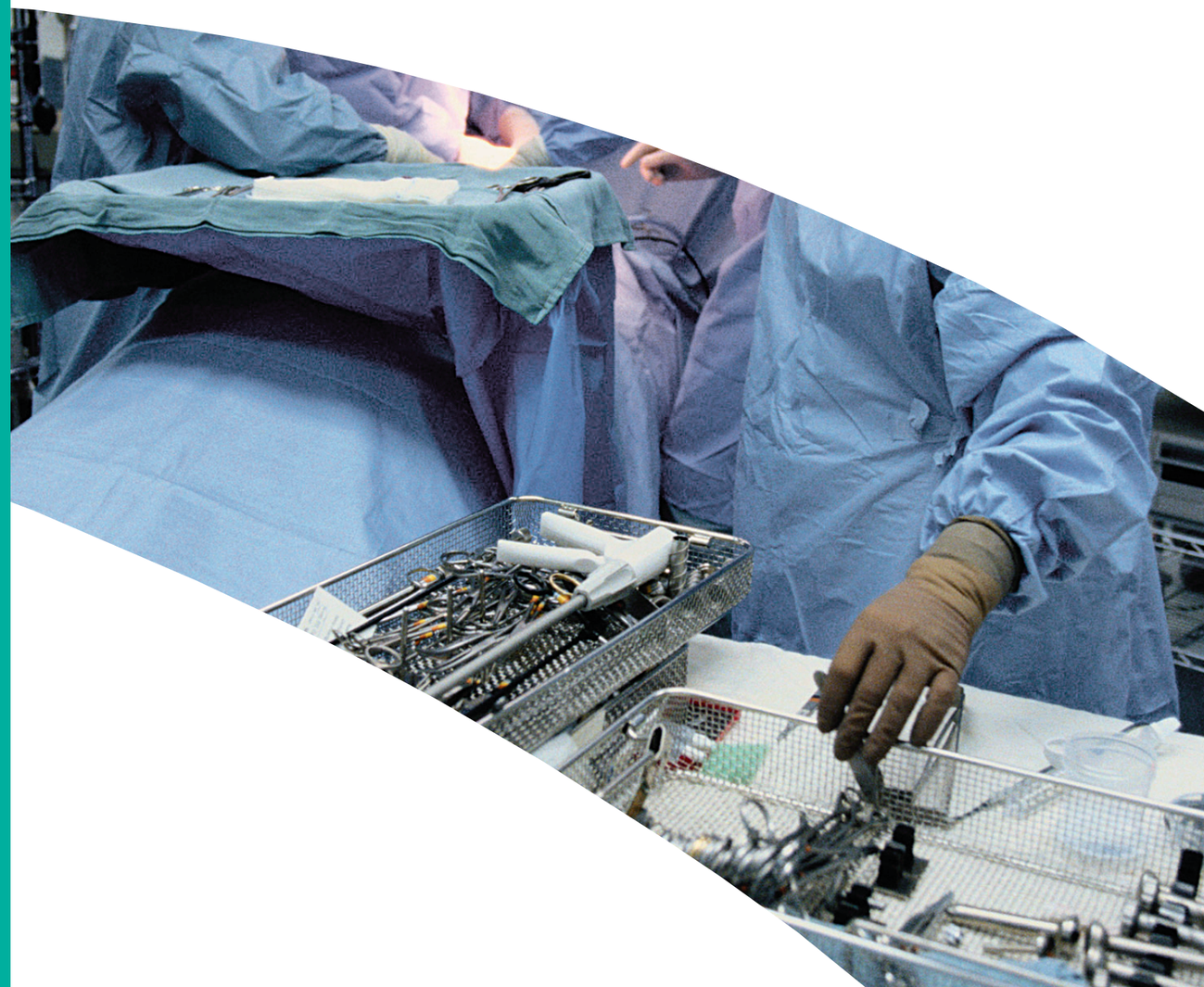
Department of Health

Decontamination
Health Technical Memorandum 01-01: Decontamination of reusable medical devices

Part A: Management and environment



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Decontamination
Health Technical Memorandum
01-01: Decontamination of reusable medical devices

Part A: Management and environment

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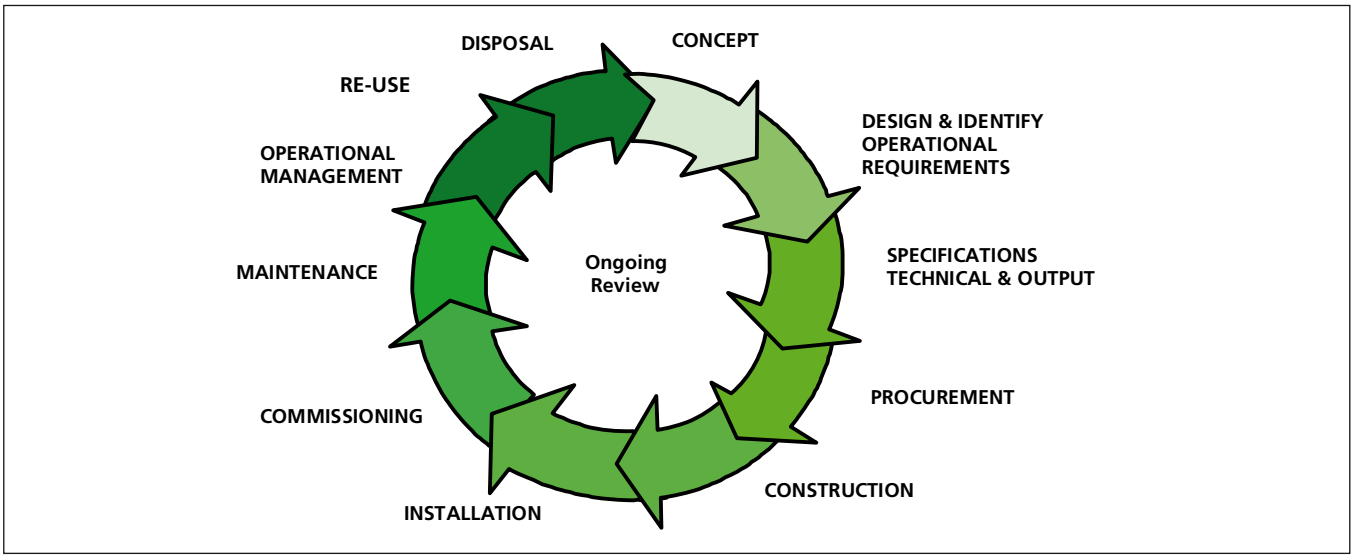
Preface

About Health Technical Memoranda

Engineering 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.

The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle:

Figure 1 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 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 unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

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

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

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

Structure of the Health Technical Memorandum suite

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

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

Health Technical Memorandum 01
: Decontamination

Health Technical Memorandum 02
: Medical gases

Health Technical Memorandum 03
Heating and ventilation systems

Health Technical Memorandum 04
Water systems

Health Technical Memorandum 05
Fire safety

Health Technical Memorandum 06
Electrical services

Health Technical Memorandum 07
Environment and sustainability

Health Technical Memorandum 08
Specialist services

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

Example: Health Technical Memorandum 06-02 Part A will represent:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 will simply represent:

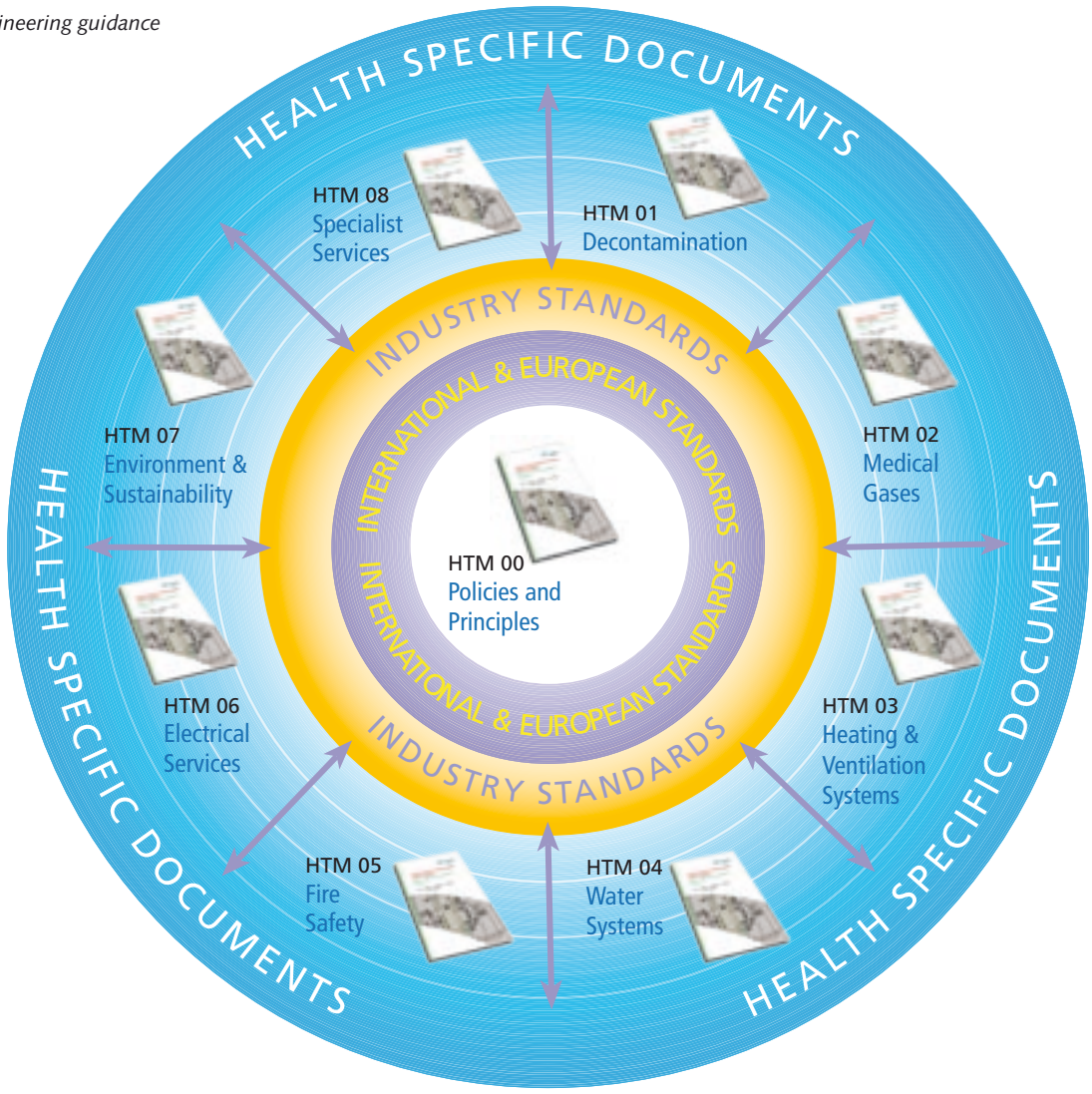
Environment and Sustainability – EnCO_2de.

