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Shared Services Partnership
Specialist Estates Services

WHTM 01-01

Welsh Health Technical Memorandum

Decontamination of surgical instruments (medical devices) used in acute care

Part A: Management and Provision

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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Building Notes (HBNs) and Health Technical Memoranda (HTMs) issued by the Department of Health in England are being superseded by specific Welsh editions, which will be titled Welsh Heath Building Notes (WHBNs) and Welsh Health Technical Memoranda (WHTMs) and which will use the same numerical coding. When using these guidelines, always refer to the relevant publications page on the NHS Wales Shared Services Partnership – Specialist Estates Services website for the latest approved document, particularly where an HBN or HTM is referred to in the text.

Intranet: **http://howis.wales.nhs.uk/ses**

Internet: **http://www.wales.nhs.uk/ses**

The All Wales Decontamination and Sterilization Advisory Group has approved this document, as part of a formal consultation process. NHS Wales Shared Services Partnership – Specialist Estates Services has published this document on behalf of the All Wales Decontamination and Sterilization Advisory Group.

This guidance is based on the HTM 01-01:2016 *Management and decontamination of surgical instruments (medical devices) used in acute care* published by Department of Health in 2016

It replaces WHTM 01-01:2013 *Decontamination of medical devices within acute services. Part A: Management and environment*

This publication can be accessed from the NHS Wales Shared Services Partnership – Specialist Estates Services website **www.wales.nhs.uk/ses**

Welsh Health Technical Memorandum 01-01
Decontamination of surgical instruments (medical devices) used in acute care
Part A: Management and Provision

Overview

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 sterilisation 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 sterilisation processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure.) for sterilisation for decontamination providers for the acute care setting.
WHTM 01-01 Part A supersedes Welsh Health Technical Memorandum 01-01 Part A (2013 edition)

WHTM 01-01 Part D supersedes Welsh Health Technical Memorandum 01/01 Part D (2013 edition)

Why has the guidance been updated?

WHTM 01-01 has been updated to take account of recent changes identified within the advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathies (ACDP-TSE) Subgroup's Annex C: General principles of decontamination. In relation to the decontamination of surgical instruments, this principally relates to paragraphs C21 and C22:

Protein detection
C21. Work commissioned by the Department of Health indicates the upper limit of acceptable protein contamination after processing in ≤5µg BSA equivalent per instrument side. A lower level necessary for neurosurgical instruments.

C22. It is necessary to use protein detection methods to check for the efficient removal of protein from surgical instruments after processing. Protein levels are used as an indication of the amount of prion protein contamination.

Ninhydrin swab kits are commonly used for this purpose, but recent evidence shows that ninhydrin is insensitive. Furthermore, proteins are poorly desorbed from instruments by swabbing.

Reference HTM 01-01 part A

Note:
The figure ≤5µg of protein has been shown to be achievable by effective cleaning processes. There is currently no definitive evidence base to link this with the absence of prion transmission risk, which is why lower levels for instruments making contact with high risk tissues (see ACDP-TSE's Annex J) is necessary.

What SSDs can do to ensure implementation of the ACDP-TSE Subgroup's recommendations

Because of the risks of prion transmission, there is a need to optimise the whole of the decontamination pathway of surgical instruments.

Reducing the time from close of procedure to reprocessing
Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal, theatre and SSD staff should ensure that instruments are transported to the SSD immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible.

This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

Cleaning validation and continuous monitoring
Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing proteins to very low levels. To be able to have a greater chance of removing these proteins, there needs to be as efficient a cleaning process as possible – therefore SSDs need to both optimise the cleaning performance of washer - disinfectors and remain within the validation parameters (such parameters will be determined during type testing and/or performance qualification).

Note:
Manufacturers must ensure the WD's are configured with operational capabilities of achieving the performance required in this revised WHTM. NWSSP-SES will provide advice and guidance on the verification required to achieve the expected standards.

Results should be recorded and monitored in accordance with WHTM 01/01 part D. Appropriate actions should be taken based on these results. SSDs should undertake:

- daily testing using process challenge devices* (along with the standard periodic tests);
- a schedule of weekly residual protein testing
- Priority for cleaning validation and continuous monitoring should be given to instruments that have contact with high-prion-risk tissues as defined by ACDP-TSE (see Table A1 in ACDP- TSE's guidance Annex A1).

* Commercial process challenge devices are being developed whose challenge simulates the attachment of prion protein to instruments and whose analysis is quantitative. When these become available and have been validated, SSDs are advised to consider their use in addition to process challenge devices based on soils in BS EN 15883-5 Annex N.

Methods for detecting residual protein
Any method used to detect residual protein, should be validated as being able to detect protein equivalent to ≤5 µg of BSA in situ on the surface of an instrument (shape of instrument may influence most effective method of detection). Methods that do not have protein as their target, such as ATP assays, cannot be used as a substitute for residual protein detection.

The use of 'in-situ' protein detection fluorescent technologies support the safe processing of reusable medical devices, and has application in situations where the design of the instrument is small enough to fit into the detection area of commercially available protein detection devices, and where those devices do not have internal lumens, non-line of sight areas or incompatible surface materials such as some plastics. There are many

devices, however, where such 'in-situ' technologies are unable to assess protein residuals due to size, design and material of construction.

The implementation of methods for residual protein detection is a local choice, provided that these methods are validated as being capable of detection of ≤5µg of protein on reusable medical devices; for higher-risk neurosurgical devices, these methods must be of a greater sensitivity.

Organisations should develop a schedule of testing and monitoring for residual proteins. The level of instruments tested will be dependent on the following considerations;

- Numbers of instrument sets being processed per day/week by the SSD;
- Types of surgical procedures, especially neurology, dentistry, ophthalmology etc.
- The instruments tested should be identified as those in use operationally as a 'live' set and not those unused or dedicated for test purposes only;
- The numbers of instruments tested will be determined by the decontamination team to provide evidence of monitoring of process over each quarterly period.

If the results are improving and consistent, the frequency and numbers tested maybe reduced in number. However, if high levels become evident as the norm, testing may need to be increased to investigate the problem, and then reduced again when the issue is under control.

Note:
A combination of different methods of fluorescent and alternative validated systems may provide a balanced solution to obtaining a complete residual protein picture for the full range of devices processed through decontamination facilities, resulting in cleaner surgical instruments and subsequently safer surgical procedures for patients.

Any decision on test regimes should be based upon localised choice, considering clinical procedures and risks undertaken within the healthcare facility.

Note:
A number of new technologies are being developed to detect proteins and residual proteins and these can be assessed upon release into the market.

Continuous improvement plans
SSDs should have in place a plan of continuous process improvement. This plan should be carried out as part of a risk management plan (see BS EN ISO 14971 on medical device risk management). There should also be a specific record that relates to residual protein trend analysis (e,g a weekly record).

Urgent action points to develop are:
The need to remove Ninhydrin and replace with cleaning efficacy testing methods proven to be more sensitive, such methods may include proven swabbing technologies and/or florescent technology [depending on local surgical requirements] with declared sensitivity to measure protein to meet standard of ≤5 µg/instrument surface.

The concerns expressed over lack of sensitivity of swabbing methods principally relate to detection based on ninhydrin reagent and do not relate to all current swab technologies.
The choice of analytical technique should take into consideration a variety of factors, such as:

- Specificity & Sensitivity
- Reproducibility and repeatability
- Instrument accuracy and bias
- Sources of error (false positives and false negatives)
- Training requirements
- Uncertainty of measurement of the technique
- Suitability for the intended purpose
- Impact on the department's efficiency and effectiveness.

The following actions should be considered as critical objectives, alongside the need to monitor of protein remaining on medical devices:

- Keep the lag time between use and reprocessing to a minimum (e.g not exceeding 24 hour maximum).
- Instrument set retention within moist environments, using systems designed appropriate for purpose.
- Examine improvement opportunities in the cleaning performance of washer- disinfectors through the optimisation of detergents, wash times, wash temperatures etc.
- Ensure the validation of washer disinfectors is based on the worst load scenario, including the loading patterns, quantity and type of load.
- Cleaning efficacy tests carried out during periodic testing and validation should meet the criteria of acceptance.
- The loading pattern and cycle operation of the WD should be in accordance with validation/PQ testing.
- Instrumentation to be reprocessed should be prepared for the WD, to maximise the exposure to the wash process and there should be minimal shadowing of devices (use of disposable bowls, receivers, gallipots prevent shadowing when reprocessing instrument sets).
- Manual pre-cleaning should target areas with accumulated and/or baked soiling. Old medical devices that have been used and reprocessed may contain soiling that cannot be easily removed using a WD only.
- Use of pre-cleaning technologies such as Ultrasonic bath/irrigators to aid the process, in particular assisting the cleaning cannulated and lumened devices.
- Constantly investigate and improve, to keep the time lapse to a minimum for used surgical instrumentation to return to the wash process. Regular audits can assist in this management area of the process.

