (1–2 ppm) of free residual chlorine at the tap.[26, 441, 661, 709–711, 726, 727] ***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.[9, 431, 710, 769] ***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]).[661, 745] ***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).[3, 9, 661, 766, 767] ***Category IB***
   2. Do not use water from the faucets in patient-care rooms to avoid creating infectious aerosols.[9, 412] ***Category IB***
   3. Restrict severely immunocompromised patients from taking showers.[9, 412] ***Category IB***
   4. Use water that is not contaminated with *Legionella* spp. for HSCT patients' sponge baths.[9, 412] ***Category IB***
   5. Provide patients with sterile water for tooth brushing, drinking, and for flushing nasogastric tubing during legionellosis outbreaks.[9, 412] ***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.[3, 9, 402, 455] ***Category IB***

D.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.[404, 661, 786] ***Category IC*** (ASHRAE: 12:2000) 131

B. Implement infection-control procedures for operational cooling towers.[404, 661, 784] ***Category IC*** (ASHRAE: 12:2000)
   1. Install drift eliminators.[404, 661, 784] ***Category IC*** (ASHRAE: 12:2000)
   2. Use an effective EPA-registered biocide on a regular basis.[661] ***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.[661] ***Category IC*** (ASHRAE: 12:2000)

C. If cooling towers or evaporative condensers are implicated in health-care associated legionellosis, decontaminate the cooling-tower system.[404, 405, 786, 787] ***Category IB***

D.VIII. Dialysis Water Quality and Dialysate

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

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.[31, 32, 666–668, 789, 791, 800, 807, 809, 1454, 1455] ***Category IA, IC*** (AAMI: ANSI/AAMI RD5:1992, ANSI/AAMI RD 47:1993)

B. **No recommendation is offered** regarding whether more stringent requirements for water quality should be imposed in hemofiltration and hemodiafiltration. ***Unresolved issue***

C. Conduct microbiological testing specific to water in dialysis settings.[789, 791, 792, 834, 835] ***Category IA, IC*** (AAMI: ANSI/AAMI RD 5: 1992, ANSI/AAMI RD 47: 1993, ANSI/AAMI RD 62:2001)
   1. Perform bacteriologic assays of water and dialysis fluids at least once a month and during outbreaks using standard quantitative methods.[792, 834, 835]
      - * Assay for heterotrophic, mesophilic bacteria (e.g., *Pseudomonas* spp).
      - * Do not use nutrient-rich media (e.g., blood agar or chocolate agar). ***Category IA, IC*** (AAMI: ANSI/AAMI RD 62:2001)
   2. In conjunction with microbiological testing, perform endotoxin testing on product water used to reprocess dialyzers for multiple use.[789, 791, 806, 811, 816, 829] ***Category IA, IC*** (AAMI: ANSI/AAMI RD 5:1992, ANSI/AAMI RD 47:1993)
   3. Ensure that water does not exceed the limits for microbial counts and endotoxin concentrations outlined in Table 18.[789, 791, 800] ***Category IA, IC*** (AAMI: ANSI/AAMI RD 5:1992, ANSI/AAMI RD 47:1993)

D. Disinfect water distribution systems in dialysis settings on a regular schedule. Monthly disinfection is recommended.[666–668, 792, 800] ***Category IA, IC*** (AAMI: ANSI/AAMI RD62:2001)

E. Whenever 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.[666–668, 792, 800] ***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 small particles and molecules ≥1 kilodalton) installed in the water line distal to the storage tank.[792] ***Category IC*** (AAMI: ANSI/AAMI RD62:2001)

D.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.[680, 863] ***Category II***
   1. Keep the ice scoop on a chain short enough the scoop cannot touch the floor, or keep the scoop on a clean, hard surface when not in use.[680, 863] ***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.[600, 863] ***Category IB***
D. Machines that dispense ice are preferred to those that require ice to be removed from bins or chests with a scoop.[687, 869] ***Category II***
E. Limit access to ice-storage chests, and keep the container doors closed except when removing ice.[863] ***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 as outlined in Box 12.[863] ***Category II***
   4. Flush and clean the 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.[861–863] ***Category IB***

D.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: ***Category II***
   1. Maintain a 15-ppm chlorine residual in the water of small hydrotherapy tanks, Hubbard tanks, and tubs.[889] ***Category II***
   2. Maintain a 2–5 ppm chlorine residual in the water of whirlpools and whirlpool spas.[905] ***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 acid level before disinfection, to enhance the biocidal activity of chlorine.[894] ***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 prior to 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 of whirlpools or spa equipment manufactured for home or recreational use. ***Unresolved issue***

D.XI. Miscellaneous Medical Equipment Connected to Water Systems

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

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.[911–915] ***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-µm filters]).[912, 914, 915, 918] ***Category IB***
   2. Dry the internal channels of the reprocessed endoscope or bronchoscope using a proven method (e.g., 70% alcohol followed by forced-air treatment) to lessen the potential for the proliferation of waterborne microorganisms and to help prevent biofilm formation.[671, 921, 923, 925, 928] ***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.[935, 936, 943, 944] ***Category IB, 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 the patient's mouth (e.g., handpieces, ultrasonic scalers, and air/water syringe).[936, 937] ***Category II***
   2. Consult with dental water-line manufacturers to
      - * determine suitable methods and equipment to obtain the recommended water quality; and
      - * determine appropriate methods for monitoring the water to ensure quality is maintained.[936, 946] ***Category II***
   3. Consult with the dental unit manufacturer on the need for periodic maintenance of anti-retraction mechanisms.[937, 946] ***Category IB***

E. Recommendations—Environmental Services

E.I. Cleaning and Disinfecting Strategies for Environmental Surfaces in Patient-Care Areas

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

A. Select EPA-registered disinfectants, if available, and use them in accordance with the manufacturer's instructions.[2, 974, 983] ***Category IB, 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 instrument/devices or any environmental surfaces; such use is counter to label instructions for these toxic chemicals.[951, 952, 961–964] ***Category IB, IC*** (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 with 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 disinfectant label instructions.[952] ***Category II***
   2. Do not use alcohol to disinfect large environmental surfaces.[951] ***Category II***
   3. Use barrier protective coverings as appropriate for noncritical equipment surfaces that are
      - * touched frequently with gloved hands during the delivery of patient care;
      - *likely to become contaminated with blood or body substances; or
      - *difficult to clean (e.g., computer keyboards).[936] ***Category II***

E. Keep housekeeping surfaces (e.g., floors, walls, and tabletops) visibly clean on a regular basis and clean up spills promptly.[954] ***Category II***
   1. Use a one-step process and an EPA-registered hospital disinfectant/detergent designed for general housekeeping purposes in patient-care areas when
      - * uncertainty exists as to the nature of the soil on these surfaces [e.g., blood or body fluid contamination versus routine dust or dirt]; or

- * uncertainty exists regarding the presence or absence of multi-drug resistant organisms on such surfaces.[952, 983, 986, 987] ***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.[2, 971, 972, 982] ***Category II***

F. Do not perform disinfectant fogging in patient-care areas.[2, 976] ***Category IB***

Environmental Fogging [December 2009]. Clarification Statement: CDC and HICPAC have recommendations in the 2003 Guidelines for Environmental Infection Control in Health-Care Facilities that state that the CDC does not support disinfectant fogging.

These recommendations refer to the spraying or fogging of chemicals (e.g., formaldehyde, phenol-based agents, or quaternary ammonium compounds) as a way to decontaminate environmental surfaces or disinfect the air in patient rooms. The recommendation against fogging was based on studies in the 1970's that reported a lack of microbicidal efficacy (e.g., use of quaternary ammonium compounds in mist applications) but also adverse effects on healthcare workers and others in facilities where these methods were utilized. Furthermore, some of these chemicals are not EPA-registered for use in fogging-type applications.

These recommendations do not apply to newer technologies involving fogging for room decontamination (e.g., ozone mists, vaporized hydrogen peroxide) that have become available since the 2003 recommendations were made. These newer technologies were assessed by CDC and HICPAC in the 2011 Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings, which makes the recommendation:

"More research is required to clarify the effectiveness and reliability of fogging, UV irradiation, and ozone mists to reduce norovirus environmental contamination. (No recommendation/ unresolved issue)"

The 2003 recommendations still apply; however, CDC does not yet make a recommendation regarding these newer technologies. This issue will be revisited as additional evidence becomes available.

G. Avoid large-surface cleaning methods that produce mists or aerosols or disperse dust in patient-care areas.[9, 20, 109, 272] ***Category IB***

H. Follow proper procedures for effective use 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.[986, 987] ***Category II***
2. Change the mop head at the beginning of the 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.[971, 988–990] ***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.[7] ***Category IB***

J. Do not use mats with tacky surfaces at the entrance to operating rooms or infection-control suites.[7] ***Category IB***

K. Use appropriate dusting methods for patient-care areas designated for immunocompromised patients (e.g., HSCT patients):[9, 94, 986] ***Category IB***

1. Wet-dust horizontal surfaces daily by moistening a cloth with a small amount of an EPA-registered hospital detergent/disinfectant.[9, 94, 986] ***Category IB***
2. Avoid dusting methods that disperse dust (e.g., feather-dusting).[94] ***Category IB***

L. Keep vacuums in good repair, and equip vacuums with HEPA filters for use in areas with patients at risk.[9, 94, 986, 994] ***Category IB***

M. Close the doors of immunocompromised patients' rooms when vacuuming, waxing, or buffing corridor floors to minimize exposure to airborne dust.[9, 94, 994] ***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 environmental surfaces by using EPA-registered disinfectants in accordance with manufacturers' instructions and safety advisories.[974, 995–997] ***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.[952, 995–997] ***Category IB***
   2. Rinse disinfectant-treated surfaces, especially those treated with phenolics, with water.[995–997] ***Category IB***

O. When using phenolic disinfectants in neonatal units, prepare solutions to correct concentrations in accordance with manufacturers' instructions, or use premixed formulations.[974, 995–997] ***Category IB, IC*** (EPA: 7 USC § 136 et seq.)

E.II. Cleaning Spills of Blood and Body Substances

A. Promptly clean and decontaminate spills of blood or other potentially infectious materials.[967, 998–1004] ***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.[967, 998–004] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.4.ii.A)
   1. Use protective gloves and other PPE appropriate for this task.[967] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.3.i, ii) 135
   2. If the spill contains large amounts of blood or body fluids, clean the visible matter with disposable absorbent material, and discard the contaminated materials in appropriate, labeled containment.[967, 1002, 1003, 1010, 1012] ***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.[967, 1010] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.4.ii.A)

C. Use EPA-registered hospital disinfectants labeled tuberculocidal or registered germicides on the EPA Lists D and 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.[967, 1007, 1010] ***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 versions of 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.[1010, 1011] ***Category II***
   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.[954, 1010] ***Category II***

E.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.[986] **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.[111] ***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, and intensive care units).[111, 1023, 1028] ***Category IB***

D. Follow proper procedures for managing spills on carpeting.
   1. Spot-clean blood or body substance spills promptly.[967, 1010, 1011, 1032] ***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 substances.[1032] ***Category IC*** (OSHA 29 CFR 1910.1030 § d.4.ii interpretation)

E. Thoroughly dry wet carpeting to prevent the growth of fungi; replace carpeting that remains wet after 72 hours.[9, 1026] ***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).[9, 111] ***Category IB***
H. Avoid the use of upholstered furniture and furnishings in high-risk patient-care areas and in areas with increased potential for body substance contamination (e.g., pediatrics units).[9] ***Category II***
I. **No recommendation is offered** regarding whether upholstered furniture and furnishings should be avoided in general patient-care areas. ***Unresolved issue***
J. Maintain upholstered furniture in good repair. ***Category II***
    1. Maintain the surface integrity of the upholstery by repairing tears and holes. ***Category II***
    2. 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 the nature of the soil. ***Category II***

E.IV. Flowers and Plants in Patient-Care Areas

A. Flowers and potted plants need not be restricted from areas for immunocompetent patients.[515, 702, 1040, 1042] ***Category II***
B. Designate care and maintenance of flowers and potted plants to staff not directly involved with patient care.[702] ***Category II***
C. If plant or flower care by patient-care staff is unavoidable, instruct the staff to wear gloves when handling the plants and flowers and perform hand hygiene after glove removal.[702] ***Category II***
D. Do not allow fresh or dried flowers, or potted plants in patient-care areas for immunosuppressed patients.[9, 109, 515, 1046] ***Category II***

E.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.[1050, 1072, 1075] ***Category II***
B. Install screens on all windows that open to the outside; keep screens in good repair.[1072] ***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.[1075] ***Category II***
D. Place laboratory specimens (e.g., fixed sputum smears) in covered containers for overnight storage.[1065, 1066] ***Category II***

E.VI. Special Pathogens

A. Use appropriate hand hygiene, PPE (e.g., gloves), and isolation precautions during cleaning and disinfecting procedures.[5, 952, 1130, 1364] ***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-resistant *Staphylococcus aureus*, or vancomycin-resistant *Enterococcus* [VRE]).[5, 1116–1118] ***Category IB***
    1. Pay close attention to cleaning and disinfection of high-touch surfaces in patient-care areas (e.g., bed rails, carts, bedside commodes, bedrails, doorknobs, or faucet handles).[5, 1116–1118] ***Category IB***
    2. Ensure compliance by housekeeping staff with cleaning and disinfection procedures.[5, 1116–1118] ***Category IB***
    3. Use EPA-registered hospital disinfectants appropriate for the surface to be disinfected (e.g., either low- or intermediate-level disinfection) as specified by the manufacturers' instructions.[974, 1106–1110, 1118] ***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) whenever possible to minimize cross-contamination with multiple-resistant microorganisms.[1102] ***Category IB***

5. Follow these same surface cleaning and disinfecting measures for managing the environment of VRSA patients.[1110, 1116–1118] ***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.[5, 1084, 1087, 1088, 1092, 1096] ***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 consultation, must supervise all environmental culturing. ***Category II***

D. Thoroughly clean and disinfect environmental and medical equipment surfaces on a regular basis using EPA-registered disinfectants in accordance with manufacturers' instructions.[952, 974, 1130, 1143] ***Category IB, IC*** (EPA: 7 USC § 136 et seq.)

E. Advise families, visitors, and patients about the importance of hand hygiene to minimize the spread of body substance contamination (e.g., respiratory secretions or fecal matter) to surfaces.[952] ***Category II***

F. Do not use high-level disinfectants (i.e., liquid chemical sterilants) on environmental surfaces; such use is inconsistent with label instructions and because of the toxicity of the chemicals.[2, 951, 952, 964] ***Category IC*** (FDA: 21 CFR 801.5, 807.87.e)

C. difficile **Update [April 2019]**

Recommendations E.VI.G. and E.VI.H. were updated to reflect changes in Federal regulatory approvals: LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).

G. Update: Use an EPA-registered product effective against *Clostridium difficile* spores for disinfection of environmental surfaces in rooms where *C. difficile* patients are treated. (New Categorization Scheme: **Recommendation**. See page 2) See LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).

H. Update: This recommendation has been superseded by recommendation E.VI.G. **See** LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores (https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).

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.[986, 1158] ***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.[967, 974, 1158] ***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 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.[951, 1199] ***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.[951, 1170, 1188, 1191, 1197–1199, 1201]

- * The contact time for the chemical used during this process should be 30 min–1 hour.[1191, 1197, 1201]
- * Blot up the chemical with absorbent material and rinse the treated surface thoroughly with water.
- * Discard the used, absorbent material into appropriate waste containment. ***Category II***

3. Use disposable, impervious covers to minimize body substance contamination to autopsy tables and surfaces.[1197, 1201] ***Category IB***

M. Use standard procedures for containment, cleaning, and decontamination of blood spills on surfaces as previously described (Environmental Services: II).[967] ***Category IC*** (OSHA: 29 CFR 1910.1030 §d.4.ii.A)

1. Wear PPE appropriate for a surface decontamination and cleaning task.[967, 1199] ***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.[967, 1199] ***Category IC*** (OSHA 29 CFR 1910.1030 §d.3.viii)

F. Recommendations—Environmental Sampling

F.I. General Information

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

A. Do not conduct random, undirected microbiologic sampling of air, water, and environmental surfaces in health-care facilities.[2, 1214] ***Category IB***

B. When indicated, conduct microbiologic sampling as part of an epidemiologic investigation or during assessment of hazardous environmental conditions to detect contamination and verify abatement of a hazard.[2, 1214] ***Category IB***

C. Limit microbiologic sampling for quality assurance purposes to

- * biological monitoring of sterilization processes;
- * monthly cultures of water and dialysate in hemodialysis units; and
- * short-term evaluation of the impact of infection-control measures or changes in infection-control protocols.[2, 1214] ***Category IB***

F.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.[945, 1214, 1223, 1224, 1238] **Category II**

B. Select a high-volume air sampling device if anticipated levels of microbial airborne contamination are expected to be low.[290, 1218, 1223, 1224] ***Category II***

C. Do not use settle plates to quantify the concentration of airborne fungal spores.[290] ***Category II***

D. When sampling water, choose growth media and incubation conditions that will facilitate the recovery of waterborne organisms.[945] ***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.[1238] ***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.[1214] ***Category II***

G. Recommendations—Laundry and Bedding

G.I. Employer Responsibilities

A. Employers must launder workers' personal protective garments or uniforms that are contaminated with blood or other potentially infectious materials.[967] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.3.iv)

G.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.[120, 1260–1262] ***Category IC*** (AIA: 7.23.B1, B2)
B. Ensure that laundry areas have handwashing facilities and products and appropriate PPE available for workers.[120, 967] ***Category IC*** (AIA: 7.23.D4; OSHA: 29 CFR 1910.1030 § d.2.iii)
C. Use and maintain laundry equipment according to manufacturers' instructions.[1250, 1263] ***Category II***
D. Do not leave damp textiles or fabrics in machines overnight.[1250] ***Category II***
E. Disinfection of washing and drying machines in residential care is not needed as long as gross soil is removed before washing and proper washing and drying procedures are used. ***Category II***

G.III. Routine Handling of Contaminated Laundry

A. Handle contaminated textiles and fabrics with minimum agitation to avoid contamination of air, surfaces, and persons.[6, 967, 1258, 1259] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.4.iv)
B. Bag or otherwise contain contaminated textiles and fabrics at the point of use.[967] ***Category IC*** (OSHA: 29 CFR 1910.1030 § d.4.iv)
    1. Do not sort or prerinse contaminated textiles or fabrics in patient-care areas.[967] ***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.[967, 1258] ***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.[967] ***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.[1253, 1267–1270] ***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 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).[1271, 1272] ***Category II***

G.IV. Laundry Process

A. If hot-water laundry cycles are used, wash with detergent in water ≥160°F (≥71°C) for ≥25 minutes.[2, 120] ***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.[1278] ***Category II***
D. Choose chemicals suitable for low-temperature washing at proper use concentration if low-temperature (<160°F [<71°C]) laundry cycles are used.[1247, 1281–1285] ***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.[2] ***Category II***

G.V. Microbiologic Sampling of Textiles

A. Do not conduct routine microbiological sampling of clean textiles.[2, 1286] ***Category IB***
B. Use microbiological sampling during outbreak investigations if epidemiologic evidence suggests a role for health-care textiles and clothing in disease transmission.[1286] ***Category IB***

G.VI. Special Laundry Situations

A. Use sterilized textiles, surgical drapes, and gowns for situations requiring sterility in patient care.[7] ***Category IB***
B. Use hygienically clean textiles (i.e., laundered, but not sterilized) in neonatal intensive care units.[997, 1288] ***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.[1289–1291] ***Category II***
E. Use caution when considering the 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 treated articles.[1306] ***Category II***
F. **No recommendation is offered** regarding using disposable fabrics and textiles versus durable goods. ***Unresolved issue***

G.VII. Mattresses and Pillows

A. Keep mattresses dry; discard them if they become and remain wet or stained, particularly in burn units.[1310–1315] ***Category IB***
B. Clean and disinfect mattress covers using EPA-registered disinfectants, if available, that are compatible with the cover materials to prevent the development of tears, cracks, or holes in the cover.[1310–1315] ***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 the mattress through the cover. ***Category II***
D. Clean and disinfect moisture-resistant mattress covers between patients using an EPA-registered product, if available.[1310–1315] ***Category IB***
E. If using a mattress cover completely made of fabric, change these covers and launder between patients.[1310–1315] ***Category IB***
F. Launder pillow covers and washable pillows in the hot-water cycle between patients or when they become contaminated with body substances.[1315] ***Category IB***

G.VIII. Air-Fluidized Beds

A. Follow manufacturers' instructions for bed maintenance and decontamination. ***Category II***
B. Change the polyester filter sheet at least weekly or as indicated by the manufacturer.[1317, 1318, 1322, 1323] ***Category II***
C. Clean and disinfect the polyester filter sheet thoroughly, especially between patients, using an EPA-registered product, if available.[1317, 1318, 1322, 1323] ***Category IB***
D. Consult the facility engineer to determine the proper location of air-fluidized beds in negative-pressure rooms.[1326] ***Category II***

H. Recommendations—Animals in Health-Care Facilities

H.I. General Infection-Control Measures for Animal Encounters

A. Minimize contact with animal saliva, dander, urine, and feces.[1365–1367] ***Category II***
B. Practice hand hygiene after any animal contact.[2, 1364] ***Category IB***
    1. Wash hands with soap and water, especially if hands are visibly soiled.[1364] ***Category IB***
    2. Use either soap and water or alcohol-based hand rubs when hands are not visibly soiled.[1364] ***Category IB***

H.II. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animal Programs

A. Avoid selection of nonhuman primates and reptiles in animal-assisted activities, animal- assisted therapy, or resident animal programs.[1360–1362] ***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 antihelminthic treatment under the regular care of a veterinarian.[1349, 1360] ***Category II***
C. Enroll animals that are trained with the assistance or under the direction of individuals who are experienced in this field.[1360] ***Category II***
D. Ensure that animals are handled by persons trained in providing activities or therapies safely, and who know the animals' health status and behavior traits.[1349, 1360] ***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.[1360] ***Category II***
    2. Report the incident promptly to appropriate authorities (e.g., infection-control staff, animal program coordinator, or local animal control).[1360] ***Category II***
    3. Promptly clean and treat scratches, bites, or other accidental breaks in the skin. ***Category II***
F. Perform an ICRA and work actively with the animal handler prior to conducting an animal-assisted activity or therapy to determine if the session should be held in a public area of the facility or in individual patient rooms. [1349, 1360] ***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.[1360] ***Category II***
    2. Groom animals to remove loose hair before a visit, or using a therapy animal cape.[1358] ***Category II***
H. Use routine cleaning protocols for housekeeping surfaces after therapy sessions. ***Category II***
I. Restrict resident animals, including fish in fish tanks, from access to or placement in 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, 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***

H.III. Protective Measures for Immunocompromised Patients

A. Advise patients to avoid contact with animal feces and body fluids such as saliva, urine, or solid litter box material.[8] ***Category II***
B. Promptly clean and treat scratches, bites, or other wounds that break the skin.[8] ***Category II***
C. Advise patients to avoid direct or indirect contact with reptiles.[1340] ***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.[1349] ***Category II***
E. **No recommendation is offered** regarding permitting pet visits to terminally ill immunosuppressed patients outside their PE units. ***Unresolved issue***

H.IV. Service Animals

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

A. Avoid providing access to nonhuman primates and reptiles as service animals.[1340, 1362] ***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.[1366, 1376] ***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, the patient, and the 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.[1376] ***Category IC*** (Justice: 28 CFR § 36.208 and App.B)

D. If a patient must be separated from his or her service animal while in the health-care facility
   - * ascertain from the person what arrangements have been made for supervision or care of the animal during this period of separation; and
   - * make appropriate arrangements to address the patient's needs in the absence of the service animal. ***Category II***

H.V. Animals as Patients in Human Health-Care Facilities

A. Develop health-care facility policies to address the treatment of animals in human healthcare facilities.
   1. Use the multidisciplinary team approach to policy development, including public media relations in order 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 case of the day for 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 using an EPA-registered product in the room after the animal is removed. ***Category II***

F. Allow sufficient ACH to clean the air and help remove airborne dander, microorganisms, and allergens [Appendix B, Table B.1.]). ***Category II***

G. Clean and disinfect using EPA-registered products or sterilize equipment that has been in contact with animals, 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***

H.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.[1395] ***Category IC*** (U.S. Department of Agriculture [USDA]: 7 USC 2131)
   1. Keep animal rooms at negative pressure relative to corridors.[1395] ***Category IC*** (USDA: 7 USC 2131)
   2. Prevent air in animal rooms from recirculating elsewhere in the health-care facility.[1395] ***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 for zoonoses with occupational health clinics in the health-care facility.[1013, 1378] ***Category IC*** (U.S. Department of Health and Human Services [DHHS]: BMBL; OSHA: 29 CFR 1910.1030.132-139)

H. Document standard operating procedures for the unit.[1013] ***Category IC*** (DHHS: BMBL)

I. Conduct routine employee training on worker safety issues relevant to the animal research facility (e.g., working safely with animals and animal handling).[1013, 1393] ***Category IC*** (DHHS: BMBL; OSHA: 29 CFR 1910.1030.132-139)

J. Use precautions to prevent the development of animal-induced asthma in animal workers.[1013] ***Category IC*** (DHHS: BMBL)

I. Recommendations—Regulated Medical Waste

I.I. Categories of Regulated Medical Waste

⚠ **Edit [February 2017]:** An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

A. Designate the following as major categories of medical waste that require special handling and disposal precautions:
- * microbiology laboratory wastes [e.g., cultures and stocks of microorganisms];
- * bulk blood, blood products, blood, and bloody body fluid specimens;
- * pathology and anatomy waste; and
- * sharps [e.g., needles and scalpels].[2] ***Category II***

B. Consult federal, state, and local regulations to determine if other waste items are considered regulated medical wastes.[967, 1407, 1408] ***Category IC*** (States; Authorities having jurisdiction [AHJ]; OSHA: 29 CFR 1910.1030 §g.2.1; U.S. Department of Transportation [DOT]: 49 CFR 171-180; U.S. Postal Service: CO23.8)

I.II. Disposal Plan for Regulated Medical Wastes

A. Develop a plan for the collection, handling, predisposal treatment, and terminal disposal of regulated medical wastes.[967, 1409] ***Category IC*** (States; AHJ; OSHA: 29 CFR 1910.1030 §g.2.i;)

B. Designate a person or persons to be responsible for establishing, monitoring, reviewing, and administering the plan. ***Category II***

I.III. Handling, Transporting, and Storing Regulated Medical Wastes

A. Inform personnel involved in the handling and disposal of potentially infective waste of the possible health and safety hazards; ensure that they are trained in appropriate handling and disposal methods.[967] ***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 as for regulated medical wastes from other patient-care areas.[2] ***Category II***

C. Use proper sharps disposal strategies.[967] ***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.[967] ***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.[967] ***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.[6, 967, 1415] ***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 that is inaccessible to vertebrate pests; use waste containers that prevent the development of noxious odors. ***Category IC*** (States; AHJ)

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; AHJ)

I.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., states, Indian Health Service [IHS], Veterans Affairs [VA]) before disposal in a sanitary landfill. ***Category IC*** (States, AHJ)

B. Follow precautions for treating microbiological wastes (e.g., amplified cultures and stocks of microorganisms).[1013] ***Category IC*** (DHHS: BMBL)
   1. Biosafety level 4 laboratories must inactivate microbiological wastes in the laboratory by using an approved inactivation method (e.g., autoclaving) before transport to and disposal in a sanitary landfill.[1013] ***Category IC*** (DHHS: BMBL)
   2. Biosafety level 3 laboratories must inactivate microbiological 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.[1013] ***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.[1013, 1419–1421] ***Category II***

D. Laboratories that isolate select agents from clinical specimens must comply with federal regulations for the receipt, transfer, management, and appropriate disposal of these agents.[1412] ***Category IC*** (DHHS: 42 CFR 73 § 73.6)

E. Sanitary sewers may be used for the 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.[1414] ***Category II***

I.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.[6, 203] ***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).[2, 6, 203] ***Category II***

C. Decontaminate bulk blood and body fluids from VHF patients using approved inactivation methods (e.g., autoclaving or chemical treatment) before disposal.[6, 203] ***Category IC, II*** (States; AHJ)

D. When discarding regulated medical waste generated during the routine (i.e., non-surgical) care of CJD patients, contain these wastes and decontaminate them using approved inactivation methods (e.g., autoclaving or incineration) appropriate for the medical waste category (e.g., blood, sharps, pathological waste).[2, 6, 948, 1199] ***Category IC, II*** (States; AHJ)

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.[1197, 1201] ***Category IB***

Part III. References

Note: The bold item in parentheses indicated the citation number or the location of this reference listed in the MMWR version of this guideline.

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Part IV. Appendices

Appendix A. Glossary of Terms

Acceptable indoor air quality: air in which there are no known contaminants at harmful concentrations as determined by knowledgeble authorities and with which a substantial majority (≥80%) of the people exposed do not express dissatisfaction.
ACGIH: American Conference of Governmental Industrial Hygienists.
Action level: the concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.
Aerosol: particles of respirable size generated by both humans and environmental sources and that have the capability of remaining viable and airborne for extended periods in the indoor environment.
AIA: American Institute of Architects, a professional group responsible for publishing the *Guidelines for Design and Construction of Hospitals and Healthcare Facilities*, a consensus document for design and construction of health-care facilities endorsed by the U.S. Department of Health and Human Services, health-care professionals, and professional organizations.
Air changes per hour (ACH): the ratio of the volume of air flowing through a space in a certain period of time (the airflow rate) to the volume of that space (the room volume). This ratio is expressed as the number of air changes per hour (ACH).
Air mixing: the degree to which air supplied to a room mixes with the air already in the room, usually expressed as a mixing factor. This factor varies from 1 (for perfect mixing) to 10 (for poor mixing). It is used as a multiplier to determine the actual airflow required (i.e., the recommended ACH multiplied by the mixing factor equals the actual ACH required).
Airborne transmission: a means of spreading infection when airborne droplet nuclei (small particle residue of evaporated droplets ≤5 μm in size containing microorganisms that remain suspended in air for long periods of time) are inhaled by the susceptible host.
Air-cleaning system: a device or combination of devices applied to reduce the concentration of airborne contaminants (e.g., microorganisms, dusts, fumes, aerosols, other particulate matter, and gases).
Air conditioning: the process of treating air to meet the requirements of a conditioned space by controlling its temperature, humidity, cleanliness, and distribution.
Allogeneic: non-twin, non-self. The term refers to transplanted tissue from a donor closely matched to a recipient but not related to that person.
Ambient air: the air surrounding an object.
Anemometer: a flow meter which measures the wind force and velocity of air. An anemometer is often used as a means of determining the volume of air being drawn into an air sampler.
Anteroom: a small room leading from a corridor into an isolation room. This room can act as an airlock, preventing the escape of contaminants from the isolation room into the corridor.
ASHE: American Society for Healthcare Engineering, an association affiliated with the American Hospital Association.
ASHRAE: American Society of Heating, Refrigerating, and Air-Conditioning Engineers Inc.
Autologous self: The term refers to transplanted tissue whose source is the same as the recipient, or an identical twin.
Automated cycler: a machine used during peritoneal dialysis which pumps fluid into and out of the patient while he/she sleeps.
Biochemical oxygen demand (BOD): a measure of the amount of oxygen removed from aquatic environments by aerobic microorganisms for their metabolic requirements. Measurement of BOD is used to determine the level of organic pollution of a stream or lake. The greater the BOD, the greater the degree of water pollution. The term is also referred to as Biological Oxygen Demand (BOD).
Biological oxygen demand (BOD): an indirect measure of the concentration of biologically degradable material present in organic wastes (pertaining to water quality). It usually reflects the amount of oxygen consumed in five days by biological processes breaking down organic waste (BOD5).
Biosafety level: a combination of microbiological practices, laboratory facilities, and safety equipment determined to be sufficient to reduce or prevent occupational exposures of laboratory personnel to the

microbiological agents they work with. There are four biosafety levels based on the hazards associated with the various microbiological agents.
BOD5: the amount of dissolved oxygen consumed in five days by biological processes breaking down organic matter.
Bonneting: a floor cleaning method for either carpeted or hard surface floors that uses a circular motion of a large fibrous disc to lift and remove soil and dust from the surface.
Capped spur: a pipe leading from the water recirculating system to an outlet that has been closed off ("capped"). A capped spur cannot be flushed, and it might not be noticed unless the surrounding wall is removed.
CFU/m^3: colony forming units per cubic meter (of air).
Chlamydospores: thick-walled, typically spherical or ovoid resting spores asexually produced by certain types of fungi from cells of the somatic hyphae.
Chloramines: compounds containing nitrogen, hydrogen, and chlorine. These are formed by the reaction between hypochlorous acid (HOCl) and ammonia (NH3) and/or organic amines in water. The formation of chloramines in drinking water treatment extends the disinfecting power of chlorine. The term is also referred to as Combined Available Chlorine.
Cleaning: the removal of visible soil and organic contamination from a device or surface, using either the physical action of scrubbing with a surfactant or detergent and water, or an energy-based process (e.g., ultrasonic cleaners) with appropriate chemical agents.
Coagulation-flocculation: coagulation is the clumping of particles that results in the settling of impurities. It may be induced by coagulants (e.g., lime, alum, and iron salts). Flocculation in water and wastewater treatment is the agglomeration or clustering of colloidal and finely-divided suspended matter after coagulation by gentle stirring by either mechanical or hydraulic means, such that they can be separated from water or sewage.
Commissioning (a room): testing a system or device to ensure that it meets the pre-use specifications as indicated by the manufacturer or predetermined standard, or air sampling in a room to establish a preoccupancy baseline standard of microbial or particulate contamination. The term is also referred to as benchmarking at 77°F (25°C).
Completely packaged: functionally packaged, as for laundry.
Conidia: asexual spores of fungi borne externally.
Conidiophores: specialized hyphae that bear conidia in fungi.
Conditioned space: that part of a building that is heated or cooled, or both, for the comfort of the occupants.
Contaminant: an unwanted airborne constituent that may reduce the acceptibility of air.
Convection: the transfer of heat or other atmospheric properties within the atmosphere or in the airspace of an enclosure by the circulation of currents from one region to another, especially by such motion directed upward.
Cooling tower: a structure engineered to receive accumulated heat from ventilation systems and equipment and transfer this heat to water, which then releases the stored heat to the atmosphere through evaporative cooling.
Critical item (medical instrument): a medical instrument or device that contacts normally sterile areas of the body or enters the vascular system. There is a high risk of infection from such devices if they are microbiologically contaminated prior to use. These devices must be sterilized before use.
Dead legs: areas in the water system where water stagnates. A dead leg is a pipe or spur, leading from the water recirculating system to an outlet that is used infrequently, resulting in inadequate flow of water from the recirculating system to the outlet. This inadequate flow reduces the perfusion of heat or chlorine into this part of the water distribution system, thereby adversely affecting the disinfection of the water system in that area.
Deionization: removal of ions from water by exchange with other ions associated with fixed charges on a resin bed. Cations are usually removed and H^+ ions are exchanged; OH^- ions are exchanged for anions.
Detritis: particulate matter produced by or remaining after the wearing away or disintegration of a substance or tissue.
Dew point: the temperature at which a gas or vapor condenses to form a liquid; the point at which moisture begins to condense out of the air. At dew point, air is cooled to the point where it is at 100% relative humidity or saturation.

Dialysate: the aqueous electrolyte solution, usually containing dextrose, used to make a concentration gradient between the solution and blood in the hemodialyzer (dialyzer).
Dialyzer: a device that consists of two compartments (blood and dialysate) separated by a semipermeable membrane. A dialyzer is usually referred to as an artificial kidney.
Diffuser: the grille plate that disperses the air stream coming into the conditioned air space.
Direct transmission: involves direct body surface-to-body surface contact and physical transfer of microorganisms between a susceptible host and an infected/colonized person, or exposure to cloud of infectious particles within 3 feet of the source; the aerosolized particles are >5 μm in size.
Disability: as defined by the Americans with Disabilities Act, a disability is any physical or mental impairment that substantially limits one or more major life activities, including but not limited to walking, talking, seeing, breathing, hearing, or caring for oneself.
Disinfection: a generally less lethal process of microbial inactivation (compared to sterilization) that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).
Drain pans: pans that collect water within the HVAC system and remove it from the system. Condensation results when air and steam come together.
Drift: circulating water lost from the cooling tower in the form as liquid droplets entrained in the exhaust air stream (i.e., exhaust aerosols from a cooling tower).
Drift eliminators: an assembly of baffles or labyrinth passages through which the air passes prior to its exit from the cooling tower. The purpose of a drift eliminator is to remove entrained water droplets from the exhaust air.
Droplets: particles of moisture, such as are generated when a person coughs or sneezes, or when water is converted to a fine mist by a device such as an aerator or shower head. These particles may contain infectious microorganisms. Intermediate in size between drops and droplet nuclei, these particles tend to quickly settle out from the air so that any risk of disease transmission is generally limited to persons in close proximity to the droplet source.
Droplet nuclei: sufficiently small particles (1–5 μm in diameter) that can remain airborne indefinitely and cause infection when a susceptible person is exposed at or beyond 3 feet of the source of these particles.
Dual duct system: an HVAC system that consists of parallel ducts that produce a cold air stream in one and a hot air stream in the other.
Dust: an air suspension of particles (aerosol) of any solid material, usually with particle sizes ≤100 μm in diameter.
Dust-spot test: a procedure that uses atmospheric air or a defined dust to measure a filter's ability to remove particles. A photometer is used to measure air samples on either side of the filter, and the difference is expressed as a percentage of particles removed.
Effective leakage area: the area through which air can enter or leave the room. This does not include supply, return, or exhaust ducts. The smaller the effective leakage area, the better isolated the room.
Endotoxin: the lipopolysaccharides of gram-negative bacteria, the toxic character of which resides in the lipid portion. Endotoxins generally produce pyrogenic reactions in persons exposed to these bacterial components.
Enveloped virus: a virus whose outer surface is derived from a membrane of the host cell (either nuclear or the cell's outer membrane) during the budding phase of the maturation process. This membrane-derived material contains lipid, a component that makes these viruses sensitive to the action of chemical germicides.
Evaporative condenser: a wet-type, heat-rejection unit that produces large volumes of aerosols during the process of removing heat from conditioned space air.
Exhaust air: air removed from a space and not reused therein.
Exposure: the condition of being subjected to something (e.g., infectious agents) that could have a harmful effect.
Fastidious: having complex nutritional requirements for growth, as in microorganisms.
Fill: that portion of a cooling tower which makes up its primary heat transfer surface. Fill is alternatively known as "packing."
Finished water: treated, or potable water.
Fixed room-air HEPA recirculation systems: nonmobile devices or systems that remove airborne contaminants by recirculating air through a HEPA filter. These may be built into the room and permanently

ducted or may be mounted to the wall or ceiling within the room. In either situation, they are fixed in place and are not easily movable.
Fomite: an inanimate object that may be contaminated with microorganisms and serves in their transmission.
Free and available chlorine: the term applied to the three forms of chlorine that may be found in solution (i.e., chlorine [Cl2], hypochlorite [OCl^-], and hypochlorous acid [HOCl]).
Germicide: a chemical that destroys microorganisms. Germicides may be used to inactivate microorganisms in or on living tissue (antiseptics) or on environmental surfaces (disinfectants).
Health-care associated: an outcome, usually an infection, that occurs in any health-care facility as a result of medical care. The term "health-care associated" replaces "nosocomial," the latter term being limited to adverse infectious outcomes occurring only in hospitals.
Hemodiafiltration: a form of renal replacement therapy in which waste solutes in the patient's blood are removed by both diffusion and convection through a high-flux membrane.
Hemodialysis: a treatment for renal replacement therapy in which waste solutes in the patient's blood are removed by diffusion and/or convection through the semipermeable membrane of an artificial kidney or dialyzer.
Hemofiltration: cleansing of waste products or other toxins from the blood by convection across a semipermeable, high-flux membrane where fluid balance is maintained by infusion of sterile, pyrogenfree substitution fluid pre- or post-hemodialyzer.
HEPA filter: High Efficiency Particulate Air filters capable of removing 99.97% of particles 0.3 μm in diameter and may assist in controlling the transmission of airborne disease agents. These filters may be used in ventilation systems to remove particles from the air or in personal respirators to filter air before it is inhaled by the person wearing the respirator. The use of HEPA filters in ventilation systems requires expertise in installation and maintenance. To test this type of filter, 0.3 μm particles of dioctylphthalate (DOP) are drawn through the filter. Efficiency is calculated by comparing the downstream and upstream particle counts. The optimal HEPA filter allows only three particles to pass through for every 10,000 particles that are fed to the filter.
Heterotrophic (heterotroph): that which requires some nutrient components from exogenous sources. Heterotrophic bacteria cannot synthesize all of their metabolites and therefore require certain nutrients from other sources.
High-efficiency filter: a filter with a particle-removal efficiency of 90%–95%.
High flux: a type of dialyzer or hemodialysis treatment in which large molecules (>8,000 daltons [e.g., β2 microglobulin]) are removed from blood.
High-level disinfection: a disinfection process that inactivates vegetative bacteria, mycobacteria, fungi, and viruses, but not necessarily high numbers of bacterial spores.
Housekeeping surfaces: environmental surfaces (e.g., floors, walls, ceilings, and tabletops) that are not involved in direct delivery of patient care in health-care facilities.
Hoyer lift: an apparatus that facilitates the repositioning of the non-ambulatory patient from bed to wheelchair or gurney and subsequently to therapy equipment (immersion tanks).
Hubbard tank: a tank used in hydrotherapy that may accomodate whole-body immersion (e.g., as may be indicated for burn therapy). Use of a Hubbard tank has been replaced largely by bedside post-lavage therapy for wound care management.
HVAC: Heating, Ventilation, Air Conditioning.
Iatrogenic: induced in a patient by a physician's activity, manner, or therapy. The term is used especially in reference to an infectious complication or other adverse outcome of medical treatment.
Impactor: an air-sampling device in which particles and microorganisms are directed onto a solid surface and retained there for assay.
Impingement: an air-sampling method during which particles and microorganisms are directed into a liquid and retained there for assay.
Indirect transmission: involves contact of a susceptible host with a contaminated intermediate object, usually inanimate (a fomite).
Induction unit: the terminal unit of an in-room ventilation system. Induction units take centrally conditioned air and further moderate its temperature. Induction units are not appropriate for areas with high exhaust requirements (e.g., research laboratories).

Intermediate-level disinfection: a disinfection process that inactivates vegetative bacteria, most fungi, mycobacteria, and most viruses (particularly the enveloped viruses), but does not inactivate bacterial spores.
Isoform: a possible configuration (tertiary structure) of a protein molecule. With respect to prion proteins, the molecules with large amounts of α-conformation are the normal isoform of that particular protein, whereas those prions with large amounts of β-sheet conformation are the proteins associated with the development of spongiform encephalopathy (e.g., Creutzfeldt-Jakob disease [CJD]).
Laminar flow: HEPA-filtered air that is blown into a room at a rate of 90 ± 10 feet/min in a unidirectional pattern with 100 ACH–400 ACH.
Large enveloped virus: viruses whose particle diameter is >50 nm and whose outer surface is covered by a lipid-containing structure derived from the membranes of the host cells. Examples of large enveloped viruses include influenza viruses, herpes simplex viruses, and poxviruses.
Laser plume: the transfer of electromagnetic energy into tissues which results in a release of particles, gases, and tissue debris.
Lipid-containing viruses: viruses whose particle contains lipid components. The term is generally synonymous with enveloped viruses whose outer surface is derived from host cell membranes. Lipid-containing viruses are sensitive to the inactivating effects of liquid chemical germicides.
Lithotriptors: instruments used for crushing caliculi (i.e., calcified stones, and sand) in the bladder or kidneys.
Low efficiency filter: the prefilter with a particle-removal efficiency of approximately 30% through which incoming air first passes. See also Prefilter.
Low-level disinfection: a disinfection process that will inactivate most vegetative bacteria, some fungi, and some viruses, but cannot be relied upon to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores).
Makeup air: outdoor air supplied to the ventilation system to replace exhaust air.
Makeup water: a cold water supply source for a cooling tower.
Manometer: a device that measures the pressure of liquids and gases. A manometer is used to verify air filter performance by measuring pressure differentials on either side of the filter.
Membrane filtration: an assay method suitable for recovery and enumeration of microorganisms from liquid samples. This method is used when sample volume is large and anticipated microbial contamination levels are low.
Mesophilic: that which favors a moderate temperature. For mesophilic bacteria, a temperature range of 68°F–131°F (20°C–55°C) is favorable for their growth and proliferation.
Mixing box: the site where the cold and hot air streams mix in the HVAC system, usually situated close to the air outlet for the room.
Mixing faucet: a faucet that mixes hot and cold water to produce water at a desired temperature.
MMAD: Mass Median Aerodynamic Diameter. This is the unit used by ACGIH to describe the size of particles when particulate air sampling is conducted.
Moniliaceous: hyaline or brightly colored. This is a laboratory term for the distinctive characteristics of certain opportunistic fungi in culture (e.g., *Aspergillus* spp. and *Fusarium* spp.).
Monochloramine: the result of the reaction between chlorine and ammonia that contains only one chlorine atom. Monochloramine is used by municipal water systems as a water treatment.
Natural ventilation: the movement of outdoor air into a space through intentionally provided openings (i.e., windows, doors, or nonpowered ventilators).
Negative pressure: air pressure differential between two adjacent airspaces such that air flow is directed into the room relative to the corridor ventilation (i.e., room air is prevented from flowing out of the room and into adjacent areas).
Neutropenia: a medical condition in which the patient's concentration of neutrophils is substantially less than that in the normal range. Severe neutropenia occurs when the concentration is <1,000 polymorphonuclear cells/μL for 2 weeks or <100 polymorphonuclear cells /mL for 1 week, particularly for hematopoietic stem cell transplant (HSCT) recipients.
Noncritical devices: medical devices or surfaces that come into contact with only intact skin. The risk of infection from use of these devices is low.

Non-enveloped virus: a virus whose particle is not covered by a structure derived from a membrane of the host cell. Non-enveloped viruses have little or no lipid compounds in their biochemical composition, a characteristic that is significant to their inherent resistance to the action of chemical germicides.
Nosocomial: an occurrence, usually an infection, that is acquired in a hospital as a result of medical care.
NTM: nontuberculous mycobacteria. These organisms are also known as atypical mycobacteria, or as "Mycobacteria other than tuberculosis" (MOTT). This descriptive term refers to any of the fast- or slow-growing *Mycobacterium* spp. found in primarily in natural or man-made waters, but it excludes *Mycobacterium tuberculosis* and its variants.
Nuisance dust: generally innocuous dust, not recognized as the direct cause of serious pathological conditions.
Oocysts: a cyst in which sporozoites are formed; a reproductive aspect of the life cycle of a number of parasitic agents (e.g., *Cryptosporidium* spp., and *Cyclospora* spp.).
Outdoor air: air taken from the external atmosphere and, therefore, not previously circulated through the ventilation system.
Parallel streamlines: a unidirectional airflow pattern achieved in a laminar flow setting, characterized by little or no mixing of air.
Particulate matter (particles): a state of matter in which solid or liquid substances exist in the form of aggregated molecules or particles. Airborne particulate matter is typically in the size range of 0.01–100 μm diameter.
Pasteurization: a disinfecting method for liquids during which the liquids are heated to 140°F (60°C) for a short time (≥30 mins.) to significantly reduce the numbers of pathogenic or spoilage microorganisms.
Plinth: a treatment table or a piece of equipment used to reposition the patient for treatment.
Portable room-air HEPA recirculation units: free-standing portable devices that remove airborne contaminants by recirculating air through a HEPA filter.
Positive pressure: air pressure differential between two adjacent air spaces such that air flow is directed from the room relative to the corridor ventilation (i.e., air from corridors and adjacent areas is prevented from entering the room).
Potable (drinking) water: water that is fit to drink. The microbiological quality of this water as defined by EPA microbiological standards from the Surface Water Treatment Rule:
a. *Giardia lamblia*: 99.9% killed/inactivated
b. viruses: 99.9% inactivated;
c. *Legionella* spp.: no limit, but if *Giardia* and viruses are inactivated, *Legionella* will also be controlled;
d. heterotrophic plate count [HPC]: ≤500 CFU/mL; and
e. >5% of water samples total coliform-positive in a month.
PPE: Personal Protective Equipment.
ppm: parts per million. The term is a measure of concentration in solution. Chlorine bleaches (undiluted) that are available in the U.S. (5.25%–6.15% sodium hypochlorite) contain approximately 50,000–61,500 parts per million of free and available chlorine.
Prefilter: the first filter for incoming fresh air in a HVAC system. This filter is approximately 30% efficient in removing particles from the air. See also Low-Efficiency Filter.
Prion: a class of agent associated with the transmission of diseases knowns as transmissible spongiform encephalopathies (TSEs). Prions are considered to consist of protein only, and the abnormal isoform of this protein is thought to be the agent that causes diseases such as Creutzfeldt-Jakob disease (CJD), kuru, scrapie, bovine spongiform encephalopathy (BSE), and the human version of BSE which is variant CJD (vCJD).
Product water: water produced by a water treatment system or individual component of that system.
Protective environment: a special care area, usually in a hospital, designed to prevent transmission of opportunistic airborne pathogens to severely immunosuppressed patients.
Pseudoepidemic (pseudo-outbreak): a cluster of positive microbiologic cultures in the absence of clinical disease. A pseudoepidemic usually results from contamination of the laboratory apparatus and process used to recover microorganisms.
Pyrogenic: an endotoxin burden such that a patient would receive ≥5 endotoxin units (EU) per kilogram of body weight per hour, thereby causing a febrile response. In dialysis this usually refers to water or dialysate having endotoxin concentrations of ≥5 EU/mL.

Rank order: a strategy for assessing overall indoor air quality and filter performance by comparing airborne particle counts from lowest to highest (i.e., from the best filtered air spaces to those with the least filtration).
RAPD: a method of genotyping microorganisms by randomly amplified polymorphic DNA. This is one version of the polymerase chain reaction method.
Recirculated air: air removed from the conditioned space and intended for reuse as supply air.
Relative humidity: the ratio of the amount of water vapor in the atmosphere to the amount necessary for saturation at the same temperature. Relative humidity is expressed in terms of percent and measures the percentage of saturation. At 100% relative humidity, the air is saturated. The relative humidity decreases when the temperature is increased without changing the amount of moisture in the air.
Reprocessing (of medical instruments): the procedures or steps taken to make a medical instrument safe for use on the next patient. Reprocessing encompasses both cleaning and the final or terminal step (i.e., sterilization or disinfection) which is determined by the intended use of the instrument according to the Spaulding classification.
Residuals: the presence and concentration of a chemical in media (e.g., water) or on a surface after the chemical has been added.
Reservoir: a nonclinical source of infection.
Respirable particles: those particles that penetrate into and are deposited in the nonciliated portion of the lung. Particles >10 μm in diameter are not respirable.
Return air: air removed from a space to be then recirculated.
Reverse osmosis (RO): an advanced method of water or wastewater treatment that relies on a semipermeable membrane to separate waters from pollutants. An external force is used to reverse the normal osmotic process resulting in the solvent moving from a solution of higher concentration to one of lower concentration.
Riser: water piping that connects the circulating water supply line, from the level of the base of the tower or supply header, to the tower's distribution system.
RODAC: Replicate Organism Direct Agar Contact. This term refers to a nutrient agar plate whose convex agar surface is directly pressed onto an environmental surface for the purpose of microbiologic sampling of that surface.
Room-air HEPA recirculation systems and units: devices (either fixed or portable) that remove airborne contaminants by recirculating air through a HEPA filter.
Routine sampling: environmental sampling conducted without a specific, intended purpose and with no action plan dependent on the results obtained.
Sanitizer: an agent that reduces microbial contamination to safe levels as judged by public health standards or requirements.
Saprophytic: a naturally-occurring microbial contaminant.
Sedimentation: the act or process of depositing sediment from suspension in water. The term also refers to the process whereby solids settle out of wastewater by gravity during treatment.
Semicritical devices: medical devices that come into contact with mucous membranes or non-intact skin.
Service animal: any animal individually trained to do work or perform tasks for the benefit of a person with a disability.
Shedding: the generation and dispersion of particles and spores by sources within the patient area, through activities such as patient movement and airflow over surfaces.
Single-pass ventilation: ventilation in which 100% of the air supplied to an area is exhausted to the outside.
Small, non-enveloped viruses: viruses whose particle diameter is <50 nm and whose outer surface is the protein of the particle itself and not that of host cell membrane components. Examples of small, non-enveloped viruses are polioviruses and hepatitis A virus.
Spaulding Classification: the categorization of inanimate medical device surfaces in the medical environment as proposed in 1972 by Dr. Earle Spaulding. Surfaces are divided into three general categories, based on the theoretical risk of infection if the surfaces are contaminated at time of use. The categories are "critical," "semicritical," and "noncritical."
Specific humidity: the mass of water vapor per unit mass of moist air. It is expressed as grains of water per pound of dry air, or pounds of water per pound of dry air. The specific humidity changes as moisture is added or removed. However, temperature changes do not change the specific humidity unless the air is cooled below the dew point.

Splatter: visible drops of liquid or body fluid that are expelled forcibly into the air and settle out quickly, as distinguished from particles of an aerosol which remain airborne indefinitely.
Steady state: the usual state of an area.
Sterilization: the use of a physical or chemical procedure to destroy all microbial life, including large numbers of highly-resistant bacterial endospores.
Stop valve: a valve that regulates the flow of fluid through a pipe. The term may also refer to a faucet.
Substitution fluid: fluid that is used for fluid management of patients receiving hemodiafiltration. This fluid can be prepared on-line at the machine through a series of ultrafilters or with the use of sterile peritoneal dialysis fluid.
Supply air: air that is delivered to the conditioned space and used for ventilation, heating, cooling, humidification, or dehumidification.
Tensile strength: the resistance of a material to a force tending to tear it apart, measured as the maximum tension the material can withstand without tearing.
Therapy animal: an animal (usually a personal pet) that, with their owners or handlers, provide supervised, goal-directed intervention to clients in hospitals, nursing homes, special-population schools, and other treatment sites.
Thermophilic: capable of growing in environments warmer than body temperature.
Thermotolerant: capable of withstanding high temperature conditions.
TLV®: an exposure level under which most people can work consistently for 8 hours a day, day after day, without adverse effects. The term is used by the ACGIH to designate degree of exposure to contaminants. TLV® can be expressed as approximate milligrams of particulate per cubic meter of air (mg/m^3). TLVs® are listed as either an 8-hour TWA (time weighted average) or a 15-minute STEL (short term exposure limit).
TLV-TWA: Threshold Limit Value-Time Weighted Average. The term refers to the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek to which nearly all workers may be exposed repeatedly, day after day, without adverse effects. The TLV-TWA for "particulates (insoluble) not otherwise classified" (PNOC) - (sometimes referred to as nuisance dust) - are those particulates containing no asbestos and <1% crystalline silica. A TLV-TWA of 10 mg/m^3 for inhalable particulates and a TLV-TWA of 3 mg/m^3 for respirable particulates (particulates ≤5 m in aerodynamic diameter) have been established.
Total suspended particulate matter: the mass of particles suspended in a unit of volume of air when collected by a high-volume air sampler.
Transient: a change in the condition of the steady state that takes a very short time compared with the steady state. Opening a door, and shaking bed linens are examples of transient activities.
TWA: average exposure for an individual over a given working period, as determined by sampling at given times during the period. TWA is usually presented as the average concentration over an 8-hour workday for a 40-hour workweek.
Ultraclean air: air in laminar flow ventilation that has also passed through a bank of HEPA filters.
Ultrafilter: a membrane filter with a pore size in the range of 0.001–0.05 μm, the performance of which is usually rated in terms of a nominal molecular weight cut-off (defined as the smallest molecular weight species for which the filter membrance has more than 90% rejection).
Ultrafiltered dialysate: the process by which dialysate is passed through a filter having a molecular weight cut-off of approximately 1 kilodalton for the purpose of removing bacteria and endotoxin from the bath.
Ultraviolet germicidal irradiation (UVGI): the use of ultraviolet radiation to kill or inactivate microorganisms.
Ultraviolet germicidal irradiation lamps: lamps that kill or inactivate microorganisms by emitting ultraviolet germicidal radiation, predominantly at a wavelength of 254 nm. UVGI lamps can be used in ceiling or wall fixtures or within air ducts of ventilation systems.
Vapor pressure: the pressure exerted by free molecules at the surface of a solid or liquid. Vapor pressure is a function of temperature, increasing as the temperature rises.
Vegetative bacteria: bacteria that are actively growing and metabolizing, as opposed to a bacterial state of quiescence that is achieved when certain bacteria (gram-positive bacilli) convert to spores when the environment can no longer support active growth.
Vehicle: any object, person, surface, fomite, or media that may carry and transfer infectious microorganisms from one site to another.

Ventilation: the process of supplying and removing air by natural or mechanical means to and from any space. Such air may or may not be conditioned.
Ventilation air: that portion of the supply air consisting of outdoor air plus any recirculated air that has been treated for the purpose of maintaining acceptable indoor air quality.
Ventilation, dilution: an engineering control technique to dilute and remove airborne contaminants by the flow of air into and out of an area. Air that contains droplet nuclei is removed and replaced by contaminant-free air. If the flow is sufficient, droplet nuclei become dispersed, and their concentration in the air is diminished.
Ventilation, local exhaust: ventilation used to capture and removed airborne contaminants by enclosing the contaminant source (the patient) or by placing an exhaust hood close to the contaminant source.
v/v: volume to volume. This term is an expression of concentration of a percentage solution when the principle component is added as a liquid to the diluent.
w/v: weight to volume. This term is an expression of concentration of a percentage solution when the principle component is added as a solid to the diluent.
Weight-arrestance: a measure of filter efficiency, used primarily when describing the performance of low- and medium-efficiency filters. The measurement of weight-arrestance is performed by feeding a standardized synthetic dust to the filter and weighing the fraction of the dust removed.

Appendix B. Air

1. 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

* This table is revised from Table S3-1 in reference 4 and has been adapted from the formula for the rate of purging airborne contaminants presented in reference 1435.
\+ Denotes frequently cited ACH for patient-care areas.
§ Values were derived from the formula:

$$t_2 - t_1 = \frac{-\ln\left(C_2/C_1\right)}{\left(Q/V\right)} \times 60$$

where
t1 = initial timepoint in minutes
t2 = final timepoint in minutes
C1 = initial concentration of contaminant
C2 = final concentration of contaminant
C2 / C1 = 1 – (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.[213] Caution should be exercised in using this table in such situations. For booths or other local ventilation enclosures, manufacturers' instructions should be consulted.

2. Air Sampling for Aerosols Containing Legionellae

Air sampling is an insensitive means of detecting *Legionella pneumophila,* and is of limited practical value in environmental sampling for this pathogen. In certain instances, however, it can be used to

a. demonstrate the presence of legionellae in aerosol droplets associated with suspected bacterial reservoirs
b. define the role of certain devices [e.g., showers, faucets, decorative fountains, or evaporate condensers] in disease transmission; and
c. quantitate and determine the size of the droplets containing legionellae.[1436] Stringent controls and calibration are necessary when sampling is used to determine particle size and numbers of viable bacteria.[1437] Samplers should be placed in locations where human exposure to aerosols is anticipated, and investigators should wear a NIOSH-approved respirator (e.g., N95 respirator) if sampling involves exposure to potentially infectious aerosols.

Methods used to sample air for legionellae include impingement in liquid, impaction on solid medium, and sedimentation using settle plates.[1436] The Chemical Corps.-type all-glass impingers (AGI) with the stem 30 mm from the bottom of the flask have been used successfully to sample for legionellae.[1436] Because of the velocity at which air samples are collected, clumps tend to become fragmented, leading to a more accurate count of bacteria present in the air. The disadvantages of this method are

a. the velocity of collection tends to destroy some vegetative cells
b. the method does not differentiate particle sizes; and
c. AGIs are easily broken in the field.

Yeast extract broth (0.25%) is the recommended liquid medium for AGI sampling of legionellae;[1437] standard methods for water samples can be used to culture these samples.

Andersen samplers are viable particle samplers in which particles pass through jet orifices of decreasing size in cascade fashion until they impact on an agar surface.[1218] The agar plates are then removed and incubated. The stage distribution of the legionellae should indicate the extent to which the bacteria would have penetrated the respiratory system. The advantages of this sampling method are

a. the equipment is more durable during use
b. the sampler can cetermine the number and size of droplets containing legionellae;
c. the agar plates can be placed directly in an incubator with no further manipulations; and
d. both selective and nonselective BCYE agar can be used. If the samples must be shipped to a laboratory, they should be packed and shipped without refrigeration as soon as possible.

3. Calculation of Air Sampling Results

Assuming that each colony on the agar plate is the growth from a single bacteria-carrying particle, the contamination of the air being sampled is determined from the number of colonies counted. The airborne microorganisms may be reported in terms of the number per cubic foot of air sampled. The following formulas can be applied to convert colony counts to organisms per cubic foot of air sampled.[1218]

For solid agar impactor samplers:

$C / (R\ H\ P) = N$ where N = number of organisms collected per cubic foot of air sampled
C = total plate count
R = airflow rate in cubic feet per minute
P = duration of sampling period in minutes

For liquid impingers:

$(C\ H\ V) / (Q\ H\ P\ H\ R) = N$ where C = total number of colonies from all aliquots plated
V = final volume in mL of collecting media
Q = total number of mL plated
P, R, and N are defined as above

4. Ventilation Specifications for Health-Care Facilities

The following tables from the AIA *Guidelines for Design and Construction of Hospitals and Health-Care Facilities, 2001* are reprinted with permission of the American Institute of Architects and the publisher (The Facilities Guidelines Institute).[120]

Note: This table is Table 7.2 in the AIA guidelines, 2001 edition. Superscripts used in this table refer to notes following the table.

Table B.2. Ventilation requirements for areas affecting patient care in hospitals and outpatient facilities[1]

Area designation	Air movement relationship to adjacent area[2]	Minimum air changes of outdoor air per hour[3]	Minimum total air change per hour [4,5]	All air exhausted directly to outdoors[6]	Recirculated by means of room units[7]	Relative humidity[8] (%)	Design temperature[9] (degrees F [C])
Surgery and critical care							
Operating/surgical cystoscopic rooms[10, 11]	Out	3	15	–	No	30–60	68–73 (20–23)[12]
Delivery room[10]	Out	3	15	–	No	30–60	68–73 (20–23)
Recovery room[10]	–	2	6	–	No	30–60	70–75 (21–24)
Critical and intensive care	–	2	6	–	No	30–60	70–75 (21–24)
Newborn intensive care	–	2	6	–	No	30–60	72–78 (22–26)
Treatment room[13]	–	–	6	–	–	–	75 (24)
Trauma room[13]	Out	3	15	–	No	30–60	70–75 (21–24)
Anesthesia gas storage	In	–	8	Yes	–	–	–
Endoscopy	In	2	6	–	No	30–60	68–73 (20–23)
Bronchoscopy[11]	In	2	12	Yes	No	30–60	68–73 (20–23)
ER waiting rooms	In	2	12	Yes[14, 15]	–	–	70–75 (21–24)
Triage	In	2	12	Yes[14]	–	–	70–75 (21–24)
Radiology waiting rooms	In	2	12	Yes[14, 15]	–	–	70–75 (21–24)
Procedure room	Out	3	15	–	No	30–60	70–75 (21–24)
Nursing							
Patient room	–	2	6[16]	–	–	–	70–75 (21–24)
Toilet room	In	–	10	Yes	–	–	–
Newborn nursery suite	–	2	6	–	No	30–60	72–78 (22–26)
Protective environment room[11, 17]	Out	2	12	–	No	–	75 (24)
Airborne infection isolation room[17, 18]	In	2	12	Yes[15]	No	–	75 (24)
Isolation alcove or anteroom[17, 18]	In/Out	–	10	Yes	No	–	–
Labor/delivery/recovery	–	2	6[16]	–	–	–	70–75 (21–24)
Labor/delivery/recovery/ postpartum	–	2	6[16]	–	–	–	70–75 (21–24)
Patient corridor	–	–	2	–	–	–	–
Ancillary							
Radiology[19]							
X-ray (surgical/critical care and catheterization)	Out	3	15	–	No	30-60	70–75 (21–24)
X-ray (diagnostic & treatment)	–	–	6	–	–	–	75 (24)
Darkroom	In	–	10	Yes	No	–	–

Area designation	Air movement relationship to adjacent area[2]	Minimum air changes of outdoor air per hour[3]	Minimum total air change per hour [4,5]	All air exhausted directly to outdoors[6]	Recirculated by means of room units[7]	Relative humidity[8] (%)	Design temperature[9] (degrees F [C])
Laboratory							
General[19]	–	–	6	–	–	–	75 (24)
Biochemistry[19]	Out	–	6	–	No	–	75 (24)
Cytology	In	–	6	Yes	No	–	75 (24)
Glass washing	In	–	10	Yes	–	–	75 (24)
Histology	In	–	6	Yes	No	–	75 (24)
Microbiology[19]	In	–	6	Yes	No	–	75 (24)
Nuclear medicine	In	–	6	Yes	No	–	75 (24)
Pathology	In	–	6	Yes	No	–	75 (24)
Serology	Out	–	6	–	No	–	75 (24)
Sterilizing	In		10	Yes	–	–	–
Autopsy room[11]	In	–	12	Yes	No	–	–
Nonrefrigerated body-holding room	In	–	10	Yes	–	–	70 (21)
Pharmacy	Out	–	4	–	–	–	–
Diagnostic and treatment							
Examination room	–	–	6	–	–	–	75 (24)
Medication room	Out	–	4	–	–	–	–
Treatment room	–	–	6	–	–	–	75 (24)
Physical therapy and hydrotherapy	In	–	6	–	–	–	75 (24)
Soiled workroom or soiled holding	In	–	10	Yes	No	–	–
Clean workroom or clean holding	Out	–	4	–	–	–	–
Sterilizing and supply							
ETO-sterilizer room	In	–	10	Yes	No	30-60	75 (24)
Sterilizer equipment room	In	–	10	Yes	–	–	–
Central medical and surgical supply							
Soiled or decontamination room	In	–	6	Yes	No	–	68–73 (20–23)
Clean workroom	Out	–	4	–	No	–	75 (24)
Sterile storage	Out	–	4	–	–	30-60	–
Service							
Food preparation center[20]	–	–	10	–	No	–	–
Ware washing	In	–	10	Yes	No	–	–
Dietary day storage	In	–	2	–	–	–	–
Laundry, general	–	–	10	Yes	–	–	–
Soiled linen (sorting and storage)	In	–	10	Yes	No	–	–
Clean linen storage	Out	–	2	–	–	–	–
Soiled linen and trash chute room	In	–	10	Yes	No	–	–
Bedpan room	In	–	10	Yes	–	–	–
Bathroom	In	–	10	–	–	–	75 (24)
Janitor’s closet	In	–	10	Yes	No	–	–

Notes:

1. The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of acute care hospitals that directly affect patient care and are determined based on health-care facilities being predominantly “No Smoking” facilities. Where smoking may be allowed, ventilation rates will need adjustment. Areas where specific ventilation rates are not given in the table shall be ventilated in accordance with ASHRAE Standard 62, *Ventilation for Acceptable Indoor Air Quality*, and ASHRAE *Handbook - HVAC Applications*. Specialized patient care areas, including organ transplant units, burn units, specialty procedure rooms, etc., shall have additional ventilation provisions for air quality control as may be appropriate. OSHA standards and/or NIOSH criteria require special ventilation requirements for employee health and safety within health-care facilities.
2. Design of the ventilation system shall provide air movement which is generally from clean to less clean areas. If any form of variable air volume or load shedding system is used for energy conservation, it must not compromise the corridor-to-room pressure balancing relationships or the minimum air changes required by the table.
3. To satisfy exhaust needs, replacement air from the outside is necessary. Table B2 does not attempt to describe specific amounts of outside air to be supplied to individual spaces except for certain areas such as those listed. Distribution of the outside air, added to the system to balance required exhaust, shall be as required by good engineering practice. Minimum outside air quantities shall remain constant while the system is in operation.
4. Number of air changes may be reduced when the room is unoccupied if provisions are made to ensure that the number of air changes indicated is reestablished any time the space is being utilized. Adjustments shall include provisions so that the direction of air movement shall remain the same when the number of air changes is reduced. Areas not indicated as having continuous directional control may have ventilation systems shut down when space is unoccupied and ventilation is not otherwise needed, if the maximum infiltration or exfiltration permitted in Note 2 is not exceeded and if adjacent pressure balancing relationships are not compromised. Air quantity calculations must account for filter loading such that the indicated air change rates are provided up until the time of filter change-out.
5. Air change requirements indicated are minimum values. Higher values should be used when required to maintain indicated room conditions (temperature and jumidity), based on the cooling load of the space (lights, equipment, people, exterior walls and windows, etc.).
6. Air from areas with contamination and/or odor problems shall be exhausted to the outside and not recirculated to other areas. Note that individual circumstances may require special consideration for air exhaust to the outside, (e.g., in intensive care units in which patients with pulmonary infection are treated) and rooms for burn patients.
7. Recirculating room HVAC units refer to those local units that are used primarily for heating and cooling of air, and not disinfection of air. Because of cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked “No.” However, for airborne infection control, air may be recirculated within individual isolation rooms if HEPA filters are used. Isolation and intensive care unit rooms may be ventilated by reheat induction units in which only the primary air supplied from a central system passes through the reheat unit. Gravity-type heating or cooling units such as radiators or convectors shall not be used in operating rooms and other special care areas. See this table’s Appendix I for a description of recirculation units to be used in isolation rooms (A7).
8. The ranges listed are the minimum and maximum limits where control is specifically needed. The maximum and minimum limits are not intended to be independent of a space’s associated temperature. The humidity is expected to be at the higher end of the range when the temperature is also at the higher end, and vice versa.
9. Where temperature ranges are indicated, the systems shall be capable of maintaining the rooms at any point within the range during normal operation. A single figure indicates a heating or cooling capacity of at least the indicated temperature. This is usually applicable when patients may be undressed

and require a warmer environment. Nothing in these guidelines shall be construed as precluding the use of temperatures lower than those noted when the patients' comfort and medical conditions make lower temperatures desirable. Unoccupied areas such as storage rooms shall have temperatures appropriate for the function intended.

10. National Institute for Occupational Safety and Health (NIOSH) criteria documents regarding “Occupational Exposure to Waste Anesthetic Gases and Vapors,” and “Control of Occupational Exposure to Nitrous Oxide” indicate a need for both local exhaust (scavenging) systems and general ventilation of the areas in which the respective gases are utilized.
11. Differential pressure shall be a minimum of 0.01" water gauge (2.5 Pa). If alarms are installed, allowances shall be made to prevent nuisance alarms of monitoring devices.
12. Some surgeons may require room temperatures which are outside of the indicated range. All operating room design conditions shall be developed in consultation with surgeons, anesthesiologists, and nursing staff.
13. The term “trauma room” as used here is the operating room space in the emergency department or other trauma reception area that is used for emergency surgery. The “first aid room” and/or “emergency room” used for initial treatment of accident victims may be ventilated as noted for the “treatment room.” Treatment rooms used for bronchoscopy shall be treated as Bronchoscopy rooms. Treatment rooms used for cryosurgery procedures with nitrous oxide shall contain provisions for exhausting waste gases.
14. In a ventilation system that recirculates air, HEPA filters can be used in lieu of exhausting the air from these spaces to the outside. In this application, the return air shall be passed through the HEPA filters before it is introduced into any other spaces.
15. If it is not practical to exhaust the air from the airborne infection isolation room to the outside, the air may be returned through HEPA filters to the air-handling system exclusively serving the isolation room.
16. Total air changes per room for patient rooms, labor/delivery/recovery rooms, and labor/delivery/recovery/postpartum rooms may be reduced to 4 when supplemental heating and/or cooling systems (radiant heating and cooling, baseboard heating, etc.) are used.
17. The protective environment airflow design specifications protect the patient from common environmental airborne infectious microbes (i.e., *Aspergillus* spores). These special ventilation areas shall be designed to provide directed airflow from the cleanest patient care area to less clean areas. These rooms shall be protected with HEPA filters at 99.97 percent efficiency for a 0.3 μm sized particle in the supply airstream. These interrupting filters protect patient rooms from maintenance-derived release of environmental microbes from the ventilation system components. Recirculation HEPA filters can be used to increase the equivalent room air exchanges. Constant volume airflow is required for consistent ventilation for the protected environment. If the facility determines that airborne infection isolation is necessary for protective environment patients, an anteroom should be provided. Rooms with reversible airflow provisions for the purpose of switching between protective environment and airborne infection isolation functions are not acceptable.
18. The infectious disease isolation room described in these guidelines is to be used for isolating the airborne spread of infectious diseases, such as measles, varicella, or tuberculosis. The design of airborne infection isolation (AII) rooms should include the provision for normal patient care during periods not requiring isolation precautions. Supplemental recirculating devices may be used in the patient room to increase the equivalent room air exchanges; however, such recirculating devices do not provide the outside air requirements. Air may be recirculated within individual isolation rooms if HEPA filters are used. Rooms with reversible airflow provisions for the purpose of switching between protective environment and AII functions are not acceptable.
19. When required, appropriate hoods and exhaust devices for the removal of noxious gases or chemical vapors shall be provided (see Section 7.31.D14 and 7.31.D15 in the AIA guideline [reference 120] and NFPA 99).

20. Food preparation centers shall have ventilation systems whose air supply mechanisms are interfaced appropriately with exhaust hood controls or relief vents so that exfiltration or infiltration to or from exit corridors does not compromise the exit corridor restrictions of NFPA 90A, the pressure requirements of NFPA 96, or the maximum defined in the table. The number of air changes may be reduced or varied to any extent required for odor control when the space is not in use. See Section 7.31.D1.p in the AIA guideline (reference 120).

Appendix I:

A7. Recirculating devices with HEPA filters may have potential uses in existing facilities as interim, supplemental environmental controls to meet requirements for the control of airborne infectious agents. Limitations in design must be recognized. The design of either portable or fixed systems should prevent stagnation and short circuiting of airflow. The supply and exhaust locations should direct clean air to areas where health-care workers are likely to work, across the infectious source, and then to the exhaust, so that the healthcare worker is not in position between the infectious source and the exhaust location. The design of such systems should also allow for easy access for scheduled preventative maintenance and cleaning.

A11. The verification of airflow direction can include a simple visual method such as smoke trail, ball-in-tube, or flutterstrip. These devices will require a minimum differential air pressure to indicate airflow direction.

Note: This table is Table 8.1 in the AIA guidelines, 2001 edition. Superscripts used in this table refer to notes following the table.

Table B.3. Pressure relationships and ventilation of certain areas of nursing facilities[1]

Area designation	Air movement relationship to adjacent area[2]	Minimum air changes of outdoor air per hour[3]	Minimum total air change per hour [4]	All air exhausted directly to outdoors[5]	Recirculated by means of room units[6]	Relative humidity[7] (%)	Design temperature[8] (degrees F [C])
Resident room	–	2	2	–	–	–[9]	70–75 (21–24)
Resident unit corridor	–	–	4	–	–	–[9]	–
Resident gathering areas	–	4	4	–	–	–	–
Toilet room	In	–	10	Yes	No	–	–
Dining rooms	–	2	4	–	–	–	75 (24)
Activity rooms, if provided	–	4	4	–	–	–	–
Physical therapy	In	2	6	–	–	–	75 (24)
Occupational therapy	In	2	6	–	–	–	75 (24)
Soiled workroom or soiled holding	In	2	10	Yes	No	–	–
Clean workroom or clean holding	Out	2	4	–	–	(Max. 70)	75 (24)
Sterilizer exhaust room	In	–	10	Yes	No	–	–
Linen and trash chute room, if provided	In	–	10	Yes	No	–	–
Laundry, general, if provided	–	2	10	Yes	No	–	–
Soiled linen sorting and storage	In	–	10	Yes	No	–	–
Clean linen storage	Out	–	2	Yes	No	–	–
Food preparation facilities[10]	–	2	10	Yes	No	–	–
Dietary warewashing	In	–	10	Yes	No	–	–
Dietary storage areas	–	–	2	Yes	No	–	–
Housekeeping rooms	In	–	10	Yes	No	–	–
Bathing rooms	In	–	10	Yes	No	–	75 (24)

Notes:

1. The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of nursing facilities that directly affect resident care and are determined based on nursing facilities being predominantly “No Smoking” facilities. Where smoking may be allowed, ventilation rates will need adjustment. Areas where specific ventilation rates are not given in the table shall be ventilated in accordance with ASHRAE Standard 62, *Ventilation for Acceptable Indoor Air Quality,* and ASHRAE *Handbook - HVAC Applications.* OSHA standards and/or NIOSH criteria require special ventilation requirements for employee health and safety within nursing facilities.
2. Design of the ventilation system shall, insofar as possible, provide that air movement is from clean to less clean areas. However, continuous compliance may be impractical with full utilization of some forms of variable air volume and load shedding systems that may be used for energy conservation. Areas that do require positive and continuous control are noted with “Out” or “In” to indicate the required direction of air movement in relation to the space named. Rate of air movement may, of course, be varied as needed within the limits required for positive control. Where indication of air movement direction is enclosed in parentheses, continuous directional control is required only when the specialized equipment or device is in use or where room use may otherwise compromise the intent of movement from clean to less clean. Air movement for rooms with dashes and nonpatient areas may vary as necessary to satisfy the requirements of those spaces. Additional adjustments may be needed when space is unused or unoccupied and air systems are deenergized or reduced.

3. To satisfy exhaust needs, replacement air from outside is necessary. Table B.3 does not attempt to describe specific amounts of outside air to be supplied to individual spaces except for certain areas such as those listed. Distribution of the outside air, added to the system to balance required exhaust, shall be as required by good engineering practice.
4. Number of air changes may be reduced when the room is unoccupied if provisions are made to ensure that the number of air changes indicated is reestablished any time the space is being utilized. Adjustments shall include provisions so that the direction of air movement shall remain the same when the number of air changes is reduced. Areas not indicated as having continuous directional control may have ventilation systems shut down when space is unoccupied and ventilation is not otherwise needed.
5. Air from areas with contamination and/or odor problems shall be exhausted to the outside and not recirculated to other areas. Note that individual circumstances may require special consideration for air exhaust to outside.
6. Because of cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked “No.” Isolation rooms may be ventilated by reheat induction units in which only the primary air supplied from a central system passes through the reheat unit. Gravity-type heating or cooling units such as radiators or convectors shall not be used in special care areas.
7. The ranges listed are the minimum and maximum limits where control is specifically needed. See A8.31.D in the AIA guideline (reference 120) for additional information.
8. Where temperature ranges are indicated, the systems shall be capable of maintaining the rooms at any point within the range. A single figure indicates a heating or cooling capacity of at least the indicated temperature. This is usually applicable where residents may be undressed and require a warmer environment. Nothing in these guidelines shall be construed as precluding the use of temperatures lower than those noted when the residents’ comfort and medical conditions make lower temperatures desirable. Unoccupied areas such as storage rooms shall have temperatures appropriate for the function intended.
9. See A8.31.D1 in the AIA guideline (reference 120).
10. Food preparation facilities shall have ventilation systems whose air supply mechanisms are interfaced appropriately with exhaust hood controls or relief vents so that exfiltration or infiltration to or from exit corridors does not compromise the exit corridor restrictions of NFPA 90A, the pressure requirements of NFPA 96, or the maximum defined in the table. The number of air changes may be reduced or varied to any extent required for odor control when the space is not in use.

Table B.4. Filter efficiencies for central ventilation and air conditioning systems in general hospitals*

Area designation	Number of filter beds	Filter bed no.1 (%)*	Filter bed no. 2 (%)*
All areas for inpatient care, treatment, and diagnosis, and those areas providing direct service or clean supplies, such as sterile and clean processing, etc.	2	30	90
Protective environment room	2	30	99.97
Laboratories	1	80	n/a
Administrative, bulk storage, soiled holding areas, food preparation areas, and laundries	1	30	n/a

Note: This table is Table 7.3 in the AIA guidelines, 2001 edition.

* Additional roughing or prefilters should be considered to reduce maintenance required for filters with efficiency higher than 75%. The filtration efficiency ratings are based on average dust sopt efficiency per ASHRAE 52.1–1992.

Table B.5. Filter efficiencies for central ventilation and air conditioning systems in outpatient facilities*

Area designation	Number of filter beds	Filter bed no.1 (%)*	Filter bed No. 2 (%)*
All areas for patient care, treatment, and/or diagnosis, and those areas providing direct service or clean supplies such as sterile and clean processing, etc.	2	30	90
Laboratories	1	80	n/a
Administrative, bulk storage, soiled holding areas, food preparation areas, and laundries	1	30	n/a

Note: This table is Table 9.1 in the AIA guidelines, 2001 edition.

* Additional roughing or prefilters should be considered to reduce maintenance required for main filters. The filtration efficiency ratings are based on dust spot efficiency per ASHRAE 52.1–1992.

\+ These requirements do not apply to small primary (e.g., neighborhood) outpatient facilities or outpatient facilities that do not perform invasive applications or procedures.

Table B.6. Filter efficiencies for central ventilation and air conditioning systems in nursing facilities

Area designation	Minimum number of filter beds	Filter bed no.1 (%)*	Filter bed No. 2 (%)*
All areas for inpatient care, treatment, and/or diagnosis, and those areas providing direct service or clean supplies	2	30	80
Administrative, bulk storage, soiled holding, laundries, and food preparation areas	1	30	n/a

Note: This table is Table 8.2 in the AIA guidelines, 2001 edition.

* The filtration efficiency ratings are based on average dust spot efficiency as per ASHRAE 52.1–1992.

Table B.7. Filter efficiencies for central ventilation and air conditioning systems in psychiatric hospitals

Area designation	Minimum number of filter beds	Filter bed no.1 (%)*	Filter bed No. 2 (%)*
All areas for inpatient care, treatment, and diagnosis, and those areas providing direct services	2	30	90
Administrative, bulk storage, soiled holding, laundries, and food preparation areas	1	30	n/a

Note: This table is Table 11.1 in the AIA guidelines, 2001 edition.

* The filtration efficiency ratings are based on average dust spot efficiency as per ASHRAE 52.1–1992.

Appendix C. Water

1. Biofilms

Microorganisms have a tendency to associate with and stick to surfaces. These adherent organisms can initiate and develop biofilms, which are comprised of cells embedded in a matrix of extracellularly produced polymers and associated abiotic particles.[1438] It is inevitable that biofilms will form in most water systems. In the health-care facility environment, biofilms may be found in the potable water supply piping, hot water tanks, air conditioning cooling towers, or in sinks, sink traps, aerators, or shower heads. Biofilms, especially in water systems, are not present as a continuous slime or film, but are more often scanty and heterogeneous in nature.[1439] Biofilms may form under stagnant as well as flowing conditions, so storage tanks, in addition to water system piping, may be vulnerable to the development of biofilm, especially if water temperatures are low enough to allow the growth of thermophilic bacteria (e.g., *Legionella* spp.). Favorable conditions for biofilm formation are present if these structures and equipment are not cleaned for extended periods of time.[1440]

Algae, protozoa, and fungi may be present in biofilms, but the predominant microorganisms of water system biofilms are gram-negative bacteria. Although most of these organisms will not normally pose a problem for healthy individuals, certain biofilm bacteria (e.g., *Pseudomonas aeruginosa, Klebsiella* spp., *Pantoea agglomerans*, and *Enterobacter cloacae*) all may be agents for opportunistic infections for immunocompromised individuals.[1441, 1442] These biofilm organisms may easily contaminate indwelling medical devices or intravenous (IV) fluids, and they could be transferred on the hands of health-care workers.[1441–1444]

Biofilms may potentially provide an environment for the survival of pathogenic organisms, such as *Legionella pneumophila* and *E. coli* O157:H7. Although the association of biofilms and medical devices provides a plausible explanation for a variety of health-care associated infections, it is not clear how the presence of biofilms in the water system may influence the rates of health-care– associated waterborne infection.

Organisms within biofilms behave quite differently than their planktonic (i.e., free floating) counterparts. Research has shown that biofilm-associated organisms are more resistant to antibiotics and disinfectants than are planktonic organisms, either because the cells are protected by the polymer matrix, or because they are physiologically different.[1445–1450] Nevertheless, municipal water utilities attempt to maintain a chlorine residual in the distribution system to discourage microbiological growth. Though chlorine in its various forms is a proven disinfectant, it has been shown to be less effective against biofilm bacteria.[1448] Higher levels of chlorine for longer contact times are necessary to eliminate biofilms.

Routine sampling of health-care facility water systems for biofilms is not warranted. If an epidemiologic investigation points to the water supply system as a possible source of infection, then water sampling for biofilm organisms should be considered so that prevention and control strategies can be developed. An established biofilm is is difficult to remove totally in existing piping. Strategies to remediate biofilms in a water system would include flushing the system piping, hot water tank, dead legs, and those areas of the facility's water system subject to low or intermittent flow. The benefits of this treatment would include

a. elimination of corrosion deposits and sludge from the bottom of hot water tanks,
b. removal of biofilms from shower heads and sink aerators, and
c. circulation of fresh water containing elevated chlorine residuals into the health-care facility water system.

The general strategy for evaluating water system biofilm depends on a comparision of the bacteriological quality of the incoming municipal water and that of water sampled from within facility's distribution system. Heterotrophic plate counts and coliform counts, both of which are routinely run by the municipal water utility, will at least provide in indication of the potential for biofilm formation. Heterotrophic plate count levels in potable water should be <500 CFU/mL. These levels may increase on occasion, but counts consistently >500 CFU/mL would indicate a general decrease in water quality. A direct correlation between heterotrophic plate count and biofilm levels has been demonstrated.[1450] Therefore, an increase in

heterotrophic plate count would suggest a greater rate and extent of biofilm formation in a health-care facility water system. The water supplied to the facility should also contain <1 coliform bacteria/100 mL. Coliform bacteria are organisms whose presence in the distribution system could indicate fecal contamination. It has been shown that coliform bacteria can colonize biofilms within drinking water systems. Intermittant contamination of a water system with these organisms could lead to colonization of the system.

Water samples can be collected from throughout the health-care facility system, including both hot and cold water sources; samples should be cultured by standard methods.[945] If heterotrophic plate counts in samples from the facility water system are higher than those from samples collected at the point of water entry to the building, it can be concluded that the facility water quality has diminished. If biofilms are detected in the facility water system and determined by an epidemiologic and environmental investigation to be a reservoir for health-care associated pathogens, the municipal water supplier could be contacted with a request to provide higher chlorine residuals in the distribution system, or the health-care facility could consider installing a supplemental chlorination system.

Sample collection sites for biofilm in health-care facilities include
a. hot water tanks
b. shower heads; and
c. faucet aerators, especially in immunocompromised patient-care areas.

Swabs should be placed into tubes containing phosphate buffered water, pH 7.2 or phosphate buffered saline, shipped to the laboratory under refrigeration and processed within 24 hrs. of collection. Samples are suspended by vortexing with sterile glass beads and plated onto a nonselective medium (e.g., Plate Count Agar or R2A medium) and selective media (e.g., media for *Legionella* spp. isolation) after serial dilution. If the plate counts are elevated above levels in the water (i.e. comparing the plate count per square centimeter of swabbed surface to the plate count per milliliter of water), then biofilm formation can be suspected. In the case of an outbreak, it would be advisable to isolate organisms from these plates to determine whether the suspect organisms are present in the biofilm or water samples and compare them to the organisms isolated from patient specimens.

2. Water and Dialysate Sampling Strategies in Dialysis

In order to detect the low, total viable heterotrophic plate counts outlined by the current AAMI standards for water and dialysate in dialysis settings, it is necessary to use standard quantitative culture techniques with appropriate sensitivity levels.[792, 832, 833] The membrane filter technique is particularly suited for this application because it permits large volumes of water to be assayed.[792, 834] Since the membrane filter technique may not be readily available in clinical laboratories, the spread plate assay can be used as an alternative.[834] If the spread plate assay is used, however, the standard prohibits the use of a calibrated loop when applying sample to the plate.[792] The prohibition is based on the low sensitivity of the calibrated loop. A standard calibrated loop transfers 0.001 mL of sample to the culture medium, so that the minimum sensitivity of the assay is 1,000 CFU/mL. This level of sensitivity is unacceptable when the maximum allowable limit for microorganisms is 200 CFU/mL. Therefore, when the spread plate method is used, a pipette must be used to place 0.1–0.5 mL of water on the culture medium.

The current AAMI standard specifically prohibits the use of nutrient-rich media (e.g., blood agar, and chocolate agar) in dialysis water and dialysate assays because these culture media are too rich for growth of the naturally occurring organisms found in water.[792] Debate continues within AAMI, however, as to the most appropriate culture medium and incubation conditions to be used. The original clinical observations on which the microbiological requirements of this standard were based used Standard Methods Agar (SMA), a medium containing relatively few nutrients.[666] The use of tryptic soy agar (TSA), a general purpose medium for isolating and cultivating microorganisms was recommended in later versions of the standard because it was thought to be more appropriate for culturing bicarbonate-containing dialysate.[788, 789, 835] Moreover, culturing systems based on TSA are readily available from commercial sources. Several studies, however, have shown

that the use of nutrient-poor media, such as R2A, results in an increased recovery of bacteria from water.[1451, 1452] The original standard also specified incubation for 48 hours at 95°F–98.6°F (35°C–37°C) before enumeration of bacterial colonies. Extending the culturing time up to 168 hours, or 7 days and using incubation temperatures of 73.4°F– 82.4°F (23°C–28°C) have also been shown to increase the recovery of bacteria.[1451, 1452] Other investigators, however, have not found such clear cut differences between culturing techniques.[835, 1453] After considerable discussion, the AAMI Committee has not reached a consensus regarding changes in the assay technique, and the use of TSA or its equivalent for 48 hours at 95°F–98.6°F (35°C–37°C) remains the recommended method. It should be recognized, however, that these culturing conditions may underestimate the bacterial burden in the water and fail to identify the presence of some organisms. Specifically, the recommended method may not detect the presence of various NTM that have been associated with several outbreaks of infection in dialysis units.[31, 32] In these instances, however, the high numbers of mycobacteria in the water were related to the total heterotrophic plate counts, each of which was significantly greater than that allowable by the AAMI standard. Additionally, the recommended method will not detect fungi and yeast, which have been shown to contaminate water used for hemodialysis applications.[1454] Biofilm on the surface of the pipes may hide viable bacterial colonies, even though no viable colonies are detected in the water using sensitive culturing techniques.[1455] Many disinfection processes remove biofilm poorly, and a rapid increase in the level of bacteria in the water following disinfection may indicate significant biofilm formation. Therefore, although the results of microbiological surveillance obtained using the test methods outlined above may be useful in guiding disinfection schedules and in demonstrating compliance with AAMI standards, they should not be taken as an indication of the absolute microbiological purity of the water.[792]

Endotoxin can be tested by one of two types of assays
a. a kinetic test method [e.g., colorimetric or turbidimetric] or
b. a gel-clot assay.

Endotoxin units are assayed by the *Limulus* Amebocyte Lysate (LAL) method. Because endotoxins differ in their activity on a mass basis, their activity is referred to a standard *Escherichia coli* endotoxin. The current standard (EC-6) is prepared from *E. coli* O113:H10. The relationship between mass of endotoxin and its activity varies with both the lot of LAL and the lot of control standard endotoxin used. Since standards for endotoxin were harmonized in 1983 with the introduction of EC-5, the relationship between mass and activity of endotoxin has been approximately 5–10 EU/ng. Studies to harmonize standards have led to the measurement of endotoxin units (EU) where 5 EU is equivalent to 1 ng *E. coli* O55:B5 endotoxin.[1456]

In summary, water used to prepare dialysate and to reprocess hemodialyzers should not contain a total microbial count >200 CFU/mL as determined by assay on TSA agar for 48 hrs. at 96.8°F (36°C), and ≤2 endotoxin units (EU) per mL. The dialysate at the end of a dialysis treatment should not contain >2,000 CFU/mL.[31, 32, 668, 789, 792]

3. Water Sampling Strategies and Culture Techniques for Detecting Legionellae

Legionella spp. are ubiquitous and can be isolated from 20%–40% of freshwater environments, including man-made water systems.[1457, 1458] In health-care facilities, where legionellae in potable water rarely result in disease among immunocompromised patients, courses of remedial action are unclear.

Scheduled microbiologic monitoring for legionellae remains controversial because the presence of legionellae is not necessarily evidence of a potential for causing disease.[1459] CDC recommends aggressive disinfection measures for cleaning and maintaining devices known to transmit legionellae, but does not recommend regularly scheduled microbiologic assays for the bacteria.[396] However, scheduled monitoring of potable water within a hospital might be considered in certain settings where persons are highly susceptible to illness and mortality from *Legionella* infection (e.g., hematopoietic stem cell transplantation units and solid organ transplant units).[9] Also, after an outbreak of legionellosis, health officials agree monitoring is necessary to identify the source and to evaluate the efficacy of biocides or other prevention measures.

Examination of water samples is the most efficient microbiologic method for identifying sources of legionellae and is an integral part of an epidemiologic investigation into health-care associated Legionnaires

disease. Because of the diversity of plumbing and HVAC systems in health-care facilities, the number and types of sites to be tested must be determined before collection of water samples. One environmental sampling protocol that addresses sampling site selection in hospitals might serve as a prototype for sampling in other institutions.[1209] Any water source that might be aerosolized should be considered a potential source for transmission of legionellae. The bacteria are rarely found in municipal water supplies and tend to colonize plumbing systems and point-of-use devices. To colonize, legionellae usually require a temperature range of 77°F–108°F (25°C–42.2°C) and are most commonly located in hot water systems.[1460] Legionellae do not survive drying. Therefore, air-conditioning equipment condensate, which frequently evaporates, is not a likely source.[1461]

Water samples and swabs from point-of-use devices or system surfaces should be collected when sampling for legionellae (Box C.1).[1437] Swabs of system surfaces allow sampling of biofilms, which frequently contain legionellae. When culturing faucet aerators and shower heads, swabs of surface areas should be collected first; water samples are collected after aerators or shower heads are removed from their pipes. Collection and culture techniques are outlined (Box C.2). Swabs can be streaked directly onto buffered charcoal yeast extract agar (BCYE) plates if the pates are available at the collection site. If the swabs and water samples must be transported back to a laboratory for processing, immersing individual swabs in sample water minimizes drying during transit. Place swabs and water samples in insulated coolers to protect specimens from temperature extremes.

Box C.1. Potential sampling sites for *Legionella* spp. in health-care facilities*

- **Potable water systems**
  incoming water main, water softener unit, 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 towers and evaporative condensers**
  makeup water (e.g., added to replace water lost because of evaporation, drift, or 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)
- **Humidfiers (e.g., nebullizers)**
  bubblers for oxygen, water used for respiratory therapy equipment
- **Other sources**
  decorative fountains, irrigation equipment, fire sprinkler system (if recently used), whirlpools, spas

* Material in this box is adapted from reference 1209.

Box C.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. (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.)
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.
   - 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 regading the sensitivity and specificity of this procedure are available.

* Material in this table is compiled from references1209, 1437, 1462–1465.

4. Procedure for Cleaning Cooling Towers and Related Equipment

I. Perform these steps prior to chemical disinfection and mechanical cleaning.

A. Provide protective equipment to workers who perform the disinfection, to prevent their exposure to chemicals used for disinfection and aerosolized water containing *Legionella* spp. Protective equipment may include full-length protective clothing, boots, gloves, goggles, and a full- or half-face mask that combines a HEPA filter and chemical cartridges to protect against airborne chlorine levels of up to 10 mg/L.

B. Shut off cooling tower.
   1. Shut off the heat source, if possible.
   2. Shut off fans, if present, on the cooling tower/evaporative condenser (CT/EC).
   3. Shut off the system blowdown (i.e., purge) valve.
   4. Shut off the automated blowdown controller, if present, and set the system controller to manual.
   5. Keep make-up water valves open.
   6. Close building air-intake vents within at least 30 meters of the CT/EC until after the cleaning procedure is complete.
   7. Continue operating pumps for water circulation through the CT/EC.

II. Perform these chemical disinfection procedures.

A. Add fast-release, chlorine-containing disinfectant in pellet, granular, or liquid form, and follow safety instructions on the product label. Use EPA-registered products, if available. Examples of disinfectants include sodium hypochlorite (NaOCl) or calcium hypochlorite (Ca[OCl]2), calculated to achieve initial free residual chlorine (FRC) of 50 mg/L: either
   a. 3.0 lbs [1.4 kg] industrial grade NaOCl [12%–15% available Cl] per 1,000 gallons of CT/EC water
   b. 10.5 lbs
   c. [4.8 kg] domestic grade NaOCl [3%–5% available Cl] per 1,000 gallons of CT/EC water; or
   d. 0.6 lb [0.3 kg] Ca[OCl]2 per 1,000 gallons of CT/EC water. If significant biodeposits are present, additional chlorine may be required. If the volume of water in the CT/EC is unknown, it can be estimated (in gallons) by multiplying either the recirculation rate in gallons per minute by 10 or the refrigeration capacity in tons by 30. Other appropriate compounds may be suggested by a water-treatment specialist.