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

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

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

Figure 2 Engineering guidance



Executive summary

Preamble

Health Technical Memorandum 2010 – 'Sterilization', Health Technical Memorandum 2030 – 'Washer-disinfectors', and Health Technical Memorandum 2031 – 'Clean steam for sterilization' have been revised and combined into the Health Technical Memorandum 01 series on decontamination.

The guidance has been revised in line with changes to relevant regulations, standards and other guidance, and also technical developments.

Health Technical Memorandum 01 supersedes Health Technical Memoranda 2010, 2030 and 2031.

- Health Technical Memorandum 01-01 – 'Decontamination of reusable medical devices' covers the various types of decontamination equipment to be used for the reprocessing of medical devices.
- Health Technical Memorandum 01-02 will cover items of decontamination equipment used in laboratories.
- Health Technical Memorandum 01-03 will cover items of decontamination equipment used in pharmacies.
- Health Technical Memorandum 01-04 will provide guidance on the decontamination of linen and infected laundry.
- Health Technical Memorandum 01-05 will cover decontamination in dental facilities.
- Health Technical Memorandum 01-06 will provide guidance on the decontamination of flexible endoscopes.
- Health Technical Memorandum 01-07 will cover decontamination in primary care.

Structure of Health Technical Memorandum 01-01

Health Technical Memorandum 01-01 Part A (this document) is entitled "Management and environment" and includes:

- a description of the overall structure of the guidance and the rationale behind the structure;
- the regulatory framework;
- roles of key personnel;
- procedures for the reporting of adverse incidents and defective equipment;
- local reprocessing (decontamination in primary care, and local decontamination);
- the management of instruments potentially contaminated with transmissible spongiform encephalopathy (TSE) infectivity.

Part B is entitled "Equipment" and will cover the design and pre-purchase considerations, validation and verification, and operational management of:

- test equipment;
- washer-disinfectors;
- sterilizers.

Aim of the guidance

The purpose of Health Technical Memorandum 01-01 is to pull together the existing Department of Health guidance on decontamination into one consolidated document for ease of reference.

Who should use this guidance

Part A is intended as a guide for management, for technical personnel with appropriate training and experience, and also for users responsible for the day-to-day running of decontamination equipment. It will also be of interest to microbiologists, infection control officers, architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

Key recommendations of Part A

Changes in decontamination management

The management of decontamination equipment is a critical engineering service.

Prior arrangements with regard to the management of decontamination equipment have been modified to strengthen existing controls.

The main recommended changes are:

- the consolidation of the roles and training of the Maintenance Person (Sterilizers) and Test Person (Sterilizers) into a new role of Competent Person (Decontamination);
- to introduce a defined role for estates management personnel responsible for decontamination called the Authorised Person (Decontamination). This role will encompass an overview of activity of the Competent Person (Decontamination) and day-to-day operational management of decontamination equipment;
- to redefine and formalise the HTM 2010-defined role of the existing Authorised Person (Sterilizers) as Authorising Engineer (Decontamination) with better definition of the role and reporting routes;
- to introduce a permit-to-work system relating to decontamination equipment similar in operation to other permit systems.

Chapter 5 of the document gives further details on the roles, responsibilities and reporting structures of all key personnel.

Acknowledgements

Peter Hooper Decontamination Consultant

Jason Holmes, Technical Adviser, National Decontamination Programme

Keith Oates

Mike Painter Chair, Engineering & Science Advisory Committee into the decontamination of surgical instruments including prion removal (ESAC-Pr)

Geoff Ridgway Senior Medical Officer, Infectious Diseases and Blood Policy, Department of Health

The Authorised Persons (AP) Group

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Decontamination Lead
Designated Person
Senior Operational Manager
User
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Authorised Person (Decontamination) (AP(D))
Competent Person (Decontamination) (CP(D))
Director of Infection Prevention and Control
Control of Infection Officer
Microbiologist (Decontamination)
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1 Scope

1.1 HTM 01-01 is divided into two parts.

1.2 Part A (this document) is entitled "Management and environment" and will include:

- a description of the overall structure of the guidance and the rationale behind the structure;
- general principles;
- the regulatory framework;
- roles of key personnel;
- Health Building Note 13.

1.3 Part B is entitled "Equipment", and will cover the design and pre-purchase considerations, validation and verification, and operational management of:

- test equipment;
- washer-disinfectors;
- sterilizers.

1.4 Each part will contain decontamination-specific information only.

Note

All general information relating to non-specific legislation previously included in the Health Technical Memoranda is covered in Health Technical Memorandum 00 to avoid duplication and for ease of access.

1.5 Potential purchasers of reprocessing equipment should ensure that they know whether the load items they intend to decontaminate are classified as medicinal products or medical devices. While the practical requirements have much in common, their implementation is very different.

Medical devices

1.6 This document covers the various types of decontamination equipment to be used for the reprocessing of medical devices (for example porous load sterilizers, sterilizers for unwrapped instruments and utensils, and washer-disinfectors).

1.7 Guidance on the application of medical devices legislation to particular cases is beyond the scope of this document, and advice should be sought from the Medicines and Healthcare products Regulatory Agency (MHRA).

Exclusions

- Health Technical Memorandum 01-01 does not cover items of decontamination equipment used in laboratories. This will be covered in Health Technical Memorandum 01-02.
- This Health Technical Memorandum does not cover items of decontamination equipment used in pharmacies. This will be covered in Health Technical Memorandum 01-03.
- The decontamination of laundry and infected linen will be covered in Health Technical Memorandum 01-04.
- Decontamination in dentistry will be covered in Health Technical Memorandum 01-05.
- The decontamination of flexible endoscopes will be covered in Health Technical Memorandum 01-06.
- Decontamination in primary care (including podiatry) will be covered in Health Technical Memorandum 01-07.

Note

Health Technical Memoranda 01-05 to 01-07 will also include operational guidelines.

- The selection and use of packaging for terminally sterilized products is not covered by this Health Technical Memorandum. The "NHS on-line National Decontamination Training Programme" offers practical advice and training on packaging (among other topics on decontamination; www.decontamination.nhs.uk; see also paragraphs 2.20–2.24).

In Northern Ireland, visit http://nidecontamination.intuition.com/lms/nhs_splash/nhs_splash.asp

Definitions

1.8 For definitions of terms used in this guidance document, see ISO 11139:2006 'Sterilization of health care products – vocabulary'.

2 Decontamination policy

Introduction

2.1 Improving and sustaining reusable-medical-device decontamination services forms an important part of the chief medical officer's strategy to combat healthcare-associated infection (HCAI; see 'Winning ways' and 'Getting ahead of the curve').

2.2 Healthcare organisations are required to provide a safe decontamination service that generates a clean and sterile product and is embedded as part of the service culture in support of successful clinical outcomes and the associated well-being of patients and staff.

2.3 Major decontamination improvement policies have focused on secondary or acute services as this is where the perceived major risks of infection transmission by surgical instruments exist. However, all sectors of healthcare owe a duty of care to patients and staff.

2.4 The risk of encountering HCAI exists in primary care as well as the secondary and tertiary care sectors. General medical and dental services and other healthcare professionals will need to have in place modern services, and (where relevant) facilities that ensure decontamination is achieved in accordance with current Department of Health policy.

2.5 This chapter sets out the nature of that duty of care across all sectors of healthcare.

Background and overview

2.6 A sample survey of NHS decontamination activity in 1999 found many instances where the local implementation of decontamination services fell short of acceptable standards (see the Department of Health's (2000) 'Decontamination review: the report on a survey of current decontamination practices in healthcare premises').

2.7 The survey identified substantial improvements that could be achieved by more effective management of decontamination systems coupled with staff development and training.

2.8 In January 2001 the Government announced that it would invest £200 million to improve decontamination services in England. Two Health Service Circulars (HSCs) supported this change-and-improvement process (HSC 2000/032 and HSC 1999/179).

In Northern Ireland: HSS(MD)4/01 and HSS(MD)16/99.

2.9 Following on from the snapshot survey, a more comprehensive review exercise was conducted which provided a basis for funding allocation and investment in the NHS. Recent surveys demonstrate a step change including cultural improvements towards acceptance of decontamination work as a core service, without which the risk of HCAI would be more pronounced.

2.10 In 2003, the Department of Health published its 'Strategy for modernising the provision of decontamination services'. This document set out 55 key recommendations for improving decontamination within the NHS. Over 20 of these recommendations focused on technical aspects of the decontamination process that organisations should ensure they adopt.

In Northern Ireland, the DHSSPS has issued policy and guidance on decontamination of surgical instruments and endoscopes, and this can be accessed on the DHSSPS website: www.dhsspsni.gov.uk.

Compliance

Compliance with legislation and Department of Health policy

2.11 In accordance with the philosophy engendered in the policy document 'Shifting the balance of power', responsibility for achieving acceptable

standards of decontamination rests with commissioners, individual trusts and provider organisations.

2.12 Units in healthcare establishments decontaminating medical devices fall into two distinct categories when considering compliance with the Medical Devices Directive (MDD):

- devices transferred between legal entities;
- devices remaining within one legal entity.

The Medical Devices Directive and the Medical Devices Regulations

The Medical Devices Directive (MDD) is transposed into UK law within the Consumer Protection Act as the Medical Devices Regulations (MDR) 2002.

For decontamination units, the appropriate MDR requirements include the control of processes and the working environment (for example satisfactory equipment validation and maintenance programmes, segregation and control of differing zones of cleanliness).