List of major changes to Part A

- New guidance included on how to ensure implementation of the ACDP-TSE's Subgroup's recommendations.

- **Chapter 5** on prion diseases updated to reflect the changes to the ACDP-TSE Subgroup's guidance (2015).

- In the section on "Separation of instruments used on high risk tissues for patients born before and after 1 January 1997" in **Chapter 6**, the management of instruments for the small number of patients born after 1 January 1997 who have already had past high risk tissue surgery using pre-1997 instruments has been amended (see paragraphs 6.8-6.10) in line with both the views of the Society of British Neurological Surgeons and the ACDP-TSE Subgroup.

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.

Acknowledgements

This guidance is based on HTM01-01:2016 *Management and decontamination of surgical instruments (medical devices) used in acute care.* Part A: *Management and provision* published by the Department of Health in 2016. NHS Wales Shared Services Partnership – Specialist Estates Services is grateful to the Department of Health for its permission to adapt the original guidance for application in Wales.

The contents of the original document were reviewed by NHS Wales Shared Services Partnership – Specialist Estates Services and decontamination representatives from from NHS Wales and Welsh Government.'

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

ACDP TSE (Subgroup): Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies (Subgroup)

AE(D): Authorising Engineer (Decontamination)

AfPP: The Association for Perioperative Practice

AP(D): Authorised Person (Decontamination)

BS: British Standard

BSA: Bovine Serum Albumin

CJD: Creutzfeldt-Jakob disease

CSSIW: Care and Social Services Inspectorate of Wales

DH: Department of Health

EN: European norm

HCAI: healthcare associated infections

HIW: Health Inspectorate Wales

ISO: International Standards Organisation

MHRA: Medicines and Healthcare products Regulatory Agency

NWSSP-SES: NHS Wales Shared Services Partnership / Specialist Estate Services

sCJD: sporadic Creutzfeldt-Jakob disease

SSD's: sterile service department

TSEs: transmissible spongiform encephalopathies

UDI: Unique Device Identification

vCJD: variant Creutzfeldt-Jakob disease

WD: washer-disinfector

WHTM: Welsh Health Technical Memorandum

Contents

Chapter 1

The need for guidance

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 disease 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 Provision' (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 Health Technical Memoranda is in Welsh Health Technical Memorandum 00 Policies and principles of healthcare engineering 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.

1.5 WHTM01-01 guidance is designed to support the commissioning, regulation, management, use and decontamination of surgical instruments used in acute care. The guidance is designed to promote continuous improvements in efficiency and outcomes in terms of safety, clinical effectiveness and patient experience by:

- providing guidance in compliance with the ACDP-TSE Subgroup's guidelines;
- clear definitions of approved Practice are provided in the WHTM, to help with this assessment;

The need for guidance

- providing the evidence base and standards for use by providers of health care and those decontaminating surgical instruments within NHS Wales or commercially, to support them in their decision making process;

- contributing to the effective management of surgical instruments through all parts of the use and reprocessing cycle (see **Figure 1**). This includes management practices related to surgical instruments in the theatre environment;

- providing guidance for service-users and patient groups on issues that are relevant to them;

- using the experience of previous pilot studies to demonstrate approaches to risk management and to the implementation of the National Institute for Health and Clinical Excellence's (NICE) interventional procedure guidance 196 – 'Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures' (hereafter referred to as NICE IPG 196 (2006)).

1.6 The WHTM 01-01 is seeking to establish:

- 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);

- a comprehensive approach to risk control and reduction across instrument management and decontamination;

- assurance over the management of surgical instruments, in terms of availability, quality and suitability;

- the preservation and advance of high-quality engineering through the support of European Norms (ENs), quality systems and standards;

- guidance for optimisation of the environment, equipment and facilities used in surgical decontamination.

1.7 WHTM 01-01 refers to NICE IPG 196 (2006) and guidance derived from the Advisory. Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies (ACDP- TSE RM) subgroup throughout. It has drawn on the findings of the National Decontamination Survey (NDS) (2008-2010) to highlight aspects of decontamination management practice that need addressing and the findings from various NDS pilot studies.

1 The need for guidance

1.8 Management recommendations centre on:

- ensuring maximum efficiency in protein detection and decontamination;
- improving instrument set integrity;
- ensuring that a separate pool of new neuroendoscopes and reusable surgical instruments is available for high risk procedures on patients born since 1 January 1997, as it is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain or blood transfusion;
- ensuring contingency for dropped or unavailable instruments;
- ensuring a continuously moist environment for instruments between use and reprocessing;
- having a system in place for surgical instrument management and to cover the quality, condition and suitability of reusable surgical instrument.

1.9 WHTM 01-01 Part A (2018) supersedes all previous versions of WHTM 01-01 Part A.

Chapter 2

Decontamination policy

Introduction background and overview

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.

2.6 It is a requirement that sterile service departments of Wales are routinely audited under and comply with the relevant Medical Devices Directive.

Compliance

Compliance with legislation and policy

2.7 Responsibility for achieving acceptable standards of decontamination rests with healthcare organisations (Health boards, NHS Trusts and provider organisations).

2.8 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 an organisation for the design and development, production, installation and servicing of medical devices and the design, development and provision of related services. It can also be used by internal and external parties, including certification bodies, to access the organisations ability to meet customer and applicable regulatory requirements. Its primary objective is to facilitate harmonised medical device regulatory requirements for quality management systems.

In 2017 the European Medical Device Regulations were published with a three year transition period. By 2020, the MDR will have replaced the MDD and the UK MDR 2008.

Devices transferred between legal entities

2.9 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.

2.10 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.

2.12 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.

Decontamination policy

Compliance with healthcare standards

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

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

2.14 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.

2.15 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.

2.16 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.

2.17 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.

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

2 Decontamination policy

Summary

2.19 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.

2.20 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 'Healthcare Standards for Wales' and provide a forward-looking aspect to progressively improving standards within approved timescales.

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

2.22 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.

2.23 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'.

Chapter 3

Standards of practice

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.

