

DECONTAMINATION OF RE-USABLE MEDICAL DEVICES

STANDARD

There is a system in place that ensures as far as reasonably practicable that all re-usable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

OVERVIEW

The decontamination of re-usable medical devices is the combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of infectious agents being transferred to individuals, or the environment.

The re-usable medical device life cycle comprises the following processes - acquisition, cleaning, disinfection, inspection, disposal, packaging, sterilization, transportation, and storage before use. This cycle is used to render a re-usable item safe for further use.

In this standard, the term reusable medical device applies to all such devices whether owned by the organisation, rented, on loan or acquired by any other means.

Re-Usable Medical Device Life Cycle

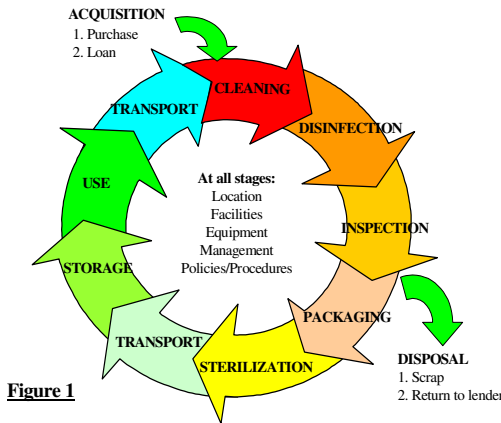


Figure 1

The decontamination process is required to make medical devices:

- Safe for users to handle
- Safe for use on the patient

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The Microbiology Advisory Committee to the Department of Health (MAC Manual), Sterilization, Disinfection, and Cleaning of Medical Equipment: Guidance on Decontamination, classifies the risk of infection associated with the decontamination of medical devices as: -

High risk

In close contact with a break in the skin or mucous membrane or introduced into sterile body areas.

Intermediate risk

In contact with mucous membranes; contaminated with particularly virulent or readily transmissible organisms; or prior to use on immunocompromised patients.

Low risk

In contact with healthy skin or not in contact with the patient.

The key references, contained within this standard, demonstrate the wide range of legislation and guidance applicable to the decontamination cycle in order to effectively achieve its objectives. These include, but are not limited to:

- The Health & Safety at Work (Northern Ireland) Order 1978 and The Management of Health and Safety at Work Regulations (Northern Ireland) 2000, which require employers to assess the risks to their employees.
- Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003, which provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents.
- EU Council Directive 93/42/EEC, concerning medical devices and the U.K. Medical Devices regulations 2002.
- EU Council Directive 99/34/EEC (the Product Liability Directive), which states that a product is defective 'if the safety of the product is not such as persons are generally entitled to expect'.

The guidance given in Health Technical Memoranda (HTM), Northern Ireland Adverse Incident Centre (NIAIC) Device Bulletins, Medical Device/Equipment Alerts and DHSSPS decontamination guidance has been designed to ensure that the hazards are minimised and that decontamination procedures comply with legislative requirements and best practice.

The Process Assessment Tool (PAT) issued under Addendum 2 HSS(MD)4/01 was designed to assist organisations in determining compliance with Decontamination standards and guidance. The use of PAT will assist organisations to complete the Controls Assurance standards.

The suggested examples of verification provided within the standard are merely auditable examples, which may be used to verify compliance with a

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particular criterion. Trusts may wish to use many other examples, which will vary depending on the nature of a particular organisation. These may be just as valid as the illustrative examples given in the standard. It should also be noted that any lists of examples throughout the standard are not exhaustive.

If all or part of the decontamination service is provided by a third party then organisations are still required to complete the controls assurance returns against the standard as if they are undertaking the work themselves. The assessment of the relevant criteria should be undertaken in conjunction with the third party provider. Organisations should obtain evidence to support the agreed scores for audit purposes. It is suggested that this requirement is included in the service agreement e.g. Service Level Agreement/Contract between organisations.

Assessment Guidance

HPSS organisations vary significantly in size and in the nature of the services they deliver. It follows that not all controls assurance standards will apply to each organisation. This is implicit in the current Departmental guidance, eg. *The Reference Table on Applicability and Expected Levels of Compliance* which should be referred to before commencing the self-assessment exercise.

Even where a standard is generally applicable to the work of an organisation it is quite possible that not all of the criteria will be materially applicable. Before self-assessing against a standard, therefore, an organisation should consider the relevance of each criterion to its own business and conduct its assessment accordingly. Thus, where a criterion is clearly relevant to an organisation, the score should be based on the **totality of the action taken to address the requirement**. Where there is little or no relevance, the criterion should be considered “not applicable” and ignored for scoring purposes as explained in the guidance on *Reporting Compliance* issued by the Department.

This approach will ensure that the assessment has no unfairly detrimental effect on the organisation’s overall score but reflects a proper evaluation of the key areas of risks identified and the actual levels of controls put in place to manage those risks.

Likewise, the *Examples of Verification* set out in the standard are just that – examples, for guidance only. Once again, it is the nature of each organisation’s business that determines the type of evidence needed to prove that appropriate controls are in place. In effect, this may mean that only some of the examples listed are relevant to a particular HPSS organisation or, indeed, that there are other more relevant examples which can be adduced as evidence of compliance. It is also the case that some evidence can be deployed to demonstrate compliance with more than one criterion or standard.

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KEY REFERENCES

Statutes

Medical Device Directive 93/42/EEC. Official Journal L169, 12/7/1993 p0001 – 0043.

Medical Devices Regulations 2002. SI 2002 No 618 The stationery Office, London.

Health and Safety at Work (Northern Ireland) Order 1978

Health and Safety at Work Order (Application of Environmentally Hazardous Substances) Regulations (Northern Ireland) 2003

Management of Health and Safety at Work Regulations (Northern Ireland) 2000 No 388

Manual Handling Operations (Northern Ireland) 1992 No 535

Personal Protective Equipment at Work Regulations (Northern Ireland) 1993 SRI NO 20

The Consumer Protection (Northern Ireland) Order 1987 SI No 2049 (N.I. 20)

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

Biocidal Products (Amendment) Regulations (Northern Ireland) 2002

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 No 455

The Carriage of Dangerous Goods by Road Regulations (Northern Ireland) 1997

Transport of Dangerous Goods (Safety Advisers) Regulations (Northern Ireland) 2000

Carriage of Dangerous Goods (Amendment) Regulations (Northern Ireland) 2002

The Pressure Systems Safety Regulations 2000

Guidance and Codes

British Standards Institution (1989) BS 5295 - 0 *Environmental cleanliness in enclosed spaces – Part 0: General introduction, terms and definitions for clean rooms and clean air devices*. British Standards Institution, London

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British Standards Institution (1990) BS 7320 *Specification for sharps containers*. British Standards Institution, London

British Standards Institution (1990) BS 3970 - 4 *Sterilizing and disinfecting equipment for medical products: Specification for transportable steam sterilizers for unwrapped instruments*. British Standards Institution, London

British Standards Institution (1994) BS EN 554 *Sterilization of medical devices – Validation and routine control of sterilization by moist heat*. British Standards Institution, London

British Standards Institution (1995) BS EN 724 *Guidance on the application of BS EN 29001 and BS EN 46001 and of BS EN 29002 and BS EN 46002 for non-active medical devices*. British Standards Institution, London

British Standards Institution (1998) BS EN 1422 *Ethylene oxide sterilizers – Requirements and test methods*. British Standards Institution, London

British Standards Institution (2001) BS EN ISO 13488 *Medical devices – Particular requirements for the application of BS EN ISO 9002* British Standards Institution, London

British Standards Institution (2001) BS EN ISO 14644 – 1 *Cleanrooms and associated controlled environments – Classification of air cleanliness*. British Standards Institution, London

British Standards Institution (2002) BS EN 980 *Graphical symbols for use in the labelling of medical devices*. British Standards Institution, London

Health Estates PEL(94)34 *Decontamination of equipment prior to inspection, service or repair*.