B. Record the type and quality of all chemicals used for disinfection, the exact time the chemicals were added to the system, and the time and results of FRC and pH measurements.

C. Add dispersant simultaneously with or within 15 minutes of adding disinfectant. The dispersant is best added by first dissolving it in water and adding the solution to a turbulent zone in the water system. Automatic-dishwasher compounds are examples of low- or nonfoaming, silicate-based dispersants. Dispersants are added at 10–25 lbs (4.5–11.25 kg) per 1,000 gallons of CT/EC water.

D. After adding disinfectant and dispersant, continue circulating the water through the system. Monitor the FRC by using an FRC-measuring device with the DPD method (e.g., a swimming-pool test kit), and measure the pH with a pH meter every 15 minutes for 2 hours. Add chlorine as needed to maintain the FRC at ≥10 mg/L. Because the biocidal effect of chlorine is reduced at a higher pH, adjust the pH to 7.5–8.0. The pH may be lowered by using any acid (e.g., nuriatic acid or sulfuric acid used for maintenance of swimming pools) that is compatible with the treatment chemicals.

E. Two hours after adding disinfectant and dispersant or after the FRC level is stable at ≥10 mg/L, monitor at 2-hour intervals and maintain the FRC at ≥10 mg/L for 24 hours.

F. After the FRC level has been maintained at ≥10 mg/L for 24 hours, drain the system. CT/EC water may be drained safely into the sanitary sewer. Municipal water and sewerage authorities should be contacted regarding local regulations. If a sanitary sewer is not available, consult local or state authorities (e.g., a department of natural resources or environmental protection) regarding disposal of water. If necessary, the drain-off may be dechlorinated by dissipation or chemical neutralization with sodium bisulfite.

G. Refill the system with water and repeat the procedure outline in steps 2–7 in I-B above.

III. Perform mechanical cleaning.

A. After water from the second chemical disinfection has been drained, shut down the CT/EC.
B. Inspect all water-contact areas for sediment, sludge, and scale. Using brushes and/or a low-pressure water hose, thoroughly clean all CT/EC water-contact areas, including the basin, sump, fill, spray nozzles, and fittings. Replace components as needed.
C. If possible, clean CT/EC water-contact areas within the chillers.

IV. Perform these procedures after mechanical cleaning.

A. Fill the system with water and add chlorine to achieve an FRC level of 10 mg/L.
B. Circulate the water for 1 hour, then open the blowdown valve and flush the entire system until the water is free of turbidity.
C. Drain the system.
D. Open any air-intake vents that were closed before cleaning.
E. Fill the system with water. The CT/EC may be put back into service using an effective water-treatment program.

5. Maintenance Procedures Used to Decrease Survival and Multiplications of *Legionella* spp. in Potable-Water Distribution Systems

Wherever allowable by state code, provide water at ≥124°F (≥51°C) at all points in the heated water system, including the taps. This requires that water in calorifiers (e.g., water heaters) be maintained at ≥140°F (≥60°C). In the United Kingdom, where maintenance of water temperatures at ≥122°F (≥50°C) in hospitals has been mandated, installation of blending or mixing valves at or near taps to reduce the water temperature to ≤109.4°F (≤63°C) has been recommended in certain settings to reduce the risk for scald injury to patients, visitors, and health care workers.[726] However, *Legionella* spp. can multiply even in short segments of pipe containing water at this temperature. Increasing the flow rate from the hot-water-circulation system may help lessen the likelihood of water stagnation and cooling.[711, 1465] Insulation of plumbing to ensure delivery of cold (<68°F [<20°C]) water to water heaters (and to cold-water outlets) may diminish the opportunity for bacterial multiplication.[456] Both dead legs and capped spurs within the plumbing system provide areas of stagnation and cooling to <122°F (<50°C) regardless of the circulating water temperature; these segments may need to be removed to prevent colonization.[704] Rubber fittings within plumbing systems have been associated with persistent colonization, and replacement of these fittings may be required for *Legionella* spp. eradication.[1467]

Continuous chlorination to maintain concentrations of free residual chlorine at 1–2 mg/L (1–2 ppm) at the tap is an alternative option for treatment. This requires the placement of flow-adjusted, continuous injectors of chlorine throughout the water distribution system. Adverse effects of continuous chlorination can include accelerated corrosion of plumbing (resulting in system leaks) and production of potentially carcinogenic trihalomethanes. However, when levels of free residual chlorine are below 3 mg/L (3 ppm), trihalomethane levels are kept below the maximum safety level recommended by the EPA.[727, 1468, 1469 228]

Appendix D. Insects and Microorganisms

⚠ **Format Change [February 2016]:** The format of this section was changed to improve readability and accessibility. The content is unchanged.

Table D.1. Microorganisms isolated from arthropods in health-care settings

Cockroaches

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter* spp.*; Citrobacter freundii; Enterobacter* spp.*, E. cloacae; Escherichia coli; Flavobacterium* spp.*; Klebsiella* spp.*; Proteus* spp.*; Pseudomonas* spp.*, P. aeruginosa, P. fluorescens, P. putida; Salmonella* spp.*; Serratia* spp.*, S. marcescens; Shigella boydii*	1048, 1051, 1056, 1058, 1059, 1062
Gram-positive bacteria	*Bacillus* spp.*; Enterococcus faecalis; Micrococcus* spp.*; Staphylococcus aureus, S. epidermidis; Streptococcus* spp.*, S. viridans*	1056, 1058, 1059
Acid-fast bacteria	*Mycobacterium tuberculosis*	1065
Fungi	*Aspergillus niger*; *Mucor* spp.; *Rhizopus* spp.	1052, 1059
Parasites	*Endolimax nana; Entamoeba coli*	1059

Houseflies

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter* spp.*; Campulobacter fetus* subsp. *Jejuni; Chlamydia* spp.*; Citrobacter fruendii; Enterobacter* spp.*; Escherichia coli; Helicobacter pylori; Klebsiella* spp.*; Proteus* spp.*; Pseudomonas aeruginosa; Serratia marcescens; Shigella* spp.	1047, 1048, 1050, 1053–1055, 1060
Gram-positive bacteria	*Bacillus* spp.*; Enterococcus faecalis; Micrococcus* spp.*; Staphylococcus* spp. (coagulase-negative), *S. aureus; Streptococcus* spp.*, S. viridans*	1048, 1060
Fungi / yeasts	*Candida* spp.*; Geotrichum* spp.	1060
Parasites	*Endolimax nana; Entamoeba coli*	1060
Viruses	Rotaviruses	1049

Ants

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter* spp.*; Escherichia coli; Klebsiella* spp.*; Neisseria sicca; Proteus* spp.*; Providencia* spp.*; Pseudomonas aeruginosa, P. fluorescens*	1057
Gram-positive bacteria	*Bacillus* spp.*, B. cereus, B. pumilis; Clostridium cochlearium, C. welchii; Enterococcus faecalis; Staphylococcus* spp. (coagulase-negative), *S. aureus; Streptococcus pyrogenes*	1057

Spiders

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter* spp.*; Citrobacter freundii; Enterobacteraerogenes; Morganella morganii*	1048
Gram-positive bacteria	*Staphylococcus* spp. (coagulase-negative)	1048

Mites, midges

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter* spp.*; Burkholderia cepacia; Enterbacter agglomerans, E. aerogenes; Hafnia alvei; Pseudomonas aeruginosa*	1048
Gram-positive bacteria	*Staphylococcus* spp. (coagulase-negative)	1048

Mosquitoes

Microorganism category	Microorganisms	References
Gram-negative bacteria	*Acinetobacter calcoaceticus; Enteobacter cloacae*	1048
Gram-positive bacteria	*Enterococcus* spp.*; Staphylococcus* spp. (coagulase-negative)	1048

Appendix E. Information Resources

The following sources of information may be helpful to the reader. Some of these are available at no charge, while others are available for purchase from the publisher.

Air and Water

- Jensen PA, Schafer MP. Sampling and characterization of bioaerosols. NIOSH Manual of Analytical Methods; revised 6/99. [This link is no longer active: www.cdc.gov/niosh/nmam/pdfs/chapter-j.pdf. Similar information may be found at Sampling and Characterization of Bioaerosols (https://www.cdc.gov/niosh/docs/2003-154/pdfs/chapter-j.pdf [PDF - 103 KB]), accessed August 2016.].
- American Institutes of Architects. *Guidelines for Design and Construction of Hospital and Health Care Facilities.* Washington DC; American Institute of Architects Press; 2001. AIA, 1735 New York Avenue, NW, Washington DC 20006. 1-800-AIA-3837 or (202) 626-7541
- ASHRAE. Standard 62, and Standard 12-2000. These documents may be purchased from: American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. 1791 Tullie Circle, NE, Atlanta GA 30329 1-800-527-4723 or (404) 636-8400.
- University of Minnesota websites: www.dehs.umn.edu Indoor air quality site: [This link is no longer active: www.dehs.umn.edu/resources.htm#indoor. Similar information may be found at Indoor Air Quality (http://www.dehs.umn.edu/iaq.htm), accessed August 2016).] Water infiltration and use of the wet test (moisture) meter: [This link is no longer active: www.dehs.umn.edu/remangi.html. Similar information may be found at Managing Water Infiltration into Buildings (http://www.dehs.umn.edu/iaq_fi.htm), accessed August 2016.]
- The CDC website for bioterrorism information contains the interim intervention plan for smallpox. The plan discusses infection control issues both for home-based care and hospital-based patient management. CDC Emergency Preparedness and Response – Smallpox (https://www.cdc.gov/smallpox/index.html) [Current version of this document may differ from original.]

Environmental Sampling

- ISO. Sterilization of medical devices – microbiological methods, Part 1. ISO standard 11737-1. Paramus NJ; International Organization for Standardization; 1995.

Animals in Health-Care Facilities

- Service animal information with respect to the Americans with Disabilities Act. Contact the U.S. Department of Justice ADA Information Line at (800) 514-0301 (voice) or (800) 514-0383 (TDD), or visit the ADA website at: [This link is no longer active: www.usdoj.gov/crt/ada/adahom1.htm. Similar information may be found at U.S. Department of Justice – Service Animals, (https://www.ada.gov/service_animals_2010.htm) accessed August 2016).]

Regulated Medical Waste

- U.S. Environmental Protection Agency. This is the Internet address on their Internet web site that will link to any state for information about medical waste rules and regulations at the state level: [This link is no longer active: www.epa.gov/epaoswer/other/medical/stregs.htm. Similar information may be found at EPA – Medical Waste (https://www.epa.gov/rcra/medical-waste), accessed August 2016.]

General Resources

- APIC Text of Infection Control and Epidemiology. Association for Professionals in Infection Control and Epidemiology, Inc. Washington DC; 2000. (Two binder volumes, or CD-ROM)
- Abrutyn E, Goldmann DA, Scheckler WE. Saunders Infection Control Reference Service, 2nd Edition. Philadelphia PA; WB Saunders; 2000.
- ECRI publications are available on a variety of healthcare topics. Contact ECRI at (610) 8256000. CRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298.

Appendix F. Areas of Future Research

Air

- Standardize the methodology and interpretation of microbiologic air sampling (e.g., determine action levels or minimum infectious dose for aspergillosis, and evaluate the significance of airborne bacteria and fungi in the surgical field and the impact on postoperative SSI).
- Develop new molecular typing methods to better define the epidemiology of health-care associated outbreaks of aspergillosis and to associate isolates recovered from both clinical and environmental sources.
- Develop new methods for the diagnosis of aspergillosis that can lead reliably to early recognition of infection.
- Assess the value of laminar flow technology for surgeries other than for joint replacement surgery.
- Determine if particulate sampling can be routinely performed in lieu of microbiologic sampling for purposes such as determining air quality of clean environments (e.g., operating rooms, HSCT units).

Water

- Evaluate new methods of water treatment, both in the facility and at the water utility (e.g., ozone, chlorine dioxide, copper/silver/monochloramine) and perform cost-benefit analyses of treatment in preventing health-care associated legionellosis.
- Evaluate the role of biofilms in overall water quality and determine the impact of water treatments for the control of biofilm in distribution systems.
- Determine if the use of ultrapure fluids in dialysis is feasible and warranted, and determine the action level for the final bath.
- Develop quality assurance protocols and validated methods for sampling filtered rinse water used with AERs and determine acceptable microbiologic quality of AER rinse water.

Environmental Services

- Evaluate the innate resistance of microorganisms to the action of chemical germicides, and determine what, if any, linkage there may be between antibiotic resistance and resistance to disinfectants.

Laundry and Bedding

- Evaluate the microbial inactivation capabilities of new laundry detergents, bleach substitutes, other laundry additives, and new laundry technologies.

Animals in Health-Care Facilities

- Conduct surveillance to monitor incidence of infections among patients in facilities that use animal programs, and conduct investigations to determine new infection control strategies to prevent these infections.
- Evaluate the epidemiologic impact of performing procedures on animals (e.g., surgery or imaging) in human health-care facilities.

Regulated Medical Waste

- Determine the efficiency of current medical waste treatment technologies to inactivate emerging pathogens that may be present in medical waste (e.g., SARS-coV).
- Explore options to enable health-care facilities to reinstate the capacity to inactivate microbiological cultures and stocks on-site.

Inverarity, Donald

From: McMahon, Alex
Sent: 08 July 2019 14:32
To: Inverarity, Donald; Gillies, Tracey; Guthrie, Lindsay
Cc: Graham, Iain; Currie, Brian
Subject: RE: question

Thanks Donald. Brian and Iain there is reference to IPT input at various stages and its scattered though various emails. Was there any dedicated infection control resource or input? If so do we know that was?

Professor Alex McMahon
Executive Director, Nursing, Midwifery and Allied Healthcare Professionals
Executive Lead, REAS and Prison Healthcare
NHS Lothian
email: [redacted]

From: Inverarity, Donald
Sent: 08 July 2019 14:08
To: Gillies, Tracey; Guthrie, Lindsay
Cc: Graham, Iain; Currie, Brian; McMahon, Alex
Subject: RE: question

IPCT were not involved in the decision to reduce air changes and were not involved in the design of ventilation systems so its difficult to comment on the rationale retrospectively.
From what I've learned from Glasgow I speculate that there may have been a perception that the air changes per hour stated in the SHTM was mainly to manage room temperature. If the room temperature was being regulated by another system (in QEUH this is done with "chill beams" but fortunately none of these are installed in RHCYP) then there may have been a perception that the number of air changes could be dropped if it wasn't appreciated that the air changes per hour are fundamental to dilution and removal of airborne pathogens too.
Likewise, opening windows to assist with air changes in areas such as critical care where patients are immobile and partially clothed and unable to regulate temperature themselves or communicate that they are cold is not appropriate as it risks hypothermia when outside air temperature may be low. Additionally unpredictable direction of air flow from an open window (much like a fan) in non critical care areas can blow aerosolised organisms in unpredictable directions that result in transmission between patients and facilitate or perpetuate outbreaks (e.g. norovirus).

From: Gillies, Tracey
Sent: 08 July 2019 12:41
To: Inverarity, Donald; Guthrie, Lindsay
Cc: Graham, Iain; Currie, Brian; McMahon, Alex
Subject: question

You'll be aware we are being sent lots of questions to answer but one important one to get an answer for today is:

Q: why did you think that moving from 6 to 4 air changes/hour was acceptable? [their wording not mine]
A: [please could you give a clinical answer- I think this was related to the pressure- and the clinical need for balanced or negative rather than positive]

Also can we be clear about 6 or 6 in mixed mode- this seems to vary across conversations?

NHS Lothian
Infection Prevention & Control

13/01/2021 15:00

Situation

Hospital: RHCYP Ward: Dental outpatients

30/12/2020 - Water staining and damp identified on the wall between dental surgery rooms 1 and 2. Investigation identified significant damage to the wall.
13/01/2021 Investigation to wall between dental 2 and 3 has also identified extensive mould.

Background

The new RHCYP is in the process of being commissioned, Outpatients (including dental) were in the 1st phases for opening.
The dental department and surgeries deal with various groups of patients including those who are immunocompromised and at high risk of infection.

Assessment

- 30/12/2020 damp identified
- Surgeries 1 and 2 closed for investigation
- Scribe document completed for the initial investigation work
- Investigation discovered extensive water damage in the wall between the two surgeries.
- 13/01/2021 Investigation to wall between surgery 2 and 3, identified extensive mould.
- Discussion re issue. Rooms to be put out of use.
- Patients listed 13/01/2021 pm must have a risk assessment completed to review the risk of proceeding with the appointment.

Recommendation

I recommend that the following be undertaken within the given timescales:

- Rooms closed for use (exception todays patients if risk assessed) Patients re allocated appointments 14/01/2021
- Associate Director for IPC to inform Executive medical director and Executive Director, Nursing, Midwifery, AHP's
- PAG to be held 13/01/2021 16:00
- Request to Bouygues for the scope and extent of current investigation and current findings to date. (13/01/2021)
- Plan to be decided to move forward (13/1/2021)

Jean Harper
Lead HAI SCRIBE Nurse, Infection Prevention and Control Nurse

Primary Distribution Group:

- Donald Inverarity, ICD
- Lindsay Guthrie, Associate Director for IPCT
- Dorothy Hanley, CNM Reprovision
- Alex McMahon, Executive Director
- Tracey Gillies, Executive Medical Director
- Peter Campbell, Associate Nurse Director
- George Curley, Director of Operations, Facilities
- Tommy Logan, Head of Operations, Hard FM

NES Infection Prevention and Control Education Team

Healthcare Built Environment

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Resources to support the workforce in gaining knowledge and skills to prevent and control potential risks posed by healthcare facilities and promote a culture of life-long learning, continuous improvement and improved patient safety.

Welcome

The resources on this site have been co-produced by NHS Education for Scotland and NHS Scotland Assure, established to be an internationally recognised national centre for reducing risks in the healthcare built environment and ensuring healthcare facilities are safe, fit for purpose, cost effective and capable of delivering sustainable services over the long term. In this context, risks refer to those commonly associated with service systems, that is, the provision of water and drainage, air ventilation, electricity, fire prevention and medical gases, with infection prevention and control as a consideration for each.

They are intended to:

- support learning and development for this diverse multi-agency and multi professional staff group including clinical, estates and facilities staff
- support the workforce in gaining the knowledge and skills to prevent and control the potential risks posed by healthcare facilities and promote a culture of life-long learning, continuous improvement and improved patient safety

The Healthcare built environment learning zone contains the following resources :

- **Learning and development strategy**
- **Knowledge and skills framework**
- **Senior leadership development**
- **Healthcare Built Environment Educational Resources**
- **Related resources and links**
- **NES IPC Education Team Newsletter - January 24**
- **Winter Prepardness 2023_24**

Meet the team

Meet the Infection Prevention and Control Education Team members responsible for the healthcare built environment portfolio of work:

Lesley Shepherd, Head of Programme
Teresa McGougan, Principal Educator
Nicola Miller, Senior Educator
Ann McQuiston, Specialist Lead
Dalzielle Duncan, Admin Officer

CONTACT US

If have you any queries regarding this workstream please contact us via email at nes.hbe@nhs.scot

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MMWR

Recommendations and Reports

October 20, 2000 / 49(RR10);1-128

Guidelines for Preventing Opportunistic Infections Among Hematopoietic Ster Cell Transplant Recipients

Recommendations of CDC, the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation

Please note: *An erratum has been published for this article. To view the erratum, please click here.*

Abbreviations Used in This Publication

ANC	absolute neutrophil count
BAL	bronchoalveolar lavage
CDA	chlorodeoxyadenosine
CJD	Creutzfeldt-Jakob disease
CMV	cytomegalovirus
CRV	community-acquired respiratory virus
DNA	deoxyribonucleic acid
EBV	Epstein-Barr virus
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
G-CSF	granulocyte colony-stimulating factor (filgastrim)
GM-CSF	granulocyte-macrophage colony-stimulating factor (sargramostim)
GVHD	graft-versus-host disease
HCW	health-care worker
HEPA filter	high-efficiency (>90%) particulate air filter
Hib	*Haemophilus influenzae* type b
HIV	human immunodeficiency virus
HLA	human lymphocyte antigen
HSCT	hematopoietic stem cell transplant; for this report, includes all blood- and marrow-derived hematopoietic stem cell transplants
HSV	herpes simplex virus
HTLV	human T-lymphotropic virus
IgA	immunoglobulin A
IgG	immunoglobulin G
IgM	immunoglobulin M
IVIG	intravenous immunoglobulin
LAF	laminar air flow
LD	Legionnaires' disease
LRI	lower respiratory infection
MIC	minimum inhibitory concentration
MRSA	methicillin-resistant *Staphylococcus aureus*
nvCJD	new variant Creutzfeldt-Jakob disease
OI	opportunistic infection
PCP	*Pneumocystis carinii* pneumonia
PCR	polymerase chain reaction
PZA/RIF	pyrazinamide/rifampin
RNA	ribonucleic acid
RSV	respiratory syncytial virus
TB	*Mycobacteria tuberculosis*
TMP-SMZ	trimethoprim-sulfamethasaxole
TST	tuberculin skin test
UCB	umbilical cord blood
URI	upper respiratory infection
VRE	vancomycin-resistant *Enterococcus*
VZIG	varicella-zoster immunoglobulin
VZV	varicella-zoster virus

The following CDC staff members prepared this report:

Clare A. Dykewicz, M.D., M.P.H.
Harold W. Jaffe, M.D., Director

Division of AIDS, STD, and TB Laboratory Research
National Center for Infectious Diseases

Jonathan E. Kaplan, M.D.
Division of AIDS, STD, and TB Laboratory Research
National Center for Infectious Diseases
Division of HIV/AIDS Prevention --- Surveillance and Epidemiology
National Center for HIV, STD, and TB Prevention

in collaboration with the Guidelines Working Group Members from CDC, the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation

Clare A. Dykewicz, M.D., M.P.H., Chair
Harold W. Jaffe, M.D.
Thomas J. Spira, M.D.
Division of AIDS, STD, and TB Laboratory Research

William R. Jarvis, M.D.
Hospital Infections Program
National Center for Infectious Diseases, CDC

Jonathan E. Kaplan, M.D.
Division of AIDS, STD, and TB Laboratory Research
National Center for Infectious Diseases
Division of HIV/AIDS Prevention --- Surveillance and Epidemiology
National Center for HIV, STD, and TB Prevention, CDC

Brian R. Edlin, M.D.
Division of HIV/AIDS Prevention---Surveillance and Epidemiology
National Center for HIV, STD, and TB Prevention, CDC

Robert T. Chen, M.D., M.A.
Beth Hibbs, R.N., M.P.H.
Epidemiology and Surveillance Division
National Immunization Program, CDC

Raleigh A. Bowden, M.D.
Keith Sullivan, M.D.
Fred Hutchinson Cancer Research Center
Seattle, Washington

David Emanuel, M.B.Ch.B.
Indiana University
Indianapolis, Indiana

David L. Longworth, M.D.
Cleveland Clinic Foundation
Cleveland, Ohio

Philip A. Rowlings, M.B.B.S., M.S.
International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry
Milwaukee, Wisconsin

Robert H. Rubin, M.D.
Massachusetts General Hospital
Boston, Massachusetts
and
Massachusetts Institute of Technology
Cambridge, Massachusetts

Kent A. Sepkowitz, M.D.
Memorial-Sloan Kettering Cancer Center
New York, New York

John R. Wingard, M.D.
University of Florida
Gainesville, Florida

Additional Contributors

John F. Modlin, M.D.
Dartmouth Medical School
Hanover, New Hampshire

Donna M. Ambrosino, M.D.
Dana-Farber Cancer Institute
Boston, Massachusetts

Norman W. Baylor, Ph.D.
Food and Drug Administration
Rockville, Maryland

Albert D. Donnenberg, Ph.D.
University of Pittsburgh
Pittsburgh, Pennsylvania

Pierce Gardner, M.D.
State University of New York at Stony Brook

Stony Brook, New York

Roger H. Giller, M.D.
University of Colorado
Denver, Colorado

Neal A. Halsey, M.D.
Johns Hopkins University
Baltimore, Maryland

Chinh T. Le, M.D.
Kaiser-Permanente Medical Center
Santa Rosa, California

Deborah C. Molrine, M.D.
Dana-Farber Cancer Institute
Boston, Massachusetts

Keith M. Sullivan, M.D.
Fred Hutchinson Cancer Research Center
Seattle, Washington

Summary

CDC, the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation have cosponsored these guidelines for preventing opportunistic infections (OIs) among hematopoietic stem cell transplant (HSCT) recipients. The guidelines were drafted with the assistance of a working group of expe in infectious diseases, transplantation, and public health. For the purposes of this report, HSCT is defined as any transplantation of blood- or marrow-derived hematopoietic stem cells, regardless of transplant type (i.e., allogeneic or autologous) or cell source (i.e., bone marrow, peripheral blood, or placental or umbilical co blood). Such OIs as bacterial, viral, fungal, protozoal, and helminth infections occur with increased frequency or severity among HSCT recipients. These evidence-bas guidelines contain information regarding preventing OIs, hospital infection control, strategies for safe living after transplantation, vaccinations, and hematopoietic ste cell safety. The disease-specific sections address preventing exposure and disease for pediatric and adult and autologous and allogeneic HSCT recipients. The goal of these guidelines is twofold: to summarize current data and provide evidence-based recommendations regarding preventing OIs among HSCT patients. The guidelines were developed for use by HSCT recipients, their household and close contacts, transplant and infectious diseases physicians, HSCT center personnel, and public heal professionals. For all recommendations, prevention strategies are rated by the strength of the recommendation and the quality of the evidence supporting the recommendation. Adhering to these guidelines should reduce the number and severity of OIs among HSCT recipients.

INTRODUCTION

In 1992, the Institute of Medicine (*1*) recommended that CDC lead a global effort to detect and control emerging infectious agents. In response, CDC published a plan that outlined national disease prevention priorities, including the development of guidelines for preventing opportunistic infections (OIs) among immunosuppressed persons. During 1995, CDC published guidelines for preventing OIs among persons infected with human immunodeficiency virus (HIV) and revised those guidelines during 1997 and 1999 (*3--5*). Because of the success of those guidelines, CDC sought to determine the need for expanding OI prevention activities to other immunosuppressed populations. An informal survey of hematology, oncology, and infectious disease specialists at transplant centers and a working group formed by CDC determined that guidelines were needed to help prevent OIs among hematopoietic stem cell transplant (HSCT)* recipients.

The working group defined OIs as infections that occur with increased frequency or severity among HSCT recipients, and they drafted evidence-based recommendatio for preventing exposure to and disease caused by bacterial, fungal, viral, protozoal, or helminthic pathogens. During March 1997, the working group presented the first draft of these guidelines at a meeting of representatives from public and private health organizations. After review by that group and other experts, these guidelines wer revised and made available during September 1999 for a 45-day public comment period after notification in the *Federal Register*. Public comments were added when feasible, and the report was approved by CDC, the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation. The pediat content of these guidelines has been endorsed also by the American Academy of Pediatrics. The hematopoietic stem cell safety section was endorsed by the Internation Society of Hematotherapy and Graft Engineering.

The first recommendations presented in this report are followed by recommendations for hospital infection control, strategies for safe living, vaccinations, and hematopoietic stem cell safety. Unless otherwise noted, these recommendations address allogeneic and autologous and pediatric and adult HSCT recipients. Additional these recommendations are intended for use by the recipients, their household and other close contacts, transplant and infectious diseases specialists, HSCT center personnel, and public health professionals.

Using These Guidelines

For all recommendations, prevention strategies are rated by the strength of the recommendation (Table 1) and the quality of the evidence (Table 2) supporting the recommendation. The principles of this rating system were developed by the Infectious Disease Society of America and the U.S. Public Health Service for use in the guidelines for preventing OIs among HIV-infected persons (*3--6*). This rating system allows assessments of recommendations to which adherence is critical.

BACKGROUND

HSCT is the infusion of hematopoietic stem cells from a donor into a patient who has received chemotherapy, which is usually marrow-ablative. Increasingly, HSCT h been used to treat neoplastic diseases, hematologic disorders, immunodeficiency syndromes, congenital enzyme deficiencies, and autoimmune disorders (e.g., systemic lupus erythematosus or multiple sclerosis) (*7--10*). Moreover, HSCT has become standard treatment for selected conditions (*7,11,12*). Data from the International Bone Marrow Transplant Registry and the Autologous Blood and Marrow Transplant Registry indicate that approximately 20,000 HSCTs were performed in North America during 1998 (Statistical Center of the International Bone Marrow Transplant Registry and Autologous Blood and Marrow Transplant Registry, unpublished data, 1998)

HSCTs are classified as either allogeneic or autologous on the basis of the source of the transplanted hematopoietic progenitor cells. Cells used in allogeneic HSCTs ar harvested from a donor other than the transplant recipient. Such transplants are the most effective treatment for persons with severe aplastic anemia (*13*) and offer the only curative therapy for persons with chronic myelogenous leukemia (*12*). Allogeneic donors might be a blood relative or an unrelated donor. Allogeneic transplants a usually most successful when the donor is a human lymphocyte antigen (HLA)-identical twin or matched sibling. However, for allogeneic candidates who lack such a donor, registry organizations (e.g., the National Marrow Donor Program) maintain computerized databases that store information regarding HLA type from millions of volunteer donors (*14--16*). Another source of stem cells for allogeneic candidates without an HLA-matched sibling is a mismatched family member (*17,18*). However, persons who receive allogeneic grafts from donors who are not HLA-matched siblings are at a substantially greater risk for graft-versus-host disease (GVHD) (*19*). Th persons are also at increased risk for suboptimal graft function and delayed immune system recovery (*19*). To reduce GVHD among allogeneic HSCTs, techniques hav been developed to remove T-lymphocytes, the principal effectors of GVHD, from the donor graft. Although the recipients of T-lymphocyte--depleted marrow grafts generally have lower rates of GVHD, they also have greater rates of graft rejection, cytomegalovirus (CMV) infection, invasive fungal infection, and Epstein-Barr viru (EBV)-associated posttransplant lymphoproliferative disease (*20*).

The patient's own cells are used in an autologous HSCT. Similar to autologous transplants are syngeneic transplants, among whom the HLA-identical twin serves as th donor. Autologous HSCTs are preferred for patients who require high-level or marrow-ablative chemotherapy to eradicate an underlying malignancy but have healthy,

undiseased bone marrows. Autologous HSCTs are also preferred when the immunologic antitumor effect of an allograft is not beneficial. Autologous HSCTs are used most frequently to treat breast cancer, non-Hodgkin's lymphoma, and Hodgkin's disease (*21*). Neither autologous nor syngeneic HSCTs confer a risk for chronic GVHI

Recently, medical centers have begun to harvest hematopoietic stem cells from placental or umbilical cord blood (UCB) immediately after birth. These harvested cells used primarily for allogeneic transplants among children. Early results demonstrate that greater degrees of histoincompatibility between donor and recipient might be tolerated without graft rejection or GVHD when UCB hematopoietic cells are used (*22--24*). However, immune system function after UCB transplants has not been we studied.

HSCT is also evolving rapidly in other areas. For example, hematopoietic stem cells harvested from the patient's peripheral blood after treatment with hematopoietic colony-stimulating factors (e.g., granulocyte colony-stimulating factor [G-CSF or filgastrim] or granulocyte-macrophage colony-stimulating factor [GM-CSF or sargramostim]) are being used increasingly among autologous recipients (*25*) and are under investigation for use among allogeneic HSCT. Peripheral blood has largely replaced bone marrow as a source of stem cells for autologous recipients. A benefit of harvesting such cells from the donor's peripheral blood instead of bone marrow i that it eliminates the need for general anesthesia associated with bone marrow aspiration.

GVHD is a condition in which the donated cells recognize the recipient's cells as nonself and attack them. Although the use of intravenous immunoglobulin (IVIG) in t routine management of allogeneic patients was common in the past as a means of producing immune modulation among patients with GVHD, this practice has decline because of cost factors (*26*) and because of the development of other strategies for GVHD prophylaxis (*27*). For example, use of cyclosporine GVHD prophylaxis has become commonplace since its introduction during the early 1980s. Most frequently, cyclosporine or tacrolimus (FK506) is administered in combination with other immunosuppressive agents (e.g., methotrexate or corticosteroids) (*27*). Although cyclosporine is effective in preventing GVHD, its use entails greater hazards for infectious complications and relapse of the underlying neoplastic disease for which the transplant was performed.

Although survival rates for certain autologous recipients have improved (*28,29*), infection remains a leading cause of death among allogeneic transplants and is a majo cause of morbidity among autologous HSCTs (*29*). Researchers from the National Marrow Donor Program reported that, of 462 persons receiving unrelated allogeneic HSCTs during December 1987--November 1990, a total of 66% had died by 1991 (*15*). Among primary and secondary causes of death, the most common cause was infection, which occurred among 37% of 307 patients (*15*).**

Despite high morbidity and mortality after HSCT, recipients who survive long-term are likely to enjoy good health. A survey of 798 persons who had received an HSC before 1985 and who had survived for >5 years after HSCT, determined that 93% were in good health and that 89% had returned to work or school full time (*30*). In another survey of 125 adults who had survived a mean of 10 years after HSCT, 88% responded that the benefits of transplantation outweighed the side effects (*31*).

Immune System Recovery After HSCT

During the first year after an HSCT, recipients typically follow a predictable pattern of immune system deficiency and recovery, which begins with the chemotherapy c radiation therapy (i.e., the conditioning regimen) administered just before the HSCT to treat the underlying disease. Unfortunately, this conditioning regimen also destroys normal hematopoiesis for neutrophils, monocytes, and macrophages and damages mucosal progenitor cells, causing a temporary loss of mucosal barrier integrity. The gastrointestinal tract, which normally contains bacteria, commensal fungi, and other bacteria-carrying sources (e.g., skin or mucosa) becomes a reservoir potential pathogens. Virtually all HSCT recipients rapidly lose all T- and B-lymphocytes after conditioning, losing immune memory accumulated through a lifetime of exposure to infectious agents, environmental antigens, and vaccines. Because transfer of donor immunity to HSCT recipients is variable and influenced by the timing c antigen exposure among donor and recipient, passively acquired donor immunity cannot be relied upon to provide long-term immunity against infectious diseases amo HSCT recipients.

During the first month after HSCT, the major host-defense deficits include impaired phagocytosis and damaged mucocutaneous barriers. Additionally, indwelling intravenous catheters are frequently placed and left in situ for weeks to administer parenteral medications, blood products, and nutritional supplements. These catheters serve as another portal of entry for opportunistic pathogens from organisms colonizing the skin (e.g., coagulase-negative *Staphylococci*, *Staphylococcus aureus*, *Candida* species, and *Enterococci*) (*32,33*).

Engraftment for adults and children is defined as the point at which a patient can maintain a sustained absolute neutrophil count (ANC) of >500/mm^3 and sustained platelet count of ≥20,000, lasting ≥3 consecutive days without transfusions. Among unrelated allogeneic recipients, engraftment occurs at a median of 22 days after HSCT (range: 6--84 days) (*15*). In the absence of corticosteroid use, engraftment is associated with the restoration of effective phagocytic function, which results in a decreased risk for bacterial and fungal infections. However, all HSCT recipients and particularly allogeneic recipients, experience an immune system dysfunction for months after engraftment. For example, although allogeneic recipients might have normal total lymphocyte counts within ≥2 months after HSCT, they have abnormal CD4/CD8 T-cell ratios, reflecting their decreased CD4 and increased CD8 T-cell counts (*27*). They might also have immunoglobulin G $(IgG)_2$, IgG_4, and immunoglobulin A (IgA) deficiencies for months after HSCT and have difficulty switching from immunoglobulin M (IgM) to IgG production after antigen exposure (3 Immune system recovery might be delayed further by CMV infection (*34*).

During the first ≥2 months after HSCT, recipients might experience acute GVHD that manifests as skin, gastrointestinal, and liver injury, and is graded on a scale of I-- (*32,35,36*). Although autologous or syngeneic recipients might occasionally experience a mild, self-limited illness that is acute GVHD-like (*19,37*), GVHD occurs primarily among allogeneic recipients, particularly those receiving matched, unrelated donor transplants. GVHD is a substantial risk factor for infection among HSCT recipients because it is associated with a delayed immunologic recovery and prolonged immunodeficiency (*19*). Additionally, the immunosuppressive agents used for GVHD prophylaxis and treatment might make the HSCT recipient more vulnerable to opportunistic viral and fungal pathogens (*38*).

Certain patients, particularly adult allogeneic recipients, might also experience chronic GVHD, which is graded as either limited or extensive chronic GVHD (*19,39*). Chronic GVHD appears similar to autoimmune, connective-tissue disorders (e.g., scleroderma or systemic lupus erythematosus) (*40*) and is associated with cellular an humoral immunodeficiencies, including macrophage deficiency, impaired neutrophil chemotaxis (*41*), poor response to vaccination (*42--44*), and severe mucositis (*19* Risk factors for chronic GVHD include increasing age, allogeneic HSCT (particularly those among whom the donor is unrelated or a non-HLA identical family membe (*40*), and a history of acute GVHD (*24,45*). Chronic GVHD was first described as occurring >100 days after HSCT but can occur 40 days after HSCT (*19*). Although allogeneic recipients with chronic GVHD have normal or high total serum immunoglobulin levels (*41*), they experience long-lasting IgA, IgG, and IgG subclass deficiencies (*41,46,47*) and poor opsonization and impaired reticuloendothelial function. Consequently, they are at even greater risk for infections (*32,39*), particularly life-threatening bacterial infections from encapsulated organisms (e.g., *Stre. pneumoniae*, *Ha. influenzae*, or *Ne. meningitidis*). After chronic GVHD resolves, which might take years, cell-mediated and humoral immunity function are gradually restored.

Opportunistic Pathogens After HSCT

HSCT recipients experience certain infections at different times posttransplant, reflecting the predominant host-defense defect(s) (Figure). Immune system recovery fo HSCT recipients takes place in three phases beginning at day 0, the day of transplant. Phase I is the preengraftment phase (<30 days after HSCT); phase II, the postengraftment phase (30--100 days after HSCT); and phase III, the late phase (>100 days after HSCT). Prevention strategies should be based on these three phases a the following information:

- **Phase I, preengraftment.** During the first month posttransplant, HSCT recipients have two critical risk factors for infection --- prolonged neutropenia and break in the mucocutaneous barrier resulting from the HSCT preparative regimens and frequent vascular access required for patient care. Consequently, oral, gastro-intestinal, and skin flora are sources of infection. Prevalent pathogens include *Candida* species, and as neutropenia continues, *Aspergillus* species. Additionally, herpes simplex virus (HSV) reactivation can occur during this phase. During preengraftment, the risks for infection are the same for autologous or allogeneic patients, and OIs can appear as febrile neutropenia. Although a recipient's first fever during preengraftment is probably caused by a bacterial pathogen, rarely is a organism or site of infection identified. Instead, such infections are usually treated preemptively or empirically (*48*) until the neutropenia resolves (*49*). Growth factors can be administered during phase I to decrease neutropenia duration and complications (e.g., febrile neutropenia) (*50*).
- **Phase II, postengraftment.** Phase II is dominated by impaired cell-mediated immunity for allogeneic or autologous recipients. Scope and impact of this defect f allogeneic recipients are determined by the extent of GVHD and its immunosuppressive therapy. After engraftment, the herpes viruses, particularly CMV, are

critical pathogens. At 30--100 days after HSCT, CMV causes pneumonia, hepatitis, and colitis and potentiates superinfection with opportunistic pathogens, particularly among patients with active GVHD. Other dominant pathogens during this phase include *Pneumocystis carinii* and *Aspergillus* species.

- **Phase III, late phase.** During phase III, autologous recipients usually have more rapid recovery of immune system function and, therefore, a lower risk for OIs than do allogeneic recipients. Because of cell-mediated and humoral immunity defects and impaired reticuloendothelial system function, allogeneic patients with chronic GVHD and recipients of alternate donor allogeneic transplants are at risk for certain infections during this phase. Alternate donors include matched unrelated, UCB, or mismatched family-related donors. These patients are at risk for infections that include CMV, varicella-zoster virus (VZV), EBV-related posttransplant lymphoproliferative disease, community-acquired respiratory viruses (CRV), and infections with encapsulated bacteria (e.g., *Ha. influenzae* and *S. pneumoniae*). Risk for these infections is approximately proportional to the severity of the patient's GVHD during phases II and III. Patients receiving mismatche allogeneic transplants have a higher attack rate and severity of GVHD and, therefore, a higher risk for OIs during phases II and III than do patients receiving matched allogeneic HSCTs. In contrast, patients undergoing autologous transplantation are primarily at risk for infection during phase I.

Preventing infections among HSCT recipients is preferable to treating infections. How ever, despite recent technologic advances, more research is needed to optimize health outcomes for HSCT recipients. Efforts to improve immune system reconstitution, particularly among allogeneic transplant recipients, and to prevent or resolve t immune dysregulation resulting from donor-recipient histoincompatibility and GVHD remain substantial challenges for preventing recurrent, persistent, or progressive infections among HSCT patients.

BACTERIAL INFECTIONS

General Recommendations

Preventing Exposure

Because bacteria are carried on the hands, health-care workers (HCWs) and others in contact with HSCT recipients should routinely follow appropriate hand-washing practices to avoid exposing recipients to bacterial pathogens (AIII).

Preventing Disease

Preventing Early Disease (0--100 Days After HSCT). Routine gut decontamination is not recommended for HSCT candidates (51--53) (DIII). Because of limited data no recommendations can be made regarding the routine use of antibiotics for bacterial prophylaxis among afebrile, asymptomatic neutropenic recipients. Although studies have reported that using prophylactic antibiotics might reduce bacteremia rates after HSCT (51), infection-related fatality rates are not reduced (52). If physicia choose to use prophylactic antibiotics among asymptomatic, afebrile, neutropenic recipients, they should routinely review hospital and HSCT center antibiotic-susceptibility profiles, particularly when using a single antibiotic for antibacterial prophylaxis (BIII). The emergence of fluoquinolone-resistant coagulase-negative *Staphylococci* and *Es. coli* (51,52), vancomycin-intermediate *Sta. aureus* and vancomycin-resistant *Enterococcus* (VRE) are increasing concerns (54). Vancomycin should not be used as an agent for routine bacterial prophylaxis (DIII). Growth factors (e.g., GM-CSF and G-CSF) shorten the duration of neutropenia after HSCT (55) however, no data were found that indicate whether growth factors effectively reduce the attack rate of invasive bacterial disease.

Physicians should not routinely administer IVIG products to HSCT recipients for bacterial infection prophylaxis (DII), although IVIG has been recommended for use i producing immune system modulation for GVHD prevention. Researchers have recommended routine IVIG*** use to prevent bacterial infections among the approximately 20%--25% of HSCT recipients with unrelated marrow grafts who experience severe hypogamma-globulinemia (e.g., IgG < 400 mg/dl) within the first 1 days after transplant (CIII). For example, recipients who are hypogammaglobulinemic might receive prophylactic IVIG to prevent bacterial sinopulmonary infections (e.g., from *Stre. pneumoniae*) (*8*) (CIII). For hypogammaglobulinemic allogeneic recipients, physicians can use a higher and more frequent dose of IVIG than is standa for non-HSCT recipients because the IVIG half-life among HSCT recipients (generally 1--10 days) is much shorter than the half-life among healthy adults (generally 1 -23 days) (*56--58*). Additionally, infections might accelerate IgG catabolism; therefore, the IVIG dose for a hypogammaglobulinemic recipient should be individualized to maintain trough serum IgG concentrations >400--500 mg/dl (*58*) (BII). Consequently, physicians should monitor trough serum IgG concentrations among these patients approximately every 2 weeks and adjust IVIG doses as needed (BIII) (Appendix).

Preventing Late Disease (>100 Days After HSCT). Antibiotic prophylaxis is recommended for preventing infection with encapsulated organisms (e.g., *Stre. pneumoni Ha. influenzae*, or *Ne. meningitidis*) among allogeneic recipients with chronic GVHD for as long as active chronic GVHD treatment is administered (*59*) (BIII). Antibiotic selection should be guided by local antibiotic resistance patterns. In the absence of severe demonstrable hypogammaglobulinemia (e.g., IgG levels < 400 mg/dl, which might be associated with recurrent sinopulmonary infections), routine monthly IVIG administration to HSCT recipients >90 days after HSCT is not recommended (*60*) (DI) as a means of preventing bacterial infections.

Other Disease Prevention Recommendations. Routine use of IVIG among autologous recipients is not recommended (*61*) (DII). Recommendations for preventing bacterial infections are the same among pediatric or adult HSCT recipients.

Recommendations Regarding *Stre. pneumoniae*

Preventing Exposure

Appropriate care precautions should be taken with hospitalized patients infected with *Stre. pneumoniae* (*62,63*) (BIII) to prevent exposure among HSCT recipients.

Preventing Disease

Information regarding the currently available 23-valent pneumococcal polysaccharide vaccine indicates limited immunogenicity among HSCT recipients. However, because of its potential benefit to certain patients, it should be administered to HSCT recipients at 12 and 24 months after HSCT (*64--66*) (BIII). No data were found regarding safety and immunogenicity of the 7-valent conjugate pneumococcal vaccine among HSCT recipients; therefore, no recommendation regarding use of this vaccine can be made.

Antibiotic prophylaxis is recommended for preventing infection with encapsulated organisms (e.g., *Stre. pneumoniae*, *Ha. influenzae*, and *Ne. meningitidis*) among allogeneic recipients with chronic GVHD for as long as active chronic GVHD treatment is administered (*59*) (BIII). Trimethoprim-sulfamethasaxole (TMP-SMZ) administered for *Pneumocystis carinii* pneumonia (PCP) prophylaxis will also provide protection against pneumococcal infections. However, no data were found to support using TMP-SMZ prophylaxis among HSCT recipients solely for the purpose of preventing *Stre. pneumoniae* disease. Certain strains of *Stre. pneumoniae* are resistant to TMP-SMZ and penicillin. Recommendations for preventing pneumococcal infections are the same for allogeneic or autologous recipients.

As with adults, pediatric HSCT recipients aged ≥2 years should be administered the current 23-valent pneumococcal polysaccharide vaccine because the vaccine can b effective (BIII). However, this vaccine should not be administered to children aged <2 years because it is not effective among that age population (DI). No data were found regarding safety and immunogenicity of the 7-valent conjugate pneumococcal vaccine among pediatric HSCT recipients; therefore, no recommendation regardir use of this vaccine can be made.

Recommendations Regarding *Streptococci viridans*

Preventing Exposure

Because *Streptococci viridans* colonize the oropharynx and gut, no effective method of preventing exposure is known.

Preventing Disease

Chemotherapy-induced oral mucositis is a potential source of *Streptococci viridans* bacteremia. Consequently, before conditioning starts, dental consults should be obtained for all HSCT candidates to assess their state of oral health and to perform any needed dental procedures to decrease the risk for oral infections after transplant (*67*) (AIII).

Generally, HSCT physicians should not use prophylactic antibiotics to prevent *Streptococci viridans* infections (DIII). No data were found that demonstrate efficacy of prophylactic antibiotics for this infection. Furthermore, such use might select antibiotic-resistant bacteria, and in fact, penicillin- and vancomycin-resistant strains of *Streptococci viridans* have been reported (*68*). However, when *Streptococci viridans* infections among HSCT recipients are virulent and associated with overwhelming sepsis and shock in an institution, prophylaxis might be evaluated (CIII). Decisions regarding the use of *Streptococci viridans* prophylaxis should be made only after consultation with the hospital epidemiologists or infection-control practitioners who monitor rates of nosocomial bacteremia and bacterial susceptibility (BIII).

HSCT physicians should be familiar with current antibiotic susceptibilities for patient isolates from their HSCT centers, including *Streptococci viridans* (BIII). Physici should maintain a high index of suspicion for this infection among HSCT recipients with symptomatic mucositis because early diagnosis and aggressive therapy are currently the only potential means of preventing shock when severely neutropenic HSCT recipients experience *Streptococci viridans* bacteremia (*69*).

Recommendations Regarding *Ha. influenzae* type b

Preventing Exposure

Adults with *Ha. influenzae* type b (Hib) pneumonia require standard precautions (*62*) to prevent exposing the HSCT recipient to Hib. Adults and children who are in contact with the HSCT recipient and who have known or suspected invasive Hib disease, including meningitis, bacteremia, or epiglottitis, should be placed in droplet precautions until 24 hours after they begin appropriate antibiotic therapy, after which they can be switched to standard precautions. Household contacts exposed to persons with Hib disease and who also have contact with HSCT recipients should be administered rifampin prophylaxis according to published recommendations (*70,71*); prophylaxis for household contacts of a patient with Hib disease are necessary if all contacts aged <4 years are not fully vaccinated (BIII) (Appendix). This recommendation is critical because the risk for invasive Hib disease among unvaccinated household contacts aged <4 years is increased, and rifampin can be effective eliminating Hib carriage and preventing invasive Hib disease (*72--74*). Pediatric household contacts should be up-to-date with Hib vaccinations to prevent possible Hit exposure to the HSCT recipient (AII).

Preventing Disease

Although no data regarding vaccine efficacy among HSCT recipients were found, Hib conjugate vaccine should be administered to HSCT recipients at 12, 14, and 24 months after HSCT (BII). This vaccine is recommended because the majority of HSCT recipients have low levels of Hib capsular polysaccharide antibodies ≥4 months after HSCT (*75*), and allogeneic recipients with chronic GVHD are at increased risk for infection from encapsulated organisms (e.g., Hib) (*76,77*). HSCT recipients wh are exposed to persons with Hib disease should be offered rifampin prophylaxis according to published recommendations (*70*) (BIII) (Appendix).

Antibiotic prophylaxis is recommended for preventing infection with encapsulated organisms (e.g., *Stre. pneumoniae*, *Ha. influenzae*, or *Ne. meningitidis*) among allogeneic recipients with chronic GVHD for as long as active chronic GVHD treatment is administered (*59*) (BIII). Antibiotic selection should be guided by local antibiotic-resistance patterns. Recommendations for preventing Hib infections are the same for allogeneic or autologous recipients. Recommendations for preventing H disease are the same for pediatric or adult HSCT recipients, except that any child infected with Hib pneumonia requires standard precautions with droplet precautions added for the first 24 hours after beginning appropriate antibiotic therapy (*62,70*) (BIII). Appropriate pediatric doses should be administered for Hib conjugate vaccine and for rifampin prophylaxis (*71*) (Appendix).

VIRAL INFECTIONS

Recommendations Regarding Cytomegalovirus

Preventing Exposure

HSCT candidates should be tested for the presence of serum anti-CMV IgG antibodies before transplantation to determine their risk for primary CMV infection and reactivation after HSCT (AIII). Only Food and Drug Administration (FDA) licensed or approved tests should be used. HSCT recipients and candidates should avoid sharing cups, glasses, and eating utensils with others, including family members, to decrease the risk for CMV exposure (BIII).

Sexually active patients who are not in long-term monogamous relationships should always use latex condoms during sexual contact to reduce their risk for exposure t CMV and other sexually transmitted pathogens (AII). However, even long-time monogamous pairs can be discordant for CMV infections. Therefore, during periods of immuno-compromise, sexually active HSCT recipients in monogamous relationships should ask partners to be tested for serum CMV IgG antibody, and discordant couples should use latex condoms during sexual contact to reduce the risk for exposure to this sexually transmitted OI (CIII).

After handling or changing diapers or after wiping oral and nasal secretions, HSCT candidates and recipients should practice regular hand washing to reduce the risk fo CMV exposure (AII). CMV-seronegative recipients of allogeneic stem cell transplants from CMV-seronegative donors (i.e., R-negative or D-negative) should receive only leukocyte-reduced or CMV-seronegative red cells or leukocyte-reduced platelets (<1 x 10^6 leukocytes/unit) to prevent transfusion-associated CMV infection (*78*) (AI). However, insufficient data were found to recommend use of leukocyte-reduced or CMV-seronega tive red cells and platelets among CMV-seronegative recipients who have CMV-seropositive donors (i.e., R-negative or D-positive).

All HCWs should wear gloves when handling blood products or other potentially contaminated biologic materials (AII) to prevent transmission of CMV to HSCT recipients. HSCT patients who are known to excrete CMV should be placed under standard precautions (*62*) for the duration of CMV excretion to avoid possible transmission to CMV-seronegative HSCT recipients and candidates (AIII). Physicians are cautioned that CMV excretion can be episodic or prolonged.

Preventing Disease and Disease Recurrence

HSCT recipients at risk for CMV disease after HSCT (i.e., all CMV-seropositive HSCT recipients, and all CMV-seronegative recipients with a CMV-seropositive donc should be placed on a CMV disease prevention program from the time of engraftment until 100 days after HSCT (i.e., phase II) (AI). Physicians should use either prophylaxis or preemptive treatment with ganciclovir for allogeneic recipients (AI). In selecting a CMV disease prevention strategy, physicians should assess the risks and benefits of each strategy, the needs and condition of the patient, and the hospital's virology laboratory support capability.

Prophylaxis strategy against early CMV (i.e., <100 days after HSCT) for allogeneic recipients involves administering ganciclovir prophylaxis to all allogeneic recipien at risk throughout phase II (i.e., from engraftment to 100 days after HSCT). The induction course is usually started at engraftment (AI), although physicians can add a brief prophylactic course during HSCT preconditioning (CIII) (Appendix).

Preemptive strategy against early CMV (i.e., <100 days after HSCT) for allogeneic recipients is preferred over prophylaxis for CMV-seronegative HSCT recipients of seropositive donor cells (i.e., D-positive or R-negative) because of the low attack rate of active CMV infection if screened or filtered blood product support is used (BI Preemptive strategy restricts ganciclovir use for those patients who have evidence of CMV infection after HSCT. It requires the use of sensitive and specific laboratory tests to rapidly diagnose CMV infection after HSCT and to enable immediate administration of ganciclovir after CMV infection has been detected. Allogeneic recipien at risk should be screened ≥1 times/week from 10 days to 100 days after HSCT (i.e., phase II) for the presence of CMV viremia or antigenemia (AIII).

HSCT physicians should select one of two diagnostic tests to determine the need for preemptive treatment. Currently, the detection of CMV pp65 antigen in leukocytes (antigenemia) (*79,80*) is preferred for screening for preemptive treatment because it is more rapid and sensitive than culture and has good positive predictive value (*79- -81*). Direct detection of CMV-DNA (deoxyribonucleic acid) by polymerase chain reaction (PCR) (*82*) is very sensitive but has a low positive predictive value (*79*).

Although CMV-DNA PCR is less sensitive than whole blood or leukocyte PCR, plasma CMV-DNA PCR is useful during neutropenia, when the number of leukocytes/slide is too low to allow CMV pp65 antigenemia testing.

Virus culture of urine, saliva, blood, or bronchoalveolar washings by rapid shell-vial culture (*83*) or routine culture (*84,85*) can be used; however, viral culture techniqu are less sensitive than CMV-DNA PCR or CMV pp65 antigenemia tests. Also, rapid shell-viral cultures require ≥48 hours and routine viral cultures can require weeks obtain final results. Thus, viral culture techniques are less satisfactory than PCR or antigenemia tests. HSCT centers without access to PCR or antigenemia tests should use prophylaxis rather than preemptive therapy for CMV disease prevention (*86*) (BII). Physicians do use other diagnostic tests (e.g., hybrid capture CMV-DNA assay, Version 2.0 [*87*] or CMV pp67 viral RNA [ribonucleic acid] detection) (*88*); however, limited data were found regarding use among HSCT recipients, and therefore, nc recommendation for use can be made.

Allogeneic recipients ≤100 days after HSCT (i.e., during phase II) should begin preemptive treatment with ganciclovir if CMV viremia or any antigenemia is detected if the recipient has ≥2 consecutively positive CMV-DNA PCR tests (BIII). After preemptive treatment has been started, maintenance ganciclovir is usually continued until 100 days after HSCT or for a minimum of 3 weeks, whichever is longer (AI) (Appendix). Antigen or PCR tests should be negative when ganciclovir is stopped. Studies report that a shorter course of ganciclovir (e.g., for 3 weeks or until negative PCR or antigenemia occurs) (*89--91*) might provide adequate CMV prevention wi less toxicity, but routine weekly screening by pp65 antigen or PCR test is necessary after stopping ganciclovir because CMV reactivation can occur (BIII).

Presently, only the intravenous formulation of ganciclovir has been approved for use in CMV prophylactic or preemptive strategies (BIII). No recommendation for ora ganciclovir use among HSCT recipients can be made because clinical trials evaluating its efficacy are still in progress. One group has used ganciclovir and foscarnet or alternate days for CMV prevention (*92*), but no recommendation can be made regarding this strategy because of limited data. Patients who are ganciclovir-intolerant should be administered foscarnet instead (*93*) (BII) (Appendix). HSCT recipients receiving ganciclovir should have ANCs checked ≥2 times/week (BIII). Researchers report managing ganciclovir-associated neutropenia by adding G-CSF (*94*) or temporarily stopping ganciclovir for ≥2 days if the patient's ANC is <1,000 (CIII). Ganciclovir can be restarted when the patient's ANC is ≥1,000 for 2 consecutive days. Alternatively, researchers report substituting foscarnet for ganciclovir if a) the HSCT recipient is still CMV viremic or antigenemic or b) the ANC remains <1,000 for >5 days after ganciclovir has been stopped (CIII) (Appendix). Because neutropenia accompanying ganciclovir administration is usually brief, such patients do not require antifungal or antibacterial prophylaxis (DIII).

Currently, no benefit has been reported from routinely administering ganciclovir prophylaxis to all HSCT recipients at >100 days after HSCT (i.e., during phase III). However, persons with high risk for late CMV disease should be routinely screened biweekly for evidence of CMV reactivation as long as substantial immunocompromise persists (BIII). Risk factors for late CMV disease include allogeneic HSCT accompanied by chronic GVHD, steroid use, low CD4 counts, delay i high avidity anti-CMV antibody, and recipients of matched unrelated or T-cell--depleted HSCTs who are at high risk (*95--99*). If CMV is still detectable by routine screening ≥100 days after HSCT, ganciclovir should be continued until CMV is no longer detectable (AI). If low-grade CMV antigenemia (<5 positive cells/slide) is detected on routine screening, the antigenemia test should be repeated in 3 days (BIII). If CMV antigenemia indicates ≥5 cells/slide, PCR is positive, or the shell-vial culture detects CMV viremia, a 3-week course of preemptive ganciclovir treatment should be administered (BIII) (Appendix). Ganciclovir should also be started if the patient has had ≥2 consecutively positive viremia or PCR tests (e.g., in a person receiving steroids for GVHD or who received ganciclovir or foscarnet at <100 days afl HSCT). Current investigational strategies for preventing late CMV disease include the use of targeted prophylaxis with antiviral drugs and cellular immunotherapy for those with deficient or absent CMV-specific immune system function.

If viremia persists after 4 weeks of ganciclovir preemptive therapy or if the level of antigenemia continues to rise after 3 weeks of therapy, ganciclovir-resistant CMV should be suspected. If CMV viremia recurs during continuous treatment with ganciclovir, researchers report restarting ganciclovir induction (*100*) or stopping ganciclovir and starting foscarnet (CIII). Limited data were found regarding the use of foscarnet among HSCT recipients for either CMV prophylaxis or preemptive therapy (*92,93*).

Infusion of donor-derived CMV-specific clones of CD8+ T-cells into the transplant recipient is being evaluated under FDA Investigational New Drug authorization; therefore, no recommendation can be made. Although, in a substantial cooperative study, high-dose acyclovir has had certain efficacy for preventing CMV disease (*10* its utility is limited in a setting where more potent anti-CMV agents (e.g., ganciclovir) are used (*102*). Acyclovir is not effective in preventing CMV disease after autologous HSCT (*103*) and is, therefore, not recommended for CMV preemptive therapy (DII). Consequently, valacyclovir, although under study for use among HSC recipients, is presumed to be less effective than ganciclovir against CMV and is currently not recommended for CMV disease prevention (DII).

Although HSCT physicians continue to use IVIG for immune system modulation, IVIG is not recommended for CMV disease prophylaxis among HSCT recipients (D Cidofovir, a nucleoside analog, is approved by FDA for the treatment of AIDS-associated CMV retinitis. The drug's major disadvantage is nephrotoxicity. Cidofovir is currently in FDA phase 1 trial for use among HSCT recipients; therefore, recommendations for its use cannot be made.

Use of CMV-negative or leukocyte-reduced blood products is not routinely required for all autologous recipients because most have a substantially lower risk for CMV disease. However, CMV-negative or leukocyte-reduced blood products can be used for CMV-seronegative autologous recipients (CIII). Researchers report that CMV-seropositive autologous recipients be evaluated for preemptive therapy if they have underlying hematologic malignancies (e.g., lymphoma or leukemia), are receiving intense conditioning regimens or graft manipulation, or have recently received fludarabine or 2-chlorodeoxyadenosine (CDA) (CIII). This subpopulation of autologous recipients should be monitored weekly from time of engraftment until 60 days after HSCT for CMV reactivation, preferably with quantitative CMV pp65 antigen (*80*) quantitative PCR (BII).

Autologous recipients at high risk who experience CMV antigenemia (i.e., blood levels of ≥5 positive cells/slide) should receive 3 weeks of preemptive treatment with ganciclovir or foscarnet (*80*), but CD34+-selected patients should be treated at any level of antigenemia (BII) (Appendix). Prophylactic approach to CMV disease prevention is not appropriate for CMV-seropositive autologous recipients. Indications for the use of CMV prophylaxis or preemptive treatment are the same for childre or adults.

Recommendations Regarding EBV

Preventing Exposure

All transplant candidates, particularly those who are EBV-seronegative, should be advised of behaviors that could decrease the likelihood of EBV exposure (AII). For example, HSCT recipients and candidates should follow safe hygiene practices (e.g., frequent hand washing [AIII] and avoiding the sharing of cups, glasses, and eating utensils with others) (*104*) (BIII), and they should avoid contact with potentially infected respiratory secretions and saliva (*104*) (AII).

Preventing Disease

Infusion of donor-derived, EBV-specific cytotoxic T-lymphocytes has demonstrated promise in the prophylaxis of EBV-lymphoma among recipients of T-cell--depleted unrelated or mismatched allogeneic recipients (*105,106*). However, insufficient data were found to recommend its use. Prophylaxis or preemptive therapy with acyclov is not recommended because of lack of efficacy (*107,108*) (DII).

Recommendations Regarding HSV

Preventing Exposure

HSCT candidates should be tested for serum anti-HSV IgG before transplant (AIII); however, type-specific anti-HSV IgG serology testing is not necessary. Only FDA licensed or -approved tests should be used. All HSCT candidates, particularly those who are HSV-seronegative, should be informed of the importance of avoiding HSV infection while immunocompromised and should be advised of behaviors that will decrease the likelihood of HSV exposure (AII). HSCT recipients and candidates should avoid sharing cups, glasses, and eating utensils with others (BIII). Sexually active patients who are not in a long-term monogamous relationship should always latex condoms during sexual contact to reduce the risk for exposure to HSV as well as other sexually transmitted pathogens (AII). However, even long-time monogam pairs can be discordant for HSV infections. Therefore, during periods of immunocompromise, sexually active HSCT recipients in such relationships should ask partner

to be tested for serum HSV IgG antibody. If the partners are discordant, they should consider using latex condoms during sexual contact to reduce the risk for exposure this sexually transmitted OI (CIII). Any person with disseminated, primary, or severe mucocutaneous HSV disease should be placed under contact precautions for the duration of the illness (*62*) (AI) to prevent transmission of HSV to HSCT recipients.

Preventing Disease and Disease Recurrence

Acyclovir. Acyclovir prophylaxis should be offered to all HSV-seropositive allogeneic recipients to prevent HSV reactivation during the early posttransplant period (*10 -113*) (AI). Standard approach is to begin acyclovir prophylaxis at the start of the conditioning therapy and continue until engraftment occurs or until mucositis resolve whichever is longer, or approximately 30 days after HSCT (BIII) (Appendix). Without supportive data from controlled studies, routine use of antiviral prophylaxis for >30 days after HSCT to prevent HSV is not recommended (DIII). Routine acyclovir prophylaxis is not indicated for HSV-seronegative HSCT recipients, even if the donors are HSV-seropositive (DIII). Researchers have proposed administration of ganciclovir prophylaxis alone (*86*) to HSCT recipients who required simultaneous prophylaxis for CMV and HSV after HSCT (CIII) because ganciclovir has in vitro activity against CMV and HSV 1 and 2 (*114*), although ganciclovir has not been approved for use against HSV.

Valacyclovir. Researchers have reported valacyclovir use for preventing HSV among HSCT recipients (CIII); however, preliminary data demonstrate that very high do of valacyclovir (8 g/day) were associated with thrombotic thrombocytopenic purpura/hemolytic uremic syndrome among HSCT recipients (*115*). Controlled trial data among HSCT recipients are limited (*115*), and the FDA has not approved valacyclovir for use among recipients. Physicians wishing to use valacyclovir among recipier with renal impairment should exercise caution and decrease doses as needed (BIII) (Appendix).

Foscarnet. Because of its substantial renal and infusion-related toxicity, foscarnet is not recommended for routine HSV prophylaxis among HSCT recipients (DIII).

Famciclovir. Presently, data regarding safety and efficacy of famciclovir among HSCT recipients are limited; therefore, no recommendations for HSV prophylaxis wit famciclovir can be made.

Other Recommendations

HSV prophylaxis lasting >30 days after HSCT might be considered for persons with frequent recurrent HSV (CIII) (Appendix). Acyclovir can be used during phase I f administration to HSV-seropositive autologous recipients who are likely to experience substantial mucositis from the conditioning regimen (CIII). Antiviral prophylaxi doses should be modified for use among children (Appendix), but no published data were found regarding valacyclovir safety and efficacy among children.

Recommendations Regarding VZV

Preventing Exposure

HSCT candidates should be tested for the presence of serum anti-VZV IgG antibodies (AIII). However, these tests are not 100% reliable, particularly among severely immunosuppressed patients. Researchers recommend that a past history of varicella accompanied by a positive titer is more likely to indicate the presence of immunity VZV than a low positive titer alone. All HSCT candidates and recipients, particularly those who are VZV-seronegative, should be informed of the potential seriousness VZV disease among immunocompromised persons and advised of strategies to decrease their risk for VZV exposure (*116--122*) (AII).

Although researchers report that the majority of VZV disease after HSCT is caused by reactivation of endogenous VZV, HSCT candidates and recipients who are VZV seronegative, or VZV-seropositive and immunocompromised, should avoid exposure to persons with active VZV infections (*123*) (AII). HCWs, family members, household contacts, and visitors who are healthy and do not have a reported history of varicella infection or who are VZV-seronegative should receive VZV vaccinatio before being allowed to visit or have direct contact with an HSCT recipient (AIII). Ideally, VZV-susceptible family members, household contacts, and potential visitors immunocompromised HSCT recipients should be vaccinated as soon as the decision is made to perform HSCT. The vaccination dose or doses should be completed ≥4 weeks before the conditioning regimen begins or ≥6 weeks (42 days) before the HSCT is performed (BIII).

HSCT recipients and candidates undergoing conditioning therapy should avoid contact with any VZV vaccine recipient who experiences a rash after vaccination (BIII) When this rash occurs, it usually appears 14--21 days after VZV vaccination (median: 22 days; range: 5--35 days) (personal communication from Robert G. Sharrar, M.D., Merck & Co., Inc.). However, to date, no serious disease has been reported among immuno-compromised patients from transmission of VZV vaccine virus, and the VZV vaccine strain is susceptible to acyclovir.

All HSCT recipients with VZV disease should be placed under airborne and contact precautions (*62*) (AII) to prevent transmission to other HSCT recipients. Contact precautions should be continued until all skin lesions are crusted. Airborne precautions should be instituted 10 days after exposure to VZV and continued until 21 days after last exposure or 28 days postexposure if the patient received varicella-zoster immunoglobulin (VZIG)**** (*62*) (AI) because a person infected with VZV can be infectious before the rash appears.

Preventing Disease

VZIG. VZV-seronegative HSCT recipients should be administered VZIG as soon as possible but ideally within 96 hours after close or household contact with a person having either chickenpox or shingles if the HSCT recipient is not immunocompetent (i.e., allogeneic patient <24 months after HSCT, ≥24 months after HSCT and on immunosuppressive therapy, or having chronic GVHD) (AII). Researchers report VZIG administration for VZV exposure as described for HSCT recipients who were VZV-seropositive before HSCT (CIII).

Because of the high morbidity of VZV-associated disease among severely immunocompromised HSCT recipients and until further data are published, HSCT physician should administer VZIG to all VZV-seronegative HSCT recipients or candidates undergoing conditioning therapy who are exposed to a VZV vaccinee having a varicel like rash (BIII). Researchers also report VZIG administration for this situation for VZV-seropositive HSCT recipients and candidates undergoing conditioning therapy (CIII). These recommendations are made because the vaccinee might be unknowingly incubating wild-type varicella, particularly during the first 14 days after varicella vaccination, and because vaccine-strain VZV has been rarely transmitted by VZV vaccinees with vesicular rashes postvaccination (*121*).

If VZV-seronegative HSCT recipients or candidates undergoing conditioning therapy are closely exposed to varicella >3 weeks after receiving VZIG, they should be administered another dose of VZIG (*120*) (BIII). Researchers also recommend VZIG administration for this condition for VZV-seropositive HSCT recipients and candidates undergoing conditioning therapy (CIII).

Antiviral Drugs. Any HSCT recipient or candidate undergoing conditioning therapy who experiences a VZV-like rash (particularly after exposure to a person with wil type varicella or shingles) should receive preemptive intravenous acyclovir until ≥2 days after all lesions have crusted (BIII) (Appendix). Any HSCT recipient or candidate undergoing conditioning therapy who experiences a VZV-like rash after exposure to a VZV vaccinee with a rash should be administered intravenous acyclov preemptively to prevent severe, disseminated VZV disease (BII). Acyclovir should be administered until 2 days after all lesions have crusted.

Long-term acyclovir prophylaxis to prevent recurrent VZV infection (e.g., during the first 6 months after HSCT) is not routinely recommended (*124--126*) (DIII); however, this therapy could be considered for use among HSCT recipients with severe, long-term immunodeficiency (CIII). When acyclovir resistance occurs among patients, HSCT physicians should use foscarnet for preemptive treatment of VZV disease (*127*) (BIII). Researchers report valacyclovir use for preventing HSV among HSCT recipients (CIII). However, preliminary data demonstrate that very high doses of valacyclovir (8 g/day) were associated with thrombotic thrombocytopenic purpura/hemolytic uremic syndrome among HSCT recipients (*115*). Controlled trial data regarding HSCT recipients are limited (*115*), and the FDA has not approved valacyclovir for use among HSCT recipients. Physicians wishing to use valacyclovir among HSCT recipients with renal impairment should exercise caution and decrea doses as needed (BIII) (Appendix). No data were found demonstrating safety and efficacy of preemptive treatment of famciclovir against herpes zoster among HSCT recipients. Consequently, no recommendation for its use can be made.

Live-Attenuated VZV Vaccine. VZV vaccine use is contraindicated among HSCT recipients <24 months after HSCT (*128*) (EIII). Use of VZV vaccine among HSCT recipients is restricted to research protocols for recipients ≥24 months after HSCT who are presumed immunocompetent. Further research is needed to determine the safety, immunogenicity, and efficacy of VZV vaccine among HSCT recipients.

Other Recommendations

An inactivated VZV vaccine has been used investigationally among HSCT recipients (*129*); however, more studies are needed before a recommendation regarding its u can be made. Recommendations for VZV prevention are the same for allogeneic or autologous recipients. Recommendations for preventing VZV disease among pedia or adult HSCT recipients are the same, except that appropriate dose adjustments for VZIG should be made for pediatric HSCT recipients (AIII) (Appendix).

Recommendations Regarding CRV Infections: Influenza, Respiratory Syncytial Virus, Parainfluenza Virus, and Adenovirus

Preventing Exposure

Preventing CRV exposure is critical in preventing CRV disease (*130,131*). To prevent nosocomial CRV transmission, HSCT recipients and their HCWs should always follow HSCT infection control guidelines (AIII). To minimize the risk for CRV transmission, HCWs and visitors with upper respiratory infection (URI) symptoms sho be restricted from contact with HSCT recipients and HSCT candidates undergoing conditioning therapy (AIII). At a minimum, active clinical surveillance for CRV disease should be conducted on all hospitalized HSCT recipients and candidates undergoing conditioning therapy; this clinical surveillance should include daily screen for signs and symptoms of CRV (e.g., URI or lower respiratory infection [LRI]) (AIII). Viral cultures of asymptomatic HSCT candidates are unlikely to be useful. HSC recipients with URI or LRI symptoms should be placed under contact precautions to avoid transmitting infection to other HSCT candi dates and recipients, HCWs, and visitors until the etiology of illness is identified (*62*) (BIII). Optimal isolation precautions should be modified as needed after the etiology is identified (AIII). HSCT recipients and candidates, their family members and visitors, and all HCWs should be informed regarding CRV infection control measures and the potential severity of CRV infections among HSCT recipients (*130--140*) (BIII). Physicians have routinely conducted culture-based CRV surveillance among HSCT recipients; however, the cost effectiveness of this approach has not been evaluated.

Influenza vaccination of family members and close or household contacts is strongly recommended during each influenza season (i.e., October--May) starting the seas before HSCT and continuing ≥24 months after HSCT (*141*) (AI) to prevent influenza exposure among the recipients or candidates. All family members and close or household contacts of HSCT recipients who remain immunocompromised ≥24 months after HSCT should continue to be vaccinated annually as long as the HSCT recipient's immuno-compromise persists (*141*) (AI). Seasonal influenza vaccination is strongly recommended for all HCWs of HSCT recipients (*142,143*) (AI).

If HCWs, family members, or other close contacts of HSCT recipients receive influenza vaccination during an influenza A outbreak, they should receive amantadine o rimantadine chemoprophylaxis for 2 weeks after influenza vaccination (BI) while the vaccinee experiences an immunologic response to the vaccine. Such a strategy is likely to prevent transmission of influenza A to HCWs and other close contacts of HSCT recipients, which could prevent influenza A transmission to HSCT recipients themselves. However, if a nosocomial outbreak occurs with an influenza A strain that is not contained in the available influenza vaccine, all healthy family members, close and household contacts, and HCWs of HSCT recipients and candidates should be administered influenza A chemoprophylaxis with amantadine or rimantadine un the end of the outbreak (*141*) (BIII).

In 1999, two neuroaminidase inhibitors (zanamivir and oseltamivir) were approved for treatment of influenza, but are not currently approved for prophylaxis. To date, experience is limited regarding use of zanamivir or oseltamivir in the treatment or prophylaxis of influenza among HSCT settings. However, HCWs, family members, other close contacts can be offered a neuroaminidase inhibitor (e.g., zanamivir or oseltamivir) using the same strategies outlined previously, if a) rimantadine or amantadine cannot be tolerated, b) the outbreak strain of influenza A is amantadine or rimantadine-resistant, or c) the outbreak strain is influenza B (*144--147*) (BI). Zanamivir can be administered to persons aged ≥12 years, and oseltamivir can be administered to persons aged ≥18 years. Patients with influenza should be placed unc droplet and standard precautions (AIII) to prevent transmission of influenza to HSCT recipients. HCWs with influenza should be excused from patient care until they a no longer infectious (AIII).

Preventing Disease

HSCT physicians should determine the etiology of a URI in an HSCT recipient or candidate undergoing conditioning therapy, if possible, because respiratory syncytial virus (RSV), influenza, parainfluenza, and adenovirus URIs can progress to more serious LRI, and certain CRVs can be treated (BIII). Appropriate diagnostic samples include nasopharyngeal washes, swabs or aspirates, throat swabs, and bronchoalveolar lavage (BAL) fluid. HSCT candidates with URI symptoms at the time conditioning therapy is scheduled to start should postpone their conditioning regimen until the URIs resolve, if possible, because certain URIs might progress to LRI during immunosuppression (*131,133,137,138*) (BIII).

Recommendations Regarding Influenza. Life-long seasonal influenza vaccination is recommended for all HSCT candidates and recipients, beginning during the influenza season before HSCT and resuming ≥6 months after HSCT (*142*) (BIII). Influenza vaccinations administered to HSCT recipients <6 months after HSCT are unlikely to be beneficial and are not recommended (*142*) (DII). HSCT recipients <6 months after HSCT should receive chemoprophylaxis with amantadine or rimantadine during community or nosocomial influenza A outbreaks (BIII). These drugs are not effective against influenza B. Additionally, antiviral-resistant strains of influenza can emerge during treatment with amantadine or rimantadine and transmission of resistant strains can occur (*148,149*). During such outbreaks, HSCT recipie 6--24 months after HSCT, or >24 months after HSCT and still substantially immunocompromised (i.e., receiving immunosuppressive therapy, have had a relapse of the underlying disease, or have GVHD) and who have not yet received a current influenza vaccination, should be vaccinated against influenza immediately (BIII). Additionally, to allow sufficient time for the patient to experience an immunologic response to influenza vaccine, chemoprophylaxis with amantadine or rimantadine ca be used for these HSCT recipients for 2 weeks after vaccination during a nosocomial or community influenza A outbreak (CIII). Influenza A chemoprophylaxis with amantadine or rimantadine has been recommended for all influenza A-exposed HSCT recipients <24 months after HSCT or ≥24 months after HSCT and substantially immunocompromised regardless of vaccination history, because of their likely suboptimal immunologic response to influenza vaccine (*142,143*). However, no recommendation regarding such chemoprophylaxis can be made because of lack of data.

To prevent severe disease, early preemptive therapy with amantadine or rimantadine has been reported for HSCT recipients with unexplained acute URI or LRI symptoms during a community or nosocomial outbreak of influenza A (*141*). However, the effectiveness in preventing influenza-related complications and the safety o this strategy have not been evaluated among HSCT recipients. Therefore, data are insufficient to make a recommendation.

Neuroaminidase inhibitors (zanimivir and oseltamivir), intravenous and aerosol ribavirin, and combination drug therapy (e.g., rimantadine or amantadine with ribavirir or interferon) (*143,150--153*) have been proposed for investigational, preemptive treatment to prevent severe influenza disease among HSCT recipients. However, because of lack of data, no recommendation for use of these strategies among HSCT recipients can be made.

Recommendations Regarding RSV. Respiratory secretions of any hospitalized HSCT candidate or recipient who experiences signs or symptoms of CRV infection sho be tested promptly by viral culture and rapid diagnostic tests for RSV (BIII). If two diagnostic samples taken ≥2 days apart do not identify a respiratory pathogen despi persistence of respiratory symptoms, BAL and further testing are advised (BIII). This testing is critical because of the high morbidity and case fatality of RSV disease among HSCT recipients (*154,155*). HSCT recipients, particularly those who are preengraftment and at highest risk for severe RSV pneumonia, should have their illnes diagnosed early (i.e., during RSV URI), and their illness should be treated aggressively to prevent fatal RSV disease (BIII).

Although a definitive, uniformly effective preemptive therapy for RSV infection among HSCT recipients has not been identified, certain strategies have been proposed including use of aerosolized ribavirin (*155,156*), RSV antibodies (i.e., passive immunization with high RSV-titered IVIG or RSV immunoglobulin) in combination wit aerosolized ribavirin (*137,157*), and RSV monoclonal antibody (*158*). Clinical trials are currently underway to evaluate the efficacy of these strategies. No recommendation regarding the optimal method for RSV prevention and preemptive therapy can be made because of limited data. Further, current data do not support u of intravenous ribavirin for preemptive therapy for RSV pneumonia among HSCT recipients (*60*) (DIII), and no commercially licensed vaccines against RSV are currently available.

Recommendations Regarding Parainfluenza Virus and Adenovirus. Immuno-prophylaxis, chemoprophylaxis, and preemptive treatment for parainfluenza virus and adenovirus infections among HSCT recipients have been proposed (*159,160*). However, no recommendation can be made in these guidelines because of insufficient da No commercially licensed vaccines against parainfluenza or adenovirus are currently available.

Other Disease Prevention Recommendations

The recommendations for preventing CRV infections and their recurrence are the same for allogeneic or autologous recipients. Generally, these recommendations appl to children or adults (*161--164*), but with appropriate adjustments in antiviral drug and influenza vaccine doses for children (Appendix).

For pediatric HSCT recipients and candidates aged >6 months, annual seasonal influenza vaccination is recommended HSCT (BIII). Children aged <9 years who are receiving influenza vaccination for the first time require two doses administered ≥1 months apart (AI). Healthy children who receive influenza vaccination for the first time might not generate protective antibodies until 2 weeks after receipt of the second dose of influenza vaccine. Therefore, during an influenza A outbreak, pediatric recipients aged <9 years, ≥6 months after HSCT, and receiving their first influenza vaccination, should be administered ≥6 weeks of influenza A chemoprophylaxis aft the first dose of influenza vaccine (*141*) (BIII) (Appendix). Amantadine and rimantadine are not FDA-approved for children aged <1 year (*141,161*) (DIII).

To prevent RSV disease, researchers report substituting RSV-IVIG for IVIG during RSV season (i.e., November--April) for pediatric recipients (i.e., children aged <18 years) who receive routine IVIG therapy (*164*) (i.e., those with hypogammaglobulinemia) (CIII) (Appendix). Other researchers report that pediatric recipients with RS can be considered for preemptive therapy (e.g., during URI or early LRI) with aerosolized ribavirin (CIII), although this therapy remains controversial (*164*) (Appendi Droplet and contact precautions for the duration of illness are required for pediatric recipients for the duration of adenovirus (*62*) (AIII).

FUNGAL INFECTIONS

General Recommendations

Preventing Exposure

Limited data were found that demonstrate to what extent preventing fungal exposures is effective in preventing infection and disease. However, HSCT recipients and candidates undergoing conditioning therapy have been advised to avoid contact with certain areas and substances, including foods, that might increase a patient's risk f fungal exposures (CII). Specific precautions have included avoiding areas of high dust exposure (e.g., excavation sites, areas of building construction or renovation, chicken coops, and caves), occupations involving soil, and foods that contain molds (e.g., blue cheese).

Preventing Disease

Growth factors (e.g., GM-CSF and G-CSF) shorten the duration of neutropenia after HSCT (*165*); however, no data were found that indicate which growth factors effectively reduce the attack rate of invasive fungal disease. Therefore, no recommendation for use of growth factors solely for prophylaxis against invasive fungal disease can be made.

Topical antifungal drugs, which are applied to the skin or mucosa (e.g., nystatin or clotrimazole), might reduce fungal colonization in the area of application. However, these agents have not been proven to prevent generation of locally invasive or disseminated yeast infections (e.g., candidiasis) or mold infections (e.g., aspergillosis) a are not recommended for their prophylaxis (DII). Performing fungal surveillance cultures is not indicated for asymptomatic HSCT recipients (*166,167*) (DII), but cultu should be obtained from symptomatic HSCT recipients (BIII).

Recommendations Regarding Yeast Infections

Preventing Exposure

Invasive candidiasis is usually caused by dissemination of endogenous *Candida* species that have colonized a patient's gastrointestinal tract (*168*). Consequently, meth of preventing exogenous yeast exposure usually do not prevent invasive yeast infections after HSCT. However, because *Candida* species can be carried on the hands, HCWs and others in contact with HSCT recipients should follow appropriate hand-washing practices to safeguard patients from exposure (AIII).

Preventing Disease

Allogeneic recipients should be administered fluconazole prophylaxis to prevent invasive disease with fluconazole-susceptible *Candida* species during neutropenia, particularly among centers where *Can. albicans* is the predominant cause of invasive fungal disease preengraftment (AI) (Appendix). Because candidiasis occurs durin phase I (*169*), fluconazole (400 mg/day by mouth or intravenously) should be administered (*169,170*) from the day of HSCT until engraftment (AII). However, fluconazole is not effective against certain *Candida* species, including *Can. krusei* (*171*) and *Can. glabrata* and is, therefore, not recommended for their prevention (DI Further studies are needed to determine the optimal duration of fluconazole prophylaxis. Preliminary studies have reported that low-dose fluconazole prophylaxis (100 -200 mg/day by mouth) among neutropenic patients has variable efficacy in preventing candidiasis (*172*). Therefore, this therapy is not recommended for HSCT recipients (DII). Oral, nonabsorbable antifungal drugs, including oral amphotericin B (500 mg suspension every 6 hours), nystatin, and clotrimazole troches, might reduce superficial colonization and control local mucosal candidiasis, but have not been demonstrated to reduce invasive candidiasis (CIII).

Other Recommendations

HSCT candidates with candidemia or invasive candidiasis can safely receive transplants (*173*) if a) their infection was diagnosed early and treated immediately and aggressively with amphotericin B or alternatively with appropriate doses of fluconazole if the organism is susceptible; and b) evidence of disease control is reported (e by serial computed tomography scans) before the transplant (BIII). Such patients should continue receiving therapeutic doses of an appropriate antifungal drug throughout phase I (BII) and until a careful review of clinical, laboratory, and serial computed tomography scans verifies resolution of candidiasis (BII).

Because autologous recipients generally have an overall lower risk for invasive fungal infection than allogeneic recipients, certain autologous recipients do not require routine antiyeast prophylaxis (DIII). However, researchers recommend administering antiyeast prophylaxis to a subpopulation of autologous recipients with underlying hematologic malignancies (e.g., lymphoma or leukemia) and who have or will have prolonged neutropenia and mucosal damage from intense conditioning regimens o graft manipulation, or have received fludarabine or 2-CDA recently (BIII). Recommendations regarding preventing invasive yeast infections among pediatric or adult HSCT recipients are the same, except that appropriate dose adjustments for prophylactic drugs should be made for pediatric recipients (Appendix).

Recommendations Regarding Mold Infections

Preventing Exposure

Nosocomial mold infections among HSCT recipients result primarily from respiratory exposure to and direct contact with fungal spores (*174*). Ongoing hospital construction and renovation have been associated with an increased risk for nosocomial mold infection, particularly aspergillosis, among severely immunocompromise patients (*175--177*). Therefore, whenever possible, HSCT recipients who remain immunocompromised should avoid hospital construction or renovation areas (AIII). When constructing new HSCT centers or renovating old ones, hospital planners should ensure that rooms for HSCT patients have an adequate capacity to minimize fungal spore counts through use of

- high-efficiency (>90%) particulate air (HEPA) filtration (*140,178,179*) (BIII);
- directed room airflow (i.e., positive air pressure in patient rooms in relation to corridor air pressure) so that air from patient rooms flows into the corridor (*180*) (BIII);

- correctly sealed rooms, including correctly sealed windows and electrical outlets (*140*) (BIII);
- high rates of room air exchange (i.e., >12 air changes/hour) (*140,178*) (BIII); and
- barriers between patient care and renovation or construction areas (e.g., sealed plastic) that prevent dust from entering patient care areas and that are
- impermeable to *Aspergillus* species (*175,179*) (BIII).

Additionally, HSCT centers should be cleaned with care, particularly after hospital renovation or construction, to avoid exposing HSCT recipients and candidates to m spores (*174,176*) (BIII).

Preventing Disease

No regimen has been reported to be clearly effective or superior in preventing aspergillosis, and therefore, no recommendation can be made. Further studies are needed determine the optimal strategy for aspergillosis prevention. Moderate-dose (0.5 mg/kg/day) amphotericin B (*181--184*), low-dose (0.1--0.25 mg/kg/day) amphotericin (*185--187*), intranasal amphotericin B spray (*188*), lipid formulations of amphotericin B (*182,189*), and aerosolized amphotericin B (*190*) have been administered for aspergillosis prophylaxis, but data are limited regarding the safety and efficacy of these formulations among HSCT recipients. Additionally, itraconazole capsules are n recommended for fungal prophylaxis among HSCT recipients (*191*) (DII) for three reasons. First, itraconazole capsules are poorly absorbed gastrointestinally, particularly among patients who are fasting (*192*) or receiving cytotoxic agents (*193*). Second, persons taking itraconazole capsules do not achieve steady-state serum levels for 2 weeks (*188,194*), and when achieved, these levels are lower than the average *Aspergillus* species minimum inhibitory concentration (MIC) among HSCT recipients (*195*). Third, itraconazole has adverse interactions with other drugs (e.g., antiepileptics, rifampin, oral hypoglycemics, protease inhibitors, vinca alkaloids, cyclosporine, methylprednisolone, and warfarin-like anticoagulants) (*196*). Trials assessing the efficacy of the recently licensed cyclodextrin oral solution and intravenous formulations of itraconazole in preventing invasive fungal disease among HSCT recipients are in progress; however, no recommendations regarding its use for *Aspergillus* species infection prophylaxis can be made. For HSCT recipients whose respiratory specimens are culture positive for *Aspergillus* species, acute invasiv aspergillosis should be diagnosed presumptively (*197*) and treated preemptively and aggressively (e.g., with intravenous amphotericin) (AIII).

The risk for aspergillosis recurrence has been high among allogeneic recipients with preexisting invasive aspergillosis. Previously, allogeneic HSCTs were avoided among persons with uncontrolled, proven aspergillosis. However, HSCT center personnel have recently reported successful allogeneic or autologous HSCT among a limited number of persons who have had successfully treated, prior invasive pulmonary aspergillosis (*198--200*). Because of limited data, no recommendations regardi strategies for preventing aspergillosis recurrence can be made.

PROTOZOAL AND HELMINTHIC INFECTIONS

Recommendations Regarding PCP

Preventing Exposure

Although a possible cause of PCP is reactivation of latent infection among immunocompromised persons, cases of person-to-person transmission of PCP have been reported (*201--206*). Generally, standard precautions should be used for patients with PCP (*62*) (BIII), but researchers have reported patients with PCP being isolated (*201,204*) and contact precautions being used if evidence existed of person-to-person transmission in the institution (CIII). This subject remains controversial, and until further data are published, HSCT recipients should avoid exposure to persons with PCP (*62*) (CIII).

Preventing Disease and Disease Recurrence

Physicians should prescribe PCP prophylaxis for allogeneic recipients throughout all periods of immunocompromise (*207*) after engraftment. Prophylaxis should be administered from engraftment until 6 months after HSCT (AII) for all patients, and >6 months after HSCT for the duration of immunosuppression for those who a) ar receiving immunosuppressive therapy (e.g. prednisone or cyclosporine) (AI), or b) have chronic GVHD (BII). However, PCP prophylaxis can be initiated before engraftment if engraftment is delayed (CIII). Researchers report an additional 1- to 2-week course of PCP prophylaxis before HSCT (i.e., day --14 to day --2) (CIII).

Preferred PCP prophylaxis is TMP-SMZ (AII); however, if TMP-SMZ is administered before engraftment, the associated myelosuppression could delay engraftment, a patients might experience sensitivity to the drug. Every effort should be made to keep such patients on the drug, including assessment of desensitization therapy, althou data regarding this technique among HSCT recipients are limited. For patients who cannot tolerate TMP-SMZ, physicians can choose to use alternative PCP prophylax regimens (e.g., dapsone) (*208*) (BIII). Use of aerosolized pentamidine (*209*) is associated with the lowest PCP prevention rates and should only be used if other agents cannot be tolerated. Atovaquone is a possible alternative drug for PCP prophylaxis among dapsone-intolerant persons with HIV infection (*210*); however, no recommendation regarding use of atovaquone among HSCT recipients can be made because of lack of data. Although data are limited, concomitant use of leucovorin (folinic acid) and TMP-SMZ is not recommended (*211,212*) (DIII). A patient's history of PCP should not be regarded as a contraindication to HSCT (*213*) (DIII).

Recurrent PCP among HSCT recipients is rare; however, patients with continued immunosuppression should remain on PCP prophylaxis until their immunosuppressio is resolved (AI). The regimen recommended for preventing toxoplasmosis recurrence among HSCT recipients (i.e., TMP-SMZ) will also prevent PCP recurrence.

Other Recommendations

PCP prophylaxis should be considered for autologous recipients who have underlying hematologic malignancies (i.e., lymphoma or leukemia), are receiving intense conditioning regimens or graft manipulation, or have recently received fludarabine or 2-CDA (*207,214*) (BIII). PCP prophylaxis should be administered ≥6 months aft HSCT if substantial immunosuppression or immunosuppressive therapy (e.g., steroids) persists (CIII). Use of PCP prophylaxis among other autologous recipients is controversial (CIII). Generally, indications for PCP prophylaxis are the same among children or adults, but pediatric doses should be used (Appendix).

Recommendations Regarding *Toxoplasma gondii*

Preventing Exposure

All HSCT recipients should be provided information regarding strategies to reduce their risk for *Toxoplasma* species exposure. Researchers report that potential donors for allogeneic HSCT be tested for *To. gondii* antibodies (*215,216*) by using FDA-licensed or -approved screening tests that include IgG antibody testing because *To. gondii* has been reported to be transmitted by leukocyte transfusion (*217*) and HSCT (*218,219*) (CIII).

Preventing Disease and Disease Recurrence

Because most toxoplasmosis among HSCT recipients is caused by disease reactivation, researchers report that candidates for allogeneic HSCT can be tested for IgG antibody to determine whether they are at risk for disease reactivation after HSCT (*215,216,218*) (CIII). However, the value of such testing is controversial because a limited number of patients who were seronegative for *To. gondii* pretransplant experienced the infection posttransplant (*220*). If testing is performed, only FDA-license or -approved screening tests should be used.

Researchers recommend toxoplasmosis prophylaxis for seropositive allogeneic recipients with active GVHD or a prior history of toxoplasmic chorioretinitis (*221,222*) but data demonstrating efficacy are limited (CIII). The optimal prophylactic regimen for toxoplasmosis among HSCT recipients has not been determined, but a propos drug is TMP-SMZ (BII), although allogeneic recipients have experienced break-through clinical disease despite TMP-SMZ prophylaxis (*218*). For patients who are TMP-SMZ--intolerant, a combination of clindamycin, pyramethamine, and leucovorin can be substituted for *To. gondii* prophylaxis (Appendix). After therapy for toxoplasmosis, HSCT recipients should continue receiving suppressive doses of TMP-SMZ or an alternate regimen for the duration of their immunosuppression (BIII) (Appendix).

Other Recommendations

Recipients of autologous transplants are at negligible risk for toxoplasmosis reactivation (*218*). No prophylaxis or screening for toxoplasmosis infection is recommend for such patients (DIII). Indications for toxoplasmosis prophylaxis are the same among children or adults, but pediatric doses should be used among children (Appendi

Recommendations Regarding *Strongyloides stercoralis*

Preventing Exposure

Allogeneic recipients should avoid contact with outhouses and cutaneous exposure to soil or other surfaces that might be contaminated with human feces (*223*) (AIII). Allogeneic recipients who work in settings (e.g., hospitals or institutions) where they could be exposed to fecal matter should wear gloves when working with patients in areas with potential fecal contamination (AIII).

Preventing Disease and Disease Recurrence

Travel and residence histories should be obtained for all patients before HSCT to determine any exposures to high-risk areas (e.g., such moist temperate areas as the tropics, subtropics, or the southeastern United States and Europe) (*223*) (BIII). HSCT candidates who have unexplained peripheral eosinophilia or who have resided in traveled to areas endemic for strongyloidiasis, even during the distant past, should be screened for asymptomatic strongyloidiasis before HSCT (BIII). Serologic testing with an enzyme-linked immunosorbent assay is the preferred screening method and has a sensitivity and specificity of >90% (*223,224*) (BIII). FDA-licensed or - approved screening tests should be used. Although stool examinations for strongyloidiasis are specific, the sensitivity obtained from ≥3 stool examinations is 60%--70 the sensitivity obtained from concentrated stool exams is, at best, 80% (*223*). A total of ≥3 stool examinations should be performed if serologic tests are unavailable or strongyloidiasis is clinically suspected in a seronegative patient (BIII).

HSCT candidates whose screening tests before HSCT are positive for *Strongyloides* species, and those with an unexplained eosinophilia and a travel or residence histo indicative of exposure to *Strongyloides stercoralis* should be empirically treated before transplantation (*225,226*), preferably with ivermectin (BIII), even if seronegativ or stool-negative (Appendix).

To prevent recurrence among HSCT candidates with parasitologically confirmed strongyloidiasis, cure after therapy should be verified with ≥3 consecutive negative st examinations before proceeding with HSCT (AIII). Data are insufficient to recommend a drug prophylaxis regimen after HSCT to prevent recurrence of strongyloidias HSCT recipients who had strongyloidiasis before or after HSCT should be monitored carefully for signs and symptoms of recurrent infection for 6 months after treatm (BIII).

Other Recommendations

Hyperinfection strongyloidiasis has not been reported after autologous HSCT; however, the same screening precautions should be used among autologous recipients (BIII). Indications for empiric treatment for strongyloidiasis before HSCT are the same among children or adults except for children weighing <15 kg, for whom the preferred drug is thiabendazole (BIII) (Appendix).