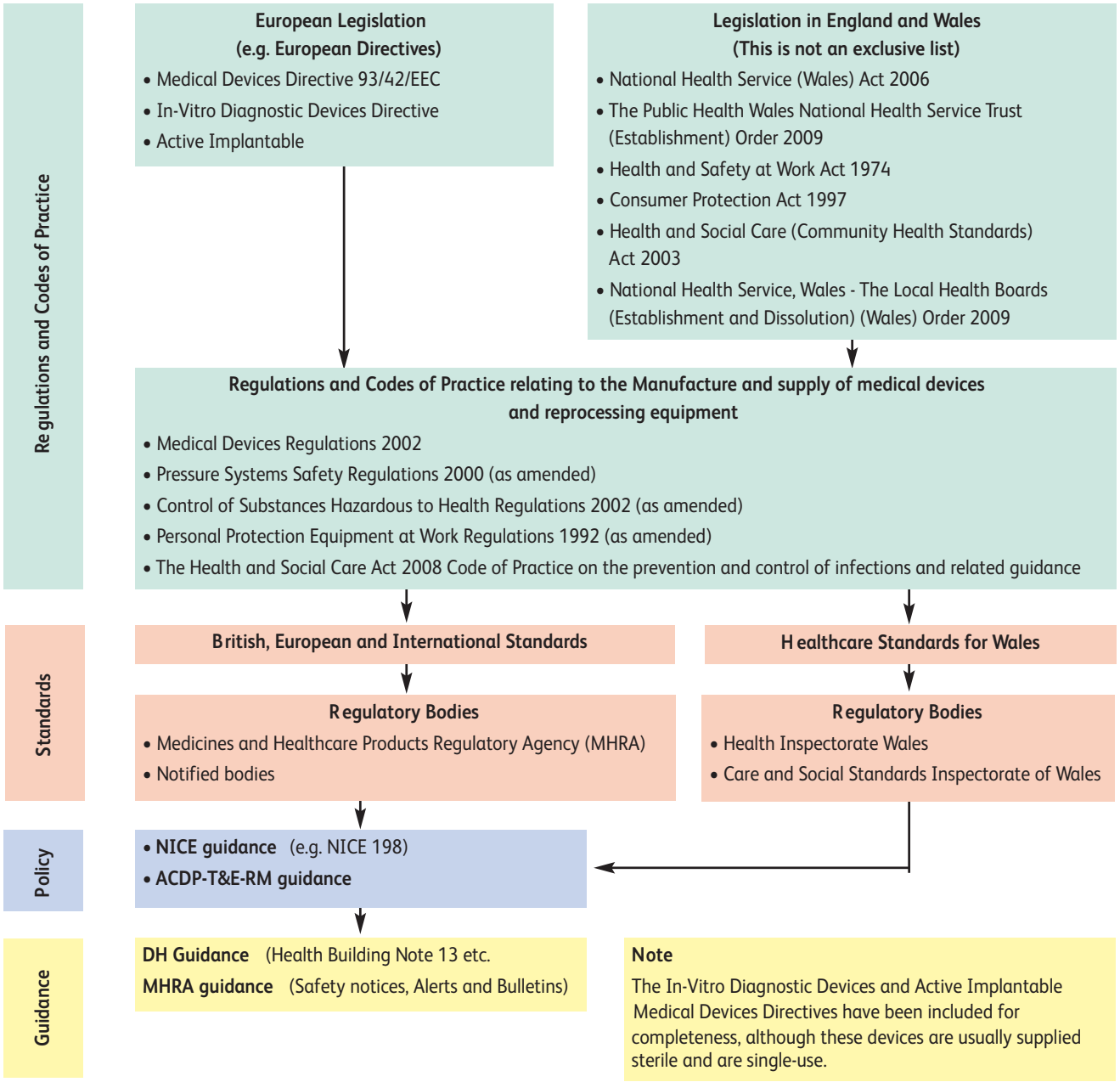


Figure 1: Overview of the interaction between the different structures within the Welsh legislative system.

3 Standards of practice

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
- In-vitro Diagnostic Devices Directive 98/79/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 sterilisers – 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:

a. the Medical Devices Regulations 2002 (as amended)

b. the Pressure Systems Safety Regulations 2000 (as amended)

c. the Control of Substances Hazardous to Health Regulations 2002 (as amended)

d. the Personal Protective Equipment at Work Regulations 1992 (as amended)

e. the Electromagnetic Compatibility Regulations (the EMC Regulations)

Note
Reference - Welsh Health Technical Memorandum (WHTM) 00 – 'Policies and principles of healthcare engineering'.

3 Standards of practice

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 (Annex 1) as listed in annexe ZA of that standard (see the Official Journal of the European Union **http://eur-lex.europa.eu/oj/direct-access.html**).

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.

Note
Some European and International Standards are under constant review and revision cycles and may be published at the same time as this Welsh Health Technical Memorandum. Standard numbers and titles sometimes change. Advice should be sought from NWSSP-SES. Information will also be available from the BSI website: **http://shop.bsigroup.com/** Standard updates can be checked by visiting **http://bsigroup.com/Contact-Us/**

Decontamination equipment

3.10 Washer-disinfectors and sterilisers (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 sterilisers 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 IIb.

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

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: Sterilisation of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilisation process for medical devices (this includes porous load and fluid sterilisers (except where used for medicinal products), and sterilisers for unwrapped instruments and utensils).
- BS EN 285: Sterilisation. Steam sterilisers. Large sterilisers.
- BS EN 13060: Small steam sterilisers.
- 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 sterilisation 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 NWSSP-SES 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.

Standards of practice

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.

Chapter 4

General Principles

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.

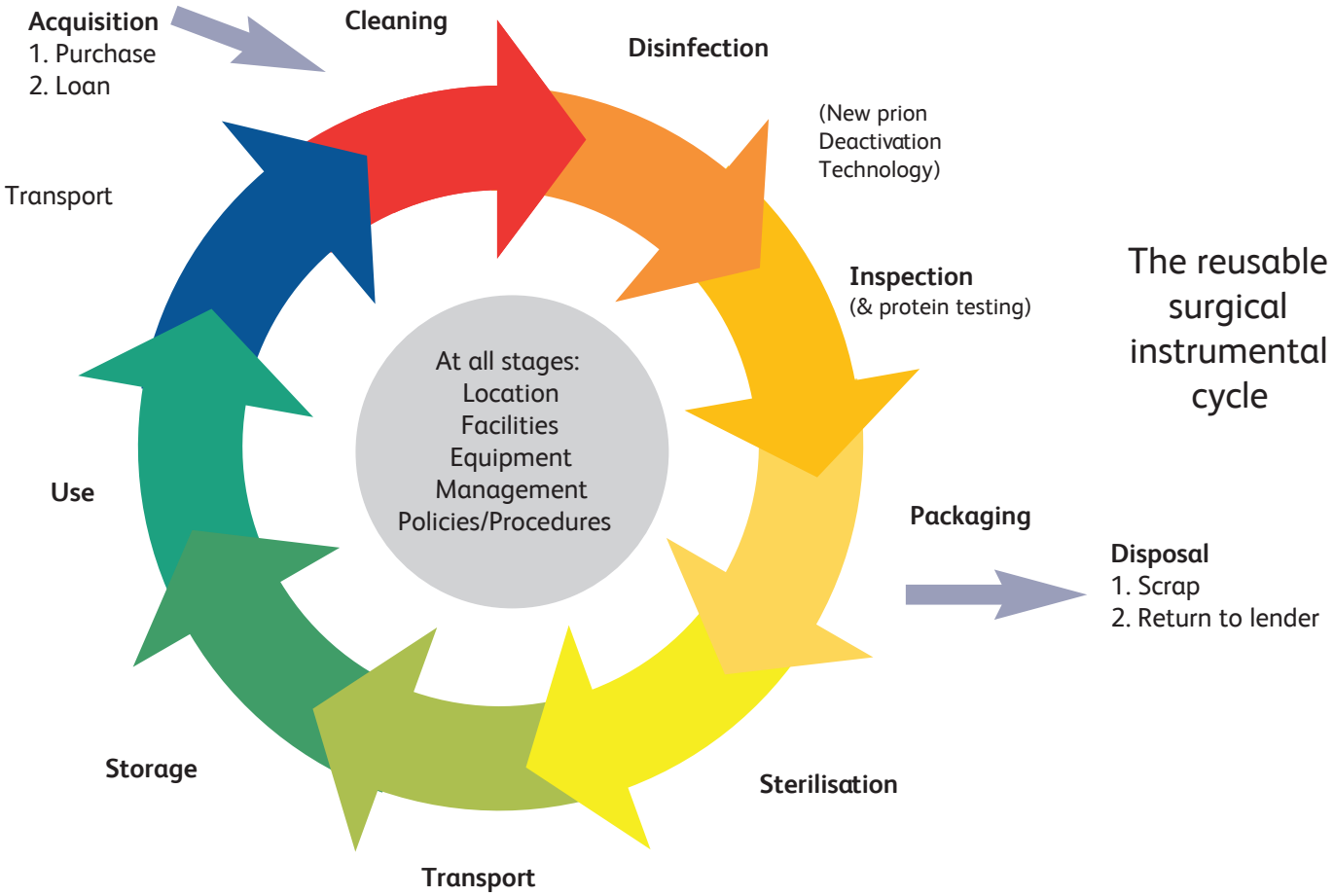


Figure 2: The reusable surgical instrument cycle

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 General Principles

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.

Note:
It is recommended, that a Sterile Services Department (SSD) is located on sites, where acute surgery is carried out (scheduled and unscheduled). This was a strategy, developed by the Welsh Government Project Board that concluded the programme of SSD refurbishment in 2005.

The evidence and research supplied through the ACDP supports the policy to reprocess in a timely manner. Transferring SSD provision away from the healthcare setting will significantly increase in the instrumentation stock required to maintain the operational demands of an acute hospital.

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 General Principles

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;

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

4 General Principles

Reducing the time from close of procedure to reprocessing

4.8 Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal, theatre and SSD staff should ensure that instruments are transported to the SSD immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible.

This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

Note:
Used instruments must be reprocessed as soon as practically possible. Such periods should not exceed 24 hours from point of use to reprocessing within the SSD, the target for such timescales should be shorter to ensure optimum cleaning of devices used for higher risk procedures.