The MDR also require that a recognised quality management system be implemented across all areas of the unit. This can be demonstrated by compliance with BS EN ISO 13485:2003. This standard specifies requirements for a quality system that can be used by an organisation for the design and development, production, installation and servicing of medical devices and the design, development and provision of related services. It can also be used by internal and external parties, including certification bodies, to access the organisation's ability to meet customer and regulatory requirements. Its primary objective is to facilitate harmonised medical device regulatory requirements for quality management systems.

Devices transferred between legal entities

2.13 Healthcare establishments offering the reprocessing of medical devices to another legal entity are subject to the requirements of the MDR. If sterile devices are produced, the intervention of a third-party audit programme must also be undertaken by a recognised notified body (NB).

A notified body (NB) is a certification organisation that the competent authority (MHRA within the UK) designates to carry out one or more of the conformity assessment procedures described in the annexes of the Regulations.

2.14 Decontamination units must also register with the MHRA and therefore may be subject to audit to the appropriate requirements of the MDR by the MHRA.

Devices remaining within one legal entity

2.15 If a healthcare establishment only provides reprocessed medical devices for use on or by patients of that same entity (that is, there is no placing on the market), the MDR do not apply.

2.16 Such decontamination departments do not need to register with the MHRA nor do they need to use an NB; nevertheless, they are subject to the duty of care imposed under product liability.

2.17 However, for the purpose of this policy, such units must still meet the appropriate essential requirements of the MDR, producing goods that are safe, "fit for purpose" and of suitable quality.

2.18 Compliance with BS EN ISO 13485:2003 will demonstrate a commitment to producing goods of appropriate quality. This is consistent with previous advice in Executive Letter EL(98)5 (in Northern Ireland, PEL(98)4) in that such units should operate to the same standards as industry and may provide a due diligence defence in the event of claims or litigation related to product liability.

Compliance with healthcare standards

2.19 The establishment and measurement of relevant healthcare standards is seen as key to ensuring effective and compliant services.

2.20 The regulatory responsibility for healthcare standards is vested with the Healthcare Commission (HCC), with the decontamination of reusable medical devices being included in its assessment programme from April 2005.

Not applicable in Northern Ireland

2.21 The decontamination standards in 'Standards for better health' and those in the National Minimum Standards (for the independent sector) require decontamination to be properly carried out in facilities that accord with guidance issued by MHRA.

2.22 Those decontamination departments registered with MHRA are already subject to the legal requirements of the MDR, with audit, inspection and review being part of this process. These registered departments will therefore not fall within the remit of the HCC for compliance with the

MDR, but will remain with their NBs and the MHRA as part of their legal requirement.

2.23 The HCC uses the appropriate "essential requirements" of the MDR as the basis for their scheme of inspection for those decontamination departments that are not required to register under the MDR.

2.24 Further to this, there is a range of alternative methods of achieving a compliant service. Detailed below are a number of specific options to assist organisations when planning local responses to comply with decontamination strategies and DH policy.

2.25 The options are:

1. Use a decontamination service that is registered with the MHRA, that is compliant with the MDR, and that uses an NB as its third-party auditor.
2. Use a decontamination service that is subject to the HCC audit and inspection programme.

Not applicable in Northern Ireland

3. Use CE-marked single-use medical devices.
4. Employ a strategy that features a combination of the above.

2.26 A key consideration in the selection of an appropriate strategy is risk management.

Summary

- Local needs and facilities will determine the ways in which the service is provided, but the decontamination service must comply with Department of Health policy and the "essential requirements" of the MDR.
- The relative merits of the options should be evident through developing a business case highlighting the options, timescales, cost benefits and reliability assessment. Any such plan should indicate the proposed compliance with 'Standards for better healthcare' and provide a forward-looking aspect to progressively improving standards within approved timescales.
- A key consideration in the selection of an appropriate strategy is risk management.

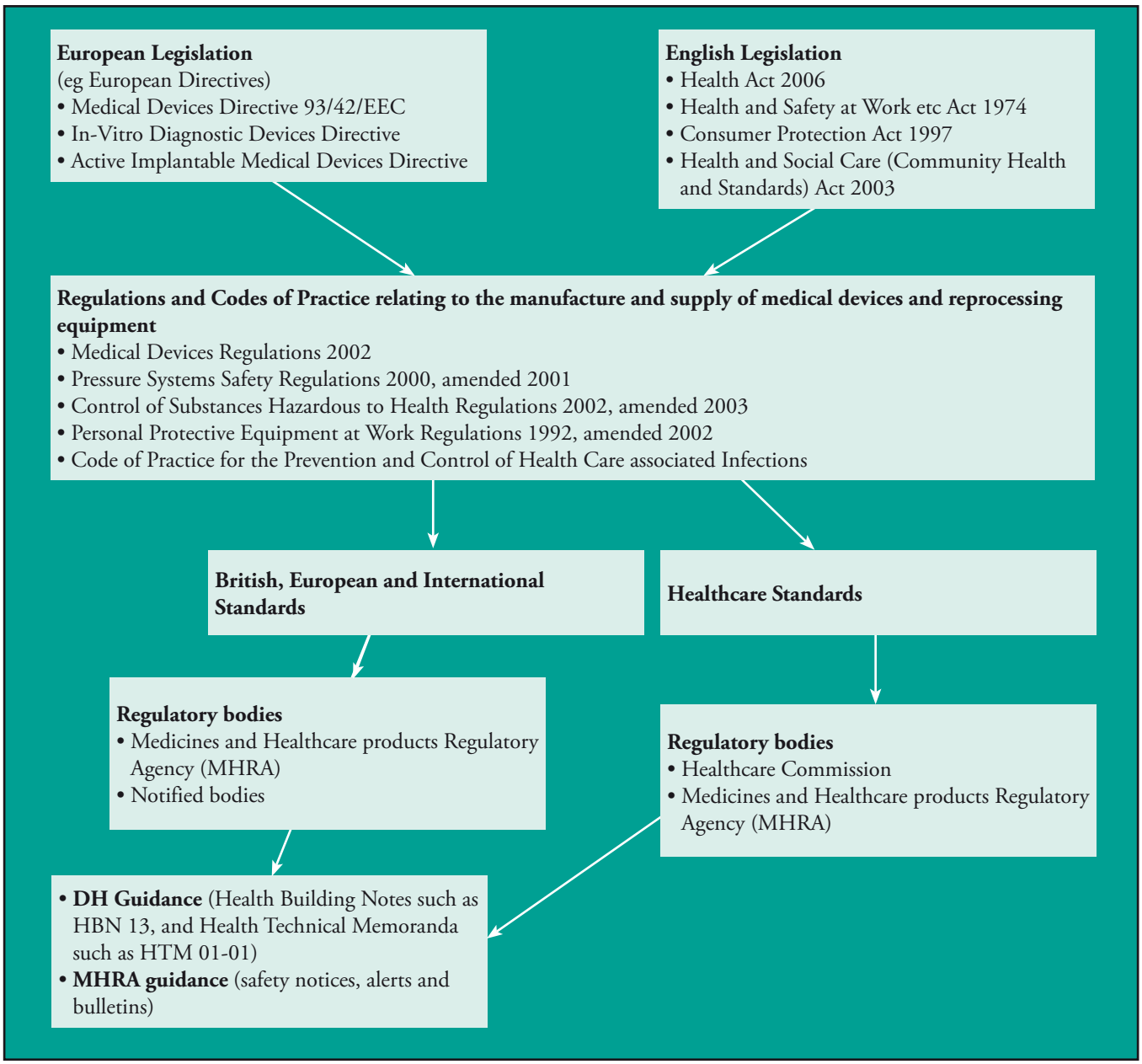
3 Regulatory framework

Overview

3.1 This chapter sets out the duty of care for decontamination services in England. The regulatory framework is applicable across all sectors of healthcare.

3.2 Figure 1 shows an overview of the interaction between the different structures within the English legislative system.

Figure 1



European legislation

3.3 There are three EU Directives relating to the manufacture and supply of medical devices:

- the Medical Devices Directive 93/42/EEC;
- the In-vitro Diagnostic Devices Directive 98/79/EEC;
- the Active Implantable Medical Devices Directive 90/385/EEC.

3.4 These three directives have been transposed into UK law as the Medical Devices Regulations 2002. (For more information about the Medical Devices Directives and compliance, visit the MHRA website www.mhra.gov.uk.)

Regulations and Codes of Practice

3.5 There are a number of regulations and Codes of Practice relating to the manufacture and supply of medical devices and reprocessing equipment. The primary regulations are:

(i) the Medical Devices Regulations 2002 (as amended 2003);

(ii) the Pressure Systems Safety Regulations 2000 (as amended 2001);

(iii) the Control of Substances Hazardous to Health Regulations 2002 (as amended 2003);

(iv) the Personal Protective Equipment at Work Regulations 1992 (as amended 2002);

(v) the Electromagnetic Compatibility Regulations (the EMC Regulations);

(vi) 'Code of practice for the prevention and control of health care associated infections 2006'.

More information on the Medical Devices Regulations is given in paragraphs 2.12–2.18. For more information on the Regulations in (ii)–(v), see Health Technical Memorandum 00 – 'Best practice guidance for healthcare engineering'.

'Code of practice for the prevention and control of healthcare-associated infections 2006'

3.6 The purpose of the Code is to help healthcare organisations plan and implement how they can prevent and control healthcare-associated infections (HCAI).

3.7 The Code sets out criteria by which healthcare organisations should ensure that patients are cared for in a clean environment, where the risk of HCAI is as low as possible. This includes the decontamination of medical devices (visit www.dh.gov.uk).

3.8 The Code itself does not have statutory force. However, failure to comply with the Code may lead to breach of the Health Act 2006 and, ultimately, action being taken by the HCC (such as improvement notices, special measures or being reported to the Secretary of State).

The Code has not been issued in Northern Ireland. The Health and Safety Executive for Northern Ireland (HSENI) website provides information on Northern Ireland health and safety legislation and codes of practice (www.hseni.gov.uk). Decontamination policy and guidance are available on the DHSSPS website: www.dhsspsni.gov.uk.

British, European and International Standards

3.9 To support the Medical Devices Directive and to assist manufacturers (including decontamination services) to interpret the essential requirements, the European Commission has published an updated list of harmonised standards. Compliance with all relevant harmonised standards on this list leads to an automatic presumption that the medical devices comply with the requirements of the Directive (see the Official Journal of the European Union http://eur-lex.europa.eu).

