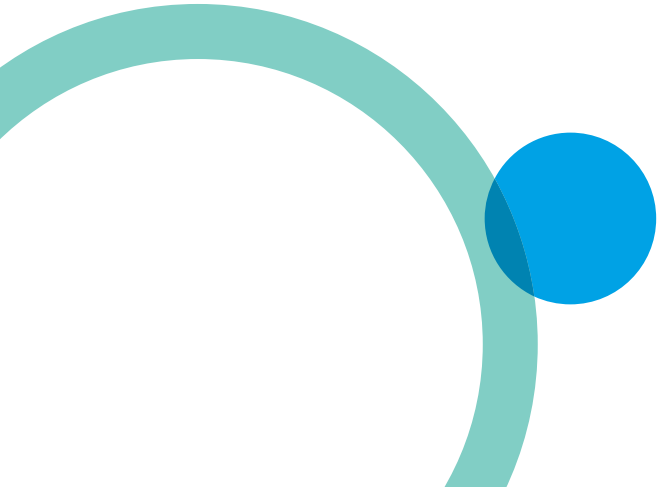
NHS National Services Scotland

Scottish Health Technical Memorandum 01-01

Decontamination of medical devices in a Central Decontamination Unit

Part A: Management



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Executive summary

The best practice guidance Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit (CDU) replaces some parts of SHTM 2010, SHTM 2030 and SHTM 2031 guidance published in 2001. SHTM 01-01 provides more detailed guidance to assist in the compliance with parts of the HFS guidance GUID 5014 'Requirements for compliant CDUs' published in 2016.

The SHTM 01-01: 2018 series comprises of seven parts as follows:

- Part A – Management
- Part B – Test equipment/methods
- Part C – Sterilization by steam
- Part D – Automated cleaning and disinfection equipment
- Part E – Sterilization by Hydrogen Peroxide or Ethylene Oxide
- Part F – Inspect, Assemble and Package
- GUID 5017 supplement – Guidance for Service Users

The SHTM 01-01 series parts are concerned with decontamination of medical devices in a Central Decontamination Unit (CDU). This guidance covers decontamination of medical devices processed through a CDU. Examples of medical devices would include surgical instruments and robotic arm instruments which are sterilized using low temperature sterilization processes. The term medical device as used in the SHTM 01-01 series applies to those that are processed through a CDU. The supplement GUID 5017 considers preparation of soiled medical devices in the clinical area prior to their transport to the CDU.

SHTM 01-01 Part A content includes quality management, the decontamination process, general validation of equipment, health and safety, infection control precautions, regulatory framework, reporting incidents outbreaks and distribution of safety alerts, repair, refurbishment and quarantine of medical devices, functional roles and responsibilities, permit-to-work system, medical devices potentially contaminated with Transmissible Spongiform Encephalopathy (TSE) infectivity, disposal and metal recycling and procurement. A glossary for the series is provided in Part A. The European Union (EU) Regulation 2017/745 on medical devices and standard EN 17664: 2017 'Processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices' are also considered in Part A.

1. Introduction

1.1 The Glennie Report published under cover of Health Department Letter (HDL) Ref: HDL (2001) 66 in August 2001 set out a framework specifically related to technical and operational requirements for decontamination of Reusable Medical Devices (RMDs). Glennie Technical Requirements has promoted significant improvement in the decontamination of RMDs such as surgical instruments. However, the majority of reference documents stated in the Glennie Technical Requirements (GTRs) have now been superseded or no longer exist. For example the Quality Management System standard EN 46002 was replaced by EN 13485 in 2003. A stakeholder event held in July 2012 set priorities for the service. Feedback from the event included the need for risk assessments and a revision of the existing 2001 GTRs.

1.2 In 2007 Ross Scott of the Health Finance Directorate wrote on behalf of the Glennie Group to remind Health Boards of the importance of attaining and maintaining accreditation of the Central Decontamination Units (CDUs) in order that they were fully 'Glennie' compliant. It stated that this was a matter of patient safety. By ensuring that units were fully compliant it would reduce the risk of person to person transmission of variant Creutzfeldt-Jakob Disease (vCJD) via re-useable medical devices as well as supporting the routine aspects of infection control. To be fully compliant a CDU required to be in conformity with the 'Glennie Technical Requirements' (GTR) detailed in the Sterile Services Provision Review Group: First Report - The Glennie Framework, published in 2001 and accredited under the 2002 Medical Device Regulations. Accreditation under the regulation required a CDU to demonstrate compliance with the requirements of the Medical Device Directive 93/42/EEC - Annex V. This required both registration with the Medicines and Healthcare products Regulatory Agency (MHRA) for the range of products being produced and independent accreditation of their quality management system (ISO 13485), by a Notified Body.

1.3. Decontamination of medical devices is now governed by the Scottish Antimicrobial Resistance and Healthcare Associated Infection (SARHAI) Strategy Group which approved the 2016 publication “Requirements for compliant Central Decontamination Units “. It states that all Theatres and CDUs in Scotland should move towards the compliance requirements deemed to be best practice thus reducing risks to patient safety. The requirements cover facilities, equipment, management and process.

1.4 As a result of this continuous evolution of technical requirements since the publication of Scottish Health Technical Memoranda (SHTMs) 2010, 2030 and 2031 in 2001 and to facilitate greater alignment with similar guidance in UK administrations, it was proposed to revise the guidance for decontamination of medical devices processed in a Central Decontamination Unit (CDU). This guidance has a new reference number SHTM 01-01 which will be composed of seven parts.

1.5 This SHTM 01-01 series replaces sections of SHTM 2010, SHTM 2030 and 2031 that are applicable to medical devices processed through CDUs. This includes surgical instruments and other medical devices which are sterilized using low temperature sterilization processes. Other equipment not relevant to medical devices in the acute sector, such as laboratory sterilizers or medical devices requiring terminal chemical disinfection such as flexible endoscopes, are outwith the scope of the SHTM 01-01 series.

1.6 This guidance is applicable to the decontamination of medical devices such as robotic arm instruments used in robotics surgery. These medical devices present new challenges to the decontamination process. These challenges may impact across many stages of the decontamination process. The medical devices may have limitations on temperatures that prevent use of standard decontamination equipment such as thermal washer disinfectors and porous load sterilizers. Therefore new and dedicated facilities and staff may be required. New product labelling and release procedures may be required including the use of biological indicators applicable to the low temperature sterilization processes employed.

SHTM 01-01 series scope

1.7 This includes medical devices that are intended for reuse and require processing to take them from their state after clinical use to the state of being cleaned, disinfected (which may be the terminal stage) and sterilized, ready for their next use. This also includes some single use medical devices that are supplied non-sterile but are intended to be used in a clean, disinfected and sterile state and therefore will require processing prior to use.

Note 1: For the purposes of this series “medical device” is taken to mean as applicable both a reusable medical device and a single use medical device that is supplied non sterile to the CDU for processing once prior to use. The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

Note 2: Elements of the medical device decontamination process that are applicable to the clinical environment can be found in the supplement guidance GUID 5017– Guidance for Service Users. The guidance indicated that surgical instruments were medical devices.

Note 3: Refer to the Glossary in section 15 for further definitions.

Part A

1.8 Part A focuses on the management of the decontamination process within the CDU. This applies to those medical devices that are intended to be processed by the user or a third party to be made ready for use.

Part B

Part B covers equipment/methods used to test a range of parameters as applicable to the range of decontamination equipment.

Part C

Part C covers guidance on sterilization by steam employing a porous load sterilizer and associated steam plant.

Part D

Part D covers guidance on automated cleaning and disinfection equipment.

Part E

Part E covers low temperature sterilization processes (namely vaporized hydrogen peroxide and ethylene oxide sterilants).

Part F

Part F covers inspection, assembly and packaging of medical devices.

Supplement- GUID 5017

The supplement covers guidance for service users.

2. Quality management

2.1 Central Decontamination Units require to be managed in line with the Quality Management System (QMS) standard EN ISO 13485: 2016. The standard is titled 'Medical devices – Quality Management systems – Requirements for regulatory purposes'. The 2007 government letter (ref F750497) Ross Scott to NHS Board Chief Executives titled Central Decontamination Unit – Accreditation, stated that CDUs should be accredited to the standard using a Notified Body.

2.2 The 2016 version of the standard EN 13485 was harmonised as cited in the 17th Nov 2017 Official Journal of the European Union – "Commission communication in the framework of the implementation of the Council Directive 93/ 42/EEC concerning medical devices (Publication of titles and references of harmonised standards under Union harmonisation legislation) (Text with EEA relevance) (2017/C 389/03)".

2.3 CEN/TR 17223: 2018 provides guidance on the relationship between EN ISO 13485: 2016 (Medical devices – Quality management systems – Requirements for regulatory purposes) and the European Medical Devices Regulation.

3. Decontamination process applicable to the CDU

3.1 The following principles for medical device decontamination process compliment those specified in the HFS GUID 5014 'Requirements for compliant Central Decontamination Units' 2016.

The medical device manufacturers and the decontamination equipment manufacturers' instructions for use (IFUs) should be followed. Staff should complete competency training on the tasks they are assigned to including relevant decontamination policies and Standard Operating Procedures (SOPs).