Such performance can be monitored as part of software based trace-ability systems and non-conformities raised as part of ongoing performance review.

Where known delays are experienced returning devices to the SSD, all instruments should be kept moist during the interim. There are a variety of methods, for example gels, sprays and use of wet towels, that could be applied to keep instruments moist; the choice of the exact method used rests with the Decontamination Manager, Decontamination Lead or local Infection Control Team following risk assessment.

Care should be taken with the use of systems to maintain the moist environment. Uncontrolled implementation could result in device corrosion or surface damage. Systems designed for purpose are the recommended methods of achieving this need.

Tracking and traceability of medical devices

4.9 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 must 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.

4 General Principles

4.10 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 (where possible) offers a simple solution to these challenges.

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

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

a. the cleaning and sterilisation 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.

4.13 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.

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

4.15 Advice and guidance on the procurement of surgical instrument management systems is available from NHS Wales Shared Services Partnership – Procurement Services. Communication with all relevant concerns should be undertaken prior to final procurement, of surgical sets. Compatibility with decontamination standards within the UK is an essential pre-requisite.

4.16 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.

4.17 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 sterilisation.

4.18 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.

4.19 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.

Note:
Traceability should be in place for the whole decontamination life cycle of devices. Automated and archived trace-ability systems have been available for many years.

Consideration should review the practicalities for the implementation of technology systems, to enable unique device identification (UDI) for each instrument carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

Organisations should increase the use of electronic systems to secure archiving of monitoring systems employed on decontamination equipment. This would alleviate the need to archive paper records for the significant time period required.

Audit systems should be put in place to ensure manual and automated recording methods are as robust as possible. With records maintained throughout the decontamination process.

Infection prevention and control policy

4.20 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**).

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

Note:
The Infection Prevention and Control teams should undertake periodic audits of facilities used at all parts of the decontamination life cycle. Such audits should be carried out to include instrument storage facilities, transportation methods and sterile services department.

Frequencies should be determined, in collaboration with the decontamination team and a quality improvement audit tools should be use as the basis of such inspections.

Decontamination training

4.22 Decontamination is a science in its own right. Staff undertaking decontamination must be appropriately educated, be deemed competent and properly trained for all responsibilities they take.

4.23 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.

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

4.25 Various educational establishments and professional bodies such as the Institute of Decontamination Sciences offer a range of training at differing levels.

Chapter 5

Human prion disease (including variant CJD and other forms of CJD)

Background

The human prion diseases are a group of rare fatal neurological disorders that occur in sporadic, genetic and acquired forms, the latter occurring by transmission from one individual (or species) to another. These conditions are all associated with the conversion of a normal protein in the body, the prion protein, to an abnormal disease-associated form that accumulates in the brain and results in neuronal degeneration and death. The abnormal prion protein is thought to be the major component of transmissible prion agents.

The most common human prion disease is the sporadic form of Creutzfeldt-Jakob disease (sCJD), with an annual incidence worldwide of one-to-two cases per million of the population. In the UK, there are between 50 and 90 cases annually, with a peak incidence in the 60–70-year age group. This disease presents with rapidly progressive dementia and a range of other neurological signs and symptoms, with death occurring in around three-to-six months of disease onset. The genetic forms of human prion disease account for around 10 % of total cases, while acquired cases account for around 1 %, including iatrogenic CJD (iCJD) in human growth hormone and dura mater graft recipients, and variant CJD (vCJD). Incubation periods in acquired human prion diseases can vary from two to over 40 years, depending on the route of exposure. vCJD was first reported as a novel human prion disease in 1996, acquired from infection by the bovine spongiform encephalopathy (BSE) agent, most likely via the oral route.

Patients with sCJD and vCJD have differences in the distribution of prion infectivity around the body. In sCJD (and also in some cases of genetic prion diseases and iCJD), abnormal prion protein appears to be restricted to the central nervous system (CNS), whereas in vCJD it has also been detected in lymphoid tissues, including tonsils, spleen and gastrointestinal lymphoid tissue. Abnormal prion protein has been detected in the lymphoid tissues of a few individuals infected with vCJD before the onset of clinical signs and symptoms of the illness, indicating asymptomatic vCJD infection.

vCJD is distinguishable from non-vCJD in a number of ways:

- It tends to affect younger people with an average (median) age of onset of around 26 years (median age at death 28 years).
- The predominant initial clinical symptom is of psychiatric or sensory problems, with coordination problems, dementia and muscle-twitching occurring later.
- The illness usually lasts about 14 months (range 6–84 months) before death.

A definitive diagnosis of vCJD can only be confirmed by examining brain tissue, usually at post-mortem, and requires the exclusion of other forms of human prion disease, particularly sCJD. In the UK, as of 2016, there have been 177 deaths from definite or probable cases of vCJD, three of which appear to have been acquired by packed red blood cell transfusion from infected donors. The peak year of deaths was 2000, since when numbers of cases have fallen progressively with no new cases reported since 2012. However, given the long incubation periods previously seen for acquired CJD, and with evidence from tissue-based prevalence studies in the general population, the potential for further cases to emerge or for potential asymptomatic abnormal prion carriage within the general population has yet to be ruled out.

5 Human prion disease (including variant CJD and other forms of CJD)

While three vCJD cases may have been transmitted by blood transfusion, there are no known cases of vCJD being transmitted by surgical instruments or endoscopes. However, it may be possible because:

- sCJD has been transmitted by neurosurgical instruments used on the brain;
- abnormal prion protein binds avidly to steel surfaces and can be very difficult to remove from surgical instruments; and
- prion infectivity has been found in a range of tissues (brain, spleen, tonsils etc) of patients who have developed symptomatic vCJD.

Guidance from the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup, formerly the TSE Working Group, details precautions to be taken when dealing with known or suspected cases and those at increased risk of human prion disease (DH 2015).

What is the relevance of decontamination to human prion diseases?
While there is still a good deal of scientific uncertainty about human prion diseases, the UK Government continues to take a precautionary approach and adapt policy as new evidence emerges. To maintain effective risk management, it is important to combine improved recognition of potentially infected individuals who are at increased risk of human prion disease with the most effective methods for surgical instrument decontamination.

5.1 The human prion diseases (including sCJD and vCJD) are a group of rare invariably fatal neurological disorders. In these diseases the normal human prion protein in the body undergoes misfolding to become an abnormal disease-associated protein, which is the major component of the transmissible agents in prion diseases.

5.2 Abnormal prion protein is heat-stable, exceptionally resistant to enzymatic digestion and, once dried onto surfaces of surgical instruments, is very difficult to remove or Inactivate by conventional decontamination processes.

5.3 Abnormal prion protein may accumulate to very high levels in the CNS of all patients with a human prion disease (including sCJD and vCJD). For this reason, the CNS is considered as a high infectivity tissue in all forms of human prion disease.

5.4 In vCJD, abnormal prion protein also accumulates at lower levels in lymphoid tissues (for example tonsils, spleen, lymph nodes and Peyer's patches in the gastrointestinal system). This accumulation appears to begin before the onset of clinical symptoms of vCJD and may therefore indicate asymptomatic vCJD infection. Lymphoid tissues are considered medium infectivity tissues in vCJD (but not in sCJD and most other human prion diseases).

5 Human prion disease (including variant CJD and other forms of CJD)

5.5 This WHTM supports commissioners and providers in implementing appropriate and effective decontamination measures to reduce the risks of transmission of human prion diseases. Owing to the difficulty of inactivating or removing human prion proteins from surgical instruments, special measures are required to prevent their potential transmission between patients.

5.6 Guidance on the relative risk of different body tissues can be found in the **ACDP-TSE Subgroup's Annex A1**. Patient risk assessment and procedures can be found in Annex J. See also Public Health England's CJD section.

Patients with CJD, suspected CJD or an increased risk of developing CJD

5.7 The ACDP-TSE Subgroup's guidance on minimising the transmission of CJD and vCJD in healthcare settings provides advice on the use and management of surgical instruments for procedures where there may be a risk of surgical transmission.

5.8 This advice applies to:

- patients with probable or confirmed CJD;
- those for whom CJD is being considered as a differential diagnosis; and
- around 5,000 people who:
  - have an increased risk of CJD because of an operation or medical treatment in the past, or
  - are at risk of inherited prion disease.
- Detailed descriptions and definitions of these risk groups can be found in paragraph 4.17 ("Patient categorization") of the ACDP-TSE's Part 4 – 'Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings'.