DHSSPS *Antimicrobial Resistance Action Plan 2002 - 2005*.

Health Building Note (HBN) 13, *Sterile Services Departments*. NHS Estates, Leeds.

Health Building Note (HBN) 13, Supplement 1. *Ethylene Oxide Sterilization*. NHS Estates, Leeds.

Health Building Note (HBN) 52, *Accommodation for Day Care Endoscopy Unit*. NHS Estates, Leeds.

Infection Control Nurses Association (2003) *Infection Control Guidance for General Practice*. ICNA: Bathgate

Institute of Sterile Services Management *Medical Devices Directorate (93/42/EEC)*

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Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management

Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health. (MAC Manual) (available on the MHRA website at www.mhra.gov.uk)

Advice Notice AN(NI)99/03: NIAIC

SAN (NI) 99/45 *Storage of Sterile Medical Devices* NIAIC

SN (NI) 2003/02 *Management of loaned medical equipment or accessories from manufacturers or other organisations* NIAIC

MDEA (NI) 2005/01 *Reporting adverse incidents and disseminating Medical Device/Equipment Alerts relating to medical devices, non-medical equipment, buildings and plant*. NIAIC

Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

SN (NI) 2001/48 *Compatibility of medical devices and reprocessing equipment with decontamination agents* NIAIC

SN (NI) 2001/28 *Safe use and disposal of sharps* NIAIC

SN (NI) 2002/29 *Steam penetration tests in vacuum benchtop sterilizers* NIAIC

DB 9901 (NI) *The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers* NIAIC

DB 9904 (NI) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* NIAIC

DB 9904 (NI) Supplement 1 *Medical Device and Equipment Management for Hospitals and Community-based Organisations: Checks and tests for newly delivered medical devices* NIAIC

DB 9904 (NI) Supplement 2 *Medical Device and Equipment Management for Hospitals and Community-based Organisations: Guidance on the sale, transfer of ownership and disposal of used medical devices* NIAIC

DB 2000/02 (NI) *Medical Devices and Equipment Management: Repair and Maintenance Provision* NIAIC

DB 2000/04 (NI) *Single use medical devices: Implications and consequences of reuse*. NIAIC

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DB(NI) 2002/06 *Benchtop Steam Sterilizers - Guidance on Purchase, Operation and Maintenance* NIAIC

NHS Estates Health (1993) Technical Memorandum HTM 2040 *The control of legionellae in healthcare premises - a code of practice.*

NHS Estates Health (1994) Technical Memorandum HTM 2025 *Ventilation in healthcare premises.*

NHS Estates (1997) Health Technical Memorandum HTM 2031. *Clean Steam for Sterilization*

NHS Estates (1997) Health Technical Memorandum HTM 2010. *Sterilization*

NHS Estates (1997) Health Technical Memorandum HTM 2030. *Washer-Disinfectors*

NHS Estates (2002) C30 *Washer/Disinfectors, A Model Engineering Specification*
<http://www.decontamination.nhsestates.gov.uk>

Circulars

DHSS Circular HSS(MD)16/99, *Controls assurance in infection control: decontamination of medical devices.*

DHSS Circular HSS(MD)15/99, Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission

DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
http://www.dhsspsni.gov.uk/hss/governance/documents/DAO_05_01.doc

HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 4/02 AS/NZS 4360: 2004 – Risk Management
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 8/02 Risk Management in the Health and Personal Social Services
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 13/02 Governance in the HPSS: Risk Management
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

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HSS (PPM) 9/2002 – Revised Public Procurement Policy for the Public Sector

Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular DAO (DFP) 25/2003 - Statement of Internal Control

<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular HSS (PPM) 6/2004 – Reporting and follow-up on serious adverse incidents: Interim Guidance

<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular HSS (PPM) 8/2004 – Governance in the HPSS: Controls assurance standards – update

<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS(MD)4/01 *Decontamination of reusable medical devices*

Addendum 3 HSS(MD)4/01 *Protocol for local decontamination of surgical instruments*

HSS(MD)15/99 *Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission.*

HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices.* (and accompanying Decontamination Guidance CD-ROM)

HSS(MD)36/2003 *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection: Publication of revised guidance*

HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*

Other Publications

Spongiform Encephalopathy Advisory Committee (1998) “*Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*” Advisory Committee on Dangerous Pathogens (ACDP) Spongiform Encephalopathy Advisory Committee (SEAC). The Stationery Office, London, and website <http://www.doh.gov.uk/cid/tseguidance>

Standards Australia (2004) *Risk Management AS / NZS 4360:2004.* Standards Association of Australia. Strathfield NSW.

Professional Estates Letter PEL(04)13, *Health Estates Decontamination Testing Service*, Health Estates

Details of Department of Health and NHS Executive publications and circulars can be found at (<http://www.doh.gov.uk/publications>) under the COIN web site.

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Details of Device Bulletins (DB), Warning Notices (HN, SN etc.) are provided on the Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) web site:

<http://www.dhsspsni.gov.uk/niaic>

Chief Medical Officer circulars HSS(MD)____ are available on the DHSSPS web site:

<http://www.dhsspsni.gov.uk/publichealth>

The HSENI web site <http://www.hseni.gov.uk> provides information on Northern Ireland Health and Safety legislation and codes of practice

NHS Estates (2001) *Infection Control in the Built Environment* The Stationery Office, London

http://www.nhsestates.gov.uk/download/publications_guidance/infectn.pdf

NHS Executive (1995) HSG (95) 18 *Hospital laundry arrangements for used and infected linen.*

Department of Health (1991) HC (91) 33 *Decontamination of Equipment, Linen or other surfaces contaminated with Hepatitis B and/or other Human Immuno-Deficiency Viruses.* Department of Health, London.

NHS Executive (1995) *Hospital Infection Control: Guidance on the control of Infection in hospitals prepared by the joint DH/PHLS Hospital Infection Working Group* HSG (95) 10 1995

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CRITERION 1

Board level responsibility for decontamination of re-usable medical devices is clearly defined and there are clear lines of accountability for decontamination matters throughout the organisation, leading to the Board

Source

- HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidelines on Implementation
- DOA (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.
- Standards Australia (2004) *Risk Management AS/ NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance
- Northern Ireland Adverse Incident Centre (NIAIC) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* DB 9904 (NI)
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

The Chief Executive is responsible for ensuring that there are effective arrangements for the decontamination of medical devices. Arrangements should include a senior member of staff with defined responsibility, (decontamination lead) who is provided with the necessary resources and authority for the task. It is expected that this officer will report directly to the Chief Executive.

The Decontamination Lead should ensure that a member of staff with operational experience in endoscope reprocessing is designated to take lead responsibility for all aspects of endoscope management. Responsibility should cover all units within an organisation in which endoscope decontamination is undertaken to ensure consistency of decontamination processes in the organisation e.g. in Day Procedure Units, Outpatient Departments, Intensive Care Units, Theatres etc.

Clear lines of accountability, for all parts of the decontamination cycle should be established defining the relationships between users and the Risk Management, Clinical Governance, and Infection Control Committees and the

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Infection Control team taking into consideration the workload of responsible staff.

An annual report on the efficacy of the decontamination process should be submitted to the Risk Management Committee for review. This committee, which includes in its membership the Chief Executive, should present the report to the Board.