Handling and storage of used medical devices by Central Decontamination Unit (CDU) staff should comply with HFS guidance 'Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use – GUID 5010 Part B: 2014 – Operational guidance'.

Process Stages

3.2 The following decontamination process stages, with their associated principles and references are summarised later, see Figure 1.

Preparation prior to Washer Disinfector

3.3 On receipt in the CDU, the medical devices should be tracked and checked as detailed in the tray-list and disassembled (if required), to remove items requiring separate processing.

Requirements for the preparation of the medical device prior to cleaning should be specified if applicable as per manufacturer's instructions for use.

A pre-cleaning method prior to use of the washer disinfector may be used when proven to be effective for difficult to clean instruments or as directed by the medical device manufacturer's instructions for use.

Cleaning – Manual and Ultrasonic

3.4 Manual and/or ultrasonic cleaning should only be employed when:

- required by the medical device manufacturer's instructions for use;
- compatible automated cleaning processes are not available;
- use of an ultrasonic irrigator is deemed to be necessary for some medical devices;
- the medical device is constructed of a lumen(s) and use of a jet gun may be required.

Cleaning and Disinfection in Washer Disinfector

3.5 Cleaning of the medical device removes contamination to the extent necessary for further processing. Disinfection is the process used to reduce the number of viable microorganisms (bioburden) on the medical device to a level as appropriate for its further handling. Cleaning and disinfection should be carried out using a validated automated process such as a thermal washer disinfector (WD) complying with EN ISO 15883 – 1: 2014 and 2: 2009, unless it is not in line with the manufacturers' IFUs.

Drying

3.6 Medical devices must be dried, before being placed in a sterile barrier package. The drying method employed should be rapid and reliable and should not contaminate the medical device with chemical, microbial or particulate contaminants. Generally medical devices should be dried as part of the washer disinfector cycle.

Inspection, maintenance & functionality testing

3.7 All cleaned and disinfected medical devices should be inspected for cleanliness, damage and where possible tested for functionality. Where advised by the manufacturer's instructions for use, medical devices should be lubricated.

Assembly

3.8 Prior to packaging, medical devices disassembled for cleaning and disinfection may require re-assembly after inspection. Some devices are left disassembled in the trayset. There should be detailed assembly instructions for each set. Each set should include a list of the contents (a specification) with appropriate fields for completion of pre and post operative checks by clinical users.

Packaging

3.9 Medical devices are required to be packed using an appropriate packaging system prior to the sterilization process.

The packaging system used should comply with standard EN 11607 part 1 and 2: 2014 (and EN 868 series 2017 where appropriate) to show compliance with the relevant safety and performance requirements of European Regulation (EU) 2017/745 and best practice guidance GUID 5010: 2014 – 'Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use'.

EN 11607 is the European standard on packaging for terminally sterilized medical devices. Part 1 describes the requirements for materials, sterile barrier systems and packaging systems.

Each packaged medical device should be clearly labelled in compliance with EN ISO 15223: 2016 with its contents and a reference from which the processing history can be traced.

Sterilization

3.10 All medical devices intended for use in invasive procedures should be sterilized using a validated sterilization process compliant with EN 556: Part 1: 2001. EN 556 is the European standard on sterilization of medical devices which specifies the requirements for medical devices to be designated “STERILE”.

Sterilization by steam using a porous load sterilizer is the preferred method when the medical devices are compatible. Manufacturers’ instructions for use should be followed.

Each sterilization process should be independently monitored to demonstrate that the process cycle conformed to validated parameters.

Each sterilization cycle should be reviewed and formally accepted as satisfactory before devices from that cycle are released as sterile and ready for use.

Process indicators compliant with EN 11140: Part 1: 2014 should be used and where applicable biological indicators compliant with EN 11138: Part 1: 2017.

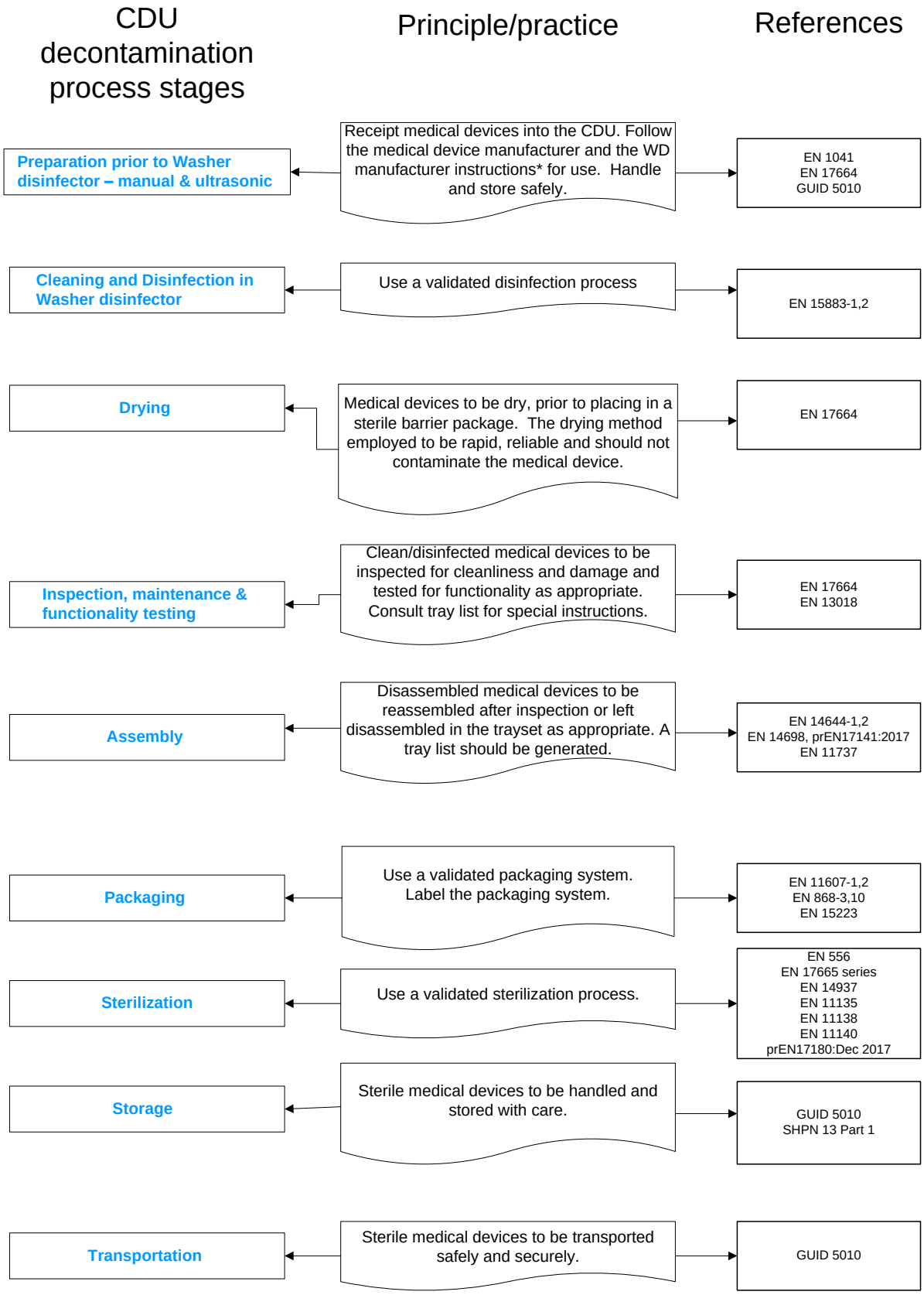
Storage

3.11 Sterile medical devices should be stored in a manner that will not compromise their quality including their sterility status.

Refer to Scottish Health Planning Note (SHPN) 13 Part 1: 2011 for sterile medical devices stored within a CDU and for sterile medical devices stored in a clinical setting refer to GUID 5010: 2014 – ‘Management of reusable surgical instruments during transportation, storage and after clinical use’.

Transportation

3.12 Sterile medical devices should be transported in a manner that will not compromise their quality including their sterility status. Refer to GUID 5010: 2014 – ‘Management of reusable surgical instruments during transportation, storage and after clinical use’.



* A written statement of compatibility may be required from the manufacturer

Figure 1: CDU decontamination process stages with their associated principles and reference standards

4. Validation/periodic testing of equipment used in the decontamination process

Validation

4.1 Validation is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

4.2 Validation is applicable to a wide range of equipment used in the decontamination process. This includes water systems, clean steam generation plant, heat sealers, containment cabinets, tracking systems, ultrasonic cleaners, washer disinfectors, sterilizers and packaging systems. Some examples of European standards that describe validation requirements will follow, see Figure 2. Specific validation requirements are given in Parts C to F within SHTM 01- 01.

4.3 Quality management system standard EN ISO 13485: 2016 states, 'the organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered'.

4.4 Validation should demonstrate the ability of these processes to achieve planned results consistently.

4.5 The organisation should document procedures for validation of processes, including:

- defined criteria for review and approval of the processes;
- equipment qualification and qualification of personnel;
- use of specific methods, procedures and acceptance criteria;
- as appropriate, statistical techniques with rationale for sample sizes;
- requirements for records;
- revalidation, including criteria for revalidation;
- approval of changes to the processes.

4.6 The organization should document procedures for the validation of the application of computer software used in production and service provision. This includes software for monitoring and measurement.