5.9 Part 4 also describes:

- The range of tissues for which surgical instrument precautions should be taken ("Tissue infectivity", paragraph 4.12).
- Recommendations for single use instruments; handling of reusable instruments; and instrument disposal ("Surgical procedures and instrument management", paragraph 4.46). Advice is set out separately for patients at risk of sCJD, iCJD and inherited prion disease and those at risk of vCJD due to the larger range of tissues involved in vCJD (tables 4c and 4d).

5 Human prion disease (including variant CJD and other forms of CJD)

- Advice on the procedures to be followed for quarantining surgical instruments is given in Annex E of the guidance. Under no circumstances should quarantined instrument sets be used on other patients unless the diagnosis of CJD or vCJD has been positively excluded.

5.10 The instrument set should be reprocessed through the SSD in the usual manner. No special precautions are necessary as proteins lifted by detergent action from the surface of a contaminated instrument will not deposit on other surfaces in the washer-disinfector. The possibility of residual abnormal prion on the instruments is of far greater concern than the possibility of contamination of instruments in other sets processed in the washer-disinfector either concurrently or subsequently.

5.11 A traceability system for equipment especially where used on patients with, or at increased risk of, human prion disease is very important. Also subsequent storage (including quarantine if indicated) or use of instruments must be recorded and where appropriate specialist advice obtained from the local Health Protection Team.

5.12 For details about action required following invasive procedures on a patient with definite or probable vCJD or presumed infected cases, see also Public Health England's 'CJD: public health action following report of new case or person at increased risk'.

Chapter 6

Management of surgical instruments

Introduction

6.1 This chapter aims to provide further guidance on the management of surgical instruments to support further risk reduction and improvements to patient outcomes.

6.2 There are technologies that may offer future potential to enhance the existing decontamination process to reduce protein, including prion protein contamination of instruments.

6.3 The following management choices have been identified:

- keeping instruments moist;
- separation of instruments used on high risk tissues for patients born before and after 1 January 1997;
- instrument audit and tracking.

6.4 Other management choices covered in this guidance include:

- loan sets;
- loan sets used in high-risk surgical procedures;
- repairs;
- instrument audit and tracking policy;
- single-use instrument tracking and records;
- decontamination of surgical instruments that have been dropped perioperatively.

Keeping instruments moist between use and reprocessing

6.5 Prions are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully. 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. (see **paragraph 5.10**).

6 Management of surgical instruments

Separation of instruments used on high risk tissues for patients born before and after 1 January 1997

6.6 It is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain. These people form a group at lower risk of prion diseases and thus at a lower risk of contaminating surgical instruments with prions. The NICE IPG 196 (2006) risk-reduction strategy requires that separate pools of instruments be used for high-risk tissue surgery, dependent on the patient's birth date. This differentiates between patients who were either born before 1 January 1997, or who were born on or after 1 January 1997, and requires that separate pools of instruments be used for each stream.

6.7 There will be a small number of patients born after 1 January 1997 who were operated on using pre-1997 instruments before the 2006 NICE guidance was issued. For these patients, further high-risk tissue surgery should use either:

- single-use instruments, provided these are available and of satisfactory quality; or
- new reusable instruments, or post-1996 instruments and either:
  - retain them for sole use on this patient; or
  - afterwards add to the pre-1997 stock1.

6.8 If instruments from the reserved post-1996 stock are used deliberately or by mistake in a patient born before 1997, they should not be returned to the post-1996 stock, but may continue to be used as part of the pre-1997 stock. The same age separation should be applied to loan sets.

Loan sets

6.9 Instrument sets that are supplied from an external source, used for that procedure only and then returned are known as loan sets. This practice increases the risks associated with the decontamination and reprocessing of such instruments, because the organisation may not be familiar with them. Organisations have also expressed concern over the decontamination status of such instruments and the lack of track and traceability, including potential for instrument leakage. It is a requirement that reusable medical devices should be decontaminated in accordance with manufacturers' instructions. Therefore, loan sets should be provided with decontamination instructions so that staff can ensure their compatibility with local decontamination processes. It should be ensured that when equipment is supplied to a healthcare provider, adequate time is allowed for cleaning, sterilisation and return of the equipment to the theatres, both prior to and after use (see the AfPP's (2010) guidance 'Loan set management principles between suppliers/manufacturers, theatres and sterile service departments' and MHRA's 'Managing medical devices').

6.10 Set integrity needs to be maintained to minimise instrument leakage and enable traceability to the patient. This extends to the control of individual instruments within loaned sets, to audit their removal and replacement.

Key Points to practical use of loan sets:
Decontamination instructions should be compatible with local processes e.g WHTM guidance
Trace-ability of instruments should be in place to record the full history of the loan sets.

Concise communication systems should be in place to ensure sets are on-site to allow full decontamination prior to use. Additionally, time should be given to ensure sets are prepared appropriately prior to return.

Consideration should be given to control of implantable screws/plates that maybe on the set.
When in the SSD, the loan set should be appropriately prepared for decontamination in a manner to allow all parts of devices to be exposed to the wash/cleaning process. This may involve decanting all items out of containers and into dedicated wash baskets.

Training should be in place to ensure decontamination staff are familiar with reprocessing techniques.
The user must reject the loan kit if they are not satisfied that full assurance measures are in place.

Loan sets used in high-risk surgical procedures

6.11 Particularly for high risk surgical procedures (see **Chapter 5**), healthcare providers using loan sets should ensure that records of such sets are maintained within their control. These records should be available for independent review and should, at a minimum, make it possible to ascertain the details of the instruments contained within the set and the surgical units within which the set has been used. Dates and session times for each use should also be recorded. The identity of patients with whom the sets have been used should be traceable from the record but, for patient confidentiality, maintained within the secure environment of the clinical service providers concerned.

6.12 Instruments within loan sets shall be subject to quality system and control measures at least equal to those normally applied in the surgical centres where they are used. This applies equally when surgeons or other team members are the sponsor of any loan arrangement.

6.13 Theatre staff and SSDs should take special care to ensure integrity of loan sets and, for instruments used on high risk tissues, their membership of pre or post 1 January 1997 instrument groups from receipt to dispatch.

Repairs

6.14 Any instrument used on high risk tissues that are removed for repair should be returned to the instrument set from which it was removed.

Instrument audit and tracking

6.15 There is a need to track and trace reusable surgical instruments throughout their use and reprocessing. This is to avoid instrument leakage and is an essential requirement of the MDR and the Code of Practice.

6.16 Records should be maintained for all the instrument sets (and supplementaries for high-risk procedures) identifying:

- the cleaning and sterilisation method used;
- a record of the decontamination equipment and cycle;
- the identity of the person(s) undertaking decontamination at each stage of the cycle;
- the patients on whom they have been used and details of the procedures involved.

Note:
Organisations should continue to review the practicalities for the implementation of technology systems, to enable unique device identification (UDI) for each instrument. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed, to make the device ready for the subsequent use throughout the intended lifetime of the device.

6.17 This information is required so that instrument sets (and supplementaries for high-risk procedures) and the patients they have been used on can be traced and the instrument sets and supplementaries recalled when necessary.

6.18 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.

6.19 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 sterilisation.

6.20 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.

6.21 NICE IPG 196 (2006) guidance requires that high-risk tissue instrument sets used with patients born since 1 January 1997 form a pool within which instruments must be retained and from which other instruments must be excluded. This is challenging when supplementary instruments are used. Teams are likely to find effective streaming of non-marked instruments difficult. The use of larger sets which include supplementary instruments will partly mitigate this risk, particularly when combined with instrument marking, tracking and audit techniques.

Single-use instrument tracking and records

6.22 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. This statement also applies to single use implantable devices.

Note:
The All Wales Decontamination Advisory Group recommends the move away from repeated processing of small orthopaedic implants, associated with trays of surgical instruments, where practically possible. Such practice is often not in accordance with manufacturer's instructions and is a risk to patient safety.

Health boards/Trusts should commit to the use of single use sterile pre-packed implants where they are available and practically possible. There are examples of organisations who have moved to total single use supply on in-house equipment.

Chapter 7

Functional responsibilities

Introduction

7.1 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.

Note:
All staff, including managers, directly or indirectly involved in decontamination of surgical instruments should be competent on the basis of appropriate education, training, skills and experience."
The ACDP-TSE Subgroup therefore recommends that decontamination staff should undertake appropriate formal training and education, through accredited providers and establishments, along with appropriate Institutes.