Recommendations Regarding *Trypanosoma cruzi*

Preventing Exposure

HSCT physicians should be aware that *Trypanosoma cruzi*, the etiologic agent of Chagas' disease, can be transmitted congenitally, through blood transfusion (*227*), an possibly through HSCT. Additionally, treatment for persons infected with *Tr. cruzi* is not always effective, even during the acute stage of infection (*227*). Therefore, potential donors who were born, received a blood transfusion, or ever lived for ≥6 months in a Chagas' disease endemic area (e.g., parts of South and Central America and Mexico) should be screened serologically for anti-*Tr. cruzi* serum IgG antibody (*228*) (BIII). Persons who lived <6 months in a Chagas'-endemic area but who had high-risk living conditions (e.g., having had extensive exposure to the Chagas' disease vector --- the reduviid bug --- or having lived in dwellings with mud walls, unmilled logs and sticks, or a thatched roof) should also be screened for evidence of *Tr. cruzi* infection (BIII). Because Chagas' disease can be transmitted congenitally, researchers report that any person with extensive multigenerational maternal family histories of cardiac disease (e.g., cardiomegaly and arrhythmias) should be screene serologically for serum IgG anti-*Tr. cruzi* antibodies (*227*) (CIII). To decrease the risk for misdiagnosis by false-positive or false-negative serologic tests, *Tr. cruzi* screening should consist of ≥2 conventional serologic tests (e.g., enzyme immunoassay, indirect hemagglutination, indirect fluorescent antibody) or ≥1 conventional serologic tests, followed by a confirmatory serologic test (e.g., radioimmunoprecipitation assay) (*229*) (BIII). Persons with active Chagas' disease should not serve as HSCT donors (DIII). Researchers also recommend deferral of HSCT donation for a past history of Chagas' disease (CIII).

Preventing Disease

HSCT candidates who are at risk for being infected with *Tr. cruzi* should be screened for serum IgG anti-*Tr. cruzi* antibody (*228*) (BIII). *Tr. cruzi* seropositivity is not a contraindication to HSCT (*228,230*). However, if an acute illness occurs in a *Tr. cruzi*-seropositive HSCT recipient, particularly during neutropenia, *Tr. cruzi* reactivati should be included in the differential diagnosis (*230*) (BIII). Researchers have proposed use of beznidazole or nifurtimox for preemptive therapy or prophylaxis of recurrent *Tr. cruzi* among seropositive HSCT recipients (*230,231*), but insufficient data were found to make a recommendation.*****

Other Recommendations

Recommendations are the same for autologous or allogeneic recipients. However, recurrence of Chagas' disease is probably less likely to occur among autologous recipients because of the shorter duration of immunosuppression. Recommendations are the same among children or adults.

HOSPITAL INFECTION CONTROL

Room Ventilation

HSCT center personnel should follow published guidelines for hospital room design and ventilation (*140,180*) (BIII). HSCT centers should also prevent birds from gaining access to hospital air-intake ducts (*140,174*) (AII). All allogeneic recipients should be placed in rooms with >12 air exchanges/hour (*232,233*) and point-of-use HEPA filters that are capable of removing particles ≥0.3 µm in diameter (*140,178,180,233*) (AIII). Correct filtration is critical in HSCT centers with ongoing construct and renovation (*179*). When portable HEPA filters are used as adjuncts to the primary ventilation system, they must be placed centrally in patient rooms so that space is available around all surfaces to allow free air circulation (BIII). The need for environmental HEPA filtration for autologous recipients has not been established. Howev HEPA-filtered rooms should be evaluated for autologous recipients if they experience prolonged neutropenia, a substantial risk factor for nosocomial aspergillosis (CII

A laminar air flow (LAF) room contains filtered air that moves in parallel, unidirectional flow --- the air enters the room from one wall and exits the room on the oppos wall (*232*). Although LAF has been demonstrated to protect patients from infection during aspergillosis outbreaks related to hospital construction (*234,235*), the value routine LAF room use for all HSCT recipients is doubtful because substantial overall survival benefit has not been reported (*236*). During 1983, LAF rooms were preferred for allogeneic recipients with aplastic anemia and HLA-identical sibling donors because use of regular rooms was associated with a mortality rate that was approximately four times higher than for those recipients treated in LAF rooms (*237*). However, the survival of aplastic anemia HSCT recipients during the late 1990s exceeds that reported during the early 1980s, and no studies have been done to determine whether HSCT recipients with aplastic anemia still have an improved surviva rate when treated in an LAF room. Therefore, HSCT centers need not construct LAF rooms for each HSCT recipient. Use of LAF rooms, if available, is optional (CII).

Hospital rooms should have directed airflow so that air intake occurs at one side of the room and air exhaust occurs at the opposite side (*140*) (BIII). Each hospital roo should also be well-sealed (e.g, around windows and electrical outlets) (*140*) (BIII). To provide consistent positive pressure in the recipient's room, HSCT centers shou maintain consistent pressure differentials between the patient's room and the hallway or anteroom at >2.5 Pa (i.e., 0.01 inches by water gauge) (*232,233*) (BIII). Generally, hospital rooms for HSCT recipients should have positive room air pressure when compared with any adjoining hallways, toilets, and anterooms, if present.

Anterooms should have positive air pressure compared with hallways (*180*). An exception is the HSCT recipient with an active disease that has airborne transmission (e.g., pulmonary or laryngeal *Mycobacteria tuberculosis* [TB] or measles). These HSCT patients should be placed in negative isolation rooms (*62*) (BIII), and a room with an anteroom is recommended for such patients (*180*) (BIII).

Whenever possible, HSCT centers should have self-closing doors to maintain constant pressure differentials among the HSCT recipients' room and anterooms, if available, and hallways (*233*) (BIII). To enable the nursing staff to observe the HSCT recipient even when the doors are closed, windows can be installed in either the door or the wall of the HSCT recipient's room (*233*) (CIII).

HSCT centers should provide backup emergency power and redundant air-handling and pressurization systems to maintain a constant number of air exchanges and roo pressurization in the center when the central ventilation system is shut off for maintenance and repair (*238*) (BIII). Additionally, infection control personnel should wor with maintenance personnel to develop protocols to protect HSCT centers at all times from bursts of mold spores that might occur when air-handling systems are restarted after routine maintenance shut-downs (BIII).

Construction, Renovation, and Building Cleaning

Construction and Renovation

Hospital construction and renovation have been associated with an increased risk for nosocomial fungal infection, particularly aspergillosis, among severely immuno-compromised patients (*175,176*). Therefore, persons responsible for HSCT center construction or renovation should consult published recommendations regarding environmental controls during construction (*239,240*) (AIII).

Whenever possible, HSCT recipients, HCWs, and visitors should avoid construction or renovation areas (*240*) (AIII). Also, equipment and supplies used by HSCT recipients or their HCWs should not be exposed to construction or renovation areas (*240*). When planning for construction or renovation, the HSCT center should inclu plans for intensified aspergillosis-control measures (AIII). Construction and renovation infection control planning committees should include engineers, architects, housekeeping staff, infection control personnel, the director of the HSCT center, the administration, and safety officers (*241*) (BIII).

When constructing new HSCT centers, planners should ensure that patient rooms will have adequate capacity to minimize fungal spore counts by following room ventilation recommendations. During outdoor construction and demolition, the intake air should be sealed (BIII), if possible; if not, filters should be checked frequently Additionally, to protect HSCT patient care areas during fire drills and emergencies, weather stripping should be placed around stairwell doors, or alternatively, the stairwell air should be filtered to the level of safety of the adjacent hospital air (BIII). False ceilings should be avoided whenever possible (*174*) (BII). If use of false ceilings cannot be avoided, the area above false ceilings should be vacuumed routinely to minimize dust and, therefore, fungal exposure to patients (*174*) (BIII).

During hospital construction or renovation, hospitals should construct rigid, dust-proof barriers with airtight seals (*242*) between patient care and construction or renovation areas to prevent dust from entering patient care areas; these barriers (i.e., sealed drywall) should be impermeable to *Aspergillus* species (*140,175,176,179,2* (BIII). If impervious barriers cannot be created around the construction or renovation area, patients should be moved from the area until renovation or construction is complete and the area has been cleaned appropriately (*176*) (BIII). HSCT centers should direct pedestrian traffic occurring near construction or renovation areas away from patient care areas to limit the opening and closing of doors or other barriers that might cause dust dispersion, entry of contaminated air, or tracking of dust into patient areas (*140*), particularly those in the HSCT center (*176*) (BIII). If possible, specific corridors, entrances, and exits should be dedicated to construction use only (*240*). An elevator to which patients do not have access also should be dedicated to construction use only (*240*). Construction workers, whose clothing might be contaminated with *Aspergillus* species spores, should use the construction elevator and avoid contact with patients, patient care areas, other elevators, and nonconstruction areas (BIII).

Hospital construction or renovation areas should have negative air pressure relative to that in adjacent patient care areas, if no contraindications exist for such pressure differential (*140,176,179,240,242*) (BIII). Ideally, air from the construction or renovation areas should be exhausted to the outside of the hospital (*176*) (BIII) or if recirculated, it should be HEPA-filtered first (BIII).

Researchers have proposed that HSCT recipients wear the N95 respirator to prevent mold exposure during transportation near hospital construction or renovation areas (CIII) because the N95 respirators are regarded as effective against any aerosol. However, to be maximally effective, N95 respirators must be fit-tested and all users m be trained. With correct personnel fit-testing and training, N95 respirators reliably reduce aerosol exposure by 90%. Without fit-testing and training, aerosol exposure would be reduced but not necessarily by 90% (*243*). For patients who cannot use or tolerate an N95 respirator, researchers have proposed using the powered air purifyi respirator (*244,245*), which can be used by patients in wheelchairs. Limitations of the powered air purifying respirator include its cost and that it is not appropriate for young children and infants. General limitations of using respirators are that no commercially available respi rator, including N95, has been tested specifically for its efficacy in reducing exposure to *Aspergillus* species in hospital construction or renovation areas, and no studies have been done that assess the usefulness and acceptability of using respirators among HSCT recipients. Standard surgical masks provide negligible protection against mold spores and are not recommended for this indication (DIII).

Newly constructed or renovated areas should be cleaned before patients are allowed to enter them (*140,176*) (AIII). Decontamination of fungal-contaminated areas tha cannot be extracted and replaced should be done using copper-8-quinolate (*179*) (BIII). Also, areas above false ceilings located under or adjacent to construction areas should be vacuumed (*174*) (BIII). Additionally, the ventilation, direction of airflow, and room pressurization should be tested and correctly adjusted before patients are allowed to enter (BIII).

Cleaning

HSCT centers should be cleaned ≥1 times/day with special attention to dust control (BIII). Exhaust vents, window sills, and all horizontal surfaces should be cleaned w cloths and mop heads that have been premoistened with an FDA- or Environmental Protection Agency (EPA)-registered hospital disinfectant (BIII). Thorough cleaning during and after any construction activity, including minor renovation projects, is critical (BIII).

HSCT center personnel should prohibit exposures of patients to such activities as vacuuming or other floor or carpet vacuuming that could cause aerosolization of fung spores (e.g., *Aspergillus* species) (*140*) (AIII). Accordingly, doors to patient rooms should be closed when vacuuming HSCT center corridors. All vacuum cleaners use in the HSCT center should be fitted with HEPA filters. An FDA- or EPA-registered disinfectant (*246,247*) should be used daily for environmental disinfection and whe wet vacuuming is performed in the HSCT center (BIII). If an HSCT center provides care for infants, phenolic disinfectants can be used to clean the floors only if the compound is diluted according to the product label; but phenolic compounds should not be used to clean basinets or incubators (*246*) (DIII).

Water leaks should be cleaned up and repaired as soon as possible but within 72 hours to prevent mold proliferation in floor and wall coverings, ceiling tiles, and cabinetry in and around all HSCT patients care areas (BIII). If cleanup and repair are delayed ≥72 hours after the water leak, the involved materials should be assumed contain fungi and handled accordingly. Use of a moisture meter to detect water penetration of walls should be used whenever possible to guide decision-making (*238*) (BIII). For example, if the wall does not have <20% moisture content ≥72 hours after water penetration, it should be removed (BIII). Design and selection of furnishing should focus on creating and maintaining a dust-free environment. Flooring and finishes (i.e., wall coverings, window shades, and countertops) used in HSCT centers should be scrubbable, nonporous, easily disinfected, and they should collect minimal dust (BIII).

Isolation and Barrier Precautions

HSCT center personnel should follow published guidelines for hospital isolation practices, including CDC guidelines for preventing nosocomial infections (*62,140,248* (AIII). However, the efficacy of specific isolation and barrier precautions in preventing noso-comial infections among HSCT recipients has not been evaluated.

HSCT recipients should be placed in private (i.e., single-patient) rooms (BIII). If contact with body fluids is anticipated, standard precautions should be followed (AIII These precautions include hand washing and wearing appropriate gloves, surgical masks or eye and face protection, and gowns during procedures and activities that ar likely to generate splashes or sprays of blood, body fluids, secretions or excretions, or cause soiling of clothing (*62*). When indicated, HSCT recipients should also be

placed on airborne, droplet, or contact precautions in addition to standard precautions (*62*) (AIII). Careful observation of isolation precautions is critical in preventing transmission of infectious agents among HSCT recipients, HCWs, visitors, and other HSCT recipients. Physicians are cautioned that HSCT recipients might have a prolonged or episodic excretion of organisms (e.g., CMV).

Researchers have proposed that HSCT recipients wear surgical mask and gloves when exiting their hospital rooms before engraftment (CIII). All HSCT recipients who are immunocompromised (phases I--III of immune system recovery) and candidates undergoing conditioning therapy should minimize the time spent in crowded areas the hospital (e.g., waiting areas and elevators) (BIII) to minimize potential exposure to persons with CRV infections.

Hand Hygiene

Hand washing is the single-most critical and effective procedure for preventing nosocomial infection (*62*). All persons, but particularly HCWs, should wash their hands before entering and after leaving the rooms of HSCT recipients and candidates undergoing conditioning therapy (*62,249*) or before and after any direct contact with patients regardless of whether they were soiled from the patient, environment, or objects (AI). HSCT recipients should be encouraged to practice safe hand hygiene (e.g., washing hands before eating, after using the toilet, and before and after touching a wound) (BIII). Hand washing should be done with an antimicrobial soap and water (AIII); alternatively, use of hygienic hand rubs is another acceptable means of maintaining hand hygiene (*250,251*). If gloves are worn, HCWs should put them on in the patient's room after hand washing and then discard them in the same patient's room before washing hands again after exiting the room. When worn, gloves should always be changed between patients or when soiled before touching a clean area (e.g., change gloves after touching the perineum and before going to a "clean" area) (AIII). Appropriate gloves should be used by all persons when handling potentially contaminated biological materials (AII). Items worn on the hands and fingers (e.g., rings or artificial nails [*248,252*]) and adhesive bandage strips, can create a nidus for pathogenic organisms that is difficult to clean. Thus, HCWs should avoid wearing such items whenever possible (BII).

Equipment

All HSCT center personnel should sterilize or disinfect and maintain equipment and devices using only EPA-registered compounds as directed by established guidelines (*140,180,246,247,253--256*) (AIII). HSCT center personnel should monitor opened and unopened wound-dressing supplies (e.g., adhesive bandages [*257,258*] and surgical and elastic adhesive tape [*259*]) to detect mold contamination and prevent subsequent cutaneous transmission to patients (BII).

Monitoring should consist of discarding all bandages and wound dressings that are out of date, have damaged packaging, or are visually contaminated by construction debris or moisture (BIII). When arm boards are used to provide support for intravenous lines, only sterile dressing materials should be used (*260*), and arm boards should be changed frequently (e.g., daily) (BIII). Additionally, unsterile tongue depressors inserted into a piece of foam tubing should not be used as splints for intravenous and arterial catheter sites because these have been associated with an outbreak of fatal invasive nosocomial *Rhizopus microsporus* among preterm (i.e., very low-birth--weight) infants (*261*) (DII). HSCT centers should not install carpeting in hallways outside (DII) or in patient rooms (DIII) because contaminated carpeting has been associated with outbreaks of aspergillosis among HSCT recipients (*262,263*).

Plants, Play Areas, and Toys

Although to date, exposure to plants and flowers has not been conclusively reported to cause fungal infections among HSCT recipients, most researchers strongly recommend that plants and dried or fresh flowers should not be allowed in the rooms of hospitalized HSCT candidates undergoing conditioning therapy and HSCT recipients (phases I--III of immune system recovery) because *Aspergillus* species have been isolated from the soil of potted ornamental plants (e.g., cacti), the surface of dried flower arrangements, and fresh flowers (*140,174,178,264*) (BIII).

Play areas for pediatric HSCT recipients and candidates undergoing conditioning therapy should be cleaned and disinfected ≥1 times/week and as needed (BIII). Only toys, games, and videos that can be kept clean and disinfected should be allowed in the HSCT center (BIII). HSCT centers should follow published recommendations for washing and disinfecting toys (*265*) (BIII). All HSCT center toys, games, and videos should be routinely and thoroughly washed or wiped down when brought into the HSCT center and thereafter ≥1 times/week and as needed by using a nontoxic FDA- or EPA-registered disinfectant (*246,247,265*) followed by a water rinse (BIII). Cloth or plush toys should be washed in a hot cycle of a washing machine or dry-cleaned ≥1 times/week and as needed (BIII). Alternatively, machine washing in a cold cycle is acceptable if laundry chemicals for cold water washing are used in proper concentration (*265*). Hard plastic toys should be scrubbed with warm soapy water using a brush to clean crevices, rinsed in clean water, immersed in a mild bleach solution, which should be made fresh daily, for 10--20 minutes, rinsed again, and allowed to air dry (*246*). Alternatively, hard plastic toys can be washed in a dishwasher or hot cycle of a washing machine (BIII). Broviac dolls****** should be disassembled upon completion of play and washed with a nontoxic FDA- or EPA-registered disinfectant (*246,247*), rinsed with tap water, and allowed to air dry before other children are allowed to play with them (BIII). Toys that cannot be washed, disinfected, or dry-cleaned after use should be avoided (BIII). Infants, toddlers, and children who put toys in their mouths should not share toys (*265*) (DIII). For children in isolation, researchers recommend the following:

- Disposable play items should be offered whenever possible (BIII).
- Before returning a washable toy used in an isolation room to the pediatric play room for use by another child, it should be cleaned again as previously described (BIII).
- When a child is taken out of isolation, toys, games, and videos used during the period of isolation and that might serve as fomites for infection should be thoroughly disinfected with a nontoxic FDA- or EPA-registered disinfectant (*246,247,265*) (BIII). After use in isolation rooms, cloth or plush toys should be placed in a plastic bag and separated from unused toys. All cloth or plush toys used in isolation rooms should be washed in a washing machine or dry-cleaned before being used in a nonisolation room (BIII). Toys that cannot be disinfected or dry-cleaned after use in an isolation room should be discarded (BIII).

Water-retaining bath toys have been associated with an outbreak of *Pseudomonas aeruginosa* in a pediatric oncology ward (*266*); therefore, these toys should not be used by immunocompromised HSCT recipients and candidates (DII). Occupational and physical therapy items should be cleaned and disinfected as previously described (BIII). Soil-based materials (e.g., clay or potting soil) should be avoided (BIII).

HCWs

HSCT center personnel should have a written comprehensive policy regarding their immunizations and vaccinations, and that policy should meet current CDC, Advisory Committee on Immunization Practices, and Healthcare Infection Control Practices Advisory Committee recommendations (*267*) (BIII). Immunizations are needed to prevent transmission of vaccine-preventable diseases to HSCT recipients and candidates undergoing conditioning therapy. All HCWs with diseases transmissible by airborne, droplet, and direct contact (e.g., VZV, infectious gastroenteritis, HSV lesions of lips or fingers, and URIs) should be restricted from patient contact and temporarily reassigned to other duties (AI). HSCT center personnel should follow published recommendations regarding the duration of work restrictions for HCWs with infectious diseases (*268,269*) (BIII). HSCT center HCWs with bloodborne viruses (e.g., HIV or hepatitis B or C viruses) should not be restricted from patient contact (DIII) as long as they do not perform procedures that pose a high risk for injury that could result in patient exposure to the HCW's blood or body fluids. Work exclusion policies should be designed to encourage HCWs to report their illnesses or exposures (AII).

HSCT Center Visitors

Hospitals should have written policies for screening HSCT center visitors, particularly children, for potentially infectious conditions. Such screening should be performed by clinically trained HCWs (BII). Visitors who might have communicable infectious diseases (e.g., URIs, flu-like illnesses, recent exposure to communicable diseases, active shingles rash whether covered or not, a VZV-like rash within 6 weeks of receiving a live-attenuated VZV vaccine, or a history of receiving an oral polio vaccine within the previous 3--6 weeks) should not be allowed in the HSCT center or allowed to have direct contact with HSCT recipients or candidates undergoing conditioning therapy (AII). No absolute minimum age requirement for HSCT center visitors exists; however, all visitors must be able to understand and follow appropriate hand washing and isolation precautions (AIII). The number of HSCT center visitors at any one time should be restricted to a number that permits the nursing staff to perform appropriate screening for contagious diseases and adequate instruction and supervision of hand washing, glove and mask use, and biosafety precautions (BIII).

Patient Skin and Oral Care

To optimize skin care, HSCT recipients should take daily showers or baths during and after transplantation (BIII), using a mild soap (BIII). Skin care during neutropen should also include daily inspection of skin sites likely to be portals of infection (e.g., the perineum and intravascular access sites) (BIII). HSCT recipients and candida undergoing conditioning therapy should maintain good perineal hygiene to minimize loss of skin integrity and risk for infection (BIII). To facilitate this precaution, HSCT center personnel should develop protocols for patient perineal care, including recommendations for gentle but thorough perineal cleaning after each bowel movement and thorough drying of the perineum after each urination (BIII). Females should always wipe the perineum from front to back after using the toilet to prevei fecal contamination of the urethra and urinary tract infections (AIII). Moreover, to prevent vaginal irritation, menstruating immunocompromised HSCT recipients shou not use tampons (DIII) to avoid the risk for cervical and vaginal abrasions. Additionally, the use of rectal thermometers, enemas, suppositories, and rectal exams are contraindicated among HSCT recipients to avoid skin or mucosal breakdown (DIII).

All HSCT candidates and their caregivers should be educated regarding the importance of maintaining good oral and dental hygiene for at least the first year after HSC to reduce the risk for oral and dental infections (AIII). For example, HSCT candidates should be informed that establishment of the best possible periodontal health before HSCT is a substantial step in avoiding short- and long-term oral infections and that maintenance of safe oral hygiene after HSCT can minimize the severity of infections and facilitate healing of mucositis, particularly before engraftment (BIII).

All HSCT candidates should receive a dental evaluation and relevant treatment before conditioning therapy begins (*270,271*) (AIII). Likely sources of dental infection should be vigorously eliminated (*271*) (AIII). For example, teeth with moderate to severe caries should be restored; ill-fitting dental prostheses should be repaired; and teeth compromised by moderate to severe periodontal disease should be extracted (*271*). Ideally, 10--14 days should elapse between the completion of tissue-invasive oral procedures and onset of conditioning therapy to allow for adequate healing and monitoring for postsurgical complications (AIII).

HSCT recipients with mucositis and HSCT candidates undergoing conditioning therapy should maintain safe oral hygiene by performing oral rinses 4--6 times/day wit sterile water, normal saline, or sodium bicarbonate solutions (*270*) (AIII). HSCT recipients and candidates should brush their teeth ≥2 times/day with a soft regular toothbrush (*270*) (BIII). If the recipient cannot tolerate these brushings, use of an ultrasoft toothbrush or toothette (i.e., foam swab on a stick), can be used (CIII), but physicians should be aware that using the latter products are less desirable than using soft regular or ultrasoft toothbrushes because the toothettes remove less dental debris (*270*). Using toothpaste is optional, depending on the recipient's tolerance (*270*) (CIII). HSCT recipients and candidates undergoing conditioning therapy who ar skilled at dental flossing should floss daily if this can be done without trauma (BIII). Routine dental supervision is advised to monitor and guide the patient's maintenar of oral and dental hygiene (BIII). To decrease the risk for mechanical trauma and infection of oral mucosa, fixed orthodontic appliances and space maintainers should r be worn from the start of conditioning therapy until preengraftment mucositis resolves, and these devices should not be worn during any subsequent periods of mucosi (*270*) (DIII). Dental and transplant teams and the patient's community dentist should coordinate removal of these appliances and long-term rehabilitation of any oral lesions (BIII). However, patients who normally wear removable dental prostheses might be able to wear them during conditioning therapy before HSCT and during mucositis after HSCT, depending on the degree of tissue integrity at the denture-bearing sites and the ability of the patient to maintain denture hygiene on a daily basis (CIII).

Preventing Bacterial Intravascular Catheter-Related Infections

HSCT center personnel are advised to implement published guidelines for preventing intravascular device-related infections (*33*) (AIII). Contact with tap water at the central venous catheter site should be avoided (BIII). For long-term central venous access among children, HSCT physicians can use a totally implantable device amor children aged <4 years if the anticipated duration of vascular access is >30 days (CII). However, such a device among children aged <4 years is not generally used as tl actual HSCT infusion site because a) problems with skin fragility contraindicate repeated punctures over the port site and b) the port device might have an insufficient number of lumens for optimal patient management immediately after HSCT.

To prevent bloodstream infections associated with needleless intravenous access devices, HSCT recipients should a) cover and protect the catheter tip or end cap durin bathing or showering to protect it from tap water contamination, b) change the device in accordance with manufacturers' recommendations, if available, and c) have a caregiver perform intravenous infusions whenever possible (*272,273*) (BII). Also, HSCT recipients and their caregivers should be educated regarding proper care of needleless intravenous access devices (*272*) (BII). No recommendation regarding the use of antibiotic-impregnated central venous catheters among HSCT recipients ca be made because of lack of data.

Control of Specific Nosocomial Infections

Recommendations Regarding* Legionella *Species

HSCT physicians should always include Legionnaires' disease (LD) in the differential diagnosis of pneumonia among HSCT recipients (*140*) (AIII). Appropriate tests confirm LD include a) culturing sputum, BAL, and tissue specimens; b) testing BAL specimens for *Legionellae* by direct fluorescent antibody; and c) testing for *Legionella pneumophila* serogroup 1 antigen in urine. The incubation period for LD is usually 2--10 days; thus, laboratory-confirmed legionellosis that occurs in a pati who has been hospitalized continuously for ≥10 days before the onset of illness is regarded as a definite case of nosocomial LD, and a laboratory-confirmed infection t occurs 2--9 days after hospital admission is a possible case of nosocomial LD (*140*). When a case of laboratory-confirmed nosocomial LD (*274,275*) is identified in a person who was in the inpatient HSCT center during all or part of the 2--10 days before illness onset, or if two or more cases of laboratory-confirmed LD occur among patients who had visited an outpatient HSCT center, hospital personnel should

- report the case(s) to the local or state health department if the disease is reportable in that state or if assistance is needed (*140*) (AIII); and
- in consultation with the hospital infection control team, conduct a thorough epidemiologic and environmental investigation to determine the likely environmenta source(s) of *Legionella* species (e.g., showers, tap water faucets, cooling towers, and hot water tanks) (*274,276*) (AI).

The source of *Legionella* infection should be identified and decontaminated or removed (AIII). Extensive hospital investigations of an isolated case of possible nosocomial LD might not be indicated if the patient has had limited contact with the inpatient center during most of the incubation period (CIII). Because HSCT recipients are at much higher risk for disease and death from legionellosis compared with other hospitalized persons (*274*), periodic routine culturing for *Legionellae* ir water samples from the center's potable water supply could be regarded as part of an overall strategy for preventing LD in HSCT centers (CIII). However, the optimal methodology (i.e., frequency or number of sites) for environmental surveillance cultures in HSCT centers has not been determined, and the cost-effectiveness of this strategy has not been evaluated. Because HSCT recipients are at high risk for LD and no data were found to determine a safe concentration of *Legionellae* organisms ir potable water, the goal, if environmental surveillance for *Legionellae* is undertaken, should be to maintain water systems with no detectable organisms (AIII). Physicia should suspect legionellosis among HSCT recipients with nosocomial pneumonia even when environmental surveillance cultures do not yield *Legionellae* (AIII). If *Legionella* species are detected in the water supplying an HSCT center, the following should be done until *Legionella* species are no longer detected by culture:

- The water supply should be decontaminated (*140*) (AII).
- HSCT recipients should be given sponge baths with water that is not contami-nated with *Legionella* species (e.g., not with the HSCT center's *Legionella* species-contaminated potable water system) (BIII).
- Patients should not take showers in LD-contaminated water (DIII).
- Water from faucets containing LD-contaminated water should not be used in patient rooms or the HSCT center and outpatient clinic to avoid creating infectious aerosols (CIII).
- HSCT recipients should be given sterile water instead of tap water for drinking, brushing teeth, or flushing nasogastric tubes during Legionellosis outbreaks (BII

HSCT center personnel should use only sterile water (i.e., not distilled unsterile water) for rinsing nebulization devices and other semicritical respiratory-care equipmei after cleaning or disinfecting and for filling reservoirs of nebulization devices (*140*) (BII). HSCT centers should not use large-volume room air humidifiers that create aerosols (e.g., by Venturi principle, ultrasound, or spinning disk) and, thus, are actually nebulizers (*140*) (DI) unless these humidifier or nebulizers are sterilized or subjected to daily high-level disinfection and filled with sterile water only (*140*) (CIII).

When a new hospital with an HSCT center is constructed, the cooling towers should be placed so that the tower drift is directed away from the hospital's air-intake system, and the cooling towers should be designed so that the volume of aerosol drift is minimized (*140*) (BII). For operational hospital cooling towers, hospitals shoul

- install drift eliminators,
- regularly use an effective biocide,
- maintain cooling towers according to the manufacturer's recommendations, and
- keep adequate maintenance records (*140*) (BII).

HSCT physicians are encouraged to consult published recommendations regarding preventing nosocomial Legionellosis (*140,277*) (BIII). No data were found to determine whether drinking tap water poses a risk for *Legionella* exposure among HSCT recipients in the absence of an outbreak.

***Recommendations Regarding Methicillin-Resistant* Sta. aureus**

HSCT center HCWs should follow basic infection control practices (e.g., hand washing between patients and use of barrier precautions, including wearing gloves whenever entering the methicillin-resistant *Sta. aureus* [MRSA] infected or colonized patient's room); these practices are essential for MRSA control (*62*) (AII). If MR is a substantial problem in the HSCT center and evidence exists of ongoing MRSA transmission, MRSA infected or colonized patients should be treated as a cohort (e. cared for exclusively by a limited number of HCWs) (BIII). HSCT transplant recipients with recurrent *Sta. aureus* infections should undergo extensive evaluation for persistent colonization, including cultures of nares, groin, axilla, and ostomy sites (e.g., tracheostomy or gastrointestinal tube) (BIII). For patients with recurrent MRSA infection, elimination of the carrier state should be attempted by applying a 2% mupirocin calcium ointment to the nares (BIII), although this strategy has been only marginally effective in certain institutions (*278*) (Appendix). High-level mupirocin-resistant MRSA has been reported in Europe, the Middle East, and South America (*279--283*) but is uncommon in the United States. As with any antibiotic, incorrect or overuse of mupirocin can result in mupirocin-resistant *Staphylococci*; therefore, mupirocin use should be reserved for infection control strategies only (*279,280*). For patients who fail mupirocin, physicians have used bacitracin, TMP-SMZ, or rifampin administered with another antibiotic, but no standardized protocol using these drugs for this indication has been evaluated and no recommendations can be ma because of lack of data. Selection of a systemic antibiotic should be guided by susceptibility patterns.

Intravascular cannulas or other implantable devices that are infected or colonized with MRSA should be removed (AIII). Patients with MRSA should be placed under contact precautions until all antibiotics are discontinued and until three consecutive cultures, taken ≥1 weeks apart, are negative (*62*) (BIII). Screening cultures for MR include the anterior nares, any body site previously positive for MRSA, and any wounds or surgical sites.

Recommendations Regarding* Staphylococcus *Species with Reduced Susceptibility to Vancomycin

All HSCT centers should have sufficient laboratory capability to identify all *Staphylococci* isolates and their susceptibility patterns to antibiotics, including vancomycin (*284,285*) (AIII). Additionally, all HSCT center personnel should conduct routine surveillance for the emergence of *Staphylococcus* species strains with reduced susceptibility to vancomycin (*285,286*) (AIII). Reduced susceptibility should be considered for all *Sta. aureus* strains that have a vancomycin MIC of ≥4 µg/mL and al coagulase-negative *Staphylococci* that have a vancomycin MIC of ≥8 µg/mL. If repeat testing of the organism in pure culture confirms the genus, species, and elevated vancomycin MICs, the following steps should be taken (*287*):

- The laboratory should immediately contact hospital infection control personnel, the patient's clinical center, and the patient's attending physician, as well as the local or state health department, and CDC's Hospital Infections Program Help Desk ([404] 639-6106 or [800] 893-0485) (*284,285,287,288*) (AIII).
- The HSCT center's infection control personnel, in collaboration with appropriate authorities (i.e., state and local health departments and CDC) should promptly initiate an epidemiologic and laboratory investigation (*287,288*) (AIII) and follow published guidelines for the control of such species (*285,287,288*) (BIII).
- Medical and nursing staff should
  - institute contact precautions (e.g., wearing of gown and gloves, using antibacterial soap for hand washing, and wearing masks when contamination of the HCW with secretions is likely) as recommended for multidrug-resistant organisms (*62,284,287*);
  - minimize the number of persons with access to colonized or infected patients (*287*); and
  - treat as a cohort colonized or infected patients (e.g., care for them exclusively with a limited number of HCWs) (*286,287*) (AIII).
- If a patient in an HSCT center is colonized or infected with *Staphylococci* that have reduced susceptibility to vancomycin, the infection control personnel should follow published guidelines for the control of such species (*285,287,288*) (BIII).

Avoiding overuse and misuse of antibiotics will decrease the emergence of *Staphylococcus* species with reduced susceptibility to vancomycin (*286,287*). There-fore, medical and ancillary staff members who are responsible for monitoring antimicrobial use patterns in the facility should routinely review vancomycin-use patterns (*284,285,287*) (AIII). Additionally, HSCT center personnel should institute prudent use of all antibiotics, particularly vancomycin, to prevent the emergence of *Staphylococcus* with reduced susceptibility to vancomycin (*284,285,287--289*) (AII). Intravascular cannulas or other implantable devices that are infected or colonized with *Staphylococcus* species strains with reduced susceptibility to vancomycin should be removed (AIII).

Recommendations Regarding VRE

Use of intravenous vancomycin is associated with VRE emergence. Vancomycin and all other antibiotics, particularly antianaerobic agents (e.g., metronidazole and thi generation cephalosporins) must be used judiciously (*284,290--292*) (AII). Oral van-comycin use can be limited by treating recurrences of *Cl. difficile* diarrhea with or metronidazole instead of vancomycin (BIII). Physicians have placed patients with a history of VRE or VRE colonization into continuous isolation during clinic visits a hospitalizations; however, this practice is controversial because certain non-HSCT recipients might clear VRE from their stools. No recommendation regarding use of continuous isolation among HSCT recipients can be made because of lack of data. To control VRE exposure, strict adherence to the following standard infection contro measures is necessary (*292*) (AI):

- Wash hands with antibacterial soap before entering and after leaving HSCT recipients' rooms, particularly those who have VRE colonization or infection; alternatively, wash hands with a waterless antiseptic agent (e.g., an alcohol-based rinse or gel) (*250*).
- Whenever possible, treat as a cohort patients who are known to be colonized or infected with VRE (*290*).
- Disinfect patient rooms and equipment (*291,293*), including surfaces of the hospital ward environment (e.g., floors, walls, bed frames, doors, bathroom surfaces) with an FDA- or EPA-registered disinfectant (*246,247*). A nontoxic disinfectant should be used for pediatric areas (BIII).
- Place patients with VRE under contact precautions until all antibiotics are discontinued (CIII) and repeated cultures are negative (*62*) (BIII). HCWs should alway wear gloves when in the VRE patient or carrier's room and discard gloves in the patient's room before exiting.

No evidence exists that treating VRE carriers is beneficial; therefore, chronic antibiotic treatment of carriers is not recommended (DIII). HSCT recipients and candidat should be screened for VRE colonization at the time of interfacility transfer to allow for immediate institution of appropriate infection control practices and to minimiz transmission of VRE between and within facilities (*294*) (BII). However, the role of outpatient surveillance in VRE control is unknown; such surveillance is costly and should not be undertaken in nonoutbreak settings (DIII). A history of having resolved VRE bacteremia or being a VRE carrier are not contraindications to HSCT (BIII)

***Recommendations Regarding* Cl. difficile**

HSCT physicians should follow published recommendations for preventing and controlling *Cl. difficile* disease, including minimizing the duration of antibiotic therapy and number of antibiotics used for any indication (*295,296*) (AIII). All patients with *Cl. difficile* disease should be placed under contact precautions for the duration of illness (*62*) (AII). All HCWs who anticipate contact with a *Cl. difficile*-infected patient or the patient's environment or possessions should put on gloves before entering the patient's room (*62,295--298*) and before handling the patient's secretions and excretions (AI). During *Cl. difficile* outbreaks, HSCT center personnel should restrict use of antibiotics (e.g., clindamycin) (*299*) (BII). To prevent transmission of *Cl. difficile* to patients during nosocomial *Cl. difficile* outbreaks, HSCT center HCWs shou a) use disposable rectal thermometers or tympanic thermometers; b) disinfect gastrointestinal endoscopes with 2% glutaraldehyde immersion for 10 minutes or use an equivalent disinfectant strategy (*255,256*); and c) perform surface sterilization of the hospital ward environment (e.g., floors, walls, bed frames, doors, bathroom surfac with an FDA- or EPA-registered sterilant (e.g., phosphate-buffered sodium hypochlorite solution [1,660 ppm available chloride]; unbuffered hypochlorite solution [50

ppm available chloride]; 0.04% formaldehyde and 0.03% glutaraldehyde [*255,295,300*]; or ethylene oxide [*247,296*]) (BII). Additionally, physicians should treat patien with *Cl. difficile* disease with antibiotics as recommended in published reports (*62,295*) (BII).

Certain researchers also recommend antibiotic treatment of *Cl. difficile* carriers (*301*). However, other researchers have reported that treatment of asymptomatic *Cl. difficile* carriers with metronidazole is not effective and that treatment with vancomycin is only effective temporarily (i.e., <2 months after treatment) (*302*). Consequently, no recommendation regarding treatment of asymptomatic *Cl. difficile* carriers can be made. Similarly, although symptomatic *Cl. difficile* disease recurrence or relapse occurs among 7%--20% of patients (*295*), data are insufficient to make a recommendation for preventing multiple *Cl. difficile* relapses.

The following practices are not recommended for *Cl. difficile* control:

- routine stool surveillance cultures for *Cl. difficile* for asymptomatic patients or HCWs, even during outbreaks (DIII);
- culturing HCWs' hands for *Cl. difficile* (DIII); or
- treating patients presumptively for *Cl. difficile* disease pending toxin results (DIII), unless the patient is very sick with a compatible syndrome or the hospital has high prevalence of *Cl. difficile* (CIII).

Prophylactic use of lyophilized *Saccharomyces boulardii* to reduce diarrhea among antibiotic recipients is not recommended because this therapy is not associated with substantial reduction in diarrhea associated with *Cl. difficile* disease (*303*) and has been associated with *Saccharomyces boulardii* fungemia (*304*) (DII).

Recommendations Regarding CRV Infections

Physicians should institute appropriate precautions and infection control measures for preventing nosocomial pneumonia among hospitalized HSCT recipients and candidates undergoing conditioning therapy, particularly during community or nosocomial CRV outbreaks (*140*) (AIII). Patients with URI or LRI symptoms should be placed under a) contact precautions for most viral respiratory infections including varicella; b) droplet precautions for influenza or adenovirus; or c) airborne precautio for measles or varicella to avoid transmitting infection to other HSCT candidates and recipients as well as to HCWs and visitors (BIII). Identifying HSCT recipients wi RSV infection and placing them under contact precautions immediately (AIII) to prevent nosocomial transmission is critical. When suctioning the respiratory tract of patients with URI or LRI symptoms, HCWs should wear gowns, surgical masks, and eye protection to avoid contamination from the patient's respiratory secretions. Al protective clothing (e.g., gown, gloves, surgical mask, and eye protection) should be put on when entering a patient's room and discarded in the same room before exiting; protective clothing should always be changed between patient rooms (*140*) (AIII). When caring for an HSCT recipient or candidate undergoing conditioning therapy with URI or LRI, HCWs and visitors should change gloves and wash hands a) after contact with a patient; b) after handling respiratory secretions or objects contaminated with secretions from one patient and before contact with another patient, object, or environmental surface; and c) between contacts with a contaminated body site and the respiratory tract of or respiratory device used on the same patient (*140*) (AII). This practice is critical because most respiratory infections are usually transmitted by contact, particularly by hand to nose and eye. Therefore just wearing a mask, without appropriate hand washing, glove-wearing, or use of eye protection insufficient to prevent transmission of CRV infections.

Researchers have proposed that HSCT recipients or candidates undergoing conditioning therapy be placed under contact precautions during nosocomial outbreaks (*131* (CIII). Even when no nosocomial or community outbreak of CRV infections exists, all persons who enter the HSCT center should be screened daily for URI symptoms including visitors and HCWs (BIII). Researchers also describe systems where HCWs provide daily verification (e.g., using sign-in sheets) that they are free of URI symptoms before being allowed to provide HSCT patient care. HCWs and visitors with URI symptoms should be restricted from contact with HSCT recipients and candidates undergoing conditioning therapy to minimize the risk for CRV transmission (*131*) (AIII). All HCWs with URI symptoms should be restricted from patient contact and reassigned to nonpatient care duties until the HCW's symptoms resolve (BIII). Visitors with URI symptoms should be asked to defer their visit to the HSCT center (*131*) until their URI symptoms resolve (BIII).

Respiratory secretions of any hospitalized HSCT candidate or recipient with signs or symptoms of CRV infection should be tested promptly by viral culture and rapid diagnostic tests for CRV (BIII). Appropriate samples include nasopharyngeal washes, swabs, aspirates, throat swabs, and BAL fluid. This practice is critical because preemptive treatment of certain CRVs (e.g., influenza and RSV) (*133*) might prevent severe disease and death among HSCT recipients. Viral shedding among HSCT recipients with CRV infection has been reported to last ≤4 months for influenza (*143*), ≤2 years for adenovirus (*305,306*), and ≤22 days for RSV (*136*); however, RSV viral shedding has been reported to last 112 days in a child with severe combined immunodeficiency (*307*). Therefore, to prevent nosocomial transmission of CRV (*13* HSCT center HCWs should recognize that prolonged CRV shedding can occur when determining the duration of appropriate precautions for CRV-infected HSCT recipients or candidates undergoing conditioning therapy (CIII). HSCT centers should use serial testing by using cultures from nasopharyngeal swabs, throat swabs or aspirates, or rapid antigen tests to help determine whether patients have stopped shedding influenza virus (BIII). Researchers have proposed that HSCT physicians conduct routine CRV surveillance among HSCT recipients to detect outbreaks and implement infection control measures as early as possible (CIII). During RSV seaso HSCT recipients and candidates with signs or symptoms should be tested for RSV infection (i.e., the presence of RSV antigen in respiratory secretions tested by enzym linked immunosorbent assay and viral culture) starting with admission to the HSCT center. All patients who are RSV-antigen positive should be treated as a cohort dur nosocomial RSV outbreaks because this practice reduces nosocomial RSV transmission (*130,131*) (BII). Symptomatic HCWs should be excluded from patient contact until symptoms resolve. HCWs and visitors with infectious conjunctivitis should be restricted from direct patient contact until the drainage resolves (i.e., usually, 5--7 days for adenovirus) and the ophthalmology consultant concurs that the infection and inflammation have resolved (*268*) (AII) to avoid possible transmission of adenovirus to HSCT recipients.

Preventing CRV exposure among HSCT recipients after hospital discharge is more challenging because of high CRV prevalence. Preventive measures should be individualized in accordance with the immunologic status and tolerance of the patient. In outpatient waiting rooms, patients with CRV infections should be separated to the extent possible from other patients (BIII).

Recommendations Regarding TB

HSCT candidates should be screened for TB by careful medical history and chart review to ascertain any history of prior TB exposure (AIII) because immunocompromised persons have higher risk for progression from latent TB infection to active disease (*244*). Also, physicians can administer a tuberculin skin test (TST) using the Mantoux method with five tuberculin units of purified protein derivative (CIII); but because of a patient's immunocompromise, this test might not be reliable. If a TST is administered, either the Tubersol® or Aplisol® formulation of purified protein derivative can be used (*244,308*). Persons with a recently positive TS or a history of a positive TST and no prior preventive therapy should be administered a chest radiograph and evaluated for active TB (*309*) (AI). For immunocompromised persons, a positive TST is defined as ≥5 mm of induration (*309,310*) because of their decreased ability to mount a delayed hypersensitivity response (CIII). Because immunosuppressive therapy decreases the sensitivity of the TST, HSCT physicians should not rely solely on the TST to determine whether latent TB infection is present and whether preventive therapy should be administered to HSCT recipients or candidates (DIII). Instead, a full 9-month course of isonicotinic acid hydrazide preventive therapy should be administered to immunocompromised HSCT recipients or candidates who have been substantially exposed to someone with active, infectious (i.e., sputum-smear positive) pulmonary or laryngeal TB, regardless of the HSCT recipient's or candidate's TST status (*309*) (BIII). A f 9-month course of isonicotinic acid hydrazide preventive therapy should also be administered to HSCT recipients or candidates with a positive TST who were not previously treated and have no evidence of active TB disease (*309*) (AIII) (Appendix). Routine anergy screening might not be reliable among HSCT recipients and candidates undergoing conditioning therapy and, therefore, is not recommended (DIII). An HSCT should not be canceled or delayed because of a positive TST (DIII).

Use of a 2-month course of a daily pyrazinamide/rifampin (PZA/RIF) regimen has been recommended as an alternate preventive therapy for persons with TB (*309*). However, limited data were found regarding safety and efficacy of this regimen among non-HIV--infected persons. Furthermore, rifampin has substantial drug interactions with certain medications, including cyclosporine, tacrolimus (FK506), corticosteroids, fluconazole, and pain medications. Therefore, routine use of the 2-month PZA/RIF prophylactic regimen among HSCT recipients is not recommended (DIII). However, this regimen can be used for HSCT candidates who are not at risk for serious rifampin drug interactions and whose HSCT is not scheduled until ≥2 weeks after completion of the 2-month PZA/RIF course (CIII). This delay will dimini the possibility of adverse effects of rifampin on drugs used for routine HSCT OI prophylaxis (e.g., fluconazole) (*311*). An HSCT candidate or recipient who has been exposed to an active case of extrapulmonary, and therefore, noninfectious TB does not require preventive therapy (DIII).

HSCT center personnel should follow guidelines regarding the control of TB in health-care facilities (*244,245*), including instituting airborne precautions and negative pressure rooms for patients with suspected or confirmed pulmonary or laryngeal TB (*62,244*) (AII). HCWs should wear N95 respirators, even in isolation rooms, to

protect themselves from possible TB transmission from patients with active pulmonary or laryngeal TB, particularly during cough-inducing procedures (*62,244,245,31* (AIII). To be maximally effective, respirators (e.g., N95) must be fit-tested, and all respirator users must be trained to use them correctly (*243*) (AIII). Unless they become soiled or damaged, changing N95 respirators between patient rooms is not necessary (DIII). Bacillus of Calmette and Guérin vaccination is contraindicated among HSCT candidates and recipients because it might cause disseminated or fatal disease among immunocompromised persons (*313,314*) (EII). No role has been identified for chronic suppressive therapy or follow-up surveillance cultures among HSCT recipients who have a history of successfully treated TB (DIII).

Infection Control Surveillance

HSCT center personnel are advised to follow standard guidelines for surveillance of antimicrobial use and nosocomial pathogens and their susceptibility patterns (*315*) (BIII). HSCT center personnel should not perform routine fungal or bacterial cultures of asymptomatic HSCT recipients (*166,167*) (DII). In the absence of epidemiolo clusters of infections, HSCT center personnel should not perform routine periodic bacterial surveillance cultures of the HSCT center environment or of equipment or devices used for respiratory therapy, pulmonary-function testing, or delivery of inhalation anesthesia (*140*) (DIII). Researchers recommend that hospitals perform routi sampling of air, ceiling tiles, ventilation ducts, and filters to test for molds, particularly when construction or renovation occurs near or around the rooms of immunocompromised patients (*167,174*) or when clinical surveillance demonstrates a possible increase in mold (i.e., aspergillosis) cases (CIII). Strategies that might decrease fungal spores in the ventilation system include eliminating access of birds (i.e., primarily pigeons) to air-intake systems, removing bird droppings from the air intake ducts, and eliminating moss from the hospital roof (*174*). Furthermore, in the absence of a nosocomial fungal outbreak, HSCT centers need not perform routine fungal cultures of devices and dust in the rooms of HSCT recipients and candidates undergoing conditioning therapy (DIII). HSCT center personnel should routinely perform surveillance for the number of aspergillosis cases occurring among HSCT recipients, particularly during hospital construction or renovation (BIII). A two-fold greater increase in the attack rate of aspergillosis during any 6-month period indicates that the HSCT center environment should be evaluated for breaks in infection control techniques and procedures and that the ventilation system should be investigated carefully (*174*) (BIII).

STRATEGIES FOR SAFE LIVING AFTER HSCT -- PREVENTING EXPOSURE AND DISEASE

Avoiding Environmental Exposures

HSCT recipients and candidates undergoing conditioning therapy, particularly allogeneic recipients, and parents of pediatric HSCT recipients and candidates should be educated regarding strategies to avoid environmental exposures to opportunistic pathogens (AIII).

Preventing Infections Transmitted by Direct Contact

HSCT recipients and candidates should wash their hands thoroughly (i.e., with soap and water) and often. For example, hands should be washed

- before eating or preparing food;
- after changing diapers;
- after gardening or touching plants or dirt;
- after touching pets or animals;
- after touching secretions or excretions or items that might have had contact with human or animal stool (e.g., clothing, bedding, toilets, or bedpans);
- after going outdoors; and
- before and after touching wounds (*249*) (AIII).

Conscientious hand washing is critical during the first 6 months after HSCT and during other periods of substantial immunosuppression (e.g., GVHD, systemic steroid use, or relapse of the underlying disease for which the transplant was performed) (AIII). Pediatric HSCT recipients and candidates should be supervised by adults duri hand washing to ensure thorough cleaning (*316*) (BIII). Hand washing should be performed with an antimicrobial soap and water (AIII); alternatively, use of hygienic hand rubs is an acceptable means of maintaining hand hygiene (*250,251*). HSCT recipients who visit or live on farms should follow published recommendations for preventing cryptosporidiosis (*5,316,317--319*) (BIII).

Preventing Respiratory Infections

To prevent respiratory infections after hospital discharge, HSCT recipients should observe the following precautions:

- Frequent and thorough hand washing is critical (BIII), but HSCT recipients should also avoid touching their mucus membranes, unless they have washed their hands first, to avoid inoculating themselves with CRV.
- HSCT recipients should avoid close contact with persons with respiratory illnesses (BIII). When close contact is unavoidable, those persons with respiratory illnesses should be encouraged to wash their hands frequently and to wear surgical masks or, at a minimum, smother their sneezes and coughs in disposable tissu Alternatively, the HSCT recipient can wear a surgical mask (CIII).
- HSCT recipients should avoid crowded areas (e.g., shopping malls or public elevators) where close contact with persons with respiratory illnesses is likely (BIII)
- HSCT candidates or recipients should be advised that certain activities and occupations (e.g., work in health-care settings, prisons, jails, or homeless shelters) ca increase their risk for TB exposure (BIII). In deciding whether a patient should continue activities in these settings, physicians should evaluate the patient's speci duties, the precautions used to prevent TB exposure in the workplace, and the prevalence of TB in the community. The decision to continue or terminate such activities should be made jointly between patient and physician (BIII). HSCT recipients should avoid exposure to persons with active tuberculosis, particularly during the first 6 months after HSCT and during other periods of substantial immunosuppression (e.g., GVHD, systemic steroid use, or relapse of the underlying disease for which the transplant was performed) (BIII).

Researchers report that allogeneic recipients should avoid construction or excavation sites or other dust-laden environments for the first 6 months after HSCT and duri other periods of substantial immunosuppression (e.g., GVHD, systemic steroid use, or relapse of the underlying disease for which the transplant was performed) to avo exposures to molds (CIII). Researchers also report that outpatient HSCT recipients should be advised of travel routes to the HSCT center that will avoid or minimize exposure to construction sites (CIII).

Coccidioidomycosis is uncommon after allogeneic HSCT; however, researchers report that HSCT recipients traveling to or residing in coccidioidomycosis-endemic ar (e.g., the American southwest, Mexico, and Central and South America) should avoid or minimize exposure to disturbed soil, including construction or excavation site areas with recent earthquakes, farms, or other rural areas (CIII). Histoplasmosis (*Histoplasma capsulatum*) after allogeneic HSCT is also rare; however, researchers re that HSCT recipients in histoplasmosis-endemic areas should avoid exposure to chicken coops and other bird-roosting sites and caves for the first 6 months after HSC and during periods of substantial immunosuppression (e.g., GVHD, systemic steroid use, or relapse of the underlying disease for which the transplant was performed) (CIII).

Smoking tobacco and exposure to environmental tobacco smoke are risk factors for bacterial and CRV infections among healthy adults and children (*320--325*); consequently, logic dictates that physicians advise HSCT recipients not to smoke and to avoid exposure to environmental tobacco smoke (CIII). However, no data wer found that specifically assess whether smoking or environmental smoke exposure are risk factors for OIs among HSCT recipients. Researchers have reported that marijuana smoking might be associated with generation of invasive pulmonary aspergillosis among immunocompromised persons, including HSCT recipients (*326--329*). Therefore, HSCT recipients should refrain from smoking marijuana to avoid *Aspergillus*species exposure (*326,330--334*) (BIII).

Preventing Infections Transmitted Through Direct Contact and Respiratory Transmission

Researchers have proposed that immunocompromised HSCT recipients and candidates who are undergoing conditioning therapy avoid gardening or direct contact wit soil, plants, or their aerosols to reduce exposure to potential pathogens (e.g., *To. gondii*, *Hi. capsulatum*, *Cryptococcus neoformans*, *Nocardia* species, and *Aspergillus* species) (CIII). HSCT recipients, particularly allogeneic recipients, could wear gloves while gardening or touching plants or soil (*335*) (CIII), and they should avoid

creating plant or soil aerosols (BIII). Additionally, they should always wash their hands afterwards (*335*) and care for skin abrasions or cuts sustained during soil or pla contact (AIII).

Persons whose occupations involve animal contact (e.g., veterinarians, pet store employees, farmers, or slaughterhouse workers) could be at increased risk for toxoplasmosis and other zoonotic diseases. Although data are insufficient to justify a general recommendation against HSCT recipients working in such settings, these exposures should be avoided during the first 6 months after HSCT and during other periods of substantial immunosuppression (e.g., GVHD, systemic steroid use, or relapse of the underlying disease for which the transplant was performed) (BIII).

Safe Sex

Sexually active HSCT recipients should avoid sexual practices that could result in oral exposure to feces (*5,316*) (AIII). Sexually active patients who are not in long-te monogamous relationships should always use latex condoms during sexual contact to reduce their risk for exposure to CMV, HSV, HIV, hepatitis B and C, and other sexually transmitted pathogens (AII). However, even long-time monogamous partners can be discordant for these infections. Therefore, during periods of immunocompromise, sexually active HSCT recipients in such relationships should consider using latex condoms during sexual contact to reduce the risk for exposure these sexually transmitted infections (CIII).

Pet Safety

Preventing Pet-Transmitted Zoonotic Infections

HSCT physicians should advise recipients and candidates undergoing conditioning therapy of the potential infection risks posed by pet ownership; however, they shoul not routinely advise HSCT recipients to part with their pets, with limited exceptions. Generally, immunocompromised HSCT recipients and candidates undergoing conditioning therapy should minimize direct contact with animals (*336,337*), particularly those animals that are ill (e.g., with diarrhea) (*335*) (BIII). Immunocompromised persons who choose to own pets should be more vigilant regarding maintenance of their pet's health than immunocompetent pet owners (BIII). This recommendation means seeking veterinary care for their pet early in the pet's illness to minimize the possible transmission of the pet's illness to the owner (*335*) (BIII). Feeding pets only high-quality commercial pet foods reduces the possibility of illness caused by spoiled or contaminated foods, thus reducing the possibility of transmitting illness from the pet to the HSCT recipient. If eggs, poultry, or meat products are given to the pet as supplements, they should be well-cooked. Any dairy products given to pets should be pasteurized (*335*) (BIII). Pets should be prevented from drinking toilet bowl water and from having access to garbage; pets should not scavenge, hunt, or eat other animals' feces (*335*) (BIII).

If HSCT recipients have contact with pets or animals, they should wash their hands after handling them (particularly before eating) and after cleaning cages; HSCT recipients should avoid contact with animal feces to reduce the risk for toxoplasmosis, cryptosporidiosis, salmonellosis, and campylobacteriosis (*335*) (BIII). Adults should supervise hand washing of pediatric HSCT recipients (BIII). Immunocompromised HSCT recipients and candidates should not clean pet litter boxes or cages or dispose of animal waste (DIII). If this cannot be avoided, patients should wear disposable gloves during such activities and wash their hands thoroughly afterwards (BIII). Immunocompromised HSCT recipients and candidates should avoid adopting ill or juvenile pets (e.g., aged <6 months for cats) (*335*) and any stray animals (*5,316*) (BIII). Any pet that experiences diarrhea should be checked by a veterinarian for infection with *Cryptosporidium* (*5,316*), *Giardia* species (*335*), *Salmonella*, a *Campylobacter* (*5,335,337*) (BIII).

Immunocompromised HSCT recipients and candidates should not have contact with reptiles (e.g., snakes, lizards, turtles, or iguanas) (DII) to reduce their risk for acquiring salmonellosis (*335,338--341*). Additionally, patients should be informed that salmonellosis can occur from fomite contact alone (*342*). Therefore, HSCT recipients and candidates should avoid contact with a reptile, its food, or anything that it has touched, and if such contact occurs, recipients and candidates should wash their hands thoroughly afterwards (AIII). Immunocompromised HSCT recipients and candidates should avoid contact with ducklings and chicks because of the risk for acquiring *Salmonella* or *Campylobacter* species infections (*338,343*) (BIII). Immunocompromised HSCT recipients and candidates should avoid contact with exotic pe (e.g., nonhuman primates) (BIII). Bird cage linings should be cleaned regularly (e.g., daily) (*337*). All persons, but particularly immunocompromised HSCT candidates and recipients, should wear gloves whenever handling items contaminated with bird droppings (*337*) (BIII) because droppings can be a source of *Cryptococcus neoformans*, *Mycobacterium avium*, or *Hi. capsulatum*. However, routine screening of healthy birds for these diseases is not recommended (*335*) (DIII). To minimize potential exposure to *Mycobacterium marinum*, immunocompromised HSCT recipients and candidates should not clean fish tanks (DIII). If this task cannot be avoided patients should wear disposable gloves during such activities and wash their hands thoroughly afterwards (*335,337*) (BIII).

Preventing Toxoplasmosis

The majority of toxoplasmosis cases in the United States is acquired through eating undercooked meat (*335,337*). However, all HSCT recipients and candidates, particularly those who are *To. gondii* seronegative, should be informed of the risks for contracting toxoplasmosis from cat feces (BIII), but need not be advised to give away their cats (DII). For households with cats, litter boxes should not be placed in kitchens, dining rooms, or other areas where food preparation and eating occur (*33* Additionally, litter boxes should be cleaned daily by someone other than the HSCT recipient during the first 6 months after HSCT and during periods of substantial immunosuppression (e.g., GVHD, steroid use, or relapse of the underlying disease for which the transplant was performed) to reduce the risk for transmitting toxoplasmosis to the HSCT recipient (BIII). Daily litter box changes will minimize the risk for fecal transmission of *To. gondii* oocysts, because fecal oocysts require ≥ days of incubation to become infectious. If HSCT recipients perform this task during the first 6 months after HSCT and during subsequent periods of substantial immunocompromise (e.g., during GVHD, systemic steroid use, or relapse of the underlying neoplastic disease for which the transplant was performed), they should we disposable gloves (*335*). Gloves should be discarded after a single use (BIII). Soiled, dried litter should be disposed of carefully to prevent aerosolizing the *To. gondii* oocysts (BIII). Cat feces (but not litter) can be flushed down the toilet (BIII). Also, persons who clean cat litter, particularly HSCT recipients, should wash their hands thoroughly with soap and water afterwards to reduce their risk for acquiring toxoplasmosis (BIII).

HSCT recipients and candidates with cats should keep their cats inside (BIII) and should not adopt or handle stray cats (DIII). Cats should be fed only canned or dried commercial food or well-cooked table food, not raw or undercooked meats, to eliminate the possibility of causing an illness that could be transmitted from the cat to th HSCT recipient (BIII). Pet cats of HSCT recipients do not need to be tested for toxo-plasmosis (EII). Playground sandboxes should be kept covered when not in use to prevent cats from soiling them (BIII). HSCT recipients and candidates undergoing conditioning therapy should avoid drinking raw goat's milk to decrease the risk for acquiring toxoplasmosis (BIII).

Water and Other Beverage Safety

Although limited data were found regarding the risks for and epidemiology of *Cryptosporidium* disease among HSCT recipients, HSCT recipients are prudent to avoid possible exposures to *Cryptosporidium* (BIII) because it has been reported to cause severe, chronic diarrhea, malnutrition, and death among other immunocompromise persons (*5,318,319*). HSCT recipients should avoid walking, wading, swimming, or playing in recreational water (e.g., ponds or lakes) that is likely to be contaminated with *Cryptosporidium*, *Es. coli* O157:H7 (*344--346*), sewage, or animal or human waste (BII). HSCT recipients should also avoid swallowing such water (e.g., while swimming) (*5,344,346*) as well as any water taken directly from rivers and lakes (*5,316*) (AIII).

HSCT recipients should not use well water from private wells or from public wells in communities with limited populations (DIII) because tests for microbial contamination are performed too infrequently (e.g., in certain locations, tests are performed ≤1 times/month) to detect sporadic bacterial contamination. However, drinking well water from municipal wells serving highly populated areas is regarded as safe from bacterial contamination because the water is tested ≥2 times/day for bacterial contamination. If HSCT recipients consume tap water, they should routinely monitor mass media (e.g., radio, television, or newspapers) in their area to immediately implement any boil-water advisories that might be issued for immunocompromised persons by state or local governments (BIII). A boil-water advisory means that all tap water should be boiled for ≥1 minutes before it is consumed. Tap water might not be completely free of *Cryptosporidium*. To eliminate the risk for *Cryptosporidium* exposure from tap water, HSCT recipients can boil tap water for ≥1 minutes before consuming it (e.g., drinking or brushing teeth) (*5*) (CIII). Alternately, they can use certain types of water filters (*316*) or a home distiller (*317*) to reduce their risk for *Cryptosporidium* (*5*) and other waterborne pathogens (CIII If a home water filter******* is used, it should be capable of removing particles ≥1 µm in diameter, or filter by reverse osmosis. However, the majority of these filters are not capable of removing smaller microbes (e.g., bacteria or viruses), and therefore, should only be used on properly treated municipal water. Further, the majority o

these devices would not be appropriate for use on an unchlorinated private well to control viral or bacterial pathogens. Bottled water can be consumed if it has been processed to remove *Cryptosporidium* by one of three processes --- reverse osmosis, distillation, or 1-µm particulate absolute filtration. To confirm that a specific bottl water has undergone one of these processes, HSCT recipients should contact the bottler directly.******** Patients can take other precautions in the absence of boil-wa advisories to further reduce their risk for cryptosporidiosis. These extra precautions include avoiding fountain beverages and ice made from tap water at restaurants, ba and theaters (*5*), fruit drinks made from frozen concentrate mixed with tap water, and iced tea or coffee made with tap water (*317*). Drinks that are likely to be *Cryptosporidium* safe for HSCT recipients include nationally distributed brands of bottled or canned carbonated soft drinks and beers (*5*); commercially packaged noncarbonated drinks that contain fruit juice; fruit juices that do not require refrigeration until after opening (e.g., those that are stored unrefrigerated on grocery shelve (*5*); canned or bottled soda, seltzer or fruit drinks; steaming hot (≥175 F) tea or coffee (*317*); juices labeled as pasteurized; and nationally distributed brands of frozen fruit juice concentrate that are reconstituted with water from a safe source (*5*). HSCT recipients should not drink unpasteurized milk or fruit or vegetable juices (e.g., apple cider or orange juice) to avoid infection with *Brucella* species, *Es. coli* O157:H7, *Salmonella* species, *Cryptosporidium*, and others (*319,347--351*) (DII).

Food Safety

HSCT candidates and household or family members who prepare food for them after HSCT should review food safety practices that are appropriate for all persons (*35* (AIII), and food preparers should be educated regarding additional food safety practices appropriate for HSCT recipients. This review and education should be done before the conditioning regimen (i.e., chemotherapy and radiation) begins (BIII). Adherence to these guidelines will decrease the risk for foodborne disease among HS recipients.

Food Safety Practices Appropriate for All Persons

Raw poultry, meats, fish, and seafood should be handled on separate surfaces (e.g., cutting board or counter top) from other food items. Food preparers should always u separate cutting boards (i.e., one for poultry and other meats and one for vegetables and remaining cutting or carving tasks) (AIII), or the board(s) should be washed wi warm water and soap between cutting different food items (AIII). To prevent foodborne illnesses caused by *Campylobacter jejuni* and *Salmonella enteritidis*, which ca cause severe and invasive infections among immunocompromised persons (*353,354*), uncooked meats should not come in contact with other foods (BIII).

After preparing raw poultry, meats, fish, and seafood and before preparing other foods, food handlers should wash their hands thoroughly in warm, soapy water. Any cutting boards, counters, knives, and other utensils used should be washed thoroughly in warm, soapy water also (AIII). Food preparers should keep shelves, counter tops, refrigerators, freezers, utensils, sponges, towels, and other kitchen items clean (AIII). All fresh produce should be washed thoroughly under running water before serving (*355*) (AIII). Persons preparing food should follow published U.S. Department of Agriculture recommendations regarding safe food thawing (*356*) (BIII).

Persons cooking food for HSCT recipients should follow established guidelines for monitoring internal cooking temperatures for meats (*357*) (AII). The only method f determining whether the meat has been adequately cooked is to measure its internal temperature with a thermometer because the color of the meat after cooking does n reliably reflect the internal temperature. Different kinds of meat should be cooked to varying internal temperatures, all ≥150 F (AII). Specifically, the U.S. Department Agriculture recommends that poultry be cooked to an internal temperature of 180 F; other meats and egg-containing casseroles and souffles should be cooked to an internal tem perature of ≥160 F. Cold foods should be stored at <40 F; hot foods should be kept at >140 F (BIII). Food preparers should

- wash their hands before and after handling leftovers (AIII);
- use clean utensils and food-preparation surfaces (AIII);
- divide leftovers into small units and store in shallow containers for quick cooling (AII);
- refrigerate leftovers within 2 hours of cooking (AII).
- discard leftovers that were kept at room temperature for >2 hours (AIII);
- reheat leftovers or heat partially cooked foods to ≥165 F throughout before serving (AII);
- bring leftover soups, sauces, and gravies to a rolling boil before serving (AIII); and
- follow published guidelines for cold storage of food (*352*) (AII).

Additional Food Safety Practices Appropriate for HSCT Recipients

HSCT recipients' diets should be restricted to decrease the risk for exposure to foodborne infections from bacteria, yeasts, molds, viruses, and parasites (BIII). Currentl a low microbial diet is recommended for HSCT recipients (*358,359*) (BIII). This diet should be continued for 3 months after HSCT for autologous recipients. Allogene recipients should remain on the diet until all immunosuppressive drugs (e.g., cyclosporine, steroids, and tacrolimus) are discontinued. However, the HSCT physician should have final responsibility for determining when the diet can be discontinued safely. Only one study has reported that dietary changes (e.g., consuming yogurt) ha decreased the risk for mycotic infections (e.g., candidal vaginitis) (*360*) (Table 3). HSCT recipients should not eat any raw or undercooked meat, including beef, poultr pork, lamb, venison or other wild game, or combination dishes containing raw or undercooked meats or sweetbreads from these animals (e.g., sausages or casseroles) (AII). Also, HSCT recipients should not consume raw or undercooked eggs or foods that might contain them (e.g., certain preparations of hollandaise sauce, Caesar an other salad dressings, homemade mayonnaise, and homemade eggnog) because of the risk for infection with *Salmonella enteritidis* (*354*) (AII). HSCT recipients shoul not consume raw or undercooked seafood (e.g., oysters or clams) to prevent exposure to *Vibrio* species, viral gastroenteritis, and *Cryptosporidium parvum* (*361--364*) (AII).

HSCT recipients and candidates should only consume meat that is welldone when they or their caretakers do not have direct control over food preparation (e.g., when eating in a restaurant) (AI). To date, no evidence exists in the United States that eating food at a fast food restaurant is riskier than eating at a conventional sit-down restaurant. Generally, HSCT candidates undergoing conditioning therapy and HSCT recipients with neutropenia (i.e., ANC < 1,000/ml^3), GVHD, or immunosuppressi should avoid exposures to naturopathic medicines that might contain molds (*365*) (DIII). HSCT recipients wishing to take naturopathic medications are advised to use them only as prescribed by a licensed naturopathic physician working in consultation with the recipient's transplant and infectious disease physicians (CIII).

Travel Safety

Travel to developing countries can pose substantial risks for exposure to opportunistic pathogens for HSCT recipients, particularly allogeneic recipients chronically immunosuppressed. HSCT recipients should not plan travel to developing countries without consulting their physicians (AIII), and travel should not occur until the period of severe immunosuppression has resolved. Generally, allogeneic recipients should not plan travel to developing countries for 6--12 months after HSCT, particularly if GVHD has occurred. Autologous recipients can travel to developing countries 3--6 months after HSCT if their physicians agree.

HSCT recipients should be informed regarding strategies to minimize the risk for acquiring foodborne and waterborne infections while traveling. They should obtain updated, detailed health information for international travelers from health organizations (*366,367*) (AIII). Generally, while traveling in developing countries, HSCT recipients should avoid consuming the following (BIII):

- raw fruits and vegetables,
- tap water or any potentially untreated or contaminated water,
- ice made from tap water or any potentially contaminated water,
- unpasteurized milk or any unpasteurized dairy products,
- fresh fruit juices,
- food and drinks from street vendors, and
- raw or undercooked eggs.

Steaming hot foods, fruits peeled by oneself, bottled and canned processed drinks, and hot coffee or tea are probably safe (*367,368*). Travelers should plan for treating their drinking water while in developing countries. If bottled water is not available, boiling is the best method of making water safe. However, if boiling water is not feasible, the traveler should carry supplies for disinfecting water (e.g., commercially available iodine disinfection tablets or a portable water filter) (*366,368*).

Antimicrobial prophylaxis for traveler's diarrhea is not recommended routinely for HSCT recipients traveling to developing countries (DIII) because traveler's diarrhea not known to be more frequent or more severe among immunocompromised hosts. However, HSCT physicians who wish to provide prophylaxis to HSCT recipients w are traveling can prescribe a fluoroquinolone (e.g., ciprofloxacin hydrochloride) or TMP-SMZ (CIII), although resistance to TMP-SMZ is now common and resistance fluoroquinolones is increasing in tropical areas (Appendix). Researchers recommend using bismuth subsalicylate to prevent traveler's diarrhea among adults (*366*). However, no data were found regarding safety and efficacy among HSCT recipients, and salicylates are not recommended for use among persons aged <18 years becau salicylates are associated with Reye's syndrome (*369*).

HSCT recipients' immunization status should be assessed and their vaccinations updated as needed before travel (*366*). Influenza chemoprophylaxis with rimantadine c amantadine can be used for immunocompromised HSCT recipients who are traveling outside the continental United States and who could be exposed to influenza A (CIII).

HSCT RECIPIENT VACCINATIONS

Antibody titers to vaccine-preventable diseases (e.g., tetanus, polio, measles, mumps, rubella, and encapsulated organisms) decline during the 1--4 years after allogene or autologous HSCT (*66,370--373*) if the recipient is not revaccinated. Clinical relevance of decreased antibodies to vaccine-preventable diseases among HSCT recipie is not immediately apparent because a limited number of cases of vaccine-preventable diseases are reported among U.S. recipients. However, vaccine-preventable diseases still pose risks to the U.S. population. Additionally, evidence exists that certain vaccine-preventable diseases (e.g., encapsulated organisms) can pose increasec risk for HSCT recipients (*66*); therefore, HSCT recipients should be routinely revaccinated after HSCT so that they can experience immunity to the same vaccine-preventable diseases as others (Table 4).

HSCT center personnel have developed vaccination schedules for HSCT recipients (*374*). One study determined that HSCT center personnel used 3--11 different vaccination schedules per vaccine (*374*); consequently, the study authors requested national guidelines for doses and timing of vaccines after HSCT to eliminate confusion among HSCT center personnel regarding how to vaccinate their patients. To address this need, an interim vaccination schedule for HSCT recipients was drafted in collaboration with partner organizations, including CDC's Advisory Committee on Immunization Practices. The purpose of the vaccination schedule in these guidelines is to provide guidance for HSCT centers (Table 4). Although limited data were found regarding safety and immunogenicity (e.g., serologic studies of antibo titers after vaccination) among HSCT recipients, no data were found regarding vaccine efficacy among HSCT recipients (e.g., which determine whether vaccinated HSCT recipients have decreased attack rates of disease compared with unvaccinated HSCT recipients). Because certain HSCT recipients have faster immune system recovery after HSCT than others, researchers have proposed that different vaccination schedules be recommended for recipients of different types of HSCT. However, date, data are too limited to do so. Therefore, the same vaccination schedule is recommended for all HSCT recipients (e.g., allogeneic, autologous, and bone marrow, peripheral, or UCB grafts) until additional data are published. In the tables, vaccines have only been recommended for use among HSCT recipients if evidence exists o safety and immunogenicity for those recipients. Vaccination of family members, household contacts, and HCWs are also recommended to minimize exposure of vaccir preventable diseases among HSCT recipients (Tables 5--8).

HEMATOPOIETIC STEM CELL SAFETY

With allogeneic HSCT, the life of the recipient might depend on the timely selection of an acceptable HLA-matched donor. Only a limited number of HLA-matched donors might be identified; hence, the transplant physician often has to accept a higher risk for transmission of an infectious agent through HSCT than would be permitted for routine blood transfusion. This section provides strategies for the HSCT physician to minimize transmission of infectious diseases, whenever possible, fr donors to recipients.********* ********** Whether to select a donor who is at risk for or who has an infectious disease transmissible by HSCT, should be determine on a case-by-case basis (AIII) and is the final responsibility of the HSCT physician (AIII). If the only possible donor is at risk for or known to be infected with a bloodborne pathogen and the patient is likely to succumb rapidly from his or her disease if an HSCT is not received, the physician must carefully weigh the risks and benefits of using potentially infected donor cells. No person should be denied a potentially life-saving HSCT procedure solely on the basis of the risk for an infectious disease. However, HSCT physicians should avoid transplanting any infected or infectious donor hematopoietic stem cell product unless no other stem cell product can obtained and the risk for death from not undergoing transplantation is deemed to be greater than the risk for morbidity or death from the infection that could potentially be transmitted (DII). If such a product is selected for use, it should be done on a case-by-case basis (*375*) and the following should be noted in the recipient's chart:

- knowledge and authorization of the recipient's HSCT physician regarding the potential for transmission of an infectious agent during HSCT, and
- advance informed consent from the recipient or recipient's legal guardian acknowledging the possible transmission of an infectious agent during the transplantati (AIII).

Subsequently, the HSCT physician should include the infectious agent in the differential diagnosis of any illness that the HSCT recipient experiences so that the infecti if transmitted, can be diagnosed early and treated preemptively, if possible. Infectious products (except those in which CMV seropositivity is the only evidence of infectiousness) should be labeled as being a biohazard or as untested for biohazards, as applicable. Tissue intended for autologous use should be labeled "For Autologo Use Only --- Use Only for (Patient's Name)."

Preventing Transmission of Infections from HSCT Donors to Recipients

All prospective HSCT donors should be evaluated through a physical history and examination to determine their general state of health and whether they pose a risk fo transmitting infectious diseases to the recipient (*376*). To detect transmissible infections, all HSCT donor collection site personnel should follow up-to-date published guidelines and standards for donor screening (e.g., medical history), physical exam, and serologic testing (*377--383*) (AIII). Initial donor screening and physical exam should be performed ≤8 weeks before the planned donation (BIII). Donor serologic testing should be done ≤30 days before donation to detect potentially transmissible infections (BII); additionally, researchers recommend that donors be retested ≤7 days before collection. If testing is done >7 days before donation, donor screening sho be repeated to ensure that no new risk behaviors have occurred during the interval between the original screening and the time of donation (BIII). This practice is critic because if new behavioral risk factors have occurred, the potential donor might need to be deferred. Screening and testing should be done on all allogeneic or syngenei donors (AIII). Screening and testing of autologous donors is recommended to ensure the safety of laboratory personnel and to prevent cross contamination (BIII). If autologous donors are not tested, their autologous units should be specially labeled and handled as if potentially infected (BIII). For donors screened in the United Stat FDA-licensed or -approved tests should be used in accordance with the manufacturers' instructions (AIII), and the donor samples should be tested in laboratories certif by the Clinical Laboratory Improvement Amendments of 1988 (AIII).

All HSCT donors should be in good general health (*376*) (BIII). Acute or chronic illness in the prospective donor should be investigated to determine the etiology. Generally, persons who are ill should not be HSCT donors (DIII). A flu-like illness in a prospective donor at the time of evaluation or between the time of evaluation a donation should prompt evaluation of and serologic testing for infections that might pose a risk to the recipient (e.g., EBV, CMV, *To. gondii*) (BIII). Persons with a positive serum EBV-viral capsid antigen IgM but negative serum EBV-viral capsid antigen IgG should not serve as donors for allogeneic T-cell--depleted HSCT, particularly for unrelated or mismatched transplants, until their serum EBV-viral capsid antigen IgG becomes positive (DIII). Persons with acute toxoplasmosis should not donate until the acute illness has resolved (DII); however, physicians should be aware that persons who are asymptomatically seropositive for *To. gondii* might transmit this infection through HSCT (*218*).

Prospective donors with symptoms of active TB should be evaluated for that disease (*383*) (BIII). Prospective donors with active TB should not donate (EIII) until the is well-controlled (e.g., no longer contagious as determined by the donor's primary physician) after appropriate medical therapy. However, no known risk exists from transplanting marrow from an untreated, tuberculin-positive donor who has no evidence of active disease. Screening potential donors for TB with Mantoux skin tests (DIII) is not necessary. Prospective HSCT donors who reside in or have traveled to areas endemic for rickettsia or other tickborne pathogens and who are suspected of having an acute tickborne infection should be temporarily deferred as donors until infection with these pathogens is excluded (DIII). Relevant pathogens include *Rickettsia rickettsii*, *Babesia microti* and other *Babesia* species, *Coxiella burnetii*, and the Colorado tick fever virus, which are the etiologic agents of Rocky Mountain spotted fever, babesiosis, Q fever, and Colorado tick fever, respectively; these pathogens have been reported to be transmitted by blood transfusion (*384--388*). Researchers recommend deferral for a past history of Q fever or babesiosis because these infections can be chronic and the babesiosis parasite might persist despite

appropriate therapy (*389*) (CIII). Additionally, researchers have recommended deferring persons with acute human ehrlichiosis (e.g., human active human granulocytic ehrlichiosis [*390*], human monocytic ehrlichiosis, as well as any infections from *Ehrlichia ewingii*) from HSCT donation (CIII).

The medical history of the prospective HSCT donor should include the following:

- History of vaccinations (*377*) during the 4 weeks before donation (AII). If the potential donor is unsure of vaccinations received, his or her records should be reviewed. HSCT donation should be deferred for 4 weeks after the donor receives any live-attenuated vaccine (e.g., rubeola [measles], mumps, rubella [German measles], oral polio, varicella, yellow fever, and oral typhoid vaccines) (EIII). This deferral will avoid the possibility of infusing a live infectious agent into an HSCT recipient. HSCT donation need not be deferred for persons who have recently received toxoid or killed (i.e., inactivated), recombinant viral, bacterial, or rickettsial vaccines as long as the donor is asymptomatic and afebrile (*389*) (BIII). Such vaccines include tetanus toxoid, diphtheria toxoid, hepatitis A and B, cholera, influenza (i.e., killed intramuscular vaccine), meningococcal, paratyphoid, pertussis, plague, polio (i.e., inactivated polio vaccine), rabies, typhoid (i.e., inactivated intramuscular vaccine), or typhus vaccines (*389*).
- Travel history (BIII) to determine whether the donor has ever resided in or traveled to countries with endemic diseases that might be transmitted through HSCT (e.g., malaria). Permanent residents of nonendemic countries who have traveled to an area that CDC regards as endemic for malaria can be accepted as HSCT donors if 1 year has elapsed since the donor's departure from the endemic area and if the donor has been free of malaria symptoms, regardless of whether he or sl received antimalarial chemoprophylaxis. Because cases of HSCT-transmitted malaria have been reported (*391,392*), persons who have had malaria and received appropriate treatment should be deferred from HSCT donation for 3 years after becoming asymptomatic. Immigrants, refugees, citizens, or residents for ≥5 years endemic countries can be accepted as HSCT donors if 3 years have elapsed since they departed the malarious area and if they have been free of malaria symptom
- History of Chagas' disease and leishmaniasis. Persons with active Chagas' disease or leishmaniasis should not serve as HSCT donors (DIII) because these disease can be transmitted by transfusion (*227,229,231,393--395*). Researchers also recommend deferral of HSCT donation if a past history exists of either of these diseases because the parasite can persist despite therapy (*227--229,231, 389,393--395*) (CIII).
- History of any deferral from plasma or blood donation. The reason for such a deferral (*376*) and whether it was based on a reported infectious disease or behavio or other risk factor should be investigated (BIII).
- History of viral hepatitis. A person with a history of viral hepatitis after his or her eleventh birthday should be excluded from HSCT donation (BIII).
- History of blood product transfusion, solid organ transplantation, or transplantation of tissue within the last 12 months (BIII). Such persons should be excluded from HSCT donation (DIII). Xenotransplant product recipients and their close contacts should be indefinitely deferred from donating any blood products, includi hematopoietic stem cells, whole blood, or other blood components including plasma, leukocytes, and tissues (*396*) (AIII). Close contacts to be deferred from donations include persons who have engaged repeatedly in activities that could result in an intimate exchange of body fluids with a xenotransplantation product recipient. Such close contacts could include sexual partners, household members who share razors or toothbrushes, and HCWs or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures.
- History of risk factors for classic Creutzfeldt-Jakob disease (CJD), including any blood relative with Creutzfeldt-Jakob disease, receipt of a human pituitary-derived growth hormone or receipt of a corneal or dura mater graft (*383,397--399*) (BIII). Potential HSCT donors should also be screened for new variant Creutzfeldt-Jakob Disease (nvCJD) risk factors, including a history of cumulative travel or residence in the United Kingdom for ≥6 months during 1980--1996 o receipt of injectable bovine insulin since 1980, unless the product was not manufactured since 1980 from cattle in the United Kingdom (*398*) (BIII). The clinical latency period for iatrogenic, classic CJD can be >30 years (*398*), and transmission of classic CJD by blood products is highly unlikely (*398*). Although no classi or nvCJD has ever been reported among HSCT recipients, persons with a history of classic or nvCJD risk factors should be excluded from donation for unrelated HSCT (DIII) if a choice exists between two otherwise equally suitable donors. The risk for transmitting classic or nvCJD from an HSCT donor to a recipient is unknown, but researchers believe that persons with nvCJD risk factors could be at higher risk for transmitting nvCJD to HSCT recipients than persons with class CJD risk factors.
- Past medical history that indicates the donor has clinical evidence of or is at high risk for acquiring a bloodborne infection (e.g., HIV-1 or -2, human T-lymphotropic virus [HTLV]-I or -II, hepatitis C, or hepatitis B) (*381,383*), including
  - men who have had sex with another man during the preceding 5 years (*381,383*) (BIII);
  - persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs during the preceding 5 years (*381*) (BIII);
  - persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates (*381*) (BIII);
  - persons who have engaged in sex in exchange for money or drugs during the preceding 5 years (*381*) (BIII);
  - persons who have had sex during the preceding 12 months with any person described previously (*381*) or with a person known or suspected to have HIV (*381*) or hepatitis B infections (BIII);
  - persons who have been exposed during the preceding 12 months to known or suspected HIV, hepatitis B- or C-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane (*381*) (BIII);
  - inmates of correctional systems (*379--381*) and persons who have been incarcerated for >72 consecutive hours during the previous 12 months (BIII);
  - persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months (*376,379,380*) (BIII); and
  - persons who within 12 months have undergone tattooing, acupuncture, ear or body piercing (*380,400,401*) in which shared instruments are known to have been used (BIII) or other nonsterile conditions existed.

Persons reporting any of these past medical histories should be excluded from donation (DIII).

The following serologic tests should be performed for each prospective donor:

- HIV-1 antigen, anti-HIV-1 and -2, anti-HTLV-I and -II, hepatitis B surface antigen, total antihepatitis B core antigen, antihepatitis C, anti-CMV, and a serologic t for syphilis (*376,379,380,383*) (AIII). Potential donors who have repeatedly reactive screening tests for HIV-1 antigen, anti-HIV-1 or -2, anti-HTLV-I or -II, antihepatitis C, hepatitis B surface antigen, or antihepatitis B core antigen should be excluded as HSCT donors (*381*) (EII). Persons who refuse infectious disease testing should also be excluded as HSCT donors (*381*) (EIII).
- Investigational nucleic acid tests to detect hepatitis C virus RNA and HIV RNA are currently being used in the United States to screen blood donors and could be used for screening HSCT donors. If nucleic acid tests are approved by FDA, these tests should be incorporated into routine screening regimens for HSCT donors When nucleic acid testing is done for HIV and hepatitis C investigationally, a positive result should exclude the potential donor.

All infectious disease testing and results should be reported to the HSCT physician before the candidate's conditioning regimen begins (*381*) (AIII). Bone marrow shou be collected using sterile technique in a medically acceptable setting and according to standard operating procedures (AIII).

HSCT transplant center personnel should keep accurate records of all HSCT received and the disposition of each sample obtained (*381*). These tracking records must b separate from patients' medical records (e.g., in a log book) so that this information is easily obtainable. Recorded information should include the donor identification number, name of procurement of distribution center supplying the HSCT, recipient-identifying information, name of recipient's physician, and dates of a) receipt by the HSCT center and b) either transplantation to the recipient or further distribution (*381*) (AIII). All centers for donation, transplantation, or collection of hematopoietic st cells should keep records of donor screening and testing, and HSCT harvesting, processing, testing, cryopreservation, storage, and infusion or disposal of each aliquot donated hematopoietic progenitor cells for ≥10 years after the date of implantation, transplantation, infusion, or transfer of the product (*378*) (AIII). However, if that da is not known, records should be retained ≥10 years after the product's distribution, disposition, or expiration, whichever is latest.

Pediatric Donors

Children aged >18 months who are born to mothers with or at risk for HIV infection, who have not been breast-fed during the past 12 months, and whose HIV antibod tests, physical examination, and medical records do not indicate evidence of HIV infection can be accepted as donors (*381*) (BIII). Children aged <18 months who are born to mothers with or at risk for HIV infection and who have not been breast-fed by an HIV-infected woman during the past 12 months can be accepted as donors on if HIV infection has been excluded according to established criteria (*402*) (BIII). Children who have been breast-fed by an HIV-infected woman during the past 12 months should be excluded as stem cell donors regardless of HIV infection status (AIII). The mother and, if possible, the father of all pediatric stem-cell donors who ar at risk for perinatal transmission of HIV and other bloodborne infections, should be interviewed by a health-care professional competent to elicit information regarding risk factors for possible bloodborne infection in the potential pediatric donor (AIII). Children who meet any of the adult donor exclusion criteria should not become HSCT donors (*381*) (EIII).

Preventing Infection from Extraneous Contamination of Donated Units

Personnel of donation, collection, or transplantation centers, cell-processing laboratories, and courier services should follow current standards for detecting and preventing extrinsic bacterial and fungal contamination of collected stem cell units at the collection site, during processing and transportation, and at the transplant cen (*376*) (AIII). Quality improvement programs and procedure manuals of collection centers, cell-processing laboratories, and transplant programs should include strategi for preventing transplant-associated infections. For example, collection centers should use aseptic techniques when collecting marrow, peripheral blood, and UCB hematopoietic stem cells (*376,378*) (AIII). Whenever possible, closed systems should be used for pooling hematopoietic stem cells during a collection procedure (BIII) because higher rates of microbial contamination seen in marrow harvests versus blood stem cell collections can be caused by use of open collecting systems (*375,403,404*). The highest risk for extraneous microbial contamination of hematopoietic stem cells occurs during extensive manipulation and processing in the laboratory (*404,405*). Potential sources include unprotected hands and laboratory equipment and freezers (*406*), particularly the liquid phases of liquid nitrogen freezer (*407*). Therefore, stem cell processing should be performed according to current standards (*378*) using approved manufacturing practices (AIII). Hematopoietic stem c units thawed in a water bath should be enclosed in a second bag (i.e., double-bagged technique) to prevent contamination of the ports or caps from unsterile bath water (*407*) (BIII). Additionally, water baths should be cleaned routinely (BIII) and certain researchers have proposed that the bath contain sterile water (*407*) (CIII). Researchers also report sterilizing liquid nitrogen freezers before initial use for hematopoietic stem cell storage (*407*) until fungal and bacterial cultures are negative (CIII).

Cell-processing laboratory personnel should implement programs to detect extrinsic bacterial or fungal contamination of collected stem cell units, ideally before transplantation (AIII). Although repeated cultures are costly (*408*), donated hematopoietic stem cells should be cultured for aerobic bacteria and fungi $\geq$1 times during initial processing and freezing (BIII). Researchers also have proposed adding anaerobic bacterial cultures and culturing twice, once at the end of processing, and once after thawing just before use (*407*) (CIII). If bacterial culture results are positive, antibiotic-susceptibility tests should be performed (BIII). Results of cultures and antibiotic-susceptibility tests should be provided to the transplant physician before release of a cryopreserved marrow or blood stem cell unit, and as soon as feasible fo transplants infused before completion of culture incubation (BIII).

Collection center, cell-processing laboratory, and transplant program personnel should maintain active surveillance of infections among persons who have received hematopoietic stem cells from those facilities to collect data regarding the number of infections after HSCT that might have been caused by exogenous contamination donor stem cells (BIII) because this type of infection has been reported (*405*).

In Utero or Fetal HSCT

No national standards exist for in utero or fetal HSCT, and the overall risks for transmitting infections to a fetus through HSCT (*409,410*) have not been determined. However, in addition to precautions appropriate for adult recipients, physicians performing in utero or fetal HSCT are advised to evaluate potential donors for evidence active infectious diseases that could cause serious congenital infections (e.g., rubella, varicella, CMV, syphilis, or *To. gondii*) in the fetus (CIII).

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* For this report, HSCT is defined as any transplantation of blood- or marrow-derived hematopoietic stem cells, regardless of transplant type (e.g., allogeneic or autologous) or cell source (e.g., bone marrow, peripheral blood, or placental/umbilical cord blood). In addition, HSCT recipients are presumed immunocompetent at ≥24 months after HSCT if they are not on immunosuppressive therapy ar do not have graft-versus-host disease (GVHD), a condition that occurs when the transplanted cells recognize that the recipient's cells are not the same cells and attack them.

** Presently, no updated data have been published.

*** Since November 1997, the United States has had a shortage of intravenous immunoglobulin (IVIG) (**Source:** CDC. Availability of immune globulin intravenous for treatment of immune deficient patients---United States, 1997--1998. MMWR 1999:48[8];159--162). Physicians who have difficulty obtaining IVIG should contact the following sources:

- American Red Cross Customer Service Center, (800) 261-5772;
- Alpha Therapeutic Corporation, (800) 421-0008;
- Baxter Healthcare Corporation, (847) 940-5955;
- Bayer Pharmaceutical Division, (800) 288-8370;
- Aventis Behring Customer Support, (800) 683-1288;
- Novartis Pharmaceuticals Corporation, (973) 781-8300, or the IVIG Emergency Hotline, (888) 234-2520; or
- Immune Deficiency Foundation, (800) 296-4433.

Physicians who are unable to obtain IVIG for a licensed indication from one of these sources should contact the Product Shortage Officer at the Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Compliance, (301) 827-6220, for assistance.

**** VZIG is distributed by FFF Enterprises, Inc., under contract with the American Red Cross, except in Massachusetts where it is distributed by the Massachusetts Public Health Biologic Laboratori (now a unit of the University of Massachusetts) (*19)* . FFF Enterprises, Inc., can be contacted at

FFF Enterprises, Inc.
41093 County Center Drive
Temecula, CA 92591
Phone: (800) 522-4448

***** For additional information regarding the epidemiology of Chagas' disease, contact CDC/National Center for Infectious Diseases/Division of Parasitic Diseases, (770) 488-7760.

****** Broviac dolls are used to demonstrate medical procedures (e.g., insertion of catheters) to children to lessen their fears.

******* For a list of filters certified under NSF Standard 053 for cyst (i.e., *Cryptosporidium* removal, contact the NSF International consumer line at (800) 673-8010 or <http://www.nsf.org/notice/crypto.html>.

******** The International Bottled Water Association can be contacted at (703) 683-5213 from 9 a.m. to 5 p.m. EST or anytime at their Internet site (<http://www.bottledwater.org>) to obtain contact information regarding water bottlers.

********* The U.S. Public Health Service is reexamining the current donor deferral recommendations regarding risk behaviors for donors of organs, cells, tissues, xenotransplantation, and reproductiv cells and tissue, including semen, and revisions to these guidelines could become necessary as the research evolves.

********** Guidelines for screening UCB donors and their mothers are evolving and will not be addressed in this document.

Table 1

TABLE 1. Evidence-based rating system used to determine strength of recommendations

Category	Definition	Recommendation
A	Strong evidence for efficacy and substantial clinical benefit	Strongly recommended
B	Strong or moderate evidence for efficacy, but only limited clinical benefit	Generally recommended
C	Insufficient evidence for efficacy; or efficacy does not outweigh possible adverse consequences (e.g., drug toxicity or interactions) or cost of chemoprophylaxis or alternative approaches	Optional
D	Moderate evidence against efficacy or for adverse outcome	Generally not recommended
E	Strong evidence against efficacy or of adverse outcome	Never recommended

Source: Adapted from CDC. 1999 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. MMWR 1999;48(RR-10):1–66.

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Figure

FIGURE. Phases of opportunistic infections among allogeneic HSCT recipients

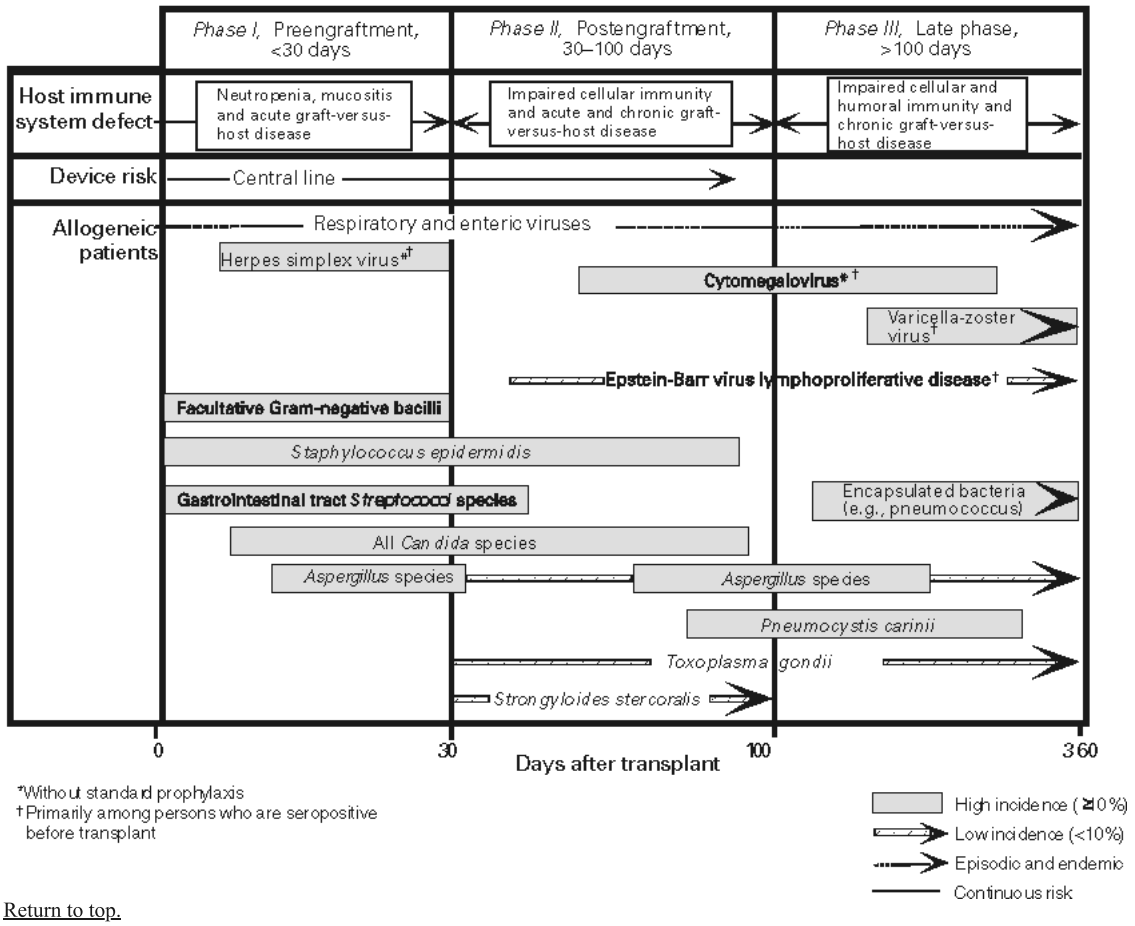

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Table 2

TABLE 2. Evidence-based rating system used to determine quality of evidence supporting recommendation

Category	Definition
I	Evidence from at least one well-executed randomized, controlled trial
II	Evidence from at least one well-designed clinical trial without randomization; cohort or case-controlled analytic studies (preferably from more than one center); multiple time-series studies; or dramatic results from uncontrolled experiments
III	Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

Source: Adapted from CDC. 1999 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. MMWR 1999;48(RR-10):1–66.