4.7 Such software applications should be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation should be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

4.8 The organization should document procedures for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barrier

systems should be validated prior to implementation and following product or process changes, as appropriate.

4.9 Records of the results and, conclusion of validation and necessary actions from the validation should be maintained.

Subject	Standard number	Title
Overall Quality Management System	EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory Purposes.
Packaging Systems	EN ISO 11607-2: 2006 +A1: 2014	Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes.
Sterilization by moist heat	EN ISO 17665-1: 2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
Sterilization by other methods	EN ISO 14937: 2009	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.
Thermal disinfection	EN ISO 15883-1: 2009 +A1:2014	Washer-disinfectors Part 1: General requirements, terms and definitions and tests.
Thermal disinfection	EN ISO 15883-2: 2009	Washer-disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
Sterilization by ethylene oxide	EN ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.

Figure 2: Examples of standards with defined validation requirements

4.10 Validation consists of tests performed by the manufacturer/supplier/manufacturer's agent or another Competent Person (Decontamination) defined as qualification exercises comprising of an installation, operational and performance qualification.

4.11 Works tests before delivery for some decontamination equipment are intended to verify that the equipment performs in conformity with the results obtained from type testing in respect of various critical attributes. For one-off designs, a more extensive programme of works tests, similar to the programme of type tests for machines in serial production, is required, and it is recommended that the purchaser arranges for their representative (either the AE(D), AP(D) or CP(D)) to attend the factory to witness these tests before accepting delivery of the decontamination equipment.

Installation qualification

4.12 Installation Qualification (IQ) is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

4.13 The supplier or agreed alternative should carry out the required installation checks on delivery of the decontamination equipment. This is to ensure that the machine has been supplied and installed correctly and is safe to operate. It should be provided with satisfactory services that do not impair the performance of the machine and that in operation the machine does not interfere with other equipment.

4.14 Ancillary equipment such as service supplies and ventilation systems should be checked by the contractor responsible for their installation.

4.15 When these checks have been completed and found satisfactory, the contractor should carry out the installation tests necessary to demonstrate that the decontamination equipment is working satisfactorily. Any assistance required from the purchaser should be agreed as part of the purchase contract.

Operational qualification

4.16 Operational Qualification (OQ) is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

4.17 When the decontamination equipment has been installed and accepted the CP(D) should carry out a sequence of operational performance tests to evaluate the basic performance and safety of the decontamination equipment.

4.18 The contractor responsible for installing the decontamination equipment should carry out any additional checks specified by the manufacturer.

Performance qualification

4.19 Performance Qualification (PQ) is defined as the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

4.20 PQ tests should be performed as part of the initial validation procedure, as part of any repeat validation procedure and whenever the User, judges that a new test is required. The performance qualification should consider the worst case scenarios in terms of challenge to the equipment/system being qualified.

4.21 Circumstances that might lead to new PQ tests would include changes to the quality of the water supply, to the process chemicals used in the cleaning and disinfection process, to the packaging system, to the loading system or the requirement to process a new type of product or packing arrangements for decontamination equipment etc.

4.22 The PQ should not be undertaken on any piece of equipment until the requirements of the installation and operational tests have been met.

4.23 Test data obtained from the PQ tests should be recorded in a written PQ report.

4.24 Within one month of the completion of the validation process the CP(D) should prepare a full validation report which should include:

- all the data supplied by the contractor, collected during the installation checks and tests with written confirmation that they meet the manufacturer's specification;
- written confirmation that the calibration of all measuring instruments fitted to the machine have been verified;
- all the data collected during the commissioning tests, with written confirmation from the CP(D) that they meet the specified requirements;
- data showing the correlation between the performance of the measuring instruments fitted to the machine and the test instruments used during commissioning and PQ;
- reports containing all the data collected during the PQ tests, with written confirmation from the CP(D) and the User;
- data from the instruments fitted to the machine, independent monitoring system data and validation instrument data, along with comments on any changes or adjustments made.

4.25 When data is in the form of electronic data files, the report should contain the data in a format compatible with local systems and storage policies.

4.26 The AE(D) should certify that all necessary tests have been carried out in accordance with standards and guidance and that the results were satisfactory.

4.27 The records of any microbiological tests should be signed by the Microbiologist or an accredited test facility.

4.28 The AP(D) or User should forward the completed validation report to the AE(D) for audit. The AE(D) should issue a report of findings to the User and any other persons as required within the organisation, the validation report should be returned to the User (via the AP(D) if local procedures dictate).

4.29 The validation report should be retained by the User. Copies may be retained as necessary by the CP(D), the AE(D), the AP(D), the Microbiologist and, where applicable, the Quality Manager.

Periodic testing of decontamination equipment

4.30 After validation the equipment should be subject to a schedule of periodic tests which may be daily, weekly, quarterly and yearly intervals. This provides evidence that the machine continues to operate within the limits established during commissioning. See the relevant parts of SHTM 01-01 Part C, D or E for the periodic test frequencies of decontamination equipment.

4.31 The User is responsible for ensuring the completion of periodic tests.

4.32 The yearly test schedule is a revalidation procedure and provides a more comprehensive test programme than the other periodic tests; it serves to demonstrate that data collected during commissioning and the PQ remain valid. Each sterilizer and washer disinfector should have a target date for annual validation. This date is determined by the User, which should be communicated to the CP(D), AP(D) and AE(D). When there is a delay in the completion of an annual revalidation test beyond the target date, it is User's responsibility to undertake a risk assessment with support from an AE(D) and AP(D). The risk assessment should consider the maintenance programme, the outcomes of other periodic testing (quarterly, weekly and daily tests) and other risks/issues emerging since the last annual validation.

Revalidation

4.33 Revalidation outwith the yearly test schedule may also be required under the following examples:

- when the equipment is to be returned to service after repair or component replacement of part of the systems that affect satisfactory attainment of the pre-set variables of the operating cycle;
- when the pre-set values of the cycle variables including the use of process chemical have been modified;
- when the software in a programmable electronic system (PES), used for control of the process, has been modified;
- whenever the User/AE(D)/AP(D) advises that revalidation is necessary:
- when the equipment fails a periodic test;
- where the results of the protein testing of medical devices are unsatisfactory;
- the equipment is modified to such an extent that it may be considered that the original data is no longer valid;
- the equipment has been moved and installed at a new site;
- the machine has been dismantled or extensively overhauled;
- revalidation fails to confirm compliance with the original data and no cause for the discrepancy can be found;
- there have been parameter changes such as to the pre-set values of the cycle variables;
- a new packaging system has been introduced that may require alteration of the configuration of the machine to ensure attainment of process requirements.

4.34 The full revalidation procedure is identical to that specified for the yearly test.

4.35 It will not always be necessary to carry out a full revalidation, and the advice of AE(D) should be sought on which tests are required following any particular event.

4.36 There are occasions when it might be necessary to repeat the full set of tests carried out during the initial validation in order to obtain a new set of data.

4.37 Failure of a test generally indicates that the equipment is not working to specification; it should be withdrawn from service and the failure investigated in line with the quality management system.

4.38 The AE(D)/AP(D) and the User should agree the course of action to be taken.

4.39 The User has the ultimate responsibility to ensure that decontamination equipment is fit for use.

5. Health and safety

5.1 The standards of health and safety are delivered through a flexible enabling system introduced in 1974 by the Health and Safety at Work Act 1974. Other legislation that follows this principal act includes:

- Confined Spaces Regulations 1997;
- The Carriage of Dangerous Goods and Use of Transportable Pressure; Equipment Regulations 2004;
- Control of Noise at Work Regulations 2005;
- Control of Substances Hazardous to Health (COSHH) Regulations 2002;
- Controlled Waste Regulations 1992. SI 1992 No 588;
- Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002;
- Disability Discrimination Act 1995 and amendments 2005;
- Electricity at Work Regulations 1989;
- Electricity Safety, Quality and Continuity Regulations 2002;
- Electrical Equipment (Safety) Regulations 1994;
- Electromagnetic Compatibility Regulations 1992;
- Employers Liability (Compulsory Insurance) Regulations 1998;
- Environment Protection Act 1990;
- Furniture and Furnishings (Fire) (Safety) Regulations 1988;
- Gas Appliances (Safety) Regulations 1995;
- Gas Safety (Installation and Use) Regulations 1998;
- Health and Safety (Display Screen Equipment) Regulations 1992;
- Health and Safety (Safety Signs and Signals) Regulations 1996;
- Low Voltage Electrical Regulations 1997. HMSO, 1997;
- (The) Management of Health and Safety at Work Regulations 1999;
- Manual Handling Operations Regulations 1992;
- Personal Protective Equipment Regulations 2002;
- Plugs and Sockets etc (Safety) Regulations 1994;
- Pollution Prevention and Control (Scotland) Regulations 2000;
- Pressure Equipment Regulations 1999;
- Pressure Systems Safety Regulations 2000;
- (The) Provision and Use of Work Equipment Regulations 1998;
- Producer Responsibility Obligations (Packaging Waste) Regulations 2005;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations;1995 (RIDDOR 95);

- (The) Regulatory Reform (Fire Safety) Order 2005;
- Simple Pressure Vessels (Safety) Regulations 1991;
- (The) Special Waste Regulations 1996;
- Supply of Machinery (Safety) Regulations 1992.