The scope of responsibility should also consider contractors and professional liability where the organisation either buys in or sells services to other organisations.

Examples of Verification

- Organisational chart indicating clear line of accountability
- Job description of designated individual(s)
- List of senior management contacts for out of hours support
- Board and committee minutes including action and audit plans
- Annual report on the application of the decontamination standards, any issues arising from non-compliance, and any progress made.
- Appropriate wording in contractual agreements, which clearly specifies responsibilities, if an external supplier is used.

Links with other standards

All standards (generic criterion)

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CRITERION 2

There is comprehensive organisation-wide implemented policy and procedures for the Decontamination of Re-usable Medical Devices.

Source

- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* DB 9904 (NI)
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* DB 9904 (NI) Supplement 1 March 2001: *Checks and tests for newly delivered medical devices*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) *Medical Device and Equipment Management: Repair and Maintenance Provision* DB 2000/2 (NI), November 2000
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

Policy and Procedures for the decontamination of re-usable medical devices and equipment across the organisation should be drawn up and implemented. A policy committee structure should be considered with a clear remit and reporting lines. Policy and Procedures to be addressed include:

- The dissemination of agreed policies to users and reprocessing staff
- The consideration of national and regional guidance in establishing local policy and procedures
- The need for safety checks concerning decontamination prior to using medical devices and equipment.
- The appropriate training of professional users, technical supervisors, clinical supervisors end-users, carers and staff on decontamination requirements.
- The maintenance and repair of medical devices and equipment (including decontamination, tracking, recall, replacement and disposal policies).

There should also be a policy on the decontamination of medical devices acquired through other methods such as renting, borrowing or on-loan (e.g. borrowed from a manufacturer or another organisation). It is important to be clear about where responsibility for decontamination lies and for any problems which may arise.

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Borrowed or on-loan medical devices must go through an acceptance procedure prior to use including the decontamination status and decontamination requirements. For example, flexible endoscopes when borrowed or on-loan should be labelled as to their decontamination status.

Trusts should ensure indemnity agreements are signed for rented, loaned or borrowed medical devices including equipment on trial.

Modifying existing medical devices or using them for purposes not intended by the manufacturer, counts as manufacture of a new medical device under the Regulations and may have safety implications and legal repercussions for the user Trust. For example, using an endoscope for purposes not intended by the manufacturer would count as manufacturer of a new medical device.

Policies and procedures should be subject to regular review and audit of their implementation and operation.

Examples of Verification

- Risk Management Strategy
- Policy and Procedures
- Policy Committee meeting minutes
- Audit of policy and procedures

Links with other standards

Governance
Risk Management
Management of Purchasing and Supply
Decontamination
Health & Safety Management
Medical Devices and Equipment Management

CRITERION 3

Appropriately qualified key personnel are in place in accordance with legislative and best practice guidance for decontamination.

Source

- Health and Safety at Work (Northern Ireland) Order 1978.
- Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- HSS(MD)4/01 *Decontamination of reusable medical devices*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* DB 9904 (NI)
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), *Medical Device/Equipment Alert MDEA(NI)2004/34, Flexible Endoscopes*, July 2004

Guidance

Key persons and responsibilities (defined in detail in HTM 2010 and/or HTM 2030) are as follows:

- The Chief Executive is ultimately accountable for the operation of the facility and the adequacy and effectiveness of the decontamination process.
- The Decontamination Lead is defined as the senior member of staff with responsibility for managing all aspects of decontamination.
- The User is defined as the person designated by management to be responsible for particular elements of the decontamination process. In a hospital the User could be, for example, the sterile service manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager. In primary care he /she could be a GP, practice manager, dentist or other health professional.
- The Competent Person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities.
- The Authorised Person (sterilizers), AP (S), carries out independent auditing and provides advice on decontamination, together with reviews and witness/validation of processes.
- The Test Person (sterilizers), TP (S), carry out validation and periodic testing of decontamination equipment.
- The Maintenance Person (sterilizers,) MP (S), is designated by management to carry out maintenance and periodic testing on decontamination equipment.
- The Microbiologist (sterilizer) is designated by management to be responsible for advising the User on microbiological aspects of decontamination, including endoscope reprocessing.

- The Infection Control Doctor is defined as the person designated by management to be responsible for advising the User on all aspects of infection control.

Examples of Verification

- Documented named individuals
- Job descriptions with individuals aware of their responsibilities
- Evidence of current relevant training/qualifications to fulfil the role
- Support of AP (S)

Links with other standards

Buildings, Land and Non Medical Equipment

Management of Purchasing and Supply

Environmental Management

Human Resources

Health and Safety

Infection Control

Medical Devices and Equipment Management

CRITERION 4

Decontamination issues are considered prior to the acquisition of re-usable medical devices and decontamination equipment through a broad-based Medical Devices and Equipment group(s), established in accordance with NIAIC Device Bulletin DB 9904(NI) include membership of staff responsible for decontamination and reprocessing.

Source

- British Standards Institution (1994) BS EN 554 Sterilization of medical devices – Validation and routine control of sterilization by moist heat. British Standards Institution, London
- DB 9904 (NI) Medical Device and Equipment Management for Hospitals and Community-based Organisations NIAIC
- DB 9904 (NI) Supplement 1 *Medical Device and Equipment Management for Hospitals and Community-based Organisations: Checks and tests for newly delivered medical devices*
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health.* (MAC Manual).
- DB 2000/02 (NI) *Medical Devices and Equipment Management: Repair and Maintenance Provision*
- DB(NI) 2002/06 *Benchtop Steam Sterilizers - Guidance on Purchase, Operation and Maintenance*
- NHS Estates (1997) Health Technical Memorandum HTM 2031. *Clean Steam for Sterilization*
- NHS Estates (1997) Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health (1997) Technical Memorandum HTM 2030. *Washer-Disinfectors*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

Medical devices and equipment group(s) when established in accordance with Device Bulletin DB9904 (NI), should include membership of the necessary key staff including re-usable medical device users (including endoscope users) and staff responsible for decontamination and reprocessing to ensure appropriate examination of the manufacturers specifications. This will ensure that new devices (including endoscopes) are compatible with decontamination equipment in place and new decontamination equipment can reprocess existing devices (including endoscopes).

The group should oversee a wide range of purchasing/acquisition issues including, where appropriate, technical specifications*. In addition, the group should ensure that the medical device manufacturer's decontamination instructions are compatible with the decontamination equipment available and policies in place. Advice on the purchase of decontamination equipment and

medical devices may be sought from the Authorised Person (Sterilizers), the Sterile Services Department manager, infection control team decontamination lead, or other suitably qualified individual.

Such a Group can: -

- Improve communication on medical device and decontamination issues
- Foster consent between clinical and technical supervisors in relation to any proposed changes
- Reduce confusion about who is responsible for medical device and equipment management tasks, training and safe medical device and equipment operation including decontamination requirements.

The remit of such a group(s) should also encompass providing advice on:

- Medical device and equipment purchasing/acquisition issues in relation to decontamination and comparisons of alternative medical devices or equipment.
- Technical specifications, regulatory compliance information and related issues
- Financial data, including consideration of full on-costs, i.e. running, maintenance and consumables costs, when preparing a medical device or equipment purchase bid, including disposable and replacement costs at the appropriate time
- Standardisation to single models where possible
- Ensuring compatibility of new endoscopes with existing endoscope reprocessing equipment (including matching the number of channels on the new endoscope with the reprocessing equipment capability, including any necessary connection kit purchases).
- Risk management considerations
- Device/equipment evaluation reports, including user experience and preferences
- Drawing up guidelines for medical device and equipment decontamination
- Monitoring of manufacturer's instructions and training concerning decontamination
- Medical device and equipment management and maintenance procedures concerning decontamination.