3.10 Although compliance with a mandated standard is not the only way of complying with the directives, it is the simplest.

Note

Some European and International Standards are currently under review and may be published at the same time as this Health Technical Memorandum. Standard numbers and titles are expected to change. Advice should be sought from an Authorising Engineer (Decontamination) with respect to the current situation of any Standard. Information will also be available from the BSI website: www.bsi-online.co.uk.

Decontamination equipment

3.11 Washer-disinfectors and sterilizers (that is, those machines specifically intended for processing

medical devices) can fall within the scope of the Medical Devices Regulations 2002.

3.12 All medical devices and accessories to devices are classified in accordance with rules outlined in Annex IX of the Directive. Of particular relevance to washer-disinfectors and sterilizers is rule 15, which states that "all devices intended specifically to be used for disinfecting medical devices" are Class IIa for conformity assessment purposes. It specifically excludes products that are intended to clean medical devices (other than contact lenses) by means of physical action.

Standards relevant to decontamination equipment

- BS EN ISO 17665-1:2006 'Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices' (this includes porous load and fluid sterilizers (except where used for medicinal products), and sterilizers for unwrapped instruments and utensils).
- BS EN 285:2006 'Sterilization. Steam sterilizers. Large sterilizers'.
- BS EN 13060:2004 'Small steam sterilizers'.
- BS EN ISO 15883-1:2006 'Washer-disinfectors. General requirements, terms and definitions and tests'.
- BS EN ISO 15883-2:2006 'Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc'.
- BS EN ISO 15883-3:2006 'Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers'.

3.13 A number of other standards are applicable to the sterilization of medical devices, including a number relating to decontamination methods not routinely used in the NHS in England. Because of the currency of this document and the standards in question, these other methods are not covered in this Health Technical Memorandum.

3.14 Advice may be sought from the Authorising Engineer (Decontamination), the MHRA or BSI.

Standards for better health

3.15 The Department of Health published 'Standards for better health' in 2004. These comprise a set of core and developmental standards that all healthcare organisations in England which treat NHS patients should be achieving.

3.16 As part of its "annual health check", the Healthcare Commission (the health watchdog in England) assesses each healthcare organisation to check whether it is complying with the core standards.

3.17 Decontamination standards in 'Standards for better health' and in the National Minimum Standards require decontamination to be properly carried out in facilities that comply with guidance issued by the MHRA (that is, safety notices, alerts and bulletins (www.mhra.gov.uk)) and with the Medical Devices Regulations 2002.

Note

Those organisations registered with the MHRA are already subject to the legal requirements of the Medical Devices Regulations – with audit, inspection and review being part of this process. These registered organisations will therefore not fall within the remit of the Healthcare Commission for compliance with the MDR but will remain with the notified body and the MHRA as part of their legal requirement.

Guidance

- Department of Health's 'Health Building Note 13 – 'Sterile services department'.
- For a list of medical device alerts, safety notices, hazard notices and device bulletins relating to decontamination, visit the MHRA's website (www.mhra.gov.uk).

For Northern Ireland, see the Northern Ireland Adverse Incident Centre (NIAIC) website: www.dhsspsni.gov.uk/niaic

4 General principles

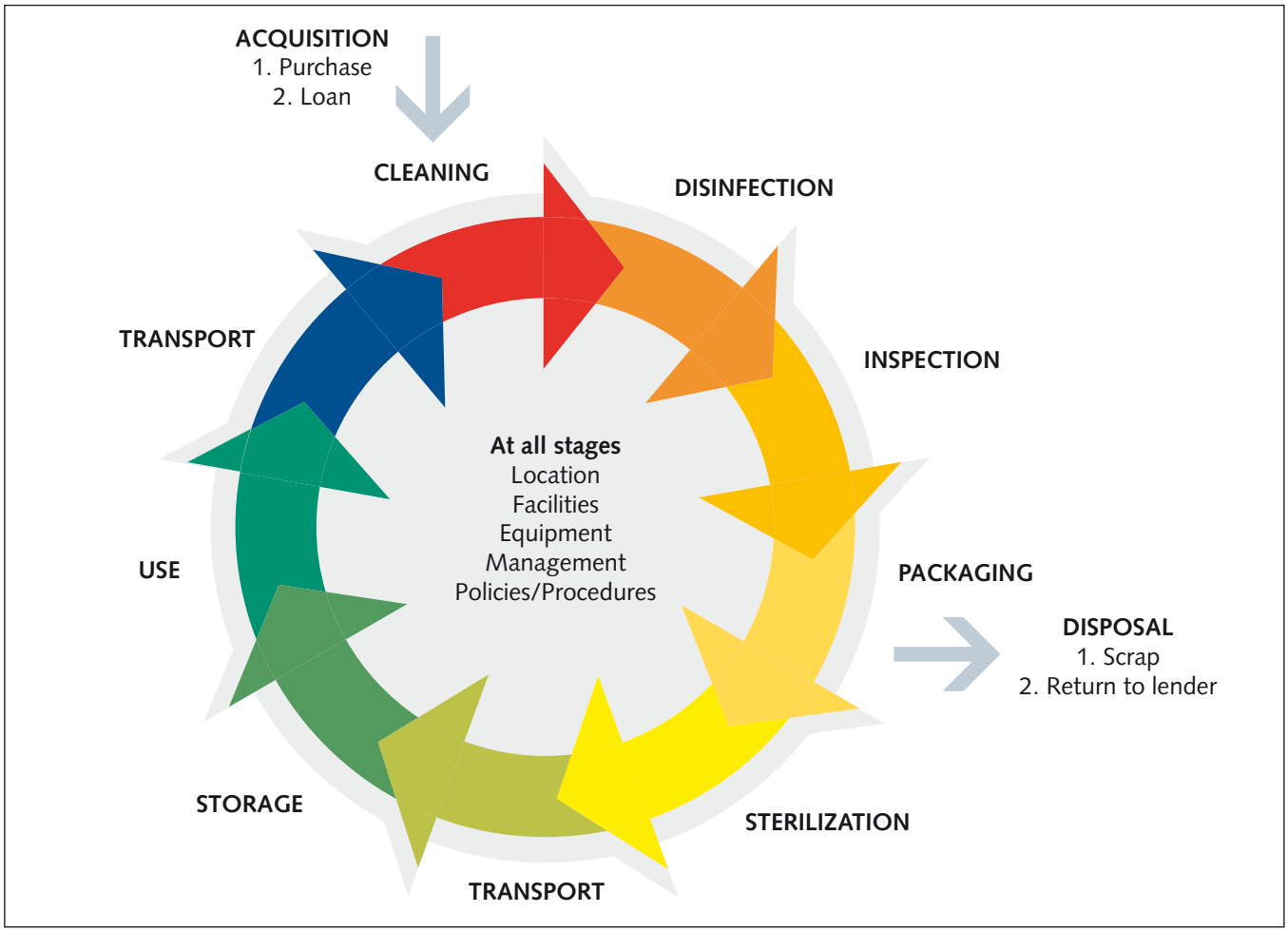
Management of decontamination services

4.1 Traditionally, decontamination has been the responsibility of the departmental heads of dedicated facilities such as sterile services departments (SSDs) or endoscopy units.

4.2 However, regardless of the location of decontamination (for example primary care or acute sector), the same standards should be applied.

4.3 Figure 2 highlights each stage of the decontamination process through which medical devices pass before every use.

Figure 2 Life-cycle of a reusable medical device



4.4 Effective decontamination requires the attainment of acceptable standards at all stages of the life-cycle. Failure to address issues in any of these stages will result in inadequate decontamination.

4.5 At all stages of reprocessing, the following issues need to be taken into account:

1. the existence of effective management arrangements;
2. the existence of policies and procedures for all aspects of decontamination work.
3. the location and activities where decontamination takes place;
4. facilities and equipment at each location;

5. ensuring the equipment used is validated, maintained and tested in accordance with manufacturer's guidelines and legislation;

Basic requirements for decontamination

4.6 In maintaining and developing organisation-wide decontamination standards and practices, the following should be included:

a. an effective quality management system must be in place to cover all aspects of the decontamination life-cycle;

b. every healthcare organisation should have a nominated Decontamination Lead (see paragraphs 5.14–5.19) with responsibility for decontamination, either at board level or someone who has line management responsibility to a senior responsible person at that level;

c. documented robust and comprehensive policies and procedures to ensure that decontamination processes are undertaken in a controlled manner to protect the health and safety of patients and staff;

d. a procurement policy which ensures that all purchased instruments are compatible with decontamination processes available within the healthcare organisation;

e. manual cleaning of devices to be restricted to those items or those components of an overall decontamination process deemed incompatible with automated processes by the device's manufacturer;

f. reprocessing of medical devices to be undertaken in dedicated facilities and outside the clinical/patient environment, preferably in accredited central facilities;

g. equipment used to decontaminate medical devices and associated equipment (for example heat sealer machines) must be fit for purpose, validated, tested and maintained in accordance with current recommendations;

h. healthcare organisations should have in place systems to track instrument trays and endoscopes through decontamination processes and to the patient;

j. a documented training scheme must be in operation with individual training records for all staff involved in reprocessing, including management involved in decontamination activities.

Tracking and traceability of medical devices

4.7 It is important to be able to trace products through the decontamination processes to which they have been subjected and to the patient on whom they have been used.

4.8 The ability to track and trace medical devices and equipment enables corrective action to be taken when necessary.

4.9 Records should be maintained for all the trays cleaned, identifying:

- the cleaning and sterilization method used;
- the name of the person undertaking the decontamination;
- details of the actual tray being processed;
- which patients have been treated with the tray.

4.10 This information is required so that instrument trays can be traced, if required, in the event of a failure in the decontamination cycle or for infection control reasons.

4.11 The use of untracked supplementary instruments should be avoided where possible and instruments grouped together into traceable trays.

4.12 Detailed guidance on the procurement of surgical instrument management systems can be found in the Model Engineering Specification: 'Surgical instrument management system specification'.

Infection control policies

4.13 All organisations should have an infection control policy that contains:

- advice on decontamination and storage of surgical instruments;
- local policies on recommended disinfectants, their application, use, storage and disposal;
- protocols for the cleaning and disinfection of surgical instruments where instruments have to be processed in a local setting;
- protocols for the use of personal protective equipment (PPE);
- risk assessments for procedures used in the reprocessing of medical devices;

- spillage procedures;
- management and treatment of needle stick/ sharp injuries.