5.2 The Health and Safety at Work Act 1974 leaves employers freedom to decide how to control the risks which they identify, that is, to look at what the risks are and to take sensible measures to tackle them. The Act is part of criminal law, and enforcement is by the Health and Safety Executive and Local Authority. Successful prosecution can result in fines or imprisonment. SHTM 00 Best practice guidance for healthcare engineering Policies and principles 2013 provides further advice in its section 3 on statutory requirements.

5.3 Employers have a responsibility to ensure Health and Safety measures are in place. They should also ensure that arrangements are in place to obtain competent health and safety advice.

6. Infection control precautions

6.1 All organisations should have medical device decontamination as part of the Board's Healthcare Associated Infection (HAI) governance structure. This may include for example an Area Infection Control Committee and an Infection Prevention and Control Senior Management Team (IPCSMT). The detailed agenda for medical device decontamination maybe devolved to a stand-alone Decontamination sub-group within the organisations Clinical Governance structure or form part of the IPCSMT agenda. Consult the National Infection Prevention and Control Manual (http://www.nipcm.scot.nhs.uk).

Procedures should be in place for items not in the manual such as safer final disposal of instruments (end of instrument life) and risk assessments for procedures used in the reprocessing of medical devices.

6.2 Management and disposal of clinical waste should be in line with Scottish Health Technical Note (SHTN) 3: 2017.

Infection Prevention and Control Teams (IPCTs)

6.3 IPCTs can give advice on:

- local policies on recommended disinfectants, their application, use, storage and disposal;
- risk assessments for procedures used in the reprocessing of medical devices;
- spillage procedures;
- environmental audits using national/local audit tools;
- guidance on many of these items can be found in the Scottish National Infection Prevention and Control Manual;
- assessing the infection risk of new and novel invasive medical devices.

6.4 Boards should comply with the mandatory Surgical Site Infection (SSI) surveillance programme as outlined in HDL(2001) 57 'A framework for national surveillance of hospital acquired infection in Scotland'. A source for healthcare guidance is the compendium of Healthcare Associated Infection Guidance.

7. Regulatory framework

7.1 The regulatory framework for medical device decontamination services in Scotland is illustrated, see Figure 3. Regulation (EU) 2017/745 on medical devices entered into force in 2017. Regulation (EU) 1025/2012 defines the concept of a harmonised standard. The regulation (EU) 2017/745 under article 8 defines the use of harmonised standards as applicable to medical devices. Annex 1 of (EU) 2017/745 establishes General Safety and Performance Requirements (GSPRs). As at 2018 the harmonised standards relate to conformity with the requirements of the Directive 93/42/EEC.
EU 2017/745 Article 8 **Use of harmonised standards** indicates devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the*

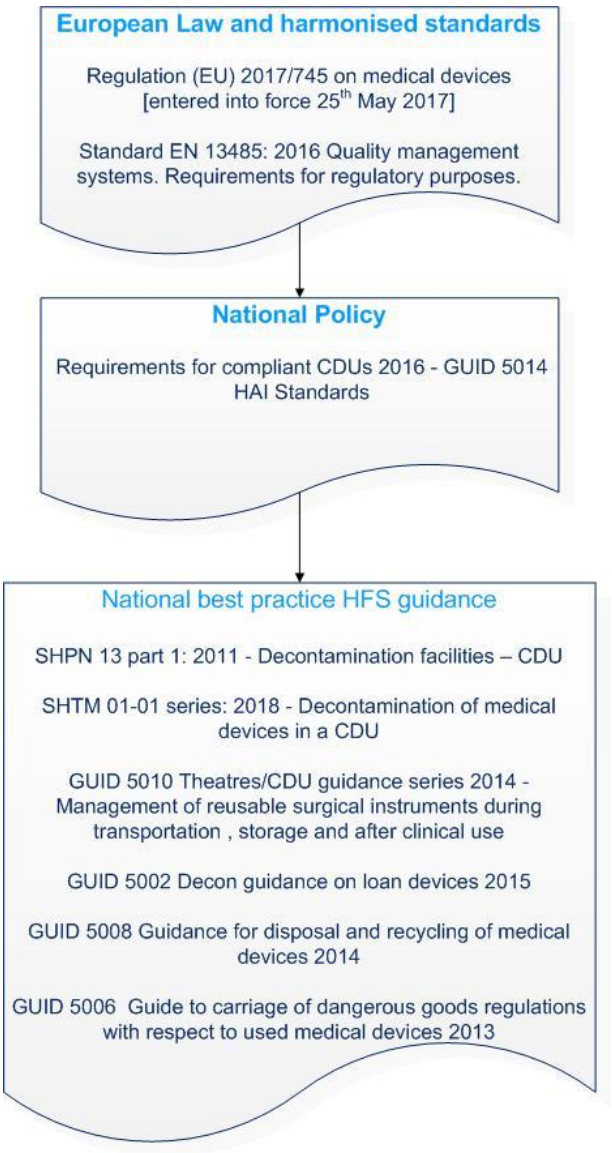


Figure 3: regulatory framework for medical device decontamination

European Union, shall be presumed to be in conformity with the requirements of the Regulation covered by those standards or parts thereof.

8. Reporting incidents outbreak and distribution of safety alerts

Introduction

8.1 All NHS Boards are required to have suitable arrangements in place for the safe provision and use of medical devices.

8.2 In EN ISO 13485: 2016 Section 8.2.3 Reporting to regulatory authorities it states, “If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.”

8.3 All adverse events/incidents, regardless of their nature, should be managed effectively through reporting, review and improvement planning. The National Framework for Learning from Adverse Events published by Healthcare Improvement Scotland (HIS) in September 2013 supports NHS boards to standardise processes of managing adverse events across all care settings in Scotland.

8.4 Examples of incidents to be reported are:

- where there is a failure to properly decontaminate a medical device;
- where the medical device manufacturer’s instructions for use are inadequate;
- where there is danger to personnel;
- where there is damage to the product;
- where there is a faulty supply of devices or equipment or software.

Adverse incident reporting procedures

8.5 The User should be familiar with the reporting procedures set out by the Incident Reporting and Investigation Centre (IRIC).

Advice on how to report adverse incidents and the forms required can be found on the IRIC website:

http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/how-to-report-an-adverse-incident/

8.6 IRIC is a part of NHS National Services Scotland (NSS) who manages the national adverse incident system and cascades safety warnings for medical devices and equipment. These systems cover services provided by NHS Boards, local authorities, partnership organisations and contractors.

Safety Alerts

8.7 The IRIC has a partnership arrangement for producing Medical Device Alerts (MDAs) and Estates & Facilities Alerts (EFAs). Once issued, they are adopted and cascaded in all four health systems across Scotland, England, Northern Ireland and Wales. The IRIC may also publish Safety Action Notices and Hazard Notices for Scotland.

8.8 Organisations should ensure Equipment Co-ordinators are in place, supported strategically and that there is continuity of cover. They should review the effectiveness of local and national incident reporting procedures annually and ensure systems are in place for monitoring trends and sharing learning. Additionally, they should review the effectiveness of safety warning cascade systems annually and that actions have been taken to mitigate the risks.

9. Repair, refurbishment and quarantine of medical devices

Repair and refurbishment

9.1 The Health Boards' medical device management system should cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment. The organisation is responsible for ensuring that their medical devices are maintained and repaired appropriately.

9.2 The frequency and type of planned preventive maintenance should be specified, in line with the manufacturer's instructions for use and taking account of the expected usage and the environment in which it is to be used.

9.3 Audits should be undertaken on all elements of maintenance and repair including keeping of records to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

9.4 The Health Boards should also ensure that there is a mechanism to obtain regular feedback from all service users of the device on the repair and maintenance process. This should include the reporting of even apparently minor non-conformances as these might lead to major failure unless remedied.

9.5 Ensure that devices are regularly checked for functionality prior to use by the service user in line with the manufacturer's instructions for use and throughout the expected lifetime of the device.

9.6 If using a third party organisation ensure there is an agreed specification regarding the level and extent of work to be undertaken and the quality of replacement items. There may be a need to consider specifying the use of Original Equipment Manufacturer (OEM) parts.

9.7 The Medicines and Healthcare Regulatory Agency (MHRA) produced 'Managing Medical Devices' April 2015 which stated the following:

Recommendations on maintenance and repair as follows:

- all medical devices and items of medical equipment are to be maintained and serviced in line with the manufacturer's service manual and advice from external agencies e.g. Medical Device Alerts;
- maintenance and repair providers preferably have a certified quality management system;
- audit and user feedback systems are in place to frequently review the processes, policies and contracts;
- all staff involved in maintenance and / or repair are appropriately trained and qualified;

- spare parts are of the correct specification and their quality and compatibility match those supplied by the OEM;
- maintenance procedures are in line with manufacturer's maintenance instructions and timescales;
- all medical devices returned for servicing and repair are properly decontaminated and a decontamination certificate produced;
- where appropriate, ensure the handover procedure is completed;
- organisations carrying out repairs and maintenance have adequate indemnity insurance.

A number of considerations should be made when appointing repair and maintenance organisations, see Figure 4.