*A number of documents provide information on the technical requirements that should be addressed prior to purchase of specific items of equipment, for example:

- HTM 2010 provides details of information to be obtained from manufacturers prior to purchasing new sterilizers. This advice includes the standards (BS or EN) to which the sterilizer should be designed and constructed and a statement of compliance, installation data and engineering requirements, etc.
- The MAC Manual provides generic advice on the decontamination information that users should expect to receive from manufacturers of CE marked re-usable devices.

- DB(NI) 2002/06 provides advice on the purchase of benchtop sterilizers
- DB 9904 (NI)
- A pre-purchase questionnaire may be used to assist in purchasing decisions

Examples of Verification

- Composition of the group/committee and terms of reference document
- Group/committee minutes and action plans
- Purchase considerations include a risk and impact analysis.
- Cost/product life cycle details
- Completion of a pre-purchase questionnaire
- Policies and procedures

Links with other standards

Buildings, Land, Plant and Non Medical Equipment
Management of Purchasing and Supply
Medical Devices and Equipment Management

CRITERION 5

All surgical instrument sets are tracked through the decontamination process and can be traced to individual patients.

Source

- HSS(MD)4/01 *Decontamination of reusable medical devices*
- SN (NI) 2003/02 *Management of loaned medical equipment or accessories from manufacturers or other organisations* NIAIC
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

It is important that systems are in place to allow each surgical set of instruments to be tracked through decontamination processes in order to ensure that all aspects of the process have been carried out effectively.

Examples of Verification

- Review of documentation e.g. sterilizer and washer disinfectant log books, records of manual cleaning, manual/electronic tracking systems
- Physical verification of decontamination processes e.g. sterilizers and washer disinfectors
- Theatre records/patients notes
- Policies and procedures

Links with other standards

Health and Safety

I&CT Management

Infection Control

Management of Purchasing and Supply

Medical Devices and Equipment Management

Records Management

CRITERION 6

All re-usable medical devices are handled, collected and delivered in a manner that reduces the risk of contamination to the product, patients, staff and any area of the healthcare facility.

Source

- British Standards Institution (1990) BS 7320 *Specification for sharps containers*. British Standards Institution, London
- *The Carriage of Dangerous Goods by Road Regulations (Northern Ireland) 1997*
- Institute of Sterile Services Management (2000) *Standards and Practice. Year 2000 edition*. Institute of Sterile Services Management
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health*. (MAC Manual)
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

The incorrect handling, collection, and delivery of medical devices may negate any decontamination process to which they have been subjected.

The Institute of Sterile Service Management recommends the following:

- Personnel should be trained to handle, collect and transport medical devices/ equipment and, where appropriate, should wear protective clothing in accordance with local safety policies and procedures, which should include methods for dealing with spillages.
- Persons aware of the potential infection hazards should separate reusable devices from clinical waste at the point of use.
- Re-usable textiles should be placed in soiled linen bags and returned to the laundry service.
- Contaminated medical devices should be confined and contained in closed leak-proof plastic bags or containers to avoid spills, the generation of aerosols or contact with staff and environmental surfaces. They should be transported as soon as possible after use to the decontamination area; the contents of the containers should be labelled to facilitate processing.
- Used equipment should be safely contained and transported to the decontamination area, and records kept of vehicles and containers used.
- Contaminated medical devices and equipment must be kept separate from clean medical devices/equipment during transportation. This is achieved by using separate containers to provide physical barriers between clean and dirty items.
- Contaminated medical devices / equipment shall only enter the department through the decontamination area.

Endoscopes should not be loaned between units if possible but if this unavoidable, purpose designed trays with disposal liners and covers should

be used. In addition, safe, timely and reliable transport should be provided for the transfer of devices from one unit to another.

Examples of Verification

- Documented policies and procedures
- Risk Assessments
- Control of Infection monitoring and audit reports
- Training Records
- Transport and Traceability Records
- Instruction for the use of devices or equipment

Links with other standards

Buildings, Land and Non Medical Equipment
Management of Purchasing and Supply
Environmental Management
Human Resources
Health and Safety
Infection Control
Medical Devices and Equipment Management
Risk Management
Fleet and Transport Management

CRITERION 7

Decontamination, storage and preparation of endoscopes for use is undertaken in accordance with Device Bulletin DB(NI) 2002/05 and current legislative requirements

Source

- HSS(MD)4/01 *Decontamination of reusable medical devices*
- *Health and Safety at Work (Northern Ireland) Order 1978*
- *Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003*
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health. (MAC Manual) Health Estates PEL(96)30, and Supplements 1 & 2*
- SN (NI) 2001/48 *Compatibility of medical devices and reprocessing equipment with decontamination agents* NIAIC
- DB(NI) 2002/05 *Decontamination of Endoscopes.*
- HTM 2030 *Washer-disinfectors*
- HSS(MD)15/99 *Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission.*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004
- Advice Notice AN(NI)99/03: NIAIC

Guidance

In accordance with the device manufacturer's instructions, rigid endoscopes should be cleaned, disinfected, inspected, packaged and sterilized using validated automated processes in a Sterile Service Department wherever possible. For rigid endoscopes that cannot tolerate steam sterilization they should be cleaned and subjected to either a high-level disinfection process, using a compatible liquid chemical disinfectant, or sterilized using a suitable low temperature process.

In strict accordance with the manufacturer's instructions, flexible endoscopes (which cannot be autoclaved) should be cleaned and subjected to high-level disinfection using a suitable and compatible liquid chemical disinfectant in an automated endoscope reprocessor (AER). Particular attention should be given to the identification of the number of channels on the endoscope to ensure that they are all manually cleaned and connected to the AER to ensure effective high-level disinfection. AERs should be used in accordance with the manufacturers instructions and for the purpose for which they have been designed – they should not be used to disinfect equipment for which they are not designed.

Manual cleaning of endoscopes should be carried out in accordance with DB(NI)2002/05 ensuring that the water temperature is appropriate for the detergent being used in accordance with the manufacturers instructions. Leak

testers should be used for appropriate endoscopes in accordance with the manufacturers instructions.

AERs should be specified, in accordance with BS 2745 and NHS Estates C30 and monitored in accordance with HTM 2030, "Washer-disinfectors". Rinse water testing in accordance with HTM 2030 should be included in the process control and monitoring procedures.

Where practical, single use accessories (including cleaning brushes) should be used and should never be reused. Reusable endoscopic accessories should be reprocessed in a Sterile Service Department using a validated automated process in accordance with the device manufacturer's instructions.

Flexible endoscopes and accessories should be traceable in accordance with the requirements of HSS(MD)15/99.

Rigid endoscopes must be stored sealed in the container or packaging in which they were sterilized. Flexible endoscopes should be dried and stored suspended vertically, preferably in purpose built ventilated lockable storage cabinets, to allow circulation of air, with vertical storage racks or cupboards cleaned daily. They should not be in contact with other endoscopes or flat surfaces, and should be re-processed prior to use.