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Table 3

TABLE 3. Foods that pose a high risk for hematopoietic stem cell transplant (HSCT) recipients and safer substitutions

Foods That Pose a High Risk	Safer Substitutions
Raw and undercooked eggs* and foods containing them (e.g., french toast, omelettes, salad dressings, egg nog, and puddings)	Pasteurized or hard boiled eggs
Unpasteurized dairy products (e.g., milk, cheese, cream, butter, and yogurt)	Pasteurized dairy products
Fresh-squeezed, unpasteurized fruit and vegetable juices	Pasteurized juices
Unpasteurized cheeses or cheeses containing molds	Pasteurized cheeses
Undercooked or raw poultry, meats, fish, and seafood	Cooked poultry, well-done meats, cooked fish, and seafood
Vegetable sprouts (e.g., alfalfa, bean, and other seed sprouts)†	Should be avoided
Raw fruits with a rough texture (e.g., raspberries)§	Should be avoided
Smooth raw fruits	Should be washed under running water, peeled, or cooked
Unwashed raw vegetables¶	Should be washed under running water, peeled, or cooked
Undercooked or raw tofu	Cooked tofu (i.e., cut into 1-inch cubes and boiled for 5 minutes in water or broth before eating or using in recipes)
Raw or unpasteurized honey	Should be avoided
Deli meats, hot dogs, and processed meats**	Should be avoided unless further cooked
Raw, uncooked grain products	Cooked grain products including bread, cooked, and ready-to-eat cold cereal, pretzels, popcorn, potato chips, corn chips, tortilla chips, cooked pasta, and rice
Maté tea††	Should be avoided
All moldy and outdated food products	Should be avoided
Unpasteurized beer (e.g., home-brewed and certain microbrewery beer)	Pasteurized beer (i.e., retail bottled or canned, or draft beer that has been pasteurized after fermentation)
Raw, uncooked brewers yeast	Should be avoided; HSCT recipients should avoid any contact with raw yeast (e.g., they should not make bread products themselves)
Unroasted raw nuts	Cooked nuts
Roasted nuts in the shell	Canned or bottled roasted nuts or nuts in baked products

* **Source**: CDC. Outbreaks of *Salmonella* serotype enteritidis infection associated with consumption of raw shell eggs—United States, 1994–1995. MMWR 1996; 45(34):737–42.

† **Source**: Taormina PJ, Beuchat LR, Slutsker L. Infections associated with eating seed sprouts: an international concern. Emerg Infect Dis 1999;5(5):626–34.

§ **Source**: Herwaldt BL, Ackers ML. Outbreak in 1996 of cyclosporiasis associated with imported raspberries. New Engl J Med 1997;336(22):1548–56.

¶ **Source**: CDC. Foodborne outbreak of cryptosporidiosis—Spokane, Washington, 1997. MMWR 1998;47(27):565–7.

** **Source**: CDC. Update: multistate outbreak of listeriosis—United States, 1998–1999. MMWR 1999;47(51):1117–8.

†† **Source**: Kusminsky G, Dictar M, Arduino S, Zylberman M, Sanchez Avalos JC. Do not drink Maté: an additional source of infection in South American neutropenic patients. Bone Marrow Transplant 1996;17(1):127.

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Table 4

TABLE 4. Recommended vaccinations for hematopoietic stem cell transplant* (HSCT) recipients, including both allogeneic and autologous recipients

For these guidelines, HSCT recipients are presumed immunocompetent at ≥24months after HSCT if they are not on immunosuppressive therapy and do not have graft-versus-host disease (GVHD).

Vaccine or toxoid	Time after HSCT: 12 months	14 months	24 months	Rating
Inactivated vaccine or toxoid				
Diphtheria, tetanus, pertussis				
Children aged <7 years*	Diphtheria toxoid-tetanus toxoid-pertussis vaccine (DTP) or diphtheria toxoid-tetanus toxoid (DT)†	DTP or DT	DTP or DT	BIII
Children aged 7 years§	Tetanus-diphtheria toxoid (Td)	Td	Td	BII
Haemophilus influenzae type b (Hib) conjugate¶	Hib conjugate	Hib conjugate	Hib conjugate	BII
Hepatitis (HepB)**	HepB	HepB	HepB	BIII
23-valent pneumococcal polysaccharide (PPV23)††	PPV23	—	PPV23	BIII
Hepatitis A§§	Routine administration not indicated			Not rated because of limited data
Influenza¶¶	Lifelong, seasonal administration, beginning before HSCT and resuming at ≥6 months after HSCT			BII
Meningococcal***	Routine administration not indicated			Not rated because of limited data
Inactivated polio (IPV)†††	IPV	IPV	IPV	BII
Rabies§§§	Routine administration not indicated			Not rated because of limited data
Lyme disease	Routine administration not indicated; limited data regarding safety, efficacy, or immunogenicity among HSCT recipients			Not rated because of limited data
Live-attenuated vaccine				
Measles-mumps-rubella (MMR)¶¶¶ **** ††††	—	—	MMR	BIII
Varicella vaccine §§§§	Contraindicated for HSCT recipients			EIII
Rotavirus vaccine	Not recommended for any person in the United States¶¶¶¶			EII

TABLE 4. (*Continued*) Recommended vaccinations for hematopoietic stem cell transplant* (HSCT) recipients, including both allogeneic and autologous recipients

* Studies report that an HSCT recipient can be primed if the donor has had primary vaccination series. Studies also report that a recipient's antibody titer bef HSCT might affect the titer 1 year after HSCT (**Source**: Lum LG. Kinetics of immune reconstitution after human marrow transplantation. Blood 1987;69[2]:369–8 No data were found regarding safety and immunogenicity of pertussis vaccination among HSCT recipients.

† DT should be used whenever a contraindication exists to pertussis vaccination.

§ HSCT recipients should be revaccinated with tetanus-diphtheria toxoids every 10 years, as routinely recommended for all adolescents and adults (**Sources**: C Diphtheria, tetanus, and pertussis: recommendations of vaccine use and other prevention measures; recommendations of the Advisory Committee on Immuni tion Practices [ACIP]. MMWR 1991;40[No.RR-10]:1–28; and CDC. Use of vaccines and immunoglobulin in persons with altered immunocompetence: recomm dations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1993;42[No.RR-4]:1–18).

¶ Hib conjugate vaccine is recommended for HSCT recipients of any age (**Sources**: CDC. Recommendations for use of *Haemophilus* b conjugate vaccines an combined diphtheria, tetanus, pertussis, and *Haemophilus* b vaccine: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MM 1993;42[No. RR-13]:1–15; and CDC. Use of vaccines and immunoglobulin in persons with altered immunocompetence: recommendations of the Advis Committee on Immunization Practices [ACIP]. MMWR 1993;42[No.RR-4]:1–18).

** Hepatitis B vaccination is recommended for all susceptible persons aged ≤18 years and for adults who have risk factors for hepatitis B virus infection (**Sourc** CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination; recommendatio of the Immunization Practices Advisory Committee [ACIP]. MMWR 1991;40[No.RR-13]:1–25; and CDC. Notice to readers: update; recommendations to prev hepatitis B virus transmission—United States. MMWR 1995;44[30]:574–5). ACIP hepatitis B vaccination recommendations indicate that high doses (40 µg/do are recommended for adult dialysis patients and other immunocompromised adults (**Source**: CDC. Notice to readers: update; recommendations to prev hepatitis B virus transmission—United States. MMWR 1995;44[30]:574–5). No data were found regarding immunocompromised children and their response higher doses of vaccine. Postvaccination testing for antibody to hepatitis B surface antigen is recommended 1–2 months after the third vaccine dose to ens protection among immunocompromised persons (**Source**: CDC. Notice to readers: update; recommendations to prevent hepatitis B virus transmission—Uni States. MMWR 1995;44[30]:574–5). Persons who do not respond to the primary vaccine series should complete a second 3-dose series.

†† The 23-valent pneumococcal polysaccharide vaccine might not be protective against pneumococcal infection among HSCT recipients. The second dose of vacc is not a booster dose, but provides a second chance for immunologic response among persons who failed to respond to the first dose (**Source**: Guinan EC, Molr DC, Antin JH, et al. Polysaccharide conjugate vaccine responses in bone marrow transplant patients. Transplant 1994;57[5]:677–84). Adjunctive antibio prophylaxis against encapsulated organisms, including pneumococcal disease, is recommended for allogeneic recipients with chronic GVHD (**Source**: Bortin M Horowitz MM, Gale RP, et al. Changing trends in allogeneic bone marrow transplantation for leukemia in the 1980s. JAMA 1992; 268[5]:607–12). No data were fou regarding safety and immunogenicity of the 7-valent conjugate pneumococcal vaccine among HSCT recipients; therefore, no recommendation regarding use of t vaccine can be made.

§§ No data were found regarding immunogenicity, safety, and efficacy of hepatitis A vaccine among HSCT recipients. Researchers report that hepatitis A vaccinat can be used for investigational use among HSCT recipients aged ≥24 months at ≥12 months after HSCT and who are at increased risk for hepatitis A or its adve consequences (e.g., persons with chronic liver disease, including chronic GVHD, and children living in areas with consistently elevated hepatitis A inciden (**Source**: CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices [AC MMWR 1999;48[No.RR-12]:1–37).

¶¶ Children aged <9 years receiving influenza vaccination for the first time require two doses. Children aged ≤12 years should receive only split-virus influe vaccine. Persons aged >12 years can receive whole- or split-virus vaccine. ACIP's and the American Academy of Pediatrics' dosing schedule should be us (**Sources**: American Academy of Pediatrics. Influenza. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Gro Village, IL: American Academy of Pediatrics, 2000:351–9; and CDC. Prevention and control of influenza: recommendations of the Advisory Committee Immunization Practices [ACIP]. MMWR 2000;49[No.RR-3]:1–38). For optimal influenza prevention, both vaccination and influenza chemoprophylaxis should used among HSCT recipients.

*** Administration of meningococcal vaccine should be evaluated for HSCT recipients who live in endemic areas or areas experiencing outbreaks (**Source**: C Control and prevention of meningococcal disease and control and prevention of serogroup C meningococcal disease: evaluation and management of suspec outbreaks. MMWR 1997;46[No.RR-5]:1–21). However, meningococcal vaccine immunogenicity and efficacy among HSCT recipients have not been studied.

††† Inactivated polio virus vaccine is immunogenic among HSCT recipients, although no data were found regarding efficacy and more data are needed regard optimal methods and timing of immunization (**Sources**: Henning KJ, White MH, Sepkowitz KA, Armstrong D. National survey of immunization practices follow allogeneic bone marrow transplantation. JAMA 1997;277[14]:1148–51; and CDC. Poliomyelitis prevention in the United States: introduction of a sequen vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine; recommendations of the Advisory Committee on Immunizat Practices [ACIP]. MMWR 1997;46[No.RR-3]:1–25).

TABLE 4. (*Continued*) Recommended vaccinations for hematopoietic stem cell transplant* (HSCT) recipients, including both allogeneic and autologous recipients

§§§ Clinicians can administer preexposure rabies vaccine to HSCT recipients with potential occupational exposures to rabies (**Source**: CDC. Human rab prevention—United States, 1999: recommendations of the Advisory Committee on Immunization Practices [ACIP] MMWR 1999;48[No.RR-1]:1–21; and publis erratum, MMWR 1999;48[1]:16). However, the safety and immunogenicity of rabies vaccination among HSCT recipients has not been studied. Preexposure rab vaccination should probably be delayed until 12–24 months after HSCT. Administration of rabies vaccine with human rabies immunoglobulin postexposure recan administered anytime after HSCT as indicated. Existing ACIP and American Academy of Pediatrics guidelines for postexposure human rabies immunoglobulina vaccine administration should be followed, which include administering 5 doses of rabies vaccine administered on days 0, 3, 7, 14, and 28 postexposure (**Sourc** American Academy of Pediatrics. Rabies. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, American Academy of Pediatrics;2000:475–82; and CDC. Human rabies prevention—United States, 1999: recommendations of the Advisory Committee Immunization Practices [ACIP] MMWR 1999;48[No.RR-1]:1–21; publish ederratum, MMWR 1999;48[1]:16).

¶¶¶ The first dose of measles-mumps-rubella vaccine should be administered ≥24 months after HSCT if the HSCT recipient is presumed immunocompetent. The secc measles-mumps-rubella dose is recommended 6–12 months later (BIII); however, the benefit of a second dose among HSCT recipients has not been evaluat During outbreaks, the second dose can be administered 4 weeks after the first dose (**Source**: CDC. Use of vaccines and immunoglobulin in persons with alte immunocompetence: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1993;42[No.RR-4]:1–18).

**** The half-life of intravenous immunoglobulin is decreased among HSCT recipients, but its effect on vaccine immunogenicity has not been evaluated. ACIP's and American Academy of Pediatrics' recommendations regarding intervals between administration of immunoglobulin preparations for various indications a vaccines containing live measles virus should be used (**Sources**: American Academy of Pediatrics. Measles. In: Pickering LK, ed. 2000 red book: report of Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2000:385–96; CDC. Measles, mumps, and rubella—vaccine and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]:1–48; and CDC. General recommendations on immunization: recommendations of the Advis Committee on Immunization Practices [ACIP]. MMWR 1994;43[No.RR-1]:1–38).

†††† Use of live vaccines (e.g., measles-mumps-rubella) is indicated only among immunocompetent persons and is contraindicated for recipients after HSCT who not presumed immunocompetent (**Sources**: CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MM 1996;45[No.RR-11]:1–36; and CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [AC MMWR 1994;43[No.RR-1]:1–38). Further research is needed to determine the safety, immunogenicity, and efficacy of varicella vaccine among HSCT recipier

§§§§ To protect HSCT recipients from varicella exposure, all varicella-susceptible health-care workers, family members, and close contacts of the recipient should vaccinated against varicella (**Source**: American Academy of Pediatrics. Varicella-zoster infections. In: Pickering LK, ed. 2000 red book: report of the commit on Infectious diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:624–38).

¶¶¶¶ **Source**: CDC. Withdrawal of rotavirus vaccine recommendation. MMWR 1999;48[43]:1007.

Additional Notes: All indicated nonlive vaccines should be administered to HSCT recipients regardless of HSCT type or presence of GVHD. Live-attenuated vaccines, (e.g., measles-mumps-rubella, varicella, Bacillus Calmette-Guérin, yellow fever, and oral typhoid vaccines) should not be administered to any HSCT recipient with active GVHD or immunosuppression (**Source**: CDC. Role of BCG [Bacillus of Calmette and Guérin] 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). To date, no adverse events have been reported (e.g., exacerbation of GVHD) among vaccinated HSCT recipients. However, data regarding immunization among HSCT recipients are limited and further studies are needed to evaluate safety, efficacy, and immunogenicity of th proposed HSCT immunization schedule. Use of combination vaccines is encouraged (**Source**: CDC. Combination vaccines for childhood immunization: recomme dations of the Advisory Committee on Immunization Practices [ACIP], the American Academy of Pediatrics [AAP], and the American Academy of Family Physicia [AAFP]. MMWR 1999;48[No. RR-5]:1–15). No contraindications to simultaneous administration of any vaccines exist, except cholera and yellow fever. Adverse events after vaccination should be reported promptly to the Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849-1100. Forms and information can be obtained from VAERS ([800] 822-7967). If the HSCT recipient has lapsed immunizations after HSCT (i.e., has missed one or more vaccine doses), the immunization schedule does not have to be restarted. Instead, the missing vaccine dose should be administered as soon as possible or during the next scheduled clinic appointment.

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Table 5

Table 5. Vaccinations for family close contacts, and health-care workers (HCWs) of hematopoietic stem cell transplantation (HSCT) recipients*

Vaccine	Recommendations for use	Rating
Hepatitis A†	Routine vaccination is recommended for persons at increased risk for hepatitis A or its adverse consequences (e.g., persons with chronic liver disease or persons traveling to hepatitis A-endemic countries) and for children aged ≥24 months living in areas with consistently elevated hepatitis A incidence.†	BII
Influenza§¶	Household contacts — Vaccination is strongly recommended during each influenza season (i.e., October–May) beginning in the season before the transplant and continuing to ≥24 months after HSCT. All household contacts of immunocompromised HSCT recipients should be vaccinated annually as long as these conditions persist.	AI
	HCWs and home caregivers — Annual vaccination is strongly recommended during each influenza season.	AI
Polio**	Vaccination is not routinely recommended for adults but should be administered when polio vaccination is indicated according to published Advisory Committee on Immunization Practices guidelines; when polio vaccine is administered, inactivated polio vaccine should be used.	AI
Measles-mumps-rubella††	Vaccination is recommended for all persons who are aged ≥12 months and who are not pregnant or immunocompromised.	AI
Rotavirus§§	Contraindicated because intussusception has been reported among infants during the first 1–2 weeks after rotavirus vaccination with substantially increased frequency.	EII
Varicella¶¶	Vaccination should be administered to all susceptible HCWs, household contacts, and family members who are aged ≥12 months and who are not pregnant or immunocompromised. When varicella vaccination is administered to persons aged ≥13 years, 2 doses are required, administered 4–8 weeks apart.	AIII

* This vaccination schedule refers only to vaccine-preventable diseases that are spread person-to-person.

† **Source**: CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-12):1–37.

§ Children aged <9 years receiving influenza vaccination for the first time require 2 doses. Children aged ≤12 years should receive only split-virus influenza vaccine. Persons aged >12 years can receive whole- or split-virus vaccine (**Sources**: CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2000;49[No. RR-3]:1–38; and CDC. Immunization of health care workers: recommendations of the Advisory Committee on Immunization Practices [ACIP] and the Hospital Infection Control Practices Advisory Committee. MMWR 1997;46[No. RR-18]:1–42).

¶ If HCWs, family members, or other close contacts of HSCT recipients receive influenza vaccination during an influenza A outbreak, they should also receive amantadine or rimantadine chemoprophylaxis for 2 weeks after the influenza vaccination (BI) while the vaccinee develops an immunologic response to the vaccine. However, if a nosocomial outbreak occurs with an influenza A strain that is not contained in the available influenza vaccine, HCWs, family members, and other close contacts of HSCT recipients and candidates should be administered influenza A chemoprophylaxis with amantadine or rimantadine until the end of the outbreak (**Source**: CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2000;49[No. RR-3]:1–38) (BIII). HCWs, family members, or other close contacts can be offered a neuraminidase inhibitor (e.g., zanamivir or oseltamivir) using the same strategies outlined previously, if one or more of the following exists: a) rimantadine or amantadine cannot be tolerated; b) the outbreak strain of influenza A is amantadine- or rimantadine-resistant; or c) the outbreak strain is influenza B (**Sources**: Monto AS, Robinson DP, Herlocher ML, Hinson JM Jr, Elliott MJ, Crisp A. Zanamivir in the prevention of influenza among healthy adults: a randomized controlled trial. JAMA 1999;282[1]:31–5; Hayden FG, Atmar RL, Schilling M, et al. Use of the selective oral neuraminidase inhibitor oseltamivir to prevent influenza. New Engl J Med 1999;341[18]:1336–43; Hayden FG, Gubareva L, Klein T, et al. Inhaled zanamivir for preventing transmission of influenza in families [Abstract LB-2]. In: Final program, abstracts and exhibits addendum, 38th Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, DC: American Society for Microbiology, 1991:1; and CDC. Neuraminidase inhibitors for treatment of influenza A and B infections. MMWR 1999;48[No. RR-14]:1–10) (BI). Zanamivir can be administered to persons aged ≥12 years, and oseltamivir can be administered to persons aged ≥18 years.

** **Caution**: Vaccine-strain polio virus in oral polio vaccine can be transmitted person-to-person; therefore, oral polio vaccine administration is contraindicated among household contacts of immunocompromised persons. If oral polio vaccine is inadvertently administered to a household contact of an HSCT recipient, ACIP's and the American Academy of Pediatrics' recommendations should be followed to minimize close contact with the immunocompromised person for 4–6 weeks after vaccination (**Sources**: American Academy of Pediatrics. Poliovirus infections. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2000:465–70; CDC. Immunization of health care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control

Table 5. (*Continued*) Vaccinations for family close contacts, and health-care workers (HCWs) of hematopoietic stem cell transplantation (HSCT) recipients*

Practices Advisory Committee. MMWR 1997;46[No. RR-18]:1–42; and CDC. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine; recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46[No. RR-3]:1–25). Although vaccine-associated paralytic poliomyelitis has not been reported among HSCT recipients after exposure to household contacts inadvertently vaccinated with oral polio vaccine, inactivated polio vaccine should be used among family members, close contacts, and HCWs to avoid person-to-person transmission of vaccine-strain poliovirus (**Source**: CDC. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine; recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46[No. RR-3]:1–25).

†† No evidence exists that live-attenuated vaccine-strain viruses in measles-mumps-rubella vaccine have ever been transmitted from person-to-person, except rubella vaccine virus from a nursing mother to her infant (**Source**: CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]:1–48).

** HCWs, family members, close contacts and visitors who do not have a documented history of varicella-zoster infection or who are seronegative should receive this vaccination before being allowed to visit or have direct contact with an HSCT recipient (AIII). Ideally, varicella-zoster–susceptible HCWs, family members, household contacts, and potential visitors of immunocompromised HSCT recipients should be vaccinated as soon as the decision to perform an HSCT is made. The vaccination dose or doses should be completed ≥4 weeks before the conditioning regimen begins or ≥6 weeks (42 days) before contact with the HSCT recipient is planned (BIII). If a varicella vaccinee develops a postvaccination rash within 42 days of vaccination, the vaccinee should avoid contact with HSCT recipients until all rash lesions are crusted or the rash has resolved (**Sources**: CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1996;45[No. RR-11]:1–36; and CDC. Immunization of health care workers: recommendations of the Advisory Committee on Immunization Practices [ACIP] and the Hospital Infection Control Practices Advisory Committee. MMWR 1997;46[No. RR-18]:1–42).

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Table 6

TABLE 6. Vaccinations for hematopoietic stem cell transplant (HSCT) recipients traveling to areas endemic for selected vaccine-preventable diseases

Vaccine	Recommendations for use	Rating
Bacillus of Calmette and Guérin (live-attenuated vaccine)	Use of live-attenuated vaccine is contraindicated among HSCT recipients at <24 months after HSCT and among all persons who are immunocompromised.* No data were found regarding use among HSCT recipients.	EIII
Cholera	Vaccination is not indicated. No data were found regarding safety and immunogenicity among HSCT recipients.†	DIII
Hepatitis A	No data were found regarding immunogenicity, safety, or efficacy of hepatitis A vaccine among HSCT recipients; therefore, intramuscular immunoglobulin use is preferred for hepatitis A prophylaxis among HSCT recipients. However, administration of intramuscular immunoglobulin does not replace avoidance behaviors (e.g., careful selection of food and water).§ Researchers recommend that hepatitis A vaccination be evaluated for investigational use among HSCT recipients aged ≥24 months; however, no recommendation can be made because of limited data.	Not rated because of limited data
Japanese B encephalitis	No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.¶	Not rated because of limited data
Lyme disease	No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.	Not rated because of limited data
Meningococcal vaccine	Vaccine should be administered to HSCT recipients traveling to endemic areas or to areas experiencing outbreaks.** However, meningococcal vaccine immunogenicity and efficacy have not been studied among HSCT recipients.	Not rated because of limited data
Plague	No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.††	Not rated because of limited data
Polio (inactivated polio vaccine only)	Booster dose can be administered as indicated.§§	CIII
Rabies	Researchers recommend that administration of a preexposure series be evaluated for persons at ≥12 months after HSCT if they anticipate travel to endemic areas.¶¶ However, no data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.	Not rated because of limited data
Typhoid, oral (live-attenuated vaccine)	Use of oral typhoid vaccine (live-attenuated strain) is contraindicated among HSCT recipients at <24 months after HSCT and among those who are immunocompromised.*** No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.	EIII
Typhoid (intramuscular)	No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.	Not rated because of limited data
Yellow fever (live-attenuated vaccine)	Use of live-attenuated vaccine is contraindicated among HSCT recipients at <24 months after HSCT and among all immunocompromised persons.††† No data were found regarding safety, immunogenicity, or efficacy among HSCT recipients.	EIII

* **Source**: CDC. Role of BCG [Bacillus of Calmette and Guérin] 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.

† **Source**: CDC. Recommendations of the Immunization Practices Advisory Committee: cholera vaccine. MMWR 1988;37(40):617–8; 623–4.

§ **Source**: CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-12):1–37.

¶ **Source**: CDC. Inactivated Japanese encephalitis virus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1993;42(No. RR-1):1–15.

** **Source**: CDC. Control and prevention of meningococcal disease and control and prevention of serogroup C meningococcal disease: evaluation and management of suspected outbreaks. MMWR 1997;46(No. RR-5):1–21.

TABLE 6. (*Continued*) Vaccinations for hematopoietic stem cell transplant (HSCT) recipients traveling to areas endemic for selected vaccine-preventable diseases

†† **Source**: CDC. Prevention of plague: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1996;45(No. RR-14):1–15.

§§ **Source**: CDC. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine; recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1997;46(No. RR-3):1–25.

¶¶ **Source**: CDC. Human rabies prevention—United States, 1999: recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR 1999;48(No. RR-1):1–21; published erratum, MMWR 1999;48(1):16.

*** **Source**: CDC. Typhoid immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1994;43(No. RR-14):1–7.

††† **Source**: CDC. Yellow fever vaccine: recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 90;39(No. RR-6):1–6.

Additional Note: Specific advice for international travelers, including information regarding endemic diseases by country, is available through CDC's automated travelers' hotline at (404) 332-4559; by facsimile at (404) 335-4565; on the Internet at <http://www.cdc.gov>; and by file transfer protocol at <ftp.cdc.gov>.

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Table 7

TABLE 7. Use of passive immunization for hematopoietic stem cell transplant (HSCT) recipients exposed to vaccine-preventable diseases

Preparation	Recommendations for Use	Rating
Cytomegalovirus immunoglobulin	Not recommended for prophylaxis among HSCT recipients because of its lack of efficacy.*	DI
Hepatitis B immunoglobulin	Immunocompromised persons who have percutaneous or permucosal exposure to hepatitis B virus should receive 2 doses administered 1 month apart. For immunocompetent persons, the need for postexposure prophylaxis depends on the vaccination history and antibody to hepatitis B surface antigen response status of the exposed person.†	CIII
Human rabies immunoglobulin	Should be administered with rabies vaccine at anytime after HSCT as indicated for postexposure rabies prophylaxis. Existing Advisory Committee on Immunization Practices guidelines for postexposure should be followed, with 5 doses of rabies vaccine administered on days 0, 3, 7, 14, and 28 postexposure.§	CIII
Respiratory syncytial virus immunoglobulin¶	Because of high rates of case fatality from respiratory syncytial virus pneumonia among HSCT recipients, HSCT physicians can administer HSCT recipients with upper or lower respiratory infection preemptive therapy with a high titer of neutralizing antibodies to prevent severe disease and death until controlled trials can be performed.**	CIII
Respiratory syncytial virus monoclonal antibody	Physicians can use respiratory syncytial virus monoclonal antibody†† investigationally as preemptive therapy (Appendix).	Not rated because of limited data
Tetanus immunoglobulin	Postexposure vaccination should be administered with or without tetanus immunoglobulin as indicated for tetanus exposure§§ that occurs anytime after HSCT.	CIII
Varicella-zoster immunoglobulin¶¶	Ideally, should be administered to HSCT recipients ≤96 hours after close contact with a person with varicella or shingles if the HSCT recipient is at a) <24 months after HSCT or b) ≥24 months after HSCT and still immunocompromised. Administration can extend the varicella incubation period from 10–21 days to 10–28 days. If the HSCT recipient experiences a varicella-zoster virus-like rash after contact with or exposure to a person with varicella or herpes zoster, antiviral drug therapy should be administered until ≥2 days after all lesions have crusted.***	AII
Intramuscular immunoglobulin	Should be administered to hepatitis A-susceptible HSCT recipients who anticipate hepatitis A exposure, (e.g., during travel to endemic areas) and for postexposure prophylaxis as indicated.††† Should also be administered after measles exposure among HSCT recipients who were not vaccinated against measles after HSCT.§§§	BIII
Intravenous immunoglobulin¶¶¶	Can be administered to HSCT recipients with severe hypogammaglobulinemia (immunoglobulin G <400 mg/dl) ≤100 days after HSCT to prevent bacterial infections**** (Appendix).	CIII

* **Source**: Boeckh M, Bowden R. Cytomegalovirus infection in marrow transplantation. In: Buckner CD, ed. Technical and biological components of marrow transplantation. Boston, MA: Kluwer Academic Publishers, 1995:97–136.

† **Source**: CDC. Immunization of health care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee. MMWR 1997;46(No. RR-18):1–42.

§ **Sources**: American Academy of Pediatrics. Rabies. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:475–82; and CDC. Human rabies prevention—United States, 1999: recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR 1999;48(No. RR-1):1–21; published erratum, MMWR 1999;48(1):16.

TABLE 7. (*Continued*) Use of passive immunization for hematopoietic stem cell transplant (HSCT) recipients exposed to vaccine-preventable diseases

¶ Researchers recommend substituting respiratory syncytial virus immunoglobulin for intravenous immunoglobulin for HSCT recipients on replacement intravenous immunoglobulin therapy during respiratory syncytial virus season (i.e., November–April) (**Source**: American Academy of Pediatrics. Respiratory syncytial virus. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000:483–7) (CIII). However, no data were found demonstrating safety and efficacy of respiratory syncytial virus immunoglobulin use among HSCT recipients.

§§ **Source**: CDC. Diphtheria, tetanus, and pertussis: recommendations of vaccine use and other prevention measures; recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1991;40(No. RR-10):1–28.

¶¶ If intravenous immunoglobulin replacement therapy (>250 mg/kg) has been administered <2 weeks before varicella or zoster rash exposure, varicella-zoster immunoglobulin administration is probably not required. Varicella-zoster immunoglobulin is distributed by the American Red Cross, except in Massachusetts, where it is distributed by the Massachusetts Public Health Biologic Laboratories (now a unit of the University of Massachusetts) (**Source**: CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1996;45[No. RR-11]:1–36).

*** **Source**: CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1996;45(No. RR-11):1–36.

††† **Source**: CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-12):1–37.

§§§ **Sources**: CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1998;47(No. RR-8):1–48; and Eibl MM, Wedgwood RJ. Intravenous immunoglobulin: a review. Immunodeficiency Reviews 1989;1:1–42.

¶¶¶ When administered, serum immunoglobulin G levels should be monitored regularly (e.g., every 2 weeks).

**** **Sources**: Antman KH, Rowlings PA, Vaughn WP, et al. High-dose chemotherapy with autologous hematopoietic stem cell support for breast cancer in North America. J Clin Oncol 1997;15(5):1870–9; and Wolff SN, Fay JW, Herzig RH, et al. High-dose weekly intravenous immunoglobulin to prevent infections in patients undergoing autologous bone marrow transplantation or severe myelosuppressive therapy. Ann Intern Med 1993;118(12):937–42.

Additional Notes : Intravenous immunoglobulin can be obtained from the American Red Cross Blood Services, although shortages occasionally occur. Physicians who have difficulty obtaining urgently needed intravenous immunoglobulin and other immunoglobulin products are advised to contact any of the following:

- American Red Cross Customer Service Center, (800) 261-5772;
- Alpha Therapeutic Corporation, (800) 421-0008;
- Baxter Healthcare Corporation, (847) 940-5955;
- Bayer Pharmaceutical Division, (800) 288-8370;
- Aventis Behring Customer Support, (800) 683-1288;
- Novartis Pharmaceuticals Corporation, (973) 781-8300, or the Intravenous Immunoglobulin Emergency Hotline, (888) 234-2520; or
- Immune Deficiency Foundation, (800) 296-4433.

Physicians who are unable to obtain intravenous immunoglobulin for a licensed indication from one of these sources should contact the Product Shortage Officer at the Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Compliance, (301) 827-6220, for assistance. Patients with immunoglobulin E anti-immunoglobulin A antibodies are at high risk for experiencing anaphylaxis from immunoglobulin administration (**Source**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4). Therefore, persons with immunoglobulin A deficiency should not be administered standard immunoglobulin preparations (DIII; BIII). However, researchers report that use of immunoglobulin A-depleted immunoglobulin preparations can be used with caution in these persons (**Sources**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4; Siberry GK, Iannone R, eds. Harriet Lane handbook: a manual for pediatric house officers. 15th ed.; St. Louis, MO: Mosby, Inc., 2000:339;739; and Stiehm ER. Human intravenous immunoglobulin in primary and secondary antibody deficiencies [Review]. Pediatr Infect Dis J 1997;16[7]:696–707).

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Table 8

TABLE 8. Vaccine information

Vaccine or toxoid	Tradename	Manufacturer/ telephone number	Storage recommendation
Diphtheria toxoid-tetanus toxoid-pertussis vaccine	Tripedia®	Aventis Pasteur, Inc. (800) Vaccine	Store at 2–8 C (36–46 F); do not freeze
	Infanrix®	SmithKline Beecham (800) 877-1158	
	Acel-Imune®	Wyeth-Lederle (800) 572-8221	
	Certiva®	North American Vaccine (888) 628-2829	
Diphtheria toxoid-tetanus toxoid-pertussis vaccine–*Haemophilus influenzae* type b	Tetramune®	Wyeth-Lederle (800) 572-8221	Store at 2–8 C (36–46 F); do not freeze
	DTP/ACTHib®	Aventis Pasteur, Inc. (800) Vaccine	
	TriHibit®		
Tetanus-diphtheria toxoid (adult) and Diphtheria-tetanus toxoid (pediatric)	Generic	Aventis Pasteur, Inc. (800) Vaccine Wyeth-Lederle (800) 572-8221	Store at 2–8 C (36–46 F); do not freeze
Haemophilus influenzae type b	ACTHib®	Aventis Pasteur, Inc. (800) Vaccine	Store at 2–8 C (36–46 F); do not freeze
	HibTiter®	Wyeth-Lederle (800) 572-8221	
	PedvaxHIB®	Merck Human Health Division (800) MerckRX (ordering) (800) NSCmerc (questions)	
	OmniHIB®	SmithKline Beecham (800) 877-1158	
Haemophilus influenzae type b-Hepatitis B	COMVAX®	Merck Human Health Division (800) MerckRX (ordering) (800) NSCmerc (questions)	Store at 2–8 C (36–46 F); do not freeze
Inactivated polio vaccine	IPOL®	Aventis Pasteur, Inc. (800) Vaccine	
Measles-mumps-rubella Measles-rubella Mumps-rubella Measles Mumps Rubella	M-M-R II® M-R-Vax II® Biavax II® Attenuvax® Mumpsvax® Meruvax II®	Merck Human Health Division (800) MerckRX (ordering) (800) NSCmerc (questions)	Store at 2–8 C (36–46 F); freezing is permissible
Varicella	Varivax®		Maintain in a frozen state of –15 C (5 F) or colder
Hepatitis A	Vaqta® Havix®	SmithKline Beecham (800) 877-1158	Store at 2–8 C (36–46 F); do not freeze
Hepatitis B	Engerix-B® Recombivax B®	Merck Human Health Division (800) MerckRX (ordering) (800) NSCmerc (questions)	Store at 2–8 C (36–46 F); do not freeze
Influenza	Fluzone®	Aventis Pasteur, Inc. (800) Vaccine	Store at 2–8 C (36–46 F); do not freeze
	Fluvirin®	Celltech Medeva Pharmaceutical (800) 234-5535	
	Flu-Shield®	Wyeth-Ayerst Laboratories (800) 358-7443	
	Fluogen®	Monarch Pharmaceuticals (888) 358-6436	
Japanese encephalitis	JE-VAX	Research Foundation for Microbial Diseases of Osaka University, Japan; Distributed by Aventis Pasteur, Inc. (800) Vaccine SmithKline Beecham	Store at 2–8 C (36–46 F); do not freeze

TABLE 8. (*Continued*) Vaccine information

Vaccine or toxoid	Tradename	Manufacturer/ telephone number	Storage recommendation
Lyme disease	LYMErix™	(800) 877-1158	Store at 2–8 C 36–46 F); do not freeze
Pneumococcal 23-valent	Pru-Immune-23®	Wyeth-Lederle (800) 572-8221	Store at 2–8 C (36–46 F); do not freeze
	Pneumovax 23®	Merck Human Health Division (800) MerckRX (ordering) (800) NSCmerc (questions)	
Meningococcal	Menomune-A/C/Y/W-135®	Aventis Pasteur, Inc. (800) Vaccine	Store at 2–8 C (36–46 F); do not freeze
Rabies	Generic	BioPort Corporation (517) 327-1500; distributed by Smith Kline Beecham (800) 877-1158	Store at 2–8 C (36–46 F); do not freeze
	Imovax Rabies® and Imovax Rabies ID®	Aventis Pasteur, Inc. (800) Vaccine	
	RabAvert™	Chiron Corporation (800) 244-7668	
Typhoid	Typhoid Vaccine U.S. P.	Wyeth-Lederle (800) 572-8221	
Typhoid Vi polysaccharide	Typhim Vi™	Aventis Pasteur, Inc. (800) Vaccine	

Notes: Persons needing additional vaccine information or CDC's Advisory Committee on Immunization Practices guidelines can contact the CDC Immunization Hotline at (800) CDC-SHOT ([800] 232-7468) or at <http://www.cdc.gov/nip>. Adverse events after vaccinations should be reported promptly to the Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849-1100. Forms and information can be obtained from VAERS at (800) 822-7967.

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Appendix

Appendix

Dosing Charts for Preventing Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients

I. Preventive regimens for adult or adolescent hematopoietic stem cell transplant (HSCT) recipients

Pathogen: Cytomegalovirus

Indication	First choice	Alternatives
Universal prophylaxis for cytomegalovirus disease among all allogeneic adult or adolescent HSCT recipients at risk throughout phase II (i.e., from engraftment to day 100 after HSCT)	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 5–7 days, followed by 5–6 mg/kg intravenously daily for 5 days/week from engraftment until day 100 after HSCT (AI)	Foscarnet, 60 mg/kg intravenously every 12 hours for 7 days, followed by 90–120 mg/kg intravenously daily until day 100 after HSCT (CIII)
Or preemptive cytomegalovirus treatment administered <100 days after HSCT to all allogeneic adult or adolescent HSCT recipients at risk: Start ganciclovir when the patient experiences any level of cytomegalovirus antigenemia or viremia or has ≥2 consecutively positive cytomegalovirus-DNA polymerase chain reaction tests	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7–14 days, followed by 5 mg/kg/day for 5 days/week until day 100 after HSCT or for a minimum of 3 weeks, whichever is longer (AI); or administer ganciclovir for a total of 3–6 weeks; antigen or polymerase chain reaction tests should be negative when ganciclovir is stopped; reinstitute ganciclovir if subsequent weekly cytomegalovirus antigenemia screening tests become positive (BI)	
Preemptive treatment for cytomegalovirus seropositive autologous adult or adolescent HSCT recipients at <100 days after HSCT: Start ganciclovir when antigenemia is ≥5 cells/slide, but CD34+-selected patients should be treated at any level of antigenemia*	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7 days, followed by 5 mg/kg/day intravenously for 5 days/week for 2 weeks (BII)	
Preemptive treatment of allogeneic adult or adolescent HSCT recipients >100 days after HSCT: Start ganciclovir when a) antigenemia is ≥5 cells/slide or b) the patient has had ≥2 consecutively positive viremia or polymerase chain reaction tests (e.g., in a person receiving steroids for graft-versus-host disease or who received ganciclovir or foscarnet at <100 days after HSCT)	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7 days, followed by 5 mg/kg/day intravenously for 5 days/week for 2 weeks (BIII)	

* **Source**: Holmberg LA, Boeckh M, Hooper H, et al. Increased incidence of cytomegalovirus disease after autologous CD34-selected peripheral blood stem cell transplantation [Clinical observations, interventions, and therapeutic trials]. Blood 1999;94(12):4029–35.

Notes: Patients who do not tolerate standard doses of ganciclovir should be administered foscarnet. Ganciclovir and foscarnet doses should be modified for renal impairment. Prehydration is required for foscarnet administration.

Pathogen: Herpes simplex virus

Indication	First choice	Alternatives
Prevention of herpes simplex virus reactivation among seropositive adult or adolescent HSCT recipients: Start acyclovir at the beginning of conditioning therapy and continue until engraftment or until mucositis resolves (i.e., approximately 30 days after HSCT for allogeneic HSCT recipients)	Acyclovir, 200 mg by mouth 3 times/day or 250 mg/m^2/dose infused over 1 hour intravenously every 12 hours (BIII)	Valacyclovir, 500 mg by mouth daily (CIII)

Note: For patients requiring prophylaxis for cytomegalovirus and herpes simplex virus after engraftment, ganciclovir alone provides effective prophylaxis for both pathogens.

Pathogen: Varicella-zoster virus

Indication	First choice	Alternatives
Prevention of varicella-zoster virus disease after exposure among adult or adolescent HSCT recipients who are at <24 months after HSCT or who are at ≥24 months after HSCT and on immunosuppressive therapy or have chronic graft-versus-host disease: Ideally, administer prophylaxis within 96 hours (preferably, within 48 hours) after close contact with a person who has chickenpox or shingles	Varicella-zoster immunoglobulin, 5 vials (1.25 ml each or 625 units total) intramuscularly (AII)	None

Pathogen: Influenza

Indication	First choice	Alternatives
Prevention of influenza A or B among adult or adolescent HSCT recipients	Lifelong annual seasonal (i.e., October–May) influenza vaccination starting before HSCT and restarting 6 months after HSCT (BIII); whole- or split-virus influenza vaccine, 0.5 ml/dose intramuscularly	None
Prophylaxis and preemptive treatment among all HSCT recipients during community and nosocomial outbreaks of influenza A	Rimantadine, 100 mg by mouth 2 times/day (CIII)	Amantadine, 100 mg by mouth 2 times/day (CIII)

Notes: Rimantadine dose should be reduced for patients with impaired renal function or for severely impaired hepatic function. Amantadine dose should be reduced for renal impairment.

Pathogen: Bacterial infections, general prophylaxis

Indication	First choice	Alternatives
Prevention of bacterial infections among allogeneic adult or adolescent HSCT recipients with severe hypogammaglobulinemia (i.e., serum immunoglobulin G level < 400 mg/dl) at <100 days after HSCT	Intravenous immunoglobulin, 500 mg/kg/week (CIII)	None

Notes: Patients with immunoglobulin E anti-immunoglobulin A antibodies are at high risk for experiencing anaphylaxis from immunoglobulin administration (**Source**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4). Therefore, persons with immunoglobulin A deficiency should not receive standard immunoglobulin products (**Source**: Siberry GK, Iannone R, eds. Harriet Lane handbook: a manual for pediatric house officers. 15th ed.; St. Louis, MO: Mosby, Inc., 2000:339;739) (DIII). However, researchers have reported that use of immunoglobulin A-depleted immunoglobulin preparations can be used with caution among these persons (**Sources**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4; Stiehm ER. Human intravenous immunoglobulin in primary and secondary antibody deficiencies [Review]. Pediatr Infect Dis J 1997;16[7]:696–707; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:41–53). Researchers also propose checking serum immunoglobulin G levels every 2 weeks among patients receiving intravenous immunoglobulin replacement therapy.

Pathogen: *Streptococcus pneumoniae*

Indication	First choice	Alternatives
Prevention of pneumococcal disease among adult or adolescent HSCT recipients	23-valent pneumococcal polysaccharide vaccine at 12 and 24 months after HSCT (BIII)	None

Note: Penicillin-resistant *Streptococcus pneumoniae* is increasing in the United States.

Pathogen: *Haemophilus influenzae* type b

Indication	First choice	Alternatives
Prevention of invasive *Haemophilus influenzae* type b (Hib) disease among adult or adolescent HSCT recipients	Hib conjugate vaccine administered at 12, 14, and 24 months after HSCT (BII)	None
Generally, HSCT recipients who are household contacts of a person with Hib disease should be administered rifampin prophylaxis* (BIII); however, prophylaxis is not needed for adult or adolescent HSCT recipients who are household contacts of a person with Hib disease if all household contacts aged <4 years are fully vaccinated	Rifampin 600 mg by mouth daily for 4 days (BIII)	

* **Source**: American Academy of Pediatrics. *Haemophilus influenzae* infections. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:262–72.

Pathogen: Methicillin-resistant *Staphylococcus aureus*

Indication	First choice	Alternatives
Elimination of methicillin-resistant *Staphylococcus aureus* carrier state among adults or adolescents to prevent this disease among chronic carriers	Mupirocin calcium ointment 2%; use a cotton-tipped applicator or equivalent to apply to nares 2 times/day for 5 days or to wounds daily for 2 weeks	None

Pathogen: *Candida* species

Indication	First choice	Alternatives
Prophylaxis for disease from fluconazole-susceptible *Candida* species among a) allogeneic adult or adolescent HSCT recipients or b) autologous adult or adolescent HSCT recipients with lymphoma or leukemia and who have or will have prolonged neutropenia and mucosal damage from intense conditioning regimens or graft manipulation or who have recently received fludarabine or 2-chlorodeoxyadenosine: Administer prophylaxis from the day of transplantation (i.e., day 0) until engraftment (i.e., approximately 30 days after HSCT) or until 7 days after the absolute neutrophil count > 1,000 cells/mm³	Fluconazole, 400 mg by mouth or intravenously daily (AI)	None

Pathogen: *Pneumocystis carinii*

Indication	First choice	Alternatives
Prophylaxis for *Pneumocystis carinii* pneumonia among a) all allogeneic adult or adolescent HSCT recipients or b) autologous adult or adolescent HSCT recipients with underlying hematologic malignancies (e.g., lymphoma or leukemia) or for those receiving intense conditioning regimens or graft manipulation or for those who have recently received fludarabine or 2-chlorodeoxyadenosine:* Administer prophylaxis from time of engraftment for ≥6 months after HSCT; continue >6 months after HSCT for the duration of immunosuppression for all persons who a) are receiving immunosuppressive therapy (e.g., prednisone or cyclosporine) or who b) have chronic graft-versus-host disease	Trimethoprim-sulfamethoxazole, 1 double-strength tablet by mouth daily or 1 single-strength tablet by mouth daily or 1 double-strength tablet by mouth 3 times/week (AII); researchers also recommend administering prophylaxis for 1–2 weeks before HSCT (i.e., day –14 to –2) (CIII)	Dapsone, 50 mg by mouth 2 times/day or 100 mg by mouth daily (BIII) or pentamidine, 300 mg every 3–4 weeks by Respirgard II™ nebulizer (CIII)

* **Source**: Tuan IZ, Dennison D, Weisdorf DJ. *Pneumocystis carinii* pneumonitis after bone marrow transplantation. Bone Marrow Transplant 1992;10(3):267–72.

Note : Patients who are receiving sulfadiazine-pyrimethamine for toxoplasmosis therapy are protected against *Pneumocystis carinii* and do not need additional prophylaxis.

Pathogen: *Toxoplasma gondii*

Indication	First choice	Alternatives
Prophylaxis of *Toxoplasma gondii* disease among seropositive allogeneic adult or adolescent HSCT recipients: Start after engraftment and administer as long as patients remain on immunosuppressive therapy (i.e., generally, until 6 months after HSCT)	Trimethoprim-sulfamethoxazole, 1 double-strength tablet by mouth daily or 1 single-strength tablet by mouth daily or 1 double-strength table by mouth 3 times/week (AII)	For those persons who are intolerant of trimethoprim-sulfamethoxazole, the following drugs can be substituted: Clindamycin, 300–450 mg by mouth every 6–8 hours; plus pyrimethamine, 25–75 mg by mouth daily; plus leucovorin, 10–25 mg by mouth 4 times/day (CIII)

Note: Among allogeneic HSCT recipients, clinical toxoplasmosis has occurred despite the use of trimethoprim-sulfamethoxazole for *Pneumocystis carinii* prophylaxis (**Source**: Slavin MA, Meyers JD, Remington JS, Hackman RC. *Toxoplasma gondii* infection in marrow transplant recipients: a 20 year experience. Bone Marrow Transplant 1994;13[5]:549–57).

Pathogen: *Strongyloides* species

Indication	First choice	Alternatives
Prevention of strongyloidiasis hyperinfection among adult or adolescent HSCT candidates whose HSCT screening tests are positive for *Strongyloides* species or who have an unexplained eosinophilia and a travel or residence history suggestive of exposure to *Strongyloides stercoralis*: Administer prophylaxis before HSCT	Ivermectin, 200 µg/kg by mouth daily for 2 consecutive days* (BIII); 1 tablet = 6 mg; doses administered as follows: Body weight (kg) — Oral dose <15 — Not recommended ≥15–24 — ½ tablet 25–35 — 1 tablet 36–50 — 1½ tablets 51–65 — 2 tablets 66–79 — 2½ tablets ≥80 — 200 µg/kg	Albendazole, 400 mg by mouth daily for 3 days or thiabendazole, 25 mg/kg by mouth 2 times/day for 2 days (BIII); maximum dose, 3 g/24 hours

***Sources**: Liu LX, Weller PF. Strongyloidiasis and other intestinal nematode infections [Review]. Infect Dis Clin North Am 1993;7(3):655–82; and Naquira C, Jimenez G, Guerra JG, et al. Ivermectin for human strongyloidiasis and other intestinal helminths. Am J Trop Med Hyg 1989;40:304–9.

Notes: Among immunocompromised patients, multiple courses at 2-week intervals might be required; however, cure might not be achievable. Safety and efficacy of ivermectin has not been established during pregnancy. Albendazole and thiabendazole are contraindicated during pregnancy.

Pathogen: Traveler's diarrhea

Indication	First choice	Alternatives
Prophylaxis among adult or adolescent HSCT recipients who are immunocompromised and who plan to travel in developing countries	Ciprofloxacin, 500 mg by mouth daily for the duration of stay in developing countries (BIII) or bismuth subsalicylate, 2 oz by mouth 4 times/day or 2 tablets by mouth 4 times/day; can be administered for ≤3 weeks to prevent travelers' diarrhea in adults aged >18 years only	Trimethoprim-sulfamethoxazole, 1 double-strength tablet by mouth daily for the duration of stay in developing country (CIII)

Notes: Use of aspirin-containing products including bismuth subsalicylate is contraindicated in persons aged <18 years unless prescribed by a physician because these products have been associated with Reye's syndrome (**Source**: Belay E, Bresee JS, Holman RC, Khan AS, Shahriari A, Schonberger LB. Reye's syndrome in the United States from 1981 through 1997. New Engl J Med 1999;340[18]:1377–82). Ciprofloxacin, norfloxacin, and ofloxacin are not approved for use among children aged <18 years.

Pathogen: *Mycobacteria tuberculosis*

Indication	First choice	Alternatives
Prevention of *Mycobacteria tuberculosis* among a) highly immunocompromised adult or adolescent HSCT recipients or candidates who have been substantially exposed to someone with active, infectious (e.g., sputum smear positive) pulmonary or laryngeal tuberculosis, regardless of the HSCT recipient's or candidate's tuberculin skin test status, or b) adult or adolescent HSCT recipients or candidates with a positive tuberculin skin test and who were not previously treated and have no evidence of active tuberculosis disease	Isoniazid, 5 mg/kg/day by mouth or intramuscularly for 9 months (i.e., for ≥270 doses);* maximum dose, 300 mg/day, and pyridoxine (vitamin B_6), 25–50 mg by mouth daily for 9 months; administer to nutritionally deficient HSCT recipients and candidates while on isoniazid preventive therapy to reduce the occurrence of isoniazid-induced neuropathy* (BIII)	None

***Source**: 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):1–58.

Notes: A twice-weekly schedule of isoniazid and pyridoxine can be administered (CIII). The twice-weekly isoniazid dose is 15 mg/kg by mouth or intramuscularly (maximum dose, 900 mg). The twice-weekly pyridoxine dose is 50–100 mg by mouth. A 2-month pyrazinamide/rifampin preventive therapy regimen can be used for HSCT candidates who are not at risk for serious rifampin drug interactions and whose HSCT is not scheduled until ≥2 weeks after the 2-month course is completed (**Sources**: CDC. Notice to readers: use of short-course tuberculosis preventive therapy regimens in HIV-seronegative persons. MMWR 1998;47[42]:911–2; and 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]:1–58) (CIII). The usual pyrazinamide dose is 15–30 mg/kg/day by mouth or 50–70 mg/kg/dose by mouth 2 times/week (maximum daily pyrazinamide dose, 2.0 gm; maximum twice-weekly dose, 3.5 gm). Rifampin dose is 10 mg/kg/day by mouth or intravenously or 10 mg/kg/dose administered 2 times/week by mouth or intravenously (maximum rifampin dose, 600 mg). Routine use of a 2-month pyrazinamide/rifampin preventive therapy regimen is not recommended after HSCT because of the risk for serious rifampin drug interactions (DIII). Persons who have been exposed to rifampin- and isoniazid-resistant tuberculosis should be placed on preventive therapy regimens that involve ≥2 antituberculosis drugs to which the infecting strain is susceptible, and a tuberculosis specialist should be consulted (**Source**: 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]:1–58) (BIII). A tuberculosis specialist should also be consulted for patients who are intolerant to isoniazid (AIII). All intermittent dosing strategies should be administered as directly observed therapy (AIII).

II. Preventive regimens for pediatric hematopoietic stem cell transplant (HSCT) recipients

Pathogen: Cytomegalovirus

Indication	First choice	Alternatives
Universal prophylaxis for cytomegalovirus disease among all allogeneic pediatric HSCT recipients at risk throughout phase II (i.e., from engraftment to day 100 after HSCT)	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 5–7 days, followed by 5 mg/kg/dose intravenously daily for 5 days/week from engraftment until day 100 after HSCT (AI)	Foscarnet, 60 mg/kg intravenously every 12 hours for 14 days, followed by 90–120 mg/kg/day until day 100 after HSCT (CIII)
Or preemptive cytomegalovirus treatment administered <100 days after HSCT to all allogeneic pediatric HSCT recipients at risk: Start ganciclovir when the patient experiences any level of cytomegalovirus antigenemia or viremia or has ≥2 consecutively positive cytomegalovirus-DNA polymerase chain reaction tests	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7–14 days, followed by 5 mg/kg/day for 5 days/week until day 100 after HSCT or for a minimum of 3 weeks, whichever is longer (AI); or administer ganciclovir for a total of 3–6 weeks; antigen or polymerase chain reaction tests should be negative when ganciclovir is stopped; reinstitute ganciclovir if subsequent weekly cytomegalovirus antigenemia screening tests become positive (BI)	
Preemptive treatment for cytomegalovirus seropositive autologous pediatric HSCT recipients at <100 days after HSCT: Start ganciclovir when antigenemia is ≥5 cells/slide, but CD34+-selected patients should be treated at any level of antigenemia*	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7 days, followed by 5 mg/kg/day intravenously for 5 days/week for 2 weeks (BII)	
Preemptive treatment of allogeneic pediatric HSCT recipients >100 days after HSCT: Start ganciclovir when a) antigenemia is ≥5 cells/slide or b) the patient has had ≥2 consecutively positive viremia or polymerase chain reaction tests (e.g., in a person receiving steroids for graft-versus-host disease or who received ganciclovir or foscarnet at <100 days after HSCT)	Ganciclovir, 5 mg/kg/dose intravenously every 12 hours for 7 days, followed by 5 mg/kg/day intravenously for 5 days/week for 2 weeks (BIII)	

* **Source**: Holmberg LA, Boeckh M, Hooper H, et al. Increased incidence of cytomegalovirus disease after autologous CD34-selected peripheral blood stem cell transplantation [Clinical observations, interventions, and therapeutic trials]. Blood 1999;94(12):4029–35.

Notes: Patients who do not tolerate standard doses of ganciclovir should be administered foscarnet. Ganciclovir and foscarnet doses should be modified for renal impairment. Prehydration is required for foscarnet administration.

Pathogen: Herpes simplex virus

Indication	First choice	Alternatives
Prevention of herpes simplex virus reactivation among seropositive pediatric HSCT recipients: Start acyclovir at the beginning of conditioning therapy and continue until engraftment or until mucositis resolves (i.e., approximately 30 days after HSCT for allogeneic HSCT recipients)	Acyclovir, 250 mg/m²/dose intravenously every 8 hours (BIII) or 125 mg/m²/dose intravenously every 6 hours (CIII)	Acyclovir 600–1,000 mg/24 hours by mouth, divided in 3–5 doses/day

Note: For patients requiring prophylaxis for cytomegalovirus and herpes simplex virus after engraftment, ganciclovir alone provides effective prophylaxis for both pathogens. Valacyclovir is not approved for use among children.

Pathogen: Varicella-zoster virus

Indication	First choice	Alternatives
Prevention of varicella-zoster virus disease after exposure among pediatric HSCT recipients who are at <24 months after HSCT or who are at ≥24 months after HSCT and on immunosuppressive therapy or have chronic graft-versus-host disease: Ideally, administer prophylaxis within 96 hours (preferably, within 48 hours) after close contact with a person who has chickenpox or shingles	Varicella-zoster immunoglobulin, 125 units (1.25 ml)/10 kg (22 lbs) of body weight administered intramuscularly; maximum dose, 625 units or 5 vials (AII); doses administered as follows:	Limited data demonstrate that a 1-week course of high-dose acyclovir might prevent varicella

Body weight (kg)	Dose	Number of vials
0–10	125 units	1
10.1–20	250 units	2
20.1–30	375 units	3
30.1–40	500 units	4
>40 kg	625 units	5

Pathogen: Influenza

Indication	First choice	Alternatives
Prevention of influenza A and B among pediatric HSCT recipients	Lifelong annual seasonal (i.e., October–May) influenza vaccination before HSCT and resuming 6 months after HSCT (BIII); doses administered as follows: Age / Number of doses / Type of influenza vaccine 6–35 mo / 0.25 ml / Split-virus* 3–8 years / 0.5 ml / Split-virus* 9–12 years / 0.5 ml / Split-virus >12 years / 0.5 ml / Whole- or split-virus	None
Prophylaxis and preemptive treatment of influenza A among pediatric HSCT recipients during nosocomial or community influenza A outbreaks	Rimantadine, for children aged 1–9 years, 5 mg/kg/day once daily or divided in 2 doses (CIII); maximum daily dose, 150 mg; for children aged ≥10 years (weight, <40 kg), 5 mg/kg/day by mouth, divided in 2 doses; for children aged ≥10 years (weight, ≥40kg), 100 mg by mouth 2 times/day	Amantadine, for children aged 1–9 years, 5 mg/kg/day; maximum daily dose, 150 mg; for children aged ≥10 years (weight, <40 kg), 5 mg/kg/day by mouth, divided in 2 doses; for children aged ≥10 years (weight, ≥40kg), 100 mg by mouth 2 times/day; maximum daily dose, 200 mg

* Children aged <9 years receiving influenza vaccination for the first time require 2 doses of vaccine spaced ≥1 months apart.

Notes: Neither rimantadine nor amantadine are Federal Drug Administration-approved for children aged <1 year. Rimantadine and amantadine doses should be reduced for patients with impaired renal function.

Pathogen: Respiratory syncytial virus

Indication	First choice	Alternatives
Prophylaxis for respiratory syncytial virus (RSV) lower respiratory infection among hypogammaglobulinemic pediatric HSCT recipients	RSV intravenous immunoglobulin can be administered in place of intravenous immunoglobulin during RSV season (i.e., November–April in the United States) for pediatric HSCT recipients who are on routine intravenous immunoglobulin therapy* (e.g., those with hypogammaglobulinemia) (CIII); usual RSV intravenous immunoglobulin dose is 750 mg/kg/month or a 1-mg/1-mg dosing substitution of RSV intravenous immunoglobulin for intravenous immunoglobulin can be used for patients who normally require high intravenous immunoglobulin doses to maintain serum immunoglobulin G >400 mg/dl; can administer more frequently than monthly as needed to keep serum immunoglobulin G >400 mg/dl	None
Preemptive treatment of RSV upper respiratory infection or early lower respiratory infection among pediatric HSCT recipients	Aerosolized ribavirin,* 6 g/300 ml sterile water to make a concentration of 20 mg/ml; administer 18 hours/day for 10 days in a tent (CIII); for HSCT recipients with lower respiratory infections who cannot tolerate a tent or who have RSV upper respiratory infection, administer ribavirin as 2 g for 2 hours every 8 hours by face mask for 10 days; use small particle aerosol generator model SPAG-2	

***Source**: American Academy of Pediatrics. Respiratory syncytial virus. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Disease. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000: 483–7.

Notes: RSV intravenous immunoglobulin is contraindicated among patients with immunoglobulin A deficiency or who might have allergic reactions or anaphylaxis when receiving blood products containing immunoglobulin A (DIII) RSV monoclonal antibody is under investigational use among HSCT recipients for treatment with ribavirin but not for prophylaxis.

Pathogen: Bacterial infections, general prophylaxis

Indication	First choice	Alternatives
Prevention of bacterial infections among allogeneic pediatric HSCT recipients with severe hypogammaglobulinemia (i.e., serum immunoglobulin G level < 400 mg/dl) at <100 days after HSCT	Intravenous immunoglobulin 400 mg/kg/month; increase dose or frequency as needed to keep serum immunoglobulin G levels > 400 mg/dl (CIII)	None

Notes: Patients with immunoglobulin E anti-immunoglobulin A antibodies are at high risk for experiencing anaphylaxis from immunoglobulin administration (**Source**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4). Therefore, persons with immunoglobulin A deficiency should not receive standard immunoglobulin products (**Source**: Siberry GK, Iannone R, eds. Harriet Lane handbook: a manual for pediatric house officers. 15th ed.; St. Louis, MO: Mosby, Inc., 2000:339;739) (DIII). However, researchers report that use of immunoglobulin A-depleted immunoglobulin preparations can be used with caution in these persons (**Sources**: Burks AW, Sampson HA, Buckley RH. Anaphylactic reactions after gamma globulin administration in patients with hypogammaglobulinemia. New Engl J Med 1986;314[9]:560–4; Siberry GK, Iannone R, eds. Harriet Lane handbook: a manual for pediatric house officers. 15th ed.; St. Louis, MO: Mosby, Inc., 2000:339;739; Stiehm ER. Human intravenous immunoglobulin in primary and secondary antibody deficiencies [Review]. Pediatr Infect Dis J 1997;16[7]:696–707; American Academy of Pediatrics. Passive immunization. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:41–53). Researchers also propose checking serum immunoglobulin G levels every 2 weeks for patients receiving intravenous immunoglobulin replacement therapy.

Pathogen: *Streptococcus pneumoniae*

Indication	First choice	Alternatives
Prevention of pneumococcal disease among pediatric HSCT recipients	23-valent pneumococcal polysaccharide vaccine at 12 and 24 months after HSCT (BIII)	None

Notes : The 23-valent pneumococcal polysaccharide vaccine should not be administered to children aged <2 years because of lack of efficacy (DI). Penicillin-resistant *Streptococcus pneumoniae* is increasing in the United States.

Pathogen: *Haemophilus influenzae* type b

Indication	First choice	Alternatives
Prevention of invasive *Haemophilus influenzae* type b (Hib) disease among pediatric HSCT recipients	Hib conjugate vaccine administered at 12, 14, and 24 months after HSCT (BII)	None
Generally, pediatric HSCT recipients who are household contacts of a person with Hib disease should be administered rifampin prophylaxis* (BIII); however, prophylaxis is not needed for pediatric HSCT recipients who are household contacts of a person with Hib disease if all household contacts aged <4 years are fully vaccinated	Rifampin, administered as follows: Age — Dose 0–1 mo — 10 mg/kg by mouth daily for 4 days >1 mo — 20 mg/kg by mouth daily for 4 days Maximum dose, 600 mg/day (BIII)	None

* **Source**: American Academy of Pediatrics. *Haemophilus influenzae* infections. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:262–72.

Pathogen: Methicillin-resistant *Staphylococcus aureus*

Indication	First choice	Alternatives
Elimination of methicillin-resistant *Staphylococcus aureus* carrier state among pediatric patients to prevent this disease among chronic carriers	Mupirocin calcium ointment 2%; use a cotton-tipped applicator or equivalent to apply to nares 2 times/day for 5 days or to wounds daily for 2 weeks*	Bacitracin is regarded safe for use among children, and the dose is the same as for mupirocin; however, no standardized protocol has been evaluated

* Safety of mupirocin calcium ointment 2% use among children aged <12 years has not be established.

Pathogen: *Candida* species

Indication	First choice	Alternatives
Prophylaxis for disease from fluconazole-susceptible *Candida* species among a) allogeneic pediatric HSCT recipients or b) autologous pediatric HSCT recipients with lymphoma or leukemia and who have or will have prolonged neutropenia and mucosal damage from intense conditioning regimens or graft manipulation or who have recently received fludarabine or 2-chlorodeoxyadenosine: Administer prophylaxis from the day of transplantation (i.e., day 0) until engraftment (i.e., approximately 30 days after HSCT) or until 7 days after the absolute neutrophil count > 1,000 cells/mm^3	Fluconazole, for children aged 6 months–13 years, administer 3–6 mg/kg/day by mouth or intravenously (AI); maximum dose, 600 mg/day; for children aged >13 years, administer 400 mg by mouth or intravenously daily (AI)	None

Pathogen: *Pneumocystis carinii*

Indication	First choice	Alternatives
Prophylaxis for *Pneumocystis carinii* pneumonia among a) all allogeneic pediatric HSCT recipients or b) autologous pediatric HSCT recipients with underlying hematologic malignancies (e.g., lymphoma or leukemia) or for those receiving intense conditioning regimens or graft manipulation or for those who have recently received fludarabine or 2-chlorodeoxyadenosine:* Administer prophylaxis from time of engraftment for ≥6 months after HSCT; continue >6 months after HSCT for the duration of immunosuppression for all persons who a) are receiving immunosuppressive therapy (e.g., prednisone or cyclosporine) or who b) have chronic graft-versus-host disease	Trimethoprim-sulfamethoxazole, 150 mg trimethoprim/750 mg sulfamethoxazole/m²/day by mouth in 2 divided doses 3 times/week on consecutive days (AII); or a single dose by mouth 3 times/week on consecutive days; or by mouth in 2 divided doses daily for 7 days; or by mouth in 2 divided doses 3 times/week on alternate days; researchers also report administering prophylaxis for 1–2 weeks before HSCT (i.e., day –14 to –2) (CIII)	Dapsone, for HSCT recipients aged ≥1 months, 2 mg/kg (maximum dose, 100 mg) by mouth daily (BIII); or intravenous pentamidine, 4 mg/kg every 2–4 weeks; or aerosolized pentamidine, for HSCT recipients aged ≤5 years, 9 mg/kg/dose; or for HSCT recipients aged >5 years, 300 mg; should be administered every month by Respirgard II™ nebulizer (CIII)

* **Source**: Tuan IZ, Dennison D, Weisdorf DJ. *Pneumocystis carinii* pneumonitis after bone marrow transplantation. Bone Marrow Transplant 1992;10(3):267–72.

Notes: Trimethoprim-sulfamethoxazole is not recommended for patients aged <2 months because of risk for kernicterus. Patients who are receiving sulfadiazine-pyrimethamine for toxoplasmosis therapy are protected against *Pneumocystis carinii* and do not need additional prophylaxis.

Pathogen: *Toxoplasma gondii*

Indication	First choice	Alternatives
Prophylaxis of *Toxoplasma gondii* disease among seropositive allogeneic pediatric HSCT recipients: Start after engraftment and administer as long as patients remain on immunosuppressive therapy (i.e., generally, until 6 months after HSCT)	Trimethoprim-sulfamethoxazole, 150 mg trimethoprim/750 mg sulfamethoxazole/m²/day by mouth in 2 divided doses 3 times/week on consecutive days (AII); or a single dose by mouth 3 times/week on consecutive days; or by mouth in 2 divided doses daily for 7 days; or by mouth in 2 divided doses 3 times/weekly on alternate days	For those persons who are intolerant of trimethoprim-sulfamethoxazole, the following drugs can be substituted: Clindamycin, 20–30 mg/kg/day by mouth, divided in 4 divided doses daily; plus pyrimethamine, 1 mg/kg by mouth daily; plus leucovorin, 5 mg by mouth every 3 days (CIII)

Note: Trimethoprim-sulfamethoxazole is not recommended for patients aged <2 months because of risk for kernicterus. Among allogeneic HSCT recipients, clinical toxoplasmosis has occurred despite the use of trimethoprim-sulfamethoxazole for *Pneumocystis carinii* prophylaxis (**Source**: Slavin MA, Meyers JD, Remington JS, Hackman RC. *Toxoplasma gondii* infection in marrow transplant recipients: a 20 year experience. Bone Marrow Transplant 1994;13[5]:549–57).

Pathogen: *Strongyloides* species

Indication	First choice	Alternatives
Prevention of strongyloidiasis hyperinfection among pediatric HSCT candidates whose HSCT screening tests are positive for *Strongyloides* species or who have an unexplained eosinophilia and a travel or residence history suggestive of exposure to *Strongyloides stercoralis*: Administer prophylaxis before HSCT	Ivermectin, 200 µg/kg by mouth daily for 2 consecutive days* (BIII); 1 tablet = 6 mg; doses administered as follows: Body weight (kg) — Oral dose <15 — Not recommended ≥15–24 — ½ tablet 25–35 — 1 tablet 36–50 — 1½ tablets 51–65 — 2 tablets 66–79 — 2½ tablets ≥80 — 200 µg/kg	Thiabendazole, 25 mg/kg 2 times daily for 2 days; maximum dose, 3 g/24 hours

* **Sources**: Liu LX, Weller PF. Strongyloidiasis and other intestinal nematode infections [Review]. Infect Dis Clin North Am 1993;7(3):655–82; and Naquira C, Jimenez G, Guerra JG, et al. Ivermectin for human strongyloidiasis and other intestinal helminths. Am J Trop Med Hyg 1989;40:304–9.

Notes: Ivermectin safety among children weighing <15 kg has not been established. Among immunocompromised patients, multiple courses of ivermectin at 2-week intervals might be required; however, cure might not be achievable. Safety and efficacy of ivermectin has not been established during pregnancy. Thiabendazole is contraindicated during pregnancy.

Pathogen: Traveler's diarrhea

Indication	First choice	Alternatives
Prophylaxis among pediatric HSCT recipients who are immunocompromised and who plan to travel in developing countries	Trimethoprim-sulfamethoxazole, 150 mg trimethoprim/750 mg sulfamethoxazole/m²/day by mouth, divided in 2 doses 3 times/week on consecutive days (CIII); can be administered for duration of stay in developing country	Trimethoprim-sulfamethoxazole, single dose by mouth 3 times/week on consecutive days

Notes: Use of aspirin-containing products including bismuth subsalicylate is contraindicated in persons aged <18 years unless prescribed by a physician because these products have been associated with Reye's syndrome (**Source**: Belay E, Bresee JS, Holman RC, Khan AS, Shahriari A, Schonberger LB. Reye's syndrome in the United States from 1981 through 1997. New Engl J Med 1999;340[18]:1377–82). Trimethoprim-sulfamethoxazole is not recommended for patients aged <2 months because of risk for kernicterus. Resistance to trimethoprim-sulfamethoxazole is common in tropical areas. Usual doses of trimethoprim-sulfamethoxazole for *Pneumocystis carinii* pneumonia prophylaxis should provide limited protection against traveler's diarrhea.

Pathogen: *Mycobacteriatuberculosis*

Indication	First choice	Alternatives
Prevention of *Mycobacteria tuberculosis* among a) highly immunocompromised pediatric HSCT recipients or candidates who have been exposed to someone with active, infectious (e.g., sputum smear positive) pulmonary or laryngeal tuberculosis, regardless of the HSCT recipient's or candidate's tuberculin skin test status, or b) pediatric HSCT recipients or candidates with a positive tuberculin skin test and who were not previously treated and have no evidence of active tuberculosis disease	Isoniazid, 10–20 mg/kg/day by mouth or intramuscularly for 9 months (i.e., for ≥270 doses);* maximum dose, 300 mg/day, and pyridoxine (vitamin B_6), 1–2 mg/kg/day by mouth daily for 9 months; dose required might vary by age and condition;† administer to nutritionally deficient HSCT recipients and candidates while on isoniazid preventive therapy to reduce the occurrence of isoniazid-induced neuropathy* (BIII)	None

* **Sources**: American Academy of Pediatrics. Tuberculosis. In: Pickering LK, ed. 2000 red book: report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics;2000:593–613; 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):1–58; and CDC. Notice to readers: use of short-course tuberculosis preventive therapy regimens in HIV-seronegative persons. MMWR 1998;47(42):911–2.

† **Source**: Siberry GK, Iannone R, eds. Harriet Lane handbook: a manual for pediatric house officers. 15th ed.; St. Louis, MO: Mosby, Inc., 2000:834–5.

Notes: A twice-weekly schedule of isoniazid and pyridoxine can be administered (CIII). The twice-weekly isoniazid dose is 20–40 mg/kg by mouth or intramuscularly (maximum dose, 900 mg). A 2-month pyrazinamide/rifampin preventive therapy regimen can be used for HSCT candidates who are not at risk for serious rifampin drug interactions and whose HSCT is not scheduled until ≥2 weeks after the 2-month course is completed. Rifampin dose is 10–20 mg/kg/day by mouth or intravenously or 10–20 mk/kg/dose by mouth or intravenously, administered 2 times/week (maximum pyrazinamide dose, 3.5 g; maximum rifampin dose, 600 mg) (**Sources**: CDC. Notice to readers: use of short-course tuberculosis preventive therapy regimens in HIV-seronegative persons. MMWR 1998;47[42]:911–2; and 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]:1–58.) (CIII). The usual pyrazinamide dose is 15–30 mg/kg/day by mouth or 50–70 mg/kg/dose by mouth 2 times/week (maximum) (maximum daily pyrazinamide dose, 2 g). Routine use of a 2-month pyrazinamide/rifampin preventive therapy regimen is not recommended after HSCT because of the risk for serious rifampin drug interactions (DIII). Persons who have been exposed to rifampin- and isoniazid-resistant tuberculosis should be placed on preventive therapy regimens that involve ≥2 antituberculosis drugs to which the infecting strain is susceptible (**Source**: 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]:1–58), and a tuberculosis specialist should be consulted (BIII). A tuberculosis specialist should also be consulted for patients who are intolerant to isoniazid (AIII). All intermittent dosing strategies should be administered as directly observed therapy (AIII).

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This page last reviewed 5/2/01

From: Hull, Ashley
Sent: 06 October 2017 13:41
To: Richards, Janette
Subject: RE: Urgent--advice required

Thanks

Ashley Hull
Commissioning Manager
RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Richards, Janette
Sent: 05 October 2017 16:10
To: Hull, Ashley; Guthrie, Lindsay; Inverarity, Donald
Cc: Cameron, Fiona; Calder, Carol A
Subject: RE: Urgent--advice required

Dear Ashley
The parents of children will continue to attend their children to the neuro Operating Thr and leave from the anaesthetic room. The whole of the theatre area is a clean area and that is why the Thr staff can return to the area in the scrubs and clogs they left the area in as long as they adhere to the dress and uniform policy
Regards
Janette

From: Hull, Ashley
Sent: 05 October 2017 15:49
To: Richards, Janette; Guthrie, Lindsay; Inverarity, Donald
Cc: Cameron, Fiona; Calder, Carol A
Subject: RE: Urgent--advice required

Good Afternoon Janette

Please could you update our position on the door between MRI and theatres is DCN theatres clean area.

Hope this makes sense.

KR
Ashley

Ashley Hull
Commissioning Manager

RHSC /DCN Site Office
Little France Crescent
Edinburgh
EH16 4JT
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Richards, Janette
Sent: 05 October 2017 13:44
To: Richards, Janette; Guthrie, Lindsay; Inverarity, Donald
Cc: Cameron, Fiona; Calder, Carol A; Hull, Ashley
Subject: RE: Urgent--advice required

Dear All,

I have spoken with Lindsay Guthrie the Lead IPCN for NHS Lothian. I have explained to her the route of travel for paediatric in patients to Thr and to the Neuro Thr on a Wednesday, and she agrees that the procedures currently in place at RHSC with parents coming into the anaesthetic room or recovery room in their own clothing and shoes can continue. However if they are going into or go into The operating Thr they must change into Thr attire including clogs/Thr foot wear.

For ward staff escorting patients, who need that extra nursing support, to the inter-operative MRI room until they are in the MRI room there is no need for ward staff to change into SCRUBS and Thr attire. If the Ward staff go into the Operating Thr they must change into Thr attire .

For Out Patients who come to the area for MRI scan the plan to have these people change into gowns etc at the changing room near reception is the acceptable procedure. If the person walks to the area in their shoes the Radiology staff will address this with regards to being MRI compliant. The frequency of cleaning in that area will address any issues on the floor.

As the radiology staff wear scrubs in the Operative MRI and Thr area they are to comply with the Uniform/dress code attached.

Regards
Janette

From: Richards, Janette
Sent: 04 October 2017 13:18
To: Guthrie, Lindsay; Inverarity, Donald
Cc: Cameron, Fiona; Calder, Carol A; Hull, Ashley
Subject: Urgent--advice required

Dear All,
I need to meet and discuss issues that have cropped up with regards to accessing the inter operative MRI Scanner at the new RHSC/DCN in the Thr areas.

I have the afternoon of Fri this week available and would like to discuss with you the flow of Out patients walking through the Thr corridors and parents accessing the Neuro Thr area from RHSC

I also attach the most recent Uniform Policy and ask if there are any infection control concerns re Thr attire.

Regards
Janette

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Inverarity, Donald

From: Rae, Janette
Sent: 19 March 2018 10:23
To: Rae, Janette
Subject: FW: Other matter

Importance: High

From: Henderson, Ronnie
Sent: 20 January 2017 12:53
To: Richards, Janette
Subject: RE: Other matter
Importance: High

Hi Janette,

That's just it, it doesn't. There is some dubiety over a couple of things:

1. Can a 4 bed bay be described as a general ward.
2. If so what is the pressure relationship to the corridor as there is just a dash in the box in the table you attach.

I am looking for infection controls' take on a scenario such as if 4 patients with infection status unknown are in the room what way do you want the air to go – To the room from the corridor or to the corridor from the room?

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Richards, Janette
Sent: 20 January 2017 12:27
To: Henderson, Ronnie
Subject: Other matter

Dear Ronnie
Please see other email re macerator over flow. This is in the response to ventilation question

Appendix 2 – Recommended air-change rates

Application	Ventilation	AC/hr	Pressure (Pascals)	Supply filter	Noise (NR)	Temp (°C)	Comments (for further information see Chapter 4)
General ward	S/N	6	–	G4	30	**18–28**	
Communal ward toilet	E	6	–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 Health Building Note 04-01 (Supplement 1)
Infectious diseases isolation room	E	10	–5	G4	30	**18–28**	Extract filtration may be required
Neutropeanic patient ward	S	10	+10	H12	30	**18–28**	
Critical care areas	S	10	+10	F7	30	*18–25*	Isolation room may be –ve pressure
Birthing room	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 pressure
Preparation room (lay-up)	S	>25	35	F7	40	*18–25*	
Preparation room/bay (sterile pack store)	S	10	25	F7	40*	*18–25*	*50 NR if a bay in a UCV theatre
Operating theatre	S	25	25	F7	40	*18–25*	
UCV operating theatre	S	25*	25	H10 or greater	50	*18–25*	*Fresh-air rate; excludes recirculation
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
Catheterisation room	S	15	+ve	F7	40	*18–22*	
Endoscopy room	S	15	+ve	F7	40	*18–25*	
Endoscopy cleaning	E	>10	–ve	–	40	–	
Day-case theatre	S	15	+ve	F7	40	*18–25*	
Treatment room	S	10	+ve	F7	35	*18–25*	
Pharmacy aseptic suite	S	20	#	H14	–	*18–22*	# See EGGMP (Orange guide) [a]
Category 3 or 4 containment room	#	>20	#	H14*	–	*18–22*	# See ACDP guide; *Filter in extract
Post-mortem room	S & E	S – 10 E – 12	–ve	G4	35	**18–22**	Provide clean air-flow path
Specimen store	E	–	–ve	–	–	–	Fan accessible from outside of store

Notes: **18–22**°C indicates the range over which the temperature may float.
18–22°C indicates the range over which the temperature should be capable of being controlled.
S = suppy
E = extract
N = natural ventilation
a – European guidelines on good manufacturing practice published by the Medicines and Healthcare products Regulatory Agency (MHRA)

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Appendix 2 in HTM 03-01 shows what the requirement is re general ward area re pressure and air changes
Regards
Janette

From: Henderson, Ronnie
Sent: 20 January 2017 09:16

To: Richards, Janette
Subject: RE: Macerator overflow

Hi Janette,

Thanks for that, I'll await your update and let Colin Grindlay know after..

On another matter, ventilation pressure regime to 4 bed bays – in your opinion should it be same as single bedrooms i.e. balanced or slightly negative to corridor (keeps any infection in the room) or is it presumed that patients in multi bed bays are not infected and pressure regime does not matter?

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Richards, Janette
Sent: 20 January 2017 08:59
To: Henderson, Ronnie
Subject: Macerator overflow
Importance: High

Dear Ronnie,

I am looking into the question you asked with regards to over flow outlet and allowing the over flow to drain to the floor.
As yet I have not found information to support this and I have spoken to tech people at Haig who would not do that either. I have a couple of more enquiries to make this morning but will have an answer for you by 2pm,
Regards
Janette

Janette Richards
Lead HAISCRIBE Infection Prevention and Control Nurse
NHS Lothian
14 Rillbank Terrace
Edinburgh
EH9 1LL
[redacted]

[redacted]

Link to Infection Control Manual

http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/A-Z/InfectionControl/Pages/default.aspx

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SBAR- Draft Risk Assessment regarding Impact of Design Ventilation on managing HAI risk in RHCYP clinical areas (not including Critical Care)

1. Situation:

NHS Lothian are required by the National Oversight Group "*to consider its clinical service model in light of the ventilation arrangements in place for general wards and other non critical areas (incorporating literature review and design information not yet available)*".

This relates to the project design provided which aims to deliver the 6 air changes required by SHTM 03-01 Part A to shared bed spaces and single room accommodation through mechanical supply for 4 air changes and 2 air changes through natural ventilation (although investigation is underway to establish if this is deliverable through window opening as had been designed).

Independent verification (by IOM) of the ventilation system has highlighted some areas where the ventilation performance requires further review and adjustment to ensure this performs in line with the design specification outlined above. This includes shared bed spaces and single room accommodation. NHS Lothian have been asked to demonstrate through risk assessment, that the Board is assured that the provision of 4 air changes per hour on mechanical supply, rather than 6 air changes per hour on mechanical supply does not compromise patient safety by introducing either an increased risk of transmission of infection or acquisition of healthcare associated infection.

2. Background:

SHTM 03-01 part A (appendix 1) and SHPN 04 Supplement 1: Isolation facilities in acute settings define the air change rates, filter requirements, mode of delivery and pressure differentials required for hospital ventilation systems. The ventilation system at RHCYP DCN was designed to deliver the following ventilation

	SHTM 03-01 requirement	Design specification	Current performance	
General ward (shared bed spaces)	6 air changes per hour (Ach/hr) – mix of supply and natural	4 air changes per hour supply	Awaiting clarification from IOM	
Single en-suite rooms	6 air changes per hour - mix of supply, extract and natural ventilation Balanced or negative pressure	4 air changes per hour supply Balanced or negative pressure	Awaiting clarification from IOM	
Isolation rooms (Positive pressure ventilated lobby-PPVL)	10 air changes per hour Lobby at 10 Pascals positive pressure	10 air changes per hour Lobby at 10 Pascals positive pressure	Awaiting clarification from IOM	
Treatment Room	10 air changes per hour		Awaiting clarification from	

	Positive pressure		IOM	

The ventilation design and performance for some shared bed spaces and single rooms does not conform to SHTM 03-01 part A, in terms of supply ventilation[Independent verification (by IOM) of the ventilation system has highlighted some areas where the ventilation performance requires further review and adjustment to ensure this performs in line with the design specification .

Lochranza ward (Haematology Oncology) does not have HEPA filters in the air supply ventilation to the single rooms which is indicated for rooms where neutropenic patients would be managed. The grade of air filter fitted in the supply air for these rooms (F9) is of a higher standard than the filters advocated for general ward areas or single rooms in SHTM 03-01 Part A Appendix 1 (G4 filter). As such the supply air in the single rooms of Lochranza is of a "cleaner" quality than a general ward but is not of a High Efficiency Particulate Air (HEPA) standard and this benefit would be immediately removed by opening a window to outside air as windows in the single rooms will open. The supply air ventilation in the 5 PPVL isolation rooms does pass through HEPA filters in the room lobbies., The 5 PPVL rooms do perform to the parameters set in SHTM 03-01 for rooms where all neutropenic patients can be safely placed. Windows in the PPVL isolation rooms do not open.

All shared and single rooms which do not have an opening window are provided with 6 air changes per hour (achieved through mechanical supply and extract).

Assessment :

3.1 A review of all clinical departments was undertaken by the clinical leads from the project team (Janice Mackenzie, Dorothy Hanley, Fiona Halcrow); lead infection prevention and control nurse (Lindsay Guthrie) and lead infection control doctor & consultant microbiologist (Dr Donald Inverarity). This was shared with key clinical colleagues in paediatrics and neurosciences for comment and input prior to submission to the NHS Lothian Executive Steering Group: Royal Hospital for Children and Young People and Department of Clinical Neurosciences for approval.

3.2 In view of planned revision of ventilation systems in Critical Care & Neonatal Unit to meet conformance with SHTM 03-01, it was agreed that these locations did not require to be part of this review, and will not be considered further in this paper.

3.3 A summary table of all wards, bed configuration and clinical service types which informed this risk assessment is provided in appendix 1. This outlines the risk profile of patients being cared for in each area based on the clinical speciality, known patient risk factors and type of treatment or interventions provided. It also identifies anticipated HAI/IPC risks associated with each clinical area.

3.4 The highest risk patient groups are defined as:

- Any haematology/oncology patient
- Any neutropenic patient
- Any other immunocompromised patient (related to underlying disease process or treatment induced)
- Any patient with Cystic Fibrosis
- Any patient with a complex wound dressing or burn treated in the Plastics Dressing Treatment Area

- Any patient with a known infection alert (known colonisation or history of infection with alert organism)
- Any patient presenting with a suspected or confirmed infection transmitted by contact, droplet or airborne transmission

This categorisation of patient risk is in line with the definitions provided in Scottish Health Facilities Note 30 Part B: HAI Scribe Implementation strategy and assessment process; Health Protection Scotland interim guidance for routine sampling of Pseudomonas in augmented care areas (2018); and HPS National Infection Prevention and Control Manual.

3.5 Paediatric renal dialysis is not provided at RHCYP. Any child or young person requiring this is referred to QEUH in Glasgow.

3.6 Paediatric organ transplantation is not provided at RHCYP. Surgery and subsequent hospital follow up is generally provided at QEUH. Rarely, a transplant recipient may be admitted for treatment in the medical ward (Dalhousie ward). These patients would be considered immunocompromised and managed in line with the NHS Lothian Prioritisation of Isolation Guidance (attached as Appendix 2).

3.7 Within Lochranza ward (Haematology/Oncology), although the five PPVL isolation rooms provide 10 Air Changes/hour and 10 Pascals positive pressure from lobby to corridor, none of the single rooms available meet the specification for 'Neutropenic patient ward' defined in SHTM 03-01 Appendix 1 (also 10 Air Changes plus 10 Pascals positive pressure). Based on current occupancy, it is estimated that there may be 5-10 neutropaenic patients being cared for in RHSC on any given day. Although it is acknowledged that not all chemotherapy regimens result in the same intensity of immunosuppression and neutropenia, within the new facility, there may be a shortfall in the number of rooms which meet the SHTM 03-01 standard for safe placement of all neutropenic patients.

3.8 Appropriate patient placement and management is considered against the HPS National Infection Prevention and Control Manual (Appendix 11) and NHS Lothian Prioritisation of Isolation Guidelines. The latter was developed by the IPCT in Lothian to assist clinical teams to risk assess and provide safe, effective patient care where demand for isolation or single room accommodation is exceeded by demand. Paediatric and Neuroscience teams have previously been directed to use this document which is applicable for placement of both paediatric and adult patients.

3.9 The review group agreed that the wards with the highest perceived overall risk of demand for isolation exceeding capacity (and thereby potential risk of onward transmission of infection) are: Castle Mey ward (Paediatric acute receiving unit); Dalhousie ward (Medical in-patients); Lochranza ward (Haematology/Oncology)

3.10 Ventilation in healthcare premises is designed to achieve a number of objectives including management of temperature and humidity, removal of odour (particularly required in wards with cancer patients receiving chemotherapy), provide a clean air path directing flow from 'clean' to 'dirty' and dilution of airborne contaminants. These latter two points are of most significance from infection prevention & control perspective.

3.11 The burden of seasonal respiratory viruses is recognised as a risk, particularly for RHCYP. This risk is however mitigated via the provision of a significantly increased availability of en-suite single room accommodation with doors. HPS National Manual Appendix 11 advocates that

patients are cared for in such rooms. The risk of droplet transmission is greatest within 3 feet/1 metre of the patient. The primary protection therefore offered by en-suite single rooms is physical separation greater than 1 metre and containment of infectious patients by means of a closed door. The impact on transmission risk of a reduced air exchange rate from 6 to 4 air changes per hour in each shared bed space is unknown.

3.12 A review of all alert organism reports for the current wards at RHSC and DCN demonstrates that the Paediatric Acute Receiving Unit (Castle Mey) is likely to experience the highest burden of patients with presentations due to respiratory viral infections, loose stool or diarrhoeal illness and will have both the highest turn over of patients and the highest demand on isolation and single rooms.

3.13 The risk of transmission of infection is also mitigated by application of other aspects of transmission based precautions i.e. enhanced cleaning with chlorine 1000ppm av chlorine, use of dedicated or single use equipment, use of appropriate facial or respiratory protection The application of standard infection prevention and control measures such as personal protective equipment used optimally, optimal hand hygiene and access to alcohol based hand rub across all clinical areas will also mitigate some risk of transmission of infection.

3.14 HFS have also asked that NHS Lothian risk assess and define the actions required if one or more air handling unit fails resulting in the loss of isolation room supply ventilation, noting that between 1 and 5 isolation rooms are provided off single air handling units in the new building. Taking cognisance of the above assessment, in the absence of an infectious disease of high consequence, and providing all other standard and transmission based precautions required by HPS NIPCM are in place, the risk of infection to patients, staff or visitors is likely to be low as SICPs would remain in use and physical isolation in a single room with doors would be maintained. Additionally an air flow from room to toilet air extract would likely continue even if supply air ventilation failed rendering the rooms at slight negative pressure or balanced pressure to the corridor with doors shut.

3.15 Depending on the nature and duration of the AHU failure, and in line with NHS Lothian Prioritisation of Isolation Guidance, a clinical risk assessment would be required in conjunction with the IPCT to determine any further actions required on a case by case basis. This would take account of: the patient's overall clinical condition, the ward type, the infection risk and mode of transmission, the risk profile of adjacent patients and isolation room capacity unaffected by the outage. Additional mitigating actions specific to infectious diseases of high consequence (such as MERS or Multi Drug Resistant TB) would also be required in the event of supply ventilation failure.

3. Recommendations

4.1 Staff at RHCYP and DCN should refer to and implement the NHS Lothian Prioritisation of Isolation Guidelines to ensure that all patients with a suspected or known infection risk, or who are vulnerable to opportunistic infections, are placed appropriately within all clinical care environments.

4.2 All NHS Lothian staff should continue to implement standard and transmission based precautions in line with national policy. This includes, but is not limited to, ensuring that patients with known or suspected infections are cared for in single or isolation room accommodation and the door to the room remains closed.

4.3 All children, young people or adults cared for in RHCYP DCN who are receiving chemotherapy, radiotherapy or who are considered to be immunosuppressed should be prioritised for single room or isolation room accommodation where possible.

4.4 In line with national policy, co-horting of children with confirmed respiratory viral illness should be considered where this is clinically appropriate and demand for single room isolation has been exceeded. Strict application of standard and transmission based precautions is required for the duration of this

4.5 A separate review and assessment of patient accommodation and patient risk in Lochranza ward is required to inform any further adjustment to the ventilation system required prior to migration of paediatric services.

Appendix 1: See separate attachment to email

HAI Risk assessment of clinical areas RHCY

Appendix 2: NHS Lothian Prioritisation of Isolation Guideline (2017)

20170112 Prioritisation of Isolat

Department of Health

Health Building Note 04-02
Critical care units

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Health Building Note 04-02
Critical care units

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 (shown below) is based on the patient's experience across the spectrum of care from home to healthcare setting and back, using the national service frameworks (NSFs) as a model.

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 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, Health Technical Memoranda and Health Technical Memorandum Building Component series.

1. Room data sheets provide an activity-based approach to building design and include data on personnel, planning relationships, environmental considerations, design character, space requirements and graphical layouts.
2. Schedules of equipment/components are included for each room, which may be grouped into ergonomically arranged assemblies.
3. Schedules of equipment can also be obtained at department and project level.
4. Fully loaded drawings may be produced from the database.
5. Reference data is supplied with ADB that may be adapted and modified to suit the users' project-specific needs.

Note

The sequence of numbering within each subject area does not necessarily indicate the order in which the Health Building Notes were or will be published/printed. However, the overall structure/number format will be maintained as described.

Executive summary

This Health Building Note provides guidance on critical care units that admit patients whose dependency levels are classified as level 2 or 3 (see 'Comprehensive Critical Care', DH 2000, for definitions of levels of critical care). However, it does not distinguish between the different requirements for level 2 and 3 patients.

It excludes facilities for the high-security isolation of patients, dedicated centres for burns patients and areas within the hospital where level 2 or 3 patients are managed on a time-limited basis.

Contents

1 Policy context

1.1 'Comprehensive Critical Care' (DH, 2000) was a pivotal publication. It introduced the concept of "critical care without walls"; identifying for the first time that a patient's clinical needs and not their location of care determined the required level and type of organ support. Patients thereafter have been described according to their required level of organ support (see levels of care on the Intensive Care Society website).

1.2 In addition 'Comprehensive Critical Care' highlighted the need for early recognition of deteriorating health and appropriate comprehensive transfer arrangements for patients to wards after recovery from critical illness. These concepts and guidance on operational service delivery such as the role of critical care networks were reinforced in 'Quality Critical Care – Beyond Comprehensive Critical Care' (DH, 2005).

1.3 NICE has subsequently issued guidance on 'Acutely ill patients in hospital' (Clinical guidelines CG50, July 2007) and 'Rehabilitation after critical illness' (Clinical guidelines CG83, 2009). Accompanying CG50, 75 acute care competencies have been detailed in 'Competencies for recognising and responding to acutely ill patients in hospital' (DH, 2009). Such guidance has led to the development of critical care outreach services.

1.4 The operational changes that have followed the release of 'Comprehensive Critical Care' have been significant. Critical care networks have developed, many of which are delivered now as managed clinical networks. The provision of mutual and collective planning of services is essential for service resilience. This means that critical care units across a conurbation will work together to meet needs.