Question	Note
Who will undertake repairs and maintenance?	e.g. the manufacturer, an authorised service agent, in-house device engineers or a combination of several.
Can the chosen party correctly maintain the device and obtain the necessary spare parts?	
How will the proposed contract or service level agreement deal with continuity of care? For example: on site repair, if needed.	
Are alternative devices available to cover periods when a device is being repaired or serviced?	
Are response times appropriate and guaranteed?	
What are the proposed servicing intervals?	Consider the types of checks and calibrations required between servicing intervals.
What information is available from the device manufacturer	e.g. circuit diagrams, preventive maintenance schedules, trouble-shooting guides, repair procedures, parts list, and special tools list in order to support third party organisations or in-house engineers.
Does the preferred supplier hold the necessary accreditation/certification to undertake the work?	For some medical devices EN ISO 13485 might be required. As a minimum EN ISO 9001 should be expected as an indication of reliability and consistency.
Does the preferred supplier have a proven track record? Do you already have a good working relationship?	
Does the preferred supplier have adequate indemnity insurance?	

Figure 4: Questions to consider when appointing repair and maintenance organisations

Sending medical devices for repair or refurbishment

9.8 Ensure that the medical device is decontaminated to an appropriate level before despatch, packed securely and accompanied by a decontamination certificate stating

the method used, see Figure 5. The decontamination process should not cause further damage. However, the emphasis should always be on presenting a medical device which is as safe as possible to handle on receipt. Consult the repair organisation or investigating body if there is any doubt. As a minimum, the external surfaces should be wiped clean, the device packaged securely and a full explanation given on the accompanying decontamination certificate. Consult HFS 2013 guidance "Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices".

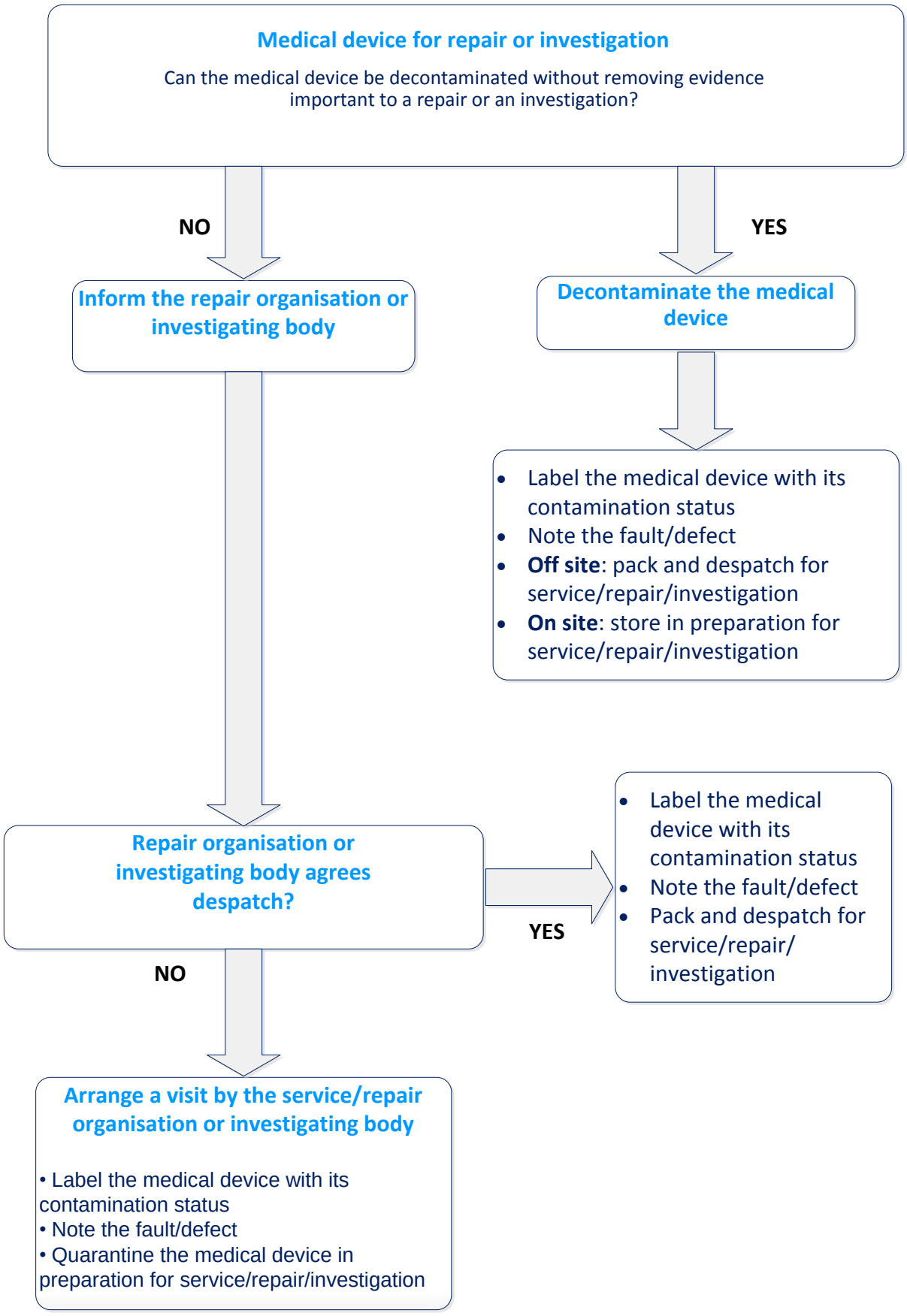


Figure 5: Assessing actions for repairing the medical device

Quarantine of medical devices

9.9 Medical devices that are worn, damaged, or require a scheduled service should be quarantined pending the repair, replacement or service.

Quarantine areas should be clearly marked as such and there should be no confusion as to the fact that it is used for storing non-conforming product or devices.

CJD/vCJD quarantine of medical devices

9.10 Part 4 and Annex L of the guidance from The Advisory Committee on Dangerous Pathogens (ACDP), The "Transmissible Spongiform Encephalopathy (TSE) Working Group allows for the quarantining of medical devices that have been used for procedures involving tissues designated as high or medium infectivity, on patients either:

- with, or at increased risk of, CJD/vCJD, for reuse exclusively on the same patient; or
- with a possible CJD/vCJD diagnosis, pending a confirmed diagnosis.

Although it is not expected that this facility will need to be used widely, Annex E August 2016 of the document provides guidance on the procedures which should be followed when quarantining medical devices at the point of use.

ACDP TSE guidance can be found at:

https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

Refer to GUID 5017: 2018 – 'Guidance for Service Users' for more information on quarantining medical devices.

10. Functional responsibilities - roles and responsibilities

Purpose/Scope

10.1 This section is intended to define the roles and responsibilities of NHSScotland decontamination staff working in the acute sector. It supersedes the defined roles and responsibilities in Scottish Health Technical Memorandum (SHTM) 2010 and SHTM 2030 published in 2001 and the interim HFS guidance GUID 5015:2017 - Roles and responsibilities of NHSScotland Decontamination Engineering staff in the acute sector.

Note: As per the government letter of 21 May 2018 from the Chief Nursing Officer Division, the Cabinet Secretary for Health and Sport agreed that Decontamination Professionals would be formally recognised as coming under the Healthcare Science framework in Scotland from May 2018.

Principles

- staff undertaking decontamination and management of decontamination should be able to demonstrate their competencies and training in the areas in accordance with their roles and responsibility;
- the roles and responsibilities of decontamination staff should be clearly defined and documented;
- decontamination staff should be encouraged to get involved in decontamination activities to demonstrate their competency in line with the NHS Education for Scotland (NES) staff competencies as outlined in the their 2016 publication 'Framework to support staff development in the decontamination of re-usable medical devices';
- each NHSScotland Board should have a governance structure in place which supports the reporting and escalation of any failures to comply with this guidance document.

Management

10.2 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.

Executive Manager

10.3 The Executive Manager has ultimate management responsibility, including allocation of resources and the appointment of personnel for the organisation in which the decontamination equipment is installed.

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

Infection Control Manager

10.4 The Infection Control Manager (ICM) role is being reviewed at the time of publication.

Decontamination Lead

10.5 Every healthcare organisation e.g. the Health Board should have a nominated Decontamination Lead.

The Decontamination Lead is responsible for:

- providing effective and technically compliant decontamination services;
- implementing an operational policy for decontamination;
- ensuring 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;
- monitoring the implementation of the operational policy for decontamination services;
- delegating 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.

Designated Person

10.6 The Designated Person is responsible for:

- providing the essential senior management link between the organisation and professional support;
- providing an informed position at board level;
- working closely with the senior operational managers to ensure that provision is made to adequately support the decontamination system.

The Boards will decide on the need for this role. The Decontamination Lead may also have this role.

Surgical Instrument Manager/Coordinator

10.7 The Surgical Instrument Manager/Coordinator is designated as the person assuming responsibility for coordinating medical devices activity between the theatre, decontamination and supply / purchase teams. The person fulfilling this role should also ensure that the inventory of medical devices is proactively reviewed and managed in accordance with best practice decontamination guidance.

User

10.8 The User is defined as the person designated by the Executive Manager to be responsible for the management of the process. The User is also responsible for the Operators. In the acute sector the User could be a Sterile Services Manager.