The use of liquid chemical disinfectants and sterilization agents is covered by the Control of Substances Hazardous to Health Regulations (COSHH). The Health and Safety Executive has set a Maximum Exposure Limit of 0.05ppm for glutaraldehyde. Failure to comply with COSHH regulations constitutes an offence and renders the employer liable under the Health and Safety at Work (Northern Ireland) Order 1978

Examples of Verification

Documented policies and procedures for the cleaning, disinfection and sterilization of endoscopes and re-usable accessories, which may include the following: -

- Physical verification that single use devices are not being re-used
- Policy defining all stages of the decontamination process, that is readily available to staff
- Audit of policies and procedures
- Documented evidence of testing, monitoring and maintenance
- Physical verification of adequate storage facilities and environmental control.
- Disinfectant, concentration, contact time, maximum number of uses, shelf life or made-up disinfectant and method of safe disposal
- Type of disinfectant utilised
- Evidence of Risk assessment undertaken to meet COSHH requirements
- Physical verification of facilities
- Personal protective equipment available
- Atmospheric monitoring

- Health surveillance
- Training programmes
- Control measures and spillage procedures

Links with other standards

Medical Devices and Equipment Management
Buildings, Land, Plant and Non-medical Equipment
Management of Purchasing and Supply
Environmental Management
Human Resources
Health and Safety
Infection Control
Records Management
Risk Management

CRITERION 8

All other re-usable medical devices are decontaminated and stored in accordance with legislative and best practice requirements

Source

- Health Building Note (HBN) 13, Supplement 1. *Ethylene Oxide Sterilization*
- Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health*. (MAC Manual)
- SAN (NI) 99/45 *Storage of Sterile Medical Devices* NIAIC
- DB(NI) 2002/06 *Benchtop Steam Sterilizers - Guidance on Purchase, Operation and Maintenance*
- DB 9901 (NI) *The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers*
- DB 2000/04 (NI) *Single use medical devices: Implications and consequences of reuse*.
- Addendum 3 HSS(MD)4/01 *Protocol for local decontamination of surgical instruments*
- NHS Estates (2002) C30 *Washer/Disinfectors, A Model Engineering Specification*
- NHS Estates Health Technical Memorandum HTM 2031. *Clean Steam for Sterilization*
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices*.
- HSS(MD)15/99 *Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission*.

Guidance

Wherever possible, the decontamination of re-usable medical devices should be carried out in the sterile services department. Decontamination is the combination of processes, including cleaning, disinfection and/or sterilization, used to render a re-usable medical device safe for further episodes of use. In order to decontaminate medical devices effectively, all organic debris (e.g. blood, tissue and other body fluids) must be removed from the item prior to disinfection and/or sterilization. Effective cleaning of medical devices prior to disinfection or sterilization is of the utmost importance in reducing the risk of transmission of infectious agents. Medical devices intended for single-use only should not be re-processed for re-use.

Policies should exist as a point of reference, and should be available for all personnel involved in any aspect of decontamination.

- All stages of the decontamination process should be clearly defined, documented and controlled

- There should be a regular review of all procedures and any changes documented
- Processing data should be retained

Devices should be cleaned in accordance with manufacturer instructions. Cleaning can be separated into mechanical processes, using an automated washer-disinfector or ultrasonic and manual processes.

Automated mechanical cleaning provides an efficient, reproducible process whose effectiveness can be validated. This is the preferred method of cleaning, as it is more consistent and easily controlled than manual methods.

Automated washer-disinfectors

- Mechanical washer-disinfectors should be specified, in accordance with BS 2745 and NHS Estates C30 and monitored in accordance with HTM 2030, "Washer-disinfectors" including rinse water quality testing in accordance with THM 2030 as part of the process control and monitoring procedures.

Manual cleaning

- Manual cleaning should be carried out in accordance with Addendum 3 HSS(MD)4/01 "Protocol for local decontamination of surgical instruments". Unless the item to be sterilized is known to be damaged by the application of heat or moisture, then moist heat sterilization using steam under pressure should always be used in preference to other methods since it is more reliable and can be monitored effectively.

Sterilizers

Particular attention should be paid to the following areas:

- Validation and management of sterilization equipment using HTM 2010
- Monitoring of the steam supply of porous load sterilizers using HTM 2031
- Ensuring ethylene oxide sterilizer installations meet HBN 13 Supplement 1

Benchtop Steam Sterilizers

DB(NI) 2002/06 and HTM 2010 provide detailed guidance on the use and testing of benchtop sterilizers. In particular, organisations should ensure that the following are not sterilized using a traditional benchtop sterilizer:

- Single use devices
- Devices in any form of wrapping (including pouches)
- Equipment with lumens or cavities
- Porous loads

Benchtop steam sterilizers should be fitted with independent process monitoring or recording equipment and frequent periodic reviews of their effectiveness against relevant guidance should be undertaken.

Benchtop sterilizers are primarily intended to be used to sterilize loads for immediate use.

Benchtop Vacuum Steam Sterilizers

- DB 9901 (NI), DB(NI) 2002/06 provide detailed guidance on the use and testing of vacuum benchtop steam sterilizers. The use of hot air ovens is not recommended for the routine sterilization of surgical instruments.

Sterile products should be stored in a clean, cool and dry environment, away from the floor and walls and out of direct sunlight.

Examples of Verification

- Physical verification that single use devices are not being re-used
- Policy defining all stages of the decontamination process, that is readily available to staff
- Audit of policies and procedures
- Documented evidence of testing, monitoring and maintenance
- Annual pressure vessel tests
- Certificate of registration of sterile services department under Medical Devices Directive 93/42/EEC (verifies compliance of sterile services department only)
- Physical verification of adequate storage facilities and environmental control.

Links with other standards

Buildings, Land, Plant and Non-medical Equipment

Health and Safety

Infection Control

Management of Purchasing and Supply

Medical Devices and Equipment Management

CRITERION 9

Decontamination equipment is subject to validation, calibration, monitoring and maintenance by appropriately qualified persons.

Source

- British Standards Institution (1990) BS 3970 - 4 *Sterilizing and disinfecting equipment for medical products: Specification for transportable steam sterilizers for unwrapped instruments*. British Standards Institution, London
- European Standard EN 1422 *Ethylene Oxide Sterilizers (Specifications)*
- Health Building Note (HBN) 13, Supplement 1. *Ethylene Oxide Sterilization*
- DB 9901 (NI) *The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers*
- DB(NI) 2002/06 *Benchtop Steam Sterilizers - Guidance on Purchase, Operation and Maintenance*
- NHS Estates Health Technical Memorandum HTM 2031. *Clean Steam for Sterilization*
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- Professional Estates Letter PEL(04)13, *Health Estates Decontamination Testing Service*, Health Estates
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

Planned maintenance is an essential part of the decontamination process. Equipment (washer-disinfectors, sterilizers etc.) to be used in validated processes requires planned preventative maintenance and periodic calibration and testing to ensure it remains in the same condition as when validated. Validated processes require monitoring of critical variables of each cycle and this should be independent of any monitoring used to control the decontamination equipment. Processes that require validation should only be carried out using automated equipment to ensure reproducibility.

Failure to maintain the equipment and its systems gives rise to the potential for inadequate decontamination.

HTM 2010, HTM 2030, DB 9901 (NI) and DB(NI) 2002/06 define the minimum standards required to ensure safe operation of the decontamination process.

The key areas are:

Washer-disinfectors (including automatic endoscope reprocessors)

The control protocols described in HTM 2030 provide the means for ensuring that a washer-disinfector is fit for its intended purpose and is subject to a planned programme of:

- Tests ensuring that standards of performance and safety are met
- Tests to monitor performance

- Preventative maintenance

The protocols also ensure that the equipment is operated in accordance with an agreed procedure by staff trained in its use and that the User is designated to exercise certain responsibilities of inspection.

The washer-disinfector should be validated in accordance with the guidance in HTM2030 and it is strongly recommended that in all cases the User receive professional advice from a microbiologist and/or an AP (S).