4.14 This policy should be written in collaboration with the infection control team.

4.15 A Department of Health code of practice exists for the related issues of decontamination, the management of medical devices and associated equipment, and infection control ('Code of practice for the prevention and control of healthcare-associated infections 2006').

Not issued in Northern Ireland

Decontamination training

4.16 Staff undertaking decontamination must be competent and properly trained.

4.17 Individual training records, detailing the individual's core competencies and any other training, should be maintained and updated regularly. Line managers are responsible for maintaining these records.

4.18 In the primary care setting, whoever owns or manages the practice is responsible for ensuring that systems are in place for ongoing staff training.

4.19 Professional bodies such as the Institute of Decontamination Sciences offers further training (for example National Vocational Qualification (NVQ) Level 3).

National E-learning training scheme

4.20 A national E-learning training scheme is available free to NHS staff and under licence to the independent sector.

4.21 The scheme describes basic training for staff involved in all aspects of the decontamination of medical devices.

4.22 All staff who reprocess medical devices or who are involved in the management of decontamination services should register and complete the scheme.

4.23 The scheme may be used as part of the NHS Knowledge and Skills Framework (KSF) through local integration into KSF post outlines.

4.24 Online registration and certification are provided as part of the scheme and may be used in local risk management arrangements.

Further information

4.25 Advice on the technical management of the instrument life-cycle is available online via the national E-learning training scheme. The scheme can be accessed at: www.decontamination.nhs.uk/lms/nhs_splash/nhs_splash.asp

In Northern Ireland, visit http://nidecontamination.intuition.com/lms/nhs_splash/nhs_splash.asp

5 Functional responsibilities

Introduction

5.1 This chapter describes the roles and responsibilities of key personnel involved in the operation, maintenance and use of decontamination processes. The job titles given are generic; they are not intended to be prescriptive job titles for terms of employment. Indeed, some of the personnel referred to may not be resident staff but people employed by outside bodies and working on contract (for example those employed by a facilities management organisation or PFI consortium).

5.2 Some staff will have other responsibilities unconnected with decontamination, and in some cases the same individual may take on more than one role.

5.3 In every case, however, it is possible to identify a User (see paragraphs 5.24–5.26) who is responsible for the day-to-day management of decontamination processes (including equipment). The philosophy of this guidance is to invest the User with the responsibility for ensuring that the equipment is operated safely and efficiently.

5.4 The User should seek professional advice from an Authorising Engineer (Decontamination) (AE(D)) on all aspects of the decontamination process, including procurement, maintenance and testing, and ensure that maintenance and testing is carried out by a suitably qualified Competent Person (Decontamination) (CP(D)) with the assistance from a Microbiologist (Decontamination) where microbiological testing is required. In exceptional cases in small healthcare establishments with limited decontamination equipment and estates staff, it may be appropriate for a suitably qualified Authorised Person (Decontamination) (AP(D)) to also provide the services of the CP(D).

Context

5.5 Engineering in the NHS is a complex and important element in the delivery of the modern healthcare infrastructure. In consequence, the management of decontamination equipment must rank in importance with other critical engineering services, for example medical gases, high voltage/low voltage electrical systems, and fire safety as key factors to be considered in any service provision risk assessment.

5.6 In common with other critical services, the installation, maintenance, repair, calibration and testing of decontamination equipment is primarily an engineering function. A system common with the management of such a function may be appropriate. Thus, it has been considered appropriate to examine prior arrangements of management of decontamination equipment and modify these arrangements to strengthen existing controls.

5.7 The changes described within this document will align the roles within decontamination with those of other critical engineering services such as medical gas pipeline systems and electrical infrastructure (as highlighted in Health Technical Memorandum 00 – 'Policies and principles') and provide a robust framework for future support to the NHS.

5.8 There is a need to ensure that those addressing themselves by the new titles proposed within this document are appropriately qualified, knowledgeable and experienced.

5.9 In brief, the primary changes are:

- to redefine and formalise the role of the existing Authorised Person (Sterilizers) (AP(S)) as AE(D) with better definition of the role and reporting routes;
- to introduce a defined role for estates management personnel responsible for decontamination called the AP(D). This role should encompass an overview of activity of the CP(D) and day-to-day operational management of decontamination equipment;
- the consolidation of the roles and training of the Maintenance Person (Sterilizers) and Test Person (Sterilizers) into a new role – that of the CP(D);

- to strengthen the requirements for a healthcare organisation that is undertaking decontamination of reusable medical devices, to use the service of an AE(D);
- the introduction of a permit-to-work system relating to decontamination equipment similar in operation to other permit systems.

Management – definition

5.10 Management is defined as the owner, occupier, employer, general manager, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises. In PFI/facilities-managed premises, the PFI/FM consortium may directly employ estates staff.

Key personnel

5.11 In this document, the following are key personnel who have specific responsibilities within decontamination:

- Executive Manager (for example chief executive);
- Decontamination Lead (this person may also act as the Designated Person if locally agreed);
- Designated Person;
- Senior Operational Manager (for example estates manager);
- User (for example sterile services manager);
- Authorising Engineer (Decontamination);
- Authorised Person (Decontamination);
- Competent Person (Decontamination);
- Director of Infection Prevention and Control;
- Control of Infection Officer;
- Microbiologist (Decontamination);
- Operator;
- Manufacturer;
- Contractor;
- Purchaser;
- Competent Person (Pressure Systems).

Executive Manager

5.12 The Executive Manager is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the decontamination equipment is installed.

5.13 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive or other person of similar authority.

Decontamination Lead

5.14 Every healthcare organisation must have a nominated Decontamination Lead with responsibility for decontamination, either at board level or who has line management responsibility to a senior responsible person at that level (see 'The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections' (Department of Health, 2006)).

5.15 The Decontamination Lead should report directly to the Executive Manager.

5.16 The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services.

5.17 The Decontamination Lead is responsible for the implementation of an operational policy for decontamination. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment. The Decontamination Lead is also responsible for monitoring the implementation of the policy.

5.18 The Decontamination Lead may delegate specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

5.19 The Decontamination Lead may also act as the Designated Person.

Designated Person

5.20 This person provides the essential senior management link between the organisation and professional support.

5.21 The Designated Person should also provide an informed position at board level.

5.22 The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination system.

Senior Operational Manager

5.23 The Senior Operational Manager is technically, professionally and managerially responsible for the engineering aspects of decontamination (for example decontamination equipment and environment).

User

5.24 The User is defined as the person designated by Management to be responsible for the management of the process. The User is also responsible for the Operators as defined in paragraph 5.55.

5.25 In the acute sector, the User could be a sterile services manager. Alternatively, in primary care he or she could be a general practitioner, dentist or other health professional.

5.26 The principal responsibilities of the User are as follows:

a. to certify that the decontamination equipment is fit for use;

b. to hold all documentation relating to the decontamination equipment, including the names of other key personnel;

c. to ensure that decontamination equipment is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records;

f. to establish procedures for product release in line with the quality management system;

g. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

The User may seek the advice of infection control teams, which may consist of a Director of Infection Prevention and Control, Control of Infection Officer or Microbiologist (Decontamination).

Authorising Engineer (Decontamination) (AE(D))

5.27 The AE(D) is defined as a person designated by Management to provide independent auditing and advice on washer-disinfectors, sterilizers and sterilization and to review and witness documentation on validation.

5.28 The AE(D) is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties.

Role of the AE(D)

5.29 This role has been developed from the prior Authorised Person (Sterilizers) arrangements. This person should be fully independent of the organisation's structure for maintenance, testing and management of the decontamination equipment.

5.30 The AE(D) should have a reporting route to the Decontamination Lead and should provide professional and technical advice to AP(D)s, CP(D)s, Users and other key personnel involved in the control of decontamination processes.

5.31 The Institution of Healthcare Engineering and Estates Management (IHEEM) sets professional standards for their voluntary registration and for the accreditation of training courses, as has been the case for the Health Technical Memorandum 2010-defined AP(S) role. The Department of Health, and where applicable the relevant health estates bodies in the devolved administrations, set the technical standards as relevant.

Responsibilities

5.32 The principal responsibilities of the AE(D) are as follows:

a. to provide to Management and others, general and impartial advice on all matters concerned with decontamination;

b. to advise Management and others on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests submitted by the AP(D);

d. to advise Management and others on programmes of periodic tests and periodic maintenance;

e. to advise Management and others on operational procedures for routine production;

f. to advise Management on the appointment of the AP(D).

5.33 Only suitably qualified AE(D)s should be used. A register is maintained by IHEEM.

Qualifications

5.34 The AE(D) should:

a. be qualified to graduate level in an appropriate discipline with demonstrable experience in the subject of decontamination. Exceptionally, those personnel with extensive relevant experience and a lower level of qualification should also be considered; each case should be considered on its merits, especially during the transitional arrangements from the present system;

b. be a member of an appropriate professional institute with demonstrable experience in the subject of decontamination;

And

(i) have passed a course such as the revised ACIST ("Advanced Course In Sterilizer Training") or an equivalent alternative;

or

(ii) be an existing AP(S) who has passed the qualifying examination for AP(S) and undertaken any necessary gap training within a period not exceeding three years from implementation of the recommendations within this document;

or

(iii) following a review, have met the requirement of the registration panel within a three-year period.

Authorised Person (Decontamination) (AP(D))

5.35 The AP(D) 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(D)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment.

Role of the AP(D)

Note

This role is not a replacement for the existing AP(S) arrangements despite the similarity in title.

5.36 The AP(D) should be able to undertake the safe and effective management of the engineering aspects of the service.

5.37 The role of AP(D) is intended to provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system. This should be an internal appointment within the organisation. It is, however, recognised that in some organisations there are so few items of decontamination equipment in use that a service provided by a third party may be adequate. In most organisations the role of AP(D) would only be one of a number of areas of similar responsibility for the individual(s) concerned. However, any additional responsibilities should not reduce the importance of the role nor impair the ability of the AP(D) to carry out his/her duties effectively.