The principal responsibilities of the User are as follows:

- to certify that the decontamination equipment is fit for use;
- to hold all documentation relating to the decontamination equipment, including the names of other key personnel;
- to ensure that decontamination equipment is subject to periodic testing and maintenance;
- to appoint operators where required and ensure that they are adequately trained;
- to maintain production records;
- to establish procedures for product release in line with the quality management system where applicable;
- 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.

Authorising Engineer (Decontamination)

10.9 The Authorising Engineer (Decontamination) (AE(D)) is defined as a person assigned to the organisation to advise on decontamination procedures, washer-disinfectors, sterilizers and associated sterilization procedures. The AE(D) is also responsible for reviewing and witnessing local Health Board documentation on validation.

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.

The AE(D) should provide professional and technical advice to the Authorised Person Decontamination (AP(D)), Competent Person Decontamination (CP(D)), Decontamination Lead, Users and other key personnel involved in the control of decontamination processes within NHSScotland healthcare facilities.

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

- to provide decontamination management and operational decontamination staff with general and impartial advice on all matters concerned with decontamination and on programmes of validation and testing;
- to audit reports on validation, revalidation and yearly tests submitted by the AP(D);
- to advise decontamination management and operational decontamination staff on programmes of periodic tests and periodic maintenance;
- to advise decontamination management and operational decontamination staff on operational procedures for routine production;

- to advise decontamination management on the appointment of the AP(D) and provide technical advice on purchasing and selection of equipment.

Authorised Person (Decontamination)

10.10 The Authorised Person (Decontamination) (AP(D)) should have technical knowledge and be appointed by the Health Board's Executive manager in conjunction with the advice provided by the AE(D). The AP(D) is responsible for the practical implementation and operation of procedures relating to the engineering aspects of decontamination equipment including the operation of the permit to-work system.

The role of AP(D) is intended to provide the organisation with an individual who, as part of the local board management infrastructure, will provide day-to-day operational management responsibility for the safety of the system. This should be an internal appointment from within the organisation. The role of the AP(D) can vary between Health Boards and is determined by the amount of decontamination equipment the individual will be responsible for. For example;

- 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 some organisations there is not enough decontamination equipment to warrant a full time AP(D). Here the role of the AP(D) would 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;
- larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role;
- some 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). Even where estates roles are contracted out, it is recommended that the AP(D) function remains the responsibility of the healthcare organisation.

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. The AP(D) should report to the Designated Person.

The AP(D) will also be responsible for:

- the engineering management of reusable medical device decontamination equipment;
- line management and/or appointment of the CP(D);
- the safe and effective systems of work for all installed decontamination equipment within their area of responsibility;
- the acceptance criteria for operational and performance testing of all installed decontamination equipment;

- liaison with the AE(D), Decontamination Lead and other decontamination stakeholders;
- authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests.

Competent Person (Decontamination)

10.11 The Competent Person (Decontamination) (CP(D)) is defined as a person designated by the AP(D) to carry out maintenance, validation and periodic testing of washer-disinfectors, sterilizers and endoscope washer disinfectors.

The principal responsibilities of a CP(D) are:

- to carry out maintenance tasks;
- to carry out repair work;
- to conduct validation tests and periodic tests as specified in Scottish Health Technical Memoranda (SHTMs) and relevant European standards;
- to witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory, and should arrange for test loads to be supplied as required.

It is recommended that an individual CP(D) does not carry out all 3 quarterly tests & the (re)validation test on a particular piece of equipment in a calendar year.

Infection Control Doctor/ Microbiologist (Decontamination)

10.12 The Infection Control Doctor/Microbiologist (Decontamination) is defined as a person designated by Executive management to be responsible for advising the User on all clinical infection control aspects of the decontamination of reusable medical devices.

Operator

10.13 The Operator is defined as a person with the authority to operate decontamination equipment in processing of medical devices.

All Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent at undertaking their assigned tasks. See the NES 2016 publication ‘Framework to support staff development in the decontamination of re-usable medical devices’.

Competent Person (Pressure Systems)

10.14 The Competent Person (Pressure Systems) (CP(PS)) is defined in the Pressure Systems Safety Regulations 2000 and is a chartered engineer responsible for drawing up a written scheme of examination for the system e.g. porous load sterilizers.

Most insurance companies maintain a technical division able to advise on appointing a CP (PS).

Each NHSScotland Health Board should have a governance structure in place which supports the reporting and escalation of any failures to comply with this guidance document.

11. Permit-to-work system

11.1 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, the Central Decontamination Unit (CDU) should operate a 'permit-to-work' system. This is to ensure that equipment such as Washer Disinfectors (WDs) and sterilizers are declared safe (or identify hazards present) to undertake repairs, maintenance and validation and that personnel working on them have documented authority to do so.

Note: Decontamination equipment may have inherent dangers when handed over to the CP(D) for repair, fault-finding or testing. These dangers will include burns and scalds, pressure and electrical energy with possible microbiological and or chemical contamination. Therefore, the equipment cannot be safe to work on as would be expected on a safety Permit to Work. These dangers will require the CP(D) to take appropriate precautions, for example, the use of PPE.

11.2 The permit-to-work system should be introduced for all decontamination equipment that is used in the CDU.

11.3 The AE(D) 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.

11.4 The User should sign the permit to allow the equipment to be taken out of use prior to the commencement of work by the CP(D) and either declare it safe or state the precautions required to protect the CP(D) from biological or chemical contaminants. Once the work is completed, the CP(D) should sign the permit to advise the User that the equipment is fit for use. The User should then sign the permit to allow the equipment back into use.

11.5 The AP(D) and the User should sign the permit to allow the equipment back into use after quarterly or annual validation tests.

11.6 In the event of work spanning a number of shifts or days, the signatures of all the CP(D)s involved should show continuity.

11.7 When particular requirements dictate (for example, when testing involves using biological indicators), other personnel should sign the permit, for example the Microbiologist (Decontamination).

11.8 When the User is unavailable, for example during an evening shift or whilst on leave, a nominated deputy can be authorised to sign the permit in their absence. However, those deputising should be made aware of the responsibility they are undertaking to declare the equipment safe (or identify hazards present) for the CP(D) to work on and, at the completion of work, safe for the equipment to return to service.

11.9 The AE(D) should formally audit the permit-to-work system records with the AP(D) at periodic intervals.

12. Management of medical devices potentially contaminated with transmissible spongiform encephalopathy (TSE) infectivity

12.1 The Creutzfeldt-Jakob Disease (CJD) risk categorisation, (see Figure 6) and deadlines for compliance were amended in HDL (2003)42 and updated in response to the Advisory Committee on Dangerous Pathogens (ACDP) guidance (Annex A.1 July 2015). The Glennie "procedure-specific" risk categorisation did not preclude the need to assess the "patient-specific" risk in accordance with the guidance of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee, "Transmissible spongiform encephalopathy agents: safe working and the prevention of infection" (Annex A1). 'Risk' is a widely used term, it is important to distinguish between high-risk procedures/tissues and high-risk patients. The technical requirements for Glennie high and medium risk procedures are such that these are achieved only in Central Decontamination Units (CDUs).

Clinical procedures: Categorisation by risk for ALL types of CJD
High Risk: All procedures that involve piercing the dura[1], or contact with the pituitary gland, cranial ganglia, intracranial components of the cranial nerves and specifically the entire optic nerve. Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve.
Medium Risk: Spinal ganglia. Procedures involving contact with lymphoreticular system (LRS) i.e., lymph nodes and other organised lymphoid tissues containing follicular structures. Gut-associated lymphoid tissue, adrenal gland, spleen, thymus and tonsil. Anaesthetic procedures that involve contact with LRS during tonsil surgery (for example laryngeal masks). Procedures in which biopsy forceps come into contact with LRS tissue. Procedures that involve contact with olfactory epithelium.
Low Risk: Anterior eye and cornea Peripheral nerves, skeletal muscle, blood and bone marrow. Placenta and urine. Dental pulp and gingival tissue. All other invasive procedures including other anaesthetic procedures and procedures involving contact with the cerebro-spinal fluid.

Figure 6: Glennie "procedure-specific" CJD risk categorisation linking to technical requirements for decontamination processes

12.2 [1] Dura mater is designated low infectivity as virtually no detectable abnormal prion protein has been found in cases of CJD. However, as grafts of these tissues are associated with CJD transmission, probably as a result of contamination by brain and because of the lengthy period of implantation in the Central Nervous System (CNS), procedures conducted on intradural tissues (i.e. brain, spinal cord and intracranial sections of cranial nerves) or procedures in which human dura mater was implanted in a patient prior to 1992, remain high risk.

12.3 Figure 6 is updated and modified from the original 2001 Glennie Technical Requirement's table. Modifications are based on the ACDP Annex A1 (as update

July 2015). Source: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group#history

12.4 This SHTM takes account of changes to the 2015/2016 Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup's general principles of decontamination and standards on washer-disinfectors for medical devices linked to improving cleaning performance. Residual protein as a marker for medical device cleanliness is important because of the continuing risks of transmission of prions (the causative agent of transmissible spongiform encephalopathies such as variant Creutzfeldt-Jakob disease (vCJD)). (PHE: Health Protection Report: Weekly Report: 10(26) Aug 2016).