1.5 The building blocks for commissioning of critical care services are now in place. A new dataset, Critical Care Minimum Dataset, was mandated from April 2006; annual reference cost submission followed and from 1 April 2011 a new model for commissioning of critical care services has been used. This model uses the mandated dataset and derivation of seven healthcare resources groups for critical care as the currency, but uses local tariffs ('Payment by Results Guidance for 2011–12', DH).

Mixed-sex accommodation in critical care units

1.6 Patient acuity determines the need for access to critical care, and although every effort is made to group members of the same sex together, this is frequently not possible. Nevertheless, it is imperative that the highest standards of privacy and dignity are maintained at all times.

1.7 For guidance on the justification for mixed sex accommodation in critical care units see PL/CNO/2010/3 – 'Eliminating Mixed Sex Accommodation'.

2 Service context

2.1 The Department of Health collects data on the number of critical care beds twice a year. For details see 'Census on number of critical care beds in England'.

3 Scope of guidance

3.1 This Health Building Note describes spaces that are unique to a critical care unit. It also describes any variations to common hospital spaces and clarifies requirements for these spaces, where necessary.

3.2 For a full list of space requirements see the following example schedules of accommodation for an 8-bed, 16-bed and 32-bed critical care unit. The example schedules provide a basis for sizing facilities at initial planning stages but exact requirements should be determined locally based on the number and case mix of patients, hospital policy for the provision of supplies and waste disposal, and the layout of the unit. Links to guidance on common spaces are provided from the schedules.

Example schedules of accommodation for critical care units								
Version 1, published 15.09.11								
				Cost guide allowances:	**Circulation and communication**	**Engineering**		
				Public	35%	23%		
				Clinical	35%	35%		
				Staff	35%	21%		
Example 1: 8-bed critical care unit								
	Room name/function	**Unit area allowance**	**Quantity**	**Net internal area**	**Circulation and communication allowance**	**Engineering allowance**	**Gross internal area**	**Notes**
Public spaces								
	Entrance: visitors		1					
	Entrance: patients, staff and supplies		1					Separate entrance for staff and supplies is an option.
J0232	Reception desk (size based on number of places)	5.5	1	5.5	1.9	1.3	8.7	1-place reception for small/medium sized units; 2-place reception for large units (>30 beds).
J1155/J1414	Waiting area: 10 places	22.5	1	22.5	7.9	5.2	35.6	Includes children's play area and 10% wheelchair places. 1 place per bed with minimum of 10.
P0711	Mini kitchen	5.0	1	5.0	1.8	1.2	7.9	1 per unit.
	WC: independent wheelchair	4.5	1	4.5	1.6	1.0	7.1	1 per small/medium sized unit; 2 per large unit (>30 beds).
Clinical spaces								
T0214-03	Staff communication base: 2 places	13.0	1	13.0	4.6	4.6	22.1	2 places per 8 beds.
B1603	Isolation room: critical care	26.0	4	104.0	36.4	36.4	176.8	Planning and design manual specifies 20% singles (subject to case mix); in an 8-bed unit with a standard 4-bed bay arrangement 50% singles may be provided.
G0510	Gowning lobby	6.0	4	24.0	8.4	8.4	40.8	
B1610	4-bed bay: critical care	143.0	1	143.0	50.1	50.1	243.1	
M0727	Interview room: 7 places	12.0	1	12.0	4.2	4.2	20.4	1 per 10 beds.
V1635	Shower room: assisted	8.0	1	8.0	2.8	2.8	13.6	Nominal allowance. Requirement subject to case mix of unit.
Clinical support spaces								
T0535	Clean utility room	16.0	1	16.0	5.6	5.6	27.2	1 per 12 beds.
G0605	Ice-making machine bay	1.5	1	1.5	0.5	0.5	2.6	1 per unit.
L1308	Near patient testing room	8.0	1	8.0	2.8	2.8	13.6	1 per 16 beds.
Y0331	Dirty utility room for bedpan processing	12.0	1	12.0	4.2	4.2	20.4	1 per 16 beds.
P0627	Pantry/refreshment room	12.0	1	12.0	4.2	4.2	20.4	1 per unit.
W0540/1450/ 1590/1594	Storage: bulky consumables, medical gas cylinders, linen and furniture	4.0	8	32.0	11.2	11.2	54.4	4 m^2 allowance per bed. Based on a review of a number of reference sites.
W1584-06	Store: clinical equipment	24.0	1	24.0	8.4	8.4	40.8	1 for small/medium sized units; 2 for large units (>30 beds).
Y0335	Decontamination room: clinical equipment	16.0	1	16.0	5.6	5.6	27.2	1 per unit. Located adjacent to clinical equipment store.
G0171	Parking bay: imaging equipment	6.0	1	6.0	2.1	2.1	10.2	1 per small/medium sized unit; 2 per large unit (>30 beds).
G0180-01	Parking bay: resuscitation trolley	2.0	1	2.0	0.7	0.7	3.4	1 per 8 beds.
Y0642	Disposal hold: 1700 litres	8.0	1	8.0	2.8	2.8	13.6	Minimum 1500 litres per 8 beds
Y1510	Cleaners' room	8.0	1	8.0	2.8	2.8	13.6	1 for small/medium sized units; 2 for large units (>30 beds).
Staff spaces								
M0251	Office: 1-person	8.0	3	24.0	8.4	5.0	37.4	For clinical director, lead nurse and tutor.
M0278-01/M0281/ M0410/M0731	Admin area: shared use (size based on number of workstations)	6.6	5	33.0	11.6	6.9	51.5	For consultants and outreach staff.
M0727	Meeting room: 7 places	16.0	1	16.0	5.6	3.4	25.0	
H1304-01	Seminar room: 8 places	17.0	1	17.0	6.0	3.6	26.5	May be sized up and shared with other departments.
D0434-01	Rest room with mini kitchen (size based on number of seats)	1.9	8	15.2	5.3	3.2	23.7	
V0554-03/V0667-01/ V0725/V1321	Changing area: staff (size based on number of lockers)	1.4	35	49.0	17.2	10.3	76.4	Includes uniform exchange area, showers and a number of individual changing rooms. Based on 32 staff who need a locker (allowing for shift changeover), plus a 10% contingency to allow for male/female split (suggested apportionment 2/3 female to 1/3 male).
V0725	Changing room: semi-ambulant	2.0	1	2.0	0.7	0.4	3.1	Additional individual changing room to allow for male and female segregation.
V1321	Shower room: ambulant	2.5	1	2.5	0.9	0.5	3.9	Additional shower room to allow for male and female segregation.
V1010	WC: ambulant	2.0	4	8.0	2.8	1.7	12.5	Serving up to 50 staff, with additional WC to allow for gender segregation.
Total allowance				**653.7**	**228.8**	**201.0**	**1083.5**	
Optional accommodation								
W0652	Blood refrigerator bay	2.0	1	2.0				Only required if blood storage not available nearby.
L1804-03	Service room: clinical equipment	12.0	1	12.0				Only required if biomedical engineering workshop not available nearby.
G0171-02	Parking bay: mobile image intensifier	2.0	1	2.0				
P0808	Vending machine	3.0	1	3.0				In lieu of visitors' mini kitchen.
D1120	Sitting room: 7 places	12.0	1	12.0				For visitors.
D1312	Relatives' overnight stay	17.0	1	17.0				For visitors. Requirement based on case mix of patients.
V1323	Shower room: semi-ambulant: standing use	5.0	2	10.0				For visitors. Requirement based on case mix of patients.

Example schedules of accommodation for critical care units								
Version 1, published 15.09.11								
				Cost guide allowances:	Circulation and communication	Engineering		
				Public	35%	23%		
				Clinical	35%	35%		
				Staff	35%	21%		
Example 2: 16-bed critical care unit								
	Room name/function	Unit area allowance	Quantity	Net internal area	Circulation and communication allowance	Engineering allowance	Gross internal area	Notes
Public spaces								
	Entrance: visitors		1					
	Entrance: patients, staff and supplies		1					Separate entrance for staff and supplies is an option.
J0232	Reception desk (size based on number of places)	5.5	1	5.5	1.9	1.3	8.7	1-place reception for small/medium sized units; 2-place reception for large units (>30 beds).
J1155/J1414	Waiting area: 16 places	33.0	1	33.0	11.6	7.6	52.1	Includes children's play area and 10% wheelchair places. 1 place per bed with minimum of 10.
P0711	Mini kitchen	5.0	1	5.0	1.8	1.2	7.9	1 per unit.
V0922	WC: independent wheelchair	4.5	1	4.5	1.6	1.0	7.1	1 per small/medium sized unit; 2 per large unit (>30 beds).
Clinical spaces								
T0214	Staff communication base: 4 places	19.0	1	19.0	6.7	6.7	32.3	2 places per 8 beds.
B1603	Isolation room: critical care	26.0	4	104.0	36.4	36.4	176.8	Planning and design manual specifies 20% singles (subject to case mix); in a 16-bed unit with a standard 4-bed bay arrangement 25% singles may be provided.
G0510	Gowning lobby	6.0	4	24.0	8.4	8.4	40.8	
B1610	4-bed bay: critical care	143.0	3	429.0	150.2	150.2	729.3	
M0727	Interview room: 7 places	12.0	2	24.0	8.4	8.4	40.8	1 per 10 beds.
V1635	Shower room: assisted	8.0	1	8.0	2.8	2.8	13.6	Nominal allowance. Requirement subject to case mix of unit.
Clinical support spaces								
T0535	Clean utility room	16.0	2	32.0	11.2	11.2	54.4	1 per 12 beds.
G0605	Ice-making machine bay	1.5	1	1.5	0.5	0.5	2.6	1 per unit.
L1308	Near patient testing room	8.0	1	8.0	2.8	2.8	13.6	1 per 16 beds.
Y0331	Dirty utility room for bedpan processing	12.0	1	12.0	4.2	4.2	20.4	1 per 16 beds.
P0627	Pantry/refreshment room	12.0	1	12.0	4.2	4.2	20.4	1 per unit.
W0540/1450/ 1590/1594	Storage: bulky consumables, medical gas cylinders, linen and furniture	4.0	16	64.0	22.4	22.4	108.8	4 m^2 allowance per bed. Based on a review of a number of reference sites.
W1584-06	Store: clinical equipment	24.0	1	24.0	8.4	8.4	40.8	1 for small/medium sized units; 2 for large units (>30 beds).
Y0335	Decontamination room: clinical equipment	16.0	1	16.0	5.6	5.6	27.2	1 per unit. Located adjacent to clinical equipment store.
G0171	Parking bay: imaging equipment	6.0	1	6.0	2.1	2.1	10.2	1 per small/medium sized unit; 2 per large unit (>30 beds)
G0180-01	Parking bay: resuscitation trolley	2.0	2	4.0	1.4	1.4	6.8	1 per 8 beds.
Y0646	Disposal hold: 3000 litres	12.0	1	12.0	4.2	4.2	20.4	Minimum 1500 litres per 8 beds.
Y1510	Cleaners' room	8.0	1	8.0	2.8	2.8	13.6	1 for small/medium sized units; 2 for larger units (>30 beds).
Staff spaces								
M0251	Office: 1-person	8.0	3	24.0	8.4	5.0	37.4	For clinical director, lead nurse and tutor.
M0278/M0281/ M0410/M0731	Admin area: shared use (size based on number of workstations)	6.6	13	85.8	30.0	18.0	133.8	For consultants and outreach staff.
M0727	Meeting room: 7 places	16.0	1	16.0	5.6	3.4	25.0	
H1304-02	Seminar room: 16 places	26.0	1	26.0	9.1	5.5	40.6	
D0434-03	Rest room with mini kitchen (size based on number of seats)	1.9	16	30.4	10.6	6.4	47.4	
V0554-03/V0667/ V0725/V1321	Changing area: staff (size based on number of lockers)	1.4	77	107.8	37.7	22.6	168.2	Includes uniform exchange area, showers and a number of individual changing rooms. Based on 70 staff who need a locker (allowing for shift changeover), plus a 10% contingency to allow for male/female split (suggested apportionment 2/3 female to 1/3 male).
V0725	Changing room: semi-ambulant	2.0	1	2.0	0.7	0.4	3.1	Additional individual changing room to allow for male and female segregation.
V1321	Shower room: ambulant	2.5	1	2.5	0.9	0.5	3.9	Additional shower room to allow for male and female segregation.
V1010	WC: ambulant	2.0	5	10.0	3.5	2.1	15.6	Serving up to 75 staff, with additional toilet to allow for gender segregation.
Total allowance				**1160.0**	**406.0**	**357.6**	**1923.6**	
Optional accommodation								
W0652	Blood refrigerator bay	2.0	1	2.0				Only required if blood storage not available nearby.
L1804-03	Service room: clinical equipment	12.0	1	12.0				Only required if biomedical engineering workshop not available nearby.
G0171-02	Parking bay: mobile image intensifier	2.0	1	2.0				
P0808	Vending machine	3.0	1	3.0				In lieu of visitors' mini kitchen.
D1120	Sitting room: 7 places	12.0	1	12.0				For visitors.
D1312	Relatives' overnight stay	17.0	1	17.0				For visitors. Requirement based on case mix of patients.
V1323	Shower room: semi-ambulant: standing use	5.0	2	10.0				For visitors. Requirement based on case mix of patients.

Example schedules of accommodation for critical care units

Version 1, published 15.09.11

				Cost guide allowances:	Circulation and communication	Engineering		
				Public	35%	23%		
				Clinical	35%	35%		
				Staff	35%	21%		

Example 3: 32-bed critical care unit

	Room name/function	Unit area allowance	Quantity	Net internal area	Circulation and communication allowance	Engineering allowance	Gross internal area	Notes
Public spaces								
	Entrance: visitors		1					
	Entrance: patients, staff and supplies		1					Separate entrance for staff and supplies is an option.
J0232	Reception desk (size based on number of places)	5.5	2	11.0	3.9	2.5	17.4	1-place reception for small/medium sized units; 2-place reception for large units (>30 beds).
J1155/J1414	Waiting area: 32 places	60.0	1	60.0	21.0	13.8	94.8	Includes children's play area and 10% wheelchair places. 1 place per bed with minimum of 10.
P0711	Mini kitchen	5.0	1	5.0	1.8	1.2	7.9	1 per unit.
V0922	WC: independent wheelchair	4.5	2	9.0	3.2	2.1	14.2	1 per small/medium sized unit; 2 per large unit (>30 beds).
Clinical spaces								
T0214-02	Staff communication base: 8 places	30.0	1	30.0	10.5	10.5	51.0	2 places per 8 beds.
B1063	Isolation room: critical care	26.0	8	208.0	72.8	72.8	353.6	Planning and design manual specifies 20% singles (subject to case mix); in a 32-bed unit with a standard 4-bed bay arrangement 25% singles may be provided.
G0510	Gowning lobby	6.0	8	48.0	16.8	16.8	81.6	
B1610	4-bed bay: critical care	143.0	6	858.0	300.3	300.3	1458.6	
M0727	Interview room: 7 places	12.0	3	36.0	12.6	12.6	61.2	1 per 10 beds.
V1635	Shower room: assisted	8.0	2	16.0	5.6	5.6	27.2	Nominal allowance. Requirement subject to case mix of unit.
Clinical support spaces								
T0535	Clean utility room	16.0	3	48.0	16.8	16.8	81.6	1 per 12 beds.
G0605	Ice-making machine bay	1.5	1	1.5	0.5	0.5	2.6	1 per unit.
L1308	Near patient testing room	8.0	2	16.0	5.6	5.6	27.2	1 per 16 beds.
Y0331	Dirty utility room for bedpan processing	12.0	2	24.0	8.4	8.4	40.8	1 per 16 beds.
P0627	Pantry/refreshment room	12.0	1	12.0	4.2	4.2	20.4	1 per unit.
W0540/1450/ 1590/1594	Storage: bulky consumables, medical gas cylinders, linen and furniture	4.0	32	128.0	44.8	44.8	217.6	4 m^2 allowance per bed. Based on a review of a number of reference sites.
W1584-06	Store: clinical equipment	24.0	2	48.0	16.8	16.8	81.6	1 for small/medium sized units; 2 for large units (>30 beds).
Y0335	Decontamination room: clinical equipment	16.0	1	16.0	5.6	5.6	27.2	1 per unit. Located adjacent to clinical equipment stores.
G0171	Parking bay: imaging equipment	6.0	2	12.0	4.2	4.2	20.4	1 per small/medium sized unit; 2 per large unit (>30 beds)
G0180-01	Parking bay: resuscitation trolley	2.0	4	8.0	2.8	2.8	13.6	1 per 8 beds.
Y0646	Disposal hold: 3000 litres	12.0	2	24.0	8.4	8.4	40.8	Minimum 1500 litres per 8 beds.
Y1510	Cleaners' room	8.0	2	16.0	5.6	5.6	27.2	1 for small/medium sized units; 2 for larger units (>30 beds).
Staff spaces								
M0251	Office: 1-person	8.0	3	24.0	8.4	5.0	37.4	For clinical director, lead nurse and tutor.
M0278/M0281/ M0410/M0731	Admin area: shared use (size based on number of workstations)	6.6	29	191.4	67.0	40.2	298.6	For consultants and outreach staff.
M0727	Meeting room: 7 places	16.0	1	16.0	5.6	3.4	25.0	
H1304-03	Seminar room: 32 places	45.0	1	45.0	15.8	9.5	70.2	
D0434-03	Rest room with mini kitchen (size based on number of seats)	1.8	32	57.6	20.2	12.1	89.9	
V0554-03/V0667-02/ V0725/V1321	Changing area: staff (size based on number of lockers)	1.4	148	207.2	72.5	43.5	323.2	Includes uniform exchange area, showers and a number of individual changing rooms. Based on 135 staff who need a locker (allowing for shift changeover), plus a 10% contingency to allow for male/female split (suggested apportionment 2/3 female to 1/3 male).
V0725	Changing room: semi-ambulant	2.0	2	4.0	1.4	0.8	6.2	Additional individual changing rooms to allow for male and female segregation.
V1321	Shower room: ambulant	2.5	2	5.0	1.8	1.1	7.8	Additional shower rooms to allow for male and female segregation.
V1010	WC: ambulant	2.0	8	16.0	5.6	3.4	25.0	Serving up to 150 staff, with additional toilet to allow for gender segregation.
Total allowance				**2200.7**	**770.2**	**680.8**	**3651.7**	
Optional accommodation								
W0652	Blood refrigerator bay	2.0	1	2.0				Only required if blood storage not available nearby.
L1804-03	Service room: clinical equipment	12.0	1	12.0				Only required if biomedical engineering workshop not available nearby.
G0171-02	Parking bay: mobile image intensifier	2.0	1	2.0				
P0808	Vending machine	3.0	1	3.0				In lieu of visitors' mini kitchen.
D1120	Sitting room: 7 places	12.0	1	12.0				For visitors.
D1312	Relatives' overnight stay	17.0	1	17.0				For visitors. Requirement based on case mix of patients.
V1323	Shower room: semi-ambulant: standing use	5.0	2	10.0				For visitors. Requirement based on case mix of patients.

4 Whole unit planning and design considerations

Departmental relationships

4.1 A critical care unit should be centrally located within an acute hospital development. It should be adjacent to and/or have easy access to (and be easily accessible from) imaging facilities and operating theatres. The emergency department should be adjacent and/or have easy access to the critical care unit.

4.2 The critical care unit requires close links to the main hospital pharmacy and microbiology laboratory; where a pneumatic tube system is used to transport specimens and computers are used for transmitting test results and placing prescription orders, physical proximity is less important.

Bed spaces

4.3 Each bed space should include the following:

- an electric bed capable of attaining chair and Trendelenberg positions, and fitted with a pressure-relieving mattress;
- a high-backed chair with foot elevation and tilting facility for the patient;
- a ceiling-mounted twin-armed pendant to accommodate a range of equipment and for the provision of medical gases and electrical and data connectivity;
- a clinical wash-hand basin;

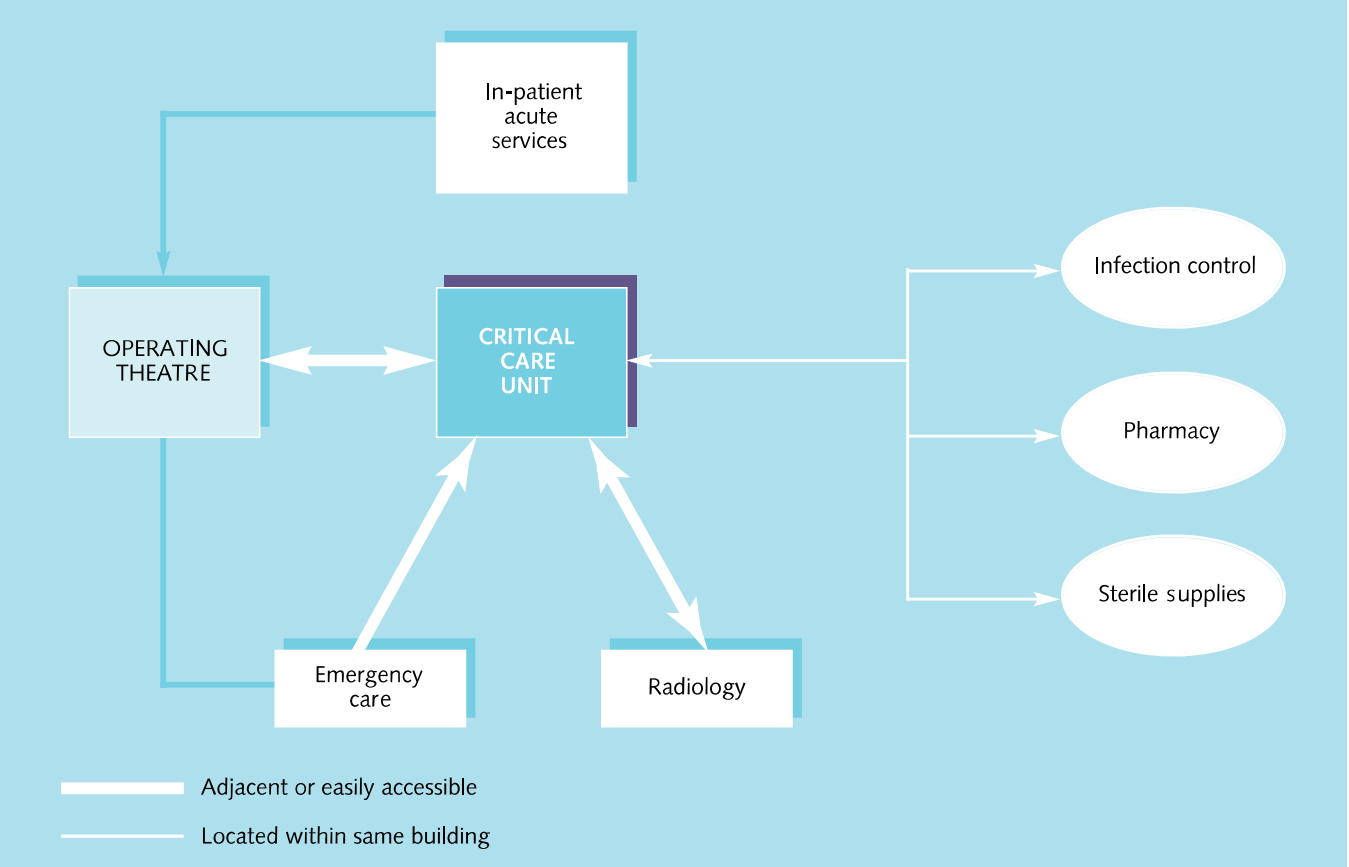


Figure 1 Departmental relationships for a critical care unit

- enclosed storage for a small quantity of consumables;
- drugs storage (wall-mounted drugs cabinet or within the patient's bedside locker);
- a ceiling-mounted hoist for lifting patients.

4.4 Storage of patients' clothes and personal effects should be dealt with in accordance with whole-hospital policy. They should not normally be kept at the bedside; however, some personal items such as family photographs can help the patient's orientation and provide emotional support.

4.5 The following outlets should be located on the pendant:

- at least 28 unswitched single socket-outlets;
- up to four data outlets, one of which should be networked to the hospital's patient record system;
- 3–4 oxygen outlets;
- two 4-bar air outlets;
- one 7-bar air outlet (where surgical equipment is used), clearly labelled with the appropriate warning;
- 2–4 medical vacuum outlets;
- anaesthetic gas scavenging points, if anaesthetic inhalation gases and/ or inhalation antibiotics are used;
- patient/staff and staff emergency call systems, including a separate switch for crash call;
- telephone outlet for internal and external calls;
- TV outlet.

4.6 The following equipment should be located on the pendant:

- computer with flat-screen monitor;
- multi-parameter patient monitoring equipment;
- 3–6 infusion pumps;
- 4–10 syringe pumps;
- blood warmer;
- feeding pump;
- ventilation and humidification equipment.

4.7 Ceiling-mounted rather than floor-mounted pendants are recommended since they avoid the need to trail cables across the floor, thereby providing better access to the patient and improved safety for staff and visitors. They are also easier to keep clean. Powered ceiling-mounted pendants enable staff of all heights to operate them easily. Care should be taken in the positioning of the pendants to ensure convenient access by staff.

4.8 The pendant should be connected to an isolated power supply and provide an uninterruptable power supply (UPS) to an agreed number of electrical outlets. IPS and UPS sockets should be colour-coded to differentiate them from one another. Additional switched and shuttered sockets, connected to ring circuits, may be provided at the bedhead for portable non-medical equipment.

4.9 The temperature within bed spaces is usually controlled by the ventilation system rather than radiators. Facilities for temperature and humidity adjustment should be provided, to parameters agreed with clinical representatives on the project team. Children should only be placed in bed spaces that provide local temperature control (due to the need to elevate the room temperature for this patient group).

4.10 The ventilation system should include mechanical cooling and provide for a range of temperatures that can be adjusted by staff, taking particular care to establish and accommodate the unusually high heat gains that may be anticipated from medical equipment. The position of ventilation grilles should minimise the risk of patients experiencing discomfort through down drafts.

4.11 The following equipment may be required at the bedside on an intermittent or continuous basis:

- mobile X-ray machine;
- haemodialysis machine;
- haemofiltration machine;
- peritoneal dialysis machine;
- EEG machines;
- electrocardiography machines;
- echocardiography machines;
- transoesophageal echocardiography machines;
- invasive cardiac output monitoring devices;
- ultrasound machines;
- gamma cameras;
- endoscopes (fibre-optic light source);

- defibrillators;
- non-invasive respiratory equipment (continuous positive airway pressure (CPAP)/bi-level positive airway pressure (BIPAP)): this may be mounted on the pendant;
- vacuum dressings.

4.12 A wall-mounted renal dialysis panel with water supply and drainage may be provided at some bed spaces to facilitate haemodialysis. Alternatively, it may be more economical to supply potable water to small water treatment units at the bed space. The specification for the water quality should be agreed with the project team.

4.13 A clock with an elapsed time control should be clearly visible from each bed space.

4.14 The bed space should be a minimum of 25.5 m^2 in order to accommodate the above equipment/ furniture. This will also allow:

- staff access to the patient from all sides of the bed;
- staff to manoeuvre the patient, themselves and equipment safely;
- five members of staff to attend to the patient in an emergency situation;
- two visitors to sit at the bedside.

4.15 All bed spaces should be capable of providing visual privacy and reasonable auditory privacy, when required. All bed spaces should have natural daylight with outside views wherever possible. Artificial lighting should be dimmable and of sufficient strength to enable surgical interventions and response to life-threatening situations at the bedside. Lighting may be provided as part of the pendant system.

4.16 Glass walls (in the case of single-bed rooms) or partitions (in the case of multi-bed areas), which can be obscured for privacy when appropriate, aid observation of patients.

4.17 A ceiling height of 3 m in bed areas is recommended in order to accommodate pendants and ceiling-mounted hoists. The position of overhead equipment requires careful consideration. The construction of the ceiling should take account of weight-bearing requirements.

5 Public spaces

Entrances

5.1 Patients and visitors should not share the same entrance, to ensure that visitors do not observe patients coming in and out of the critical care unit. Deceased patients should be transported using the patients' entrance. Staff may share an entrance with either visitors or patients. However, a dedicated entrance for visitors may provide them with a calmer, less busy environment. Supplies should be delivered via the same entrance used by staff.

5.2 The entrance for visitors requires an intercom-controlled entry system or similar linked to the reception desk and staff communication base(s). CCTV should also be considered, with monitors at the reception desk and staff communication base(s) to assist with identification of visitors out-of-hours.

5.3 Where access control measures are in place, close-proximity cards rather than swipe cards or keypads should be used, as they are easier to clean and offer better infection control.

Reception desk

5.4 The entry system for the visitors' entrance, CCTV monitor, if provided, and a telephone for internal and external calls should be located here. The reception desk should have natural surveillance of the visitors' entrance and/or point of entry to clinical areas.

Visitors' waiting area and associated facilities

5.5 On arrival, visitors will be admitted immediately to the appropriate clinical area or asked to wait in the waiting area. There should be a door between the waiting area and clinical areas, controlled by staff, to prevent visitors wandering into clinical areas. Beverage-making facilities and WCs should be available nearby. The waiting area may include a TV. A separate visitors' sitting room may be of value for those spending long periods of time within the vicinity of the critical care unit.

Visitors' overnight accommodation

5.6 Overnight accommodation for visitors may be provided within the hospital, or the hospital may have an arrangement with a nearby hotel. Where children are being treated, overnight accommodation for parents should be provided. Enlarged single bedrooms provide the option of adding an extra bed for parents to stay overnight.

6 Clinical spaces

Staff communication base(s)

6.1 Ideally, staff at the base(s) should be able to see all multi-bed spaces under their control and the entry point to clinical areas. Control of the visitors' entry system will be transferred from the reception desk to the communication base(s) at night.

6.2 Alarms to signify the failure of medical gas and power outlets within the bed spaces should be located here. Central consoles for multi-parameter patient monitoring equipment should also be located here.

6.3 A telephone for internal and external calls will be required. Task lighting should be provided for use at night to prevent disturbing patients. Each base should be partially enclosed to control noise transfer.

Isolation rooms

6.4 Single-bed rooms with lobbies are required for the isolation of patients to control the spread of infection or for the protection of immuno-suppressed patients.

6.5 Single-bed rooms should be rectangular, not L-shaped, with an entrance wide enough to allow bulky equipment to pass easily – at least a door and a half wide. Care should be taken to ensure that the door opening is sufficient to allow the passage of the bed and equipment.

6.6 The ventilation system should be designed to provide simultaneous source and protective isolation. A balanced supply and extract ventilation to each isolation room and gowning lobby is, therefore, proposed. The lobby, which functions as

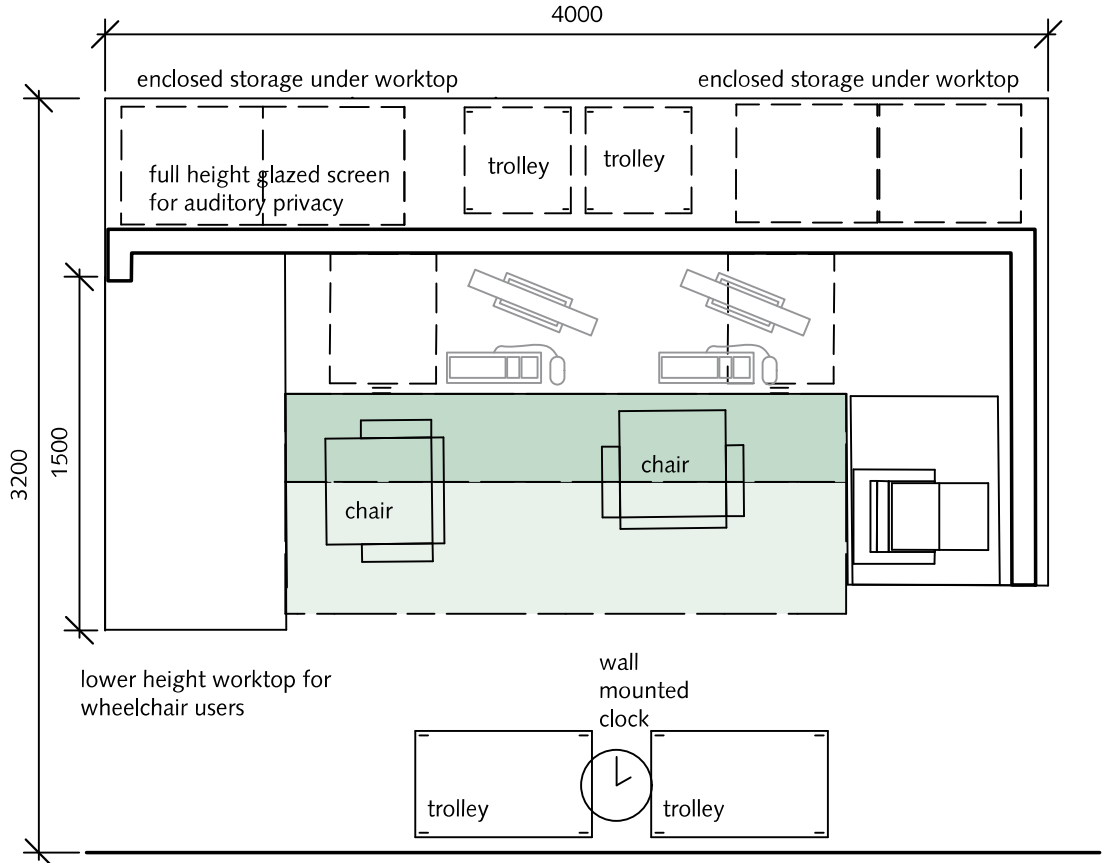


Figure 2 Critical care 2-place staff communication base

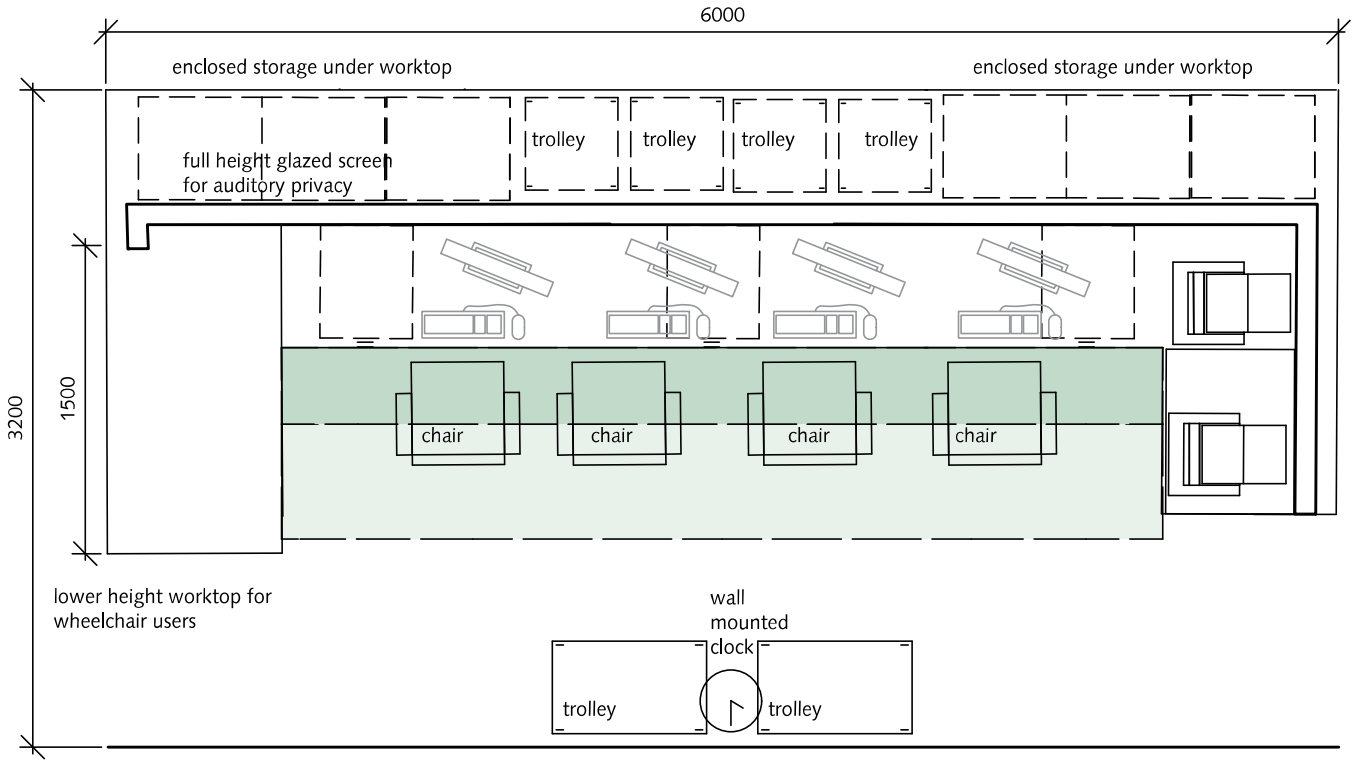


Figure 3 Critical care 4-place staff communication base

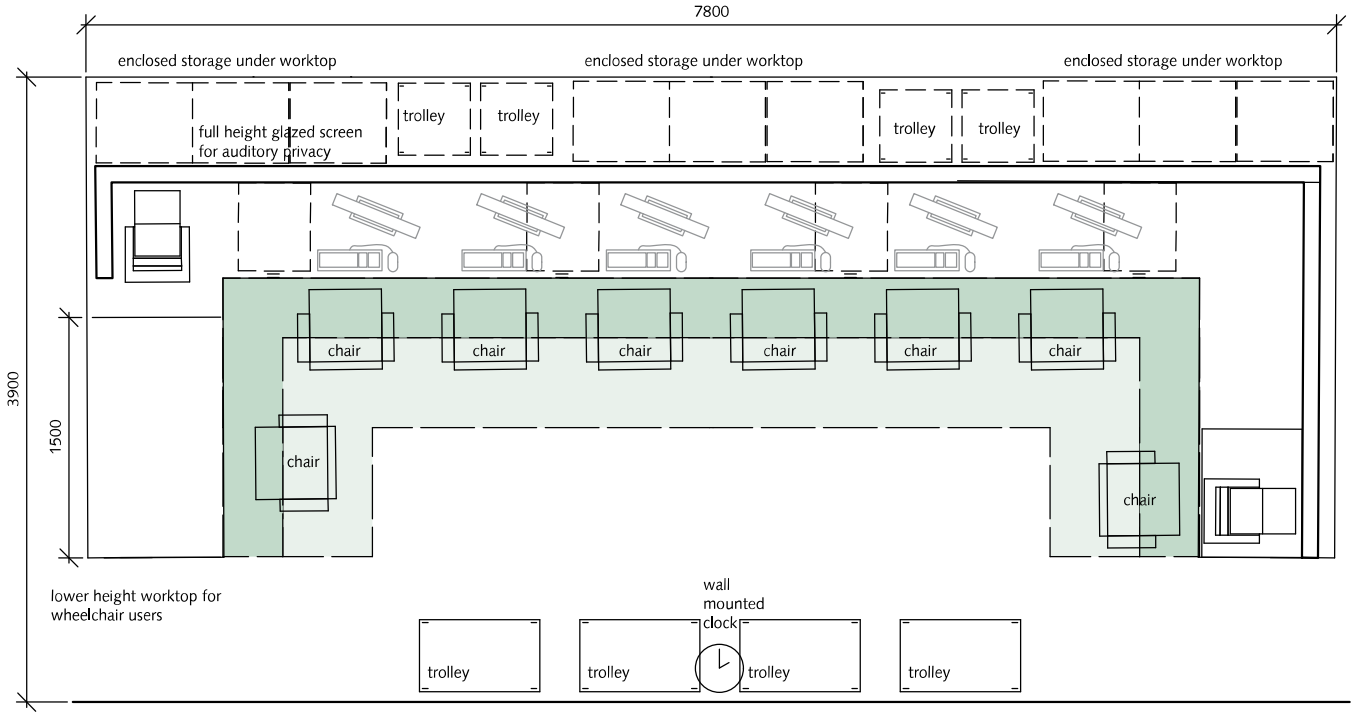


Figure 4 Critical care 8-place staff communication base

an airlock, requires a relatively high and balanced supply and extract air change rate to be effective against airborne organisms moving between circulation areas and isolation rooms.

6.7 Ceilings and windows should be sealed. Doors should be tight-fitting, with seals to minimise air transfer.

6.8 Isolation rooms should have local temperature controls that are accessible to nursing staff and may require humidity within the range 40–60% Rh, depending on the specialty.

6.9 The precise number of isolation rooms will depend on the case mix of the critical care unit. For example, units that routinely admit neutropenic haematology patients may require up to 50% of their beds to be provided as isolation rooms with lobbies. No unit should, however, have less than 20% of their beds as isolation rooms.

Multi-bed areas

6.10 A 2.5 m-wide unobstructed circulation space should be provided at the foot of each bed space. It is imperative to maintain the required bed separation for infection control reasons and to aid positioning of equipment.

6.11 The temperature in the multi-bed areas should be centrally controlled.

6.12 Requirements for scrub troughs should be determined locally based on patient case mix.

6.13 Project teams should select a curtain system that meets the following criteria:

- when the curtains are pulled around the bed space, there should be 100% visual privacy;
- it should be possible to pull the curtains back completely against the wall;

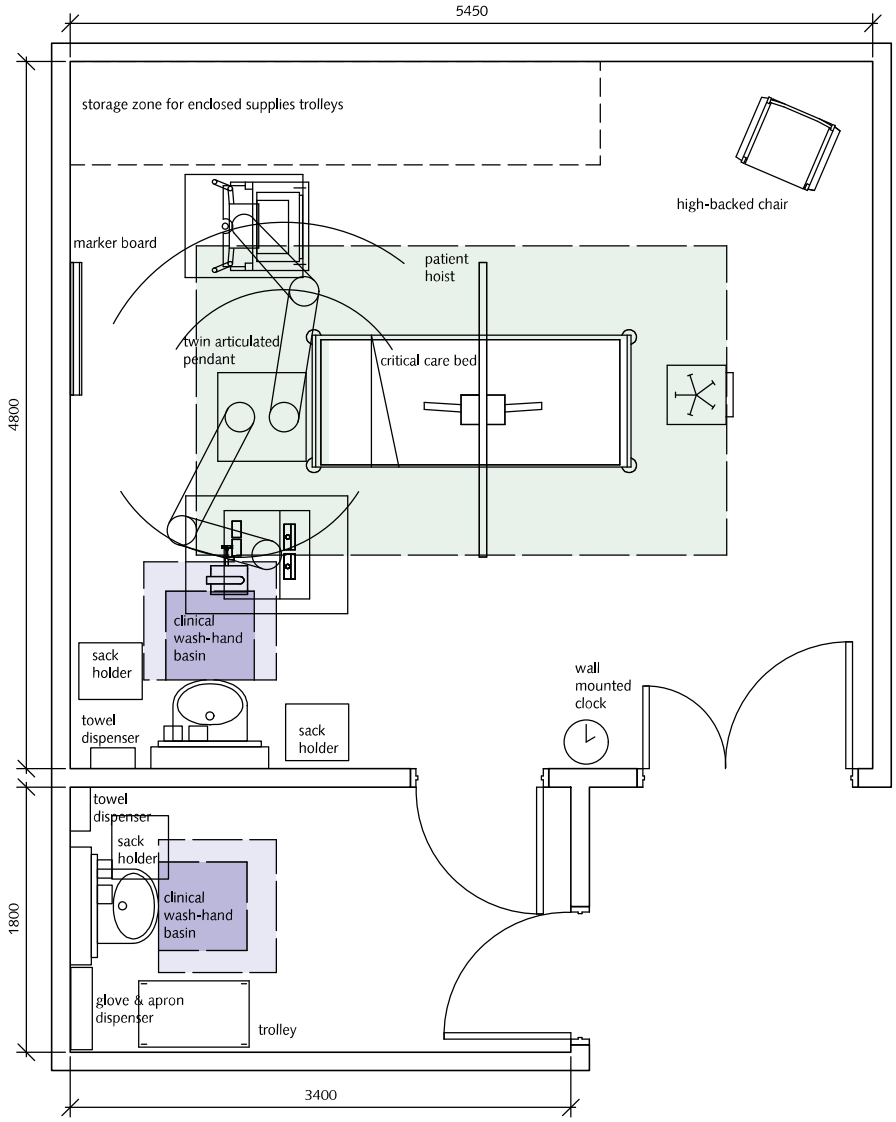


Figure 5 Critical care isolation room and lobby

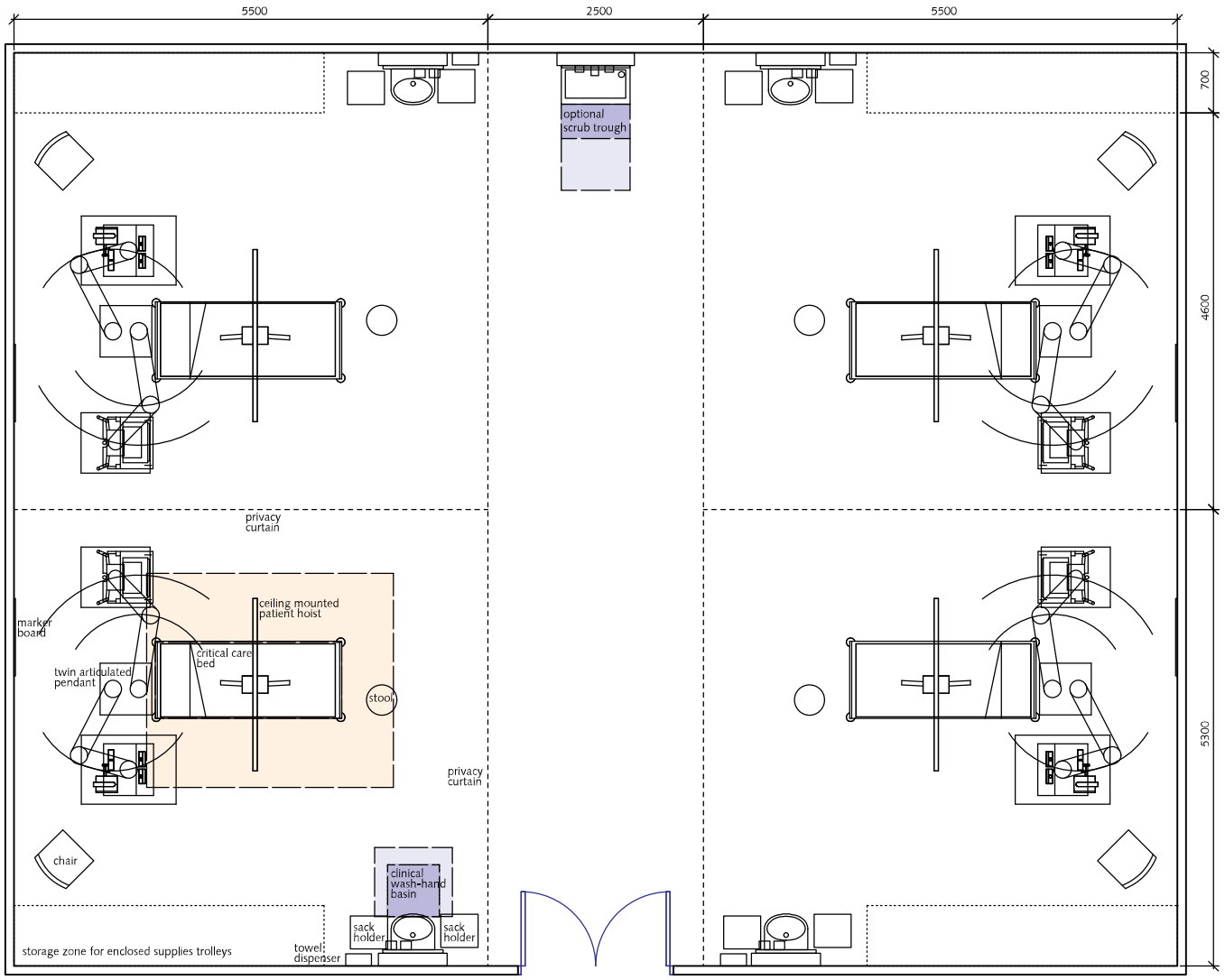


Figure 6 Critical care 4-bed bay

- the density of the curtains should reduce the level of general noise transmitted and also improve the level of auditory privacy in the bed-space;
- the curtains should be easily movable and disposable.

Interview rooms

6.14 Interview rooms should be provided within the vicinity of the bed spaces to enable staff to speak to visitors in privacy. The rooms should be in a quiet location.

7 Clinical support spaces

Ice-making machine bay

7.1 An industrial ice-making machine should be provided to facilitate hypothermic interventions. It should be located in a designated bay.

Storage for bulky consumables, medical gas cylinders, linen and furniture

7.2 The example schedules include a combined storage allowance for bulky consumables, medical gas cylinders, linen and furniture. However, these four categories of item should be stored separately. (It is assumed that non-bulky sterile supplies and consumables are held in the clean utility rooms.)

7.3 The project team should ensure that the provision of standby medical gases reflects the emergency procedures and contingency plans for the unit. The medical gas cylinder store(s) should be easily accessible from clinical areas and enclosed in fire-resisting construction.

7.4 The furniture store(s) will need to accommodate bulky equipment, including mattresses, when not in use, chairs, bariatric equipment and cots.

Clinical equipment store(s)

7.5 A dedicated area should be provided for the storage and charging of transfer equipment (transport trolley, monitors, syringes, ventilators, suction pumps). Dedicated ventilation may be required to remove gases and heat from chargers. An area for hanging endoscopes and transoesophageal echocardiography probes is also required. The clinical equipment store(s) should be within easy access of the bed areas.

Clinical equipment decontamination room

7.6 Clinical equipment should be cleaned following use prior to transfer to the clinical equipment store(s) or, if the equipment requires maintenance, to the equipment servicing room. A clinical equipment decontamination room should be provided for this purpose. This room should be adjacent to the clinical equipment store(s).

Imaging equipment bay

7.7 An open bay should be provided close to the clinical equipment store(s) for the storage of imaging equipment and protective lead aprons. A socket-outlet should be provided for charging equipment.

7.8 Lead aprons should be stored vertically to maintain their protective capability. Suitable wall brackets attached to a load-bearing wall, or mobile stands, are required for this purpose. The bay should also accommodate a mobile X-ray machine, a minimum of one ultrasound machine, and a transoesophageal echocardiography machine. A larger bay is required if mobile image intensifiers are used.

7.9 Regulations pertaining to the use of ionising radiation, such as IR(ME)R 2000 and IRR99, must be complied with.

Resuscitation trolley bays

7.10 It is essential that adequate provision is made for siting resuscitation trolleys within the critical care unit. The precise equipment positioned on these trolleys should be determined locally.

Blood refrigerator bay (optional)

7.11 A blood refrigerator will only be required if a blood store is not available nearby. If provided, the fridge should be located in a designated bay and should be networked to the central system to permit traceability of blood. The use of blood refrigerators is governed by national and local blood transfusion service regulations.

Clinical equipment service room (optional)

7.12 Facilities are required for equipment servicing as defined in equipment manufacturers' user manuals, supplemented by any formally agreed local instructions. A dedicated room should be provided in the critical care unit for this purpose if an existing biomedical engineering workshop is not located nearby. When provided as part of the critical care unit, this room should be adjacent to the clinical equipment decontamination room.

8 Staff spaces

1-person offices

8.1 The clinical director, lead nurse and Faculty of Intensive Care Medicine tutor require dedicated 1-person offices.

Admin areas

8.2 The following staff may require access to a workstation, but these may be provided in an open-plan office environment:

- clinical staff (doctors, nurses, allied health professions);
- outreach staff;
- audit clerk;
- technician;
- secretarial staff;
- IM&T staff;
- organ donation staff;
- research staff.

8.3 Workstations for clinical staff should provide quick and easy access to the patient bed areas in case of an emergency.

Seminar room

8.4 Access to a seminar room within the vicinity of the critical care unit must be provided. An intercom system should be installed between the seminar room and the clinical areas to recall staff in an emergency. The seminar room may double up as a skills laboratory, for example for training in resuscitation, using mannikins, defibrillators, and simulated body parts for venepuncture or suture practice.

Rest rooms

8.5 Staff rest rooms should be located far enough away from patient bed areas for staff to withdraw, but also close enough for them to return quickly to the patient bed areas in case of an emergency. Rest rooms require call systems to recall staff to the clinical areas in case of an emergency.

Changing areas

8.6 Space is required within the changing areas for the storage and disposal of scrub suits and footwear.

9 References

'Comprehensive Critical Care', DH 2000.

Intensive Care Society website.

'Quality Critical Care – Beyond Comprehensive Critical Care'. DH, 2005.

'Acutely ill patients in hospital'. NICE Clinical guidelines CG50, July 2007.

'Rehabilitation after critical illness'. NICE Clinical guidelines CG83, 2009.

'Competencies for recognising and responding to acutely ill patients in hospital'. DH, 2009.

Critical Care Minimum Dataset.

'Payment by Results Guidance for 2011–12', DH.

PL/CNO/2010/3 – 'Eliminating Mixed Sex Accommodation'.

'Census on number of critical care beds in England'.

IR(ME)R 2000 (the Ionising Radiation (Medical Exposure) Regulations 2000).

IRR99 (the Ionising Radiations Regulations 1999).

Inverarity, Donald

From: Henderson, Ronnie
Sent: 11 December 2018 08:55
To: Inverarity, Donald
Cc: Olson, Ewan; Guthrie, Lindsay
Subject: RE: Isolation Room Heater Batteries

Hi Donald,

Can you go to the main site security office at the site cabins and I will pick you up from there. I believe Lindsay is coming as well so have copied her in.

I will pick you up from security at 12:00 and bring you to our office where you can get PPE

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Inverarity, Donald
Sent: 10 December 2018 16:27
To: Henderson, Ronnie
Cc: Olson, Ewan
Subject: RE: Isolation Room Heater Batteries

Hi Ronnie,
It will be myself and Dr Ewan Olson who will be coming tomorrow to represent microbiology. Where should we meet you?
Thanks
Donald

From: Henderson, Ronnie
Sent: 06 December 2018 16:35
To: Inverarity, Donald
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'; Sutherland, SarahJane; Guthrie, Lindsay; Cameron, Fiona
Subject: RE: Isolation Room Heater Batteries

Thanks Donald,

I'll put that in my diary.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Inverarity, Donald
Sent: 06 December 2018 16:29
To: Henderson, Ronnie
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'; Sutherland, SarahJane; Guthrie, Lindsay; Cameron, Fiona
Subject: RE: Isolation Room Heater Batteries

Hi Ronnie,
I can make Tuesday 11th at midday. I'm waiting to hear which of the other microbiologists with engineering aspects of infection control training can be free at that time and once I know I'll forward you their names. I'll be at RIE that morning anyway so no need for a parking space.
Thanks
Donald

From: Henderson, Ronnie
Sent: 06 December 2018 15:53
To: Inverarity, Donald
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'; Sutherland, SarahJane; Guthrie, Lindsay; Cameron, Fiona
Subject: RE: Isolation Room Heater Batteries

Hi Donald,

I have availability as follows;

Fri 7/12 Before 11:00
Mon 10/12 After 10:00
Tue 11/12 12:00 – 15:00
Wed 12/12/18 No availibility
Thu 13/12 09:00 – 13:00

If you let me know which of these suits best and who will be coming and I will arrange the necessary access. If you are travelling by car I can also arrange a parking space for you

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France

NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Inverarity, Donald
Sent: 06 December 2018 15:36
To: Henderson, Ronnie
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'; Sutherland, SarahJane; Guthrie, Lindsay; Cameron, Fiona
Subject: RE: Isolation Room Heater Batteries

Hi Ronnie,
Thanks for your e-mail. Given how crucial it is to get this right, I think it would be best if we could meet and physically see what is being proposed in the building as well as on paper.
Janette has retired so I am copying in colleagues from infection control who would need to be aware of this development.
Can you suggest some days/times when viewing might be possible?
Thanks
Donald

From: Henderson, Ronnie
Sent: 06 December 2018 15:16
To: Inverarity, Donald
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'
Subject: Isolation Room Heater Batteries
Importance: High

Hi Donald,

As you are probably aware the issues surrounding the location of heater batteries in the isolation room lobbies is still rumbling on. We have now had an updated proposal from Multiplex and their designers that I feel moves us closer to an acceptable solution, however I do not want to commit to it without seeking your input/approval.

The proposal can be summarised as follows:

1. Blank off pipework to existing heater batteries above lobby ceiling and drain down. Blanking off to occur at tee off point from main pipe runs. Infrastructure to be left in place for future use.
2. Install ceiling mounted radiant panel with sensor in extract ductwork and adjustable controller external to room.

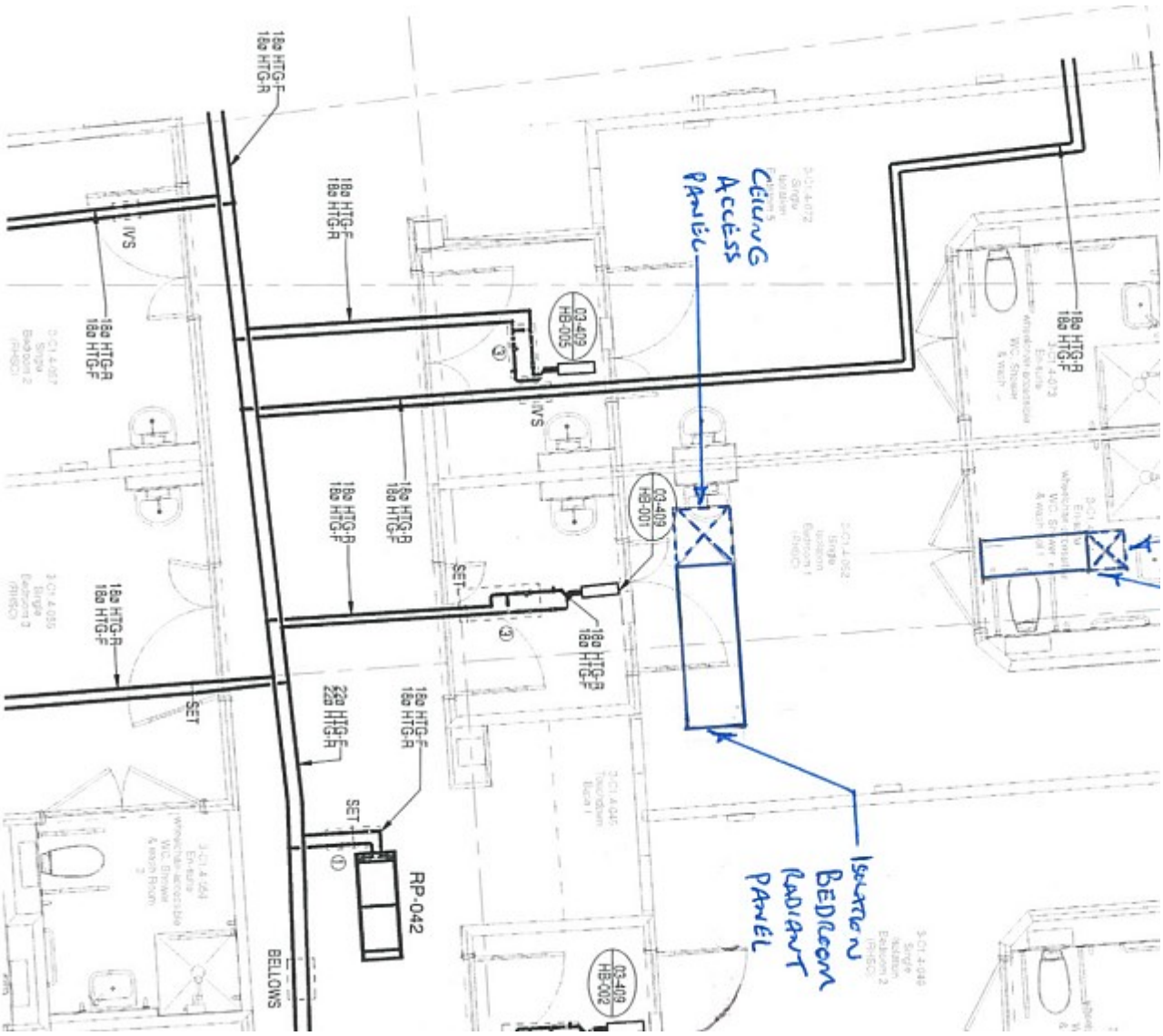
Advantages:

- Panel is fixed flat to ceiling and sealed
- Gives a secondary source of heat that can be adjusted by staff to patients needs
- No drip tray required
- Requires no regular maintenance and any ad hoc repairs can be programmed around room availability.

Disadvantages:

- Additional pipework above isolation room ceiling (already has water services for en suites and WHB running there)
- Another airtight ceiling hatch may be required

For further information please see example of proposed layout of ceiling mounted radiant panel.



Can you please have a look at this and provide any comments and if required we can meet and view an isolation room.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

ISSUES RELATING TO LOCATION OF HEATER BATTERIES

1. Introduction

Due to the specific needs of certain patient groups and spaces there is a requirement to provide higher or lower temperatures than those provided within general areas of the relevant department. In order to meet this requirement water filled batteries are installed local to the space. The relevant guidance covering the location of these batteries is SHTM 03-01, specifically the following clauses:

'4.71 Where possible, wet-trimmer heater-batteries should be located in plant areas.'

'4.72 Where it is necessary to locate heater-batteries in false ceilings etc, consideration should be given to the use of electric heaters. If this is not practicable, drip-trays should be installed under both the battery and the control valve assembly to protect the ceiling. A moisture sensor and alarm should be fitted in the tray. In any event, to facilitate maintenance access, they should be located above corridors or other non-critical areas and never above patient occupied spaces.'

2. Background to Issue

Due to space constraints limiting the available space in corridor voids for ductwork several batteries have been installed above both critical and clinical spaces. Of particular concern is the heater batteries located above all Isolation room lobbies as any work required on these immediately puts the associated isolation room out of use. Uncontrolled leaks from these may also penetrate the sealed ceiling and introduce pathogens into the airstream supplying the patient space. Small leaks can be mitigated by providing drip trays, ideally connected to drain to prevent ponding of stagnant water, and fitted with monitored leak detection. This solution does not eliminate the need for maintenance personnel to access the above ceiling space which will again put the room out of use.

Other concerning locations are above rooms such as CT, X-Ray, Fluoroscopy, Dental and MRI Tech rooms.

3. Engagement

Correspondence with infection control (Donald Inverarity & Janette Rae) has identified serious concerns about the Isolation rooms battery location to the extent that it is unacceptable to them for it to remain there.

Discussion has also taken place with Mike Conroy regarding the radiology related locations which cover the majority of the remaining issues.

Concerns have been fed back to Multiplex and site reviews have been undertaken.

4. **Options for Resolution**

Multiplex have provided drawings showing the location of all heater batteries which fall into 3 categories:

- Batteries they propose to relocate to non clinical/critical locations
- Batteries where drip tray, leak detection and drainage will be provided in current location
- Batteries where it will be both difficult to move and difficult to connect a drip tray to drain – these to be risk assessed with NHSL

The first option would be the preferred solution and Multiplex had indicated on the drawings their intent to move all isolation room batteries to the corridor. The drawings were returned with comments and Multiplex were to advise whether they could be addressed.

5. **Current Position**

Despite earlier commitments Multiplex have withdrawn their proposal to relocate isolation room batteries citing 'interjection' of the independent tester which implies they have sought and received his approval for their position. NHSL have re stated their view that this is unacceptable in these locations. Further dialogue is still required to confirm solutions for the other locations.

Discussions with the independent tester have clarified his input which can be summarised as, providing the risk of leaving it in its current location is no greater than relocating it to the corridor then it should be possible to leave it there. NHSL provided evidence as to why the risk was greater in the current location focusing on the need to move a patient from the room any time a leak occurred or maintenance was required. The reasoning behind the corridor being the better proposal was stated by NHSL as that in the event of a leak or maintenance it would be possible to isolate the heater battery without disrupting the air flow to the isolation room and repair or maintenance could be scheduled for a time when it was possible to turn off ventilation to the room.

A compromise to this was discussed with the Independent Tester whereby the isolation valves for the battery would be located in the corridor along with the ability to safely drain the battery and associated pipework. This would still present a problem in the event of a major leak with the possibility that water and pathogens may penetrate the ceiling and contaminate the airstream, however it is worth noting that this could occur with several other wet services already above the ceiling. This idea is worth investigating further.

It is important to acknowledge that there are locations where it will be extremely difficult, very costly, and significantly time consuming to alter ductwork and services to facilitate the relocation of the heater battery. This does not alter the fact that they are installed in non compliant locations however, with the exception of the isolation rooms issue, this can hopefully be addressed by undertaking suitable risk assessment and deploying mitigation.

6. **Summary & Recommendations**
    - NHSL find the location of heater batteries above the Isolation Room Lobbies to be unacceptable
    - NHSL to consider possibility of locating isolation valves and drain points in corridor but leaving battery above lobby ceiling.
    - Multiplex to make every effort to provide drip tray, drainage, & leak detection to all locations
    - NHSL will participate in a risk assessment process to determine mitigation actions for other clinical locations
    - NHSL to update residual risk register once agreed solutions are identified

Inverarity, Donald

From: Olson, Ewan
Sent: 06 December 2018 16:36
To: Inverarity, Donald; Laurenson, Ian; Kalima, Pota; Henderson, Naomi; MacSween, Karen
Cc: Gadsby, Naomi
Subject: RE: Isolation Room Heater Batteries

This looks better.

However I am slightly concerned about the blanking off of the pipework.

We would need to be happy that this will not create a nidus for biofilm formation.

Can we see any time the infrastructure would be used in future?

Would it be better to strip out the redundant pipework and heater batteries?

Ewan

From: Inverarity, Donald
Sent: 06 December 2018 16:25
To: Laurenson, Ian; Olson, Ewan; Kalima, Pota; Henderson, Naomi; MacSween, Karen
Cc: Gadsby, Naomi
Subject: FW: Isolation Room Heater Batteries
Importance: High

Dear All,
I'm forwarding this to you for your views as you are already aware of some of the concerns we have had about the design of these rooms. I've replied to Ronnie and asked if we can see what is being proposed in the building as well as on paper before giving a reply.
It looks like the only time I can be free to view will be Tuesday next week (11th) at midday. I had hoped that we could delay things until Pota was back but that doesn't look feasible.
If any of you are at RIE at that time or can be free to join me I would value having a second opinion/perspective from another microbiologist(s) familiar with the issues.
Many thanks
Donald

From: Henderson, Ronnie
Sent: 06 December 2018 15:16
To: Inverarity, Donald
Cc: Rae, Janette; Currie, Brian; 'Kolodziejczyk, Kamil K'
Subject: Isolation Room Heater Batteries
Importance: High

Hi Donald,

As you are probably aware the issues surrounding the location of heater batteries in the isolation room lobbies is still rumbling on. We have now had an updated proposal from Multiplex and their designers that I feel moves us closer to an acceptable solution, however I do not want to commit to it without seeking your input/approval.

The proposal can be summarised as follows:

1. Blank off pipework to existing heater batteries above lobby ceiling and drain down. Blanking off to occur at tee off point from main pipe runs. Infrastructure to be left in place for future use.
2. Install ceiling mounted radiant panel with sensor in extract ductwork and adjustable controller external to room.

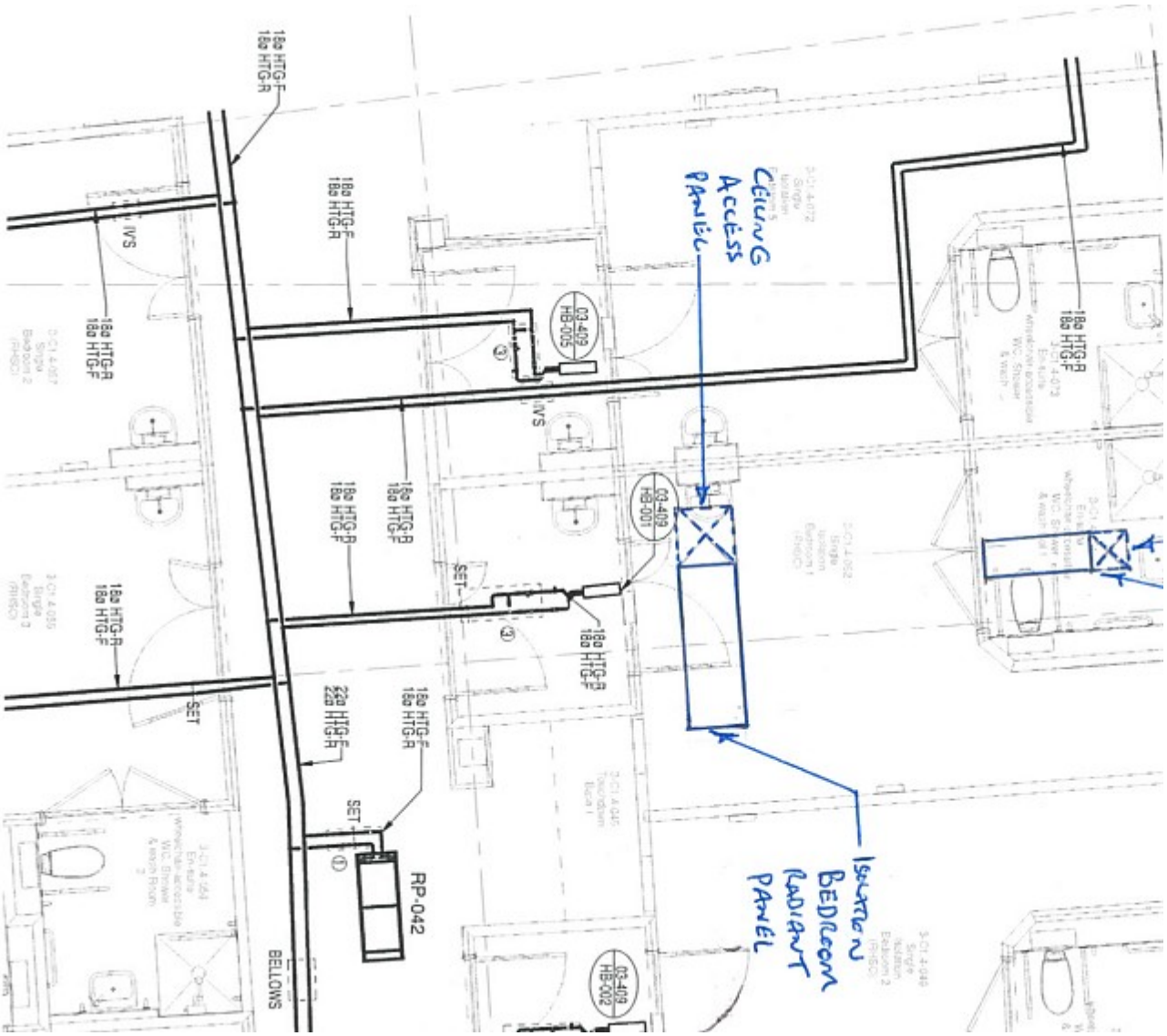
Advantages:

- Panel is fixed flat to ceiling and sealed
- Gives a secondary source of heat that can be adjusted by staff to patients needs
- No drip tray required
- Requires no regular maintenance and any ad hoc repairs can be programmed around room availability.

Disadvantages:

- Additional pipework above isolation room ceiling (already has water services for en suites and WHB running there)
- Another airtight ceiling hatch may be required

For further information please see example of proposed layout of ceiling mounted radiant panel.



Can you please have a look at this and provide any comments and if required we can meet and view an isolation room.

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

	Room No	Room Name	Area (m2)	Ceiling Ht (m)	Volume (m3)	Current Design					Option A 7 ACH within Single Beds *High Velocity at Grille - Potetial Noise Issue above 6 ACH*					Option B 6 ACH within Multi-Beds					Option C 8 ACH within Single Beds *High Velocity at Grille - Potetial Noise Issue above 6 ACH*					Room Name
						Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	
	1-B1-009	Bay 1	115.5	2.7	311.9	348.0	1252.8	348.0	1252.8	4.0	5.0	433.1	1559.3	433.1	1559.3	6.0	519.8	1871.1	519.8	1871.1	4.0	346.5	1247.4	346.5	1247.4	Bay 1
	1-B1-019	Single Room 8	26.0	2.7	70.2	78.0	280.8	78.0	280.8	4.0	7.0	136.5	491.4	136.5	491.4	4.0	78.0	280.8	78.0	280.8	8.0	156.0	561.6	156.0	561.6	Single Room 8
	1-B1-020	Single Room 7	26.0	2.7	70.2	78.0	280.8	78.0	280.8	4.0	7.0	136.5	491.4	136.5	491.4	4.0	78.0	280.8	78.0	280.8	8.0	156.0	561.6	156.0	561.6	Single Room 7
	1-B1-021	Single Room 9	26.3	2.7	71.0	79.0	284.4	79.0	284.4	4.0	7.0	138.1	497.1	138.1	497.1	4.0	78.9	284.0	78.9	284.0	8.0	157.8	568.1	157.8	568.1	Single Room 9
	1-B1-031	Bay 2	110.8	2.7	299.2	332.0	1195.2	332.0	1195.2	4.0	5.0	415.5	1495.8	415.5	1495.8	6.0	498.6	1795.0	498.6	1795.0	4.0	332.4	1196.6	332.4	1196.6	Bay 2
CLOSED	1-B1-037	Single Room 17	27.2	2.7	73.4	82.0	295.2	82.0	295.2	4.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	Single Room 17
CLOSED	1-B1-063	Bay 3	102.8	2.7	277.6	312.0	1123.2	312.0	1123.2	4.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	Bay 3
	1-B1-065	Neonatal Bay 4	60.0	2.7	162.0	181.0	651.6	181.0	651.6	4.0	5.0	225.0	810.0	225.0	810.0	6.0	270.0	972.0	270.0	972.0	4.0	180.0	648.0	180.0	648.0	Neonatal Bay 4
	1-B1-075	Neonatal Cot 22	15.1	2.7	40.8	46.0	165.6	46.0	165.6	4.1	7.0	79.3	285.4	79.3	285.4	4.0	45.3	163.1	45.3	163.1	8.0	90.6	326.2	90.6	326.2	Neonatal Cot 22
						1536	5529.6	1536	5529.6			1563.98	5630.31	1563.98	5630.31		1568.55	5646.78	1568.55	5646.78		1419.30	5109.48	1419.30	5109.48	
												-27.975	-100.71	-27.975	-100.71		-32.55	-117.18	-32.55	-117.18		116.70	420.12	116.70	420.12	
		Single Bed																								
		4 Bed				394.0	1418.4																			

A47310563

From: Gillies, Tracey
Sent: 02 July 2019 09:36
To: Executive, Chief
Subject: Fw: Summary email or critical care ventilation

Sent from my BlackBerry 10 smartphone on the EE network.

From: Inverarity, Donald [redacted]
Sent: Tuesday, 2 July 2019 09:22
To: Gillies, Tracey
Subject: RE: Summary email or critical care ventilation

4 air changes per hour is less than the minimum for any clinical area (general wards are supposed to be 6 air changes per hour). Single room WC are 3 but thats the only area where SHTM 03-01 would advise less than 6. Interestingly a SCBU is only 6 air changes per hour so it might be able to aim for the standard of a SCBU?

Health Facilities Scotland

Appendix 1: Recommended a

Application	Ventilation	ac/Hour	Pressure (Pascals)	Supply Filter
General ward	S / N	6	-	G4
Communal ward toilet	E	10	-ve	-
Single room	S / E / N	6	0 or –ve	G4
Single room WC	E	3	-ve	-
Clean utility	S	6	+ve	G4
Dirty utility	E	6	-ve	-
Ward Isolation room	-	-	-	-
Infectious disease Iso room	E	10	-5	G4
Neutropenic patient ward	S	10	+10	H12
Critical Care Areas	S	10	+10	F7
Birthing Room	S & E	15	-ve	G4
SCBU	S	6	+ve	F7

From: Gillies, Tracey
Sent: 02 July 2019 08:41
To: Inverarity, Donald
Subject: Re: Summary email or critical care ventilation

Do we know who would be suitable for 4 air changes per hour

Sent from my BlackBerry 10 smartphone on the EE network.

From: Inverarity, Donald
Sent: Monday, 1 July 2019 22:48
To: Gillies, Tracey
Subject: RE: Summary email or critical care ventilation

After you had left the meeting, Ronnie and I had some discussion about the 10 air changes per hour for critical care that features in HTM 03-01 and SHTM 03-01 and he is going to contact the author of the document, Malcolm Thomas, to get more understanding on how that figure of 10 was decided. Malcolm is possibly the most informed hospital ventilation engineer in the UK and works now as a freelance ventilation consultant. He also designed the negative pressure isolation rooms that feature in the new building and Ronnie has consulted with him before during this project. If Malcolm can`t answer that point I`d be very surprised.
Donald

From: Gillies, Tracey
Sent: 01 July 2019 22:23
To: Inverarity, Donald
Subject: Re: Summary email or critical care ventilation

No problem thanks I will try and summarise thinking and key questions first thing tomorrow
Important that we explore all options. Iain and I will also speak to lawyers who did settlement in case they have seen something similar before and have suggestions
It would be helpful to have some sense of what the 10 air changes an hour is based on-
How much is science, how much is received wisdom and how much because that's what the SHTM says.
So would be 8 ok??
T

From: Inverarity, Donald
Sent: Monday, 1 July 2019 22:03
To: Gillies, Tracey
Subject: RE: Summary email or critical care ventilation

Sorry, just checking email now after [redacted]. Mobile is [redacted] if needed but I see Ronnie has corrected me. I hadn't realised there were single rooms that weren't isolation rooms. The isolation rooms have different air handling units so are unaffected.
Thinking about it this evening one possible way, in theory, to increase the air changes per hour to 10 would be to reduce the volume of the room(s) being served by the air handling unit that is delivering the 4 air changes per hour by. The number of air changes is equal to the air flow rate (which for us appears to be a constant determined by the air handling unit running at maximum) divided by room volume so to increase the number of air changes (without installing a new air handling unit that delivers a higher air flow rate), the volume of the room(s) served has to reduce proportionally.
Clearly though reducing the volume of the area served by the air handling unit would need a loss of bed capacity or storage space etc. Thats just my simplistic understanding as a medic and an engineer might be better at working out how much the room volume would need to reduce and whether that was feasible based on the design of the ventilation system etc.
All the best

Donald

From: Gillies, Tracey
Sent: 01 July 2019 18:14
To: Inverarity, Donald
Subject: RE: Summary email or critical care ventilation

Can you remind me of your mobile? I thought it was all rooms not just 4b

---

From: Inverarity, Donald
Sent: 01 July 2019 18:12
To: Graham, Iain; Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation

Some additional edits from me in green.
Donald

From: Graham, Iain
Sent: 01 July 2019 17:59
To: Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation

Engineering colleagues will need to review my additions for accuracy.

Iain

Iain F Graham
Director of Capital Planning and Projects
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
[redacted]
[redacted]

From: Gillies, Tracey
Sent: 01 July 2019 17:45
To: Currie, Brian; Graham, Iain; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: Summary email or critical care ventilation

Please correct or amend any misunderstandings:
• IOM have tested critical care ventilation in RHCYP in 4 bedded and single rooms
•It delivers 4 air changes at balanced or slight negative pressure in the multiple occupancy 4 bedded rooms. (Single rooms are not affected).
•The required standard as per SHTM 03-01 Appendix 1 (version 2 February 2014) for Critical Care areas is 10 air changes and less than 10 air changes per hour may facilitate airborne spread of viruses more than if 10 was achieved.

•the only known way to improve air changes with current plant is to accept positive pressure ventilation (ie increasing further the opportunity for spread primarily of pathogens with airborne transmission e.g. respiratory viruses between individuals (staff, visitors and patients) in 4 bedded rooms)

• a bigger plant would be required to deliver the correct air changes – the team are identifying what potential for existing system capacity enhancements might be (ie ramping up the existing air handling plant) and / or within the constraint of the existing ducting (so it would only be the external plant affected).

•this leads us to question whether the space is fit for purpose

•If occupied now, there is risk to patients, visitors and staff of airborne virus transmission (?how much) and difficulties in correcting (would probably require a decant*)

• if not occupied now, move needs postponed

Note - This*would be needed for lesser timeframe) for a planned maintenance programme of works over the course of occupation of the facility.

Survey of Isolation Facilities

Site: Royal Hospital for Sick Children.....
Date: 09 Jan 2020.....

Bldg	Location	Type	HBN04 Supplement 1 Log Book (Held by Estates)						Nurse Records		Equipment			Comments
			Schematic	Design Info	Validation	Verification	PPM	Mods	ΔP	Freq/by	Room WHB	Ante WHB	Alarm	
RHSC	HDU Cubicle 9	8	tbc	tbc	tbc	Yes	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable
RHSC	HDU Cubicle 12	8	tbc	tbc	tbc	Yes	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable
RHSC	ITU Cubicle 1	8	tbc	tbc	tbc	Yes	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable
RHSC	ITU Cubicle 2	8	tbc	tbc	tbc	Yes	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable
RHSC	SAU 1	6	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Waiting Area
RHSC	SAU 2	6	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Play Room
RHSC	SAU 3	6	tbc	tbc	tbc	Yes	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Isolation
RHSC	SAU 4	6	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable T/Room
RHSC	SAU 5	8	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Discharge
RHSC	SAU 6	8	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Consult
RHSC	SAU 7	6	n/a	n/a	n/a	n/a	Yes	Nil	No	n/a	Yes	n/a	via BMS Only	Switchable Consult

Legend:	Negative/Variable Pressure	Totals		Neutral Pressure	Totals
Type 1	Ante Room and En-Suite		Type 9	Ante Room and En-Suite	
Type 2	2 Room Shared Ante Room and Individual En-Suite		Type 10	2 Room Shared Ante Room and Individual En-	
Type 3	2 Room Individual Ante Rooms and Shared En-Suite		Type 11	2 Room Individual Ante Rooms and Shared En-	
Type 4	Ante Room No En-Suite		Type 12	Ante Room No En-Suite	
Type 5	2 Room Shared Ante Room No En-Suite		Type 13	2 Room Shared Ante Room No En-Suite	
Type 6	En-Suite But No Ante Room		Type 14	En-Suite But No Ante Room	
Type 7	2 Room with shared En-Suite But No Ante Rooms		Type 15	2 Room with shared En-Suite But No Ante	
Type 8	No En-Suite and No Ante Room		Type 16	No En-Suite and No Ante Room	

Available and In-date
Available and not in date/use

Surveyor: J Minhinnick AE(V)

A47310563

Inverarity, Donald

From: McMahon, Alex
Sent: 17 June 2019 13:13
To: Goldsmith, Susan; Crombie, Jim; Currie, Brian; Mackenzie, Janice; Graham, Iain
Cc: Kalima, Pota; Fitzpatrick, Ann X; Cameron, Fiona; Sutherland, SarahJane; Horsburgh, Carol; Inverarity, Donald; Guthrie, Lindsay; Henderson, Ronnie; Pennykid, Jennifer
Subject: FW: HAI SCRIBE RHCYP Risks and Mitigations

Susan and Jim (others)

Please see below Donald's comments which he is happy that I share.

Can you ensure that you provide the necessary paper work to Donald and Lindsay well in advance of the ventilation group meeting on the 4th July as if there is any further work required in advance of opening the door on the 9th July this could prove challenging.

Donald and Lindsay along with Sarah Jane are here to assist.

Alex

Professor Alex McMahon
Executive Director, Nursing, Midwifery and Allied Healthcare Professionals
Executive Lead, REAS and Prison Healthcare
NHS Lothian
[redacted]

From: Inverarity, Donald
Sent: 17 June 2019 10:51
To: Guthrie, Lindsay; Kalima, Pota
Cc: McMahon, Alex
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations

If paediatric patients are moving from RHSC to the new site to Little France on 9th July there will need to be functioning ventilation in isolation rooms and functioning operating theatres (perhaps more immediately crucial for patient safety than isolation room ventilation) by the 9th July so although Thu 4th July is the date of the new Ventilation Steering group (which will never have met before this date), I'd be very uncomfortable not seeing the theatre/isolation room ventilation validation reports well before that date as it leaves virtually no time to fix anything significant that is uncovered in the independent validation process before patients are transferred and likely to need access to these (fully functioning) facilities.

All the best
Donald

From: Guthrie, Lindsay
Sent: 17 June 2019 10:04
To: McMahon, Alex; Mackenzie, Janice; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Inverarity, Donald; Kalima, Pota

Cc: Currie, Brian; Crombie, Jim; Henderson, Ronnie; Pennykid, Jennifer
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations

Hi Alex

I would expect to see the documentation for **Risk 2** made available to the Water Safety Group on June 20th, and **Risk 1** ventilation information to be made available to the Ventilation Steering Group on 4th July.

I would suggest those are the 2 most pressing issues that we would seek assurance on, and in the absence of the information requested I'm not sure that the IPCT can give a realistic assessment of clinical risk.

The remaining issues are seeking information to inform an understanding of ongoing risk (such as mould development associated with previous leaks).

Regards
Lindsay

From: McMahon, Alex
Sent: 15 June 2019 08:30
To: Guthrie, Lindsay; Mackenzie, Janice; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Inverarity, Donald; Kalima, Pota
Cc: Currie, Brian; Crombie, Jim; Henderson, Ronnie; Pennykid, Jennifer
Subject: Re: HAI SCRIBE RHCYP Risks and Mitigations

Thanks for sharing Lindsay.

What I got have a sense of, is what is the magnitude of these actions that remain to be complete in terms of risk to pts and in turn opening safely?

I didn't see any timelines. I'm assuming they have to be completed (do they?) before we move pts in?

Alex

Sent from my BlackBerry 10 smartphone on the EE network.

From: Guthrie, Lindsay
Sent: Friday, 14 June 2019 4:07 PM
To: Mackenzie, Janice; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Inverarity, Donald; Kalima, Pota
Cc: Currie, Brian; Crombie, Jim; Henderson, Ronnie; Pennykid, Jennifer; McMahon, Alex
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations

Hi Janice
Please find attached a summary of the IPCT review of the residual risk register, with some further actions suggested, and evidence required.

Kind regards
Lindsay

From: Mackenzie, Janice
Sent: 05 June 2019 14:52
To: Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Inverarity, Donald; Kalima, Pota
Cc: Currie, Brian; Crombie, Jim; Henderson, Ronnie; Pennykid, Jennifer
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations

Dear All

Further to our meeting today please find attached an electronic version of the Residual Risk Register, please can you treat as confidential.
<< File: 080519 RHCYP DCN Residual Risks.xlsx >>
As agreed at the meeting if you can get back to us if you require any further information/evidence in relation to any of the residual risks

Kind regards

Janice

Janice MacKenzie
Clinical Director
RHSC + DCN - Little France

Multiplex
RHSC & DCN Project Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

[redacted]
<< OLE Object: Picture (Device Independent Bitmap) >>
www.nhslothian.scot.nhs.uk/proudhistoriesnewchapters

From: Henderson, Ronnie
Sent: 04 June 2019 17:02
To: Pennykid, Jennifer; Currie, Brian; Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Crombie, Jim; Inverarity, Donald; Mackenzie, Janice
Subject: RE: HAI SCRIBE RHCYP Risks and Mitigations
Importance: High

All,

Please find agenda for tomorrow's meeting below:

1. '86' Item List
2. Residual Risk register

3. Water Safety

- Current Status
- Sampling & Analysis Results
- AE's Meeting

4. Ventilation

- Current Status
- Independent Validation

5. HAI SCRIBE Stage 4
6. AOCB

Regards

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

-----Original Appointment-----
From: Pennykid, Jennifer
Sent: 01 May 2019 10:00
To: Pennykid, Jennifer; Henderson, Ronnie; Currie, Brian; Guthrie, Lindsay; Horsburgh, Carol; Sutherland, SarahJane; Cameron, Fiona; Fitzpatrick, Ann X; Crombie, Jim; Inverarity, Donald; Mackenzie, Janice
Subject: HAI SCRIBE RHCYP Risks and Mitigations
When: 05 June 2019 12:30-14:00 (UTC+00:00) Dublin, Edinburgh, Lisbon, London.
Where: MacKinlay Room RHCYP

<< File: Updated Directions to Site 150398.pdf >>
Dear Jennifer,

I've booked the MacKinlay room for you.

Please go to the "Turnstiles" (shown on map) where the Security team will let you in and then go to the RHCYP Entrance (shown on map) where the Main Reception is. Please sign in at the reception desk.

I'd be grateful if you could send me a list of people attending the meeting so that we can add them to the visitors list to allow them through the security turnstiles.

Many thanks.

With kind regards,

Mashoodha Shah
Project Support Officer

NHS Lothian
RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

From: Gillies, Tracey
Sent: 02 July 2019 08:41
To: Inverarity, Donald
Subject: Re: Summary email or critical care ventilation

Do we know who would be suitable for 4 air changes per hour

Sent from my BlackBerry 10 smartphone on the EE network.

From: Inverarity, Donald
Sent: Monday, 1 July 2019 22:48
To: Gillies, Tracey
Subject: RE: Summary email or critical care ventilation

After you had left the meeting, Ronnie and I had some discussion about the 10 air changes per hour for critical care that features in HTM 03-01 and SHTM 03-01 and he is going to contact the author of the document, Malcolm Thomas, to get more understanding on how that figure of 10 was decided. Malcolm is possibly the most informed hospital ventilation engineer in the UK and works now as a freelance ventilation consultant. He also designed the negative pressure isolation rooms that feature in the new building and Ronnie has consulted with him before during this project. If Malcolm can`t answer that point I`d be very surprised.
Donald

From: Gillies, Tracey
Sent: 01 July 2019 22:23
To: Inverarity, Donald
Subject: Re: Summary email or critical care ventilation

No problem thanks I will try and summarise thinking and key questions first thing tomorrow
Important that we explore all options. Iain and I will also speak to lawyers who did settlement in case they have seen something similar before and have suggestions
It would be helpful to have some sense of what the 10 air changes an hour is based on-
How much is science, how much is received wisdom and how much because that's what the SHTM says.
So would be 8 ok??
T

From: Inverarity, Donald
Sent: Monday, 1 July 2019 22:03
To: Gillies, Tracey
Subject: RE: Summary email or critical care ventilation

Sorry, just checking email now [redacted]. Mobile is [redacted] if needed but I see Ronnie has corrected me. I hadn't realised there were single rooms that weren't isolation rooms. The isolation rooms have different air handling units so are unaffected.
Thinking about it this evening one possible way, in theory, to increase the air changes per hour to 10 would be to reduce the volume of the room(s) being served by the air handling unit that is delivering the 4 air changes per hour by. The number of air changes is equal to the air flow rate (which for us appears to be a constant determined by the air handling unit running at maximum) divided by room volume so to increase the number of air changes (without installing a new air handling unit that delivers a higher air flow rate), the volume of the room(s) served has to reduce proportionally.
Clearly though reducing the volume of the area served by the air handling unit would need a loss of bed capacity or storage space etc. Thats just my simplistic understanding as a medic and an engineer might be better at working out

how much the room volume would need to reduce and whether that was feasible based on the design of the ventilation system etc.
All the best
Donald

From: Gillies, Tracey
Sent: 01 July 2019 18:14
To: Inverarity, Donald
Subject: RE: Summary email or critical care ventilation

Can you remind me of your mobile? I thought it was all rooms not just 4b

---

From: Inverarity, Donald
Sent: 01 July 2019 18:12
To: Graham, Iain; Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation

Some additional edits from me in green.
Donald

From: Graham, Iain
Sent: 01 July 2019 17:59
To: Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation

Engineering colleagues will need to review my additions for accuracy.

Iain

Iain F Graham
Director of Capital Planning and Projects
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
[redacted]
[redacted]

From: Gillies, Tracey
Sent: 01 July 2019 17:45
To: Currie, Brian; Graham, Iain; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: Summary email or critical care ventilation

Please correct or amend any misunderstandings:
• IOM have tested critical care ventilation in RHCYP in 4 bedded and single rooms
•It delivers 4 air changes at balanced or slight negative pressure in the multiple occupancy 4 bedded rooms. (Single rooms are not affected).

•The required standard as per SHTM 03-01 Appendix 1 (version 2 February 2014) for Critical Care areas is 10 air changes and less than 10 air changes per hour may facilitate airborne spread of viruses more than if 10 was achieved.

•the only known way to improve air changes with current plant is to accept positive pressure ventilation (ie increasing further the opportunity for spread primarily of pathogens with airborne transmission e.g. respiratory viruses between individuals (staff, visitors and patients) in 4 bedded rooms)

• a bigger plant would be required to deliver the correct air changes – the team are identifying what potential for existing system capacity enhancements might be (ie ramping up the existing air handling plant) and / or within the constraint of the existing ducting (so it would only be the external plant affected).

•this leads us to question whether the space is fit for purpose

•If occupied now, there is risk to patients, visitors and staff of airborne virus transmission (?how much) and difficulties in correcting (would probably require a decant*)

• if not occupied now, move needs postponed

Note - This*would be needed for lesser timeframe) for a planned maintenance programme of works over the course of occupation of the facility.

From: Currie, Brian
Sent: 05 July 2019 13:46
To: Henderson, Ronnie; Mackenzie, Janice
Subject: FW: QEUH building related HAI issues prom GG&C ICD perspective

Importance: High

FYI and discussion.

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Inverarity, Donald
Sent: 05 July 2019 13:28
To: McMahon, Alex; Gillies, Tracey; Curley, George; Currie, Brian; Graham, Iain
Cc: Guthrie, Lindsay; Kalima, Pota; Cameron, Fiona
Subject: QEUH building related HAI issues prom GG&C ICD perspective
Importance: High

Dear All,
Please see the reply I received this morning from my equivalent, Dr Teresa Inkster, in NHS GG&C based at QEUH and issues there she has had to deal with from an HAI risk which we need to be aware of. She is happy for this information to be shared with NHS Lothian.

Hi Donald

SHTM 0301 allows for thermal wheel technology provided they are fitted with a purge sector. However thermal wheels come with the risk of dirty extract air mixing with clean supply

In our paediatric haem-onc ward (non BMT patients) we experienced a significant number of outbreaks over a 2 year period. These proved difficult to control despite aggressive IC measures.

As part of the investigation we asked for an external review of the ventilation system. What we found was air changes of < 3 (due to chilled beams), rooms at slightly negative pressure to corridor, thermal wheel technology and ductwork configuration issues.