5.38 When the scope and range of services dictates, healthcare organisations may wish to consider the appointment of more than one AP(D) to ensure that appropriate cover is provided. In these circumstances the organisation should appoint a senior AP(D). In any event, organisations will need to ensure that cover is available during the absence of the AP(D) due to annual leave, sick leave etc. Larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role.

5.39 Even where estates roles are contracted out, it is recommended that the AP(D) function remains the responsibility of the healthcare organisation.

5.40 It is recommended that the AP(D) reports professionally to the Designated Person.

Responsibilities

5.41 The AP(D) will also be responsible for:

- the engineering management of decontamination equipment;
- line management and/or appointment of the CP(D);
- the safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;
- the acceptance criteria for operational and performance testing of all installed decontamination equipment;
- liaison with the AE(D), Decontamination Lead and other interested professionals;
- authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests;

- operation of the permit system;
- ensuring the continued registration of the CP(D)s, as appropriate;
- liaising with the User, and other technical support personnel, to enable them to discharge their responsibilities for management of decontamination effectively.

Qualifications

5.42 The AP(D) should be qualified to at least Higher National Certificate (HNC) level, or equivalent, in an engineering discipline. He/she should have knowledge of the specific equipment installed on-site and not simply a generic overview of decontamination equipment.

5.43 The AP(D) should have received appropriate training and be conversant with periodic testing. He/she should have completed an accredited course for CP(D)s and successfully passed the examination.

Note

In some circumstances, the AP(D) can perform the role of the CP(D) – subject to the necessary skills, education and experience. However, the reverse cannot apply.

Competent Person (Decontamination) (CP(D))

5.44 The CP(D) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilizers.

Role of the CP(D)

5.45 This role involves the amalgamation of the Health Technical Memorandum 2010-defined roles of the Maintenance Person (Sterilizers) (MP(S)) and Test Person (Sterilizers) (TP(S)). The new CP(D) may be either directly employed labour or provided as a service to the trust from third parties. Healthcare organisations may wish to maintain the separate functional roles of testing and maintenance. In this case, the acronyms CP(D)(T) (for the test person) and CP(D)(M) (for the maintenance person) could be used as alternatives. The content of this role will relate to the skills matrix, which will be developed as indicated in the note box after paragraph 5.64.

5.46 The CP(D) should report directly to an appropriate member of the estates department (for example AP(D)) or should be subcontracted by them.

Responsibilities

5.47 The principal responsibilities of the CP(D) are as follows:

a. to carry out the maintenance tasks outlined in Health Technical Memorandum 01-01 Part B;

b. to carry out additional maintenance and repair work at the request of the User;

c. to conduct the validation tests specified in Health Technical Memorandum 01-01 Part B and to prepare the validation report;

d. to conduct the periodic tests specified in Health Technical Memorandum 01-01 Part B and to prepare reports as required by the User;

e. to conduct any additional tests at the request of the User.

5.48 For those CP(D)s who carry out maintenance duties, they should be a engineering craftsman with evidence to demonstrate competence in the maintenance of one or more types of decontamination equipment. The CP(D) should be in a position to deal with breakdowns, and have the ability to diagnose faults and carry out repairs, or to arrange for repairs to be carried out by others.

Qualifications

5.49 The CP(D) should:

a. be qualified to at least HNC level in engineering or microbiological sciences;

b. have completed an accredited course for CP(D)s and successfully passed the examination;

c. have been recently employed in an NHS hospital with responsibility for validation and periodic testing for one or more decontamination processes;

or alternatively:

(i) have a certificate demonstrating satisfactory completion of an accredited course (City and Guilds or equivalent) in the validation and periodic testing of at least two decontamination processes/machine types;

(ii) have at least three years' experience in the validation and periodic testing of porous-load sterilizers and at least one other decontamination process/machine type.

Note on transition arrangements

It is likely that, in the first instance, Authorising Engineers (Decontamination) will be made up of former Authorised Persons (Sterilizers) within the IHEEM voluntary registration system. It is anticipated that for this and the associated roles of Authorised Person (Decontamination) and Competent Person (Decontamination), there will be adjustments made with respect to the necessary training, voluntary registration, skills matrix and regulation of roles during 2007/2008. This will allow for a transition period of three years for additional and new-entrant training. It will also allow for the development and accreditation of courses as an enabling measure.

Director of Infection Prevention and Control

5.50 The Director of Infection Prevention and Control reports to the chief executive and the board. He/she is responsible for infection control aspects of decontamination. If the person has a degree in microbiology, he/she may also fulfil the role of the Microbiologist (Decontamination).

Control of Infection Officer

5.51 The Control of Infection Officer is defined as a person designated by Management to be responsible for advising the User on all infection control aspects.

Microbiologist (Decontamination)

5.52 The Microbiologist (Decontamination) is defined as a person designated by Management to be responsible for advising the User on microbiological aspects of disinfecting and sterilizing non-medicinal products. He/she should also be defined as the person responsible for advising the User on the microbiological aspects of handling, washing, disinfecting and sterilizing used medical devices.

5.53 The Microbiologist (Decontamination) should have a relevant degree (for example microbiology or medicine) and should be a member of the healthcare organisation.

5.54 The principal responsibilities of the Microbiologist (Decontamination) are as follows:

a. to advise the User on the microbiological aspects of decontamination procedures for non-medicinal products;

b. to audit the documentation from all decontamination equipment that has been tested by microbiological methods.

Operator

5.55 The Operator is defined as any person with the authority to operate a washer-disinfector or a sterilizer, including the noting of instrument readings and simple housekeeping duties.

Manufacturer

5.56 The Manufacturer is defined as a person or organisation responsible for the manufacture of a washer-disinfector or sterilizer.

Contractor

5.57 The Contractor (or supplier) is defined as a person or organisation designated by Management to be responsible for the supply and installation of the washer-disinfector or sterilizer, and for the conduct of the installation checks and tests. The Contractor (or supplier) may also be the manufacturer of the machine.

Purchaser

5.58 The Purchaser is defined as the person or organisation that orders the washer-disinfector or sterilizer and is responsible for paying for it.

Competent Person (Pressure Systems)

5.59 The Competent Person as defined in the Pressure Systems Safety Regulations 2000 is not the same person as the Competent Person (Decontamination) defined in this Health Technical Memorandum. The former is a chartered engineer responsible for drawing up a written scheme of examination for the system. The latter is the person who carries out maintenance, validation and periodic testing of washer-disinfectors and sterilizers.

5.60 Most insurance companies maintain a technical division able to advise on appointing a CP(PS). The AE(D) should also be able to provide advice.

Exemplar structure

5.61 Figure 3 shows a typical operational management structure. This relates to the engineering disciplines associated with decontamination equipment in a healthcare organisation.

5.62 There have been profound changes in the management philosophy of the NHS, including a move towards self-management (for example foundation hospitals in England) and for contracting-out of services. It is therefore not possible to prescribe a management structure of decontamination that is universally applicable given the wide range of circumstances in which decontamination equipment might be employed – that is, from a large off-site centralised sterile services department (SSD) to a small local decontamination unit.

5.63 Any locally-agreed variation in the structure should uphold the essence of control, management and professional criteria advocated by this document and should not compromise the ethos of the proposals.

5.64 The approach chosen for this guidance is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role, but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to might not be resident staff but be employed by outside bodies and working on contract.

Competency matrix and certificates

There is a wide range of decontamination equipment in healthcare organisations and a corresponding range of technical competencies required to undertake the relevant and necessary maintenance and testing procedures.

Staff should be suitably qualified to work on this range of equipment (although it is not practicable for most staff within an organisation to be "experts" in all types of decontamination equipment and processes). Similarly, training courses and qualification programmes need to be flexible enough to focus on specific requirements of the individuals.

It is therefore proposed to introduce a "competency matrix" for those staff engaged in the maintenance, repair, testing and auditing of decontamination equipment. (This will be achieved in collaboration with the registration body.)

Many subject areas are considered to be core modules for any competency certificate or qualification programme. All technical staff (AE(D), AP(D), CP(D)) should have demonstrable competence in those areas and/or have received training appropriate to their responsibilities.

The competency matrix should be used to determine the range of duties undertaken by the AP(D), CP(D) and the AE(D). Certification of competence should be used to identify the range of services and the types of equipment or processes that can be dealt with by each individual. For example, some CP(D)s may be defined as competent to undertake the range of services up to and including quarterly testing (as previously defined for MP(S) and TP(S)), with others defined as covering the full range of services. A similar approach would be adopted with the AE(D) and the particular processes with which an individual could deal. However, it would be expected that, for any particular process in which the AE(D) was deemed competent, the full range of services would be provided.

The functional roles of CP(D)s will be defined as part of the skills matrix and will be subject to the necessary skills, knowledge and experience.

Training

5.65 Personnel at all levels should have a sound general knowledge of the principles, design and functions of decontamination equipment. They should be trained on those types and models of equipment with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety and the safety of others. Training given to individuals should be recorded and reviewed regularly.

5.66 Accredited courses on sterilization, washer-disinfectors and decontamination suitable for personnel at all levels are run at registered training providers. Further information is available from AE(D)s. A comprehensive list of registered AE(D)s can be found on the IHEEM website (www.iheem.org.uk).

