Decontamination of medical devices within acute services

Part A: Management and environment
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Note: Heath Building Notes (HBNs) and Health Technical Memoranda (HTMs) issued by the Department of Health in England are being superseded by specific Welsh editions which will be titled Welsh Heath Building Notes (WHBNs) and Welsh Health Technical Memoranda (WHTMs). Until this process is complete, where a WHBN or WHTM is referred to in the text but has not yet been published, refer to the relevant publications page on the NHS Wales Shared Services Partnership – Facilities Services website for the latest approved document.

Intranet: howis.wales.nhs.uk/whe

Internet: www.wales.nhs.uk/whe
Overview

Scope of Welsh Health Technical Memorandum 01-01 parts A to E

Welsh Health Technical Memorandum (WHTM) 01-01 gives guidance on the whole decontamination cycle in the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The technical concepts are based on British (BS), European (EN) and International (ISO) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

The management of decontamination equipment is a critical engineering service.

WHTM 01-01 Part A provides a description of the overall structure of the guidance and the rationale behind the following:

- 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 covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials;
- design and pre-purchase considerations;
- validation and verification.

Part C covers standards, technical guidance, operational requirements, and testing and validation protocols when using steam for sterilization within the acute care setting.

Part D covers standards, technical guidance, operational requirements, and testing and validation protocols when using washer-disinfectors as part of the decontamination cycle within the acute care setting.

Part E covers non steam sterilization processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure) for sterilization for decontamination providers for the acute care setting.


WHTM 01-01 Parts B to E supersede Health Technical Memoranda 2010, 2030 and 2031.

Who should use WHTM 01-01 Part A

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.
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Abbreviations

**ACDP-TSE RM Subgroup:** Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies Risk Management Subgroup (formerly the TSE Working Group)

**ACDST:** Advisory Committee on Decontamination Science and Technology

**AE(D):** Authorising Engineer (Decontamination)

**AP(D):** Authorised Person (Decontamination)

**BS:** British Standard

**BSE:** Bovine Spongiform Encephalopathy

**CJD:** Creutzfeldt-Jakob disease

**CMO:** Chief Medical Officer

**CP(D):** Competent Person (Decontamination)

**DH:** Department of Health

**DE (W):** Decontamination Engineer (Wales)

**EN:** European norm

**ISO:** International Standards Organisation

**MDD:** Medical Devices Directive

**MDR:** Medical Devices Regulations

**MHRA:** Medicines and Healthcare products Regulatory Agency

**NDS:** National Decontamination Survey

**NICE:** National Institute for Health and Care Excellence

**NWSSP-FS:** NHS Wales Shared Services Partnership – Facilities Services

**OPA/NAC:** o-phthalaldehyde/N-acetyl-L-cysteine

**PO:** posterior ophthalmic

**QMS:** quality management system

**sCJD:** sporadic Creutzfeldt-Jakob disease

**SSD:** sterile services department

**TSEs:** transmissible spongiform encephalopathies

**vCJD:** variant Creutzfeldt-Jakob disease

**WHTM:** Welsh Health Technical Memorandum
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Executive Board Lead
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Senior Operational Manager
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Authorising Engineer (Decontamination) (AE(D))
Decontamination Engineers (Wales) at NWSSP-FS
Authorised Person (Decontamination) (AP(D))
Competent Person (Decontamination) (CP(D))
Lead for Infection Prevention and Control
Microbiologist (Decontamination)
Operator
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Chapter 1  Scope

General

1.1 WHTM 01-01 Part A covers the policy, management approach and choices available in the formulation of an appropriately developed, risk-controlled, operational environment within acute healthcare facilities. It also includes the provision of services by Sterile Service Departments to primary and community services, where contracted.

1.2 The technical concepts are based on British (BS), European (EN) and International (ISO) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non availability of instruments.

1.3 Part A ‘Management and environment’ (this document) includes:
• a description of the overall structure of the guidance and the rationale
• behind the structure;
• general principles;
• the regulatory framework;
• roles of key personnel;
• principles based on Health Building Note 13.

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

1.4 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

1.5 This document covers the various types of decontamination equipment to be used for the reprocessing of medical devices (for example, porous load sterilizers and washer-disinfectors). Sterilizers for unwrapped instruments have no place in acute medical care and should be removed from service. Healthcare organisations should ensure they have sufficient numbers of instrument sets available to allow central reprocessing. If an organisation makes use of unwrapped instrument sterilizers in a community environment, the reprocessing system should be managed in accordance with the principals of WHTM 01-05. All Health care organisations in Wales have access to an MDD accredited SSD and should therefore manage and record their risks associated with any decision to use sterilizers designed for unwrapped instruments, ensuring sign off by the board level Quality and Risk Management Committee.

1.6 Guidance on the application of medical devices legislation to particular cases (e.g. innovative surgical equipment) is beyond the scope of this document and advice should be sought from the Medicines and Healthcare products Regulatory Agency (MHRA).

Outsourcing

1.7 The options for those healthcare organisations that do not undertake decontamination services include:
• Using a decontamination service that is registered with the MHRA that is compliant with the MDR, and that uses a notified body as its third-party auditor.
• Using CE-marked single-use medical devices.

1.8 The relative merits of the options should be evident through development of a business case, highlighting the options, timescales, cost benefits and reliability assessment.
Exclusions

1.9 Welsh Health Technical Memorandum 01-01 Part A excludes the following:

- Items of decontamination equipment used in laboratories. This will be covered in Welsh Health Technical Memorandum 01-02.
- Items of decontamination equipment used in pharmacies. This will be covered in Welsh Health Technical Memorandum 01-03.
- The decontamination of laundry and infected linen. This will be covered in Welsh Health Technical Memorandum 01-04.
- Decontamination in dentistry. This is covered in Welsh Health Technical Memorandum 01-05.
- The decontamination of flexible endoscopes. This will be covered in Welsh Health Technical Memorandum 01-06.

Definitions

1.10 For definitions of terms used in this guidance document see ISO 11139: Sterilization of health care products – vocabulary.
Chapter 2  Decontamination policy

Introduction
2.1 Improving and sustaining reusable-medical-device decontamination services forms an important part of the strategy to combat healthcare-associated infection (HCAI).
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 government 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 Decontamination review: the report on a survey of current decontamination practices in healthcare premises, 2000).
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 March 2001 the Welsh Assembly Government announced that it would invest £8 million to improve decontamination services in Wales. Welsh Health Circulars WHC 99 (157) and WHC 99 (158) supported this change-and-improvement process. The Welsh Assembly Government-managed project delivered MDA accreditation by all SSDs in Wales by July 2005.
2.9 It is imperative that sterile service departments of Wales are routinely audited under and comply with the relevant Medical Devices Directive.

Compliance
Compliance with legislation and policy
2.10 Responsibility for achieving acceptable standards of decontamination rests with healthcare organisations (Health Boards, NHS Trusts and provider organisations).
2.11 Units in healthcare establishments decontaminating medical devices fall into two distinct categories when considering compliance with the Medical Devices Directive 93/42/EEC and the subsequent amendments to the directive and medical device regulations in accordance with 2007/47/EC:
- 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) 2007/47/EC is transposed into UK law within the Consumer Protection Act as the Medical Devices Regulations (MDR) 2008 No.2936.