All of this combined was felt to be a factor in these outbreaks as mixing of dirty and clean air was occurring. HPS were asked to investigate and the conclusion of their report was that our outbreaks were not due to practice or IC issues but to the environment. Difficult to prove that retrospectively but it makes sense

Therefore, I would suggest that thermal wheel technology in a high risk area is reviewed, if you have it. I also would recommend getting detailed info regarding the ventilation spec in your haem onc ward - as I mentioned it was non BMT patients affected

I have listed below for you issues that have been identified as a risk in our new build since opening , I hope this helps

-Dialysis points - leaks and mould in walls due to untightened connection points and in one case faulty plumbing with backflow from a sluice area

- Water system - contaminated at outset and no control measures implemented

- Water coolers - poor maintenance and dead legs in the system, were positive for Gram negs in water incident

- dishwashers on wards - not fitted correctly and grew fungus including Exophiala in CF patients , we removed them

- Taps - taps in high risk units with flow straighteners , these were not maintained and were heavily contaminated with Gram negatives. We have replaced with a Marwick tap with copper bioguard

- Patient bathrooms in haem onc and CF- poor fittings, non water resistant gyproc, unsealed areas - significant problems with mould

- poor sink design with splash risk - we have replaced haem onc sinks with the new armitage shank shark fin model

- Drains - use of an aluminium sphigot which was heavily corroded and laden with black slime - retrograde biofilm creep into sink, resulted in Gram negative bacteraemias in haem onc patients

- Vents - makes sure you have a regular cleaning schedule , we had issues with dust dropping into rooms

- Air con units - not recommended for high risk areas. Again maintenance an issue and we grew Aspergillus from them

Multi Bed – Ventilation Amendment Proposal to Achieve Room Balance
WW-SZ-XX-DC-XXX-010

Proposed Solution to Rooms Identified as Being of Concern

Room Reference Location	Ventilation Layout Drawing Number	Room Number	Room Description	Proposed Solution	Severity of Works			Ductwork Fabricated
					Local	Medium	Major	Yes/No
A	WW-Z4-00-PL-524-001K	G-A2-054	Multi Bed (4) Room Occupancy 10 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 10ac/hr. Ducts servicing en-suite & toilets to be retained at their original sizes. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork main. Supply & Extract Duty 174l/s. (Equates to 17 people).		✓		Yes
B	WW-Z4-00-PL-524-001K	G-A2-046	Multi Bed (4) Room Occupancy 10 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 10ac/hr. Ducts servicing en-suite & toilets to be retained at their original sizes. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork main. Supply & Extract Duty 174l/s. (Equates to 17 people).		✓		Yes
C	WW-Z4-00-PL-524-002L	G-A2-028	Multi Bed (4) Room Occupancy 10 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 10ac/hr. Ducts servicing en-suite & toilets to be retained at their original sizes. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork main. The main itself will be increased in size over a defined length. Supply & Extract Duty 174l/s. (Equates to 17 people).		✓		Yes
D	WW-Z4-01-PL-524-001J	1-B1-063	Multi Bed (4) Room Occupancy 15 People	Retain the supply ventilation at 4ac/hr. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. The existing general extract ductwork currently serving the room has been increased in size and another grille added to it to serve the room. This will achieve a balanced room pressure. New branch duct to be connected locally into the existing general extract ductwork main. Supply & Extract Duty 312l/s. (Equates to 31 people).		✓		Yes
E	WW-Z4-01-PL-524-001J	1-B1-031	Multi Bed (4) Room Occupancy 15 People	Retain the supply ventilation at 4ac/hr. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. The existing general extract ductwork currently serving the room has been increased in size and another grille added to it to serve the room. This will achieve a balanced room pressure. New branch duct to be connected locally into the existing general extract ductwork main. Supply & Extract Duty 332l/s. (Equates to 33 people).		✓		Yes
F	WW-Z4-01-PL-524-001J	1-B1-009	Multi Bed (4) Room Occupancy 15 People	Retain the supply ventilation at 4ac/hr. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. The existing general extract ductwork currently serving the room has been increased in size and another grille added to it to serve the room. This will achieve a balanced room pressure. New branch duct to be connected locally into the existing general extract ductwork main. The main itself will be increased in size over a defined length. Supply & Extract Duty 348l/s. (Equates to 34 people).		✓		Yes

Issue	Date	By	Checked
1	08.02.17	BR	SMcK
2	14.02.17	BR	SMcK
3	22.02.17	BR	SMcK
4	11.05.17	BR	SMcK
5	23.05.17	BR	SMcK
6	14.06.18	BR	SMcK
7	06.04.18	BR	SMcK

Multi Bed – Ventilation Amendment Proposal to Achieve Room Balance
WW-SZ-XX-DC-XXX-010

Room Reference Location	Ventilation Layout Drawing Number	Room Number	Room Description	Proposed Solution	Severity of Works			Ductwork Fabricated
					Local	Medium	Major	Yes/No
G	WW-Z3-03-PL-524-001G	3-C1.3-011	Multi Bed (4) Room Occupancy 14 People	Retain the supply ventilation at 4ac/hr and the en-suite and shared wet room ventilation at 10ac/hr. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork main. The main itself will be increased in size over a defined length. Supply & Extract Duty 176l/s. (Equates to 17 people).		✓		Yes
H	WW-Z3-03-PL-524-001G	3-C1.3-013	Multi Bed (4) Room Occupancy 14 People	Retain the supply ventilation at 4ac/hr and the en-suite and the shared wet room ventilation at 10ac/hr. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork main. The main itself will be increased in size over a defined length. Supply & Extract Duty 174l/s. (Equates to 17 people).		✓		Yes
I	WW-Z4-03-PL-524-001G	3-C1.2-026	Multi Bed (4) Room Occupancy 14 People	Retain the supply ventilation at 4ac/hr. Bay 1 toilets, ventilation is 10ac/hr and shared en-suite ventilation is 17ac/hr. Introduce a new general extract and dirty extract ductwork and grilles into the respective rooms to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general and dirty extract ductwork mains. Door grilles will be provided within the shared en-suite, shared en-suite ventilation will be 17ac/hr. Supply & Extract Duty 176l/s. (Equates to 17 people).		✓		Yes
J	WW-Z4-03-PL-524-001G	3-C1.2-023	Multi Bed (4) Room Occupancy 14 People	Retain the supply ventilation at 4ac/hr. Bay 1 toilets, ventilation is 10ac/rd and shared en-suite ventilation is 17ac/hr. Introduce a new general extract and dirty extract ductwork and grilles into the respective rooms to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general and dirty extract ductwork mains. Door grilles will be provided within the shared en-suite, shared en-suite ventilation will be 17ac/hr. Supply & Extract Duty 176l/s. (Equates to 17 people).		✓		Yes
K	WW-Z4-03-PL-524-002G	3-C1.1-018	Multi Bed (4) Room Occupancy 15 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 17ac/hr. Ducts serving the en-suites and toilets to be increased in size. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch duct to be connected locally into the existing general extract ductwork main. Door grilles will be provided within the en-suite and toilets. Supply & Extract Duty 184l/s. (Equates to 18 people).		✓		Yes
L	WW-Z4-03-PL-524-002G	3-C1.1-046	Multi Bed (4) Room Occupancy 15 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 17ac/hr. Ducts serving the en-suites and toilets to be increased in size. Introduce new general extract ductwork and grille into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch duct to be connected locally into the existing general extract ductwork main. Door grilles will be provided within the en-suite and toilets. Supply & Extract Duty 186l/s. (Equates to 18 people).		✓		Yes

Issue	Date	By	Checked
1	08.02.17	BR	SMcK
2	14.02.17	BR	SMcK
3	22.02.17	BR	SMcK
4	11.05.17	BR	SMcK
5	23.05.17	BR	SMcK
6	14.06.18	BR	SMcK
7	06.06.18	BR	SMcK

Multi Bed – Ventilation Amendment Proposal to Achieve Room Balance
WW-SZ-XX-DC-XXX-010

Room Reference Location	Ventilation Layout Drawing Number	Room Number	Room Description	Proposed Solution	Severity of Works			Ductwork Fabricated
					Local	Medium	Major	Yes/No
M	WW-Z4-01-PL-524-001J	1-B1-065	Multi Cot (3) Room Occupancy 9 People	Retain the supply ventilation at 4ac/hr. Introduce new general extract ductwork and grilles into the room to provide 4ac/hr. Branch duct to be connected locally into the existing general extract ductwork. The existing general extract ductwork currently serving this area has been increased in size. This will achieve a balanced room pressure. Supply & Extract Duty 144l/s. (Equates to 14 people).		✓		Yes
N	WW-Z4-01-PL-524-002F	1-L1-100	Multi Bed (4)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
O	WW-Z4-01-PL-524-002F	1-L1-097	Multi Bed (4)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
P	WW-Z4-03-PL-524-001F	3-C1.8-027	Multi Bed (4)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
Q	WW-Z4-03-PL-524-001F	3-C1.8-016	Multi Bed (4)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
R	WW-Z3-03-PL-524-002G	3-C1.4-084	Multi Bed (4)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
S	WW-Z3-03-PL-524-002G	3-C1.4-061	Multi Bed (6)	No change to the existing room ventilation provision and ductwork design, room is currently positive to corridor.	N/A	N/A	N/A	N/A
T	WW-Z4-03-PL-524-002G	3-D9-022	Multi Bed (3) Room Occupancy 11 People	Retain the supply ventilation at 4ac/hr and the en-suite ventilation at 10ac/hr. Introduce new general extract ductwork and grilles into the room to provide 4ac/hr overall. This will achieve a balanced room pressure. Branch ducts to be connected locally into the existing general extract ductwork mains. One of the mains itself will be increased in size over a defined length. Supply & Extract Duty 122l/s. (Equates to 12 people)		✓		Yes

Notes :-

1) Room occupancy is taken from the Clinical Output Based Specifications.
2) Bedroom ventilation is based on a fresh air rate allowance of 10l/s per person in line with SHTM 03-01.

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1	08.02.17	BR	SMcK
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5	23.05.17	BR	SMcK
6	14.06.18	BR	SMcK
7	06.06.18	BR	SMcK

RDD	
Reviewable Design Data : Section 5 of Schedule Part 6	
	Board
Name	J. MACKENZIE
Date	26/7/18
Sign	[redacted]
Level	A
Comment:	
In accordance with the Levels as set out in Clause 4 Effect of Review and Schedule Part 8 (Review Procedure); Level A : No Comment Level B : Proceed subject to Amendment as noted Level C : Subject to amendment as noted Level D : Rejected	

Brookfield MULTIPLEX | BM [redacted]
Built to outperform.

Contractor Document Review
RHSC & DCH Edinburgh

A ☑ No Comment
B ☐ Noted subject to comments
revise and resubmit within 7 business days
C ☐ Rejected - revise and resubmit within 7 business days

BM Checked by: [redacted]
Date: 27/7/18

[redacted]

Order Nr: **P1600009/P016-01490** **Cost Code: 8204**.

THE ARTICLES OF AGREEMENT

THIS AGREEMENT is made on the 24th day of February 2020.

BETWEEN

Imtech Engineering Services Central Limited ("the Contractor")
(Company registration No. *00443522*)

whose address is G&H House, Hooton Street, Carlton Road, Nottingham, NG3 5GL
and

HOARE LEA LLP ("the Consultant"). (Company registration No. OC407254)

whose address is 155 Aztec West, Almondsbury, Bristol, England, BS32 4UB

THE PARTICULARS OF AGREEMENT

IHS Lothian Limited (Company registration No. SC493676) ("the Main Contractor")

is proposing to appoint or has appointed the Contractor as a specialist sub-contractor to execute work under a design/build Sub-Contract in relation to

Commence with designs using reasonable endeavours to proceed in accordance with the indicative programme provided by the Main Contractor.This shall be inclusive of such necessary works, surveys or investigations at the Site as may be required in order to prepare such detailed Designs in respect of the Ventilation Works("**Advance Design Works").** Whilst the Consultant shall commence with the whole of the Advanced Design Works, this Appointment is limited to commencing such works and not undertaking scope in excess of the maximum value of £150,000.00 which shall be superseded following the conclusion of the Contractor's appointment for the main works. ("the Works")

at

the Royal Hospital for Sick Children, Child, and Adolescent Mental Health Service and the Department of Clinical Neurosciences adjoining the Royal Infirmary of Edinburgh, Little France, Edinburgh ("the Project")

The Contractor has decided to appoint the Consultant to provide professional services described in Appendix 2 for the Project and the Consultant has agreed to accept the appointment on the terms and conditions set out within this Agreement.

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

This Agreement contains the following defined terms:

"Appendices"	the Appendices to the Agreement, as completed by the parties.
"Brief"	means the Brief describing the Contractor's requirements for the Works to the Project referred to in Appendix 1.
"Design Documents"	means all drawings, plans, bill of quantities, specifications, designs, calculations and other documents including electronically generated data prepared by or on behalf of the Consultant in relation to the Project.(as detailed in Appendix 4)
"Project"	means the Project described in Appendix 1.
"Services"	means the Services to be provided by the Consultant under this Agreement, including the Services listed in Appendix 2.
"Sub- Contract"	the Contract entered into between the Contractor and the Main Contractor.
"Works"	the Works to be carried out by the Contractor under the Sub-Contract for the Main Contractor.

1.2 The attached Appendices 1,2,3,4,5 & 6 form part of this Agreement

1.3 The clause headings in this Agreement are for convenience only and do not affect its interpretation.

1.4 Words importing the singular meaning include where the context so allows the plural meaning and vice versa.

1.5 Words of one gender include both genders and words denoting natural persons include firms and companies and all are to be construed interchangeably in that manner.

2.0 APPOINTMENT

The Contractor appoints the Consultant and the Consultant agrees to act as Building Services Drawing Package Provider to include, but not limited to the following based upon the terms and conditions of this Agreement.

The works consist as follows:

1. Identify co-ordination issues in the contract issue design in all areas of the building and to communicate those areas for the project team to review. This includes capturing Fulcro co-ordination items previously highlighted to the design teams.

2. Generate with the engineering team an agreed materials matrix & 'Golden rules' to enable family/database creation, this is utilised for accurate modelling & data output.

3. Carry out building spatial co-ordination, validation & Generate clash detection reports.

4. Confirm spatial fit of plant & Equipment

5. To identify and highlight risk areas in regards to: Coordination, Completeness & Tolerances. These items are to be raised in the form of agreed mark-up sheets which require to include;

- Plans
- Elevations
- Sections
- 3D Screen grabs/shots
- Grid Locations
- Architecture
- Structure
- MEP

6. Produce all co-ordinated installation drawings to construction standards for scoped services (See Appendix 4) based upon the designer's information. This includes the provision for the following;
- Fully coordinated Services Drawings including interfacing & co-ordinating with CDP drawings.
- Single Services Drawings High & low Level
- All Scoped Services Systems Schematics
- Details & Sections Drawings
- BWIC Drawings
- Record Drawings
- Trade Interface Drawings
- Conversion of all co-ordinated 3D modelling data to 2D

7. Produce weekly reports in an agreed format confirming areas that require additional design input from the consultant teams.

8. Attend weekly / fortnightly co-ordination workshops to discuss reporting output

9. Work with the engineering team to prepare pre drawing checklists to ensure all equipment and materials are 'approved' to be included within drawn areas prior to commencement of any fabrication & construction drawings.

10. Issue CADMEP models weekly to the CDE (Common Data Environment) in line with the Imtech collaborate working protocol complete with report containing model completion percentages.

11. Issue all drawings to the CDE in line with the Imtech collaborate working protocol in Formats as listed below;

    - DWG's
    - PDF's
    - NWD's

12. Revise drawings based on design team comments

13. Ensure any matters identified under items 1 to 12 above undertaken by the Consultant are in strict accordance with the requirements of the Works identified by the Main Contractor.

3.0 COMMENCEMENT & TERM

The Consultant's Appointment shall be considered as having commenced from the date stated in this Agreement or if earlier, from the time when the Consultant commenced the provision of the Services set out in this Agreement. The appointment will continue until the completion of the Services or until it terminated by either party in accordance with this Agreement. However, the liability of the Consultant under this Agreement shall continue until 12 years from the date that practical completion is certified under the Sub-Contact for the project, except with respect to claims which have been notified before that date.

4.0 SCOPE OF SERVICES & DUTIES OF CONSULTANT

4.1 The Consultant shall as and when required carry out the Services listed in Appendix 2.

4.2 In performing the Services, the Consultant shall exercise the degree of reasonable skill, care and diligence to be expected of an appropriately qualified and competent Professional Consultant experienced in carrying out Services of the type defined in this Agreement for projects of a similar scope purpose and size as the Project. Notwithstanding any other provision in this Agreement, the Consultant's duty, in the performance of the scope of Services and obligations derived from third party agreements and other documents in or connected with this Agreement, shall be limited to the exercise of reasonable skill and care only and nothing in or connected with this Agreement shall imply or import any form of fitness for purpose or any guarantee of life expectancy.

4.2 The Consultant shall comply with any reasonable directions given by the Contractor or is duly authorised representative and shall designate a Consultant's Representative who shall be deemed to have full authority to give and receive Notices.

4.3 In the exercise of its duties, the Consultant shall

4.4.1 Provide all information reasonably required by the Contractor, promptly and in good time so as not to delay or disrupt the progress of the Project or as detailed in Appendix 2.

4.4.2 Provide the Contractor with regular reports on progress and on matters of interest and, in particular, the Consultant will promptly bring to the attention of the Contractor any matters which might affect the programme or cost of the project.

4.4.3 Coordinate its Services with those to be provided by other Consultants and any Contractors appointed by the Contractor and, to the extent required by this Agreement, monitor and report on the activities of other Consultants and Contractors.

4.4.4 Comply with all relevant legislation and statutory requirements including, but not limited to the latest CDM (Construction, Design and Management) Regulations and Joint Fire Code.

4.4.5 Not specify or authorise for use in this project any materials that are generally known to be deleterious to health and safety or to the durability of works in the particular circumstances in which they are to be used or which otherwise are not in accordance with relevant British Standards, Codes of Practice and Euro Codes.

4.4.6 Ensure that key personnel of the Consultant identified in this Agreement will not be removed or replaced without first notifying the Contractor and obtain its consent, not to be unreasonably withheld.

4.4.7 Not without the further approval of the Contractor, alter the Consultant's design to any material extent once the design has been approved by the Contractor.

5.0 FEES AND PAYMENT

5.1 The Contractor shall pay the Consultant the fees for the Services in accordance with the Terms of this Agreement and as set out in Appendix 3.

5.2 Unless otherwise stated in Appendix 3, payments due to the Consultant under this Agreement shall become due for payment 15 days after the monthly interim application 'Applied To Date' in the attached schedule (the payment due date"). The Consultant's applications for payment must state the sum that the Consultant considers to be due as at the payment due date and the basis upon which that sum is calculated.

5.3 The final date for payments ("the final payment due date") shall be 20 days from the date upon which the payment became due.

5.4 The Contractor shall, as per the dates detailed in the Payment Schedule (refer to Appendix 3) give a "Pay Notice" specifying the sum that the Contractor considers to be due or to have been due at the payment due date and the basis on which that sum is calculated. This sum, subject to any Pay Less notice issued by the Contractor under clause 5.5, shall be the sum payable to the Consultant on or before the final date for payment. If a Pay notice is not given by the Contractor, the amount of the payment due to the Consultant shall be, subject to any Pay Less notice given by the Contractor under clause 5.5, the sum stated in the Consultant's application for payment or invoice submitted in accordance with clause 5.2.

5.5 If the Contractor intends to pay less than the amount in the Pay notice or the sum stated in the Consultant's application for payment or invoice submitted in accordance with clause 5.2, whichever shall apply under clause 5.4, then not later than 2 days before the final payment due date of any payment, the Contractor may give written notice (a "Pay Less notice") to the Consultant which shall specify the sum the Contractor considers to be due or to have been due at the final payment due date and the basis on which the sum has been calculated. The amount to be paid to the Consultant shall not be less than the sum stated as due in the Pay Less notice.

5.6 No payment will be made until a~~n original~~ copy of this Agreement, is signed and initialled where required by the Consultant and provided to the Contractor.

6.0 ADDITIONAL SERVICES

6.1 If the Contractor requests any Services that, in the opinion of the Consultant, are not expressly or by implication covered in Appendix 2, the Consultant must immediately inform the Contractor if it intends to claim any extra fee for those services. The notice must be accompanied by an initial estimate of the likely cost and of any impact on the programme for the Project.

6.2 Once the Contractor has considered the Consultant's notice and received any further information it requires, the Contractor within a reasonable time will inform the Consultant in writing whether it agrees to the value of the said additional works. Under no circumstances must any additional services be carried out without written authority from the Contractor.

6.3 In the event that a formal instruction is issued to the Consultant, the Consultant must immediately act upon this instruction and notify the Contractor of any costs as outlined in clauses 6.1 and 6.2.

7.0 COPYRIGHT LICENCE

7.1 The Consultant hereby grants to the Contractor an irrevocable royalty-free non-exclusive licence to use, copy and reproduce all and any of the Design Documents for any purpose whatsoever connected with the Project including but without limitation the execution, completion, operation, maintenance, letting, management, sale,

advertisement, alteration, reinstatement and repair of the Project. The Consultant shall not be liable for any such use by the Contractor of the Design Documents for any purpose other than that for which the same were prepared and provided by the Consultant.

7.2 The licence referred to in clause 7.1 carries the right to grant sub-licences, shall be transferable to third parties and shall continue in force notwithstanding any termination of the Agreement and/or the Consultant's employment under the Agreement.

7.3 The Consultant warrants that the use of the Design Documents for the purpose of the Project and/or pursuant to the licence granted pursuant to clause 7.1 shall not infringe the rights of any third party.

8.0 PUBLIC LIABILITY AND PROFESSIONAL INDEMNITY INSURANCES

8.1 The Consultant shall maintain public liability in the sum of £10M any one claim and professional indemnity insurance in the sum of £10M any one claim and unlimited in the period of insurance but subject to separate aggregate limits of indemnity for all claims notified within the period of insurance relating to pollution/contamination, cladding, fire safety and asbestos (The limit of liability in respect of asbestos related claims is GBP 5,000,000 in the aggregate) and for the length of time sufficient to cover the Consultant's liabilities under this Agreement. This insurance shall be arranged with reputable insurers and maintained for so long as the Consultant has any liability to the Contractor under this Agreement. The Consultant will whenever reasonably requested produce to the Contractor suitable evidence of the terms of its policy and of the payment of the premiums.

8.2 If professional indemnity insurance ceases to be available in the market at commercial terms or rates of premium the Consultant must notify the Contractor without delay. The parties will then discuss and attempt to agree how best to protect their respective positions in the absence of such insurance.

9.0 ASSIGNMENT & SUBCONTRACTING

9.1 The Contractor may assign its interest in this Agreement with the consent of the Consultant, which shall not be unreasonably withheld or delayed.

9.2 The Consultant shall not without the written consent of the Contractor assign or transfer any of its rights or obligations under this Agreement to any third party.

9.3 If the Consultant wishes to sublet any of the Services it must first obtain the written consent of the Contractor. Subletting shall not in any way relieve the Consultant of any of its obligations under this Agreement and the Consultant will be fully liable to the Contractor for the work of any sub-consultant.

10.0 TERMINATION

10.1 This Agreement may be terminated by notice:

10.1.1 By the Contractor if the Consultant commits a material breach of this Agreement and (in the case of a breach capable of remedy) fails to take steps to remedy the breach within 7 days of being requested to do so in writing;

10.1.2 By either party (the Consultant must give the Contractor 7 days-notice of this occurrence) if the other is unable to pay its debts when they fall due or an application for an administrator is presented to the court or a receiver or manager or trustee in bankruptcy is appointed or a resolution passed for its winding up.

10.1.3 By the Contractor giving 7 days-notice if it decides not to proceed with the Project at any time;

10.1.4 By either party if the Contractor suspends the performance of the Services for more than 180 days.

10.2 Except where termination is due to the breach of contract or insolvency of the Consultant, the Contractor shall upon termination pay only reasonable costs incurred, valued on a fair and reasonable basis, due up to the date of termination incurred by the Consultant which are directly attributable to termination.

10.3 In the case of termination by the Contractor on account of the Consultant's breach of contract or insolvency, the Contractor may withhold payment of any and all outstanding fees and expenses until it has ascertained and set off or recovered from the Consultant any additional costs which it incurs as a direct result of the termination of this Agreement.

10.4 ~~The Contractor shall be entitled to set off against any sums (including retention) otherwise due to the Consultant under this Agreement, the amount of any damages, cost, losses and expenses incurred by the Contractor or which the Contractor in good faith estimates it is likely to incur as a result of any breach of this Agreement by the Consultant and/or the amount of any damages, cost, losses and expenses incurred by the Contractor or which the Contractor in good faith estimates it is likely to incur as a result of any breach by the Consultant of any contracts or other agreements entered into between the parties~~.

11.0 SUSPENSION

11.1 The Contractor may suspend the performance of any of the Services by giving reasonable notice to the Consultant.

11.2 If suspension of the Services continues for more than 180 days either party may give notice to terminate this Agreement.

11.3 Upon suspension by the Contractor the Consultant shall be paid only reasonable costs incurred, valued on a fair and reasonable basis, due up to the date of suspension.

12.0 CONFIDENTIALITY

12.1 The Consultant agrees that during the term of this appointment, and for a period of two years after its termination for whatever reason, it will not disclose to any party other than in the normal course of its duties under this Agreement any information concerning the Project or any other information of a confidential nature which may come into its possession as a result of this appointment unless expressly authorised in writing by the Contractor.

12.2 The Consultant must obtain the written consent of the Contractor before it issues any press release or publishes or permits the publication of any information concerning the Project.

13.0 NOTICES

13.1 Any notice under this Agreement must be given in writing. A notice will be treated as being properly given if it is delivered by hand or sent by registered post to the address of the recipient shown in this Agreement or any new address of which notice has been given under this clause.

13.2 Notice delivered by hand shall be treated as delivered at the time of delivery, unless this occurs outside the normal working hours of the recipient in which case delivery shall be treated as occurring on the next working day. Notice sent by registered post shall be treated as delivered after two working days.

14.0 RESOLUTION OF DISPUTES

14.1 Without prejudice to either parties' right to refer any dispute to Adjudication at any time, if any dispute or difference arises in connection with this Appointment, directors or other senior representatives of the parties with authority to settle the dispute will, within 7 days of a written request from one party to the other, meet in a good faith effort to resolve the dispute.

14.2 If the dispute is not resolved at that meeting, the parties may attempt to settle it by mediation in accordance with the CEDR Model Mediation Procedure. Unless otherwise agreed between the parties, the mediator will be nominated by CEDR. To initiate the mediation a party must give notice in writing ('ADR notice') to the other party to the dispute requesting mediation.

14.3 The dispute may be referred to adjudication at any time. Neither party shall take any steps in any proceedings relating to any dispute unless and until an adjudicator has delivered his decision on the dispute to the parties in accordance with this clause.

14.4 Clause 14.3 shall be subject to any rule of law to the contrary, shall not prejudice any of the parties' rights where the adjudicator lacks jurisdiction and shall not prevent either party issuing a claim for but shall prevent any further steps being taken.

14.5 The adjudicator shall be nominated at the request of the referring party by the Royal Institution of Chartered Surveyors

14.6 The procedure for the adjudication will be that set out in the Scheme for Construction Contracts.

14.7 If a dispute arising under this Agreement concerns matters arising in a dispute between the Contractor and another consultant or contractor appointed in connected with the project, the Contractor shall be entitled to require either that the dispute be referred to the adjudicator who has been appointed in relation to that other dispute or that the adjudicator appointed under this Agreement shall also be appointed as adjudicator in relation to that other dispute.

14.8 This Agreement shall be subject to English law and entirely without prejudice to clause 14.3. any dispute, if not resolved by agreement or by adjudication will be finally resolved by the English Courts.

15.0 GOVERNING LAW

This Agreement shall be governed by English Law.

16.0 PREVIOUS AGREEMENT

The provisions of this Agreement supersede the provisions of all or any previous agreements or understandings between the parties in relation to the subject matter of this Agreement.

17.0 RIGHTS OF THIRD PARTIES

Subject to clause 9, a person who is not a party to this Agreement shall not have any rights under or in connection with it by virtue of the Contracts (Rights of Third Parties) Act 1999.

18.0 PARTNERSHIP

Save where the Consultant is an LLP, where the Consultant is a partnership, each of the partners from time to time shall be jointly and severally liable for all obligations of the Consultant under this Deed.

19.0 WARRANTIES

The Consultant has agreed and has made due allowance within his fee for providing a reasonable quantity of collateral warranties for the benefit of reasonably agreed third parties, on reasonable terms, which are required to be procured from the Consultant by the Contractor under the Sub-Contract.

20.0 PI INSURANCE

Not Used

21.0 LIMITATION

Notwithstanding anything to the contrary in this Agreement, and without prejudice to any provision in this Agreement whereby liability is excluded or limited to a lesser amount, the total liability of the Consultant under or in connection with; this Agreement, whether in contract or in tort, in negligence (other than for personal injury, death, fraud and/or fraudulent misrepresentation),indemnity or for breach of statutory duty or otherwise shall not exceed the sum of £10,000,000 (Ten million pounds).

The Consultant shall have no asbestos related duties or obligations.

The Consultant shall not be held responsible or liable for any delay, breach or failure to complete an obligation under or in connection with this agreement caused by either the Employer or any party with whom the Consultant has no contractual relations.

IN WITNESS of which this Agreement was executed on the date specified above.

EXECUTED and DELIVERED as a DEED for and on behalf of HOARE LEA)
)

DAVID ARMSTRONG
Print name of signatory

[redacted]
Signature

~~Director~~ Member DRA RCM

RICHARD MOUNTJOY SMITH
Print name of signatory

[redacted]
Signature

Member
~~Director/Company Secretary~~
DRA RCM

EXECUTED and DELIVERED as a DEED for and on behalf of)
)

DAVID KERNAN
Print name of signatory

[redacted]
Signature

Director

Neil Evans
Print name of signatory

[redacted]
Signature

Director/Company Secretary

APPENDIX 1

The Brief provided by the Contractor

1. ~~The Brief is attached to this Agreement (See completed BSRIA 'A Design Framework for Building Services 2nd Edition ref **{Brief ref}**.. dated . **{Brief Date}**../or Appendix 1 – Allocation of Responsibilities)~~

Or

2. ~~The Brief is described in the formal Tender Enquiry dated **{Enquiry Date}**., the brief as set out under Section 2 of this agreement, **{ list another reference documents}**.and any other numbered documents forming part of this agreement (See attached list)~~

Or In accordance with enclosed *IHSL Agreement Exert* (15 pages)

APPENDIX 2

Services to be provided

Services

1. ~~The Services are attached to this Agreement (See completed BSRIA 'A Design Framework for Building Services 2nd Edition ref **{Services ref}**.. dated .**{Services Date}**../or Appendix 2 – Extent of Services – MEP systems)~~

Or

2. ~~The Brief is described in the formal Tender Enquiry dated **{Enquiry Date}**., the brief as set out section 2 of this agreement, , the current BSRIA 'A Design Framework for Building Services 2nd Edition', **{list another reference documents}** and any other numbered documents forming part of this agreement (See attached list)~~

Or

3. The Services are as follows:
   As per Appendix 1 to this agreement

APPENDIX 3

The Schedule of Consultant's Fees

Fees for the Services shall be as follows:

1. ~~The payment of fees for Services is to be on a lump sum basis, the fee shall be a lump sum of~~

   ~~£{Fee} - ({Fee in Words})~~

   ~~Payable via monthly application (As per Appendix K of the enquiry – see attached)~~

Or

2 The payment of fees for the Services is to be time-based, the following attached rates shall apply (Expenses incurred in performing the Services are included in the rate):

The payment fee for Services shall be capped at a maximum aggregate value of £150,000.00 (*one hundred and fifty thousand pounds*).

Grade	Hourly rate
Partner	£140
Director	£110
Associate Director	£100
Senior Associate	£95
Associate	£85
Principal Engineer	£82
Senior Engineer	£65
Engineer	£55
Graduate	£45
Administration	£40

Payable by monthly instalments from the effective date of the Agreement

APPENDIX 4

Drawing List

1. ~~The Drawing List for the Services are attached to this Agreement~~

~~Or~~

~~2. The Drawing List for the Services are described in a separate document referenced~~

Or

3. The Consultants shall identify the list of drawings that are to be produced for the Project. Attached Appendix 5 to be populated and returned back to the client.

   Drawing list should be accompanied by a drawing programme indicating release dates of each drawing.

APPENDIX 5

Programme for the Services

Programme

1. ~~The Programme for the Services are attached to this Agreement~~

Or

2. The Programme for the Services are described in a separate document referenced

Or

3. ~~The Programme for the Services are as follows:~~


Imtech

APPENDIX 6

Preferred Suppliers

~~1.~~ ~~The Preferred Suppliers for the Services are as the attached list to this Agreement~~

Or

2. The Preferred Suppliers for the Services are listed in a separate document referenced

Or

3. ~~The Preferred Suppliers for the Services are listed as follows~~:

RHSC AND DCN

NOTE FOR NHS LOTHIAN FOLLOWING WORKSHOP 20 AND 21 FEBRUARY 2018

Representatives of NHSL, IHSL and MXP attended a two day workshop 20 and 21 February 2018. As well as seeking to engender positive communication between the contracting parties and other relevant stakeholders, the purpose of the workshop was to establish "**what**" the final design and construction of the building will be. That necessarily needs to be ascertained before any proper discussion could take place about "**when**" (the programme) and "**how much**" (whether there was any commercial deal to be struck in relation to the associated costs).

We understand that the outcome of the two day workshop can be summarised as follows:-

1. A potential accommodation in relation to all Project Co Changes has been identified with the exception of the ventilation and possibly the HV issues regarding the ring distribution;

2. A potential accommodation in relation to all Board Changes has been identified;

3. A way forward in relation to the other non-compliances has been identified.

In other words, with the exception of the ventilation an agreed way forward (subject to all parties following the action plans agreed at the workshop) in relation to what is being built has been achieved.

All of the discussions proceeded on the basis that this was an "all or nothing" deal. Discussions necessarily need to proceed on that basis because all parties are compromising and are only prepared to do so if there is a commercially palatable deal in the round.

Another helpful product of the workshop is that it allows NHSL to assess the strength of the parties' respective positions. To date, communication from IHSL and their supply chain has been exceptionally poor. This improved somewhat during the workshops and NHSL now has a better understanding of their position.[i] We can use that to assess where the potential vulnerabilities may be for the NHSL.

Based on the information currently available to us we have prepared the following table which summarises the various risks, the current status of those risks, the strengths and weaknesses of NHSL's position and potential solutions / options available to NHSL in light of the information currently available to us.

In the Appendix we have included some additional narrative to explain:-

1. Our current understanding of IHSL's (or MXP's) position in relation to personal bar; and

2. Our initial views on the opinion now received from MXP's senior counsel in relation to ventilation.

MacRoberts LLP
28 February 2018

Table of comments on relative strengths and weaknesses of NHSL's position

Issue/Risk	Background/Status	Strengths of NHSL's position	Weaknesses of NHSL's position	Overview and potential solutions/options available to NHSL to mitigate risks
Ventilation	Decision pending on DRP	• Independent expert evidence supportive of NHSL's position. • Relevant facts as we understand them supportive of NHSL approach. • MPX's Senior Counsel Opinion appears to be based on incomplete information.	• DRP is Costly and time consuming. • Significant programme implications. • Dispute needs to be crystallised with IHSL as IHSL is currently "sitting on the fence" but NHSL can do this within a short period invoking the clause 13 procedure.	NHSL has the option to rely upon the IT or pursue DRP. If NHSL chooses to pursue DRP NHSL has more control over the process and can seek to mitigate the delays to the programme. However, this will be a costly and time consuming process with a litigation risk. That risk, time and cost is prevented if NHSL relies upon the IT, but there is no guarantee that the IT will not change his position. Even if he does not IHSL may pursue DRP in any event. **Recommendation**: To be reviewed on receipt of Senior Counsel's opinion, but our current view is that the **advantages of DRP outweigh the risks**. Based on the information currently available we consider it **more likely than not that NHSL will be successful at DRP**.
Project Co Changes	There are significant non-conformances with the Works which IHSL has proposed NHSL should accept as Project Co Changes.	• Project Co Change procedure is not designed to relieve IHSL from complying with its contractual obligations. • Non-conformant Works should be rectified so as to be conforming. • Good bargaining tool as no obligation on NHSL to accept Project Co Changes although NHSL has obligation to	• IHSL personal bar argument – NHSL has apparently agreed that it will 'accept' certain aspects of the Works which do not meet the Board's Construction Requirements (or Project Co Proposals)	NHSL is in a **strong position** on IHSL Changes. Personal Bar arguments can be countered with the "no waiver" provisions in the Project Agreement unless IHSL is able to point to actual agreement by NHSL to accept the IHSL Change. To date we have received no substantive evidence of this. **Recommendation**: Consider accepting IHSL Changes only as part of negotiated resolution.

Issue/Risk	Background/Status	Strengths of NHSL's position	Weaknesses of NHSL's position	Overview and potential solutions/options available to NHSL to mitigate risks
		consider in good faith taking account of all relevant issues (see paragraph 3 of Section 5 of Schedule Part 16). • Savings should be shared on a 50% / 50% basis. • No EOT risk - any time associated with this should be IHSL's risk.		
Board Changes	NHSL has sought certain changes to the Works. NHSL had been assured by IHSL at meetings that there was no programme impact in relation to the Board Changes. Where there are additional direct costs to the Board as a result of these works, those direct costs have generally been agreed.	• IHSL has given NHSL assurances that Board Changes would not result in the time for completion being extended. Accordingly, personal bar arguments may work against IHSL here. • IHSL has not followed contractual process, i.e. have not included any Extension of Time ("EOT") claim in their Estimate of the cost of the Change and therefore no contractual basis to seek EOT (this would be consistent with and tend to support NHSL's position that assurances were given that there was no impact on programme).	• IHSL argues entitlement to EOT for changes to the Work scope • NHSL at risk for direct cost of change not programme implications (on basis that IHSL has not followed the contractual process to entitle IHSL to an EOT).	The full extent of the alleged Board Changes is not known to us, but assuming there have been a lot of changes, NHSL could consider whether there is a negotiated position to be achieved where NHSL gives some time and money for some Board Changes, despite the previous assurances and apparent failures of IHSL to follow the contractual procedures. This potentially could be achieved by moving out the concession period but not making any further capital contribution for the Works. The downsides of doing this for NHSL are:- • reduces financial impact on IHSL and supply chain with no financial upside/or sharing of financial upside to NHSL; • NHSL to consider whether there are other costs of continuing to run the existing Sick Kids facility longer than anticipated that will not otherwise be recoverable.

Issue/Risk	Background/Status	Strengths of NHSL's position	Weaknesses of NHSL's position	Overview and potential solutions/options available to NHSL to mitigate risks
				To fully assess the potential risk to NHSL it would be necessary to consider all of the relevant correspondence in connection with each Board Change, but it will be difficult for IHSL to successfully argue it is entitled to an EOT where the contractual process has not been followed by IHSL. Accordingly, we consider NHSL will be in a **strong position** on this issue. **Recommendation**: Consider additional time / money as part of negotiated resolution.
RDD Status C – ongoing design of incomplete works	A significant amount of design (and Works) have still to be completed and not all designs (in particular) have been submitted for review in accordance with the Review Procedure in Schedule Part 8.	• NHSL entitled to review RDD under the Review Procedure and entitled to insist on amendments until matters are Level A or B status • Where IHSL carries out work which is not approved by NHSL under the Review procedure then IHSL does so at risk (clause 12.6). • IT has indicated he will not sign off completion until all RDD is approved at Level A or B.	• IHSL arguing there has been personal bar by NHSL • IHSL is in control of production of design information and there could be further non compliances NHSL does not know about	NHSL is in a **strong position** because it has no obligation to accept IHSL Changes (unless they comply with the BCRs and PCPs) and this can be used as a potential bargaining tool. The IT is supportive of NHSL's position. Personal Bar is not a concern unless NHSL has as a matter of fact agreed matters with IHSL and is bound by such agreement. **Recommendation**: Continue to review design in line with contractual timeframes and spot-check as built position. Consider accepting IHSL design Changes only as part of negotiated resolution.
SA1 (Additional Interface works)	The original SA1 issued by NHSL in December 2016 for the carrying out	• CCTV is at IHSL risk because IHSL is	• NHSL seeking to procure the Toucan	NHSL has secured all rights required from Consort.

Issue/Risk	Background/Status	Strengths of NHSL's position	Weaknesses of NHSL's position	Overview and potential solutions/options available to NHSL to mitigate risks
	of the CCTV Works, Hard Landscaping Works, Toucan Crossing Works, Street Lighting Works and additional rights to remain on Car Park E has been replaced by a Project Co Change issued by IHSL in December 2017 requesting access to install and maintain the CCTV Works only. No discussion at Workshop.	obliged to install this prior to completion of RHSC/DCN. • Car Park E is subject to a Project Co Change.	Crossing Works and Landscaping Works with an alternative contractor as they need to be carried out at some point for amenity and long term safety reasons.	NHSL does not need to carry out the landscaping works through IHSL nor MXP. The works will be secured through an alternative contractor. This means NHSL is in a **strong position** as regards IHSL's Project Co Change because IHSL has more need to secure the rights to carry out CCTV works. Without those rights IHSL ought not to get PC certification from the IT. **Recommendation**: NHSL should seek confirmation from the IT on his position re. signing off the facility with the absence of these works. Consider alternative ways to do landscaping works or factor into negotiated resolution.
SA2 (Boundary Adjustment)	NHSL wants to change boundaries of the RHSC/DCN and Consort RIE sites to reflect a more pragmatic responsibility for hard FM activities. Not discussed at the Workshop.	• It is not essential to change the boundaries and if IHSL is not cooperative then the boundaries as between the two hospitals can remain as per current arrangements.	• SA2 (Boundary Adjustment) if agreed this will result in Board Service Change and NHSL would have to bear cost consequences of extending IHSL's services – post completion of the RHSC/DCN - to the extended RHSC/DCN site.	Although this would be a Board Change (with resulting increased costs to IHSL Services) it should also result in costs savings for reduced FM Services from Consort at the RIE. NHSL is in a **strong position** as the boundary change is not essential more a "nice to have". All parties can continue operating within the current contractual arrangements. **Recommendation**: Unless this becomes essential to NHSL, we suggest it is parked.

Appendix

1. Personal Bar

It is understood that MXP (and possibly IHSL) is seeking to argue that NHSL has adopted a positive approach to Changes and is now barred from reneging on that. This is an argument based upon the Scots law doctrine of personal bar. The requirements of personal bar can be summarised as follows:-

- where A has by his words or conduct justified B in believing that a certain state of facts exists; and
- B has acted upon such belief to his prejudice;
- A is not permitted to affirm against B that a different state of facts existed at the same time.

Particular emphasis is placed upon the word "justified:" it is an objective test. To found a plea of personal bar, the representation must be such that the reasonable man would regard it as intended to be believed and relied upon. If it conveys to the reasonable man that it was seriously intended, and that the person to whom it was made was being invited to believe it and act upon it, it matters not that the party making the representation may not in fact have intended that it be relied upon.

The representation as to a state of facts may include the fact of a position adopted by a party in relation to its rights. In other words, if IHSL could point to NHSL making a representation that NHSL did not intend to enforce its rights in relation to a particular issue then that would amount to a fact that, provided the other criteria set out above are met, could found a plea of personal bar.

However, personal bar arguments are always uncertain and insecure bases for the remedies sought. They are fact sensitive and every set of circumstances would need to be judged on its own merits.

Furthermore, there are specific provisions in the Project Agreement which prevent IHSL from pursuing a personal bar argument. Reference is made in particular to clause 8.5 and clause 65 of the Project Agreement.

Before we can give a definitive view on the prospects of IHSL successfully pursuing a personal bar argument we would need to analyse the relevant facts and circumstances relative to each particular issue. Broadly, whilst this is a possible avenue that IHSL could seek to exploit, it is a high hurdle. At this stage, we would classify the risk to NHSL of IHSL being able to successfully maintain a personal bar argument as low.

2. Ventilation

We have now received the opinion Multiplex have obtained from Senior Counsel. His position can be summarised as follows:-

- The Environmental Matrix ("EM") is the key document which sets out the requirements for ventilation design for the bedrooms. It takes precedence over the ADB sheets and Room Data Sheets. Note 1 of the EM is relied upon to support that position.
- The Environmental Matrix received Level B approval on 15 April 2016. That version had no comment about the ventilation to the four bedded rooms.
- The design was finalised between May and September 2016 and IHSL was thereafter committed to build in accordance with that approved design.
- There is no conflict within the BCRs such that clause 2.5 is engaged because CEL 19 (2010) and SHTM 03-01 allow departure from the ADB Sheets and this was approved per the Environmental Matrix. Good Industry Practice does not require balanced / negative pressure (reliance is placed upon DSSR's opinion in this regard).

Based on the information available to us, this appears to be a misrepresentation of the position. There was a relevant comment on the EM Rev 5 in relation to the four bedded room ventilation as follows:-

"Detailed proposal awaited on bedroom ventilation to achieve balanced/negative pressure to corridor".

The initial response from IHSL is noted as “The single bedrooms have had their ensuite extract increased to achieve a balance within the room, this has been noted within the matrix.”

The “feedback” from NHSL is “Note 26 and ventilation type have not been altered.” The “Reconciliation” is “Refer to matrix.”

The reference to “bedrooms” is not beyond doubt and the “reconciliation” on the table may suggest the issue has been resolved. Nonetheless, the other contemporaneous correspondence does lend support to NHSL’s position.

The correspondence Mr Ellis relies upon to support MXP’s position does not fully corroborate their approach and ignores the other correspondence. In any event, even if Multiplex’s position is correct, we understand that the ventilation has not been designed or constructed with “positive to en suite” pressure.

Accordingly, we consider that Senior Counsel’s opinion may be based upon incomplete / inaccurate information as to the relevant facts. We await an opinion from Gerry Moynihan QC on behalf of NHSL.

[i] This note deals with matters at PA level only. A different analysis may be appropriate in a question between IHSL and MXP, but that is not immediately relevant to NHSL given that its contract is with IHSL. For the most part it is understood that the arrangements are back to back in any event.

CONFIDENTIAL - RHSC + DCN
Board preparation for the RHSC + DCN Principals Meeting on 20 and 21 Feb 18.
DRAFT REV 0E - 16 Feb 18

	Issue Description	Category of issue	Current status	Board opinion on Impact to Project Co (timing, cost, duration)	Board opinion on Project Co Position	Board Position	Possible Board Compromise	Impact of Compromise on the Board	Category (TBC)
	Issues on non-exhaustive list of potential non-compliances schedule on 13th February by Facilitators with Parties								
1	Lighting in fire-fighting stairwells	Risk to life of all occupants of the building.	MPX confirmed current installation is compliant, Board disagree.	Minor - electrical works Likely cost 8 staircases @ approx. £15k	Negotiable	Issue is non-negotiable Timing is negotiable	The requirement is definite, however possible compromise on timing (post PC pre- occupation).	Possible impact on Boards commissioning programming, with potential to extend the commissioning period. Completion Certificate would be awarded by the Independent Tester with non-complaint firefighting stairwells.	
2	Non-fire rated IPS / UPS cabling	Risk to patients in critical clinical areas, theatres etc locations.	MPX working on a revised design, detail of revised design is essential.	Major - electrical works Scale of works depends on the proposed solution, at least several weeks work @ approx. £200k to £300k	Negotiable	Non-negotiable	None	NA	
3	No earth bonding in certain required areas	Risk to all patients.	MPX working on a revised installation, sample room agreed, and circa 25% of rooms have been amended so far.	Minor - electrical works which is currently being carried out in full by Multiplex.	Negotiable	Non-negotiable	None	NA	
4	Bedroom ventilation pressure regime and air change rate rooms for neutropenic patients	Haematology and Oncology patients.	MPX have installed a non-compliant system, however the Board will be able to operationally manage around the issue.	Major - if the Board alter position on operational workaround.	Non-negotiable	Negotiable	The Board accept a Project Co Change.	Reduced operational flexibility. But manageable.	
5	25% spare capacity	Cost - future developments.	A nonspecific Derogation was agreed at FC, however details of any proposal for a reduction in 25% was to be agreed through the Review Procedure. Evidence on site that 25% spare capacity has not been provided. MPX has provided high level response in Feb 18, no previous consultation with the Board.	Critical - Extremely difficult to fix	Negotiable	Negotiable	Financial rebate to the Board	High cost of future flexibility	

6	HV distribution	Patient safety risk - life critical - potential complete loss of power to the Facility.	MPX working on a revised design.	Major - electrical works	Now appears negotiable as MPX progressing the design in the background.	Non-negotiable	None	NA	
7	4 bed ventilation	Patient safety risk - inability to cohort. Risk of infection	MPX confirmed current installation is compliant, Board disagree. MPX challenging Independent Tester interpretation of the contract, Noting the IT has since repeated his agreement with the Boards interpretation. ?	Major - mechanical works High cost and several months work.	Negotiable as Compromise design was prepared in Feb 17, however not progressed.	Negotiable, however must be completed before handover.	The Board accept a Project Co Change for a reduced air change rate, but achieve negative / balanced pressure. There are 20 rooms involved in total however on a risk analysis there are 13 for which sorting the problem is desirable, and 7 in which it is essential.	Less dilution of airborne containments and odours in the room. Reduced operational flexibility and reduced flexibility for change of ward use in the future.	
8	Bedhead trunking earth bonding points **[with IPS sockets]**	Patient safety risk.	Bedhead trunking has insufficient earth bonding points, MPX to investigate.	Minor - electrical works	Negotiable	Non-negotiable	None	NA	
9	Lack of non IPS sockets in **[critical care, radiology, ED resus, transitional care and theatres]** / Currently the IPS sockets are supplying the non-medical equipment	Patient safety risk	MPX confirmed current installation is as submitted through RDD and compliant, Board disagree.	Medium - electrical works Every area that has blue sockets - large volume of work.	Negotiable	Non-negotiable	None	NA	
10	Drainage above IPS room / above IPS panels **[refer also to item 23 below, appears to be a duplicate – CLARITY REQUIRED ON THE ISSUE]**	Risk to critical equipment which in turn is a life safety risk.	MPX has submitted a Project Co Change 055, however there is currently insufficient information for the Board to consider the Project Co Change.	Major - plumbing works Re-routing of pipework out with the rooms. Quantity currently unknown due to lack of detail in the Project Co Change.	Negotiable	Issue is Non-negotiable; however, the solution is negotiable. All subject to understanding the detail of the Change.	The Board accept the Project Co Change for Fusion welded pipes, however this cannot be done until the detail of the Change has been clarified.	Residual risk of a leakage from the pipes, and the Board may have to pay for replacement of the Equipment.	
11	Protection of electrical cables	Risk to life of all occupants of the building. Risk of fire.	MPX confirmed current installation is compliant. The Board have concerns from site visits the cables have been undersized, and require the calculations to undertake their duty of care. MPX have refused to disclose the calculations.	Depending on the outcome of the calculations - Possible Major - electrical works	Depends on the calculations - Negotiable	Depends on the calculations - Non-negotiable	Depends on the calculations – None – there would be no compromise available if the calculations were incorrect.	NA	
12	Lack of tamper proof flush fitted sockets in CAMHS **[and other anti-ligature rooms]**	Risk to life of patients and staff.	MPX have installed a non-compliant tamper proof flush fitted sockets. Raised by the Board	Minor - electrical works	Negotiable	Negotiable, but strong Board position.	1) The requirement is definite, however possible compromise on timing,	1) The timing compromise would have a minor impact	

			through the Room Reviews. Currently unclear on MPX position.				2) A further compromise is the Board could undertake the works as a Derogated Low Value Change.	on the Boards commissioning period. 2) The Derogated Low Value Change compromise would result in a small cost to the Board if conceded.	
13	Single bedroom ventilation air changes	Patient Comfort.	MPX have installed a non-compliant system, Board awaits a Project Co Change.	Major - if the Board does not accept the Project Co Change.	Non-negotiable	Negotiable	The Board accepts a Project Co Change for a reduced air change rate, but achieve negative / balanced pressure.	Reduced patient comfort.	
14	Smoke clearance in fire-fighting stairwells	Risk to life of all occupants of the building.	MPX working on a revised design.	Medium - mechanical works	Negotiable	Non-negotiable	None	NA	
	Issues out-with records/schedules discussed on 13th February by Facilitators with Parties								
15	Access hatches in theatre suites	Infection Control and potential loss of activity in clinical areas.	MPX working on a revised design that includes reducing the number of hatches, and changing the type of hatch to a sealed hatch.	Medium - fit out works	Negotiable	Negotiable	The Board accepts a Project Co Change that would allow Project Co to retain some sealed hatches in clinical areas where services can't be moved.	The downtime from hatches is less than pulling down ceilings. The downtime is related to the services needing to remain above clinical areas so relate to the BCR clause re services in clinical areas. infection control objections.	
	Issues on the "variation" schedule/record discussed on 13th February by Facilitators with Parties								
16	Helipad height reduction	Project Co Change – non-compliance with the Boards Construction Requirements	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Critical - helipad would have to be rebuilt	Non- Negotiable	Negotiable	The Board accepts the Project Co Change	No new known risk.	
17	Link building (change in level)	Project Co Change – non-compliance with the Boards Construction Requirements	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Critical - Whole Facility would have to be re-built	Non- Negotiable	Negotiable	The Board accepts the Project Co Change	Subject to site inspection –slightly uneven floor	
18	Movement joints **[in clinical areas]**	Project Co Change – non-compliance with the Boards Construction Requirements	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Critical - Whole Facility would have to be re-built, or internal layouts re-designed.	Non-Negotiable	Negotiable	The Board accepts the Project Co Change	Reduction in room sizes, increased cleaning, and increased maintenance.	

19	Node rooms basement	Project Co Change – non-compliance with the Boards Construction Requirements	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Critical - additional rooms would have to be found.	Non-Negotiable	Negotiable	The Board accepts the Project Co Change	Increased risk of water damage	
20	Car Park - E	Project Co Change – non-compliance with the Completion Criteria.	MPX is requesting a delayed handback of Car Park E through a Project Co Change to relieve them of their contractual obligations.	Major - delayed Completion, or lack of office and welfare Facilities.	Negotiable relative to the extent of car park available to the Board.	Negotiable relative to the extent of car park available to the Board.	The Board accepts the Project Co Change The Board require the use of all car park E spaces, and requires Project Co retain off site car parking.	Impact on Boards ability to commission the Facility. Restricted commissioning parking. Completion Certificate would be awarded by the Independent Tester with non-complaint Car Park E.	
21	4 bed lifts	Project Co Change – non-compliance with the Project Co Proposals.	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Critical - lift shaft would have to be excavated to the basement.	Non- Negotiable	Negotiable	The Board accepts the Project Co Change	Minimal operational efficiency impact.	
22	FCU waterless traps	Project Co Change – non-compliance with the Project Co Proposals.	MPX has installed a non-compliant design and is seeking a Project Co Change to relieve them of their contractual obligations.	Medium - plumbing works.	Non-Negotiable relative to installation (already installed). Negotiable relative to price.	Negotiable	The Board accepts the Project Co Change and a small rebate.	None	
23	Node rooms / exclusion & critical areas - high level drainage **[refer also to item 10 above, appears to be a duplicate CLARITY REQUIRED ON THE ISSUE]**	Project Co Change – Non-compliance with the BCR's. Risk to critical equipment which in turn is a life safety risk.	MPX have submitted Project Co Change 055, however there is currently insufficient information for the Board to consider the Project Co Change.	Major - plumbing works Re-routing of pipework out with the rooms. Quantity currently unknown due to lack of detail in the Project Co Change.	Negotiable	Issue is Non-negotiable; however, solution is negotiable. All subject to understanding the detail of the Change and the areas impacted.	The Board accept the Project Co Change for Fusion welded pipes, however this cannot be done until the detail of the Change has been clarified.	Residual risk of a leakage from the pipes, and Board may have to pay for replacement of the Equipment.	
24	Ambulatory canopy	Board Change – commercial	The Board has submitted a Board Change for the removal of a canopy, however the cost of not installing the canopy has not been agreed.	Major - MPX potentially do not have the legal rights to install.	Negotiable relative to price. Non-negotiable relative to construction, due to legal issues.	Negotiable	The Board accept a reduced credit.	Board valuation £300k Project Co valuation £60k Accepting Project Co Valuation would cost the Board - £240k	
25	MRI room alteration	TBC	More information required		TBC				

	Further discussion - "in principle" discussion on the following items regarding completion								
1	Service Yard Entrance	TBC	More information required	TBC	TBC	TBC - Non- negotiable	Pre- PC		
2	External signage	TBC	More information required	TBC	TBC	TBC - Negotiable	Post PC		
3	Vacation notices	TBC	More information required	TBC	TBC	TBC - Non- negotiable	TBC - Pre- PC		
4	Training requirements	TBC	More information required	TBC	TBC	TBC - Negotiable	Post PC		
5	Outstanding RDD	TBC	More information required	TBC	TBC	TBC - Non- negotiable	Pre- PC		

RHSC & DCN RDS Environmental Matrix
Covering Multi-Bed Wards, Associated Bathrooms and Toilets

Room No.	Department	Room Name	Qty	Room Function	Temp (max)	Temp (min)	Heating Type	Heating Control	Cooling (present)	Cooling (type)	Ventilation (type)	Supply (ac/hr)	Extract (ac/hr)	Relative pressure	Min filtration	Surface temp	Water temp	Normal lux	Night lux	Local lux	Standby grade	Colour render	Control	Plane
G-A2-028	A2	Observation Bay	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Ceiling Cassette - Chilled Water	Natural, Central Supply & Extract	4	4 via bedroom & ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
G-A2-046		Bay 2	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Ceiling Cassette - Chilled Water	Natural, Central Supply & Extract	4	4 via bedroom & ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
G-A2-054		Bay 1	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Ceiling Cassette - Chilled Water	Natural, Central Supply & Extract	4	4 via bedroom & ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
1-B1-009	B1	Bay 1	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
1-B1-031		Bay 2	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
1-B1-063		Bay 3	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
1-B1-065		Neonatal Bay 4	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.1-018	C1.1	Bay 2 (beds 15-18)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.1-019		Bay 2 - Ensuite	1	Bathroom	28	20	Radiant Panels	Remote Sensor Adj.	No	None	Central Dirty Extract	0	17	Negative	None	43	41	200	n/a	None	A	80	Automatic Controls	Floor 0m
3-C1.1-020		Bay 2 - Toilet	1	Toilet	28	18	Adjacent Space Transfer Air	None	No	None	Central Dirty Extract	0	17	Negative	None	n/a	41	200	n/a	None	A	80	Automatic Controls	Floor 0m
3-C1.1-046		Bay 1 (beds 10-14 excl 13)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4 via bedroom & ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.1-047		Bay 1 - Toilet	1	Toilet	28	18	Adjacent Space Transfer Air	None	No	None	Central Dirty Extract	0	17	Negative	None	n/a	41	200	n/a	None	A	80	Automatic Controls	Floor 0m
3-C1.1-048		Bay 1 - Ensuite	1	Bathroom	28	20	Radiant Panels	Remote Sensor Adj.	No	None	Central Dirty Extract	0	17	Negative	None	43	41	200	n/a	None	A	80	Automatic Controls	Floor 0m
3-C1.2-023	C1.2	Bay 2 (beds 5-8)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.2-025		Bay 1 - Ensuite	1	Bathroom	28	20	Radiant Panels	Remote Sensor Adj.	No	None	Central Dirty Extract	0	17	Negative	None	43	41	200	n/a	None	A	80	Automatic Controls	Floor 0m
3-C1.2-026		Bay 1 (beds 1-4)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.3-011	C1.3	Bay 1 (Bed 2-5)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Ceiling Cassette - Chilled Water	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-C1.3-013		Bay 2 (beds 6-9)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Ceiling Cassette - Chilled Water	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m
3-D9-022	D9	Bay 1 (beds 3-5)	1	Multi-bed Wards	28	18	Radiant Panels	Remote Sensor Adj.	Yes	Comfort Cooled Fresh Air	Natural, Central Supply & Extract	4	4 via bedroom ensuite	Balanced	F7	43	41	100	5	300	A	80	switch / dimmer	Bed / Trolley 1.45m

Ken Hall MULTIPLEX CONSTRUCTION EUROPE	Fwd: General Ward - Ventilation Amendment Proposal … GENERAL CORRESPONDE...	12/12/2017 MPX-GC-023500
John Edwards ARCADIS LLP (UK)	Re: General Ward - Ventilation Amendment Proposal T… GENERAL CORRESPONDE...	12/12/2017 ECH-GC-000106

RHSC and DCN
Little France
Edinburgh
Scotland United Kingdom

ARCADIS Design & Consultancy for natural and built assets

MAIL TYPE	MAIL NUMBER	REFERENCE NUMBER
General Correspondence	ECH-GC-000106	MPX-GC-019836

Re: General Ward - Ventilation Amendment Proposal To Achieve Room Balance

From	Mr John Edwards - Arcadis LLP (UK)
To	Mr Ken Hall - Multiplex Construction Europe
Sent	Tuesday, 12 December 2017 11:51:03 AM GMT (GMT +00:00)
Status	N/A

ATTRIBUTES

Attribute 1	Stage 3 - RHSC & DCN Construction Phase
Attribute 2	33. M&E Building Services

MESSAGE

Ken

Many thanks

Regards

John

From: K Hall
Sent: 12/12/2017 9:46:57 AM GMT (GMT +00:00)
To: John Edwards
Mail Number: MPX-GC-023500
Subject: Fwd: General Ward - Ventilation Amendment Proposal To Achieve Room Balance

John

Copy of the vent drawings and schedule relating to the ventilation mods NHSL have requested.

Regards

Ken

From: K Hall
Sent: 04/08/2017 2:14:50 PM BST (GMT +01:00)
To: Douglas Anderson, Graeme Greer, Kamil Kolodziejczyk, Colin MacRae, Brian Currie, Ronnie Henderson
Cc: Wallace Weir, John Ballantyne, Graham Coupe, Colin Grindlay, Andrew McColl, George McLatchie, Darren Pike, David Martin, Stewart McKechnie, Brian Rutherford
Mail Number: MPX-GC-019836
Subject: General Ward - Ventilation Amendment Proposal To Achieve Room Balance

As discussed at today's meeting, copy of vent drawings and summary schedule (issue 5) for review at the next meeting, Wednesday 09th August 2017, 14.00Hrs.

Regards
Ken

RHSC – DCN Edinburgh
Air Movement Report For Single Bedrooms (Draft)

Wallace Whittle

1.0 Introduction

We have been asked to review the air movement within the single bedrooms under various ventilation scenarios.

1. Windows and trickle vents closed, no natural ventilation, mechanical ventilation only provided to the bedrooms.

2. Windows and window trickle vents open, natural and mechanical ventilation provided to the bedrooms.

3. Some of the windows and window trickle vents open and some closed, mixture of natural and mechanical ventilation to the bedrooms.

2.0 Interpretation of SHTM 03 Ventilation for Healthcare Premises

A single room within Appendix 1 : Table A1 : Recommended air-change rates is given under the ventilation column as supply/extract/natural, with 6 ac/hr and room pressure as zero or negative. The single room WC from the table is 3 ac/hr and room pressure is negative.

Current bedroom ventilation design is supply into the room at 4 ac/hr with opening windows and trickle vents to provide natural ventilation, this gives a balanced room pressure as long as the window is open.

The single bedroom WC extract has been enhanced to 10 ac/hr and the room pressure is negative.

3.0 Ventilation Scenario's

Scenario 1

1. Bedroom is positively pressurised by supply air.
2. En-suite is negative pressure to the bedroom.
3. Excess bedroom air flows to the corridor via doors.
4. Corridor is provided with extract ventilation, pressure is balanced.

Scenario 2

1. Bedroom has balanced pressure.
2. En-suite is negative pressure to the bedroom.
3. Excess bedroom air flows out the open windows and trickle vents.
4. Corridor is provided with extract ventilation, pressure is negative to surrounding bedrooms and other rooms.

RHSC – DCN Edinburgh
Air Movement Report For Single Bedrooms (Draft)

Wallace Whittle

Scenario 3

1. Bedrooms with open windows have balanced pressure and bedrooms with closed windows are positively pressurised by supply air.
2. En-suite is negative pressure to the bedroom.
3. Excess bedroom air flows out the open windows or through the bedroom doors if the windows are closed.
4. Corridor is provided with extract ventilation, pressure is negative to surrounding bedrooms.

Refer to Appendix 1 for the Air Flow and Resultant Room Pressure drawings.

The original reference design as detailed within the Environmental Matrix is as follows:-

Bedroom - Supply 4Ac/Hr & Room Pressure Positive.
WC – Extract 10Ac/Hr & Room Pressure Negative.

4.0 Conclusion

Reviewing the three air flow and resultant room pressure scenario drawings G1547/(57)SK01-SK03:

When the windows and trickle vents are utilised for natural ventilation the bedroom pressure is balanced and the corridor becomes negative.

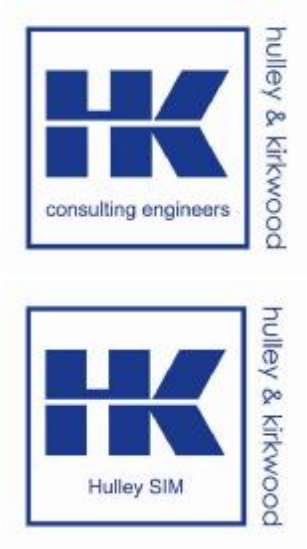
If some of the windows and trickle vents are closed, these bedrooms will become positive and the bedrooms with open windows again will be balanced, where the corridor is negative.

Should all the bedroom windows and trickle vents be closed, the bedroom pressure is positive and the corridor shall be balanced as the corridor extract rate will match the supply air coming from the bedrooms via their doors.

The window trickle vents should be left open when the rooms are occupied, this will ensure that the bedroom pressure is balanced.

By utilising the proposed mixed mode ventilation proposal for the bedrooms, ie. opening windows and trickle vents with the supply air reduced from 6Ac/Hr to 4Ac/Hr direct into the bedroom, this will provide the most energy efficient solution for the space.

We believe that we have complied with the reference design concept as detailed within the original Environmental Matrix.



Royal Hospital for Sick Children/
Department of Clinical Neuro-Sciences
Ward Room
Thermal Comfort Analysis

February 2012

Hulley & Kirkwood Consulting Engineers Ltd

The Stack

Ground Floor

Papermill Wynd

McDonald Road

Edinburgh

EH7 4QL

(**t**): +44(0) 131 558 4888

(**f**): +44(0) 131 558 4889

(**e**): hk.edinburgh@hulley.co.uk

(**w**): www.hulley.co.uk

.....Making Buildings Work

Prepared By: Jonathan McMillan

Authorised By: Michael O'Donnell

Rev.: -

Date: 21/02/12

Doc. location: K\Edinburgh2\projects\Drawings\11276A\Documentation\Rpts&Sch\Comfort Analysis\11276a_Thermal Comfort Analysis.doc

Royal Hospital for Sick Children/
Department of Clinical Neuro-Sciences

Ward Room
Thermal Comfort Analysis

February 2012

REV	DESCRIPTION	PREPARED BY	DATE
Issue No. 1	First issue	Jonathan McMillan	17/02/12

Index

1.0 Introduction

This study has been prepared by Jonathan McMillan for Hulley Sim, a sustainable building design and simulation division within Hulley & Kirkwood Ltd. The purpose of this study is to:

- Determine peak annual internal temperature profiles for typical single ward room accommodation, within the proposed Royal Hospital for Sick Children & Department of Clinical Neuro-Sciences Building, through dynamic thermal simulation for the Reference Design Stage envisaged solution of providing ward rooms with mechanical ventilation and comfort cooled fresh air.

- To verify that mechanically ventilated and comfort cooled ward rooms have summertime peak temperatures which do not exceed the NHSL maximum internal temperature of 25°C.

- To demonstrate that with natural ventilation only ward rooms could potentially experience significant hours of internal temperatures above 25oC and up to 28°C and in many cases more than 50 hours above 28°C referred to in SHTM 03-01 guidance.

Executive Summary

- The profiles in Simulations 1 & 2 show that the internal temperatures in ward rooms can be maintained at comfortable levels with 4 ACH (air changes per hour) of cooled fresh air supply mechanical ventilation and could be controlled in summertime between 22°C and 25°C maximum.

- The results for Simulation 3 demonstrate that during peak summertime conditions, the ward rooms internal temperatures are predicted to rise above 28°C with natural ventilation only in almost all rooms simulated. Further interrogation shows significant hours between 25oC and 28oC experienced, representing a period extending across summer months.

1.1 Dynamic Thermal Modelling

Dynamic thermal modeling (DTM) has been utilized to establish building thermal profiles. The RHSC / DCN Building, as per the final 1:200 Reference Design Stage architectural layouts was simulated with respect to varying time dependant internal and external conditions affecting heat gains, bulk air flow movement & solar gain. The accuracy of the model, and hence the validity of any proposals, are governed by the assumptions made, and the resolution of the model's geometry. The model's geometry was accurately drawn from 1:200 departmental layouts supplied by the Architect, Nightingale Associates. Assumptions on the occupancies and internal heat gains were based on typical values for specific operational area usage. The input data, including the local weather data, is processed by thermodynamic algorithms in order to predict the environmental conditions experienced in each of the operational areas. The latest version of IES Virtual Environment modelling software has been used (IES version 6.4). The details of which are given in Table 1.1.

Calculation Engine:	Apache
Calculation Engine (version):	V6.4
Interface to Calculation Engine:	IES Virtual Environment

Table 1.1. Calculation Tool Details

1.2 Simulation Progression

In order to understand the effect of multiple system variables and possible system control options the following simulations were performed;

- **Simulation 1** – Ward rooms served by mechanical fresh air supply, rated to 4 ACH (Air Changes per Hour), cooled to control zone temperatures to 25°C or less. Windows in simulated spaces are closed continually.

- **Simulation 2** - Ward rooms served by mechanical fresh air supply, rated to 4 ACH (Air Changes per Hour), cooled to control zone temperatures to 25°C or less.

  In addition to mechanically supplied fresh air, each simulated zone is subject to natural ventilation through a 100mm restricted window opening of dimensions typically 1.3m by 1.6m wide providing 0.416m^2 of free ventilation opening area. Natural ventilation is simulated through the dynamic bulk airflow programme Macro Flow. Bulk airflow movement is driven by the following factors:

  - Window opening area specific to each simulated space and opening configuration.
  - External dry bulb temperature, derived from local historic weather data
  - External barometric pressure, derived from local historic weather data

- **Simulation 3** – No mechanical cooled fresh air supply ventilation. Natural ventilation is simulated as per Simulation 2.

  It should be noted that Simulation 3 is provided as a means of comparison, to illustrate the conditions which would occur if mechanical ventilation with cooling were not provided, which NHSL would not find acceptable given experiences in the adjacent ERI for ward rooms reliant on natural ventilation alone, hence the briefed maximum internal temperature of 25°C

It should be noted that The Reference Design Envisaged Solution does not rely on natural ventilation alone in any way to maintain internal temperatures within comfort levels and provides a robust level of control of internal temperatures and therefore thermal comfort by employing cooled mechanical fresh air supply ventilation which could operate in conjunction with supplementary natural ventilation as well as without it.

2.0 Simulation Component Properties

2.1 Building Fabric and Window Design

The following building fabric U-Values have been incorporated into the dynamic thermal simulation model. Solar glass has been specified for regions of the façade predicted to be exposed to high levels of solar gain through direct sunlight exposure. Glazing in all other areas has been defined as a clear Low-E glass. The material properties for the simulation model have been defined as follows;

	U-Value W/m^{2}K
External Wall	0.21
Floor	0.20
Roof	0.20
Fire Doors	1.7
Windows	1.7

Glass Construction Typical	
Outer Layer	8mm Clear Float Glass
Cavity	16mm Air Cavity
Inner Layer	8mm Clear Float Glass
Low-E glass material Properties - Typical	
U-value	2.0
g-value	61%
Light Transmission	75%
Solar glass material Properties - Typical	
U-value	1.9
g-value	40%
Light Transmission	66%

It should be noted that for the purposes of this study, in the absence of both an evolved prescriptive glazing strategy and elevation details, glazing has been set to meet the minimum guidelines set out in HTM 55 regarding window size, location and opening restrictions. For the purposes of this simulation all opening windows have been set such that opening area is equivalent to that achieved if a 100mm restrictor were fitted to a top hung window measuring 1.3m by 1.6 m, providing a minimum natural ventilation free area of 0.416m^2.

Cold bridging details

IES Virtual Environment incorporates cold bridging details by using specific ψ values, measured W/(m.K), for the relevant building element junctions.

	Junctions involving metal cladding	Junctions not involving metal cladding
Type of Junction	ψ (W/(m.K))	ψ (W/(m.K))
Roof-Wall	0.6	0.12
Wall-Ground Floor	1.15	0.16
Wall-Wall Corner	0.25	0.09
Wall – Floor (not ground)	0.07	0.07
Lintel above window	1.27	0.3
Sill below window	1.27	0.04
Jamb at window/door	1.27	0.05

2.2 Building Air Tightness

The infiltration rate was set to represent an air permeability of 7.5$m^3/h/m^2$ at 50Pa. This is a minimum backstop within the Section 6 Compliance model.

2.3 Internal Conditions & Associated Heat Gains

The various operational zones were subject to internal gains determined from National Calculation Method (NCM) templates and operational schedules. NCM templates were used to describe the daily activities and associated gains for the following room types.

- Bedroom
- Patient Accommodation Day
- Multi-bed Wards

For the National Calculation Method (NCM) templates detailed above, the following gains are taken into account;

Occupancy sensible	99.6	**w/m^2** with 12.5 **m^2** per person
Occupancy latent	40.04	**w/m^2** with 12.5 **m^2** per person
Lighting	6.5	**w/m^2**
Activity specific equipment	5.0	**w/m^2**
Miscellaneous small power	5.0	**w/m^2**

Each of the above gains are controlled by daily schedules for various operational usage.

Occupancy gains have been controlled by daily schedules which increase the number of occupants to three during anticipated visiting hours.

In addition to the typical NCM gains detailed for each zone, the amount of passive solar gain is calculated using our solar analysis package VE Suncast. Suncast uses detailed solar axis and azimuth tables to determine the angle and intensity of incident solar radiation on each exposed surface. Refer to section 2.4 for details of the tables used.

2.4 External Conditions

Each scenario was simulated with respect to statistically predicted weather data and the local solar path, determined by the location and orientation of the site. Details of the solar path and annual ambient thermal profile can be seen in sections 2.4.1 & 2.4.2 respectively.

2.4.1 Solar Axis and Azimuth

The following data is embedded within IES and is used to determine the magnitude of solar gain experienced due to direct sunlight exposure.

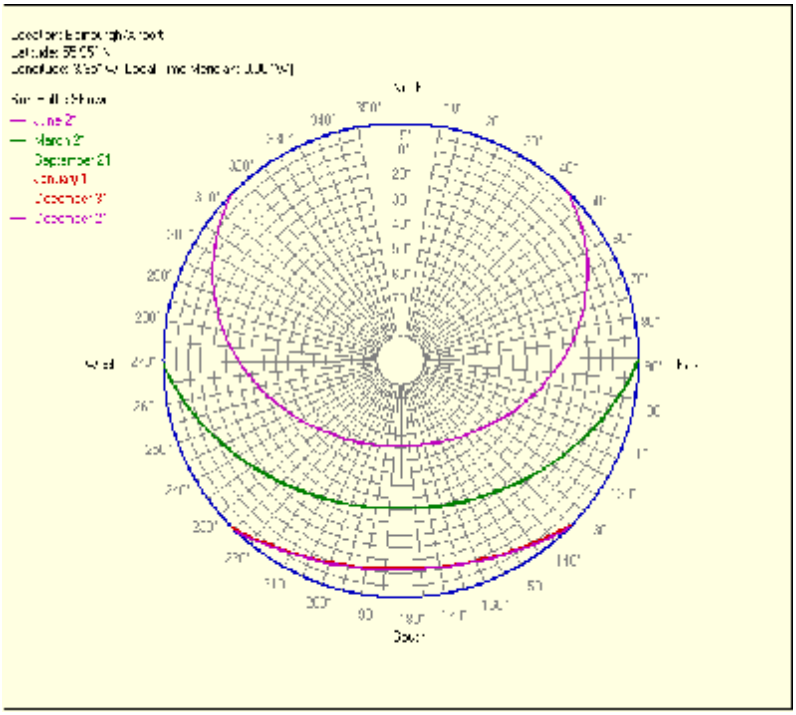
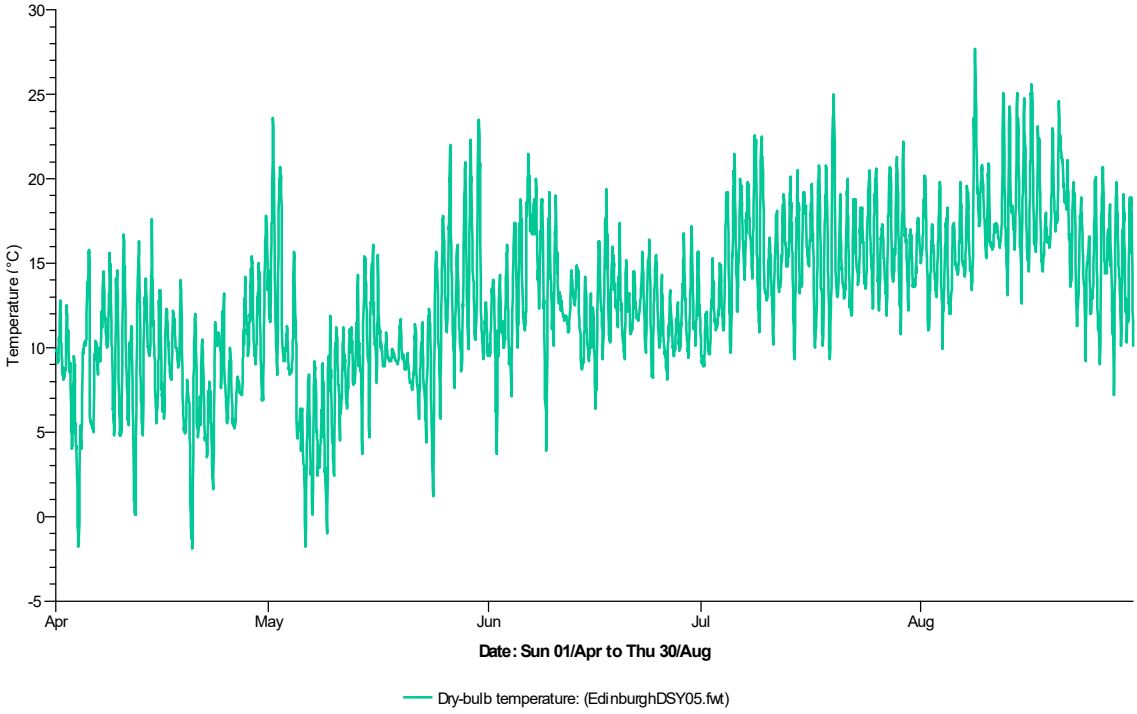


Figure 2.4.1 Solar Path Data

2.4.2 Ambient External Dry Bulb Temperature

The Design Summer Year (DSY) weather file for Edinburgh has been used. The Design Summer Year consists of an actual 1-year sequence of hourly data, selected from the 20-year data sets to represent a year with a hot summer



2.5 Space Conditioning Systems

Thermal templates have been created to reflect the space heating and ventilation systems present in the Royal Hospital for Sick Children & Department of Clinical Neuro-Sciences Reference Design Stage building envisaged solution.

Ward ventilation systems incorporated can be described as follows;

- LTHW radiant panels with local TRV temperature control with tempered and comfort cooled fresh air supply and dirty extract ventilation via adjacent en-suites through central mechanical AHU plant and central dirty extract plant.

- Summertime fresh air supply can be cooled to 16 degrees Celsius to maintain an ambient air temperature of 22 degrees Celsius, if necessary, in ward areas. Natural ventilation can be utilised as desired in addition to cooled fresh air supply. However in operational reality, management procedures would ensure an appropriate use of opening windows should ambient temperatures be greater than internal temperatures to conserve energy.

2.6 Building Geometry

A geometrically accurate representation of the proposed Royal Hospital for Sick Children & Department of Clinical Neuro-Sciences Reference Design Stage envisaged building was constructed from final 1:200 Reference Design Stage architectural layouts using the Model IT package within the IES Virtual Environment. This can be seen in figures 2.6.1 to 2.6.3 below.

As this study concerns the thermal comfort of ward rooms throughout the building, with the aim of verifying that mechanically ventilated and cooled ward rooms have summertime peak temperatures which provides for robust levels of thermal comfort whereby internal temperatures of 25°C or less can be provided throughout summertime months.

A selection of rooms has been chosen to represent the likely worst case combination of;

- Exposure to solar gain
- Density of occupation
- Provision of mechanically supplied cooled air.

As such critical care and high dependency type ward rooms which receive air change rates in the region of 10ACH, have not been analysed in this study.
Room types that have been analysed are illustrated in figure 2.6.5 below.

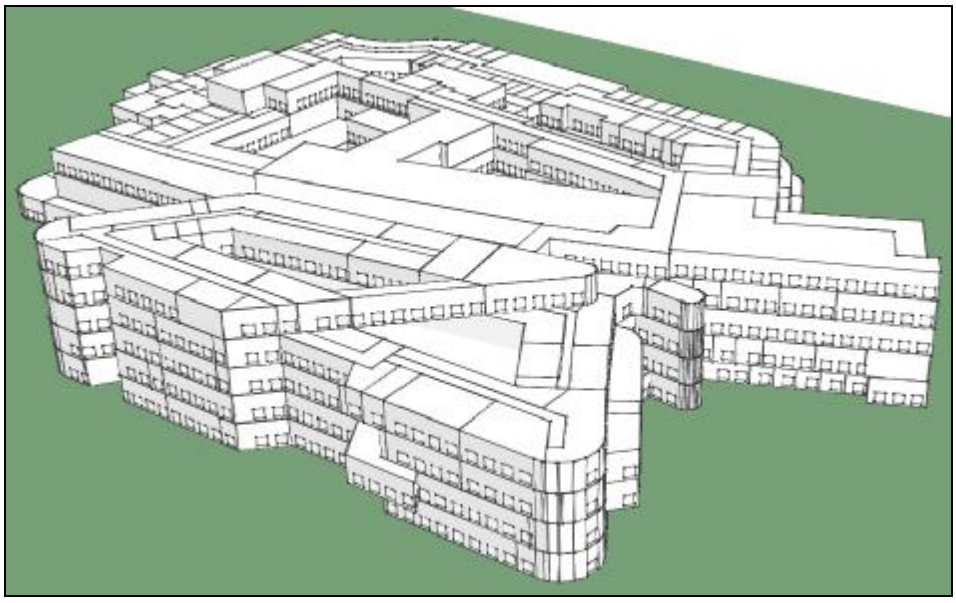


Figure 2.6.1 Model Geometry

2.6/….

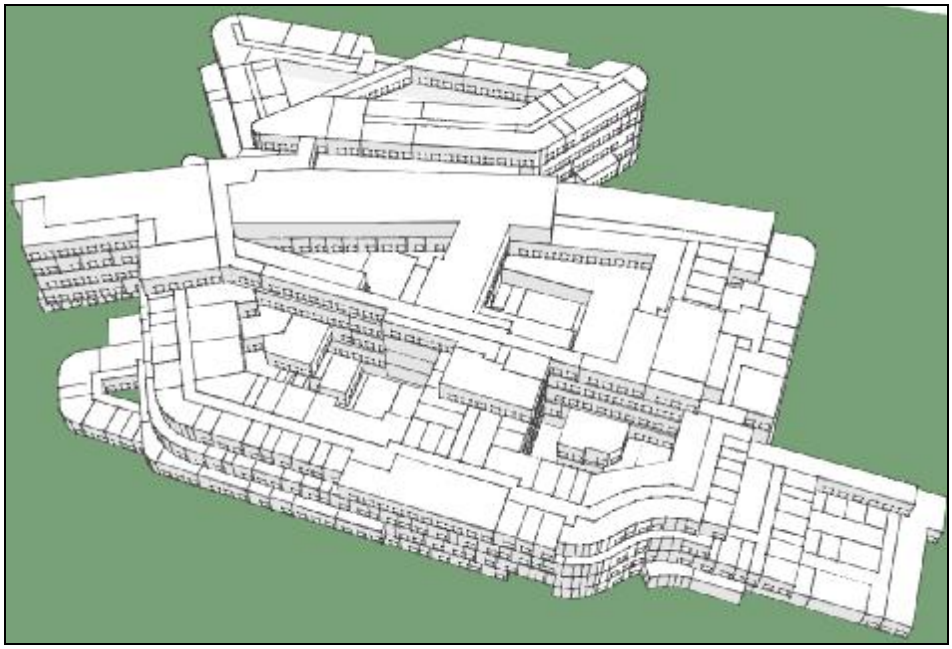


Figure 2.6.2 Model Geometry

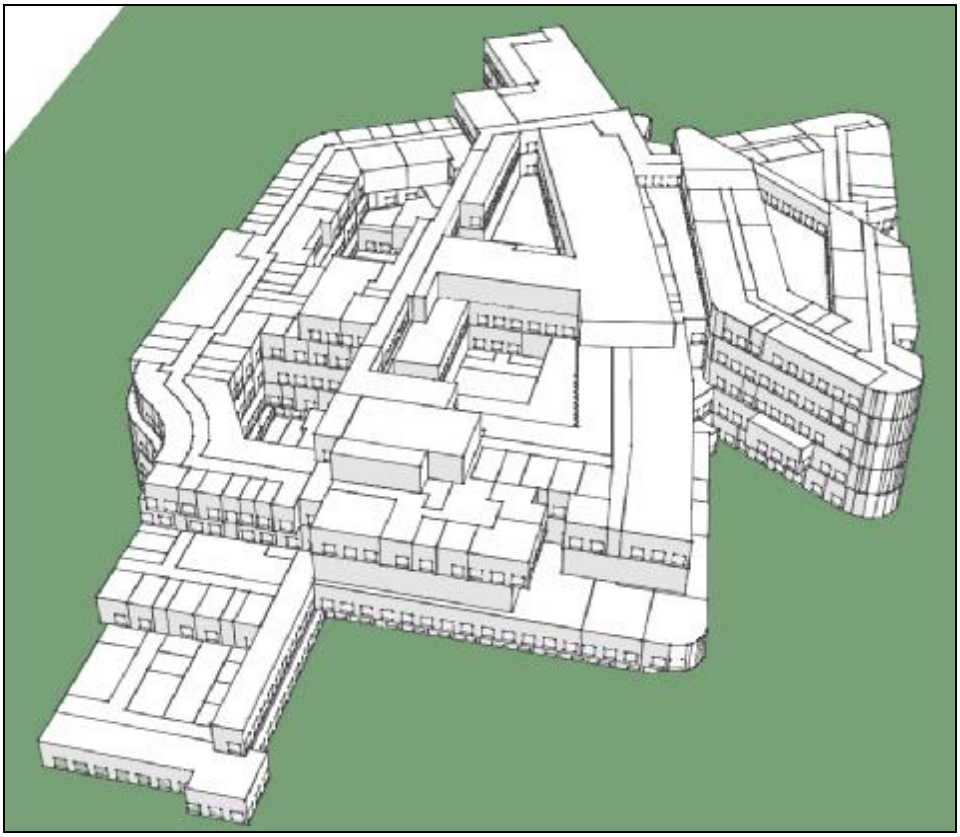


Figure 2.6.3 Model Geometry

2.6/….

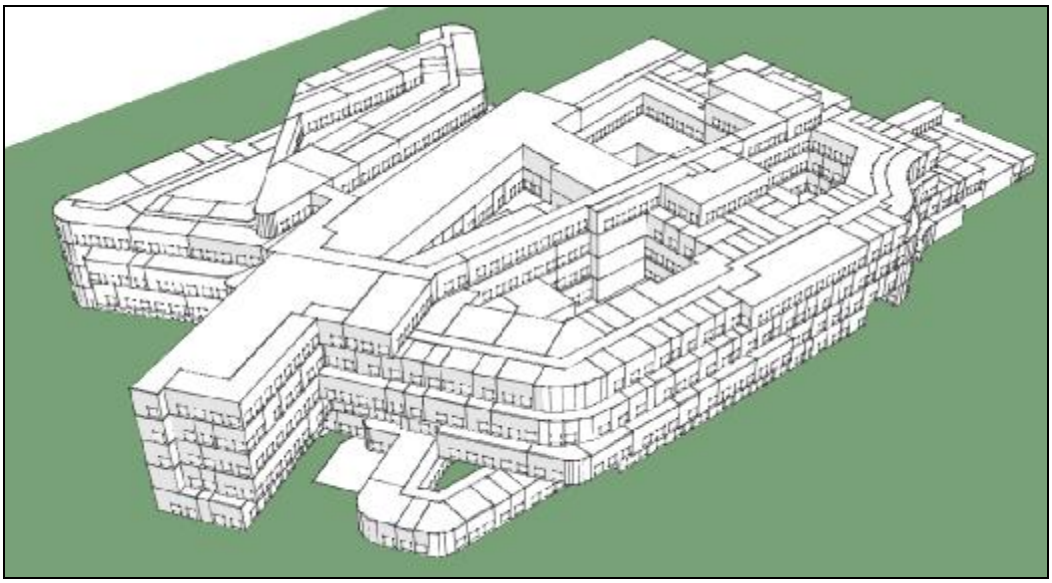


Figure 2.6.4 Model Geometry

2.6.1 Analysed Rooms

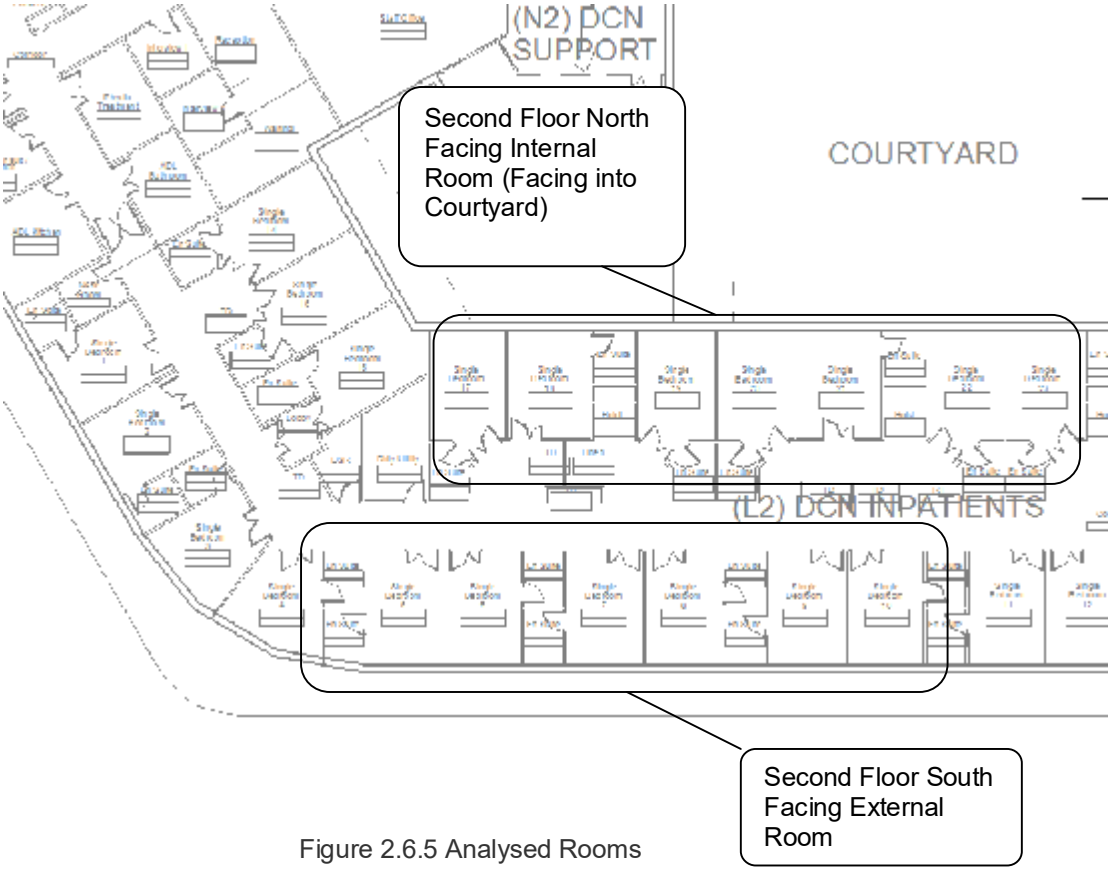


Figure 2.6.5 Analysed Rooms

3.0 Thermal Profile Results

Sections 3.1 – 3.2 present graphical results for room temperature (Dry Resultant Temperature) for both the whole summer period and for the day on which the peak temperature was recorded. For peak day graphs the following system variables are presented in order to place peak temperatures in context;

- Room Temperature profile (Dry Resultant Temperature).
- External Dry bulb temperature profile, derived from local historical weather data.
- Solar gain profile, derived from "Suncast" solar shading calculations and from the intrinsic material properties of building glazing systems.
- Internal room gains in kW, comprising occupancy, lighting, equipment and external conduction.

Note that due to the dynamic nature of the thermal simulation and the multiple variables which drive the simulation, peak temperatures for individual rooms will often occur on different days.

Simulation Summary Results

The following tables, Table 3.0.1 – 3.0.6, detailed overleaf provide an overview of "Hours Above" given temperature bands for each Simulation which are detailed below for ease of reference.

- **Simulation 1** – Ward rooms served by mechanical fresh air supply, rated to 4 ACH (Air Changes per Hour), cooled to control zone temperatures to 25^{o}C or less. Windows in simulated spaces are closed continually.

- **Simulation 2** - Ward rooms served by mechanical fresh air supply, rated to 4 ACH (Air Changes per Hour), cooled to control zone temperatures to 25^{o}C or less.

In addition to mechanically supplied fresh air, each simulated zone is subject to natural ventilation through a 100mm restricted window opening of dimensions typically 1.3m by 1.6m wide providing 0.416m^2 of free ventilation opening area. Natural ventilation is simulated through the dynamic bulk airflow programme Macro Flow. Bulk airflow movement is driven by the following factors:

- Window opening area specific to each simulated space and opening configuration.
- External dry bulb temperature, derived from local historic weather data
- External barometric pressure, derived from local historic weather data

- **Simulation 3** – No mechanical cooled fresh air supply ventilation. Natural ventilation is simulated as per Simulation 2.

Room	Bedroom 1						
Room Type	Exposed External Facing Single Ward Bedroom (South Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	1559	555	79	0	0	0	0
Simulation 2 - Hours Above	1610	594	96	0	0	0	0
Simulation 3 - Hours Above	3005	2096	1329	958	554	239	82

Table 3.0.1 Bedroom One Results

Room	Bedroom 2						
Room Type	Exposed External Facing Single Ward Bedroom (South Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	1305	336	17	0	0	0	0
Simulation 2 - Hours Above	1352	363	19	0	0	0	0
Simulation 3 - Hours Above	3079	2140	1278	815	425	167	46

Table 3.0.2 Bedroom Two Results

Room	Bedroom 3						
Room Type	Exposed External Facing Single Ward Bedroom (South Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	1064	211	10	0	0	0	0
Simulation 2 - Hours Above	1104	235	13	0	0	0	0
Simulation 3 - Hours Above	2830	1867	1185	800	431	170	55

Table 3.0.3 Bedroom 3 Results

Room	Bedroom 4						
Room Type	Sheltered Court Yard Facing Single Ward Bedroom (North Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	1115	75	0	0	0	0	0
Simulation 2 - Hours Above	1075	26	0	0	0	0	0
Simulation 3 - Hours Above	2956	1973	1125	687	269	76	6

Table 3.0.4 Bedroom 4 Results

Room	Bedroom 5						
Room Type	Sheltered Court Yard Facing Single Ward Bedroom (North Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	897	26	0	0	0	0	0
Simulation 2 - Hours Above	935	30	0	0	0	0	0
Simulation 3 - Hours Above	3321	2044	1021	534	176	29	0

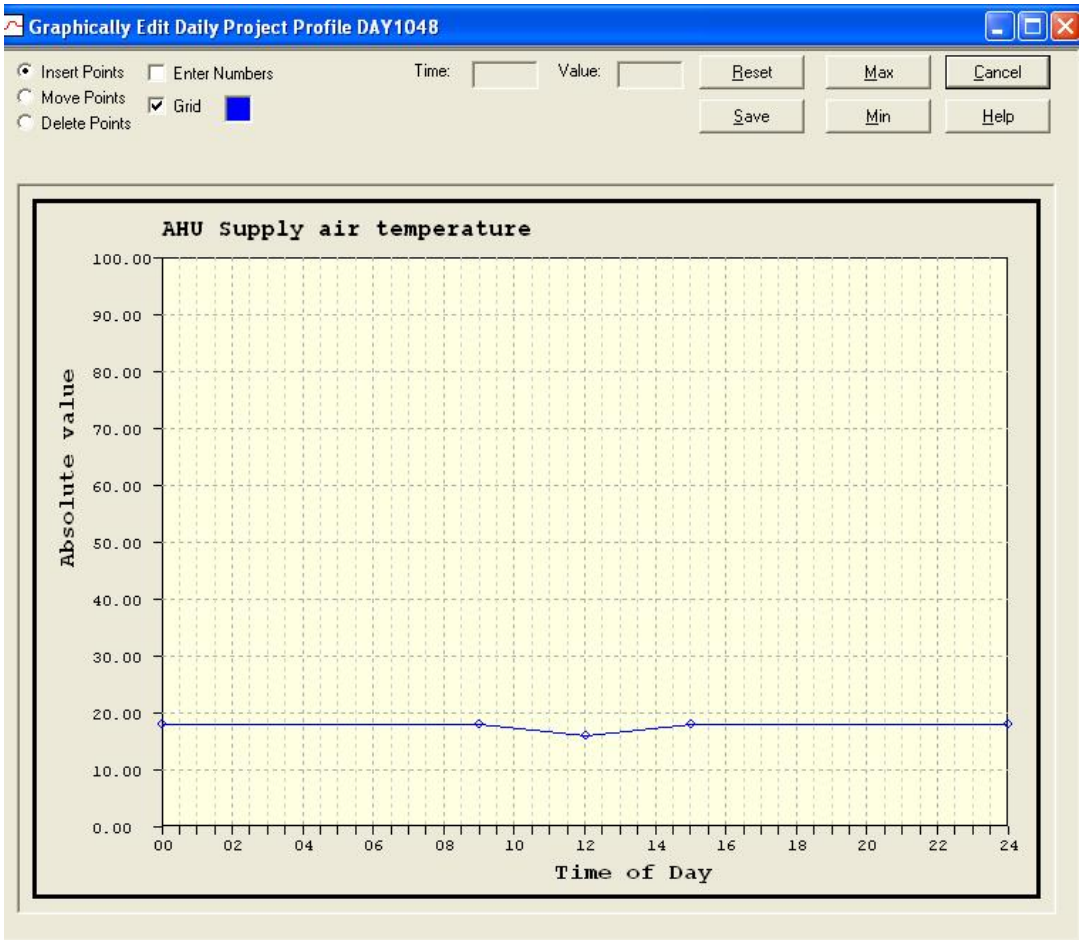
Table 3.0.5 Bedroom 5 Results

Room	Bedroom 6						
Room Type	Sheltered Court Yard Facing Single Ward Bedroom (North Facing)						
Temperature Band	22 C	23 C	24 C	25 C	26 C	27 C	28 C
Simulation 1 - Hours Above	1039	50	0	0	0	0	0
Simulation 2 - Hours Above	1070	55	0	0	0	0	0
Simulation 3 - Hours Above	2953	1972	1139	711	293	87	15

Table 3.0.6 Bedroom 6 Results

3.1 Simulation 1

§ Mechanical Ventilation with cooled fresh air supply. Supply air temperature profile as follows;



§ No Natural Ventilation – Macro flow window opening profile disabled. Windows closed.