Benchtop Sterilizers

DB 9901 (NI), DB(NI) 2002/06 and HTM 2010 provide testing and maintenance requirements for benchtop sterilizers. In particular:

- The User is responsible for ensuring that daily, quarterly and annual testing is carried out.
- Weekly tests and safety checks should be undertaken
- Planned maintenance should be carried out as per the sterilizer manufacturer's instructions and HTM 2010
- The records of the above tests should be kept in a logbook (see DB(NI) 2002/06).

Ethylene Oxide Sterilization

Where ethylene oxide sterilization is employed, the following is required, as defined in HBN 13 supplement 1.

- The sterilizer should be specified, installed, commissioned and processes validated following the guidance in HTM 2010 or other recognised sterilization standards.
- The use of a microbiological system for routine monitoring of the process
- Since ethylene oxide is toxic and leaves residues, the aeration and degassing during quarantine of the product must be included as part of the validation process

The guidance in HTM 2010 should also be followed.

The Pressure Systems Safety Regulations 2000, which are a statutory requirement, apply to any vessel that contains steam at any pressure. It applies to most, if not all, benchtop steam sterilizers and to other equipment in which steam is generated e.g. some washer-disinfectors. These regulations require a Competent Person (Pressure Vessels) who is not the User (see criterion 13), to be designated to exercise certain responsibilities. These include verifying the suitability of the written scheme of examination and performing the examination in accordance with the written scheme.

Examples of Verification

- Schedules and documentation for installation checks, validation tests and periodic tests by AP (Sterilizers)
- Plant history file and a sterilizer process log
- Log of daily and weekly testing for benchtop sterilizers
- Testing and maintenance is carried out by individuals with the appropriate skills / training (see HTM 2010 or HTM 2030)

- Protocol for test failures
- ICT monitoring and reports given to ICC

Links with other standards

Buildings, Land and Non Medical Equipment

Management of Purchasing and supply

Human Resources

Health and Safety

Infection Control

Medical Devices and Equipment Management

Records Management

CRITERION 10

Ethylene oxide sterilizers are operated and used in accordance with legislative and best practice requirements.

Source

- *Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003*
- Health Building Note (HBN) 13, Supplement 1. *Ethylene Oxide Sterilization*

Guidance

Ethylene oxide is hazardous. It is toxic, flammable and a wide range of mixtures with air are explosive. It is also classified as a human carcinogen and therefore needs to be handled safely, with necessary precautions taken.

HBN 13, supplement 1 provides details of the requirements for the installation of ethylene oxide sterilizers. This includes, but is not limited to, a number of operational safety requirements defined in paragraph 2.5, which should be present as well as fire precautions stated in paragraph 3.5.

The operational safety requirements specific to positive pressure sterilizers is also described in HBN13 Supplement 1.

Schedule 1 of the Control of Substances Hazardous to Health (COSHH) Regulations lists ethylene oxide as a substance, which is subject to maximum exposure limit for inhalation. These limits are reviewed annually and up-dated by amendments. These limits must be regarded as safe work exposures.

Where products are sterilized by ethylene oxide using a third party, evidence of compliance and validation with this criterion should be sought.

Examples of Verification

- Operational procedures
- Prominent display of procedures for detailed processes
- List of authorised operators and safeguards to prevent unauthorised access
- Physical verification of environment
- Availability of goggles and respirators for use in an emergency or maintenance
- Physical verification against requirements in HBN 13, supplement 1
- Environmental sampling and COSHH test results

Links with other standards

Health and Safety
Risk Management

CRITERION 11

All medical devices, decontamination equipment and surfaces are appropriately dealt with after use on patients known to have or who are in a risk category for CJD.

Source

- HSS(MD)15/99 *Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission.*
- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices.*
- Spongiform Encephalopathy Advisory Committee (1998) "*Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*" (Advisory Committee on Dangerous Pathogens (ACDP) Spongiform Encephalopathy Advisory Committee (SEAC))
- HSS(MD)36/2003 *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection: Publication of revised guidance*

Guidance

"Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection" provides guidance to employers on the precautions necessary to minimise the exposure of employees and others to TSE agents from work activities. HSS(MD)15/99 and HSS(MD)36/2003 outline the ACDP/SEAC guidance and state ' it is essential that all existing cleaning and sterilization procedures operate to the highest standards'.

Detailed guidance can be found on all other aspects within the document "Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection" which is available from <http://www.doh.gov.uk/cjd/tseguidance>

Examples of Verification

- Documented procedures
- Local guidance which reflects national TSE requirements
- COSHH assessments
- Training logs.
- Availability and staff awareness of source documents

Links with other standards

Health and Safety
Infection Control
Human Resources
Risk Management

CRITERION 12

All decontamination equipment that does not meet the requirements of current standards and test methods is upgraded or replaced as soon as practicable in accordance with a planned replacement programme.

Source

- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices*
- HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*
- DB 9904 (NI) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* NIAIC
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004
- HSS(MD)4/01 *Decontamination of reusable medical devices*
- HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*

Guidance

HPSS organisations should have in place a programme to upgrade or replace as soon as practicable any decontamination equipment that does not meet the requirements of current standards.

A continuous review process should be in place in order to determine the best value for money means of providing the service. Consideration of centralised or decentralised services should be part of this review.

Examples of Verification

- Risk assessment of decontamination processing
- Action plan to mitigate identified risks
- Risk treatment plans to mitigate any residual risks
- ICT monitoring, audit and action reports
- Decontamination equipment validation results
- Organisation's Development and Operational Strategy
- Estates Strategy
- Documented planned replacement programme

Links with other standards

Buildings, Land and Non Medical Equipment
Management of Purchasing and Supply
Infection Control
Medical Devices and Equipment Management
Records Management

CRITERION 13

All medical devices that cannot be easily cleaned and/or those in poor condition, are identified and subject to a planned replacement programme with equipment that is easier to clean, or replaced by a single use alternative.

Source

- DB 9904 (NI) *Medical Device and Equipment Management for Hospitals and Community-based Organisations* NIAIC
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health. (MAC Manual)* Health Estates PEL(96)30, and Supplements 1 & 2
- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices*
- Health Estates PEL(94)34 *Decontamination of Equipment prior to Inspection, Service and Repair*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004 HSS(MD)4/01 *Decontamination of reusable medical devices*
- HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*

Guidance

Decontamination processes are less effective on instruments that are difficult to clean and/or in poor condition. Medical Devices (including rigid and flexible endoscopes) that cannot be easily decontaminated and/or those that are in poor condition should be replaced in accordance with a planned replacement programme.

For certain complex medical devices, it may be necessary to disassemble the device prior to decontamination. The manufacturer's instructions should be followed and all the surfaces exposed to the cleaning processes. It is also important that medical devices are correctly loaded into the automated washer-disinfectors including using a validated connection set for flexible endoscopes so that the maximum cleaning efficacy can be achieved.

Automated mechanical cleaning provides an efficient, reproducible process whose effectiveness can be verified. It is more consistent and more easily controlled, than manual methods.

Therefore, consideration should be given to purchasing medical devices that can be mechanically cleaned or replaced by a single use alternative.

Examples of Verification

- Risk assessment of instrument decontamination processing
- Action plan to mitigate identified risks
- Risk treatment plans to mitigate any residual risks
- ICT monitoring, audit and action reports

- Decontamination validation results
- Organisation's Operational Strategy
- Documented planned replacement programme
- Instrument inventories
- Manufacturers cleaning instructions

Links with other standards

Management of Purchasing and Supply

Infection Control

Medical Devices and Equipment Management

Records Management

Risk Management

CRITERION 14

Sterile Services Department facilities meet the standards and requirements for the segregation of controlled environments.