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. This standard specifies requirements for a quality system that can be used by
Devices transferred between legal entities

2.12 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).

Note

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.

2.13 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 – MDD Directive

2.14 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. However, it is a Welsh Government requirement within NHS Wales that all SSDs operate within the MDR.

2.15 Compliance with BS EN ISO 13485 will demonstrate a commitment to producing goods of appropriate quality. 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

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

2.17 The regulatory responsibility for healthcare standards is vested with the Health Inspectorate Wales (HIW) and the Care and Social Services Inspectorate of Wales (CSSIW).

2.18 The Welsh Government document ‘Doing Well, Doing Better: Standards for Health Services in Wales’ (2010) requires decontamination to be properly carried out in facilities that accord with guidance issued by MHRA.

2.19 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, therefore, will not fall within the remit of HIW and CSSIW for compliance with the MDR, but will remain with their NBs and the MHRA as part of their legal requirement.

2.20 HIW and CSSIW will use the appropriate essential requirements of the MDD as the basis for their scheme of inspection for those decontamination departments that are not required to register under the MDR.

2.21 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 policy.

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 HIW or CSSIW audit and inspection programme.
3. Use CE-marked single-use medical devices.
4. Employ a strategy that features a combination of the above.

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

Summary

2.24 Local needs and facilities will determine the ways in which the service is provided, but the decontamination service must comply with government policy and the MDR.

2.25 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 the Welsh Government document ‘Doing Well, Doing Better: Standards for Health Services in Wales’.
(2010) and provide a forward-looking aspect to progressively improving standards within approved timescales.

2.26 A key consideration in the selection of an appropriate strategy is risk management.
Chapter 3  Regulatory framework

Overview

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

3.2 Figure 1 below shows an overview of the interaction between the different structures within the legislative system in England and Wales.

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**Figure 1** Overview of the interaction between the different structures within the Welsh legislative system.

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European Legislation (e.g. European Directives)
- Medical Devices Directive 93/42/EEC
- In-Vitro Diagnostic Devices Directive
- Active Implantable

Legislation in England and Wales
(This is not an exclusive list)
- National Health Service (Wales) Act 2006
- The Public Health Wales National Health Service Trust (Establishment) Order 2009
- Health and Safety at Work Act 1974
- Consumer Protection Act 1997
- Health and Social Care (Community Health Standards) Act 2003
- National Health Service, Wales - The Local Health Boards (Establishment and Dissolution) (Wales) Order 2009

Regulations and Codes of Practice relating to the Manufacture and supply of medical devices and reprocessing equipment
- Medical Devices Regulations 2002
- Pressure Systems Safety Regulations 2000 (as amended)
- Control of Substances Hazardous to Health Regulations 2002 (as amended)
- Personal Protection Equipment at Work Regulations 1992 (as amended)
- The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance

British, European and International Standards
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Notified bodies

Healthcare Standards for Wales
- Health Inspectorate Wales
- Care and Social Standards Inspectorate of Wales

Regulatory Bodies
- NICE guidance (e.g. NICE 198)
- ACDP-T&E-RM guidance

Guidance
- DH Guidance (Health Building Note 13 etc.
- MHRA guidance (Safety notices, Alerts and Bulletins)

Note
The In-Vitro Diagnostic Devices and Active Implantable Medical Devices Directives have been included for completeness, although these devices are usually supplied sterile and are single-use.
European legislation

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

- MDD 93/42/EEC as amended by DIRECTIVE 2007/47/EC
- Active Implantable Medical Devices Directive 90/385/EEC as amended by DIRECTIVE 2007/47/EC

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

3.5 Washer-disinfectors and sterilizers – that is, those machines specifically intended for the decontamination of reusable medical devices – can also fall within the scope of the MDR.

3.6 For more information about the Medical Devices Directives and compliance, visit the MHRA website.

Regulations

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

- the Medical Devices Regulations 2002 (as amended)
- the Pressure Systems Safety Regulations 2000 (as amended)
- the Control of Substances Hazardous to Health Regulations 2002 (as amended)
- the Personal Protective Equipment at Work Regulations 1992 (as amended)
- the Electromagnetic Compatibility Regulations (the EMC Regulations)

British, European and International Standards

3.8 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 essential requirements of the Directive (AnnexeI) as listed in annexe ZA of that standard (see the Official Journal of the European Union eur-lex.europa.eu/JOIndex.do).

3.9 Although complying with a harmonised standard is not the only way of demonstrating compliance with the essential requirements, it is frequently the simplest.

Decontamination equipment

3.10 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.

3.11 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:

All devices intended specifically to be used for disinfecting medical devices are in Class IIa. Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class Ib.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

Note

More information on the Medical Devices Regulations is given in paragraphs 2.12–2.26. For more information on sections (ii)-(v) of the Regulations, see Welsh Health Technical Memorandum 00 – ‘Best practice guidance for healthcare engineering’.
Standards relevant to decontamination equipment

3.12 The list of standards given in Appendix 2 was correct at the time of publication and this is the core document list. Others can be referenced and be used to inform the management of decontamination of reusable medical devices in a healthcare organisation.

3.13 Standards relevant to decontamination equipment:
- BS EN ISO 17665-1: 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: Sterilization. Steam sterilizers. Large sterilizers
- BS EN 13060: Small steam sterilizers
- BS EN ISO 15883-1: Washer-disinfectors. General requirements, terms and definitions and tests
- BS EN ISO 15883-2: 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: Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
- BS EN ISO 15883-4: Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes

3.14 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. Because of the currency of this document and the standards in question, these other methods are not covered in this Welsh Health Technical Memorandum.

3.15 Advice may be sought from the Authorising Engineer (Decontamination), NWSSP-FS or the MHRA.

Standards for health

3.16 The Welsh Government document ‘Doing Well, Doing Better: Standards for Health Services in Wales (2010) sets the core and developmental standards that all healthcare organisations in Wales which treat NHS patients should be achieving.

3.17 All healthcare organisations in Wales will be expected to assure themselves and the communities they serve that they are achieving or working towards these standards of care. Healthcare Inspectorate Wales will carry out external, independent assessments of organisations to ensure compliance with, or progress towards meeting the Standards.

3.18 Decontamination standards in Doing Well, Doing Better: Standards for Health Services in Wales 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, therefore, will not fall within the remit of HIW or CSSIW for compliance with the MDR but will remain with the notified body and the MHRA as part of their legal requirement.

Guidance

3.19 For guidance refer to the following:
- 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).

Outsourcing

3.20 The options for those healthcare organisations that do not undertake decontamination services include:
- Using a decontamination service that is registered with the MHRA that is compliant with the MDR, and that uses a notified body as its third party auditor (compliance with BS EN ISO 9001, ISO 13485 and Dir 93/42/EEC.
- Using CE-marked single-use medical devices. The relative merits of the options should be evident through an analysis which covers the options, clinical requirements, timescales, cost benefits, reliability assessment and quality thresholds.
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).

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

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

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.