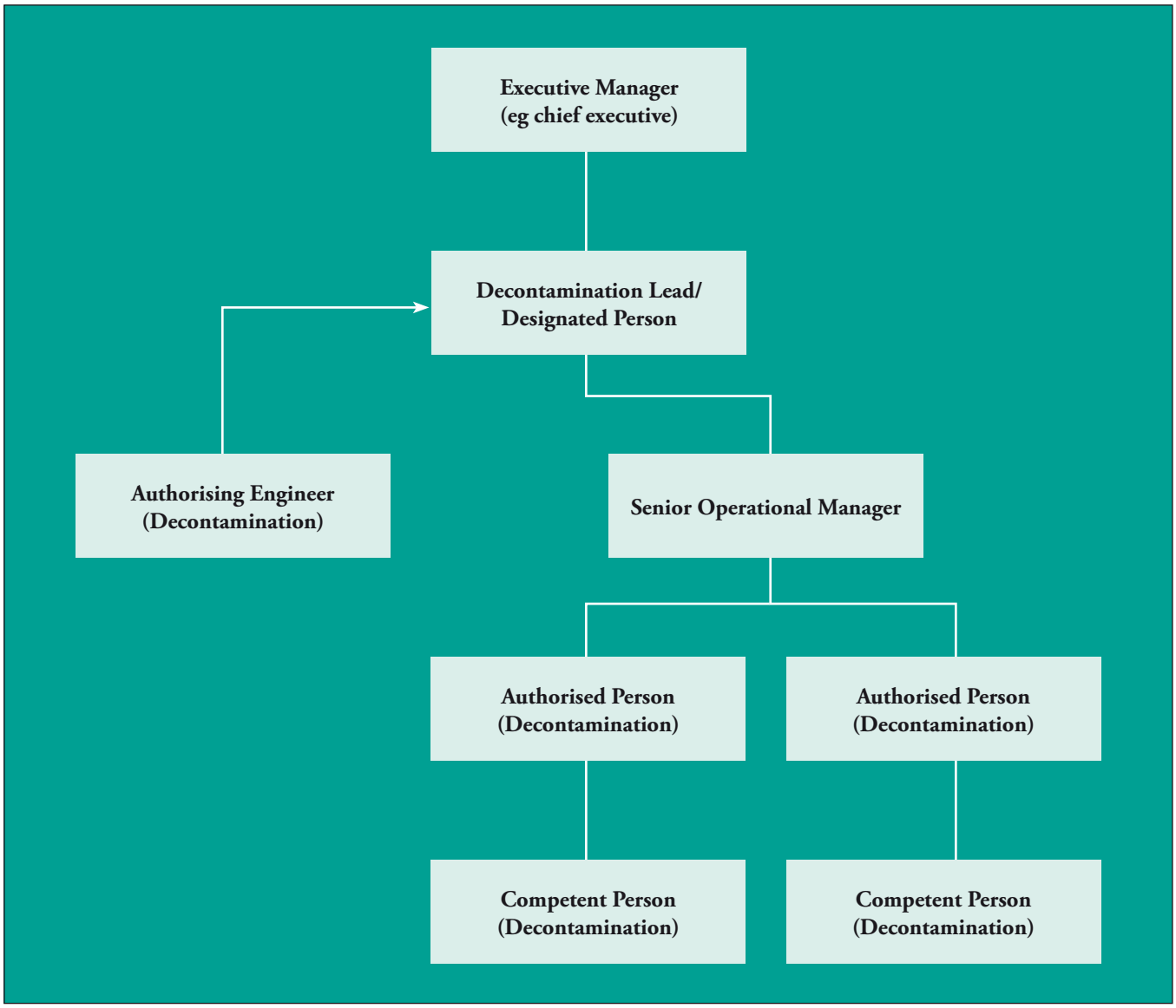
Note

There is a need to review existing training requirements and the developments of new arrangements for the new role of Authorised Person (Decontamination). For some of the roles, this will be a formalisation and phased adaptation of existing training, whilst others may need radical change. A competency matrix is to be developed (see Note above), which will aid the selection of appropriate training and allow modular delivery tailored to specific roles. Aside from those comprehensive courses designed to cover core competencies and allow a person to apply for CP(D), AP(D) or AE(E) status,

training courses will be aimed at specific areas to allow participants to enlarge their skill set through the matrix.

Prospective training providers should be technically accredited by IHEEM before being able to offer a path to registration with the aim of having consistent standards irrespective of their supply route. It is anticipated that in time, all courses will need to be academically accredited with an approved body (City and Guilds, BTEC etc) for course delivery.

Figure 3 Decontamination equipment: operational management structure (England)



6 Permit-to-work system

6.1 In order to address concerns with regard to situations where equipment is taken out of use and returned into use without the mutual agreement of the technical staff and users, a permit-to-work system is proposed. The permit system will involve the User and other key personnel.

6.2 The permit system should be introduced for all decontamination equipment that is used in healthcare facilities to:

- decontaminate reusable medical devices and goods;
- produce sterile products; or
- make-safe infected items.

Note

For information on how to access permit-to-work documentation/forms, users should seek advice from the AE(D).

6.3 The User should sign the permit to allow the equipment to be taken out of use for routine testing, repair and maintenance by the CP(D).

6.4 The CP(D) should sign the permit to allow the equipment back into use after routine maintenance and **weekly** testing. The User should also sign the permit to allow the equipment back into use.

6.5 After repairs following a breakdown and after **quarterly** or **annual** testing, both the AP(D) and the User should sign the permit to allow the equipment back into use. The CP(D) carrying out the work should also sign the permit. In the event of work spanning a number of shifts or days, the signatures of all the CP(D)s involved should show continuity.

6.6 The AE(D) should sign the initial permit to use the equipment after installation and validation testing (or revalidation testing for existing equipment that has been reinstalled). The User should sign the permit to accept the equipment into use.

6.7 In addition, when particular requirements dictate (for example when testing involves using biological indicators), other personnel should sign the permit (for example the Microbiologist (Decontamination), QC pharmacist or laboratory safety officer).

6.8 The AE(D) should formally audit the permit system records at intervals not exceeding one year.

7 Reporting of incidents

Introduction

7.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in England is set out in the MHRA's medical device bulletin DB2005(01): 'Reporting adverse incidents and disseminating medical device alerts'.

In Northern Ireland, PEL(04)22 Supplement 1 outlines equivalent procedures and guidance, and can be accessed from the Northern Ireland Adverse Incident Centre (NIAIC) website (www.dhsspsni.gov.uk/niaic) along with procedures for reporting of incidents.

7.2 Management should designate, for each item of decontamination equipment, a responsible person to act as liaison officer for the reporting of incidents. For the purposes of this document, the User is assumed to fill this role.

7.3 The User should be familiar with the reporting procedures established by the Department of Health's Estates and Facilities Division and the MHRA, and with statutory reporting requirements (in Northern Ireland, the Northern Ireland Adverse Incident Centre (NIAIC)). Training may be required.

7.4 Operators and others concerned with the operation of items of decontamination equipment should know what action to take in the event of an incident or failure.

7.5 The User should ensure that a sufficient supply of the correct reporting forms is available at all times.

7.6 The AE(D) should advise, for each item of decontamination equipment, which types of defect are to be considered as serious. The list should include all defects that may result in:

- a failure to properly decontaminate a product;
- danger to personnel; or
- damage to the product.

7.7 If a serious defect occurs, the item of decontamination equipment should be withdrawn from service and should not be used until all necessary repairs have been made and a repeat validation has been carried out. If the defect involves a pressure vessel, an inspection by the CP(PS) is required.

Department of Health reporting procedures

7.8 Certain types of defect should be reported to the Department of Health. Reportable defects are those where some central action might be helpful in bringing about necessary improvements in the standards of safety, design, construction, performance reliability or economics. Examples of reportable defects include the following:

a. accidents involving sterilizers;

b. failures of the integrity of the pressure vessel – that is, failures of door mechanisms, explosions and bursting or cracking of parts of the chamber, door, jacket or structural members;

c. incipient or potential defects likely to lead to such failures;

d. failures of the basic safety devices connected with the closing or opening of the door and pressurisation of the chamber;

e. failures of electrical safety;

f. any constructional features which do not conform to safety codes or with accepted good practice, or are hazardous in some way;

g. any unusual circumstances which may jeopardise safety or proper functioning (for example if safety devices or the automatic process controls can be defeated under certain conditions);

h. inability of a properly maintained and operated machine to meet its specified performance standards;

j. unreliability, persistent malfunction, frequent failures of particular components or any other feature which generates excessive or abnormally expensive maintenance or operational requirements, having regard to the intensity of use and operating conditions;

k. electromagnetic interference to or from other equipment, and particularly to computer control systems.

7.9 Adverse incidents should be reported either to the Department of Health or to the MHRA (in Northern Ireland, the Northern Ireland Adverse Incident Centre (NIAIC)).

7.10 All adverse incidents involving transportable (bench-top) sterilizers should be reported to the MHRA. The reporting procedure is set out in its medical device bulletin DB2005(01) – 'Reporting adverse incidents and disseminating medical device alerts'.

7.11 Adverse incidents involving permanently installed sterilizers should be reported to the Department of Health. The reporting procedure is set out in the Department's 'Reporting defects and failures relating to non-medical equipment, engineering plant, installed services, buildings and building fabrics'.

7.12 The User should display a notice on, or near, each item of decontamination equipment setting out the appropriate reporting procedure.

Statutory reporting procedure

7.13 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (amended 2001) place responsibilities on employers to report certain incidents and dangerous occurrences to the local office of the Health & Safety Executive (HSE). The action to be taken following any incident or malfunction with an item of decontamination equipment that is likely to cause a hazard should be detailed in the healthcare organisation's procedures to ensure compliance with this legal requirement.

7.14 The User should notify the HSE immediately, normally by telephone, if any of the following occurs:

a. any fatal injuries to employees or other people in an accident connected with the operation of an item of decontamination equipment;

b. any major injuries to employees or other people in an accident connected with the operation of the sterilizer;

c. any of the dangerous occurrences listed in the Regulations.

7.15 The User should send a written report to the HSE (in Northern Ireland, the HSENI) within seven days of any incident including:

a. any of the notifiable incidents listed above;

b. any other injury to an employee which results in their absence from work or being unable to do their normal work for more than three days;

c. any of the cases of ill-health listed in the Regulations.

7.16 A record should be kept of any injury, occurrence or case of disease requiring a report. This should include the date, time and place, personal details of those involved, and a brief description of the nature of the event.

7.17 Examples of dangerous occurrences applicable to sterilizers include:

a. the explosion, collapse or bursting of any closed vessel;

b. electrical short-circuit or overload causing fire or explosion;

c. any explosion or fire resulting in the suspension of normal work for more than 24 hours;

d. an uncontrolled or accidental release or escape of any pathogens or substance from any apparatus or equipment;

e. any incident where breathing apparatus malfunctions in such a way as to deprive the wearer of oxygen.

7.18 Examples of reportable diseases applicable to sterilizers include:

a. poisoning by sterilant;

b. any illness caused by a pathogen.

7.19 Full details can be found in the HSE's 'A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995'.

In Northern Ireland, the HSENI website (www.hseni.gov.uk) provides information on Northern Ireland health and safety legislation and codes of practice.

7.20 Incidents and dangerous occurrences that are reported to the HSE should also be reported either to the MHRA or to the Department of Health, as appropriate, by telephone during the first working day after the incident and then followed by a written report.