Source

- British Standards Institution (1989) BS 5295 - 0 *Environmental cleanliness in enclosed spaces – Part 0: General introduction, terms and definitions for clean rooms and clean air devices*. British Standards Institution, London
- British Standards Institution (1995) BS EN 724 *Guidance on the application of BS EN 29001 and BS EN 46001 and of BS EN 29002 and BS EN 46002 for non-active medical devices*. British Standards Institution, London
- British Standards Institution (2001) BS EN ISO 14644 – 1 *Cleanrooms and associated controlled environments – Classification of air cleanliness*. British Standards Institution, London
- Health Building Note (HBN) 13, *Sterile Services Department*
- Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management .
- HSS(MD)4/01 *Decontamination of reusable medical devices*
- HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*

Guidance

To achieve the required standard there must be segregation of soiled returns and clean supply (see HBN 13 for advice).

There will be separate areas for the following:

- Reception, sorting and decontamination of reusable medical devices and equipment
- Inspection and function testing of decontaminated devices / equipment
- Preparation and assembly of packs
- Pre-sterilization holding areas
- Sterilization
- Processed goods storage
- Distribution of processed items
- Raw materials preparation and storage
- Administration and training
- Staff changing and rest areas

All personnel entering and leaving the cleanroom must do so through a dedicated entrance / exit and wear appropriate clothing whilst in the area.

All persons requiring entry to the clean production area should:

- Enter through the dedicated gowning area
- Wear head cover and dedicated footwear
- Thoroughly wash and dry hands and don a clean, non-linting gown
- Exit through the gowning area where clean room clothing will be removed and discarded into an appropriate facility. The use of clean - room clothing outside of the clean area contributes to the risk of contamination and should be prohibited.

HBN 13 refers to the design of new SSD facilities. Its standards should be compared with those in existing departments as part of the risk assessment and management process. Adoption of the design standards as a principle is encouraged, and action plans to bring existing facilities up to this standard should form part of the organisation's risk treatment plan.

Examples of Verification

- Physical verification of workflows
- Documented procedures for control of personnel in all controlled environments
- Risk assessment of existing facilities detailing areas at risk from lack of segregation.
- Action plan to mitigate identified risks
- Risk treatment plans to mitigate any residual risks
- ICT monitoring, audit and action reports

Links with other standards

Buildings, Land, Plant and Non-medical Equipment

Management of Purchasing and Supply

Health and Safety

Infection Control

Records Management

Risk Management

Waste Management

CRITERION 15

All other locations in which the decontamination of re-usable medical devices (including flexible endoscopes) is carried out are dedicated for the purpose and appropriately designed, maintained and controlled.

Source

- British Standards Institution (1989) BS 5295 - 0 *Environmental cleanliness in enclosed spaces – Part 0: General introduction, terms and definitions for clean rooms and clean air devices*. British Standards Institution, London
- British Standards Institution (2001) BS EN ISO 14644 – 1 *Cleanrooms and associated controlled environments – Classification of air cleanliness*. British Standards Institution, London
- British Standards Institution (1995) BS EN 724 *Guidance on the application of BS EN 29001 and BS EN 46001 and of BS EN 29002 and BS EN 46002 for non-active medical devices*. British Standards Institution, London
- *Health and Safety at Work (Northern Ireland) Order 1978*
- *Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003*
- Health Building Note 1992 (HBN) 13, *Sterile Services Department*
- Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management
- NHS Estates Health Technical Memorandum HTM 2040 (1993) *The control of legionellae in healthcare premises - a code of practice*
- Health Building Note (HBN) 52, *Accommodation for Day Care Endoscopy Unit*. NHS Estates, Leeds.
- NHS Estates Health Building Note (HBN) 52, *The control of legionellae in healthcare premises - a code of practice*
- NHS Estates Health Technical Memorandum HTM 2025 *Ventilation*
- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices*.
- HSS(MD)15/99 *Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission*.
- HSS(MD)4/01 *Decontamination of reusable medical devices*
- HSS(SC)3/04 *Decontamination of Re-usable Surgical Instruments*

Guidance

Any location in which the decontamination process takes place should:

- Be physically separated from all other work areas, including patient treatment areas
- Be accessible from a service corridor.
- Be mechanically ventilated. (HTM 2025/ 2040).
- Have walls and other surfaces finished with flush junctions, be smooth, water resistant and able to withstand frequent cleaning.
- Have floors sealed with a washable non-slip finish.
- Have adequate lighting available to permit good working practices.
- Have hand washing and personal protective equipment facilities located in or near to the decontamination area

The Infection Control Team must be consulted at an early stage when any new item of decontamination equipment, changes to the unit layout, or changes to water supply arrangements may affect the efficient operation of the decontamination service.

Examples of Verification

- Physical verification of workflows
- Documented procedures for control of personnel in the clean area
- Risk assessment of locations
- Action plan to mitigate identified risks
- Risk treatment plans to mitigate any residual risks
- ICT monitoring, audit and action reports

Links with other standards

Buildings, Land, Plant and Non Medical Equipment

Management of Purchasing and Supply

Health and Safety

Human Resources

Infection Control

CRITERION 16

The risk management process contained within the Risk Management standard is applied to all aspects of decontamination of re-usable medical devices

Source

- *Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003*
- *Transport of Dangerous Goods (Safety Advisers) Regulations (Northern Ireland) 2000*
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

Decontamination risks can be systematically identified using a number of approaches including:

- Review of incidents
- Review of safety notices
- Inspections / assessments
- Review of audit reports
- Workshops for all staff

The COSHH regulations provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents. Schedule 9 of the COSHH regulations specifically refers to biological agents that include TSE agents.

There are a number of guidance documents which draw attention to the hazards which are implicit in the practice of decontamination, including HTM 2010, HTM 2030 and the Northern Ireland Adverse Incident Centre Device Bulletins, Medical Device/Equipment Alerts and MAC manual.

Clinical risk management issues associated with the operation of outdated decontamination equipment should be given an appropriate high level of priority when developing replacement programmes for new equipment.

The following risk management elements of the Risk Management Standard should be in place:

- All identified risks should be documented as part of a risk register and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented in order of priority and alongside other risk treatments, which are necessary to deal with the wider risks, faced by the organisation.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed frequently
- Senior management and the Board should be informed of any significant risks and associated risk treatment plans
- All relevant staff and stakeholders should receive information on systems in place to minimise risks associated with the decontamination process.
- Staff training should be undertaken

Examples of Verification

- Risk register
- Risk treatment plans
- Equipment replacement programmes
- Staff training records/ information log
- Correspondence with stakeholders
- ICT monitoring and reports to ICC

Links with other standards

Risk Management

Infection Control

Medical Devices and Equipment Management

CRITERION 17

All staff involved in decontamination processes have access to up-to-date legislation and guidance.

Source

- Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health*. (MAC Manual)
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices* (and accompanying Decontamination Guidance CD-ROM)

Guidance

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Department of Health.

As a minimum, staff should have access to the key references listed on the front of this standard.

There are many sources of information on European and national legislation and decontamination guidance.

Department of Health, Social Services & Public safety guidance can be accessed at

(<http://www.dhsspsni.gov.uk>) and in particular HSS(MD) circulars at (<http://www.dhsspsni.gov.uk/publichealth/letters.html>)

Advice and guidance documents are listed on the NIAIC homepage (<http://www.dhsspsni.gov.uk/niaic>).

The Health and Safety Executive for Northern Ireland's website (<http://www.hseni.gov.uk>) contains up-to-date information on legislation and guidance.

Details of Northern Ireland legislation can be obtained from

(<http://www.northernireland-legislation.hmsso.gov.uk>)

Full text copies of UK legislation issued from 1st January 1997 can be downloaded from

(<http://www.official-documents.co.uk>) which contains information on UK official documents.