Figure 2 Stages of the decontamination process for a medical device
Basic requirements for decontamination

4.6 With WHTM 01-01, the Welsh Government is seeking to establish:
   a. the prevention and control of the risk of transmission of infection through surgical instruments – with specific reference to the theoretical risk of human prion diseases transmission (transmissible spongiform encephalopathies, or TSEs);
   b. a comprehensive approach to risk control and reduction across instrument management and decontamination;
   c. assurance over the management of surgical instruments, in terms of availability, quality and suitability;
   d. the preservation and advance of high-quality engineering through the support of European Norms (ENs), quality systems and standards;
   e. guidance for optimisation of the environment, equipment and facilities used in surgical decontamination.

4.7 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 Executive Board Lead for decontamination. The Executive Board Lead will delegate responsibility for decontamination to the Decontamination Lead;
   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, service users 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 devices’ manufacturer;
   f. reprocessing of medical devices to be undertaken in dedicated facilities and outside the clinical/patient environment, in facilities accredited to the MDD;
   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 rigid 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

4.8 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. Screw, plates or implantable items used in patient procedures and included in sterile packs pose a particular challenge. Whether individual or part of an instrument set, any such items should be fully traceable. All processing information must be documented in accordance with the manufacturer’s guidance. This should include the number of times an item has been processed as there will be a finite reprocessing life of the product.

Traceability information should be kept as stated within the Quality Management system (QMS) of the processing unit. Any of the related information, which may include the number of times processed, graphical information or any other processing records, should be accessible if required in circumstances such as product recall or investigations due to unexpected failure of an item. These records need to link directly to patients where they were used.

The risk management option to move to the use of pre-sterile single use implantable items as adopted universally in Scotland and to a lesser extent in Wales and England, offers a simple solution to these challenges. The policy option to require adoption of single use implantable devices in Wales has been discussed in Welsh Government and is likely to become a future requirement.

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

4.10 Records should be maintained for all the trays cleaned, identifying:
a. the cleaning and sterilization method used;
b. the name of the person undertaking the decontamination;
c. details of the actual tray being processed;
d. which patients have been treated with the tray;
e. the equipment cycle details and numbers.
(As a rule, a storage period of 12 years is deemed appropriate for retention of such information)

4.11 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.

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

4.13 Advice and guidance on the procurement of surgical instrument management systems is available from NHS Wales Shared Services Partnership - Procurement Services.

4.14 The reunification of instruments with their sets following repair or replacement benefits from accurate instrument identification. Tracking is likely to mitigate other factors, including those associated with operative failure due to the absence of key instruments or arising from poor adherence to scheduled instrument maintenance – particularly those which have electrical components.

4.15 For those instruments, including delicate components such as electronic devices or imaging related markers, the use of single instrument identification may be of special value. When marking is combined with properly managed decontamination procedures the individual instrument may be correctly identified as requiring a non-standard approach to washing, disinfection or sterilization.

4.16 Individual instruments may have warranties associated with them which carry a guarantee. However, if the individual warranted instrument cannot be reliably identified to a standard which is satisfactory to the supplier, then it is unlikely that the warranty can be evoked. A similar argument applies to instruments such as arthroscopy scissors, which are limited in terms of the number of use cycles, authorised by the manufacturer under CE marking.

4.17 When single-use surgical instruments are used, they must be separated from reusable surgical instruments and disposed of at the end of the procedure. It is important that the single-use instruments are not allowed to enter reusable instrument sets.

**Infection prevention and control policy**

4.18 All organisations should have an infection prevention and control policy that contains:

a. advice on decontamination and storage of surgical instruments;
b. local policies on recommended disinfectants, their application, use, storage and disposal;
c. protocols for the cleaning and disinfection of surgical instruments where instruments have to be processed in a local setting;
d. protocols for the use of personal protective equipment (PPE);
e. risk assessments for procedures used in the reprocessing of medical devices;
f. spillage procedures;
g. management and treatment of needle stick/sharp injuries;
h. guidance on staff health;
i. safe final disposal of instruments (end of instrument life);
j. management of dropped instruments (Appendix 2).

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

**Decontamination training**

4.20 Decontamination is a science in its own right. Staff undertaking decontamination must be competent and properly trained.

4.21 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.

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

4.23 Professional bodies such as the Institute of Decontamination Sciences offer a range of training at differing levels.
Chapter 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 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.

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 5.24–5.28) 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)) and the decontamination engineers at NWSSP-FS (See Figure 3 Decontamination Management Structure for Wales) 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. Consequently, 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 Welsh 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 guidance requires:
   a. the role of Authorising Engineer (Decontamination) (AE(D)) who must be registered with the Registrar at IHEEM (Institute of Hospital Engineering and Estate Management). The Registrar is a member of the IHEEM Decontamination Technical Platform (DTP);
   b. the role of the Authorised Person (AP(D)) which is an estates management role responsible for decontamination. This role should encompass an overview of activity of the Competent Person (Decontamination) and day-to-day operational management of decontamination equipment;
c. the role of the Competent Person (Decontamination) (CP(D)). This is a new role based on the consolidation of the roles of Maintenance Person (Sterilizers) and the Test Person (Sterilizers). In larger organisations it may be preferable to separate these roles and responsibilities to ensure good practice, i.e. CP(D) Testing and CP(D) Maintenance. (See Figure 3 Decontamination Management Structure for Wales);

d. healthcare organisations that are undertaking decontamination of reusable medical devices, to use the services of NWSSP-FS Decontamination Engineers and the AE(D);

e. the introduction of a permit-to-work system relating to decontamination equipment similar in operation to other permit systems.

Definition of ‘management’

5.10 Management of a healthcare organisation performing decontamination is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises, including decontamination.

Key personnel

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

- a. Executive Board Lead (for example, Chief Executive)
- b. Decontamination Lead
- c. Surgical Instrument Manager (combined responsibilities)
- d. Senior Operational Manager (for example, Estates Manager)
- e. User (for example, Sterile Services Manager)
- f. Authorising Engineer (Decontamination)
- g. Decontamination Engineers (Wales) at NWSSP-FS
- h. Authorised Person (Decontamination)
- i. Competent Person (Decontamination)
- j. Lead for Infection, Prevention and Control
- k. Microbiologist (Decontamination)
- l. Operator
- m. Manufacturer
- n. Contractor
- o. Purchaser
- p. Competent Person (Pressure Systems)

Executive Board Lead

5.12 The Executive Board Lead 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, chief executive or designated board executive of similar authority.

Decontamination Lead

5.14 Every healthcare organisation must have a nominated Decontamination Lead with responsibility for decontamination.

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

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.

Senior Operational Manager

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

Note: In some organisations this may be the responsibility of the management team.

User

5.20 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 5.58. In the acute care setting, the User should preferably be a
member of the Institute of Decontamination Science or other equivalent professional bodies.

5.21 In the acute sector, the User could be a Sterile Services Manager. In the primary care sector, he or she could be a general practitioner, dentist or other health professional.

5.22 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 prevention and control team;
   h. to ensure the surgical instrument management is carried out.

5.23 There is a need to ensure that the management of surgical instruments (medical devices) is carried out. The role is a combined responsibility for coordinating activity between the theatre, decontamination and supply/purchase teams. The person fulfilling that role should also ensure that the inventory of surgical instruments is proactively reviewed and managed in accordance with this guidance, clinical requirements and industry best practice.