It also suggests that, although there is no current professional registration of decontamination personnel, it would be best practice for senior SSD staff (for example the user) to be members of a relevant professional body such as the IDSc.

All medical device decontamination sciences staff are aligned to the national profiles for healthcare science. Implementing the generic job descriptions (JDs) for medical device decontamination sciences staff will improve patient safety and staffing structures within medical device decontamination sciences departments – example generic JDs are available on the IDSc website.

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

7.3 In every case, however, it is possible to identify a user (see **paragraphs 7.20-7.24**) 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.

7.4 The user should seek professional advice from the Authorising Engineer's (Decontamination) (AE(D)) and decontamination engineers at NWSSP-SES (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).

7 Functional responsibilities

Context

7.5 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.

7.6 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.

7.7 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 of healthcare engineering) and provide a robust framework for future support to the NHS.

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

7.9 In brief, the guidance requires:

a. the role of Authorising Engineer (Decontamination) (AE(D)) should 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));

d. healthcare organisations that are undertaking decontamination of reusable medical devices, to use the services of NWSSP-SES 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.

7 Functional responsibilities

Definition of ‘management’

7.10 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. 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-SES

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)

7 Functional responsibilities

Executive Board Lead

7.11 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.

7.12 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

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

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

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

7.16 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.

7.17 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.

7.18 The Decontamination Lead should have received formal training, specific for management of medical device decontamination on undertaking the role.

Senior Operational Manager

7.19 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.

7 Functional responsibilities

User

7.20 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 7:55 In the acute care setting, the user should preferably be a member of the Institute of Decontamination Science or other equivalent professional bodies.

7.21 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.

7.22 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.

7.23 There is a need to ensure that the management of surgical instruments (medical devices) is carried out. The role is a combined responsibility for co-ordinating 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.

7 Functional responsibilities

7.24 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 on of instruments between sets (including preventing the movement of supplementary instruments between sets) in consultation with clinical specialists and decontamination teams; 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;

c. ensure that missing or damaged surgical instruments are replaced preserving the appropriate set structure;

d. oversee the monitoring of condition and suitability for surgical instruments;

e. oversee the audit process for instrument sets from procurement through to use, decontamination and final disposal;

f. ensure instrument sets never used are reviewed and/or disposed of;

g. oversee actions to provide a mechanism for routinely revalidating instrument-set content (for example, annual sign off of the tray checklist by surgical teams);

h. manage the loaning of instrument sets to and from external suppliers using the audit techniques given in this guidance;

i. purchase new instrument and sets (including, as a minimum, the documented approval of the theatre team, decontamination specialists and Control of Infection Lead);

j. ensure repaired instruments are returned to the original instrument set;

k. oversee a standardised approach to instrument nomenclature throughout the healthcare organisation;

l. ensure all instrument sets have an accurate version-controlled checklist validated by the surgical team (preferably in an electronic format);

m. determine that all instrument stores (including wards and departments) are audited on a regular basis, and all redundant items removed from circulation;

7 Functional responsibilities

n. ensure a mechanism is in place for addressing instrument set usage non-conformities such as wet packs, torn tray wrap etc.;

o. 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);

p. ensure the healthcare organisation holds an accurate database of its instrument-set inventory including tray type, location of use and stock level;

q. ensure all instrument sets which are critical in stock levels are risk assessed, to maximise patient safety and inform instrument set investment;

r. ensure compliance with all manufacturers' guidance and information for reprocessing of any implantable items (e.g. including screws and plates);

s. 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).

7.25 The surgical teams are responsible for:

a. Ensuring all instrument sets which are critical in stock levels are risk assessed to maximise patient safety and inform instrument set investment.

b. Ensuring the leakage of surgical instruments between sets is minimised by effective process mapping using recommended audit procedures, post-operative checks, the signing of tray contents lists, ensuring instrument sets contents are kept together through the procedures.

Note
NWSSP-SES 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))

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

7.27 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.

7 Functional responsibilities

Role of AE (D)

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

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

Responsibilities of the AE (D)

7.30 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;

7.31 NWSSP-SES undertakes the role of Authorising Engineer for the NHS in Wales.

7.32 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.

7 Functional responsibilities

Decontamination Engineers (Wales) at NWSSP-SES

7.33 The Decontamination Engineers (Wales) (DE(W)) supports the AE(D) and undertake the testing programme of decontamination equipment on behalf of the Welsh Government.

Role and Responsibility of the DE(W)

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

d. 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;

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

Authorised Person (Decontamination (AP(D))

7.35 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.

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

7.37 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.

7 Functional responsibilities

7.38 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). Larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role.

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

7.40 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)

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

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

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 and AE(D) of all installed decontamination equipment;

e. liaison with the AE(D) and/or DE(W) at NWSSP-SES, Decontamination Lead and other interested professionals;

f. authorising the use of decontamination equipment after repair or refurbishment and after quarterly tests;

g. operation of the permit system in line with guidance specified in this document;

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.

7 Functional responsibilities

Qualifications of the AP(D)

7.42 The AP(D) must have knowledge of the specific equipment installed on-site and not simply a generic overview of decontamination equipment.

7.43 The AP(D) must 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))

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

Role of the CP(D)

7.45 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 provision of testing and/or maintenance. 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).

7.46 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)/AE(D).

Responsibilities of the CP(D)

7.47 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).

7 Functional responsibilities

7.48 For those CP(D)s who carry out maintenance duties, they should be a qualified engineering technician/craftsman with evidence to demonstrate competence in the maintenance of one or more types of decontamination equipment. The CP(D) with responsibility for maintenance should have relevant experience 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)

7.49 The CP(D) should:

a. be able to clearly demonstrate adequate technical competence working with decontamination equipment they work with(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 sterilisers and at least one other decontamination process/machine type.

e. Received appropriate training from equipment manufacturers on how to carry out maintenance/service tasks.

7.50 If the CP(D) does not undertake duties for a prolonged period, the need for refresher training may need to be implemented. (Decision to be assessed between AE(D) and AP(D).

Note:
The CP(D) should receive certificated training to include 'machine maintenance' off equipment manufacturers. Such certification should be retained by the AP(D) responsible for the relevant organisation.
If the CP(D) does not undertake duties for a prolonged period, the need for refresher training may need to be implemented. (Decision to be assessed between AE(D) and AP(D).

Lead for Infection Prevention and Control

7.51 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.

7 Functional responsibilities

Microbiologist (Decontamination)

7.52 The Microbiologist (Decontamination) is defined as a person designated by Management to be responsible for advising the user on microbiological aspects of disinfecting and sterilising 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 sterilising used medical devices.

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

7.54 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

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

7.56 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

7.57 The Manufacturer is defined as a person or organisation responsible for the manufacture of a washer-disinfector or steriliser. 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 sterilisers).

7 Functional responsibilities

Contractor

7.58 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 steriliser, and for the conduct of the installation checks and tests. The Contractor (or supplier) may also be the manufacturer of the machine.

Purchaser

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

Competent Person (Pressure Systems)

7.60 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 Welsh 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 sterilisers.

7.61 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

7.62 **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.

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

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

7 Functional responsibilities

Training

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

7.66 Accredited courses on sterilisation, 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
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.