12.5 This guidance provides information on how Central Decontamination Units can mitigate the risk to patients. In line with previous government programmes for risk reduction in decontamination the priority will be with devices categorized as highest risk for CJD followed by medium and low risk for CJD. The requirements linked to cleaning efficacy monitoring are in addition to CDUs meeting the Requirements for compliant Central Decontamination Units published by HFS 2016. The ambition is that all medical devices involved in CJD high and medium risk procedures will be able to demonstrate appropriate objective quality assurance and quality control data indicating cleanliness of medical devices in accordance with ACDP TSE requirements.

Refer to the Appendix for further information on human prion disease.

Cleanliness of medical devices

12.6 The standard EN 15883-1: 2014 – "Washer-disinfectors Part 1: General requirements, terms and definitions and tests" defines cleaning as "removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use." When defining cleanliness states of invasive medical devices, there must be a link between performance requirements and test method criteria for determining cleaning efficacy in washer disinfectors (EN ISO 15883 series) and pass/fail criteria for reprocessed medical devices. Failure to link these two processes will lead to operational difficulties in achieving medical device cleanliness outcomes. This link should be established during the commissioning process of the washer disinfector commencing with witnessed type testing and followed through to performance qualification and subsequent periodic testing.

12.7 Protein levels are used as an indication of the amount of prion protein contamination and have been used in previous risk assessment for potential risk of iatrogenic CJD transmission (DOH Risk Assessments for vCJD and surgery 2001 & 2005).

ACDP TSE Requirements for decontamination of medical devices

12.8 The ACDP TSE Feb 2015 guidance (Part 4: 4.51 and Annex C: C3-4 and C21-22) indicates: "Effective decontamination of medical devices is key to reducing the risk of transmission of CJD through surgery. TSE agents are particularly resistant to standard physical and chemical methods of inactivation and decontamination. Therefore, effective cleaning is of great importance in the removal of these agents. Research demonstrates that allowing surgical instruments to dry for more than fifteen

minutes before reprocessing greatly increases the amount of residual protein contamination. Protein levels are used as an indication of the amount of prion protein contamination. It is necessary to use protein detection methods to check for the efficient removal of protein from medical devices after processing."

12.9 The ACDP committee considering Transmissible Spongiform Encephalopathies (TSE) established acceptable protein limits on medical devices.

12.10 The ACDP-TSE 2015 guidance annex C indicates "the upper limit of acceptable protein contamination after processing is 5µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments".

12.11 The ACDP rationale is as follows:

- The figure of 5µg of protein had been shown during a pilot trial to be achievable by effective cleaning processes;
- The measurement is per side of instrument rather than per unit area of an instrument. Prion proteins have been shown to be infectious by contact (Flechsig et al 2001; Kirby et al 2012). Infection transmission would be related to the total area of an instrument that makes contact with patient tissues. Thus, while not a perfect relationship, the assessment of protein levels per side of an instrument is likely to be a greater predictor of risk control than an assessment based on a unit area of an instrument. (AAMI TIR 30:2011; Alfa & Olson 2016; Cronmiller et al 2006; Kruger 1997; Pineau & De Philippe 2013; US DoH & FDA 2015.

12.12 To clarify the ACDP - TSE February 2015 annex C requirement as stated (in 12.10) above, a number of definitions were developed by the SHTM 01-01 working group as follows:

- 'after processing' in this occasion only is deemed to be after disinfection and not after sterilization of the medical device;
- 'per instrument side' is deemed to be a single side of the medical device;
- 'instrument side' is deemed to be the exposed surface of the medical device when looking down from above when the medical device is placed on a horizontal surface.

Methods to reduce protein levels

Reducing the time from close of procedure to reprocessing

12.13 Proteins are easier to remove if they have not dried onto the surface of a medical device (Lipscomb et al 2007; Secker et al 2011; Secker et al 2015). To enable efficient protein removal, theatre and CDU staff should ensure that medical devices are transported to the CDU 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 medical devices.

12.14 ACDP TSE Annex C 2015 section C4 states "research indicates that allowing surgical instruments to dry for more than fifteen minutes before reprocessing greatly increases the amount of residual protein contamination. Improved cleaning efficiency

of medical devices will also be aided by manual wiping of medical devices as part of good theatre etiquette. Reducing the wait times between use and loading into the CDU washer disinfector are also key quality performance indicators that help the cleaning efficacy and CDUs and theatres should undertake regular audits of return times to the CDU.

Keeping medical devices moist between use and reprocessing

12.15 If devices cannot be returned in a timely manner, it is important that the medical devices are kept moist using appropriate methods approved and verified by the CDU. Refer to GUID 5017: 2018 - Guidance for Service Users for more information on quarantining medical devices.

12.16 After use medical devices sets that have been allowed to dry out are more difficult to clean. Maintaining the environment around soiled medical devices in a moist atmosphere significantly assists the cleaning process (Secker et al 2011; Secker et al 2015 & Smith et.al. 2018).

Optimisation of Washer disinfectors

12.17 Ensure that during procurement the washer disinfectors requested is specified to deliver the required cleaning level to meet the ACDP guidance on prion proteins. The washer disinfector performance requires to be verified before buying/installing.

12.18 Validation of the WD should consider the worst case scenario as regards the load placed in the WD and its configuration. The WD load conditions in production should not be a greater challenge than that validated.

12.19 Validation of the WD should aim to achieve a lower level of protein on the processed medical devices meeting the requirements of 5µg protein (BSA) limit per instrument side as set in the ACDP TSE 2015 Annex C guidance. Cleaning efficacy is determined by visual examination and by use of protein detection methods listed in NP 187. Protein testing should be undertaken by trained staff in accordance with the relevant standard operating procedure.

12.20 The cleaning performance of washer disinfectors (WDs) should be optimised by considering a range of parameters including water, detergents, cycle time etc. It should be noted that research undertaken by Lee Palmer demonstrated the impact of water temperature at the prewash stage on the cleaning performance of the WD. The research indicated there was an optimal range in the pre-wash stage temperature.

Operation of the WD

12.21 Once validation of the WD is complete the use of the WD in production cycles should be in compliance with those validated load conditions. I.e. no overloading and allow effective contact of the cleaning solution with all surfaces of the medical devices.

Pre-cleaning

12.22 If all previous methods (12.13 to 12.21) once tried, do not reduce the protein to the required limit, introducing pre-cleaning for medical devices should be considered.

12.23 A study conducted by S. Murphy in 2015 titled “Comparative study of pre-cleaning methodologies on the cleaning efficacy of challenging surgical instruments” concluded that manual cleaning of medical devices, prior to placing in the WD, although challenging, was likely to be effective in helping CDUs meet the ACDP TSE 2015 requirements.

Quality Assurance exercise for testing the protein levels on RMDs

Method of protein testing

12.24 Standard Operating Procedures (SOP) will be published for each test method. Adherence to the SOP and staff competency will influence the results of the protein test.

12.25 This single test exercise requires a minimum of triplicate testing of the reusable medical devices to demonstrate consistency. Test requirement - Sample 50 medical devices per washer disinfector in a quarter (13 week period). Repeat this twice more over the year giving a total of 150 medical devices tested per washer disinfector. The protein testing of medical devices may be carried out weekly over a 13 week period (totalling 50 medical devices) to give a better understanding of the ongoing washer disinfector performance. The test process (see Figure 7) should be carried out using a protein detection test in the NP 187 contract on medical devices with the most challenging surfaces i.e. those with crevices, hinges or large surface areas etc.

.12.26 Ninhydrin swab kits are commonly used for protein detection, but recent evidence shows that ninhydrin is insensitive (Nayuni et al 2013). Subsequent test carried out by HFS suggested there are other non-ninhydrin swabbing systems that have comparable sensitivity to that of the scanning technique tested (Holmes, et al., 2017). The study leads to the selection of recommended test methods as listed in NP 187. Staff training and adherence to the manufacturer’s instructions/Standard Operating Procedure contributes to the accuracy of measurement, especially for swabbing techniques. For example, incubation temperature, amount of reagent, contact time and interpretation of colour changes etc.

12.27 To clarify the ACDP - TSE February 2015 annex C requirement stated previously (in 12.10), a number of definitions are given as below:

- ‘after processing’ in this occasion only is deemed to be after disinfection and not after sterilization of the medical device;
- ‘per instrument side’ is deemed to be a single side of the medical device;
- ‘instrument side’ is deemed to be the exposed surface of the medical device when looking down from above when the medical device is placed on a horizontal surface.

Interpretation and reporting results

12.28 Refer to the SOP for interpretation of colour change if testing using a swab. On completion of the exercise a report should be submitted to HFS containing the full results of the protein monitoring exercise.

Repeat tests

12.29 Consult the flow chart Figure 7 (Test process method when measuring residual protein) for the steps to be taken in the case where test samples results do not meet the target level. The corrective actions should be noted along with any repeat test sample results.

12.30 As shown in Figure 7, if after consultation with the AP(D) and AE(D) a revalidation test of the WD is considered necessary, then subsequently further protein testing of medical devices would be required.