5.24 Specifically, the responsibility of the User will cover the following:
   a. make judgements on the suitability of reusable instruments in consultation with surgical teams and those responsible for decontamination. This work will be assisted by the formation of a working group for ongoing collaboration;
   b. determine appropriate instrument-set structures designed to assist in the prevention of leakage of instruments between sets (including preventing the movement of supplementary instruments between sets) in consultation with clinical specialists and decontamination teams;
   c. ensure that guidance on tracking and traceability is appropriately applied to all instruments (this includes loan sets and implantable items which includes screws and plates) and collaborate with those responsible for patient records to ensure any patient with whom they are used can be identified and linked to the sets or individual instruments used;
   d. ensure that missing or damaged surgical instruments are replaced preserving the appropriate set structure;
   e. oversee the monitoring of condition and suitability for surgical instruments;
   f. oversee the audit process for instrument sets from procurement through to use, decontamination and final disposal;
   g. ensure instrument sets never used are reviewed and/or disposed of;
   h. oversee actions to provide a mechanism for routinely revalidating instrument-set content (for example, annual sign off of the tray checklist by surgical teams);
   i. ensure the leakage of surgical instruments between sets is minimized by effective process mapping using recommended audit procedures, post-operative checks, the signing of tray checklists by theatre sister, and decontamination facility processing techniques (that is, specific instrument set contents are kept together throughout the decontamination cycle);
   j. ensure instrument sets with observed missing or damaged content are updated through targeted investment and ensure the healthcare organisation has documented policies in place for the operational management of its instrument-set inventory;
   k. manage the loaning of instrument sets to and from external suppliers using the audit techniques given in this guidance;
   l. purchase new instrument and sets (including, as a minimum, the documented approval of the theatre team, decontamination specialists and Control of Infection Lead);
   m. ensure repaired instruments are returned to the original instrument set;
   n. oversee a standardised approach to instrument nomenclature throughout the healthcare organisation;
   o. ensure all instrument sets have an accurate version-controlled checklist validated by the surgical team (preferably in an electronic format);
p. determine that all instrument stores (including wards and departments) are audited on a regular basis, and all redundant items removed from circulation;
q. ensure a mechanism is in place for addressing instrument set usage non-conformities such as wet packs, torn tray wrap etc.;
r. provide and oversee mechanisms to ensure all instruments in the healthcare organisation’s inventory are fit for purpose (for example, regular review of appropriate records);
s. ensure the healthcare organisation holds an accurate database of its instrument-set inventory including tray type, location of use and stock level;
t. ensure all instrument sets which are critical in stock levels are risk assessed, to maximise patient safety and inform instrument set investment.
u. ensure compliance with all manufacturers’ guidance and information for reprocessing of any implantable items (e.g. including screws and plates)
v. ensure that the reprocessing records for implantable devices (including screws and plates) will need to be retained as identified in the Quality Management System (QMS).
w. ensure compliance with all manufacturers’ guidance and information for reprocessing of any implantable items. A robust mechanism is required that records the manufacturers’ recommendations for products, ensuring they are retained in the appropriate sections of the QMS such as the manufacturers’ reprosession instructions file and the retention of records requirements. The processing records for implantable devices will need to be retained as required in the QMS. The User should be able to retrieve reprocessing information when required and link to the patient(s) it has been used on.

Note
NWSSP-FS undertakes the monitoring role of decontamination departments and equipment in the NHS in Wales on behalf of the Welsh Government (WG). This role covers technical advice to the WG and the Health Boards/Trusts along with the full testing and monitoring requirements as specified within this document.

Authorising Engineer (Decontamination) (AE(D))

5.25 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.

5.26 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)

5.27 This role should be fully independent of the Health Boards’ and healthcare facilities’ structure for maintenance, testing and management of the decontamination equipment.

5.28 The AE(D) should have a reporting route to the Decontamination Lead and should provide professional and technical advice to the Welsh Government, NWSSP-FS, AP(D)s, CP(D)s, Users and other key personnel involved in the control of decontamination processes in healthcare facilities.

5.29 The Institute of Healthcare Engineering and Estates Management (IHEEM) sets professional standards for their registration and for the accreditation of training courses, as has previously been the case for the Health Technical Memorandum 2010-defined AP(S) role. The Department of Health (England) and, where applicable, the Welsh Government, set the technical standards as relevant.

Responsibilities of the AE(D)

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

a. to provide 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);
g. to provide technical advice on purchasing and selection of decontamination equipment for the users;
h. to provide technical advice on the relevant guidance for Wales on decontamination equipment and procedures;

5.31 NWSSP-FS undertakes the role of Authorising Engineer for the NHS in Wales.

5.32 The Institute of Healthcare Engineering and Estate Management (IHEEM) supports and operates the DTP (Decontamination Technology Platform) which is made up of IHEEM-registered AE(D)s.

Decontamination Engineers (Wales) at NWSSP-FS

5.33 The Decontamination Engineers (Wales) (DE(W)) support and undertake the testing programme of decontamination equipment on behalf of the Welsh Government.

Role and Responsibilities of the DE(W)

5.34 The DE(W) will also be responsible for:

a. the engineering technical advice of decontamination equipment to all users;

b. the safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;

c. the acceptance criteria for operational and performance testing of all installed decontamination equipment; this includes the validation and re-validation testing of the specified equipment such as steam sterilizers, washer disinfectors, steam systems, AERs on behalf of the Welsh Government;

d. participate and undertake technical audits of decontamination facilities and equipment on behalf of Welsh Government and NWSSP-FS.

e. close liaison with the AE(D), AP(D), Decontamination Lead, Users and other interested professionals to enable them to discharge their responsibilities for management of decontamination effectively;

f. authorising the use of decontamination equipment after major repair or refurbishment and after any testing as required on the machines, including:

- technical advice on purchasing and selection of decontamination equipment for the users;

- technical advice on the relevant guidance for Wales on decontamination equipment and procedures.

g. ensuring the continued support of and liaison with the site CP(D)s, as appropriate.

Authorised Person (Decontamination) (AP(D))

5.35 The AP(D) will be an individual representing a health care organisation possessing adequate technical knowledge and having received appropriate training, appointed in writing by the health care organisation (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.

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

5.40 The healthcare organisation has a responsibility to ensure that the AP(D) reporting structure has a line of professional accountability.

Responsibilities of the AP(D)

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

a. the engineering management of decontamination equipment – site-specific only;

5 Functional responsibilities
b. line management and/or appointment of the
CP(D)s on each site or for each organisation;
c. safe and effective systems of work for all
installed decontamination equipment within
his/her area of responsibility;
d. the acceptance criteria for operational and
performance testing as decided with the
relevant users of all installed decontamination
equipment;
e. liaison with the AE(D) and/or DE(W) at
NWSSP-FS, Decontamination Lead and other
interested professionals;
f. authorising the use of decontamination
equipment after major repair or refurbishment
and after quarterly or annual tests;
g. operation of the permit system;
h. ensuring the continued local registration of the
CP(D)s, as appropriate;
i. liaising with the User, and other technical
support personnel, to enable them to discharge
their responsibilities for management of
decontamination effectively.