3.1.1 External Facing Room

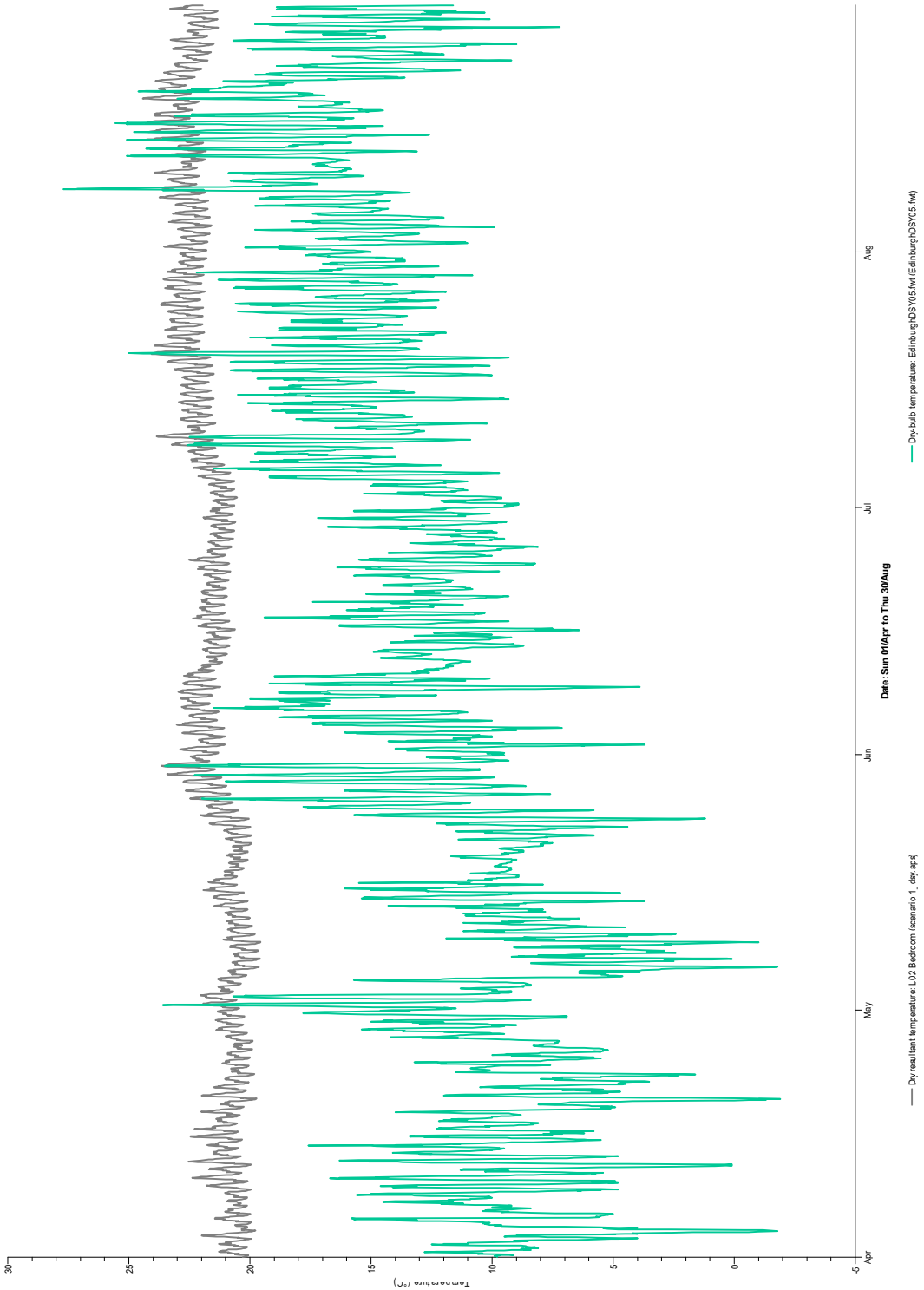


Figure 3.1.1 Simulation 1 - Mechanical Ventilation with Cooled Fresh Air Supply - External Facing Room - Summertime Temperature Profile

3.1.2 External Facing Room

Figure 3.1.2 Simulation 1 - Mechanical Ventilation with Cooled Fresh Air Supply External Facing Room - Peak Day Temperature Profile with influencing gains

3.1.3 Courtyard Facing Room

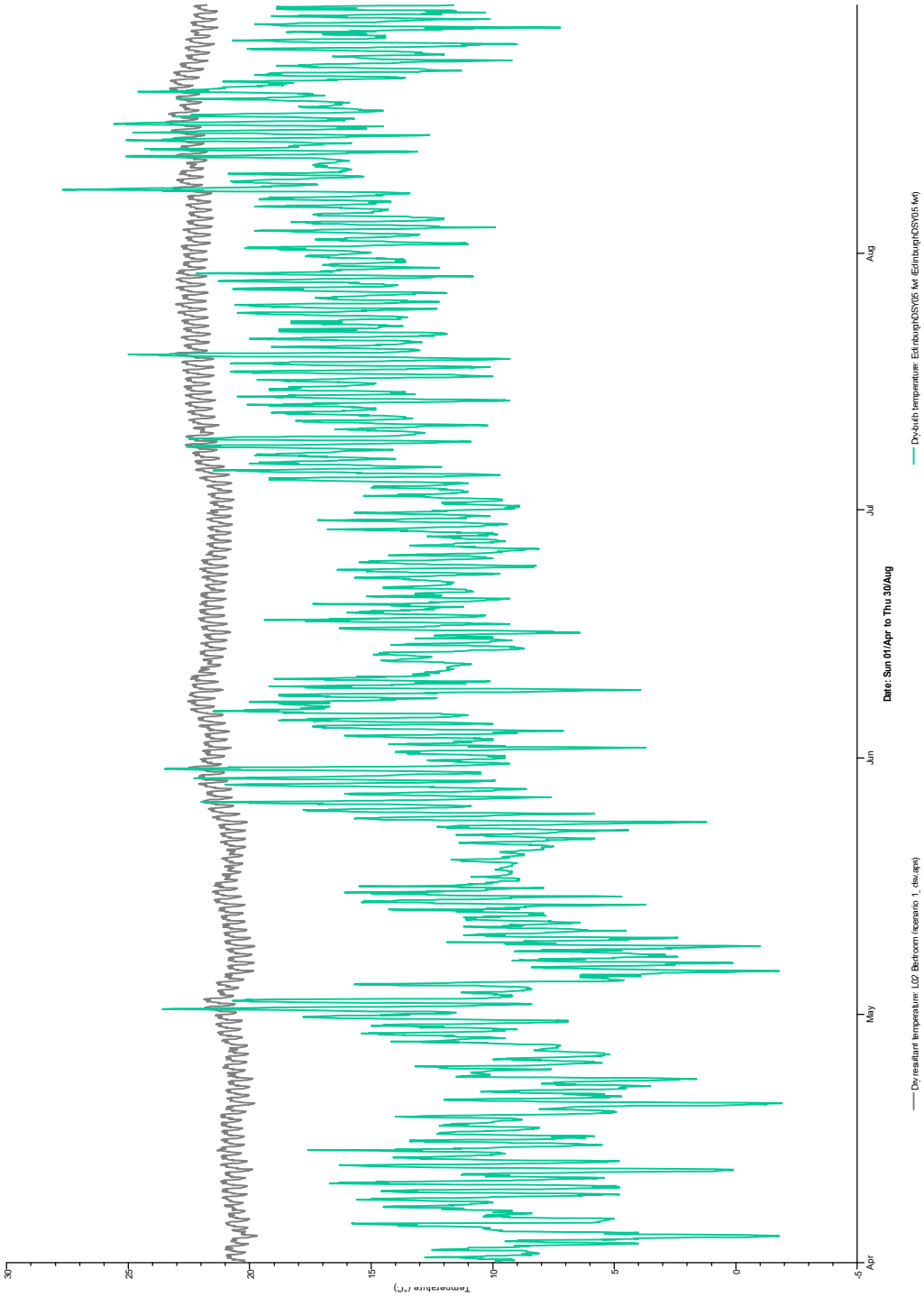


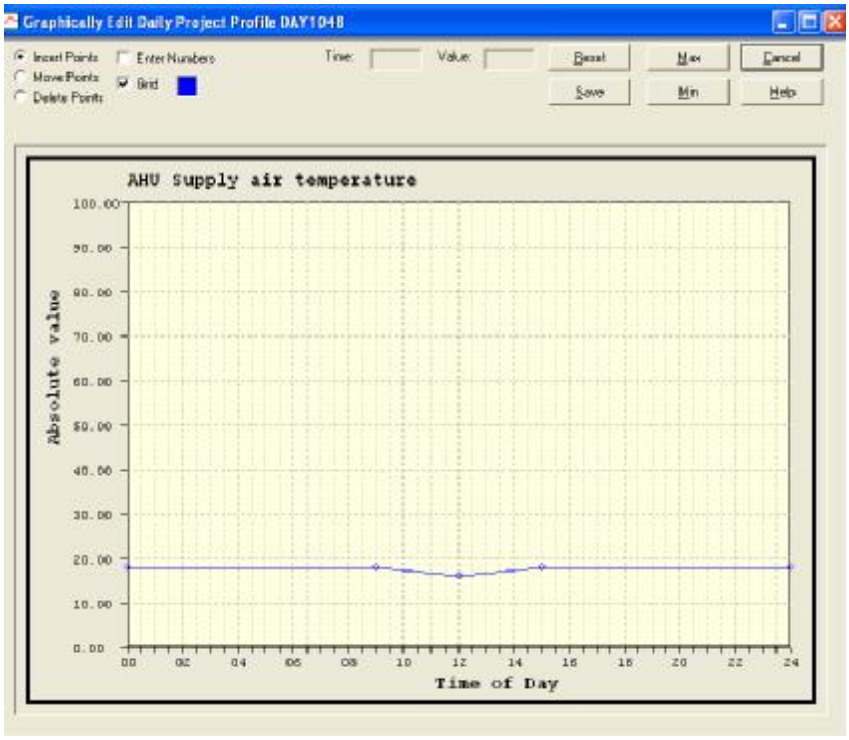
Figure 3.1.3 Simulation 1 - Mechanical Ventilation with Cooled Fresh Air Supply - Courtyard Facing Room - Summertime Temperature Profile

3.1.4 Courtyard Facing Room

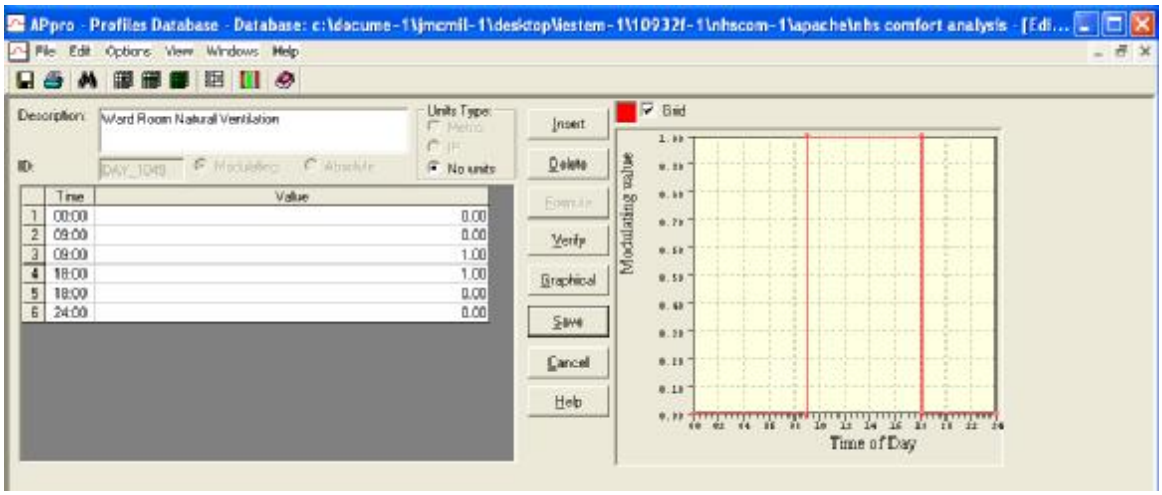
Figure 3.1.4 Simulation 1 - Mechanical Ventilation with Cooled Fresh Air Supply - Courtyard Facing Room - Peak Day Temperature Profile with influencing gains

3.2 Simulation 2

§ Mechanical Ventilation with cooled supply. Supply air temperature profile as follows;



§ Natural Ventilation – Macro flow window opening profile enabled. Windows open from 09:00 to 18:00. Modulating profile applied as follows;



3.2.1 External Facing Room

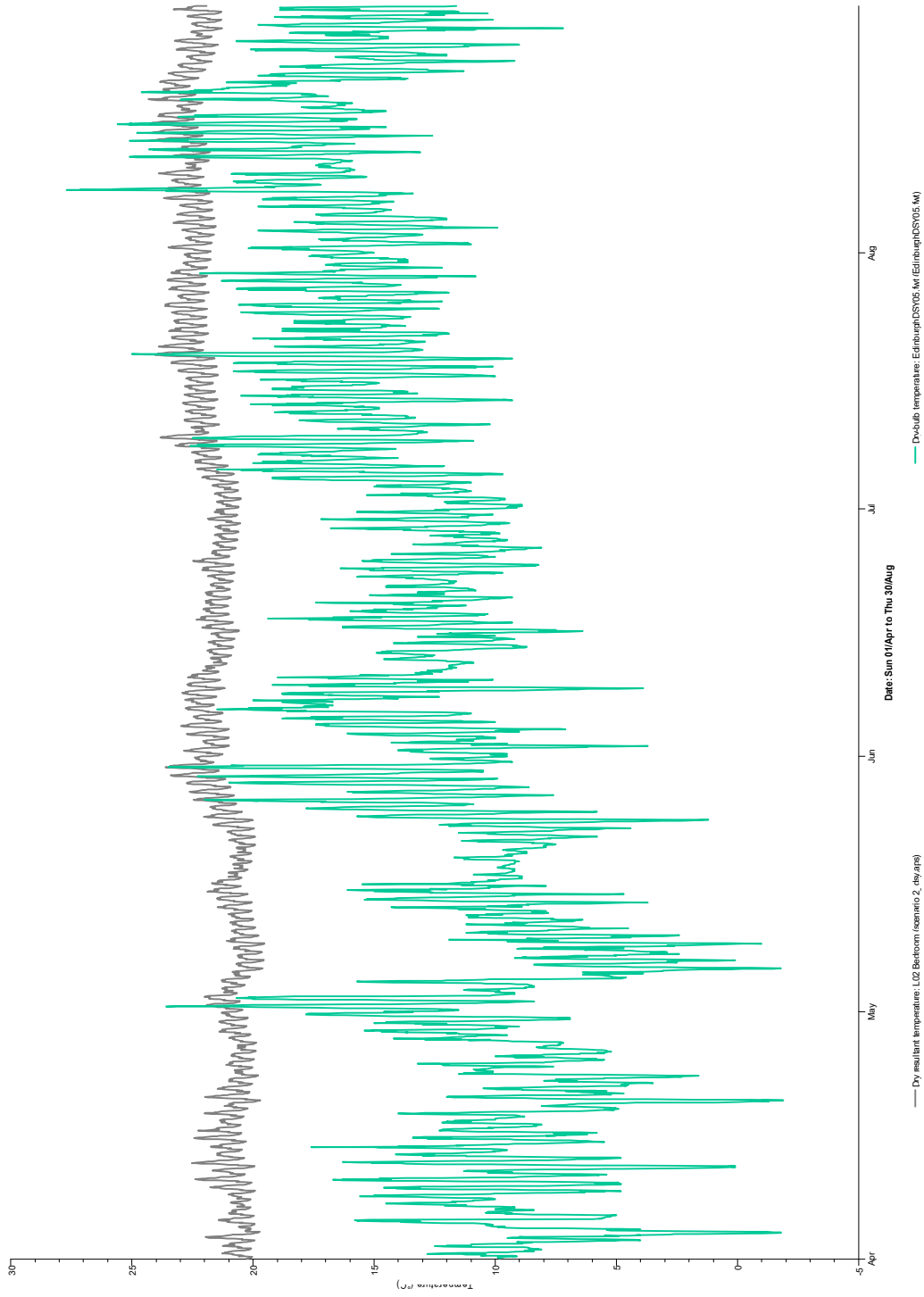


Figure 3.2.1 Simulation 2 - Mechanical Ventilation with Cooled Fresh Air Supply and Natural Ventilation - External Facing Room Summertime Temperature Profile

3.2.2 External Facing Room

Figure 3.2.2 Simulation 2 - Mechanical Ventilation with Cooled Fresh Air Supply and Natural Ventilation - External Facing Room - Peak Day Temperature Profile with influencing gains

3.2.3 Courtyard Facing Room

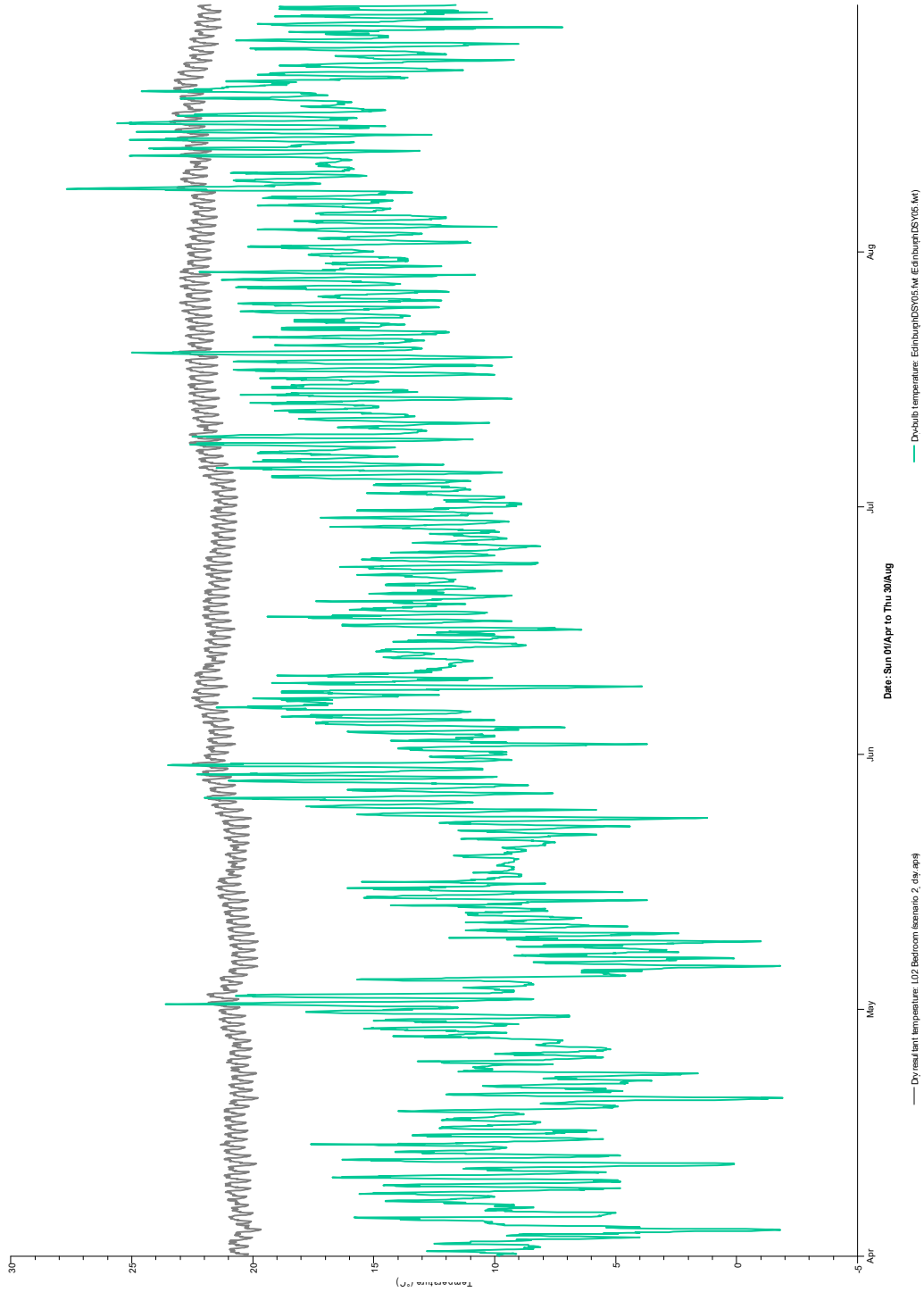


Figure 3.2.3 Simulation 2 - Mechanical Ventilation with Cooled Fresh Air Supply and Natural Ventilation - Courtyard Facing Room Summertime Temperature Profile

3.2.4 Courtyard Facing Room

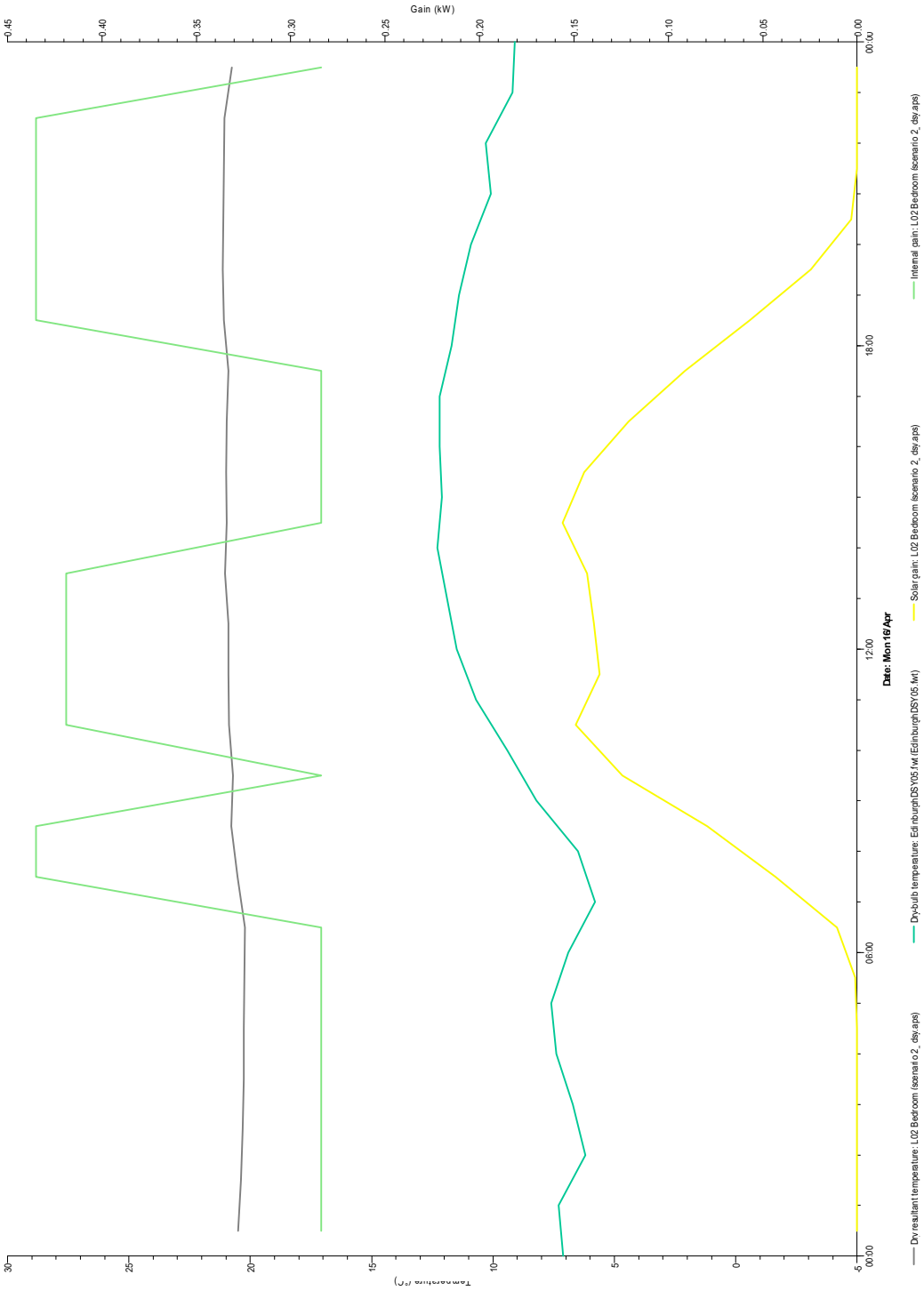
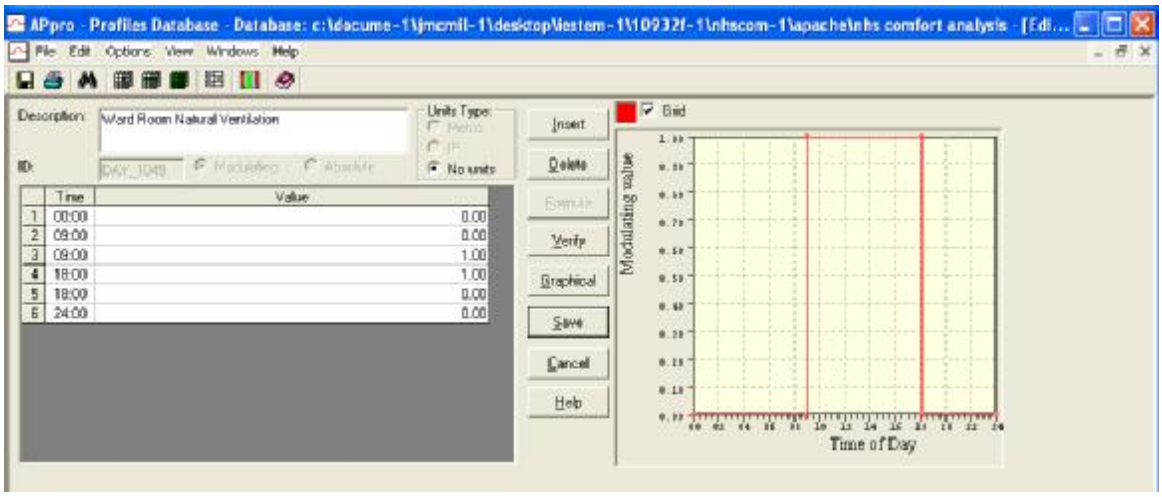


Figure 3.2.4 3 Simulation 2 - Mechanical Ventilation with Cooled Fresh Air Supply and Natural Ventilation - Courtyard Facing Room - Peak Day Temperature Profile with influencing gains

3.3 Simulation 3

§ No mechanical, comfort cooled fresh air supply.

§ Natural Ventilation – Macro flow window opening profile enabled. Windows open from 09:00 to 18:00. Modulating profile applied as follows;



3.3.1 External Facing Room

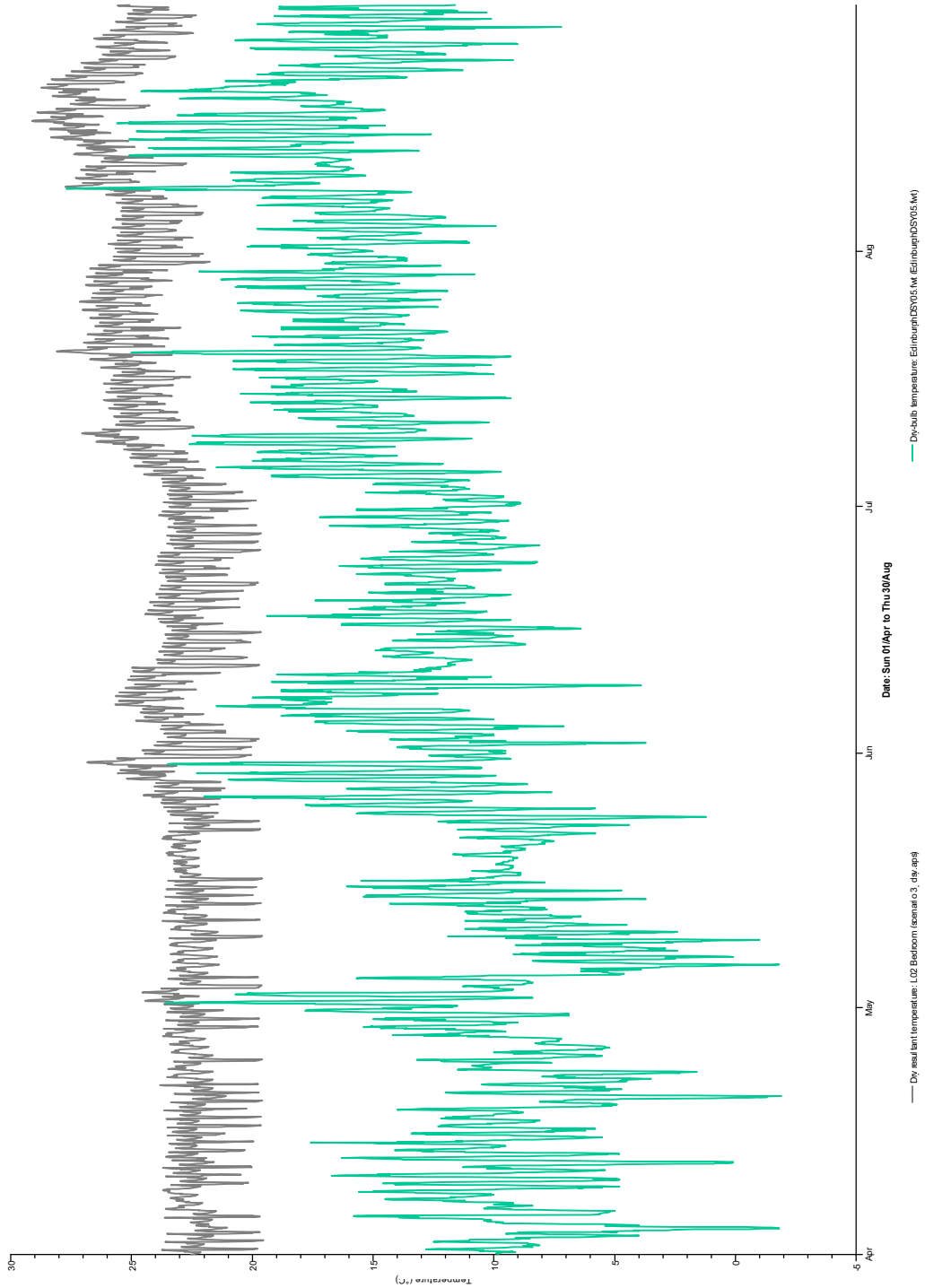


Figure 3.3.1 Simulation 3 – Natural Ventilation Only - External Facing Room - Summertime Temperature Profile

3.3.2 External Facing

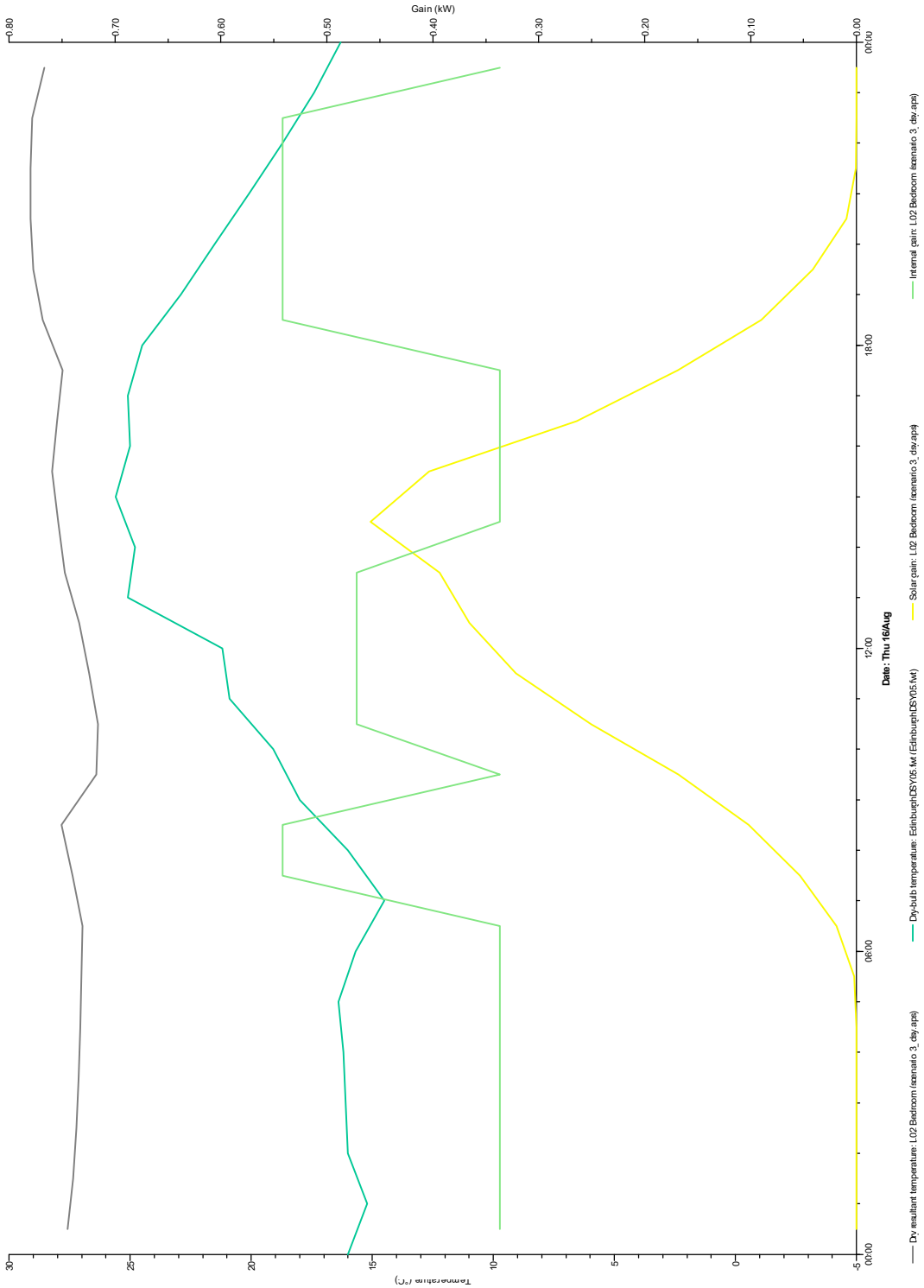


Figure 3.3.2 Simulation 3 – Natural Ventilation Only - External Facing Room - Peak Day Temperature Profile with influencing gains

3.3.3 Courtyard Facing Room

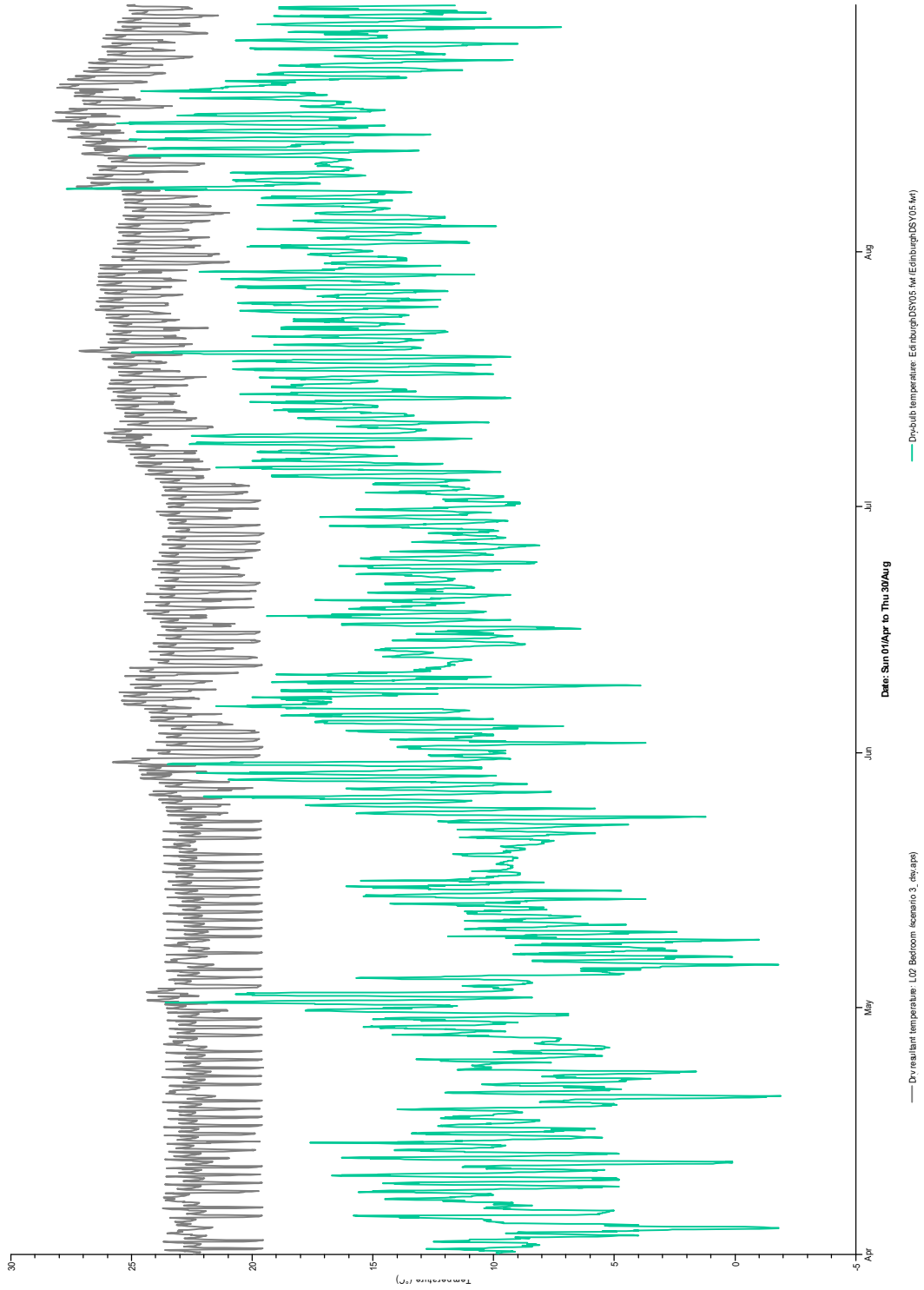


Figure 3.3.3 Simulation 3 – Natural Ventilation Only - Courtyard Facing Room - Summertime Temperature Profile

3.3.4 Courtyard Facing

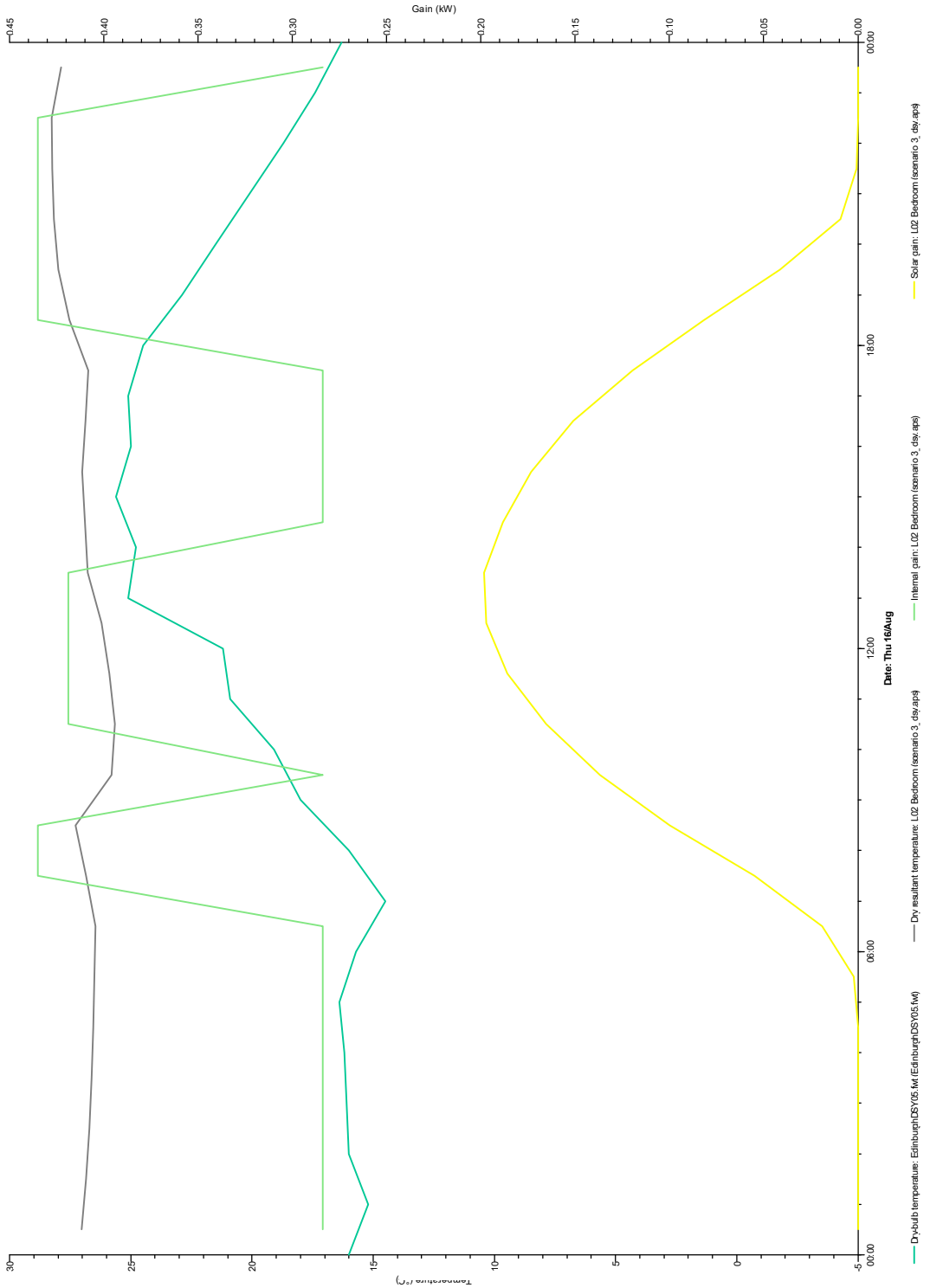


Figure 3.3. Simulation 3 – Natural Ventilation Only - Courtyard Facing Room - Peak Day Temperature Profile with influencing gains

4.0 Conclusions

- The thermal profiles observed in Simulations 1 & 2 show that the internal temperatures in ward rooms can be maintained at comfortable levels with mechanical ventilation and cooling available, and could be controlled throughout summertime providing a robust level thermal comfort as illustrated in the Summary Results Table in Section 3.0.

- The results for Simulation 3 demonstrate that during peak summertime conditions, the ward rooms internal temperatures experience significant hours between 22oC and 28oC representing compromised thermal comfort levels for much of the summer months. NHSL would not find this level of performance acceptable given experiences within the ERI for ward rooms reliant on Natural Ventilation alone.

- It should be noted that the envisaged approach is not intended to be prescriptive and that alternative approaches where put forward beyond the Reference Design could also be valid provided the conditions of planning are not compromised and can be complied with and that level of thermal comfort achieved satisfies the clients brief and expectations.

5.0 Concluding Remarks

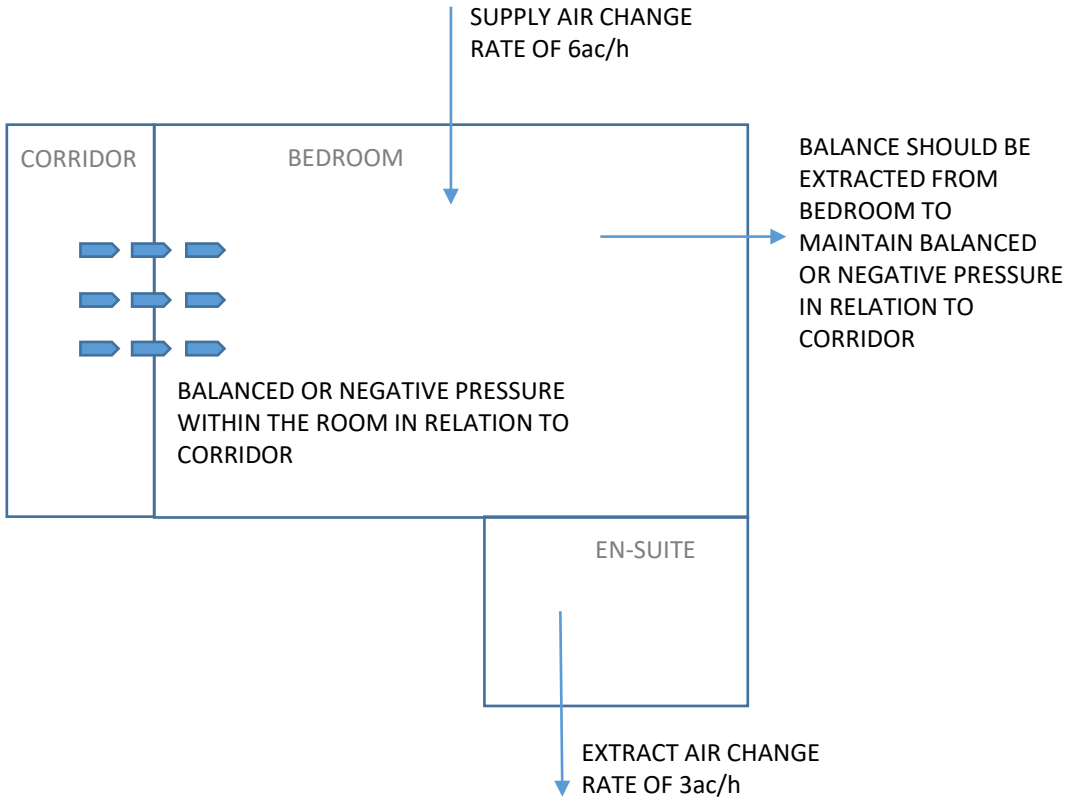
The simulation results given in this report are based on the output of a complex, dynamic Energy model, which takes account of the following design criteria:

- Architect's drawings
- Weather data
- Simulation Software
- Internal Conditions
- Construction materials
- Space Conditioning system efficiency

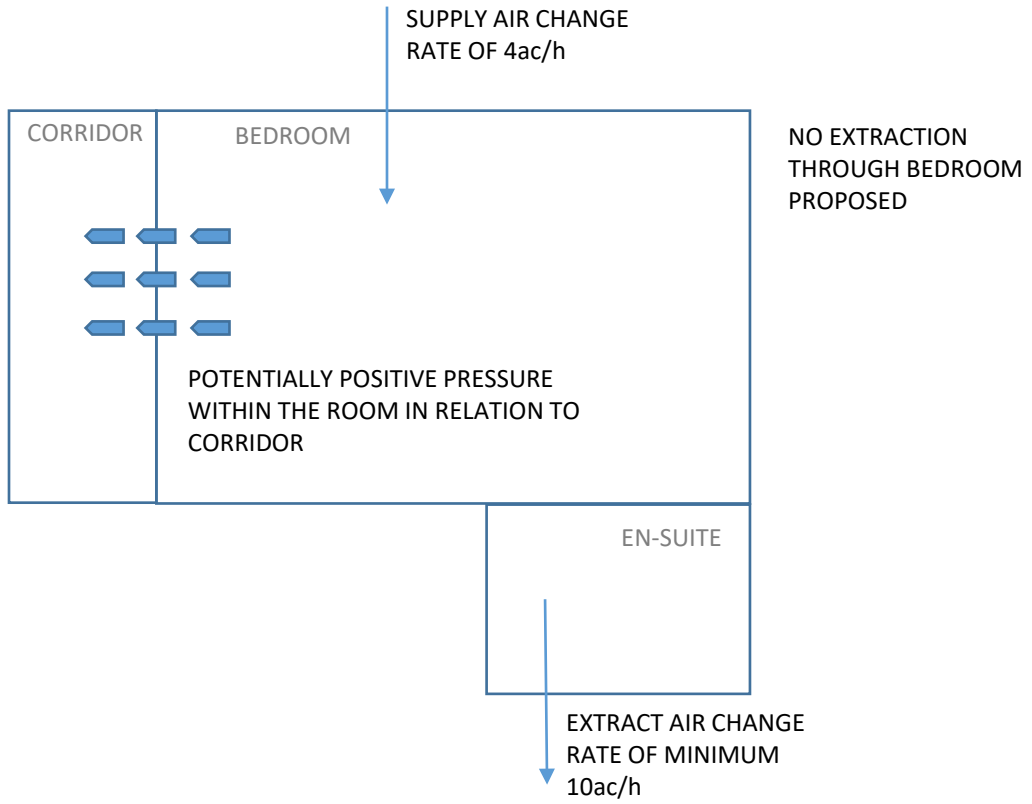
Any output from the model is only as accurate as the input of the variables associated with the above criteria.

It is essential that all parties understand and accept the various criteria, as these 'drive' the performance of the building.

SHTM RECCOMMENDATION



PCo DESIGN



PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

AGENDA

Meeting Title: RHSC + DCN Programme Board

Date/Time: 24th July 2017 / 14.00 – 16.00

Location: MacKinlay Room, RHSC&DCN Project Office, Little France Crescent

Item		*Lead*
1.	**Introductions / Apologies**	JC
2.	**Previous Action Notes from** - *Matters Arising*	JC
3.	**Project Dashboard** *(paper enclosed)*	BC
4.	**Construction Progress Update** *(verbal)*	BC
5.	**Compliance Issues and Commissioning Delay** *(paper to follow)*	BC
6.	**Risk Management Update – Top 6 Risks** *(paper enclosed)*	BC
7.	**Compromises Schedule** *(schedule enclosed)*	BC
8.	**Finance Update** *(paper enclosed)*	AB
9.	**Disposable of Imaging Equipment** *(paper enclosed)*	MC
10.	**State of Readiness for Handover** *(paper enclosed)*	JKS
11.	**Any Other Business**	

Future Meeting

- *Monday 18 September 2017, 14:00 – 16:00, MacKinlay Room, RHSC & DCN Project Office, Little France*

PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

MEETING NOTE

Meeting Title: RHSC + DCN Programme Board

Date/ Time: 15 May 2017, 13:00 – 14:00

Location: MacKinlay Meeting Room, RHSC & DCN Site Office, Little France

Attendees:

Jim Crombie	Chief Officer + Project Owner (Chair)
Lynsey Cullen	Senior Communications Officer
Brian Currie	Project Director
Eddie Doyle	Associate Medical Director, Women's + Children's Services
Alison Mitchell	Non – Executive Director
Fiona Mitchell	Director, Women's + Children's Services
Jackie Sansbury	Head of Commissioning
Sorrel Cosens	Project Manager
Cathy Richards	Clinical Lead, CAMHs
Martin Egan	Director of e-Health
George Curley	Director of Operations – Facilities
Janice Mackenzie	Clinical Project Director
Lynda Cowie	Chief Nurse, RHSC

Apologies:

Lynn Allan	Project Accountant
Mike Conroy	Radiology Sector Manager
Fiona Halcrow	Project Manager
David Hood	General Manager, WGH
Susan Goldsmith	Director of Finance
Jenny McKinnon	Partnership Representative
Angela Timoney	Director of Pharmacy
Carol Harris	Head of Communications
Alison Hynd	Head of Physiotherapy, RIE & WGH
Carol Potter	Director of Finance – NHS Fife; SEAT Representative
Donna Stevenson	Associate Director, Scottish Futures Trust
Chris Stirling	Site Director, WGH
Aris Tyrothoulakis	Pan Lothian Service Director – DATCC
Catherine Young	Business Manager, Scheduled Care
Michael Pearson	General Manager, Surgical Services, RIE
Iain Graham	Director of Capital Planning + Projects
Gwyneth Bruce	Head Occupational Therapist - CAMHS
Andrew Bone	Assistant Head of Finance
Gillian Cunningham	General Manager, RIE
Mairi McCrae	Physiotherapy Manager

Re-provision of RHSC + DCN at Little France

PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

Item ***Action***

1. Introductions/ Apologies

Apologies were noted as above.

2. Previous Action Notes from March

The action note of the previous meeting was accepted as a true and accurate record.

SA6A (rights to undertake construction works to face of RIE) is moving forward now and with lenders. Given the delay, the actual works will not be undertaken as per programme and may be pushed back to post Handover. SA6B (alteration of boundary) is being progressed with Consort ready to go to the lenders in June 17

3. Project Dashboard

Brian Currie spoke to the project dashboard.

The RAG dials remain in the same range as the previous meeting with the exception of the "programme" dial which is moving into the red zone.

At a recent Board to Board meeting IHSL announced that they will deliver by 12 October although they still remain unwilling to discuss in any meaningful way the potential delay to the programme. This date is becoming increasingly doubtful given that Multiplex has unofficially reported a four week delay and IHSL reported a 1 week delay. The impact of the four week slippage is being considered by JS & JMcK which would see clinical moves to be done at either, before Easter or both before and following on from Easter. A weekly progress report with metrics to measure progress was previously requested from IHSL but nothing has materialised as yet.

Key documents and deliverables are significantly behind and IHSL are reluctant to commit to any specific timeline details. Brian will be attending the next Board to Board meeting in early June where there will be further discussions on the programme and will endeavour to get a clearer picture of where the indicators are at. In regards to completion, formal notice to the Independent Tester is required three months prior to date of proposed completion and this is currently programmed for 12 July.

Room Reviews still remain behind schedule. Apart from readiness of rooms, many quality issues are emerging. JMacK gave examples of poor quality and inconsistency of finishes being recorded. Damage to rooms possibly caused by contractors returning to rooms to rectify changes has been identified as the cause. A pattern of the same issues within all rooms being reviewed is now emerging. Other ongoing problems being picked up are damage to doors, a poor standard of decoration/finishing quality and also power regularly being unavailable. It was agreed that this is clearly not acceptable and that NHS Lothian now requires definite reassurance around consistency of work. These problems may relate to the change process which is very cumbersome and has proved extremely challenging for IHSL/MPX's supply chain, most noticeably the performance and attitude of Mercury Engineering. Drawings which have been updated or changed via the RDD or change process are not being implemented and this is now resulting in clear mistakes with incorrect fixtures and fittings being installed. JC suggested this would need to be raised as a formal agenda item at the next Board to Board Meeting.

BC / JS

BC / JC

BC noted that the office will relocate at the end of June to directly across the road, in top left corner of currently car park E.

The Board noted the Dashboard update.

4. Construction Progress Update *(verbal)*

Brian Currie provided the Board with a verbal update on construction progress as covered above.

5. Change Management Report

BC spoke to the Change Management Report.

Since the last meeting only a small amount of movement in forecast costs has occurred with a slight increase of £100k which relates to:-

- Room Naming
- ED Signage
- IOMRI Partitions
- FM Storage

JC requested a financial update with confirmation of the project revenue and budget for the next meeting.

Brian indicated that negotiations continue on Compensation Events with the Constractor on the Off Site Flood Works.

Brian also advised that any changes from now would require be delivered post handover.

6. Risk Management Update

Brian Currie spoke to the risk management extract.

Same 6 risks continually stand as previously agreed. JC asked that these risks be added as an agenda item for June's meeting to allow full discussion of each.
Delay to the programme has the potential to cause direct impact on the finance equipment delivery and eventually the commissioning process

7. Commissioning Update

Jackie Sansbury spoke to Commissioning Update
NHSL Commissioning Plan remains incomplete as no Building Commissioning Programme has been received from IHSL.
Workforce numbers are almost all agreed with one outstanding issue which is related to paediatric Orthopaedics who currently attend RIE. FM updated on joint discussions between orthopaedics and Paediatrics to agree a way forward. The proposals will be brought back to the programme board at a later date.

Andrew Bone is due to write out to each of the departments with finalised agreed establishments.

8. Joint Commissioning Plan

Jackie Sansbury spoke to the Joint Commissioning Plan

The Joint Commissioning Plan is a Contractual requirement which NHSL have delivered on time. The contents of the plan covers interface issues between NHSL, Multiplex, IHSL and Bouygues and so it does not reflect majority of NHS activities.

An Open Day planned for the first Saturday in February 2018. This Open Day is for partner agencies such as Scottish Government and not for NHSL staff. Staff will be covered during their familiarisation process.

Work is currently taking place within Communications around a Scoping Campaign which relates to the countdown of the opening. Discussions around this will be ongoing at tomorrow's Communication Meeting.
A few key lessons will be learned from Glasgow. Lindsey mentioned the need to have a "Good News" press release following on from the move and this is included in the planning. Glasgow found that they had released all their good news before the moves and this allowed the press to focus on bad news arising from the commissioning process.
It was agreed that follow up filming after settling in period would be a better option than live filming at the time of the move.

9. RHSC Service Update

Fiona Mitchell spoke to the RHSC Service update
A key issue was the need for more staff within the department of Haematology and Oncology services particularly around day care services. This has become evident following a recent audit which demonstrated changes to drug regimes. A paper has been sent to CMT and the SMT on this.
The one stop dispensing has been delayed and a recovery plan is currently being implemented. The Head of Pharmacy is focusing on the plan and does not envisage any high risk to the implementation.

9. DCN Service Update

Jackie Sansbury spoke to the DCN Service update

Two key issues were identified. The recent appointment of a joint Clinical Nurse Manager/commissioning post which recognises the importance of operational responsibility for the resign work. This will be as a one year post. Secondly there has been a focus on pathways with a significant amount of work surrounding the pain pathways clinic and. Interoperative MRI Scanning ongoing.

10. CAMHS Service Update

Cathy Richards spoke to the CAMHS Service Update

Work continues to resolve the Out Of Hours Service and policies. A paper will be brought to the next meeting.

Re-provision of RHSC + DCN at Little France

11. Any Other Business

George Curley highlighted that there is a potential risk arising from programme delay as on a recent visit to the current RHSC at Sciennes Road by Fire Scotland it became clear that they were no longer comfortable to defer remedial work. George to advise cost and implementation date of these works at next Programme Board.

NHS Lothian

RHSC + DCN - Little France |Programme Board Report|24th July 2017

RHSC + DCN – Little France Progress July 2017

Executive Summary

	Progress	Blockage	Clarification	Next
Time	BioQ Signage granted Planning Permission. SA6a signing soon (rights to undertake works outside boundary). Exit Strategy for Off Site Flood Works agreed.	IHSL continue to advise 12th Oct Completion – see attached paper.	Impact on equipment deliveries, staff recruitment, migration of services. Outcome of DRP and compliance implementation.	
Cost £	SPEN Compensation Event agreed on Off Site Flood Works (see Finance Paper).	No agreement of measurement of Change where scope reduced.	IHSL supply chain attitude to costing changes continues to be problematic.	No assurance from IHSL that all changes will be implemented prior to completion.
Quality	Pharmacy Aseptic Suite to be handed over 28 July as planned. Temp suite to vacate 11 Sept. Staff visits all positive. FM recruitment very good response.	Room Reviews -quality variable. Witness + Testing sporadic. No progress with SA1. Major compliance issues (HV, Ventilation, MRI). H+S issues (vehicle / pedestrian segregation) remain at RIE – NHSL and Consort in dialogue.	Major Non Compliances – HV Resilience, 4 Bed Room Ventilation, MRI most onerous reqs). Slow progress by IHSL on completion paperwork for Ind Tester – Derogations, Completion Criteria etc. IHSL to confirm all mitigation measures in place – temp road crossing at QMRI.	Move to DRP whilst continuing to explore options to realise Board's reqs. (HV, Ventilation, MRI). SFT highlighted areas and themes of Quality Control from Cole Report and Grenfell. Detailed response for next meeting. RIE Car Parking Strategy to be agreed and implemented.

Commissioning

- Further development of the detail of the commissioning period continues. This includes mapping who will be in the building during the 14 week commissioning period, by company/organisation, what they are doing and exactly where in the building.
- Workshops are being planned to cover key handover issues such as the detail of the Bouygues and NHS Lothian early access period to support occupancy including cleaning of the space, delivery and installation of equipment, staff training and familiarisation etc during what is essentially still the construction period and the site is under the control of Multiplex as Lead Contractor.
- Work is progressing on the staff familiarisation programme clarifying the details of the content and the input required by others. This will be supplemented by the super user training and dates for the initial sessions are now available and being diarised. The training includes the NHS FM staff and the Bouygues staff and members of the project team.
- A meeting has also taken place with the NHS Lothian Fire Safety Team to discuss their input to the commissioning process. The key requirements include fire evacuation training which is needed for all staff from their new wards/departments as well as daily updates to the fire evacuation plans to take account of the numerous turnkey activities taking place. This is likely to be a major commitment for this team over the 4 month commissioning period.
- Meetings are taking place with the support services such as Medical Physics, Pharmacy, Medical Gas Testing Team and the Radiation Protection Advisors to detail and schedule their input.
- Meetings are ongoing with the Recruitment Team to support the recruitment of staff, starting with FM before moving onto the clinical teams. There is a dedicated RHSC and DCN campaign web page to assist with recruitment and content for this site is being prepared outlining Edinburgh and the Lothians as a good place to work. This content will be supplemented by interviews and photos of different staff members and some overview of the clinical excellence in some of these departments.
- The fourth meeting of the catering short life working group has taken place and a paper is being prepared with a proposal for the way forward for non-patient catering. This will have funding implications.

Equipment

- Detailed meetings continue with the imaging turnkey companies and Multiplex to finalise the details around the installation of this equipment. The demarcation reports prepared with Multiplex are being finalised and draft programmes for these works are nearing completion.
- Maintenance contract requirements for each new item of equipment if being assessed as the items are procured ad this information is being shared with Finance to support the development of the additional capital charges.
- Work on finalising specifications for group 3 equipment is ongoing although to date very few of these items have been ordered. In general terms only items which will initially go into service in the existing sites are being ordered at this time.

Design

- Continues to still be a small number of significant design issues to be resolved and these are now part of high level discussions with IHSL, NHSL and the Independent Tester.
- Another programme for Room Reviews has been issued, most of the dates have changed, with reviews now programmed until the end of September. The programme still takes no account yet of the need to re-review rooms and to mitigate against this we have now put in a Reserve Team for every day in August and September, which does have significant resource implications for the Project Team . The quality of the work continues to be variable and the Board is making a large number of 'observations'. In the zones reviewed recently there are still a number of rooms not reviewed as there is no power or the room has not been completed.
- There is still a substantial amount of RDD information being issued for review and sign-off. There continues to be a steady stream of RFIs in relation to a number of design and fixture & fittings that we are responding to.
- Design workshops continue in relation to Internal Wayfinding & Signage and Intra-operative MRI. Key suiting for every door with a key in the building has now been done and issued back to Multiplex.
- TCT are visiting again this month for a 2nd site visit to view progress and address any issues with the construction in these areas. A design meeting has been held with ECHC to progress the design of their shop.
- Design of NHSL Cafe and Grab & Go is almost finalised.
- The last site visit for users will be on the 4th August as these cannot continue to be supported due to the intensive room review programme and many departments can now not be visited as they have been locked down.

Commercial & Legal

- SA6a – expected to be concluded with Consort w/c 17/07/17
- SA6b – continues to be progressed with Project Co and Consort
- SA1 – NHSL could not accept IHSL indemnities

Programme

- IHSL have advised NHSL and the Independent Tester of anticipated actual completion date of 12 October 2017.

NHS Lothian

RHSC + DCN - Little France |Programme Board Report|24th July 2017

Stakeholder Management and Communication

- A funding application that was submitted to the ECHC for the development of a dedicated children's services website was unsuccessful. Feedback has not been provided.
- The construction break through into the RIE took place. Media activity may take place in August 2017.
- Countdown digital screens are in place. These screens will display project updates, patient information regarding the move and any related messages in four locations (RHSC, DCN and CAMHS)
- Recruitment campaign support is ongoing.

RIE Health, Safety & Logistics

Health & Safety

- Pedestrian safety remains a concern in the RIE Campus with long standing issues still to be resolved in key business areas. Risk of incident remains very high.
- Good pro-activity between contractors on campus at SWH&S meetings with low numbers of incidents being reported to the group.
- Access to with Service Yard B has control element on vehicle and pedestrian access. Continues to working well.
- Hospital Square works have progressed well. Good work on H&S aspects by Multiplex and Crummock.
- Real concerns on pending flood gate works on "blue light" route to ED.
- Real concerns on newly opened "temporary crossing" for new access to RHCYP for construction team. High volumes of people on crossing, sight lines are not good, new awareness signage requested and additional management by Multiplex required. Blue light traffic could be delayed to PCI if this is not better managed on a daily basis!

Logistics

- Large vehicle numbers on site remains high but are well managed and raising few concerns.
- Gate 4a activities going well since gate switch with no reported issues to date on PCI blue light route or bus services.
- Contractor Traffic Management Plans working well respecting blue light routes and NHSL core requirements.
- Positive initiatives in place from Multiplex on the management of large delivery vehicles!
- Hospital Square works are causing a few issues with vehicle management in the PCI / Day Case area. QMRI Bus Stop closed for safety reasons. Taxi Rank returned to outside of Anne Rowling and is being monitored closely on a daily basis.
- Concerns about perimeter road construction and surface break up. Enabling works defects are underway with BBCSUK carrying out remedial works in numerous areas on the perimeter road. We are awaiting a programme for the Bus Hub major remedial works from Consort and we have concerns already from Lothian Buses.

RIE Clinical Enabling

Pharmacy (Aseptic Suites, Store and Reception Areas)

- The pharmacy construction project will completed on 28th July 2017.
- The new aseptic will open the first week of September 2017.

Medical Photography

- The first phase of this project will start in October 2017 as a variation to the Acute Medical Unit Project.

eHealth, Health Records and Telecommunications

eHealth

- Node room fit out has commenced and currently running to schedule.
- Desktop equipment is almost finalised with 863 for transfer and 322 to be bought new.
- Ongoing review of printers with a concern that the printer estate will increase considerably.
- Specifications and discussions with suppliers for equipment in meeting rooms is underway. Focusing on specialist AV equipment such as interactive boards and video conferencing to support MDTs, management meetings etc.
- Trak build underway with clinic templates being gradually submitted with DCN build well underway. RHSC are in the process of compiling their clinic templates with Trak team needing visibility of these very soon.

Health Records

- Health Records continue to work towards their move with a view that the libraries will move in January 2018.
- Workload in Reception areas in relation to Outpatients in the Children and Young Persons is causing some concern in terms of the activity that will have to managed by the two reception areas manned by Health Records. Discussion to commence with the services to move this forward.

Telecommunications

- Procurement for telecommunication provision is a concern if the framework is not in place timely for the commissioning period. Alternative provision is available for the early access areas in Sept but these would go on a different number range.
- Telephone numbers for new build should be available by end of July for publishing in patient leaflets etc.
- Initial discussions with Multitone have started and full site survey to be scheduled. Potential for costs to be significant with a concern that the Multitone contract comes to an end at the end of the year.
- Initial approach to new provider for pagers, Pageone has been made with a survey to be scheduled.

Art & Therapeutic Design

- http://www.beyondwalls.blog/ has been launched to showcase the art and therapeutic design programme and contributors.
- ATD project costs still in discussion: patient entertainment system.
- Change instruction are complete for: courtyards, interview rooms, sanctuary and bereavement suites; CAMHS department, sitting rooms, drop-in centre, play and dining rooms, the Pod, adolescent spaces, sky ceiling projections in treatment rooms, interactive rehabilitation, Snoezelen room, programmable (gallery) spaces and archive cabinets in public corridors. Broadly these came in on or near to budget and the funders have responded positively to the proposal to use some of the recovered VAT on their donations to deliver the full design intention.
- Terms for the donation and running of the Ronald McDonald House are with legal advisers.
- Terms for the occupation and running of the Radio Lollipop studio have been concluded and signed.

Contract Management (RHSC+DCN / RIE)

• Continuing discussions with IHSL in terms of Facilities Management and Contract Management aspects.

• Continuation of contract monitoring programming, planning and procedures for the operational phase. A strong focus has developed towards the planned handover and the requisite information required to achieve the Completion Criteria.

• Draft Proforma's, procedures and reports from IHSL are being submitted for the Board to review. These documents detail how IHSL intend to operate and what information they will impart during the operational phase. These are being reviewed by the Facilities Management team and reported back to IHSL through both informal joint meetings and through Aconex as a formal mechanism.

• Continuation and progress of developing tools to administer and integrate contract management into the contract i.e. The Contract Administration Manual and the Contract Management Plan.

• Liaison Committee nr 07 took place on06 June 2017 to discuss ongoing matters. Following this meeting there was a scheduled meeting with NSS HFS and SFT. This allowed a focus on the Project Agreement generally and how the contract will operate in the operational phase which will take place in the future. The next meeting is scheduled to take place on 01/08/17. Terms of Reference, Agenda' and Notes have been issued.

• SFT ran a Payment Mechanism Workshop on 14 July 2017 with NHS and IHSL. This was refresh on the contractual mechanism within the Project Agreement. This allowed a factual insight into the way the contract will operate in practice and draft scenarios took place to allow calculation of payment deductions for poor performance.

• Review of RIE operational aspects including information provisions e.g. Programmed Maintenance (Life-Cycle), Building User Guide and review of existing RIE Project Agreements.

• The Travel Planning and Active Travel aspects continue at pace following the recent appointment of Sweco (Grontmij) through the Scotland Excel Framework. There has been much activity with the completion of Travel Plan surveys to all sites affected by the project. The collection of raw data will inform the Travel Plan, which is one of many Planning Condition for this project. Following topographical surveys and assessments there is a now a draft Active Travel Report for the Cameron Toll to the Edinburgh bioQuarter which assesses the relative merits of a physical transport intervention and how this may be achieved. Traffic Surveys counts commenced mid-May. Meetings continue in regard to transportation planning with NHSL, UoE, Scottish Enterprise, Edinburgh Council and Sweco (Grontmij). Further meetings have now been scheduled to progress matters. Discussions ongoing with the Bioquarter Partners i.e. Scottish Enterprise/Edinburgh Bioquarter, The City of Edinburgh Council and UoE to ensure a collaborative approach.

• Regular scheduled Interface meetings are continuing to take place between NHSL and IHSL together with Consort and Engie. Coordination is taking place with RIE Logistics and the remainder of the aspects of the key enabling works to ensure suitable and appropriate levels of planning are taking place.

• A shadow helpdesk has been in operation for circa 36 months to monitor progress by Engie in terms of Helpdesk operation. Sustained effort is required to promote service improvement within this area. Meetings are taking place with Consort/ Engie to assist and at a senior level.

• RIE contract documentation is being sourced and filed in an appropriate format / layout. A document and correspondence register has now been established to register contractual correspondence.

Facilities Management

Soft FM

- Short life working group reviewing options for non patient catering service concluded, paper to be updated and submitted to the programme board. Catering outlets received and reviewed through RDD.
- Recruitment programme in place; FM Open Day well attended; internal interviews for Security/Helipad Officer and Logistics Supervisor commenced with external interviews arranged for 14 July; training programme in place; Prince's Trust programme arranged for next FM Academy; Domestic and Portering posts advertised internally with external dates being released by the end of July.
- Interface meeting held with Consort / Engie, with workshops agreed, initial focus is Security
- FM workshop held to agree procedures for joint working in basement and service yard
- Commodity groups and equipment specification progressing
- Joint operational procedures with clinical and FM services progressing

Hard FM

- In house Hard FM structure and budget nearly concluded
- Witnessing & Testing ongoing albeit less than expected to date
- Review of Bouygues documents ongoing
- NHSL/Bouygues joint procedures ongoing

Decommissioning

- De-cluttering ongoing
- Decommissioning monthly meetings ongoing

PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

RHSC & DCN – LITTLE FRANCE
PROGRAMME BOARD – 24/7/17

Risk Management Update

Recommendation/ action required:

The Programme Board is asked to

Author:	**Director:**
Callum Gordon Commissioning Manager RHSC and DCN Re-provision	Brian Currie Project Director RHSC and DCN reprovison

NHS LOTHIAN

RHSC & DCN Programme Board
24th July 2017

Brian Currie

RISK MANAGEMENT UPDATE

1 Purpose of the Report

1.1 The Chair of the Programme Board requested additional information regarding progress being made on the top 6 high risks on the RHSC/DCN Project Risk Register. The purpose of this report is to update the board on progress concerning those risks.

Any member wishing additional information should contact the Lead in advance of the meeting.

2 Recommendations

2.1 The Programme Board is asked to confirm they are assured that risks are being managed and progressed.

3 Discussion of Key Issues

3.1 At the November 2015 Programme Board, The Project Director reported that to address concerns raised during an internal audit of risk management practice in the project, the register had been transferred to Datix and is maintained, revised and updated with risk owners and handlers. The register is a standing item on the programme board agenda.

3.2 During regular review, risks are added, revised and closed. Because of the architecture of Datix and the organisational structure in Finance, the Project sub-Risk Registers (e.g. Equipment, Commissioning and Facilities) are retained in the Lothian Report format in Excel. Risks are sometimes raised onto the Project Register or closed from the Datix Register and downgraded to the sub registers. The Project Risk register and the closed risk reports are standing Programme Board Agenda items.

4 Key Risks

4.1 The High Risks on the Register:

4.1.1 3934 Affordability of FM Services

Portering Domestic, Security and Materials Management establishments are now resolved. Non patient catering and Contract management are outstanding. A paper is in preparation proposing a funded pilot for non-patient catering opening out of hours to test viability of services.

4.1.2 4141 Staff Parking

Remains high risk. Application for parking permits and subsequent review and allocation is planned for September 2017.

4.1.3 4145 Availability of PICU Nurses

Remains high risk. is cited as: *"Availability of specialist staff - PICU nurses"*. While there has been some recent success in recruitment, there are a number of vacancies outstanding.

4.1.4 3857 Performance Project Co.

NHSL's disappointment in relation to various aspects of the project (Construction Programme, Commissioning, Rooms Reviews, Change Process, Completion Criteria, Derogations and Non Compliances) was captured in a letter to Wallace Weir, PCo Representative from the Board's Representative dated 24th May, 2017.

A reply was forthcoming dated 30th June, 2017 to which the Board replied on the 13th July, 2017. The topics have been discussed at every Board to Board meeting in recent months and assurances have been given by IHSL that the actual anticipated completion date of 12th October, 2017 will be achieved and that all deliverables will be in place to facilitate this.

The Board's project team, inconjunction with technical advisers, are not convinced of this and a proposal to move back the migration of services is being tabled at the next Programme Board for their consideration.

The ability of IHSL to manage their supply chain remains a cause for concern and hence high risk.

4.1.5 4027 Impact of concurrent capital projects on RHSC & DCN Reprovision: e Health

Remains high risk. At this time the eHealth work streams are being progressed and resources managed accordingly to deliver tasks for all the work streams: Infrastructure; ICT Equipment; Telecoms; Health Records and System Administration. There are overarching concerns that any further changes to the schedule will have an impact on resources and conflict with many other projects which includes new builds such as REH; Roodlands and many healthcare centres across NHS Lothian and at the same time all eHealth teams will be delivering business as usual.

The fit out of the node and server rooms, commenced on the 5th June and complete 31st August 2017 with there being a concern that the eHealth work streams would have to consolidate if there are any further delays. This won't only impact the delivery of infrastructure but the delivery of all other elements of eHealth including; procuring and deployment of equipment to the site; updating and delivery of the changes to systems such as Trak (REH and RHSC & DCN demands of System Admin Resources). At this time resources are being managed effectively and is being monitored on an ongoing basis.

4.1.6 4139 Patient Catering DCN

This risk has been downgraded. It is cited as: *"Change of service from plated to bulk catering which requires meals to be plated at ward level. This is not currently a ward staff activity. Plating and portion control is not a current ward activity and this is time intensive."*

The Reprovision Risk register is revised with the following additions to the entry: "Other clinical areas manage this within existing establishments (but in lower acuity). Work ongoing for solution" It is on the DCN and Facilities Commissioning agendas and a Short Life Working Group including Facilities and Nursing being arranged.

4.1.7 4186 Neurointerventional Service Unavailability over DCN Transfer

Is high risk cited as: *"Potential inability of Glasgow Neuroscience Service to cover service during DCN transfer."* The risk was opened subsequent to last programme board and is a standing item for discussion and resolution in a number of fora including RHSC & DCN Commissioning Group. The current DCN WGH equipment due to transfer has significant downtime associated with intermittent faults. A range of solutions are under consideration.

5 Risk Register

5.1 The Project Risk register and the closed risk reports are standing Programme Board Agenda items.

6 Involving People

6.1 The Project Risk Register is on Datix. All Project Members and key operational stakeholders have access to the register. Every 2 months register is updated on Datix, extracted to excel, held on shared folders and discussed in a range of meetings.

7 Resource Implications

7.1 There are currently no resource implications.

Brian Currie
Project Director

[redacted]

Compromises Schedule

The following list details some of the items the Board has had to / is currently considering compromising during the Construction Phase of the project. The impact of the compromise has been split into the following categories:

1. Financial
2. Operational

Item	Title	Reason for Compromise	Technical Solution	Description of Compromise	Impact	Consulted	Status
1	Ventilation in Single Bedrooms	Project Co's design is not in line with SHTM guidance in relation to air changes. Currently the only extract is via the ensuite, meaning this is 'dirty extract' which can't be used for heat recovery.	Single bedrooms have reduced air supply rates to maintain correct pressure regime. There is not solution proposed to provide heat recovery from the bedrooms.	Less air supply to the bedroom than recommended by SHTM and increased extract through en-suite which will affect running cost of the Facility. No ability to recover heat from en-suite dirty extract.	Operational	Ronnie Henderson Dorothy Hanley Janice Mackenzie Fiona Halcrow Janette Richards Pota Kalima Haem/onc Clinical Team	Under Review
2	Neutropenic Patients	As per SHTM and Clinical Specs, the rooms for neutropenic patients should be designed as isolation rooms (+10 positive pressure). However, there are 10 single rooms which Project Co have designed to balanced pressure.	No Solution proposed	NHS took a decision to operationally manage the department rather than asking Project Co to change the design.	Operational	Ronnie Henderson Dorothy Hanley Janice Mackenzie Fiona Halcrow Janette Richards Pota Kalima Haem/onc Clinical Team	Under Review
3	Drainage Exclusion Zone	Project Co were unable to divert drainage from certain exclusion zones requested within the BCRs.	1. Some drainage stacks still appear in the rooms. The stacks were boxed out and diverted to adjoining corridor. 2. Some redesign has taken place to divert drainage pipes which has included in some shower trays being fitted in ensuites. 3. Some rooms needed to be redesigned to accommodate drainage requirements. Note some drainage still appears in MRI rooms which has to be removed.	The Board have had to accept the following: 1. Boxed out drainage stacks - Additional pipework (bends, joints etc) potentially create weak points of the pipework where leakage may occur. More onerous maintenence regime required. 2. Shower trays in some ensuites require a different cleaning and maintenence regime. 3. Accepted changes in the layout of a small number of rooms making the layout different from some type of rooms within other department/s. 4. There are some less critical rooms where the drainage could not be re-designed.	Operational	Ronnie Henderson Janice Mackenzie Fiona Halcrow Dorothy Hanley CAMHS Lead	Ongoing review as issues arise
4	Theatre Canopy	Project Co did not provide remote air handling within the design for the canopy leading to an increase in the size of the canopies from what was reviewed by the Board during PQ reviews.	No Solution proposed	Increased size of canopy in two of the RHSC theatres has resulted in a change of location of surgeon pendants meaning they are further from operating table, impacting on how theatre teams will work. The Board have also had to compromise the location of the anaesthetic pendants in other theatres and the separate monitor arms in RHSC theatres.	Operational	Patrick Macaulay Ashley Hall Fiona Halcrow All signed off by the Clinicians	Agreed
5	CAMHs intensive nursing suite external area	Project Co's Courtyard design drawings did not illustrate the covered section of the courtyard.	Project Co are currently looking at alternative screens to maximise light coming into the space and extending the size of the courtyard to allow some space that is not covered. The bricks will also be painted. There is no solution for removing the cover.	The intensive nursing suite external area in CAMHS is (unexpectedly) covered, and therefore unsuitable for use by patients without redesign as there is no part of the courtyard open to sky – The Board and Project Co have now reached a compromise and are awaiting an updated drawing and spec to confirm Project Co have proposed a solution to resolve the issue.	Operational	Janice Mackenzie Sorrel Cosens	Under Review
6	No Lift to basement in Core 3	Project Co did not construct lift core 3 to accommodate a lift access to the basement.	There is no alternative solution.	The Board had to accept the lift within core 3 will not serve the basement, however, this compromises the FM routes as it requires DCN beds to be brought down the RHSC lifts or the FM lift and reduces contingencies.	Operational	Brian Corrie Jackie Sansbury Jane Campbell	Project Co Change still to be issued

7	Removal of WC (G-Q1-068)	Project Co are having to increase the size of one of the switch cupboards.	MPX request to relocate one of the switch cupboards in the radiology department to WC (G-Q1-068) to support the increase in size of switch cupboard (G-Q1-156) and the resuscitation trolley	To optimise patient safety and operational functionality the Board have agreed for the WC (G-Q1-068) to be removed to accommodate the resuscitation trolley (G-Q1-064). There will be a new arrangement for both the resuscitation and linen bay (G-Q1-063)	Operational	Janice Mackenzie Fiona Halcrow Dorothy Hanley Mike Conroy Radiology Representatives	Project Co Change still to be issued
8	Location of MRI Chillers	Project Co's original design had chillers located outside the red line boundary without legal rights to do so.	The chillers have been relocated to the roof above Department C2.	The pipe run has increased making it more expensive to install and replace and harder to maintain. It will also have an effect on the operation of the chillers by adding extra strain on the system due to the pipework's length, also requiring an additional resilience chiller. After extensive discussion on access, maintenance and replacement the solution has been proposed that includes the use of lifts.	Financial and Operational	Jackie Sansbury Dougie Coull Mike Conroy	Under Review
9	Gauss Lines in IOMRI	Project Co did not consider the Gauss lines in the original design of the room and are currently not contained within the IOMRI room	1. The lobby between MRI and OT had to be created to ensure: - the extend of gauss lines do not protrude to operating theatre. - suitable access for maintenance for faraday cage door. 2. Some sockets in the anaesthetic room need to be relocated as they are within the fringe field. The room will have to be re-designed, however, the implications of this are still being discussed.	1. The Board will have to change procedures within the area below and above the MRI to 'controlled access'. BYES will need to implement a procedure for this to ensure safety of their staff. 2. It reduces the size of the theatre adjacent to the MRI machine. 3. Currently unknown if the area and room redesign will work.	Operational	Jackie Sansbury Dougie Coull Mike Conroy	Under Review
10	Removal of Sprinklers	Project Co have removed the sprinklers from the Pod and Atrium to allow the proposed ATD design within the Pod to be accommodated.	Project Co's solution is to minimise the allowable fire load in the POD/Atrium area to 2.5MW.	Maximum allowable fire load strategy implemented in the POD restricting the future usage of the public space. Therefore, the Board are compromised in terms of flexible use of the space due to restrictions on the fire load including limitations on the type and size of Christmas tree.	Operational	Clive Armstrong Billie Hamilton Jim Gardner	Under Review
11	Movement Joint	Through lack of coordination between the Architects and Structural Designers, Project Co has designed the movement joint through the key exclusion zones identified in the BCR's.	Project Co are currently working on solutions including moving internal partitions so the joint falls within the partition wall and installing special seals within the clinical areas.	The maintenance and lifecycle implications are still to be confirmed with the Board but it is likely to be more onerous. Therefore, the affected rooms will likely be unavailable more often and will require more intensive cleaning regime	Financial Operational	Brian Currie Jackie Sansbury Janice Mackenzie Fiona Halcrow Stuart Davidson Jane Campbell Janette Richards Dorothy Hanley	Project Co Change still to be issued
12	New Facility constructed at different level to the existing RIE.	Project Co used incorrect levels when constructing the facility. As a result there is a difference in level between the link building and the existing RIE.	There are 4 locations within the link building and 1 within the RIE there are steps within the floor slab and screed is having to be built up to form slopes to account for the change in level	Not best practise to have slopes within hospital corridors. Potentially more difficult to move trollies around in this area.	Operational	Brian Currie Janice Mackenzie Fiona Halcrow Jane Campbell Jackie Sansbury	Project Co Change Under Review
13	Trolley Area in the Lift lobby in Energy Centre Ground floor	The size of the trolley area was reduced by Project Co, only allowing for 5 trollies (instead of 6)	There is no solution.	The Board need to change operational procedures to account for fewer trollies which will lead to inefficiencies.	Operational	Jane Campbell Stuart Davidson Jackie Sansbury	Agreed
14	Waste Area in Service Yard	Project Co has designed the area in the service yard to a small to allow the full facility to use standard clinical bins because of storage space in the service yard	No solution to reduction in size.	The Board have had to change their operational policy for bins that are now smaller, will need emptied more frequently and will need to dip smaller bins into larger. This meant that the Board needed to buy both a bin tipper and bin washer	Operational and Financial	Jane Campbell Stuart Davidson Jackie Sansbury	Agreed
15	Turning circle in Service Yard	Due to the size of the service yard and the additional requirement for a bin washer and tipper, delivery lorries do not have a full turning circle to change direction and must reverse to accommodate delivery unloading.	Delivery vehicles will need to perform reverse manoeuvre with use of a reversing assistant and timed delivery slots.	Designed solution not available, service yard to be tightly managed with software for timed deliveries to be procured and reversing assistants trained and available.	Operational	Jackie Sansbury Jane Campbell Stuart Davidson	Agreed

16	Basement Transformer Replacement	Project Co have located Transformers in the basement which makes it difficult for them to be moved as they can't be taken out via the lifts due to size and weight restrictions.	Project Co's solution includes opening a hole in the concrete slab in the lift lobby	This closes the area in the ground floor and basement area in the energy centre. Therefore the Board will not be able to use this area while the replacement in undertaken. This time period is still to be confirmed. There is no alternative so all deliveries and some FM operations will stop during this period. This has not yet been covered by the access and maintenance strategy.	Operational	Stuart Davidson	Agreed
17	Height reduction in basement areas/service yard	The height within the service yard was meant to be no less then 2400mm, however, there are areas within the service yard and basement Project Co have constructed with a reduced height of 2100mm.	There is no alternative solution.	There will be a negative affect on the atmosphere within the enclosed area of the service yard with a much more enclosed space. There is also restrictions with the movement and handling within the basement.	Operational	Ronnie Henderson Jane Campbell	Under Review
18	Vents in Courtyards	Following FC, Project Co introduced vents in some of the courtyards	Project Co are enhancing the landscaping within the affected courtyards	The Board have reduced useable space within the courtyards.	Operational	Sorrel Cosens Janice Mackenzie	Agreed
19	Odours from helipad entering RIE and RHSC clinical areas including theatres.	Project Co had not assessed the effect of helicopter emission during the design of the helipad. Project Co then revised the design and lowered the helipad which may have worsened the situation.	Project Co are still to propose a solution to manage the emissions.	unknown until Project Co confirm their solution.	Operational	Brian Currie Jackie Sansbury Janice Mackenzie Fiona Halcrow Stuart Davidson	Project Co Change still to be issued
20	Foul Pump at Kitchen Door in the basement	Project Co's foul drainage design in the basement locates the pump within the corridor outside the kitchen area. This has the potential to create a uncomfortable odours in an area where food is being prepared and a frequent thoroughfare to those using the basement.	There is no solution proposed by Project Co but design must be HAI scribe compliant.	Maintenance of the pump will close off this section of the corridor and affect FM activities. On a more general note staff will potentially have to work in an uncomfortable odour that again effects the overall atmosphere of the basement working environment.	Operational	Stuart Davidson Jane Campbell	Agreed
21	no concealed grid for ceilings	Project Co changed the ceiling grid and tile specification and installation of same without consultation with Board after original specification has been reviewed as RDD.	In all areas of suspended ceiling with the exception of the kitchen, revised spec with exposed grid and Bio guard Acoustic tiles is being installed.	Board presented with a fait accompli when rooms presented for review. The compromise is an aesthetic issue.	-	Janice Mackenzie Fiona Halcrow	Awaiting Project Co Change
22	Lift Size too small for Anglo installation and Replacement	The lifts within the facility are too small to allow installation and replacement of Anglo Equipment	An access door has been constructed in the 1st floor of link building and anglo will need craned/raised into position from a platform.	This procedure will cost more and will introduce restriction in the area.	Financial	Stuart Davidson Jackie Sansbury	Agreed
23	Attenuation system under car parks	Project Co have not provided disabled parking signs at the end of each individual disable space as required in the British Standards	No solution as Project Co advise that the attenuation system under the car park stops foundations being constructed at the parking bays and the reference does not meet British Standards.	Against best practice and not consistent across Campus site.	Operational	Jackie Sansbury Stuart Davidson Steven Alderson	Agreed
24	Access to fire dampers	Project Co has located fire dampers in a position obstructed by services making them difficult to access.	Project Co are re-designing access to fire dampers	Due to the location of some fire dampers the access will take considerable amount of time to re-set following annual drop tests or in the event of actual alarm.	Operational	Ronnie Henderson	Project Co Change Under Review
25	Parents Beds	Project Co's original parent bed design did note allow enough circulation space to get to the patient or on the other side of the bed to clean and make up the bed	The bed has been made smaller	The Parent bed may be too small for some parents and therefore they may not be able to sleep comfortably beside their child.	Operational	Janice Mackenzie Fiona Halcrow Dorothy Hanley Jackie Sansbury Jane Campbell RHSC Nursing Team Reps	Agreed
26	LTHW Change	Project Co amended the route of LTHW pipework with no cost savings offered.	The LTHW being constructed in the link tunnel between energy centre and basement.	There is a drop in ceiling and a change in the light position that again has a negative affect on the atmosphere in the basement	Operational	Stuart Davidson	Project Co Change Under Review
27	No parent shower for parents in the 4 bedded rooms	Project Co's original design did not provide any parent showers on the ward for parents in the 4 bedded rooms because NHS policy doesn't allow parents to use the children's showers	The Board issued a Board Change to transform one of the Grab and Go's into a Parent's shower room.	This has cost additional money to provide	Financial	Janice Mackenzie Fiona Halcrow Dorothy Hanley Jane Campbell	Agreed

28	Inconsistencies between Design and Construction	The Board are finding a lot of instances where items have been constructed / fitted in the wrong space. For example 1. BMS control (BMS999) and Cleaner sockets (OUT0056) are not where they are illustrated on the drawings. 2. Cupboard in the wrong place in Sphere 3. In Sphere an observation window was higher than designed.	In order to minimise impact or reworks the Board take a view at the time the issue is raised whether the mistake needs to be corrected by Project Co.	The Board considered that some mistakes could be accommodated with some having no impact and others needing slight changes to operational procedures.	Operational	Janice Mackenzie Fiona Halcrow Dorothy Hanley	Under Review
29	Entrance Matting	Project Co did not provide entrance matting at all doors to external areas however, it is not possible to change the floor slab to incorporate recessed floor mats in all areas.	Project Co have provided several different details including: 1. Fixed but raised matting 2. Locating recessed mats outside 3. Board supplying some mats as group 3 that can be removed when not needed.	The Board are having to provide some mats as group 3.	Operational and Financial	Jackie Sansbury Jane Campbell Stuart Davidson	Agreed
30	Temperature Control Valves	Project Co have not provided electronically actuated valves to individual radiant panels that allows BMS control of temperature.	Thermostats are located in each room that allow slight changes to localised room temperature	The Board could not incorporate temperature control into enhancements to the patient bedside environment	-	Ronnie Henderson Janice Mackenzie Fiona Halcrow Sorrel Cosens	

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NHS Lothian

RHSC + DCN – LITTLE FRANCE

PROGRAMME BOARD – 24 July 2017

SUMMARY FINANCIAL POSITION - CAPITAL

Recommendation/ action required:

The Programme Board is asked to:

- Note the position.
- Note the risk that the project may not deliver a break even position against allocated budget.

Author:	**Director:**
Garry Luke Project Accountant RHSC+DCN – Little France	Brian Currie Project Director RHSC+DCN – Little France

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NHS LOTHIAN
Royal Hospital for Sick Children & Department of Clinical Neurosciences
Programme Board

24 July 2017

SUMMARY FINANCIAL POSITION AT 12 JULY 2017

1. Purpose

1.1 The purpose of this report is to provide the programme board with a summary of the forecast capital expenditure in relation to the re-provision of the current Royal Hospital for Sick Children and Department of Clinical Neurosciences, at Little France.

2 Recommendations

2.1 The Programme Board members are asked to:

- Note the projected overspend position.
- Note the risk that the project may not deliver a break even position against allocated budget.

3 Overall Forecast

3.1 As previously reported to the board, it is currently anticipated that there will be an overspend against the approved non-NPD Capital budget. Table 1, shown below, outlines the current forecast against approved budget at FBC, as well as illustrating movements in the forecast position from the last reported position at the March 2017 meeting of the board.

	Approved Budget at FBC	Forecast as at March 2017	Current Forecast	Variance from FBC	Variance from March 2017 Forecast
	£k	£k	£k	£k	£k
Reference Design	2,541	2,541	2,541	0	0
Petrol Station Site	550	702	702	(152)	0
Enabling & Town planning	22,174	22,691	22,691	(517)	0
Offsite Flood	4,298	6,294	6,999	(2,701)	(705)
Clinical Enabling	13,641	10,948	10,799	2,842	149
Equipment	36,880	35,095	35,095	1,785	0
Change / SA's	0	2,804	3,968	(3,968)	(1,164)
Total	**80,083**	**81,075**	**82,794**	**(2,711)**	**(1,719)**

Table 1 –Overall Non- NPD Capital Forecast

3.2 It should be noted that the above figures are inclusive of £2.427m of contingency funding, of which £2.277m sits within equipment budgets, and £0.150m is allocated to change costs.

3.3 Discussion of the material movements from the last reported position is contained below.

4 Enabling & Town Planning:

4.1 Although there is no projected movement from the March 2017 forecast, it is important to note that the costs included in the current forecast assume that costs incurred in respect of variation management for both NHSL and Consort are to end in October 2017, and that traffic management costs will continue to be incurred until the facility is fully operational in March 2017. Any slippage to these dates would incur further unfunded cost.

5 Offsite Flood

5.1 Table 3, shown below, outlines the movements in forecast expenditure in relation to the ongoing off-site flood prevention works.

Offsite Flood	Contractor Appointment	March 2017 Forecast	July 2017 Forecast	Variance from Original	Variance from March Forecast
	£k	£k	£k	£k	£k
Tendered Works	2,497	2,497	2,497	0	0
VAT on works	499	499	499	0	0
Approved CE's	0	415	1,878	(1,878)	(1,463)
Anticipated CE's	0	1,200	315	(315)	885
VAT on CE's	0	323	439	(439)	(116)
Sub Total - Total Works Cost	**2,997**	**4,935**	**5,629**	**(2,632)**	**(694)**
NHSL TA Fees / Design	690	1,128	1,133	(443)	(5)
NHSL Legal	87	83	83	4	0
Surveys	179	22	24	155	(2)
Enabling	110	128	131	(21)	(3)
Contingency	200	0	0	200	0
Total Forecast / Variance	**4,263**	**6,294**	**6,999**	**(2,736)**	**(703)**

Table 3 –Forecast Off-Site Flood Capital Spend

5.2 As has been described to the board previously, the nature of the NEC3 Type C contract means that NHSL is exposed to costs for compensation events (CE's). To date, a number of CE's have occurred, leading to

significant additional cost to the board and subsequent delays in project completion. The value of CE costs agreed to date is £1.878m, with a further forecast cost of £0.315m included for CE payments not yet agreed.

5.3 The above figures assume completion of off-site flood works in October 2017, if these dates were to slip there would be further cost to the board in respect of ongoing technical and project management fees.

5.4 VAT on the main works is irrecoverable, and therefore contributes towards the project overspend as costs increase.

6 Clinical Enabling

6.1. Projected clinical enabling costs have reduced from the March 2017 forecast, predominantly due to reductions on anticipated spend within the Pharmacy (£0.142m reduction), and Renal and Critical Care (£0.007m reduction) projects.

7 Equipment

7.1 Overall budget allocated to equipment costs remains at £35.095m, with projected expenditure on new build equipment projected to be £29.124m; a reduction from the prior forecast. The procurement process for the purchase of that equipment continues to progress, with 62% of the total by value committed as at July 2017. As the procurement process nears conclusion a greater degree of certainty in terms of the final equipment spend will be achieved.

7.2 Contingency budgets currently equal £2.277m, representing an increase from the position in March due to the aforementioned reduction in projected new build equipment and a reduction in clinical enabling equipment spend within Critical Care and Pharmacy. However there remains an element of risk around future purchase prices and, as such, any further transfer of this contingency to fund overspends in other project areas would require risk assessment.