Examples of Verification

- Staff are aware of, and have access to relevant legislation and guidance
- Internet access
- Department procedures comply with legislation and best practice
- SSD has an up-to-date library of regulations and standards

Links with other standards

All standards (generic criterion)

CRITERION 18

Education and training in appropriate aspects of decontamination practice is provided to relevant healthcare staff, including those working in a clinical environment

Source

- British Standards Institution (2002) BS EN 980 *Graphical symbols for use in the labelling of medical devices*. British Standards Institution, London
- Institute of Sterile Services Management (2000) *Standards and Practice*. Year 2000 edition. Institute of Sterile Services Management
- DB 9904 (NI) *Medical Device and Equipment Management for Hospitals and Community-based Organisations*: NIAIC
- DB(NI) 2002/05 *Decontamination of Endoscopes*: NIAIC.
- DB(NI) 2002/06 *Benchtop Steam Sterilizers - Guidance on Purchase, Operation and Maintenance*. NIAIC
- *Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health*. (MAC Manual)
- DB 9901 (NI) *The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers*: NIAIC
- NHS Estates Health Technical Memorandum HTM 2010. *Sterilization*
- NHS Estates Health Technical Memorandum HTM 2030. *Washer-Disinfectors*
- Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Medical Device/Equipment Alert MDEA(NI)2004/34, *Flexible Endoscopes*, July 2004

Guidance

Personnel at all levels should have a general knowledge of the principles and practice of decontamination processes. Staff involved in the operation of decontamination equipment should be trained in those types and models with which they are concerned and the allocation of funding for such training should be given appropriate priority in overall training budget allocation.

As part of staff appraisal systems, a training needs assessment for personnel at all levels should be undertaken leading into the development of staff training plan objectives. Progress on achievement of training plan objectives for decontamination should form part of the reporting mechanism to Trust Boards.

The Decontamination Lead should ensure that a member of staff with operational experience in decontamination is designated to take lead responsibility for all staff decontamination training and for auditing staff performance. When new medical devices or decontamination equipment is procured, appropriate training should be provided to staff to ensure that any new features on the medical device (e.g. a new channel on a flexible endoscope) is identified and that the operation of the decontamination equipment is undertaken in accordance with the manufactures instructions. All staff should have their knowledge of decontamination regularly appraised and

updated with staff feedback encouraged to ensure continued ownership and relevance.

Examples of appropriate training are:

- Departmental policies, procedures and standards
- Infection control
- Quality issues in the department
- Accident / incident reporting
- Health and Safety issues including chemical and environmental hazards
- Lifting and handling techniques
- Safe operation of equipment
- Personal hygiene, personal protective equipment and dress codes
- Communications within the organisation
- Fire hazards and regulations
- Awareness of legislation and best practice guidance
- The correct and safe method of cleaning medical devices
- The use of benchtop sterilizers
- Graphical symbols described in EN 980

The Institute of Sterile Services Management (ISSM 2000) suggests that SSD personnel should be trained to the following minimum standard:

- Departmental managers should be members of the Institute of Sterile Services Management
- Supervisory staff should be trained to NVQ level 3, or equivalent in supervisory management; additionally, supervisors should be accredited by the ISSM technical training programme for this grade
- Technicians should be trained to NVQ level 3 or equivalent ISSM technician training programme leading to accreditation of skills in eleven key sections within the department.
- Decontamination issues should be included in induction programmes and ongoing education for existing staff, including update of policies, feedback of audit results and the action needed to correct deficiencies.

Other healthcare workers designated as operators of decontamination equipment must be adequately trained and competent, and subject to ongoing training.

Examples of Verification

- Correspondence with stakeholders
- Documented training programme
- Risk register
- Risk treatment plans
- Staff appraisal systems
- Training needs assessments
- Training Plans linked to objectives
- Individual training logs / records
- Training reports to Trust Board

Links with other standards

Buildings, Land, Plant and Non Medical Equipment
Management of Purchasing and Supply
Environmental Management
Fire Safety
Human Resources
Health and Safety
Infection Control
Medical Devices and Equipment Management
Risk Management
Waste Management

CRITERION 19

Key indicators capable of showing improvements in the safety and efficacy of the system in place for decontamination of re-usable medical devices and/or providing early warning of risk, are used at all levels of the organisation, including the Board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- DOA (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

The organisation should develop indicators, which demonstrate that all stages of the decontamination process are being properly managed and risks are minimised.

Ideally the indicators should be designed to demonstrate improvement in managing the risks associated with the management of the decontamination process over time. The number of indicators devised should be sufficient to monitor the decontamination service. It is not necessarily the case that the Board will use all the indicators. The Board should select those which are useful for ensuring that the internal controls are working satisfactorily and objectives for managing the decontamination process are being met.

One indicator is degree of compliance with this standard. Some other examples of indicators currently in use are:

- Percentage compliance with validation and testing of decontamination equipment in accordance with published standards and guidance documents
- Number of benchtop sterilizers in use
- Number of clinical areas undertaking local decontamination
- Number of areas with written policies/procedures
- Numbers of non-compliance with pack specification

All organisations should be engaged in development and use of key indicators for their own internal performance, but they should also maximise the value of such measures by benchmarking themselves against like organisations, whether those are other HPSS Trusts or others who measure similar processes.

The English CASU benchmarking site can be accessed at (<http://www.casu.org.uk>)

Examples of Verification

- Documented analysis of key parameters that could form the basis of benchmarking
- Documented identification of suitable comparator organisations.
- Documented identification of the key areas to be compared and benchmarked.
- Evidence of usage at all levels.

Links with other standards

All standards (generic criterion)

CRITERION 20

The system in place for decontamination is monitored and reviewed by management and the Board in order to make improvements.

Source

- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- DOA (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

It is the responsibility of the Chief Executive, the designated individual and the Board to monitor and review all aspects of decontamination, including:

- Accountability arrangements
- Process, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

The designated individual will review the detailed issues surrounding decontamination and report / inform the infection control committee

The Risk Management Committee will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the Board.

The Clinical Governance Committee may also play a significant role in monitoring and reviewing decontamination issues as it impacts on the quality of clinical service provision. The Audit Committee should review internal audit findings.

Examples of Verification

- Internal audit report(s)
- Audit committee minutes
- Infection Control Committee minutes
- Risk Management Committee minutes
- Clinical Governance Committee minutes
- Audit plans, reports and risk mitigation plans.
- Record of incidents and untoward events together with action taken to mitigate potential risk
- Decontamination working group/committee minutes

Links with other standards

All standards (generic criterion)

CRITERION 21

The Board seeks independent assurance that an appropriate and effective system of managing decontamination issues is in place and that the necessary level of controls and monitoring are being implemented.

Source

- NHS Executive (1995) *NHS Internal Audit Manual 1995*. NHS Executive, London.
- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- HSS (PPM 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 4/2005 – AS/NZS 4360: 2004 – Risk Management
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- NHS Internal Audit Manual
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed; bearing in mind it's timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the Board.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the Board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of, other review bodies as far as is practical.

More specific external assurance for this standard may be gained from visits by:

- Health Estates
- Authorised Person (Sterilizers)

- A 'Notified Body' involved in assessing compliance with the Medical Devices Directive 93/42/EEC

Details of Department of Health and NHS Executive publications and circulars can be found at (<http://www.doh.gov.uk/publications>) using the COIN web site.

Examples of Verification

- Schedule of planned reviews
- Copy of reports
- Committee minutes
- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff involved in the review.

Links with other standards

All standards (generic criterion)