In Northern Ireland, contact the HSENI (www.hseni.gov.uk) or the NIAIC (www.dhsspsni.gov.uk/niaic).

8 Local reprocessing

Introduction

8.1 Local reprocessing is the reprocessing of medical devices that is undertaken at the point of use rather than in a sterile services department (SSD).

8.2 Local reprocessing is commonly associated with primary care (dentistry, general practice, podiatry, ophthalmology etc) and is usually undertaken by staff associated with the healthcare organisation where the devices are to be reprocessed.

8.3 Local processing can form part of a decontamination strategy that takes account of the ethics promoted within the "essential requirements" of the MDD, and which also ensures that decontamination services are safe, fit for purpose and of suitable quality.

8.4 Users should ensure that this strategy is consistent with:

- the Department of Health's policy document 'Decontamination of re-usable medical devices in the primary, secondary and tertiary care sectors – 2007 clarification and policy summary' (www.dh.gov.uk); and
- PL CMO (2007)2 (professional letter from the Chief Medical Officer) – 'Decontamination of surgical instruments in light of National Institute for Health and Clinical Excellence (NICE) guidance' (www.dh.gov.uk).

Important – remember:

The standards for decontamination and its associated equipment are the same regardless of the locality of the decontamination equipment – be it local to the clinical setting (for example primary care) or centralised in an SSD.

Risk assessments

8.5 If decontamination services are to be retained in-house, an appropriate risk assessment should be completed to support their continuation.

Options

8.6 Those healthcare organisations which undertake local reprocessing should evaluate the options for decontamination available to them and make an informed choice as to the most suitable route to follow. These options are:

a. centralise all decontamination to an accredited SSD;

b. use only single-use devices;

c. undertake decontamination locally to all applicable standards;

d. a combination of the above.

Note

Further guidance will be available in the forthcoming Health Technical Memorandum 01-06 – 'Flexible endoscope decontamination' and Health Technical Memorandum 01-07 – 'Decontamination in primary care' (this will also include podiatry).

9 Management of instruments potentially contaminated with transmissible spongiform encephalopathy (TSE) infectivity

Introduction

9.1 Transmissible spongiform encephalopathies (TSEs) (otherwise known as prion diseases) are rare, fatal degenerative diseases affecting the central nervous system (CNS), which occur in humans and certain other mammals.

9.2 There are several recognised TSEs, including Creutzfeldt-Jakob Disease (CJD) in humans, bovine spongiform encephalopathy (BSE) in cattle, and scrapie in sheep.

9.3 TSEs are caused by unconventional infectious agents currently thought to be infectious proteins (apparently without nucleic acid) known as prions, which do not share the normal properties of viruses or bacteria.

9.4 A common feature of all TSEs is the appearance of microscopic vacuoles in the grey matter of the CNS, giving a sponge-like appearance, from which the conditions derive their name. This change is accompanied by the accumulation of the abnormal form of the prion protein in the CNS.

9.5 TSE agents exhibit an unusual resistance to conventional chemical and physical decontamination methods. They are not significantly affected by disinfectants such as formalin and ethylene oxide, and infectivity persists after standard autoclaving (for example 134ºC for three minutes). They are also extremely resistant to high doses of ionising and ultraviolet irradiation, and some residual activity has been shown to survive for long periods in the environment (www.advisorybodies.doh.gov.uk/acdp/tseguidance).

Note

Research and subsequent advice on this issue is continually changing. Up-to-date information and further links can be obtained from the Department of Health's website (www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/fs/en).

Guidance from the Transmissible Spongiform Encephalopathies Working Group

9.6 The Transmissible Spongiform Encephalopathies Working Group (TSE Working Group) of the Advisory Committee on Dangerous Pathogens (ACDP) has categorised surgical procedures on patients known, or suspected, to have CJD into high, medium and low, depending on the type of tissue involved (visit ACDP's website for further details: www.advisorybodies.doh.gov.uk/acdp/tseguidance/tseguidancepart4-30mar07.pdf).

9.7 The processes for decontaminating medical devices so as to minimise the risk of transmission of a TSE agent must be properly controlled. The TSE Working Group has published guidance on its website: www.advisorybodies.doh.gov.uk/acdp/tseguidance/tseguidance_annexc.pdf.

9.8 The TSE Working Group has also published separate guidance on the decontamination of endoscopes: www.advisorybodies.doh.gov.uk/acdp/tseguidance/annexf_amended-30mar07.pdf.

Note

At the time of writing, advice on the decontamination of other specialised equipment is being revised and will be available at a later date.

The CJD Incidents Panel

9.10 The CJD Incidents Panel (a sub-group of the TSE Working Group) is an expert advisory committee set up by the Chief Medical Officer to advise hospitals, trusts and public health teams on how to manage incidents involving possible transmission of CJD between patients. From time to time this panel may advise that certain instruments that have been used on a patient known, or suspected, to have CJD should be quarantined and then possibly permanently removed from use.

9.11 A facility exists at the Health Protection Agency's Centre for Emergency Preparedness and Response at Porton Down to receive such instruments from affected trusts. Details are available from the following website: www.hpa.org.uk/business/secure_storage.htm.

Guidance from the National Institute for Clinical Excellence (NICE)

Note

NICE estimates that an effective anti-prion decontamination agent is likely to become available for routine use in the NHS during the next few years. However, until the safety of these methods and their efficacy against human prions is known, the current TSE Working Group's guidelines on decontamination as detailed in paragraph 9.7 should be followed.

9.12 NHS trusts are required to implement new guidance from NICE on handling surgical instruments used in certain procedures in order to minimise the risk of CJD transmission ('Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures' (www.nice.org.uk/guidance/IPG196)).

Recommendations

9.13 The main recommendations are as follows:

- Steps should be taken urgently to ensure that instruments in contact with high-risk tissues do not move from one instrument set to another. (For the purposes of the NICE guidance, high-risk tissues are defined as the central nervous system and posterior eye.)
- Supplementary instruments that come into contact with high-risk tissues should remain with the set to which they have been introduced.
- Rigid rather than flexible neuroendoscopes should be used wherever possible.
- All accessories used through neuroendoscopes should be single-use.
- For children born after 1 January 1997 who are due to undergo high-risk (see first bullet point) procedures, a special, separate pool of reusable surgical instruments and new neuroendoscopes should be used.
- Apart from neuroendoscope accessories, the guidance does not advocate a wholesale move to single-use instruments. It specifically advises that single-use instruments should only be used if they are of equivalent quality to reusable instruments.

Implementation of the guidance

9.14 Implementation of the NICE guidance will require auditing of current practice and protocols.

9.15 The purchasing of additional instruments can be taken forward immediately.

9.16 The purchase of separate endoscopes for use on children born after 1997 should be prioritised.

9.17 The extent of instrument migration between different sets is not known, and it is not clear whether tracking to tray level (in accordance with Health Service Circular 2000/032) is adequate to monitor supplementary instruments added to instrument sets, or instruments removed following damage or for maintenance. Consequently, the Department of Health intends to assist all trusts in implementing the NICE guidance by taking the following measures:

- an investigation of the extent of instrument migration between high-risk sets will form part of the planned National Decontamination Survey 2007;
- a statistically relevant survey is to be conducted to consider the quality-assurance standards prevalent in those procedures carried out on tissue categorised by NICE as high-risk.

Chief Medical Officer's Professional Letter

9.18 The Department of Health has also published Professional Letter PL CMO (2007)2 – 'Decontamination of surgical instruments in light of National Institute for Health and Clinical Excellence (NICE) Guidance' (www.dh.gov.uk).

9.19 This letter is a reminder that centres providing neurological and posterior eye surgery should be developing arrangements to implement the above NICE guidance, and it sets out the Department's plans to issue further advice on decontamination in 2007.

9.20 This Professional Letter sets out the main issues raised by the NICE guidance and associated considerations and recommendations of ESAC-Pr (see text box).

Single-use instruments and quality

9.21 NICE has not advocated a wholesale move to the use of single-use instruments.

9.22 It has emphasised that single-use instruments should be of equivalent quality to reusable instruments.

9.23 The importance of maintaining the high quality of instruments is borne out by experience with single-use instruments in tonsillectomy, where small design deficiencies have had significant surgical consequences.

9.24 Vigilance of design quality and manufacturing stability is key, and instrument design should be of a particular standard, once proven.

9.25 Therefore, procurers and users should work closely with instrument manufacturers where surgical instruments need to be carefully specified. It should also be ensured that all instruments function appropriately in terms of safety, fitness for purpose and quality.

Note

Tomkinson et al (2005) have reported that safe single-use instruments can be procured but require a specified design, a quality review and a "locked" design (that is, where the manufacturer has agreed that no changes will be made to the instrument procured) with ongoing audit.

In view of the relatively small numbers of instruments used nationally in neurosurgery and in posterior ophthalmic procedures, the authors also recommended national rather than local fault/failure post-procurement audits.

Role of the Engineering & Science Advisory Committee into the decontamination of surgical instruments including prion removal (ESAC-Pr)

ESAC-Pr aims to take forward, for potential practical application, the body of maturing research relating to the decontamination of surgical instruments with the emphasis on protein removal and prion deactivation.

ESAC-Pr supports the NICE guidance (see above) on the use of surgical instruments in procedures that are high-risk for the possible transmission of the TSE agent that causes CJD.

ESAC-Pr has established a working group that will produce advice on the applicability of the various anti-prion technologies that are on, or close to coming on, the market, as part of the surgical instrument decontamination cycle.

10 Environment

10.1 The facilities in which medical devices are to be reprocessed should have appropriately segregated processes.

10.2 The environmental conditions in such facilities should be controlled to prevent contamination (this includes both microbial and particulate contamination). ("Environmental conditions" not only refers to the cleanliness of surfaces, fittings and equipment, but also to ventilation and air quality in respect of filtration, airflow patterns and relative air pressures.)

10.3 Health Building Note 13 provides comprehensive guidance to assist individuals and organisations to make informed decisions about how to meet these standards.

NHS employees in England can download Health Building Note 13 free of charge from the Department of Health's Estates and Facilities Division's Knowledge and Information Portal homepage at: www.estatesknowledge.dh.gov.uk.

Printed copies are available from The Stationery Office Ltd (TSO). Tel: 0870 600 5522. Fax: 0870 600 5533. Online bookstore: www.tsoshop.co.uk

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