Qualifications of the AP(D)

5.42 The AP(D) 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, depending on local needs, 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 from 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 healthcare
organisation 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 can be developed at a local level
dependent on training and work based experience.
Consultation with the AE(D or DE(W) is
recommended (See Figure 3 Decontamination
Management Structure for Wales).

5.46 The CP(D) should report directly to an
appropriate member of the estates department for
example, the AP(D) and liaise with the DE(W).

Responsibilities of the CP(D)

5.47 The principal responsibilities of the CP(D) are:
a. to carry out the maintenance tasks outlined in
Welsh Health Technical Memorandum 01-01
Parts C and D;
b. to carry out additional maintenance and repair
work at the request of the User;
c. to conduct the periodic tests specified in Welsh
Health Technical Memorandum 01-01 Parts C
and D and to prepare reports as required by
the User;
d. to conduct any additional tests at the request
of the User, AE(D) or DE(W).

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)
maintenance 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 of the CP(D)

5.49 The CP(D) should:
a. be able to clearly demonstrate adequate
technical competence working with
decontamination equipment (e.g. activities
such as maintenance);
b. have completed an accredited course for CP(D)s
and successfully passed the examination;
c. have a certificate demonstrating satisfactory
completion of an accredited course in the
validation and periodic testing of at least two
decontamination processes/machine types;
d. 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.

**Lead for Infection Prevention and Control**

5.50 The Lead for Infection Prevention and Control is defined as a person designated by Management to be responsible for advising the User on all infection control aspects.

**Microbiologist (Decontamination)**

5.51 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.

5.52 The Microbiologist (Decontamination) should be suitably qualified and nominated by the healthcare organisation.

5.53 The principal responsibilities of the Microbiologist (Decontamination) are:
   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**

5.54 The Operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties.

5.55 Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent to undertake their assigned tasks.

**Manufacturer**

5.56 The Manufacturer is defined as a person or organisation responsible for the manufacture of a washer-disinfector or sterilizer. The manufacturer should ensure that the decontamination equipment is designed, manufactured and tested within a quality system. The manufacturer should also carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a one-off and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance with the relevant British or European Standard by means of a type test for the particular type and size of decontamination equipment. (See BS EN 15883 Parts 1 and 2 for type-test details for washer-disinfectors and BS EN 285 for type-test details for sterilizers.)

**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 (latest edition) is not the same person as the Competent Person (Decontamination) defined in this Health Technical Memorandum. The former is an 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.

**Decontamination management structure for Wales**

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

5.62 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.

5.63 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.

**Note**

The decontamination management structure can differ between hospitals and between Health Boards across Wales. **Figure 3 Decontamination Management Structure for Wales** illustrates the generic engineering decontamination management and structures required to discharge the specific responsibilities, but the actual appointed personnel can differ depending on scale and the central policy of the healthcare organisation. Most hospitals and Health Boards have decontamination committees which are made up of professionals, including decontamination leads, estates officers, appointed AP(D), SSD managers, infection control, individual directorate managers and microbiologists. Each committee should be formed under local agreements and needs with specific terms of reference. The committees are then able to make collective decisions and local policy.

**Training**

5.64 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.

5.65 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**

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.
Functional responsibilities

Welsh Government

NWSSP-Facilities Services

Authorising Engineer (Decontamination) - Wales
AE(D) - Wales

Decontamination Engineers – Wales
DE(W) – NWSSP-FS

Health Boards/Trusts
Executive Board Decontamination Lead
Decontamination Lead

Senior Operational Manager
Technically responsible for aspects of decontamination at each Health Board or individual managed site

Users/Managers

Authorised Person/s Decontamination
AP(D)
(Health Board Trust)

Competent Person/s Decontamination
CP(D) – Maintenance
CP(D) – Testing
(May be Health Board Trust or Private Contractor)

Note
Depending on the size, usage or location(s) of the decontamination units and equipment, the numbers of staff appointed to the AP(D) and CP(D) roles can be increased to meet the operational demands of the service.

Figure 3 Decontamination management structure for Wales
Chapter 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 suggested. 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 organisations to:
   a. decontaminate reusable medical devices and goods;
   b. produce sterile products;
   or
   c. make-safe infected items.

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 relevant 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 testing, both, AP(D) and the User should sign the permit to allow the equipment back into use. The DE(W) from NWSSP-FS and the User should sign the permit following the annual testing. 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) or the DE(W) under authorized delegation, 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), the QC pharmacist or laboratory safety officer).

6.8 The AE(D) should formally audit the permit system records with the AP (D) at periodic intervals.

Note
For information on how to access permit-to-work documentation/forms, users should seek advice from the AE(D) and AP(D) in conjunction with the user. A suggested Permit-to-Work template can be found in Appendix 3.
Chapter 7 Reporting of incidents

Introduction

7.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in Wales is set out in the MHRA’s medical device bulletin DB2011(01): Reporting adverse incidents and disseminating medical device alerts.

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 (NHS orders for governance) established by the Welsh Government and the MHRA, and with statutory reporting requirements.

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) and DE(W) 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. a failure to properly decontaminate a product;

b. danger to personnel;

c. 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.

Defect reporting procedures

7.8 Certain types of defect should be reported to NWSSP-FS. 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:

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 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;

i. 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;

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

7.9 Adverse incidents should be reported to the MHRA and as set out in the Welsh Government MDA/2004/054 (Wales).

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 DB2011(01) – Reporting adverse incidents and disseminating medical device alerts.

7.11 Adverse incidents involving permanently installed sterilizers should be reported to the MHRA and NWSSP-FS. The reporting procedure is set out in the Welsh Government MDA/2004/054 (Wales) - 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/Responsible Person within the Organisation should notify the HSE immediately, normally by telephone, if any of the following occur:

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 Management responsible within the healthcare organisation should send a written report to the HSE in Wales 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 guidance, A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations.

7.20 Incidents and dangerous occurrences that are reported to the HSE should also be reported either to the MHRA or to the Welsh Government, as appropriate, by telephone as soon as possible and by the latest during the first working day after the incident and then followed by a written report.
Chapter 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). Local reprocessing is inappropriate in acute medical settings where every Health Board and Trust in Wales has access to a MDD accredited department with decontamination scientists on hand to manage services in accordance with this document. However, this limited chapter is included to make this clear point but also recognises that Health Boards and Trusts in Wales and their decontamination structures also have community services where local reprocessing may be an option.

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. For those services directly managed by the Health Board/Trust, purchase of sufficient instrument sets for out-posted clinic use and central reprocessing by the Boards'/Trusts’ HSDU offers the best risk-based solution.

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 healthcare standards and the Chief Medical Officer (Wales) Professional Letter - Decontamination and Sterilization Services in Wales and CMO 2007/03 - Decontamination of Surgical Instruments in light of National Institute for Health and Care Excellence (NICE) guidance.

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. (The preferred setting for decontamination to be carried out is within MDD accredited Sterile Service Department).