7 Functional responsibilities

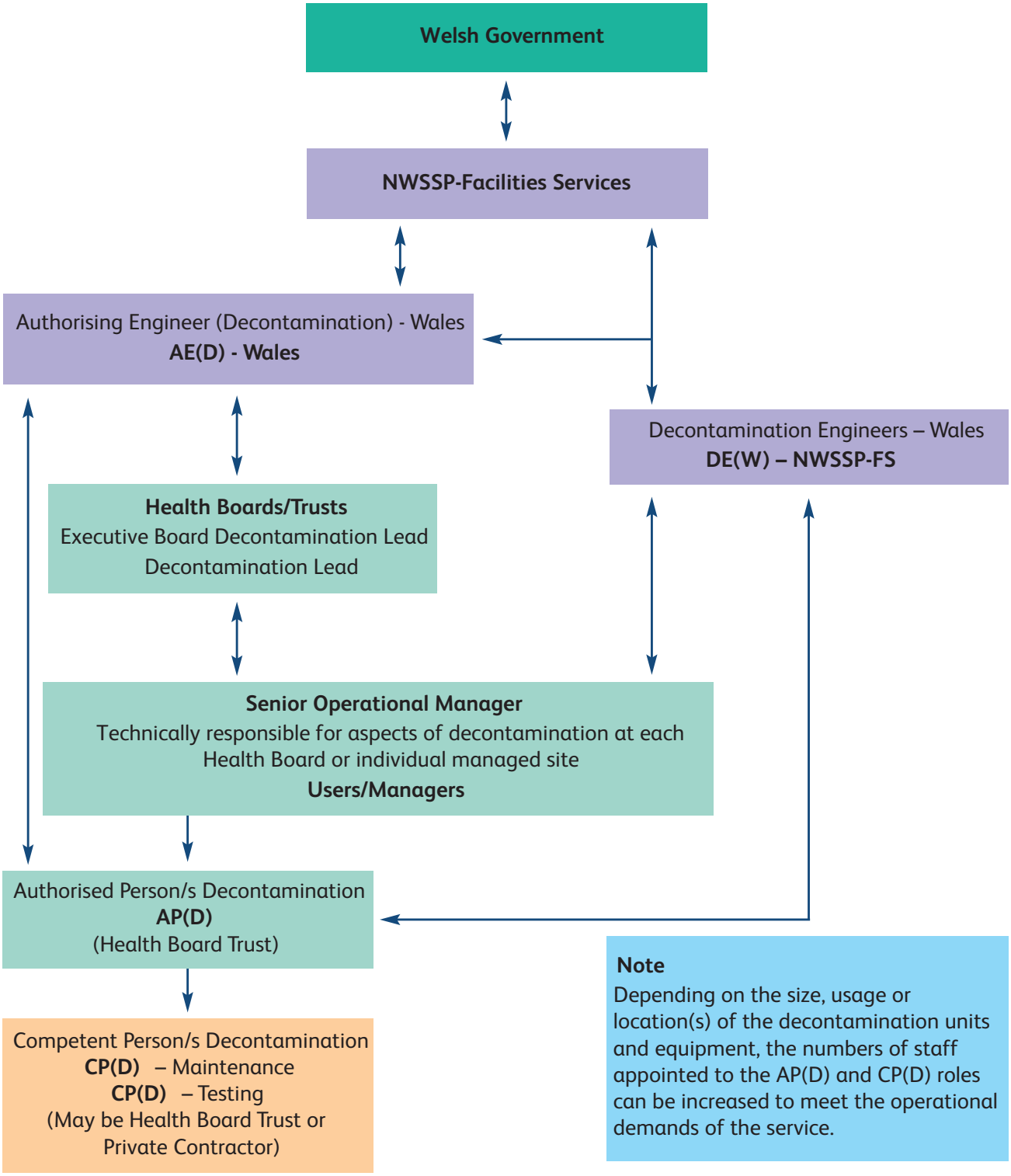


Figure 3 Decontamination management structure for Wales

Chapter 8

Permit-to-work system

8.1 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 following aspects should be considered with respect to the protection a Permit to Work System brings to the organisation:

- Risk
- Human factors;
- Management of the work permit systems;
- Management resources available;
- Unconscious and conscious incompetence;
- Objectives of the work permit system;
- Types of work permits required;
- Contents of the work permits;
- Management of contractors on-site;

The operation of a good permit to work system reduces the possibility of process failure as a result of the following issues:

- Failure to undertake work activities in a safe manner during validation and maintenance;
- Accidental reconfiguration of the validated process:
- Failure to comply with the work permit system:
- Accidents associated with engineers working within the facility;
- Communication failure associated with engineering activities:

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

a. decontaminate reusable medical devices and goods;

8 Permit-to-work system

b. produce sterile products; or

c. make-safe infected items.

Safety rules and procedures are necessary to ensure that the integrity and performance of the relevant decontamination systems are maintained, and hence ensuring standards of patient safety are achieved.

8.3 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).

8.4 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.

As part of the accountability, three copies of the permit should be produced. The user, the CP(D) and the AP(D) should all retain copies for their records.

8.5 After repairs following a breakdown and after quarterly testing, both, AP(D) and the CP(D) should sign the permit to allow the equipment back into use. The DE(W) from NWSSP-SES 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.

Note:
Permits should be issued for internal and external staff undertaking work activities and for any activity that potentially contradicts the safe working of the equipment covered by the permit.

8.6 The AE(D) or the DE(W) under authorised 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.

8.7 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).

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

8 Permit-to-work system

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**.

A well managed 'permit to work' system will help to ensure the equipment used to decontaminate medical devices functions as intended and as commissioned. Experience shows that organisations are sometimes reluctant to implementing such systems, quoting a number of reasons and obstacles why permits cannot be implemented.

Additionally all CP(D)'s undertaking work covered by the permit shall adhere to all relevant safe working practises/policies of the organisation and attend any induction requirements identified.

The AP(D) should maintain relevant competency certificates to document that all CP(D)'s working on the equipment has received relevant training for the required work activity. The AP(D) shall also continually assess the performance of the CP(D) and identify any concerns with standards of work or any re-occurring fault conditions.

The CP(D) shall ensure that they provide the AP(D) relevant paperwork on completion of the permit, to document that the equipment is functioning to the validated specification. This may include job-sheets, cycle print-out or a test report.

Chapter 9

Reporting of incidents

Introduction

9.1 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.

9.2 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.

9.3 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.

9.4 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.

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

9.6 The AE(D) or DE(W) upon delegation, 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; or

c. damage to the product.

9.7 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

9.8 Certain types of defect should be reported to NWSSP-SES. 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 sterilisers;

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.

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

9.10 All adverse incidents involving transportable (bench-top) sterilisers should be reported to the MHRA.

9.11 Adverse incidents involving permanently installed sterilisers should be reported to the MHRA and NWSSP-SES. 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.

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

Statutory reporting procedure

9.13 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (latest revision) 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.

9 Permit-to-work system

9.14 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 steriliser;

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

9.15 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.

9.16 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.

9.17 Examples of dangerous occurrences applicable to sterilisers 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.

9 Permit-to-work system

9.18 Examples of reportable diseases applicable to sterilisers include:

a. poisoning by sterilant;

b. any illness caused by a pathogen.

9.19 Full details can be found in the HSE guidance, A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations.

9.20 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 10

Local reprocessing

Introduction

10.1 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.

10.2 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.

10.3 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.

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).

Use of automated and validated technologies is essential where local reprocessing is undertaken, to include the use of washer disinfectors, dedicated for reprocessing of medical devices. Additionally, there is the need to ensure there are adequate trace-ability systems in place to record all activities and link to patients.

Risk assessment

10.5 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.

Chapter 11

Environment

11.1 The facilities in which medical devices are to be reprocessed should have appropriately segregated processes and adequate ancillary services (e.g. water, ventilation, drainage etc) to maintain an appropriate environment for work activity.

11.2 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).

11.3 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-SES).

11.4 Ancillary systems used to supply decontamination facilities (e.g. water purification/ventilation plant), should be subject to appropriate service, maintenance or validation procedures in line with national guidance or manufacturers recommendations.

Appendix 1

Standards relevant to decontamination

Standards relevant to decontamination processes and equipment

BS EN ISO 11737-1. Sterilisation of medical devices. Microbiological methods. Determination of a population of microorganisms on products.

BS EN ISO 11737-2. Sterilisation of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilisation process.

BS EN ISO 14937. Sterilisation of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilisation process for medical devices.

BS EN ISO 17665-1. Sterilisation of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilisation process for medical devices.
(This includes porous load and fluid sterilisers (except where used for medicinal products), and sterilisers for unwrapped instruments and utensils.)

BS EN 285. Sterilisation. Steam sterilisers. Large sterilisers.

BS EN 13060. Small steam sterilisers.

BS EN 1422. Sterilisers for medical purposes. Ethylene oxide sterilisers. Requirements and test methods.

BS EN 14180:2014. Sterilisers for medical purposes. Low temperature steam and formaldehyde sterilisers. Requirements and testing.

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 13485. Medical devices. Quality management systems. Requirements for regulatory purposes.

Standards relevant to decontamination management

BS EN ISO 13485. Medical devices. Quality managements systems. Requirements for regulatory purposes.

A1 Appendix 1 Standards relevant to decontamination

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 sterilisers 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. Sterilisation of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for terminally sterilised medical devices.

BS EN 556-2. Sterilisation of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for aseptically processed medical devices.

BS EN 1041:2008+A1:2013. Information supplied by the manufacturer of medical devices.

BS EN ISO 14971. Application of risk management to medical devices.