Equipment Forecast	March 2017 Forecast	July 2017 Forecast	Variance
	£k	£k	£k
New Build / NPD Equipment	29,733	29,124	609
Contingency	1,500	2,277	(777)
MRI St Johns	1,200	1,200	0
Clinical Enabling	2,662	2,494	168
Total	**35,095**	**35,095**	**0**

Table 4 –Forecast Equipment Spend

7. Change

7.1. Change costs resulting from change instructions by the board are funded through a combination of NHSL capital funding and donations from charitable bodies. The below table outlines change costs attributable to NHSL which are currently included in the project change tracker, versus the March 2017 forecast, with estimated amounts included for SA legal fees based on prior experience.

Change Costs	March 2017 Forecast	July 2017 Forecast	Variance
	£k	£k	£k
Main works	1,931	3,094	(1,163)
NHS QS & Legal Fees	204	204	0
Consort Legal Fees	120	120	0
IHSL Fees	300	300	0
Compensation for late handover	100	100	0
Legal Fee Contingency	150	150	0
Total	**2,805**	**3,968**	**-1,163**

Table 5 –Forecast Change Capital Spend

7.2. As is shown above, there has been a significant increase in projected change costs due to change instructions issued by the board. The below table summarises the key changes which have contributed to the above increase.

Change	March 2017 Cost	July 2017 Cost	Variance
	£k	£k	£k
Chiller Pipework	256	328	(72)
Vending Storage	31	64	(33)
Emergency Department Sign	10	32	(22)
Courtyards	215	145	(70)
Room Naming	20	94	(74)
Landscaping Outside Blue Line Boundary	0	600	(600)
Number Plate Recognition	10	66	(56)
First Fix Equipment	0	40	(40)
External Lighting	0	19	(19)
IOMRI	0	51	(51)
Bio Quarter Street furniture	0	108	(108)
Miscellaneous Low Value	0	19	(19)
Total	542	1,566	(1,163)

Table 6 –Detailed Breakdown – Change Costs

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Garry Luke
Project Accountant
13/07/2017
[redacted]

PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

RHSC & DCN – LITTLE FRANCE

PROGRAMME BOARD

24 JULY 2014

MRI PROVISION FOR THE NEW RHSC/DCN BUILDING

Recommendation/ action required:

The Programme Board is asked to approve the disposal/Selling of MRI and CT at both RHSC and DCN

Author:	**Director:**
Mike Conroy Radiology Manager DATCC	Brian Currie Project Director RHSC and DCN Reprovision

NHS LOTHIAN

Programme Board Meeting 24th July 2017

Brian Currie, Project Director

MRI PROVISION FOR THE NEW RHSC/DCN BUILDING

1 Purpose of the Report

1.1 The purpose of this report is to recommend that the Board approves the disposal/Selling of MRI and CT at both RHSC and DCN

Any member wishing additional information should contact the Executive Lead in advance of the meeting.

2 Recommendations

The Board is recommended to:

2.1 Approve the proposed changes as noted below.

3 Discussion of Key Issues

3.1 Currently there is 1 CT and 1 MRI on the RHSC site and 2 MRI (DCN and Main radiology department) and 2 CT (DCN and Main radiology department) on WGH site. Once the DCN has relocated, an additional CT has been commissioned for the WGH main Radiology department to ensure the 2000 In-Patients remaining on the WGH have capacity to be imaged and the current workload on mobile CT van can be absorbed back into funded NHS capacity. The MRI workload associated with DCN, which includes sessions on the main radiology scanner, will transfer to the little France site and the remaining In-patient workload will be absorbed into the remaining single MRI scanner in the main radiology Department. The data supporting this strategy was ratified by the external Capita report in 2015.

3.2 Post relocation of DCN and RHSC will leave 1 MRI and 1 CT available for disposal/selling/utilising on each site. The RHSC site will be closed and it is assumed that the equipment will be removed and sold to the most cost effective bidder as the equipment is out with its recommended replacement cycle (12years old)

3.3 Within DCN there are various options to consider, it is expected that the CT scanner will be sold/disposed as a new service is being commissioned in the main radiology department. The options around MRI are to be discussed further in this paper.

3.4 The University of Edinburgh have a MRI scanner housed within DCN that provides capacity for NHS Stroke and in-patients at a cost of £76K pa, the university wish to retain this facility as long as possible due to long term research projects..

3.5 The Current market value at this moment in time (April 17) for the equipment being replaced is:

- RHSC
  - MRI £300K - £100K
  - CT £125K - £15K
- DCN
  - MRI £200K - £150K
  - CT £100K – 40K

All these prices will decrease over the next 12 months as the equipment ages.

3.6 Option Appraisal – DCN MRI

- Option 1 - Sell/Dispose DCN MRI
  - Advantages
    - Releases capital
  - Disadvantages
    - No NHS contingency on WGH site if MRI fails.
    - Loss of potential capacity as the equipment will have 18 months asset life left once DCN relocates which could be utilised.

- Option 2 - Retain MRI and staff accordingly
  - Advantages
    - Provides Contingency for MRI on WGH site, if main department scanner fails.
    - Provides additional capacity as and when required
    - Ensures equipment on site is maximised for its full asset life.
  - Disadvantages
    - Doesn't release capital
    - Increased revenue costs (Circa £900K for staff and maintenance)
    - The longevity of the MRI in DCN is related to the potential need to vacate the space to make way for the cancer centre project.

- Option 3 - Retain MRI and use for backup only
  - Advantages
    - Provides Contingency for MRI on WGH site, if main department scanner fails.
    - Ensures equipment on Site is maximised for its full asset life.
  - Disadvantages
    - Doesn't release capital
    - Increased revenue costs (Circa £100K, does not include staff)

        - The longevity of the MRI in DCN is related to the potential need to vacate the space to make way for the cancer centre project.

- Option 4 – Utilise University MRI for Backup and sell/dispose existing scanners.
    - Advantages
        - Releases capital
        - Provides Contingency for MRI on WGH site, if main department scanner fails.
        - University currently provides back up for DCN MRI on a routine basis for stroke MRI.

    - Disadvantages
        - The longevity of the MRI in DCN is related to the potential need to vacate the space to make way for the cancer centre project.
        - Equipment will have 18 months asset life left once DCN relocates

3.7 The preferred option is Number 4 as it is the most cost affective option in the short to medium term. The University of Edinburgh have confirmed they would see this as a favourable option for themselves.

4 Key Risks

4.1 If activity changes on the WGH site due to new techniques requiring MRI scanning such as Multiparametric imaging of the prostate, activity could increase to the point that another MRI scanner on the WGH site will be needed in the next few years rather than in the next 5 years.

4.2 The decision on when the cancer centre project is commissioned affects all potential options, as the DCN building will need to be closed which in turn would decommission the UoE MRI and the NHS DCN MRI (if we kept it going). If Radiology required more capacity at this point on the WGH site, options would be to resort to expensive private sector mobile MR capacity or purchase a new MRI.

5 Risk Register

5.1 None to note

6 Resource Implications

6.1 If the Equipment is sold, at today's prices an opportunity exits to make £725K which also includes the removal from the building. With all options there will be a

revenue tail from funding an additional MRI that is fully staffed to paying the university for ad hoc support in terms of downtime.

Mike Conroy
Radiology Manager
18th May 2017
[redacted]

PROUD HISTORIES | NEW CHAPTERS

NHS Lothian

RHSC & DCN – LITTLE FRANCE
PROGRAMME BOARD – 24/07/17

STATE OF READINESS

Recommendation/ action required:

The Programme Board is asked to note the current position in terms of the state of readiness in respect of the Contract Management related Completion Criteria.

Author:	**Director:**
Stuart Davidson Contracts Manager RHSC and DCN Reprovision	Brian Currie Project Director RHSC and DCN Reprovision

NHS LOTHIAN

Programme Board Meeting
24/07/17

Project Director

STATE OF READINESS

1 Purpose of the Report

1.1 The purpose of this report is to recommend that the Board note the current position in terms of the state of readiness in respect of the Contract Management related Completion Criteria.

Any member wishing additional information should contact the Executive Lead in advance of the meeting.

2 Recommendations

The Board is recommended to:

2.1 Note the contractual deliverables by IHS Lothian under the terms of the Project Agreement and the ramifications of not providing the requisite information timeously and in the required format.

3 Discussion of Key Issues

3.1 The Project Agreement places a requirement on IHS Lothian (IHSL) to produce and agree documentation and handover information with NHS Lothian at least three months before the issue of a Certificate of Practical Completion (Actual Completion). Information includes how IHSL will work and how they will work with the Board in jointly interfacing with hospital activities. Appendix 1 details the background to the Project Agreement and how the Board can be satisfied in terms of Performance requirements and monitoring.

3.2 Project Co (IHSL) is responsible for reporting any Availability and Performance Failures. The Board needs to have mechanisms in place to be able to verify the completeness and the accuracy of reporting which should include any failures recorded within the monthly performance reports. These are contained within the Contract Management Plan and Contracts Administration Manual.

3.3 Without the documentation and qualitative information imparted by Project Co this will affect the Boards operational phase and also the Boards post-completion activities. It will affect Project Co Service Providers ability to safely manage the facility and it will prohibit the Board from duly exercising its obligations under the

Construction (Design and Management) Regulations 2015 to provide information on the safe use and operation of the building.

3.4 The extent of engagement beyond what is anticipated as reasonable may incur additional costs and resources to ensure what is expected is attained.

4 Key Risks

4.1 The timing and qualitative aspects of the contractual deliverables are at risk. If the information is absent then Project Co will ultimately fail to meet a performance criteria under the Payment Mechanism and financial penalties will result during the operational phase.

4.2 If the requisite information is not prepared timeously this will have an effect on the Boards operational activities. Information includes how IHSL will work and how they will work with the Board in jointly interfacing with hospital activities.

It will also hinder the progression of post-completion activities as we would not be able to impart Health & Safety Information to contractors engaged by the Board – a legislative requirement under the Construction (Design and Management) Regulations 2015.

4.3 There is also a risk that the pressure to complete on the agreed date may render some documentation / information absent or poorly drafted.

5 Risk Register

5.1 There is a risk arising directly from the delay of the requisite information and the qualitative aspects absent arising from review.

6 Resource Implications

6.1 There are resource implications related to handover and commissioning activities and these are being factored into forward planning for the targeted end date. Should the targeted end date not be achieved there may be additional costs incurred.

Stuart Davidson
Contracts Manager
17/07/17
[redacted]

List of Appendices

Appendix 1: Contract operation summary

Appendix 1

Part 6 and Schedule Part 12 of the Project Agreement contains the Service Requirements which establishes facilities management (Hard FM) requirements to be achieved by Project Co, through their services subcontractor, after completion.

Service Commencement

Project Co has to satisfy to the Independent Tester to support their completion notification that the following matters have been addressed:

· Mobilisation Plan

· Project Co's Staff

· Helpdesk

· Project Co Plans (as below)

· Facilities Handover (including Government's Soft Landings as below)

The required Project Co Plans are identified as below.

· Interface Protocol

· Service Delivery Plan

· Trust Services Training Plan

· Mobilisation Plan

· Communications Plan

· Contingency Plan

· Health & Safety Plan

· Fire Safety Management Plan

· Building User Guide

· Quality Management Plan

· Environmental Management Plan

· Five Year Maintenance Plan

· Schedule of Programmed Maintenance

· Lifecycle Profile

· Lifecycle Schedule

· Energy, Utilities & Water Management Plan

· Energy Efficiency Plan

The Government Soft Landings relates to a recent initiative by the Government "to be used to bridge the gap between expectation and reality by engaging users and operators to review and comment upon the design, construction, commissioning and handover proposals."

Within 18 months from services commencement Project Co will achieve accreditation in their management systems in respect of Health & Safety, Quality Management and Environmental Management Systems. These accreditations shall be maintained throughout the tenure of the contract.

Helpdesk Services

Project Co will provide a Helpdesk service 24 hours per day, 365(6) days a year in respect of the Services.

Maintenance

Project Co will be responsible for providing maintenance, service contracts, repairs, replacements & preventative regimes to all elements of the Facilities, grounds, structure, fabric, mechanical and electrical services, as well as fixtures, fittings signage and specialist installations and equipment.

Replacement of Lifecycle Assets

Project Co will carry out the renewal and replacement of Lifecycle Assets in order to maintain the Facilities in accordance with the Agreement, to meet Availability requirements/Services Quality Standards and in accordance with the Lifecycle Schedule.

Unprogrammed Maintenance

All elements of the Facilities will comply with the Service Standards, Schedule Part 6 (Construction Matters), the Handback Requirements and the requirements of manufacturers' original and subsequently amended specifications, guidelines and warranties. Where Faults occur in the Facilities, Project Co will Respond and Make

Safe and Rectify such Faults within the Maintenance Service Respond and Make Safe Times and Rectification Times.

Equipment

To the extent that Project Co is required to maintain Equipment, it will be responsible for supplying, administering and distributing Equipment evaluation records required by the NHS.

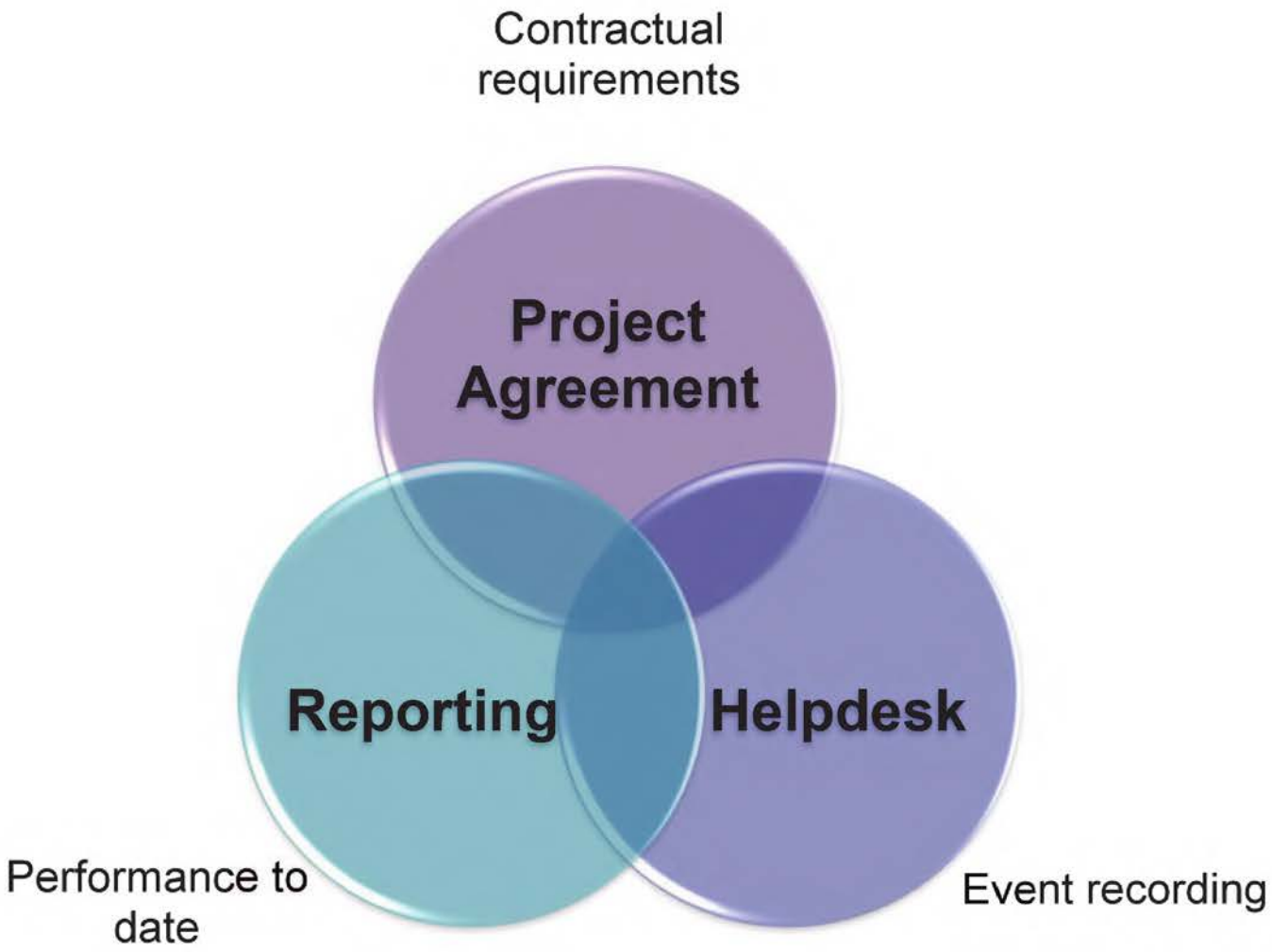
Energy & Utilities Management

Project Co will ensure the efficient, effective, safe and timely supply of energy, utilities and controls (electricity, gas and water, etc.) across all areas of the Site in order to ensure continued operation of the Facilities, 24 hours per day, 365(6) days per year for the duration of the Agreement.

In order to derive maximum benefit from this Project Agreement Project Co (IHSL) are required to deliver against circa 70 Performance Standards throughout the Project Term. They will regularly report against this criteria and deliver monthly and annualised reports stating such.

Where performance on the ground is negative and impacting on our services we have the mechanism through the Project Agreement to levy financial deductions. This is a means to incentivise performance levels. This is done via the Payment Mechanism (Paymech).

Performance Management Linkages



The payment mechanism lies at the heart of the NPD contract. The primary purpose of the payment mechanism is to incentivise Project Co (IHSL) to provide the services to the required standards.

If these standards are not met Project Co (IHSL) will incur financial deductions, if they are met Project Co (IHSL) receives full payment.

The NPD Contract details the deductions which should be applied in the event of Availability and/or Performance Failures occurring. These deductions are integral to

the value for money for the public sector and must be enforced in accordance with the terms of the contract.

Project Co (IHSL) is responsible for reporting any Availability and Performance Failures. The Board needs to have mechanisms in place to be able to verify the completeness and the accuracy of reporting which should include any failures recorded within the monthly performance reports.

Deductions from Monthly Service Payments and Service Failure Points (SFPs)

If at any time during the Operational Term an Unavailability Event or a Performance Failure shall occur the Board shall subject to criteria be entitled to make Deductions from the relevant Monthly Service Payment in respect of that Unavailability Event or Performance Failure. The maximum aggregate of all Deductions that the Board can make from a Monthly Service Payment shall be the Adjusted Service Payment.

Events

Reported through the Helpdesk - an incident or state of affairs:-

(a) not meeting the Service Requirements; or

(b) not satisfying the Availability Conditions

Logged on the Helpdesk and remains an Event unless fails Rectification Time

Performance Failures (PF)

An incident not meeting the Service Requirements; which has not been rectified within the relevant Rectification Time, if applicable

If not rectified within Rectification Period then Additional Period(s) run and further PFs can accrue.

If no Rectification Time then there is an immediate Performance Failure (PF) and if not remedied within Remedial Periods further PFs accrue will still apply.

Availability Condition

To remain Available, each area must continue to meet all of the Availability requirements:

- Accessibility Condition
- Safety Condition
- Use Condition and
- Prescribed Health Function Condition or, as appropriate,
- the Prescribed Operational Function Condition
- Use Parameters and relevance of Room Data sheets

The area does not need to be unusable or unused - continued use impacts on the amount of deductions

There is an Annual review of weightings.

Rectification Time

The Rectification Time is stated in the Service Requirements

In some cases there is none and hence immediate deduction applies.

The period commences

Logged Event Time (notification to helpdesk) is extended if the Board denies access to the area and in so doing prevents Rectification of that Event

When it goes wrong - consequences

Warning Notices issued by the Board

Increased monitoring by the Board at Project Co' cost

Exercise of remedial rights

Replacement of a non performing Sub Contractor

Project Co (IHSL) Event of Default (which can lead to termination)

The Helpdesk

It is vital to ensure that our staff understand how and when to report problems which are affecting them and in the delivery of patient care. There will either be contact made with our own in-house Estates & Facilities Helpdesk or the Project Co (IHSL) Helpdesk. To that end we are producing and influencing documentation to cater for all aspects and to communicate this. This will largely cater for reactive issues.

For planned and programmed maintenance works we have requested annualised and five-yearly look ahead programmes to ensure adequate planning and co-ordination can take place to absolutely minimise inconvenience to building users.

The Building User Guide

We are assisting in producing a Building User Guide which will cater from the outset as a one-stop guide to all you need to know about the operation of the building and its services. From the Family Hotel, ward level, Common Facilities all the information need to operate the facility safely and efficiently. This will be targeted at different levels dependent upon the audience.

This sits amongst a suite of documentation produced by Project Co (IHSL) together with jointly produced processes to ensure a robust level of co-ordination and co-operation takes place.

NHS Lothian

RHSC/DCN Edinburgh HV issues

19th Jun 2016

Health Facilities Scotland

1. Introduction

1.1. Health Facilities Scotland (HFS), were contacted my NHS Lothian (NHSL) via a telephone call on Tuesday 13th June 2016 to request a review of the High Voltage installation at The Royal Hospital for Sick Children (RHSC) in Edinburgh.

1.2. The initial request was backed up by email on 14th June 2016 which also provided some written context and schematics. The schematics provided are

- HV Schematic at Financial Close WW-XX-XX-SC-530-01_01-1
- HV Schematic revision F WW-XX-XX-SC-530-01-6 rev F
- Basement access 7 maintenance drawing (no drawing number)
- HV Cable routes (no drawing number)
- Energy Centre General Arrangement HLM-Z5-SL-PL-220-001_F

1.3. The questions asked by NHSL are as follows:-

- Does the installed fire wall separation of the substations comply with guidance and does the current arrangement constitute four separate substations?
- Does the route of the HV cables comply with SHTM 06 to provide critical care resilience?
- Does the HV solution provide a high degree of resilience if there is a loss of site wide HV supplies and in particular if there is a failure to substation 2A and 2B?
- Does the proposed solution adequately allow for partial or total shut down of the HV network in the event of a fire or some other emergency?
- Is the ventilation system appropriate for the substations?
- Should the LV and HV sections of the substation be segregated?
- What is Health Facilities Scotland's interpretation of the ventilation pressure requirements for four bed wards?

1.4. The questions posed in 1.3 will be considered and responded to in section 2.

2. Questions and responses

2.1. <u>Does the installed fire wall separation of the substations comply with guidance and does the current arrangement constitute four separate substations?</u>

- Can you confirm that the substations and surrounding plant rooms are defined as a "place of special fire risk" as per current Appendix A of Scottish Building Standards Non-Domestic Technical Handbook (NDTH)?
- The following are extracts from NDTH:-

2.1.8 Places of special fire risk

a place of special fire risk should be enclosed by compartment walls with a medium fire resistance duration. [note: for hospitals medium is 1hour fire resistant]

2.9.3 Travel Distance *see Table 2.11 Recommended travel distance (m)*

Within plant rooms or within roof top plant rooms: 1 Direction = 18m, >1 Direction = 45m

Within a place of special fire risk: 1 Direction = 9m, >1 Direction = 18m

2.9.10 Escape from inner room

Occupants within an inner room could become trapped where there is an outbreak of fire in the adjoining access room. Therefore, escape should only be by way of one other room, and the inner room should:

not be used as sleeping accommodation

have an escape route that does not pass through more than one access room

the access room should be fitted with a suitable automatic fire detection and alarm system to warn the occupants of the inner room of an out break of fire

the access room should not be a place of special fire risk.

2.9.16 However if the door is an emergency door or a door serving a place of special fire risk, the side-hung door should open in the direction of escape regardless of occupancy levels.

2.9.26 Due to a very high fire risk, with potential for rapid fire growth, a place of special fire risk should only be accessed from a protected zone by way of a protected lobby. This is to give additional protection to the protected route of escape.

2.14.9 Venting of heat and smoke from basements

Smoke outlets should ....

where they serve a place of special fire risk, they are separate from smoke outlets from other areas, and

Annex 2B: ***Additional guidance for hospitals***

Fire hazard departments

The departments in list A below should:

never be directly below, nor directly adjoin, the operating theatres, intensive therapy units or special care baby units, and

be provided with a fire suppression system (as in clause 2.1.2) where they are directly below, or directly adjoin, any other hospital department to which patients have access.

LIST A

boiler house

central stores

commercial enterprises

flammable stores

laundry

main electrical switchgear

main kitchens

refuse collection and incineration

works department.

A door from a hospital street to an adjoining compartment should:

be located so that an alternative independent means of escape from each compartment is available, and

not be located in the same sub-compartment as a door to a protected zone containing a stairway or lift.

Annex 2B.6 ...

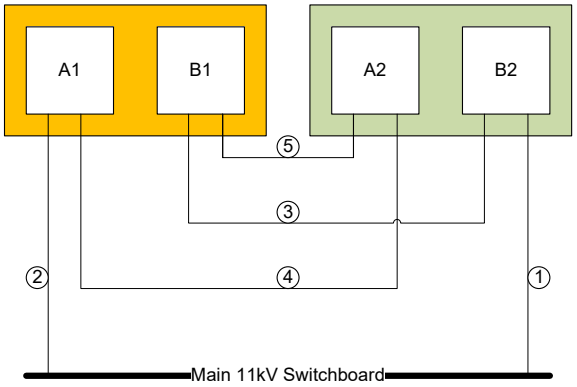
Different fire-fighting facilities should not be provided throughout the varying storey heights of a building. Once the topmost storey height of a building has been established, the intention is that fire-fighting facilities recommended at that height should be applied throughout the escape stair. Similarly, where a building contains a basement, the recommendations become more demanding the greater the depth.

Table 2.18 Facilities on escape stairs in hospitals with hospital streets:

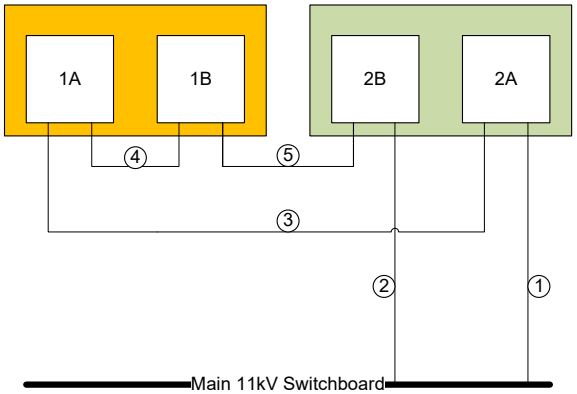
Basements at a depth <10m: fire-fighting stair (see clause 2.14.3); ventilation to stair (see clause 2.14.6); unvented fire-fighting lobby (see clause 2.14.5); dry fire main (outlet located at every departmental entrance).

2.2. Does the route of the HV cables comply with SHTM 06 to provide critical care resilience? Does the HV solution provide a high degree of resilience if there is a loss of site wide HV supplies and in particular if there is a failure to substation 2A and 2B? Does the proposed solution adequately allow for partial or total shut down of the HV network in the event of a fire or some other emergency? (Note: these questions considered together).

- Simplified schematics of the HV cabling and substation solutions are as follows:-



Financial close simplified schematic



Construction simplified schematic

- There is a material change between the financial close schematic (WW-XX-XX-SC-530-01_01-1) and the current construction schematic (WW-XX-XX-SC-530-01-6 revision F) with respect to the HV feeder cables.
- WW-XX-XX-SC-530-01-6 now shows the main feeder cables from the HV switchboard going to substations 2A and 2B. If both substations are lost (in say a fire event) there would be no HV circuit to Substations 1A and 1B.
- The financial close schematic shows the high voltage ring split between Substations A1 and B2. It is not clear from the schematics why this change has taken place.
- It is our opinion that the arrangement shown in WW-XX-XX-SC-530-01-6 is not as resilient as the solution shown in WW-XX-XX-SC-530-01_01-1. Further it is not clear how the solution shown in WW-XX-XX-SC-530-06 meets the various requirements for resilience with SHTM 06-01 (i.e. 4.37, 4.39, 4.40, 6.3 etc). Has a distribution risk assessment been carried out by the designers and clinical colleagues on the various electrical supplies to category 1 to 5 areas?
- It is noted that the Distribution network operator's (DNO's) HV switchgear and cables are close coupled to the main HV switchboard in the energy centre. Has a risk assessment been carried out for this arrangement and what is the fire strategy for this area?

2.3. Is the ventilation system appropriate for the substations?

- We are unable to comment on the ventilation rates to the substations as this is out with the scope of this report.
- The extract fans are shown in the substation. This means that they will not be able to be maintained without an authorised person for high voltage AP (HV), a permit to work and limitation of access permit. This may cause operation issues and SHTM 03-01 Part A 4.17 notes "Care should be taken during installation to ensure that electrical and mechanical services are not installed in positions that will reduce or impede access."
- Whist the extract fans are shown as duty and standby, there is no note on the resilience of the supply system. Further if these units (supply and extract) are fed via a single cable, this may be a cause for concern from a resilience perspective.

2.4. Should the LV and HV sections of the substation be segregated?

- SHTM 06-01 7.19 notes that "The access to any HV substation, including the HV side of a transformer, should be arranged so as to prevent unauthorised access (see Scottish Health Technical Memorandum 06-03)." It is not clear from the drawings how segregation from the HV and LV sections of the substations are achieved. Section 7 of SHTM 06-01 notes that "For the purpose of this guidance, HV substations are deemed to be the total area of the HV switchgear and transformer enclosure."
- SHTM 06-01 part A 9.41 notes advises that "Care should be taken to ensure that only HV Authorised Persons (AP (HV)) have access to the HV equipment."
- Section 3 of SHTM 06-03 outlines the Management policy for HV installations and this should be cross referenced to the installation to address any gaps.
- In addition SHTM 06-01 part A 7.18 requires that internal substations should have "a minimum of two sets of door openings connecting directly to a safe haven, on opposite sides, to provide suitable escape routes. Additional door openings will be required to ensure that the maximum travel distance to a safe haven is no greater than 9m." It is not clear that this is met given the potential layout of plant and equipment in the various rooms.
- The access strategy for plant and equipment is not clear from the drawings provided. How is a major item of plant, such as a transformer, intended to be replaced?
- Has the use of fire suppressions systems been considered and risk assessed for the substations (SHTM 06-03 7.25 et al).
- What clinical services are provided above each of these substations, the fire separation between the sub station and these areas and what is the resilience plan if there is a failure in these areas?

2.5. What is Health Facilities Scotland's interpretation of the ventilation pressure requirements for four bed wards?

- SHTM 03-01 Part A, Appendix 1, Table A indicates the air change rates and pressure regime for clinical areas within healthcare premises. There is no four bed ward noted

in Table A, however it would not be unreasonable to treat this area as one would a single bed ward with respect to ventilation as the measures for infection control would be the same. Therefore the room should be neutral or slightly negative with respect to the corridor.

- SHTM 03-01 Part A clause 1.35 et al details the Management Action with Clause 1.37 highlighting the need to seek guidance from Clinical colleagues.
- SHTM 03-01 Part A clause 1.39 et al details the Design and validation process. Table 2 highlights the model to be followed and item 2 outlines some the design questions to be asked and resolved.

3. Guidance reference

3.1. The following guidance documents have been used as reference documentation (al parts)

- SHTM 00
- SHTM 03-01
- SHTM 06-01
- SHTM 06-02
- SHTM 06-03
- SHTM 85
- Scottish Building Standards Non-Domestic Technical Handook

From: Hanley, Dorothy
Sent: 20 May 2019 08:59
To: Currie, Brian
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Attachments: Record of General Risk Assessment ventilation _combinedrev300118.pdf

Importance: High
Sensitivity: Confidential

From: Currie, Brian
Sent: 14 March 2019 13:30
To: Goldsmith, Susan
Cc: Crombie, Jim
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High
Sensitivity: Confidential

Susan

Thanks for passing on further correspondence from Alex and Donald Inverarity.

I respond to various points contained in numerous recent emails as follows:

1 Infection Control involvement in the project

I reiterate my email of 12/03/19 at 8.06 and 12/03/19 at 10.09 with further clarification in yellow:

On further reading of the chain of emails from Lindsay Guthrie to Alex can we just advise that Sarah Jane Sutherland, Lead HAI Scribe Advisor, and IPCN Emma Collett last visited the project on Monday 28th January, 2019 at 9.15am.

The purpose of this visit was to reassure Sarah Jane that Janette (recently retired HAI Scribe advisor) was fully involved in the room review process and in anticipation of an imminent completion or handover of the facility. Janette was provided with the timetable for our first and second round of reviews and she chose which ones she wanted to attend. To ensure a consistent approach was taken to the reviews a checklist of what to look at was developed, which was discussed with Janette. The project team have been consistently checking that previous observations made by them have been addressed and to identify any further observations that have occurred since the 2nd room reviews though to completion.

A further meeting on 27th February with one of the project's Commissioning Managers also took place to review previous documentation signed off by Janette Richards.
However, it is accepted that given the uncertainty of the actual completion date, to almost the day before it occurred, ICPT were not involved in the actual day of completion. It is worth emphasising that patients will not occupy the facility until 9th July, 2019. It is our intention to carry out a pre handover check when all construction activity by IHSL/MPX completes in June.

We can confirm that the Board's Infection Control have been involved from the early stages in the project including competitive dialogue, evaluation of some parts of the submission; actively

contributing with the clinical teams to the clinical area design development and approval process reviewing relevant specifications for items such as sanitary ware, flooring, vent coverings etc.

We have been fortunate in that there has always been a nominated IPCN for Reprovision and they have been an integral part of the process participating in key meetings and, if they could not be present at meetings, taking the opportunity to comment on meeting outputs where required and following up on issues in consultation with project and other clinical staff.

Throughout each of the stages of the project they have provided expert advice on elements such as isolation room design and functionality, room ventilation design, and HAI Scribe.

They have also joined project team personnel in reviewing the rooms for adherence to design brief, quality of finish and functionality, (including ease of cleaning and compliance with SHTM ~~and HEI guidance~~) and advised us on aspects of the building that they felt HEI inspectorate may consider during any future inspections.

2 Water Quality

Before updating you on the current water quality status on site we are at a loss to understand Donald's comment that "there was no further communication". The email attached to Donald's email is clearly a response (text in red) from our Hard FM Commissioning Manager. Indeed, we have still to receive a response to our request from Donald on whether the presence of Psedomonas species is an indicator of future risk of Pseudomonas Aeuriginosa

Current update is that all test results from latest full batch of sampling have come back clear for Legionella. Pseudomonas positives were found in 2 of 14 samples with elevated TVC counts, this from a total sample of 115. Further disinfection has taken place and the 14 elevated TVC locations will be re-sampled with results due by 20/03/19, until such times as these come back clear MPX are continuing with their responsibilities for water safety management. Further sampling will be carried out by Bouygues in the next 2 weeks once the current batch are all confirmed as clear and in addition there will be a further round of sampling at a time to be agreed prior to full operation. In the intervening period between the last two sampling exercises, Bouygues will implement a robust water management system involving flushing of little used outlets as per the positive obligation in the settlement agreement. It will be for the NHSL water safety management group to decide if this is enough reassurance as it complies with SHTM 04-01.

3 Ventilation to Isolation Rooms

All windows to isolation rooms and their lobbies are fixed pane windows (they do not open) except lobby 1-B1-033 which has been reported as a defect. I suspect Donald viewed room 1-B1-068 where works to correct an earlier identified defect were incomplete, this has now been resolved.

4 Theatre Ventilation Validation

Theatre ventilation commissioning, include cascade and UCV validation took place between October 2018 and February 2019 and all certificates and reports have been examined and verified by Arcadis as Independent Tester. These are available on the project data storage system 'Zutec'. These have however been rendered void by the agreed post completion works to enhance fire safety across the site and will be fully re tested and validated which will be witnessed by NHSL and the Independent Tester once these works are complete. In the meantime the information on the system can be reviewed by ICD and IPC at any time to ensure they meet their requirements. MPX will carry out air sampling on completion of their builders clean and prior to NHSL equipping the area. It is assumed IPC will wish to repeat this prior to theatres becoming fully operational.

5 Sub optimal Air Exchange Rates in clinical areas

During the review of the environmental matrix it was identified that air exchange rates within the single and 4 bedded rooms did not meet the recommendations of SHTM 03-01. Risk assessments were carried out and discussed with infection control staff (sample attached). A workable solution has been implemented which includes mixed mode ventilation where natural ventilation provides the difference between 4 and 6 ac/hr.

6 Consequences of water damage event

The project's Clinical Director and a Commissioning Manager toured the Facility on 5th July, 2019 with Janette Richards, Dr Pota Kalima and MPX and the remedial and reinstatement process proposed by IHSL/MPX was accepted in addressing the departments that were affected by the water damage. Donald's recommendation, in his email of 25/07/2018 to the project's Clinical Director that a building survey using a moisture meter to assess dryness of walls should be undertaken at the appropriate time will be undertaken. We assume the outcome of such a survey would suffice in providing the reassurance being sought by Fiona. To the best of our knowledge, and we believe also the Independent Tester's, all materials and systems damaged by water have been replaced.

We hope this clarifies the communications with Infection Control to date but needless to say we would welcome a walk round by Donald and members of the IPCT at any time as suggested by Alex.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Goldsmith, Susan
Sent: 13 March 2019 17:10
To: Currie, Brian
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High
Sensitivity: Confidential

Brian as discussed!

Thanks Susan

From: McMahon, Alex [redacted]
Sent: 13 March 2019 16:19
To: Crombie, Jim [redacted] Goldsmith, Susan [redacted]; Gillies, Tracey [redacted]
Cc: Inverarity, Donald [redacted]
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High
Sensitivity: Confidential

All

I caught up with Donald after the DCN IMT. He said he would send me this email and I have his permission to forward on. For transparency I have copied Donald in.

The content gives me some cause for concern. Jim and Tracey can we take the opportunity to discuss this with Donald tomorrow afternoon. I know Jim you and I are meeting others at 4 but I think if we can take 5 mins just for a quick discussion that would be helpful.

In the meantime happy to take thoughts but one action we I am going to instruct is that Donald and members of the IPCT do a walk around of the whole building with the appropriate personnel.

Donald asks for sight of reports as set out below, Jim/Susan can we make these available as well.

Alex

From: Inverarity, Donald
Sent: 13 March 2019 15:37
To: McMahon, Alex
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Sensitivity: Confidential

Dear Alex,
Following our discussion after the DCN IMT today, I'd like to raise a further issue that relates to water quality and ventilation in the new hospital site.
Please see the (confidential) e-mail dialogue attached which was sent to me by the commissioning team in the week before the building was handed over to NHS Lothian. It was highlighted that there were concerns about Pseudomonas aeruginosa and more concerningly Legionella in the water. Despite replying expressing concern particularly over the finding of Legionella, there was no further communication with me about the issue. I don't know where in the building this was found and I don't know what corrective action is/has been taken. Consequently it is not possible to risk assess whether there is a clinical risk to immunocompromised patients when they occupy the building without knowing if there are water issues in the clinical areas where such patients will be managed. Even if they have been addressed and corrected by the time patients are admitted later in the year, they would still count as higher risk areas that would deserve more scrutiny to ensure the level of Legionella remains low and would present a persisting clinical risk if in a clinical area.
I also mentioned to you the paediatric isolation rooms which are designed as positive pressure ultraclean rooms with HEPA filtered air and yet the windows open to the outside unfiltered Edinburgh air defeating the purpose of the room. I don't know if any corrective action has taken place regarding this design flaw which was identified by Lindsay, Ewan Olsen and myself when we were invited to review the design of the room and its ventilation pre handover.
Although given assurances that pre hand over there would be validation performed on all theatre ventilation, as ICD I've never seen any of these validation reports and neither have any of my consultant microbiologist colleagues albeit we were given a tour of the ventilation system and theatres as they were being built.
All the best
Donald

From: Cameron, Fiona
Sent: 12 March 2019 12:25
To: Currie, Brian
Cc: McMahon, Alex; Guthrie, Lindsay; Inverarity, Donald
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Brian

Alex sent on your email I am unsure what HEI guidance you are referring to. Healthcare Environment Inspectorate do not have standards for buildings. I can confirm any reviews, recommendations IPC made would be in alignment with the SHTM guidance by HFS for building works. I agree we did have involvement and a dedicate person i.e. our HAI SCRIBE lead involved. However as per communications with Alex IPC were not involved in handover as per SCRIBE guidance recommendations

I cannot reliably say if all our recommendations were accepted. I am aware as a result of the cancelled FOI there was discussion re air exchanges rates perhaps being suboptimal in clinical areas and we don't know what the outcome of that report was. The HAI SCRIBE documents or minutes of your project meetings should be able to confirm.

Another example IPCT can only assume the building engineer who accepted the building on behalf of NHS Lothian saw evidence of theatre validation See p114-124 of SHTM 03-01. IPC to the best of my knowledge have not seen a validation report (section 8.64-8.65 of SHTM 03-01). The validation/commissioning report should be a clearly understood document that outlines that the theatre is working optimally, not just engineering data, which allows us to have confidence in the efficiency of theatre ventilation and would go some way to provide the board with a level of assurance.

In addition not have we seen what evidence was provided to give NHS Lothian assurance that the consequences of the flood were fully addressed. Did the contractors provide assurance that all water damaged construction materials were replaced and there is no unnecessary residual damp material, particularly not in clinical areas. As previously advised by our ICD Dr Inverarity, damp building materials that are left in place to dry out over time are predisposed to growing moulds and fungus and that could take some time to show. The clinical risk that can result in depends on where the damp material is situated e.g. theatre or isolation room designed to protect patients from infection. Did the contractor provide a comprehensive assessment for residual damp in clinical areas or was this checked by an external authority to the contractor as I think was recommended by Dr Inverarity at the time.

Alex I have copied Lindsay and Donald as they may also wish to comment as Lead Nurse and Lead ICD

Fiona

Ms Fiona Cameron
Head of Service
NHS Lothian Infection Prevention & Control Services
[redacted]

For more information visit the IPCT IPCT Intranet Homepage

From: McMahon, Alex
Sent: 12 March 2019 08:08
To: Cameron, Fiona
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High

Professor Alex McMahon
Executive Director, Nursing, Midwifery and Allied Healthcare Professionals
Executive Lead, REAS and Prison Healthcare
NHS Lothian
[redacted]

From: Currie, Brian
Sent: 12 March 2019 08:06
To: Goldsmith, Susan; McMahon, Alex
Subject: FW: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High

Susan / Alex

FYI - see below.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 16:45
To: Currie, Brian
Cc: Crombie, Jim; Graham, Iain
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP

Thanks Brian – this is very helpful and much appreciated.
Regards
Judith

From: Currie, Brian [redacted]
Sent: 11 March 2019 16:43
To: MACKAY, Judith (NHS LOTHIAN)
Cc: CROMBIE, James (NHS LOTHIAN); iain.graham[redacted]
Subject: RE: Infection control + Ventilation Issues from Sunday Herald Article on Glasgow QEH- RHCYP
Importance: High

Judith

Hopefully the following will be useful:

Infection Control

We can confirm that the Board's Infection Control have been involved from the early stages in the project including competitive dialogue, evaluation of some parts of the submission; actively contributing with the clinical teams to the clinical area design development and approval process reviewing relevant specifications for items such as sanitary ware, flooring, vent coverings etc.

We have been fortunate in that there has always been a nominated IPCN for Reprovision and they have been an integral part of the process participating in key meetings and, if they could not be present at meetings, taking the opportunity to comment on meeting outputs where required and following up on issues in consultation with project and other clinical staff.

Throughout each of the stages of the project they have provided expert advice on elements such as isolation room design and functionality, room ventilation design, and HAI Scribe.

They have also joined project team personnel in reviewing the rooms for adherence to design brief, quality of finish and functionality, (including ease of cleaning and compliance with SHTM and HEI guidance).

Let me know if you need more on HAI Scribe and contractual obligations.

Ventilation

Through witnessing of commissioning activities we can verify that the correct grade of filters are installed in the various air handling units and the ductwork is designed in accordance with relevant guidance. Regular inspections are carried out and alarm monitoring also occurs via the building management system and warns of deteriorating filter conditions.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 14:53
To: Currie, Brian
Subject: RE: Infection control- RHCYP

Thanks Brian.

From: Currie, Brian [redacted]
Sent: 11 March 2019 10:14
To: MACKAY, Judith (NHS LOTHIAN)
Cc: iain.graham[redacted] fiona.cameron[redacted]
Subject: RE: Infection control- RHCYP
Importance: High

Judith

We will summarise what involvement Infection Control have had in the project to date, how HAI Scribe works and contractual obligations in terms of infection control standards.

The specific ventilation issues raised at Glasgow will also be responded to in relation to this project as I said earlier.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 09:27
To: Currie, Brian
Cc: Graham, Iain; Cameron, Fiona
Subject: RE: Infection control- RHCYP

Hi again Brian,
Most of this details the standard daily infection control measures we would expect to operate once the building is open. Presumably we can say the building has been built to industry standards (and that's a start) but I would expect the QEUH could have done the same?

If (and I do mean; if) our own infection control team was not involved specifically, then :

- is there something explicit in the contract that gives us assurance that the building was designed to satisfy all latest infection control standards?
- Retrospectively, do we know it doesn't have the same design weaknesses (in ventilation duct design and safety alarms) that is the issue with QEUH?

On that first point , there's been reference to the HAI Scribe but I don't know what (or who??!) the scribe is. Not looking for the contract – just a means by which we can describe in layperson's terms how we derive assurance that the design takes account of infection control requirements.

Thanks!

Judith

Judith Mackay
Director of Communications, Engagement and Public Affairs | NHS Lothian
[redacted]

From: Currie, Brian [redacted]
Sent: 11 March 2019 08:09
To: MACKAY, Judith (NHS LOTHIAN); iain.graham[redacted]
Cc: CROMBIE, James (NHS LOTHIAN)
Subject: RE: Infection control- RHCYP
Importance: High

Judith

Please see a draft MS Word version and final letter recently sent to Miles Briggs which should deal with the majority of questions on Infection Control.

In terms of the specific ventilation issues we will get back to you asap.

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: MACKAY, Judith (NHS LOTHIAN) [redacted]
Sent: 11 March 2019 07:39
To: Currie, Brian; Graham, Iain
Cc: Crombie, Jim
Subject: Infection control- RHCYP

Morning all,

I anticipate questions from media today about the formal involvement of Infection Control expertise in the design of RHCYP / DCN in the wake of criticisms about the apparent lack of documented evidence of their involvement in the design / commissioning / handover of QEUH.

Please see this piece from yesterday's Sunday Herald.

https://www.heraldscotland.com/news/17489840.50m-repair-bill-for-glasgows-troubled-queen-elizabeth-university-hospital/

Can we state categorically that Infection Prevention and Control Team were fully and formally (in a governance sense) involved in the commissioning or handover process of RHCYP/DCN?

We are also likely to be asked explicitly if we know / have assurance that the design does not suffer from the same ventilation duct / safety alarm weaknesses as QEUH.

Since these were 2 of the issues that led to some delay late last year am I correct in thinking we were are satisfied RHCYP does not share same design issues on those counts?

Thanks for your help with this,

Regards

Judith

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ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie, Clinical Director Dorothy Hanley, RHSC Commissioning Lead Fiona Halcrow, Project Manager	**Date of Original Assessment:**	05/07/17. Reviewed 29/1/18
Manager Responsible:	Janice MacKenzie		
Department:	RHSC & DCN Reprovision Project		

Subject of Assessment: Consider Task or Environment.

Bedroom Ventilation design in 4 bedded rooms does not meet the recommendations of SHTM 03-01, as the current design has the 4 bedded rooms as being positive pressure.

To allow cohorting of patients with the same air-borne infections these rooms require to be balanced or negative pressure.

The Board have previously accepted that there is no need for cohorting of patients within DCN as they can operationally manage this due to the number of single rooms and types of patients and the need for cohorting of infectious patients would be extremely rare.

Whilst the Board can rationalise the number of 4 bedded rooms where the ventilation needs to change within RHCYP it should be noted that this does reduce overall flexibility and future-proofing. A further review was undertaken with the Children's CMT in January 2018 of the initial risk assessment completed in July 2017 to ascertain what 4 bedded rooms would be essential. Given the different patient groups related to specific wards, separate risk assessments have been undertaken (see attached). Individual risk assessments have identified that the need for cohorting of patients is only an issue for the Children's Service. Risk assessment highlights that it is **essential** to change the ventilation in 7 of the 4 bedded rooms within RHCYP. It would be **desirable** to change the ventilation in 6 of the 4 bedded rooms within RHCYP. No change to 7 of the 4 bedded rooms in RHCYP and DCN

The risk assessments have been discussed with the Children's CMT and Infection Control & Prevention who have confirmed that not having the ability to cohort patients is not acceptable from a patient safety perspective. A summary of risk for each area is provided after Section 3.

Step 1: What are the Hazards?

Overall Risks:-

- The inability to cohort patients with air-borne infections in a clinically safe environment
- Clinical risk to isolating babies and children under two years of age with airway compromise i.e RSV
- Need for increased staffing requirements due to the observation and interventions required in this patient group if nursed in singe rooms
- Reduction in overall flexibility and future proofing would be limited if change of use of a ward/s was required
- Reputational risk as one of the key drivers, as outlined in the FBC, is to provide improved modern facilities that overcome the challenges currently faced within the existing facilities that cannot be adapted to provide the best services possible.

See separate risk assessments for inpatient ward/s as the risk rating for each ward/s is different dependent upon the patient group and clinical risk

Step 2: Who might be harmed and how?

See separate risk assessments for specific ward/s

Step 3: What are you already doing? (Existing Precautions)

Generic Precautions

- Isolation rooms have positive pressure lobby which acts as an air curtain and also have a hepa-filter to prevent the transfer of air-borne infection from the corridor into the room or the room into the corridor.
- All single rooms have balanced or slightly negative pressure.
- Increase in the number of single and isolation rooms (See separate risk assessment for the number of isolation and single rooms by ward) from 30% to 62%.
- Ability to flex beds between adjacent wards giving greater flexibility
- Within RHCYP wards there will be technology to remotely monitor patient oxygen saturation levels and heart rate

Summary of Risk by Ward/s (Essential to have ventilation changed)

Ward/s	Proposed Action	Risk Rating If No Change	Risk Rating if Change Implemented
RHCYP - PARU	All three 4bedded rooms (A2- 028, 046 & 054)	15	4
RHCYP – Medical Inpts	All two 4bedded rooms(C1.1-018 & 046)	10	3
RHCYP – Critical Care	One 4 bedded room low acuity HDU (B1-	9	3

	063) & 3 bedded room surgical neonates (B1-065)		

Summary of Risk by Ward/s (Desirable to have ventilation changed)

RHCYP – Critical Care	4 bedded room intensive care (1-B1-009)	8	2
RHCYP – Surgical Long Stay Ward	All two 4 bedded rooms (C1.2-023 & 026)	6	2
RHCYP - Neurosciences	All two 4 bedded rooms (C1.3-011 & 013)	6	2
RHCYP – Medical Day Case Unit	One 3 bedded room (D9-022)	6	2

Summary of Risk by Ward/s (No change to ventilation)

RHCYP – Surgical Short Stay Ward	No change to ventilation in the two 4 bedded rooms	1	
RHCYP – Critical Care	No change to high acuity 4 bedded room (B1-031)	1	
RHCYP – Haematology Oncology Day Care	No change to ventilation in the two multi-bed day care areas	1	
DCN – Acute Care Ward	No change to ventilation in the two 4 bedded rooms	1	

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Clear Guidance in the Building Users Guide as to what 4 bedded rooms can be used to cohort patients with air-borne infections See separate risk assessments for specific actions by ward/s	Jane Campbell	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project - **RHCYP PARU (A2)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within PARU

Step 1: What are the Hazards?

Significant clinical risk to isolating babies and children under two years of age with airway compromise, some of whom may have co-morbidities where isolation in single room carries additional clinical risk.

If PARU has no cohort areas the hazards are:-

- There is a risk that the 6 shelled beds would require to be opened and additional staffing resource would be required
- Additional staffing would be required to safely care for these patients in single rooms due to the level of observation and intervention required. This has not been accounted for in the agreed workforce plan.
- Reduction in the overall capacity within RHCYP as more single rooms would be required to be used to board patients potentially resulting on the cancellation of elective patients.
- Reliance on remote patient monitoring for oxygen saturation and heart rate to ensure patient safety is increased

The Children's CMT have confirmed that all three of the 4 bedded rooms to have negative/balanced pressure

Step 2: Who might be harmed and how?

Patients: -

- Boarding of patients into other specialities is a recognised clinical risk.
- Patients from whom cohorting may be safest clinical option despite the availability of a single room e.g a child under two years of age with respiratory infection plus co-morbidity (cardiac or neurological) who because of their complex underlying condition need constant observation.

Step 3: What are you already doing? (Existing Precautions)

PARU has 34 beds:-

- 3 x 4 bedded rooms
- I x isolation room
- 21 x single rooms

Increased number of beds in single rooms and 4 bedded rooms as opposed to 6 bedded rooms (in existing hospital).

Procuring a remote monitoring system for oxygen saturation and heart rate to alert staff to a potential deterioration in patient's condition

Level of Risk with no cohort area 15

Level of Risk with cohort area 4

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Careful selection of patients for boarding	Nursing & Medical Teams	Ongoing	
Use of remote technology to assist with monitoring of patients in single rooms	Nurse in Charge & Consultant	Ongoing	
Clear guidance in the Building Users Guide regarding cohorting of patients with air-borne infections	Jane Campbell	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director		
Department:	RHSC & DCN Reprovision Project – **RHCYP Medical Inpatients (C1.1)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Medical Inpatients

Step 1: What are the Hazards?

Despite the fact it is planned that PARU will take all of the acute general admissions, reliance on a cohort area within this ward is only marginally reduced, particularly in times of peak activity when PARU would be unable to accommodate all of the RSV patients.

The Children's CMT have confirmed that all three of the 4 bedded rooms to have negative/balanced pressure

Step 2: Who might be harmed and how?

Patients from whom cohorting may be safest clinical option despite the availability of a single room e.g a child under two years of age with respiratory infection plus co-morbidity (cardiac or neurological).

Step 3: What are you already doing? (Existing Precautions)

Increased number of single and isolation rooms within medical inpatients:-

- 2 x 4 bedded bays
- 4 x Isolation Rooms
- 11 x single rooms

Procuring a remote monitoring system for oxygen saturation and heart rate to alert staff to a potential deterioration in patient's condition

Level of Risk if no change made 10

Level of Risk with Cohort Areas 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Careful selection of patients for boarding	Nursing & Medical Teams	Ongoing	
Use of remote technology to assist with monitoring of patients in single rooms	Nurse in Charge & Consultant	Ongoing	
Clear guidance in the Building Users Guide regarding cohorting of patients with air-borne infections	Jane Campbell	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP Critical Care (B1)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Critical Care Unit

Step 1: What are the Hazards?

Clinical risk is still relatively high if no cohort area available and therefore operationally to retain the ability to cohort within B1-063 (low acuity HDU) and B1-065 (surgical neonates) is essential and it would be clinically and operationally desirable for B1-009 (intensive care).

The Children's CMT have confirmed that all three of the 4 bedded rooms to have negative/balanced pressure

Step 2: Who might be harmed and how?

Patients through spread of infection.

Step 3: What are you already doing? (Existing Precautions)

Critical Care (B1) – 24 beds

- 1 x 4 bedded rooms (low acuity)
- 2 x 4 bedded bays (intensive care & high acuity)
- 1 x 3 bedded room (surgical neonates)
- 4 x isolation rooms
- 5 x single rooms

The increased number of single rooms and a higher nurse to patient ratio within the Critical Care Unit will help mitigate the risk of nursing patients in single rooms

Level of Risk if no cohort area 9

Level of Risk if cohort retained 3

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that two 4 bedded rooms (ITU & high acuity high dependency) and one three bedded room (surgical neonates) cannot be used to cohort patients with air-borne infections	Jane Campbell	March 2018	
Careful placement of patients within the designated areas	Senior Nurse in Charge & Consultant	Ongoing	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP – Surgical Wards (C1.2 & C1.8)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients with air-borne infections within the Surgical Wards

Step 1: What are the Hazards?

- It would be clinically and operationally desirable for the 2x 4 bedded rooms in Surgical Long Stay (C1.2-023 & 026) to provide future proofing and flexibility
- Clinical risk is low as increased number of single rooms within Medical wards reduces the need to board patients into the surgical wards from the medical wards
- Compromise possible in not altering ventilation in the 4 bedded rooms in Surgical Short Stay but reduces flexibility and future proofing

Step 2: Who might be harmed and how?

Patients through spread of infection.
Potential cancellation of elective surgical cases as staff group will be required to deliver 1:1 care who potentially could be cared for within a cohort area

Step 3: What are you already doing? (Existing Precautions)

There are two surgical wards:-

Surgical Short Stay has 14 beds:-
- 2 x 4 bedded rooms
- 6 x single rooms

Surgical Long Stay has 15 beds:-
- 2 x 4 bedded rooms
- 7 x single rooms

Increased number of beds within PARU and medical inpatients to reduce the need to board patients

Level of Risk if no cohort area in either ward 6

Level of Risk if cohort retained in Surgical Long Stay 2

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP – Neurosciences (C1.3)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Neurosciences Ward

Step 1: What are the Hazards?

- It would be clinically and operationally desirable for the 2x 4 bedded rooms to provide future proofing and flexibility
- Clinical risk is low as increased number of single rooms within Medical wards reduces the need to board patients into the neuroscience ward from the medical wards

Step 2: Who might be harmed and how?

Patients through spread of infection.
Potential cancellation of elective cases as staff group will be required to deliver 1:1 care who potentially could be cared for within a cohort area

Step 3: What are you already doing? (Existing Precautions)

The Neurosciences Ward has 12 beds

- 2 x 4 bedded rooms
- 1 x isolation room
- 3 x single rooms

Increased number of single rooms including one isolation room within this ward to allow the ward to care for neurosciences patients with an infection within the ward and not board in other wards which is the case in the existing hospital.

Level of Risk if no cohort area 6

Level of Risk if cohort retained 2

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	Mach 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP – Medical Day Case Unit (D9)**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients within Medical Day Case Unit

Step 1: What are the Hazards?

- It would be clinically and operationally desirable for the 3 multi-bedded room to provide future proofing and flexibility
- Clinical risk is low as increased capacity and number of single rooms within Medical wards reduces the need to have to open the MDCU for medical inpatients

Step 2: Who might be harmed and how?

Patients through spread of infection.
Potential cancellation of elective surgical cases as staff group will be required to deliver 1:1 care who potentially could be cared for within a cohort area

Step 3: What are you already doing? (Existing Precautions)

The Medcial Day Case Unit has:-

- 1x3 bedded room (less sqm per space than an inpatient ward)
- 2 x single rooms

Increased capacity within the medical wards andsingle rooms and isolation rooms within these wards

Level of Risk if no cohort area 6

Level of Risk if cohort retained 2

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	Mach 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
08/02/19	Janice Mackenzie	Consideration of IT feedback and ongoing discussions with IHSL	Approved by CMT 29/1/18

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Peter Campbell	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Peter Campbell, Deputy Associate Nurse Director – Children's Services		
Department:	RHSC & DCN Reprovision Project – **RHCYP Haematology/Oncology Ward (C1.4)**		

Subject of Assessment: Consider Task or Environment.

Patient pathway for day care patients with a known infection

Step 1: What are the Hazards?

This is a combined inpatient and day care facility, however the design separates these two areas. Operationally the clinical team have already agreed a compromise where patients with infections coming to day care would be dealt with in the consulting room within day care or the inpatient facility. The Board have previously accepted that they can operationally manage these areas without a change in ventilation to the 2 day care rooms.

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

Haematology/Oncology Ward has 17 inpatient beds and 9 day care beds/trolleys:-

- 5 x isolation rooms
- 12 x single rooms
- 1 x 6 bedded day care room
- 1 x 3 bedded day care room

Operational policy has been agreed for the management of day care patients with an infection

Level of Risk 1

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state the type of pressure in the Day Care areas	Jane Campbell	March 2018	
Written patient pathway and operational policy for the management of day care patients with an infection	Charge Nurse & Lead Consultant	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

NHS Lothian

ID:

Record of General Risk Assessment

Name of Assessor(s): Posts Held:	Janice Mackenzie Dorothy Hanley Fiona Halcrow	**Date of Original Assessment:**	05/07/17
Manager Responsible:	Hester Niven, Clinical Nurse Manager DCN		
Department:	RHSC & DCN Reprovision Project – **DCN Wards**		

Subject of Assessment: Consider Task or Environment.

Ability to cohort patients with air-borne infections within DCN wards

Step 1: What are the Hazards?

The Board have previously accepted that they can operationally manage these wards due to the number of single rooms and types of patients and the need for cohorting of infectious patients would be extremely rare

Step 2: Who might be harmed and how?

N/A

Step 3: What are you already doing? (Existing Precautions)

DCN has three wards:-

DCN Acute Care (L1) – 24 beds
- 2 x 4 bedded rooms
- 1 x isolation room
- 15 x single rooms

DCN Inpatients Wards (L2) – 43 beds
- 2 x isolation room
- 41 x single rooms

Significant increase in the number of single rooms as compared to existing facility

Level of Risk 1

Step 4: Action Plan

What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
In the Building Users Guide need to state that these 4 bedded rooms cannot be used to cohort patients with air-borne infections	Jane Campbell	March 2018	

Step 5: Review Table

Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)

From: Alison Parton [redacted]
Sent: 04 June 2019 12:36
To: Henderson, Ronnie
Cc: Hull, Ashley; Currie, Brian; Greer, Graeme
Subject: RE: Independent Validation
Attachments: EST#487 Edinburgh RI.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Ronnie
Please find attached my first stab at preparing a quotation for you, please accept this as an indication of costs and may change following your meeting with Paul tomorrow.
Please do not hesitate to contact me with any queries you may have.
Kind Regards,
Alison

From: Henderson, Ronnie
Sent: 30 May 2019 16:54
To: Alison Parton
Cc: Hull, Ashley ; Currie, Brian ; Greer, Graeme
Subject: Independent Validation
Importance: High

Hi Alison,
Good to talk to you earlier.
As discussed we are looking for independent validation to SHTM 03-01 of 10 theatres (7 of which are UCV but can also be used as conventional), 19 isolation rooms, 1 angiography procedures room, 1 intra-operative MRI, and ITU/HDU/NNU. There are also 3 standard MRI's, & 2 CT's, which are non interventional, if these are required under 03-01.
Due to the large volume I will forward all relevant drawings tomorrow and look to set up an introduction and planning meeting for early next week with a view to carrying the validation out week beginning 17/6.
If you could liaise with your Edinburgh office and confirm availability for that week as well as indicative time and cost I will raise the order.
Thanks and best regards
Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian
RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ
[redacted]

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Alison Parton
Accounts Manager

IOM Consulting Limited
Brookside Business Park
Cold Meece
Stafford
ST15 0RZ

[redacted]

Web: http://www.iom-world.org
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working for a healthy and sustainable world

Brookside Business Park
Cold Meece, Stone
Staffordshire, ST15 0RZ

Tel: 01785 333 200
Fax: 01785 333 228

EST#487

04/06/2019

For the attention of Ronnie Henderson
NHS Lothian
Royal Infirmary of Edinburgh

Dear Ronnie

Thank you for your recent enquiry regarding the validation and testing of 3 Conventional Operating Theatres, 7 UCV Theatres, 19 isolation rooms, angiography procedures room, 1 intra-operative, ITU, HDU, NNU, 3 standard MRI's and 2 CT's.

IOM will carry out the following tests in accordance with SHTM 03-01 and will include the following testing;

Conventional Operating Theatre

- Supply and extract airflow measurements in each theatre and associated peripheral rooms with subsequent calculation of air change rates
- Airflow measurements within the Recovery areas if applicable
- Pitot duct traverse to measure total quantities of fresh air supply (where possible)
- Pressure differentials across doors to provide the pressure cascade figures
- Electronic particle counting to assess the air filtration efficiency between inlet air and theatre supply air
- Noise measurements in the theatre and peripheral rooms, using a Type 1 Integrated sound level meter
- Audit of air handling units in accordance with Appendix 1, Part B of SHTM 03-01. This audit will include a thorough internal and external visual inspection of all sections of the air handling unit to assess the condition of the unit and its associated services and plant
- Audit of the operating suite in accordance with Appendix 2, Part B of SHTM 03-01
- UKAS accredited airborne microbiological sampling and enumeration in an empty theatre, to include 4 airborne sample plates and a control plate per theatre, incubated at 37°C for 24h±2h followed by 22°C for 24h±2h.
- Check that the fire damper proving tests has been carried out (para. 8.28 SHTM 03-01)

- Check controls/warning lights and surgeons panel display function
- Dirty filter simulation to assess whether the AHU can deliver the design airflow volume even under dirty filter conditions
- Smoke visualisation test to assess mixing / dilution
- Full validation report

Ultra Clean Ventilation

- Airflow measurements at 2m and 1m below the UCV canopy
- Pitot duct traverse to measure total quantities of fresh air supply (where possible)
- Particle count check at the face of the HEPA filters and seals to check for potential leakage paths
- Entrainment testing of the UCV canopy using an electronic particle counter
- Noise measurements under UCV canopy and in peripheral rooms, using a Type 1 Integrated sound level meter
- Supply and extract airflow measurements in associated peripheral rooms
- Airflow measurements within the Recovery areas if applicable
- Pressure differentials across doors to provide the pressure cascade figures
- Pressure differentials to be checked with the UCV canopy in setback
- Audit of air handling unit in accordance with Appendix 1, Part B of SHTM 03-01. These audits include a thorough internal and external visual inspection of all sections of the air handling unit to assess the condition of the unit and its associated services and plant
- Audit of the operating suite in accordance with Appendix 2, Part B of SHTM 03-01
- Check that the witnessing of the fire damper proving tests has been carried out (para. 8.28 SHTM 03-01)
- Check controls/warning lights and surgeons panel display function
- Dirty filter simulation to assess whether the AHU can deliver the design airflow volume even under dirty filter conditions
- Smoke visualisation test to assess mixing / dilution
- Full validation report

Charges

The total price to undertake the measurements as described above will be £27,459.00* plus VAT.

Any additional time required on site, for example, due to delays and system unavailability which is beyond IOM's control, or where IOM are requested to assist with adjustments to airflows and balancing, will be charged at £80.00 per hour.

Please do not hesitate to contact me should you wish to discuss any aspect of this quotation in further detail.

Yours sincerely

[redacted]

Alison Parton
Healthcare Ventilation Dept.

IOM CONSULTING LIMITED

STANDARD TERMS AND CONDITIONS OF SERVICE ("these Conditions")

Interpretation

1 In these Conditions:-

"Authorised Person" means an employee of IOM holding the office of project manager in relation to the Services, an employee holding the office of director or a legally appointed director of IOM;

"Client" means the party named in the Quotation for whom IOM has agreed to provide the Services;

"IOM" means IOM Consulting Limited, a company incorporated under the Companies Acts (Company Registration Number SC205670), having its registered office at Research Avenue North, Riccarton, Edinburgh, EH14 4AP;

"Quotation" means IOM's quotation for the Services provided to and accepted by the Client; and

"Services" means the services to be provided by IOM to the Client as set out in the Quotation and, where applicable, as varied under these Conditions.

The Services

2.1 IOM will carry out the Services with all the reasonable skill, care and diligence to be expected from a professional person or firm in the performance of similar services under these Conditions and in accordance with relevant industry standards current at the time. IOM may provide the Services using members of staff from various geographic locations across the United Kingdom.

2.2 IOM will promptly notify the Client if any aspect of the Services is found to be, or expected to be, significantly different from that addressed in the Quotation as a result of (a) site conditions; (b) new information; and/or (c) safety and/or environmental factors if this is likely to have an effect on the fees and expenses payable by the Client or schedule of the Services. In such circumstances, IOM reserves the right to vary the Services on the basis that the Client agrees to bear the costs of additional work in accordance with the terms of clause 3.4.

2.3 Unless otherwise agreed between the Client and IOM, all reports produced in the performance of the Services will be addressed to the Client only. Reports shall only be used by the Client for the purpose set out in the Quotation and shall not be relied upon or used for any other purposes or by any other party without the prior written permission of an Authorised Person.

Charges and Payment

3.1 In consideration for the provision of the Services, the Client shall pay to IOM the fees (including the fees of sub-contractors where appropriate), inclusive of VAT, and expenses specified in the Quotation.

3.2 The estimate of fees and expenses for the Services are as set out in the Quotation. Both the estimate and the charge out rates and expenses quoted in the Quotation will remain valid for a period of 30 days from the date of the Quotation. IOM reserves the right to apply an increased level of fees (such increase to be notified to the Client) in the event that the period during which the Services are provided extends beyond a period of 6 months.

3.3 Unless otherwise stated in the Quotation:-

3.3.1 the charge out rates quoted shall be charged for all consultant time spent on the provision of the Services, including travelling time; and

3.3.2 all expenses will be charged at cost plus a reasonable handling charge.

3.4 Any increase in the scope or extent of the Services from that specified in the Quotation will be subject to additional charges, such charges being calculated at the charge out rates agreed in respect of the Services, or, if no specific rates were agreed for that specific type of work, at the charge out rates charged by IOM for that type of work.

3.5 IOM reserves the right to charge a cancellation fee for any work cancelled at short notice and for any pre-authorised non-refundable expenses that are quoted in addition to the fees. The cancellation fee will apply as follows:

100% fee Less than 1 working days' notice prior to the scheduled works
75% fee Less than 3 working days' notice prior to the scheduled works
50% fee Less than 5 working days' notice prior to the scheduled works

3.6 This agreement is divisible. Where more than one report is produced in the performance of the Services, each report shall be deemed to arise from a separate agreement and shall be invoiced separately. Any invoice for a report produced in the performance of the Services shall be payable in full within 14 days of the date of the invoice, without reference to and notwithstanding any defect or default in delivery of any other report produced in the performance of the Services. Notwithstanding this, IOM may issue interim fees to the Client if IOM, in its sole discretion, considers it reasonable and appropriate to do so in the circumstances.

3.7 In the event that the Client fails to pay any invoice in full within 14 days of the due date, IOM reserves the right (without prejudice to the terms of clause 10.2 below) to:-

3.7.1 charge interest on the amount outstanding at the rate of 5% per annum over the base rate from time to time of the Bank of England. Notwithstanding this, IOM may in the alternative claim interest at its discretion under the Late Payment of Commercial Debts (Interest) Act 1998; and

3.7.2 suspend the provision of the Services until the amount outstanding has been paid, it being expressly agreed that IOM shall have no liability for any loss, injury or damage suffered by the Client or any other person as a result of the suspension of provision of the Services pursuant to this clause.

Confidentiality

4.1 Neither party will, at any time, disclose any information of a confidential nature relating to the other party acquired during the performance of the Services to any third party (other than to its employees, officers, representatives or advisers who need to know such information for the purposes of carrying out its obligations under the Quotation) without the prior written consent of the other unless (a) such information is already in the possession of the third party prior to its disclosure (other than as a result of the breach of any obligation of confidence owed to the party in question); (b) such information is already common knowledge or becomes so through no fault of that party; or (c) either party is compelled to disclose such information under a duty or obligation owed to or imposed by any court of competent jurisdiction, regulatory or government authority or body.

4.2 For the avoidance of doubt, the duty of confidentiality set out in clause 4.1 shall continue to apply without limit of time after the completion or termination of the provision of the Services subject to the exclusions detailed in that clause.

Intellectual Property

5.1 All copyright, trademark, patent and other intellectual property rights in all original drawings, designs, proposals, reports, recordings and other original works, discoveries or inventions made by IOM in the course of the provision of the Services or otherwise as a result of the provision of the Services shall belong to and remain vested in IOM and shall be treated as confidential by the Client in accordance with clauses 4.1 and 4.2.

5.2 IOM will grant a personal, non-exclusive, non-transferable royalty free perpetual licence in favour of the Client to use the same for the purposes specified in the Quotation subject always to the right of IOM to terminate the licence in the event that the Client fails to make payment of IOM's fees and expenses on the due date.

IOM Personnel

6.1 During the provision of the Services, and for a period of 12 months after termination of the provision of the Services, neither the Client nor any company associated with the Client, shall offer employment to any member of staff of IOM involved in the provision of the Services nor solicit or attempt to entice away any such employee without the prior written agreement of a director of IOM.

Liability and Insurance

7.1 Other than in respect of death or personal injury caused by IOM's negligence, IOM shall not be responsible for any loss, damage, delay, loss of market, costs or expenses of whatsoever nature or kind and howsoever sustained or occasioned, except as provided for in these Conditions.

7.2 Subject to clause 7.1, IOM shall under no circumstances whatever be liable to the Client, whether in contract, delict (including negligence), breach of statutory duty, or otherwise, for any loss of profit, or any indirect or consequential loss howsoever arising.

7.3 IOM's liability shall be limited to the extent of any damage, injury or loss that is directly attributable to the failure of IOM, its employees, subcontractors and/or agents to comply with the obligations on the part of IOM as provided in these Conditions. For the avoidance of doubt, IOM shall have no liability to indemnify the Client in respect of any indirect or consequential losses or damages whatsoever and howsoever arising.

7.4 The Client acknowledges and accepts that the fees and expenses do not contain a premium sufficient to cover IOM's risk of unlimited liability in respect of the Services and that a limitation of liability is reasonable bearing in mind the relevant circumstances, including the cost and availability or otherwise of insurance cover. Without prejudice to the remainder of this clause, IOM shall be liable to the Client for such direct losses of the Client as are attributable directly to IOM's work limited to an aggregate amount equivalent to ten times the fees charged subject always to a maximum of £5,000,000.

7.5 IOM will maintain cover in respect of public liability and professional indemnity insurance during the course of provision of the Services and for a period of one year thereafter, provided always that such insurance is available at commercially reasonable rates. Details of the policies are available on reasonable request. In the event that IOM ceases to carry such cover as a result of it ceasing to be available at commercially reasonable rates, IOM will promptly notify the Client of that fact.

7.6 Where in the provision of the Services any employee of IOM is required to act in a representative capacity by carrying out instructions or acting on behalf of the Client, IOM shall be deemed to be acting as the Client's agent. The Client hereby agrees to indemnify both IOM and IOM's employee(s) against any claim for which IOM and IOM's employee(s) may be liable for as a result of acting as the agent of the Client by reason of the acts or omissions of the Client.

Force Majeure

8.1 If IOM is delayed in the provision of the Services by any act or default of the Client or any other party or by any cause beyond the reasonable control of IOM, the period of completion of the Services shall be extended by a reasonable period and IOM will be entitled for payment of any additional costs reasonably incurred which are attributable to the delay.

8.2 Neither party shall be liable or deemed liable to the other party for failure or delay in meeting any obligation hereunder due to acts of God, warfare, industrial dispute (whether of its own employees or those of others), acts of terrorism, flood, fire, environmental incident, any other natural disaster, acts of Government or regulatory authority or any other cause beyond the reasonable control of the party which has a duty to perform provided that the affected party has given the non-affected party prompt written notice, with full details, following the occurrence of the cause relied upon. In such circumstances, the affected party shall be entitled to a reasonable extension of the time for performing such obligations provided that if the period of delay or non-performance continues for 90 days, the non-affected party may terminate the provision of the Services by giving not less than 14 days' written notice to the other party.

Communication

9.1 IOM frequently makes use of e-mail when communicating with clients and any other advisers or parties involved in providing the Services. The Client authorises IOM to use e-mail communication as IOM see fit in the course of providing the Services. The Client understands and acknowledges that the electronic transmission of information by e-mail on the Internet or otherwise has inherent risks and that such communications may become lost, delayed, intercepted, corrupted or be otherwise altered, rendered incomplete or fail to be delivered. IOM shall use reasonable endeavours to ensure that electronic communications that are sent are free from viruses and any other material which may cause inconvenience or harm to any other computer system and the Client undertakes to do likewise with any electronic communications they may send to IOM. However, because the electronic transmission of information cannot be guaranteed to be secure or error-free and its confidentiality may be vulnerable to access by unauthorised third parties, IOM shall have no responsibility or liability to the Client on any basis other than our bad faith or wilful default in respect of any error, omission, claim or loss arising from or in connection with the electronic communication or information to the Client (or the Client's reliance on such information). Without prejudice to the foregoing, IOM may advise the Client from time to time of methods of authentication and validation of electronic communications which IOM may wish to use and which IOM may also require the Client to use.

9.2 All correspondence shall normally be by first class mail, facsimile or electronic mail other than correspondence dealing with termination, which shall be by recorded delivery.

Termination

10.1 Either party may terminate the provision of the Services by serving one month's written notice on the other party.

10.2 IOM may terminate the provision of the Services, without liability, by serving written notice on the Client where:-

10.2.1 the Client fails to make any payment of an invoice on the due date; or

10.2.2 the Client is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986, or being an individual or partnership is declared bankrupt; or

10.2.3 a trustee, receiver, administrative receiver or similar officer is appointed in respect of the whole or any part of the business or assets of the Client.

10.3 In the event of termination under this clause 10, the Client will pay IOM for the Services performed up to and including the date of termination.

Status of These Conditions

11.1 These Conditions constitute the entire agreement and understanding between IOM and the Client and supersedes any previous arrangement, understanding or agreement between the parties relating to the provision of the Services.

11.2 No variation to these Conditions shall be binding unless agreed in writing and signed on behalf of IOM by an Authorised Person.

11.3 No rights or obligations may be assigned or delegated by either party without the prior written agreement of the other party.

11.4 No waiver by IOM of any breach of these Conditions by the Client shall be considered as a waiver of any subsequent breach of the same or any other provision.

11.5 The provisions of these Conditions are severable and if any provision is held to be invalid or unenforceable by any court of competent jurisdiction, then such invalidity or unenforceability shall not affect the remaining provisions of these Conditions.

11.6 These Conditions shall be governed by and construed in accordance with Scots Law. The Client agrees that the Scottish Courts shall have exclusive jurisdiction over any dispute that arises between the parties.

IHS LOTHIAN LTD **Disputed Works Schedule Appendix 1 Item 18 (Formally Project Co Change 050)**

Date – 28/08/2018	**Reference IHSL - 050**

Title - Neutropenic Patients Ventilation

1.0 Detail of Change

Financial Close Position

At Financial Close, Project Co proposed the following design and construction solution for single bed rooms within the Haematology and Oncology Department (C1.4)

Room Type & Department	FM Room Code	Pressure (Pascals) Differential to Corridor	Air Change / Hour
Single Bed Rooms Haematology and Oncology	3-C1.4-059	0 (balanced)	4
	3-C1.4-057	0 (balanced)	4
	3-C1.4-055	0 (balanced)	4
	3-C1.4-046	0 (balanced)	4
	3-C1.4-032	0 (balanced)	4
	3-C1.4-018	0 (balanced)	4
	3-C1.4-016	0 (balanced)	4
	3-C1.4-013	0 (balanced)	4
	3-C1.4-010	0 (balanced)	4

Furthermore, the following single rooms were added as part of Board Change Notice (RHSC DCN 032 & 035) for the expansion of the Haematology and Oncology Department following the removal of the Biochemistry Department (U1).

Single Bed Rooms	3-C1.4-074	0 (balanced)	4
	3-C1.4-076	0 (balanced)	4
	3-C1.4-078	0 (balanced)	4

Proposed Project Co Change

Project Co are not proposing to alter the design. However, the Boards view is that the design is non-compliant with Schedule Part 6, Sub Section C, Clause 2.1 (Approach to Design) and Clause 8 (Mechanical & Electrical Engineering Requirements) of and Sub Section D, C1.4 Haematology & Oncology Inpatients & Day Care Clinical Output Based Specification and SHTM 03-01 (Ventilation for healthcare premises Part A – Design and validation) Table A1 (Appendix 1: Recommended air change rates).

In summary, the Haematology and Oncology Department treat a range of medical issues which can be dealt with in a number of situations. The Financial close design proposes this solution as a mix of single bedrooms and full isolation suites. The Board would have preferred all single rooms in haematology and Oncology to have been suitable for neutropenic patients.

2.0 Reasons

Project Co's Financial Close design assigned balanced pressure to the neutropenic single bedrooms. The conclusion of design workshops held throughout the Construction Phase confirmed that, a balanced pressure regime will be managed operationally and is acceptable on the basis that 5 isolation suites are provided in accordance with SHTM 03-01.

3.0 Implications

Project Co require relief from the following:

- Section 2.1 (Approach to Design) of Sub-Section C (General Requirements) of Section 3 (Boards Construction Requirements) of Schedule Part 6(Construction Matters), which states:
  Project Co shall take cognisance of all the architectural and building services implications of the requirements described in the Board's Construction Requirements in this Schedule Part 6 Section 3 Sub-Section D (Specific Clinical Requirements) and Sub-Section E (Specific Non-Clinical Requirements).

- Section 8 (Mechanical & Electrical Engineering Requirements) of Sub-Section C (General Requirements) of Section 3 (Board's Construction Requirements) of Schedule Part 6 (Construction Matters), which states:
  Project Co shall take cognisance of all the building services implications of the requirements described in Section D (Specific Clinical Requirements) and Sub-Section E (Specific Non-Clinical Requirements) of Sub-section C of the Board's Construction Requirements.

- Section 1.1.1 (Scope of the Service) of C1.4 (Haematology & Oncology Inpatients & Day Care Clinical Output Based Specification) of Sub-Section D (Specific Clinical Requirements), which states:
  The paediatric Haematology and Oncology Unit, (Inpatient and Day Care services), is to provide a 24 /7 service for the care of all patients with cancer or blood dyscrasia (a pathologic condition in which any of the constituents of the blood are abnormal in structure, function, or quality, as in leukaemia or haemophilia). Patients and families will attend for assessment, investigations, treatment, ongoing care planning, and palliative and end of life care.

  The type of services provided include:

  - *Chemotherapy*
  - *High dose therapy with autologous bone marrow or peripheral*
  - *blood stem cell transplant*
  - *Psycho-social support and counselling for patients and families.*
  - *Management of children with febrile neutropenia*
  - *Management of any complications relating to cytotoxic therapy*
  - *including chemotherapy and radiotherapy*
  - *Administration of immunotherapy*
  - *Blood transfusion*
  - *Immunoglobulin infusion*
  - *Management of chicken pox (primary infection and*
  - *contact)/shingles in haem/onc patients*
  - *Management of haemophilia patients*
  - *Management of patients with sickle cell disease/crisis.*
  - *Palliative care*

- Table A1 (Appendix 1: Recommended air-change rates) of Scottish Health Technical Memorandum (SHTM) 03-01, Ventilation for healthcare premises Part A – Design and validation, as follows:

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	

Due to the current design, the Board is required to prepare specific standard operating procedure for management of infection and patients not using the isolation rooms within this department.

4.0 Attachments

N/A

From: Campbell, Jacquie
Sent: 01 July 2019 18:58
To: McMahon, Alex; Inverarity, Donald; Graham, Iain; Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director); Judith.mackay[redacted]
Cc: Goldsmith, Susan
Subject: RE: Summary email or critical care ventilation

Yes Alex will be focus of our discussion tomorrow.
Iain. Tim will be at the briefing for 845 , would be helpful if you and I can meet before hand
Jacquie

Sent with BlackBerry Work (www.blackberry.com)

From: "McMahon, Alex"
Sent: 1 Jul 2019 18:19
To: "Inverarity, Donald" ; "Graham, Iain" ; "Gillies, Tracey" ; "Currie, Brian" ; "Guthrie, Lindsay" ; "Mackenzie, Janice" ; "Curley, George" ; "Henderson, Ronnie" ; "Doyle, Edward" ; "Mitchell, Fiona (Director)" ; "'MACKAY, Judith (NHS LOTHIAN)'"
Cc: "Goldsmith, Susan" ; "Campbell, Jacquie"
Subject: Re: Summary email or critical care ventilation

There is an executive briefing session at 8.30 tomorrow morning. Jacquie would Iain and yourself be able to brief Tim and others of the position as of tonight and also re theatre ventilation and what the realistic position is for going live on Friday? I am sorry I am not around but I have also copied Judith from comms in.

Alex

Sent from my BlackBerry 10 smartphone on the EE network.

From: Inverarity, Donald
Sent: Monday, 1 July 2019 6:11 PM
To: Graham, Iain; Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation

Some additional edits from me in green.
Donald

From: Graham, Iain
Sent: 01 July 2019 17:59
To: Gillies, Tracey; Currie, Brian; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: RE: Summary email or critical care ventilation
Engineering colleagues will need to review my additions for accuracy.
Iain
Iain F Graham
Director of Capital Planning and Projects

NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
[redacted]
[redacted]

From: Gillies, Tracey
Sent: 01 July 2019 17:45
To: Currie, Brian; Graham, Iain; Guthrie, Lindsay; Inverarity, Donald; Mackenzie, Janice; Curley, George; Henderson, Ronnie; Doyle, Edward; Mitchell, Fiona (Director)
Cc: McMahon, Alex; Goldsmith, Susan; Campbell, Jacquie
Subject: Summary email or critical care ventilation

Please correct or amend any misunderstandings:

• IOM have tested critical care ventilation in RHCYP in 4 bedded and single rooms

•It delivers 4 air changes at balanced or slight negative pressure in the multiple occupancy 4 bedded rooms. (Single rooms are not affected).

•The required standard as per SHTM 03-01 Appendix 1 (version 2 February 2014) for Critical Care areas is 10 air changes and less than 10 air changes per hour may facilitate airborne spread of viruses more than if 10 was achieved.

•the only known way to improve air changes with current plant is to accept positive pressure ventilation (ie increasing further the opportunity for spread primarily of pathogens with airborne transmission e.g. respiratory viruses between individuals (staff, visitors and patients) in 4 bedded rooms)

• a bigger plant would be required to deliver the correct air changes – the team are identifying what potential for existing system capacity enhancements might be (ie ramping up the existing air handling plant) and / or within the constraint of the existing ducting (so it would only be the external plant affected).

•this leads us to question whether the space is fit for purpose

•If occupied now, there is risk to patients, visitors and staff of airborne virus transmission (?how much) and difficulties in correcting (would probably require a decant*)

• if not occupied now, move needs postponed

Note - This*would be needed for lesser timeframe) for a planned maintenance programme of works over the course of occupation of the facility.

From: Currie, Brian [redacted]
Sent: 03 July 2019 10:00
To: Wallace Weir; Darren Pike
Cc: Campbell, Jacquie; Graham, Iain; Mitchell, Fiona (Director); Mackenzie, Janice; Henderson, Ronnie
Subject: RHCYP + DCN - Little France - Critical Care Ventilation
Attachments: Air Change Options_Critical Care_02 June 2019.xlsx

Importance: High

Wallace / Darren

Following various joint meetings and workshops this week, I can confirm, on behalf of NHS Lothian, that you are requested to proceed with adjusting the installed ventilation system in Critical Care to achieve air change rates as per option A on the attached schedule. You are to provide as a minimum 7 air changes/hour in all single bedrooms (with the exception of room 1 B1 037) and 5 air changes/hour in all four bedded rooms (with the exception of room 1 B1 063).

You have intimated that you shall commence the necessary activities on Thursday, 4th July and you anticipate completion on Saturday, 6th July, 2019 at which stage the air change rates in the relevant critical care rooms shall achieve the air change rates as per Option A of the attached schedule. This instruction is subject to the terms of the Project Agreement and other than the above changes to air rates, all other current Project Agreement standards and requirements (including those for the ventilation system) apply to this instruction.

Please liaise with the project team's Commissioning Manager Ashley Hull and Project Clinical Director, Janice Mackenzie regarding access, coordination and area prioritisation.

Documentation formalising the position will follow in due course. Meantime the Board is proceeding to instruct that these works are urgently undertaken under reservation of its rights.

Many thanks

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

	Room No	Room Name	Area (m2)	Ceiling Ht (m)	Volume (m3)	Current Design					Option A 7 ACH within Single Beds *High Velocity at Grille - Potetial Noise Issue above 6 ACH*					Option B 6 ACH within Multi-Beds					Option C 8 ACH within Single Beds *High Velocity at Grille - Potetial Noise Issue above 6 ACH*					Room Name
						Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	ACH	Supply (l/s)	Supply (m3/hr)	Extract (l/s)	Extract (m3/hr)	
	1-B1-009	Bay 1	115.5	2.7	311.9	348.0	1252.8	348.0	1252.8	4.0	5.0	433.1	1559.3	433.1	1559.3	6.0	519.8	1871.1	519.8	1871.1	4.0	346.5	1247.4	346.5	1247.4	Bay 1
	1-B1-019	Single Room 8	26.0	2.7	70.2	78.0	280.8	78.0	280.8	4.0	7.0	136.5	491.4	136.5	491.4	4.0	78.0	280.8	78.0	280.8	8.0	156.0	561.6	156.0	561.6	Single Room 8
	1-B1-020	Single Room 7	26.0	2.7	70.2	78.0	280.8	78.0	280.8	4.0	7.0	136.5	491.4	136.5	491.4	4.0	78.0	280.8	78.0	280.8	8.0	156.0	561.6	156.0	561.6	Single Room 7
	1-B1-021	Single Room 9	26.3	2.7	71.0	79.0	284.4	79.0	284.4	4.0	7.0	138.1	497.1	138.1	497.1	4.0	78.9	284.0	78.9	284.0	8.0	157.8	568.1	157.8	568.1	Single Room 9
	1-B1-031	Bay 2	110.8	2.7	299.2	332.0	1195.2	332.0	1195.2	4.0	5.0	415.5	1495.8	415.5	1495.8	6.0	498.6	1795.0	498.6	1795.0	4.0	332.4	1196.6	332.4	1196.6	Bay 2
CLOSED	1-B1-037	Single Room 17	27.2	2.7	73.4	82.0	295.2	82.0	295.2	4.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	Single Room 17
CLOSED	1-B1-063	Bay 3	102.8	2.7	277.6	312.0	1123.2	312.0	1123.2	4.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	Bay 3
	1-B1-065	Neonatal Bay 4	60.0	2.7	162.0	181.0	651.6	181.0	651.6	4.0	5.0	225.0	810.0	225.0	810.0	6.0	270.0	972.0	270.0	972.0	4.0	180.0	648.0	180.0	648.0	Neonatal Bay 4
	1-B1-075	Neonatal Cot 22	15.1	2.7	40.8	46.0	165.6	46.0	165.6	4.1	7.0	79.3	285.4	79.3	285.4	4.0	45.3	163.1	45.3	163.1	8.0	90.6	326.2	90.6	326.2	Neonatal Cot 22
						1536	5529.6	1536	5529.6			1563.98	5630.31	1563.98	5630.31		1568.55	5646.78	1568.55	5646.78		1419.30	5109.48	1419.30	5109.48	
												-27.975	-100.71	-27.975	-100.71		-32.55	-117.18	-32.55	-117.18		116.70	420.12	116.70	420.12	
		Single Bed				394.0	1418.4																			
		4 Bed																								

A47310563

From: Currie, Brian
Sent: 03 July 2019 10:48
To: Henderson, Ronnie
Subject: FW: RHCYP + DCN - Little France - Critical Care Ventilation

Importance: High

FYI

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Graham, Iain
Sent: 03 July 2019 10:44
To: Currie, Brian
Subject: RE: RHCYP + DCN - Little France - Critical Care Ventilation
Importance: High

MAJOR CONCERNS RAISED ABOUT THE RISKS OF DOING THE PERMANENT WORKS WITH PATIENTS IN SITU. TIM / JACQUIE joined the call with HFS and HPS.

The level of duct replacement works – based on Glasgow experiences, sceptical about timeframes and suggestions of simplicity. Really need to have the assurances that the solution will be deliverable.

Other concerns / assurances needed:

Include – Heat levels
Humidity levels
Noise at outlets, diffusers
Pressure regime during works being maintained
Fire damper implications
Changing / implications on filtration – needs to be upped to ensure that the ACH

Safer to stay put – contingency if it doesn't work or needs patients moved on.

6 months in abeyance.

Iain

Iain F Graham
Director of Capital Planning and Projects
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
[redacted]
[redacted]

From: Currie, Brian
Sent: 03 July 2019 10:00
To: 'Wallace Weir'; 'Darren Pike'
Cc: Campbell, Jacquie; Graham, Iain; Mitchell, Fiona (Director); Mackenzie, Janice; Henderson, Ronnie
Subject: RHCYP + DCN - Little France - Critical Care Ventilation
Importance: High

Wallace / Darren

Following various joint meetings and workshops this week, I can confirm, on behalf of NHS Lothian, that you are requested to proceed with adjusting the installed ventilation system in Critical Care to achieve air change rates as per option A on the attached schedule. You are to provide as a minimum 7 air changes/hour in all single bedrooms (with the exception of room 1 B1 037) and 5 air changes/hour in all four bedded rooms (with the exception of room 1 B1 063).

You have intimated that you shall commence the necessary activities on Thursday, 4th July and you anticipate completion on Saturday, 6th July, 2019 at which stage the air change rates in the relevant critical care rooms shall achieve the air change rates as per Option A of the attached schedule. This instruction is subject to the terms of the Project Agreement and other than the above changes to air rates, all other current Project Agreement standards and requirements (including those for the ventilation system) apply to this instruction.

Please liaise with the project team's Commissioning Manager Ashley Hull and Project Clinical Director, Janice Mackenzie regarding access, coordination and area prioritisation.

Documentation formalising the position will follow in due course. Meantime the Board is proceeding to instruct that these works are urgently undertaken under reservation of its rights.

Many thanks

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Henderson, Ronnie
Sent: 03 July 2019 11:02
To: Currie, Brian
Subject: RE: RHCYP + DCN - Little France - Critical Care Ventilation

Brian,

Comments in red below

Ronnie

Ronnie Henderson
Commissioning Manager Hard FM
RHSC & DCN - Little France
NHS Lothian

RHSC & DCN Site Office
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

From: Currie, Brian
Sent: 03 July 2019 10:48
To: Henderson, Ronnie
Subject: FW: RHCYP + DCN - Little France - Critical Care Ventilation
Importance: High

FYI

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

From: Graham, Iain
Sent: 03 July 2019 10:44

To: Currie, Brian
Subject: RE: RHCYP + DCN - Little France - Critical Care Ventilation
Importance: High

MAJOR CONCERNS RAISED ABOUT THE RISKS OF DOING THE PERMANENT WORKS WITH PATIENTS IN SITU. TIM / JACQUIE joined the call with HFS and HPS.

The level of duct replacement works – based on Glasgow experiences, sceptical about timeframes and suggestions of simplicity. Really need to have the assurances that the solution will be deliverable. Existing ductwork retained except new supply and extract branch to connection point

Other concerns / assurances needed:

Include – Heat levels Ventilation will be on during works until final point of break in and a/ch rates will be 5 to multi bed and 7 to single bed
Humidity levels
Noise at outlets, diffusers This is a potential risk but not quantifiable at the moment
Pressure regime during works being maintained Yes except at point of break in for approx 5 hours.
Fire damper implications CSFD's installed to new branches and fire wall breaches
Changing / implications on filtration – needs to be upped to ensure that the ACH Will be accounted for in final design

Safer to stay put Existing location greater clinical risk – contingency if it doesn't work or needs patients moved on.

NHSL successfully carried out a major project in critical care at RIE in similar circumstances.

6 months in abeyance.

Iain

Iain F Graham
Director of Capital Planning and Projects
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
[redacted]

From: Currie, Brian
Sent: 03 July 2019 10:00
To: 'Wallace Weir'; 'Darren Pike'
Cc: Campbell, Jacquie; Graham, Iain; Mitchell, Fiona (Director); Mackenzie, Janice; Henderson, Ronnie
Subject: RHCYP + DCN - Little France - Critical Care Ventilation
Importance: High

Wallace / Darren

Following various joint meetings and workshops this week, I can confirm, on behalf of NHS Lothian, that you are requested to proceed with adjusting the installed ventilation system in Critical Care to achieve air change rates as per option A on the attached schedule. You are to provide as a minimum 7 air changes/hour in all single bedrooms (with the exception of room 1 B1 037) and 5 air changes/hour in all four bedded rooms (with the exception of room 1 B1 063).

You have intimated that you shall commence the necessary activities on Thursday, 4th July and you anticipate completion on Saturday, 6th July, 2019 at which stage the air change rates in the relevant critical care rooms shall achieve the air change rates as per Option A of the attached schedule. This instruction is subject to the terms of the Project Agreement and other than the above changes to air rates, all other current Project Agreement standards and requirements (including those for the ventilation system) apply to this instruction.

Please liaise with the project team's Commissioning Manager Ashley Hull and Project Clinical Director, Janice Mackenzie regarding access, coordination and area prioritisation.

Documentation formalising the position will follow in due course. Meantime the Board is proceeding to instruct that these works are urgently undertaken under reservation of its rights.

Many thanks

Regards

Brian

Brian Currie
Project Director - NHS Lothian
RHCYP + DCN
4th Floor Management Suite
Little France Crescent
Edinburgh
EH16 4TJ

[redacted]

PROUD HISTORIES | NEW CHAPTERS

SCOTTISH HOSPITALS INQUIRY

Bundle 13 – Miscellaneous - Volume 8