Risk assessments

8.5 If local decontamination services for any healthcare organisation 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. The options are:

a. centralise all decontamination to an accredited SSD;

b. use only single-use devices;

c. undertake decontamination locally to all applicable standards and guidance, maintained with periodic auditing recommendations;

d. a combination of the above.
Chapter 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, 134°C 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.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group).

Guidance from ACDP TSE Risk Management Subgroup (formerly TSE Working Group)

9.6 The TSE Risk Management Subgroup (formerly 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.

9.7 The processes for decontaminating medical devices so as to minimise the risk of transmission of a TSE agent must be properly controlled.

9.8 The TSE Risk Management Subgroup has also published separate guidance on the decontamination of endoscopes.

Guidance from the National Institute for Health and Care Excellence (NICE)

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.

9.9 A facility exists at the Public Health England's Centre for Emergency Preparedness and Response at Porton Down to receive such instruments from affected Local Health Boards/NHS Trusts.

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 Risk Management Subgroup's guidelines on decontamination as detailed in paragraph 9.7 should be followed.

9.10 Local Health Boards/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.

Note

Research and subsequent advice on this issue is continually changing so it is important for organisations to amend policies and procedures in alignment with latest Department of Health and Chief Medical Officer (Wales) publications.
Recommendations

9.11 The main recommendations are as follows:

a. 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.)

b. Supplementary instruments that come into contact with high-risk tissues should remain with the set to which they have been introduced.

c. Rigid rather than flexible neuroendoscopes should be used wherever possible.

d. All accessories used through neuroendoscopes should be single-use.

e. 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.

f. 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

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

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

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

9.15 The extent of instrument migration between different sets is not known, and it is not clear whether tracking to tray level (in accordance with Welsh Health Circular (99) 158) is adequate to monitor supplementary instruments added to instrument sets, or instruments removed following damage or for maintenance.

Effectively managing “On loan” surgical instruments


9.17 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.

9.18 This Professional Letter sets out the main issues raised by the NICE guidance and associated considerations and recommendations of the Advisory Committee on Decontamination Services and Technology (ACDST).

Single-use instruments and quality

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

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

9.21 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.

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

9.23 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. (It is strongly recommended that SMTL should be consulted if there is a doubt regarding the specification of surgical instrumentation).

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
Inactivation of prions using novel technologies

9.24 A range of technologies that may be valuable in the inactivation of prions is becoming available. These technologies include: the use of proteolytic enzymes; strong alkaline solutions including sodium hydroxide; instrument exposure to cold plasmas; and high chemical activity gas or vapour agents such as ozone or activated hydrogen peroxide.

9.25 Further information on the technical aspects of these new technologies can be referenced in WHTM 01-01 Part E.
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 (with guidance from NWSSP-FS). This document can be accessed from the NWSSP-FS website. www.wales.nhs.uk/whe
Appendix 1:
A patient and public perspective

Background from DH pilot studies concerning the implementation of NICE IPG 196 and general Welsh NHS advice

Planned exercise and research programmed by DH for new guidance advice

A survey, carried out by DH, was designed to investigate the extent to which risk-reduction measures aimed at minimizing the possibility of prion transmission via surgery involving high risk (in vCJD infectivity terms) tissues have been applied. Specific reference is made to the implementation of guidance contained within the NICE IPG 196 (2006), which deals with instrument management in pursuit of risk reduction via the retention of instruments within stable neurosurgical and PO sets. NICE IPG 196 (2006) also recommends that separate and identifiable instrument sets for patients born before and after 1 January 1997 are provided and rigorously maintained. Further advice from the Advisory Committee on Decontamination Science and Technology (ACDST, formerly the Engineering and Science Advisory Council’s Transmissible Spongiform Encephalopathy Working Group, ESAC-TSE WG, and disbanded at the end of 2010) is incorporated. The survey included compliance with EN/ISO/BS engineering standards which, whilst not specific to prion transmission, are thought from experimental evidence to contain elements which have an effect on such risk. ACDP-TSE RM has published an extensive series of guidance documents aimed at risk control in connection with prion transmission, some of which concern surgical or other interventional procedures.

Are Patients at risk of CJD infection from surgical instruments?

The infectious agent that causes CJD and related diseases is made of protein and is very difficult to destroy. It binds to the surface of stainless steel surgical instruments and can potentially act as a remarkably efficient reservoir of infectivity. Traditional decontamination methods cannot guarantee the removal of all the protein from the surface of instruments and the total de-activation of the agent. If people who are already infected with CJD and are not aware of it have surgery, they could potentially infect the instruments used during the surgery and this infection can then potentially be passed on to other people. Steps are constantly being taken to develop new technologies and better sterilization techniques to remove and deactivate the agent, and this guidance covers the adoption of such technology as it becomes available. This aims to make surgery as safe as possible for the patient. Research is being coordinated by the DH research working group on the decontamination science.

How does this affect patients?

It is important that patients who may need a surgical procedure, or carers for someone who may need surgery, get the best treatment possible and that they should feel that everything is being done to safeguard their well-being.

As healthcare professionals we all have a “duty of care” to ensure that Best Practice is employed or planned at all times, taking into account the latest research or guidance information.

What is being done to improve patient safety?

The guidance implements a number of quality standards and guidelines from regulatory and learned bodies to ensure:

1. surgical instruments are coded and tracked and remain within their instrument set (note -, individual marking of each device may prove impractical with current technologies available; however, healthcare organizations should ensure they are working towards compliance with NICE guidelines);
2. surgical instruments can be traced back to the patients they have been used on (note – this is only possible with total electronic trace-ability systems, including theatres);
3. extra instruments required for a particular procedure are used only once or kept within the set for that procedure;
4. a separate pool of instruments is kept for children born after 1 January 1997 to make sure that they are not exposed to the CJD agent;
5. sterilization procedures and facilities within the hospital are fit-for-purpose and meet the WHTM 01-01 (Parts A to E) and HBN 13, 2004;
6. the instruments sets are maintained within a moist environment in the interim period after use and prior to reprocessing in the SSD;

7. the effectiveness of the cleaning of soiled instrumentation is optimized by ensuring all surfaces of complex medical devices are exposed to all aspects of decontamination cycle;

8. Instrument audit and tracking and logging of instrumentation repairs;

9. Management of loan sets (Welsh Health Circular, WHC (08) 015 – Effectively Managing ‘On loan’ Surgical Instruments);

10. that the time taken between instrument use and the return to SSD for further reprocessing and cleaning is as short as practically possible;

11. where high-risk surgical procedures are required (for example, neurosurgery or post-ophthalmic surgery), appropriate risk assessment is carried out and reflected in the local policies to cover all aspects of patient pathway;

12. the method used for cleaning, washing and sterilization is suitable and will not damage the instrument;

13. hospitals carry out risk assessments wherever possible to prevent failures in the decontamination procedures.

14. single-use instrument tracking and records;

15. latest guidance from WG/NWSSP-FS and DH is included when and where ever possible and experts in the field are consulted;

16. local policy is put in place to cover the handling of high risk patients.

Instrument management

Evidence from the research identifies that certain aspects of decontamination guidance are better followed than others, and that further development is needed to raise standards across all of the relevant areas. It is necessary to ensure the guidance is in place on the management of surgical instruments to support further risk reduction and improvements to patient outcomes.