BS EN ISO 17664. Sterilisation of medical devices. Information to be provided by the manufacturer for the processing of re-sterilisable medical devices.

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.

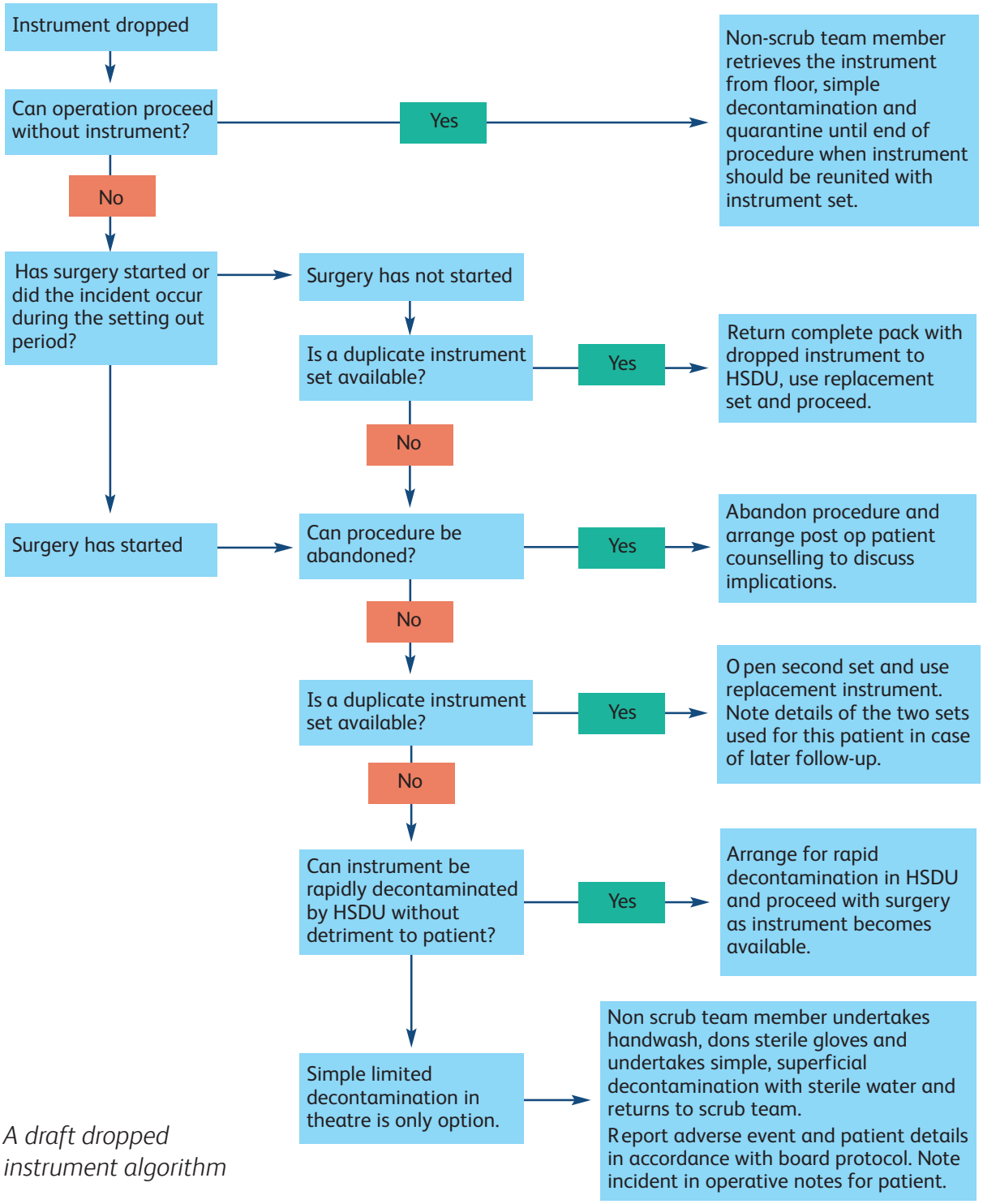
This has many advantages. In the vast majority of cases, CJD or outbreaks related to instruments are a rare event. This will mean that a second set of instruments will be recorded for a specific patient. If two sets were used and the patient were a CJD case and tracking had to occur, this would mean 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.

A2 Appendix 2 The Management of dropped instruments

Process:



A draft dropped instrument algorithm

A3 Appendix 3 Permit to work on decontaminated equipment

Appendix 3

Permit to work on decontaminated equipment

Thanks to Betsi Cadwaladr UHB for their work producing this permit to work template.

DECONTAMINATION EQUIPMENT – PERMIT TO WORK – in accordance with WHTM01-01 Part A

Hospital / Trust - _____ Permit No 01/00001

The purpose of this permit is to ensure that other than weekly testing no maintenance or other testing is carried out on decontamination equipment without the approval of the Authorised Person – Decontamination.

Part 1 AP (D): Description of work and authorization / permission to proceed:

Location / Department of decontamination equipment_____
Manufacturer _____ Asset No _____
Serial No _____ Model No _____

The Following work is to be carried out:

_____
_____
_____

The work will take place between _____ hours on __/___/____ and _____ hours on __/____/___

NO OTHER WORK WILL BE CARRIED OUT UNDER THIS PERMIT

User Permission (to be completed by Authorised User / Department Manager / Person in charge)
I herby give permission for the above equipment to be taken out of use and the above described work can be carried out
It has not been possible to guarantee that the decontamination equipment is free of contaminants.

Name _____ Signature _____
Date _____ Time _____
Position _____

Authorised Person

I herby give permission for the work as described to proceed

AP (D) – Name (Print) _____ Sign_____ Date _____ Time _____

Part 2 CP (D): Acceptance of work and conditions

I accept responsibility for the work as described
No other work will be carried out by me or persons working under my control
I am **fully conversant** with the work described and relevant health and safety requirements

CP (D) – Name (Print) _____ Sign_____ Date _____ Time _____

Part 3 CP (D): Detail of work carried out

Work Performed	*(Tick appropriate box)*
Breakdown maintenance / Repair	
Routine Servicing / maintenance	
Quarterly Periodic Testing	
Yearly Periodic Testing	
Installation / PQ/PRQ	

Explanation of work carried out _____
_____
_____
_____

The work on the above decontamination equipment has been *completed / suspended**
The decontamination equipment *may / may not* be returned to service*

**Delete as applicable*

Appropriate tests have been carried out to verify the performance of the equipment in accordance with WHTM. (See Equipment logbook for further details)

CP (D) – Name (Print) _____ Sign_____ Date _____ Time _____

Part 4 AP (D): Authorisation to use Decontamination Equipment

The Decontamination Equipment may be taken into use*
The Decontamination Equipment may not be taken into use, as further work under a new permit is now necessary*

**Delete as applicable*

AP (D) – Name (Print) _____ Sign_____ Date _____ Time _____

Part 5 – Acceptance of Decontamination Equipment Status by Authorised User / Department Manager / Person in charge

I declare that all aspect of the work has been explained to me. I hereby accept the decontamination Equipment back into service*

I understand that further work is required and will ensure that the Decontamination Equipment will remain out of use.*
**Delete as applicable*
Name _____ Signature _____
Date _____ Time _____
Position _____

Original (White) copy to be retained in book by Authorised Person (D)
Pink copy to Department Manager
Yellow Copy to Competent Person (D)

References

References

Acts and Regulations

Radio Equipment and Telecommunications Terminal Equipment Regulations 2000. SI 2000 No 730.

Radio Equipment and Telecommunications Terminal Equipment (Amendment) Regulations 2003. SI 2003 No 1903.

Construction (Design and Management) Regulations 2007.

British Standards

BS 5839-1:2017. Fire detection and fire alarm systems for buildings. Code of practice for design, installation, commissioning and maintenance of systems in non-domestic premises.

BS 7671:2008. Requirements for electrical installations. IET Wiring Regulations. Seventeenth edition. Institution of Electrical Engineers, 2008.

Department of Health publications

Health Technical Memorandum 05-01 – 'Managing healthcare fire safety'.

Health Technical Memorandum 05-03 Part B – 'Fire detection and alarm systems'.

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

Other

Fire and UwFS Incident reporting system. **http://nww.firesystems.wales.nhs.uk/fire/login.cfm**

Regulatory Reform (Fire Safety) Order 2005.

Smoke-free Premises etc. (Wales) Regulations 2007.