Management of surgical instruments in WHTM 01-01 (Parts A to E) relates to those used in acute care. In this context, management of surgical instruments should make sure that all risks associated with surgical procedures are removed where practically possible.

It is important to understand that it takes a minimum time of 5/6 hours to produce a sterile instrument set within an SSD and timing cannot be altered to accommodate demand, yet every effort is made to effect a return of the set(s) as soon as possible.

Keeping instruments moist between use and reprocessing

Prions are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully onto a surface. Keeping the environment around soiled instruments at or near saturation humidities (moist) prevents full attachment of hydrophobic proteins such that they are more efficiently removed by cleaning.

A number of means are available to generate moist conditions, including the use of enclosed containers/bagged trays used with single-use moist pads, gels, foams, water sprays or other methods as determined locally. Operation costs can be high depending on the type used and the amount of instrumentation that has to be kept moist as opposed to being reprocessed rapidly. However, whatever method is used, care should be taken to ensure that all parts or surfaces of the surgical instruments are constantly exposed to the moist environment. The use of the various systems available to maintain the instruments in the recommended environment for elongated times will add to the revenue costs of the organization.

It is recommended that the Sterile Services Department (SSD) is located on sites where surgery associated with acute facilities is carried out. This was a strategy developed during the Welsh Government Project Board that operated between 2001 and 2005 when SSDs in Wales were developed to meet the needs of the Medical Device Directive.

Experience shows that planned delays in returning instrument sets to the SSD will result in a significant increase in the need for additional instrumentation stock to maintain the operational demands of a busy hospital. Increased transportation resources and time taken will also add to the daily running costs and increase turn around time for the end users.

For Further Information refer to additional information included in WHTM 01-01 Parts A and B – Informative Supplement.
Appendix 2:

The Management of dropped instruments

Introduction
The all Wales Decontamination Committee has been considering the issue of management of dropped instruments, recognising the clear disadvantage of reinstituting theatre based sterilisation processes using bench top autoclaves etc. Thus the two alternatives that have been considered to date are:

1. Local decontamination of the dropped instrument (by whatever means ranging from local wipe over to fast track via HSDU).
2. Use of supplementary packs of every lone valuable instrument that cannot easily be substituted and then management of that new instrument thereafter with the original set.

Each of the above has its disadvantages. A third way is proposed.

The Third Way:
The primary reason we need to manage this issue is so that instrument sets can be traced to patients, primarily in relation to CJD i.e. the work of the CJD Incidents Panel but could apply to any other apparent instrument related cross infection event/outbreak.

Agreeing the above, then the third way suggests that if a unique instrument is dropped, then this can be managed by opening up a complete new set of instruments for the same operation, using the new instrument that had been dropped from the original set and replacing it on completion to the new set.

Having done this, in the records, it is important to record that the two sets have been used on the one patient.

This has many advantages. In the vast majority of cases, CJD or outbreaks related to instruments are a rare event. This will mean that a second set of instruments will be recorded for a specific patient. If two sets were used and the patient were a CJD case and tracking had to occur, this would mean a list of 20 names, rather than 10, with four rather than two in the immediate after cycles as being at particular risk.

However, operation on an unknown CJD patient is a very rare event, as are instrument related outbreaks. Similarly, a simple audit in Wales indicated that a dropped instrument is a rare event. Nevertheless, when an instrument is dropped, there is a lack of clarity over what procedure to follow.

Would it matter if leakage occurred between these two sets at the time they were both run through theatre? No - because we have the subsequent data to identify who the instruments were subsequently used upon. Bear in mind that while there could be a lot of mixing over time, this should not matter as we only get interested in the last 10 operations for CJD purposes and leakage is not an issue for any other reason.

Process:
The following algorithm is for debate and subsequent adoption by health board risk processes.
Instrument dropped

Can operation proceed without instrument?

- Yes
  - Surgery has started
    - Can procedure be abandoned?
      - Yes
        - Non-scrub team member retrieves the instrument from floor, simple decontamination and quarantine until end of procedure when instrument should be reunited with instrument set.
      - No
        - Surgery has not started
          - Is a duplicate instrument set available?
            - Yes
              - Return complete pack with dropped instrument to HSDU, use replacement set and proceed.
            - No
              - Abandon procedure and arrange post op patient counselling to discuss implications.
          - No
            - Can instrument be rapidly decontaminated by HSDU without detriment to patient?
              - Yes
                - Non scrub team member undertakes handwash, dons sterile gloves and undertakes simple, superficial decontamination with sterile water and returns to scrub team. Report adverse event and patient details in accordance with board protocol. Note incident in operative notes for patient.
              - No
                - Simple limited decontamination in theatre is only option.

- No
  - Has surgery started or did the incident occur during the setting out period?
    - Yes
      - Surgery has started
        - Can procedure be abandoned?
          - Yes
            - Open second set and use replacement instrument. Note details of the two sets used for this patient in case of later follow-up.
          - No
            - Arrive rapid decontamination in HSDU and proceed with surgery as instrument becomes available.
    - No
      - Surgery has not started
        - Is a duplicate instrument set available?
          - Yes
            - Non-scrub team member retrieves the instrument from floor, simple decontamination and quarantine until end of procedure when instrument should be reunited with instrument set.
          - No
            - Abandon procedure and arrange post op patient counselling to discuss implications.

A draft dropped instrument algorithm
Appendix 3:  
Permit to work on decontamination equipment

PERMIT TO WORK ON DECONTAMINATION EQUIPMENT

This permit only relates to the hazards caused by the possible microbiological or chemical contamination of the decontamination equipment. The decontamination equipment is not guaranteed safe against any other source of risk. Information regarding point of isolation and method statements can be obtained separately from the AP(D).

| Location/Department of decontamination equipment: | | |
| Manufacturer: | Asset No. | |
| Serial No. | Model No. | |

Permit issued by AP (D)

| Name: | Signature: |
| Re-issued permit: Yes [ ] / No [ ] | Relates to previously issued permit No: |
| Date of issue: | Time of issue: |
| Date permit expires: / | Time: / Hour Min (24 hr) |

User acknowledgement

I confirm that the decontamination equipment has been decontaminated and cleaned as required to render it safe for maintenance and repair.*

It is not possible to guarantee that the decontamination equipment is free of contamination. Guidance on safe working practices is attached.*

*Delete as applicable

User details (To be completed by Authorised User / Department Manager / Person in charge)

| Name: | Signature: |
| Date: / /20 | Time: / Hour Min (24 hr) |

Receipt

I accept responsibility for carrying out work on the above decontamination equipment.*

I have received the guidance on safe working practices.*

*Delete as applicable

CP(D) Name: Signature: 

| Date: / /20 | Time: / Hour Min (24 hr) |

Details of work carried out

| Warranty [ ] | Contracted service/Test [ ] | Repair [ ] | Other [ ] |
| Quarterly maintenance / Test [ ] | Bi-annual maintenance / Test [ ] | Annual maintenance / Test [ ] |

Explanation of work carried out.
PERMIT TO WORK ON DECONTAMINATION EQUIPMENT

Hand back

The work on the above decontamination equipment has been completed/suspended.*

The decontamination equipment may/may not be returned to service.*

*Delete as applicable

CP(D) Name: __________________________ Signature: __________________________

Date: _______ / _______ / 20 _______ Time: _______ / _______ HourMin (24 hr)

Cancellation

The permit is now cancelled.

The above equipment is safe and fit for use.

AP(D) Name: __________________________ Signature: __________________________

Date: _______ / _______ / 20 _______ Time: _______ / _______ HourMin (24 hr)

I accept the above equipment back into service as fit for use.

User Name: __________________________ Signature: __________________________

Date: _______ / _______ / 20 _______ Time: _______ / _______ HourMin (24 hr)

THIS PERMIT IS ONLY VALID WHEN COMPLETED BY AP(D), CP(D) AND USER

NO WORK IS PERMITTED UNLESS A VALID PERMIT IS IN PLACE

CP(D) MUST REPORT TO THE PERSON IN CHARGE ON ARRIVAL AND DEPARTURE FROM THE DEPARTMENT
References

Acts and Regulations

All the acts and regulations shown below can be accessed from the www.legislation.gov.uk website

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations
Consumer Protection Act
Control of Substances Hazardous to Health Regulations (COSHH)
Electromagnetic Compatibility Regulations
Health and Social Care (Community Health Standards) Act 2003
Health and Safety at Work etc Act 1974
Health and Social Care (Community Health and Standards) Act
Medical Devices Regulations
National Health Service (Wales) Act 2006
National Health Service, Wales - The Local Health Boards (Establishment and Dissolution) (Wales) Order 2009
Personal Protective Equipment Regulations
Pressure Equipment Regulations
Pressure Systems Safety Regulations
Public Health Wales National Health Service Trust (Establishment) Order 2009
Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

British Standards Institution

British Standards relevant to decontamination processes and equipment

BS EN 285+A2 Sterilization. Steam sterilizers. Large sterilizers
BS EN 13060 Small steam sterilizers
BS EN 14180 +A2. Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers
Requirements and testing
BS EN ISO 11737-1 Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products
BS EN ISO 11737-2 Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process
BS EN ISO 14937 Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
BS EN ISO 15883-1 Washer-disinfectors. General requirements, terms and definitions and tests
BS EN ISO 15883-2 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 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
BS EN ISO 15883-4 Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes
BS EN ISO 17665-1 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 ISO 15883-3 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste
Standards relevant to decontamination management
BS EN ISO 13485 Medical devices. Quality managements systems. - Requirements for regulatory purposes
BS EN ISO 9001 Quality management systems

Standards relevant to safety requirements for decontamination equipment
BS EN 61010-2-040 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
BS EN ISO 13849-2 Safety machinery. Safety-related parts of control systems. Validation

Standards relevant to medical devices
BS EN 556-1 BS EN 556-1 Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for terminally sterilized medical devices
BS EN 556-2 Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for aseptically processed medical devices
BS EN 1041 Information supplied by the manufacturer of medical devices
BS EN ISO 14971 Application of risk management to medical devices
BS EN ISO 17664 Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices

Department of Health
www.gov.uk/government/organisations/department-of-health
Decontamination review: the report on a survey of current decontamination practices in healthcare premises, 2000

European legislation

Guidance from the ACDP TSE Risk Management Subgroup (formerly TSE Working Group) 2012

Health & Safety Executive
www.hse.gov.uk/index.htm

Healthcare guidance and publications
The publications below are available from the NHS Wales Shared Services Partnership - Facilities Services websites
Intranet: bowis.wales.nhs.uk/tohe
Internet: www.wales.nhs.uk/tohe

Health Building Note 13 – Sterile services department.
Welsh Health Technical Memorandum 00 – Best practice guidance for healthcare engineering.
Welsh Health Technical Memorandum 01-01 Part B – Equipment.
Welsh Health Technical Memorandum 01-01 Part C – Porous Load Sterilizers
Welsh Health Technical Memorandum 01-01 Part D – Washer Disinfectors
Welsh Health Technical Memorandum 01-05 – Decontamination in dental facilities.
Welsh Health Technical Memorandum 01-01 - Decontamination of medical devices within acute services. Part A: Management and environment

Welsh Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes.
Health Technical Memorandum 02-01 – Medical gas pipeline systems

Medicines and Healthcare products
www.mhra.gov.uk
DB 2011(01) - Reporting Adverse Incidents and Disseminating Medical Device Alerts
www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON111565

National Institute for Health and Care Excellence (NICE)
www.nice.org.uk/
Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures (IPG 196)
www.nice.org.uk/guidance/IPG196

Welsh Government
www.wales.gov.uk
Chief Medical Officer (Wales) Professional Letter - Decontamination and Sterilization Services in Wales
Decontamletter12092007.pdf NHS Wales Intranet only
CMO 2007/03 - Decontamination of Surgical Instruments in light of National Institute for Health and Care Excellence (NICE) guidance
http://howis.wales.nhs.uk/sites3/Documents/254/CMO20073.pdf NHS Wales Intranet only

Commitment to purpose: Eliminating preventable healthcare associated infections (HCAIs)

Doing Well, Doing Better: Standards for Health Services in Wales, 2010
www.wales.gov.uk/docs/dhss/publications/100419standardsforhealthservicesen.pdf

Health Protection Legislation (Wales) Guidance 2010
http://wales.gov.uk/topics/health/protection/communicabledisease/legislation/regulations/?lang=en

MDA/2004/054 (Wales) Reporting Adverse Incidents – Guidance on New Arrangements for NHS Wales Organisations
howis.wales.nhs.uk/sites3/documents/321/Medical%20Device%20Alert%202004.pdf

WHC (99) 157 Controls Assurance in Infection Control: Decontamination of Medical Devices
howis.wales.nhs.uk/doclib/WHC(99)157.htm NHS Wales Intranet only
WHC (99) 158 Variant Creutzfeldt Jakob Disease (vCJD) Minimising the Risk of Transmission
howis.wales.nhs.uk/doclib/WHC(99)158.htm NHS Wales Intranet only
WHC (08) 015 Effectively Managing ‘On loan’ surgical instruments
www.wales.nhs.uk/documents/WHC%282008%29015.pdf
WHC(2001)04 Decontamination of Medical devices
http://www.wales.nhs.uk/documents/whc200104.htm

Other publications
Useful links

Care and Social Services Inspectorate Wales
http://wales.gov.uk/cssiwsubsite/newcssiw

Healthcare Standards for Wales
http://www.hiw.org.uk

HOWIS – Health of Wales Information Service
Internet: www.wales.nhs.uk/
NHS Wales Intranet: howis.wales.nhs.uk/

Institute of Decontamination Sciences.
www.idsc-uk.co.uk/

Institute of Healthcare Engineering and Estate Management.
www.iheem.org.uk/

Welsh Health Circulars
Internet: www.wales.nhs.uk/researchandresources/publications 2000-2008
NHS Wales Intranet: howis.wales.nhs.uk/whcirculare.cfm 1976 - 2008

NHS Wales Shared Services Partnership - Facilities Services
Internet: www.wales.nhs.uk/whe
NHS Wales Intranet: howis.wales.nhs.uk/whe