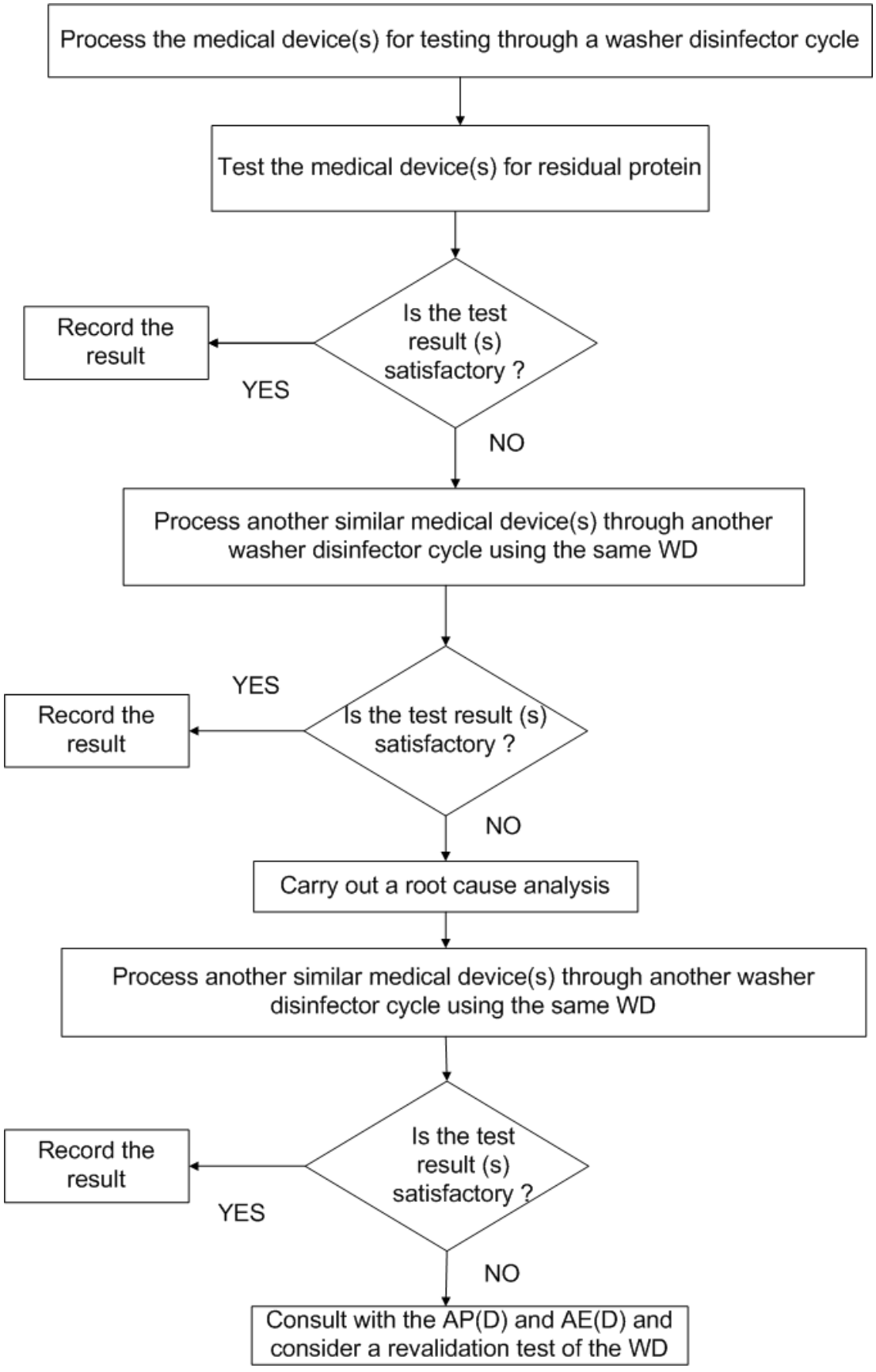


Figure 7: Test process method when measuring residual protein

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

12.31 It is hypothesised that people born since 1 January 1997 have had lower exposure to prions via the food chain as stated in the National Institute for Heath and Care Excellence (NICE) 196 Guidance. These people form a group at lower risk of prion diseases and thus at a lower risk of contaminating medical devices with prions. The NICE IPG 196 (2006) risk-reduction strategy requires that separate pools of medical devices 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 medical devices be used for each stream.

12.32 There will be a small number of patients born after 1 January 1997 who were operated on using pre-1997 medical devices 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:

a) retain them for sole use on this patient; or

b) afterwards add to the pre-1997 stock*

*(this reflects guidance by the Society of British Neurological Surgeons and the ACDP-TSE Subgroup in preparation).

12.33 If medical devices 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, see Figure 8. The same age separation should be applied to loan sets.

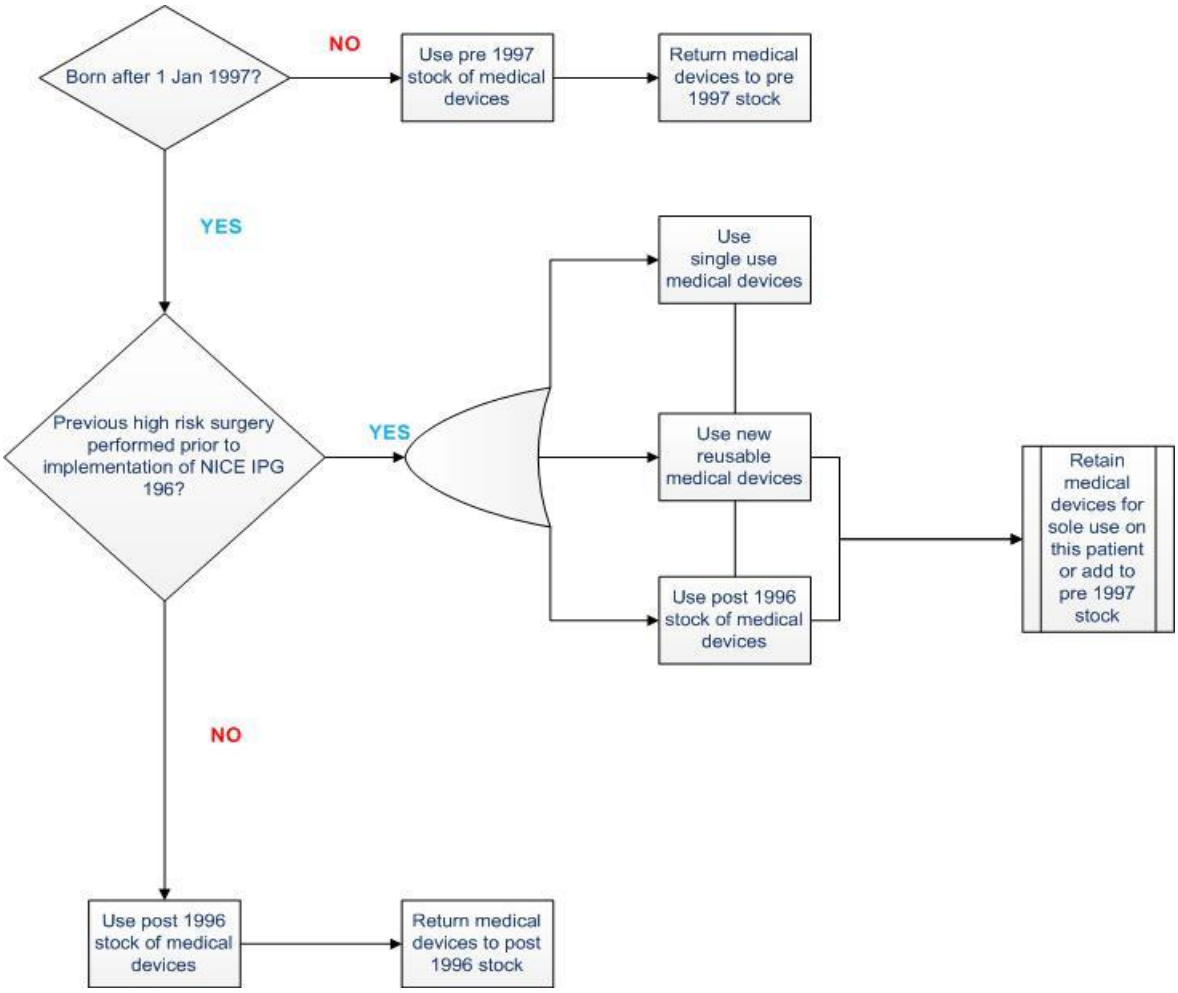


Figure 8: Medical device stock identification for high risk tissue surgery

Loan sets

12.34 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 migration. It is a requirement that reusable medical devices are decontaminated in accordance with manufacturers' instructions for use. 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, sterilization and return of the equipment to the theatres, both prior to and after use. Refer to HFS guidance GUID 5002: 2015 – "National decontamination guidance on loan devices (reusable): roles and responsibilities" and MHRA's 'Managing medical devices' on loan medical devices.

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

12.36 Particularly for CJD high risk surgical procedures (see Figure 8), 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 medical devices 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.

12.37 Medical devices within loan sets should be subject to a quality system and control measures at least equal to those normally applied in the surgical centres where they are used. This applies equally when clinicians or other team members are the sponsor of any loan arrangement.

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

Repairs

12.39 Any medical device used on CJD high risk tissues (see classification Figure 5) that are removed for repair should be returned to the instrument set from which it was removed.

Instrument audit and tracking

12.40 There is a need to track and trace medical devices throughout their use and reprocessing. This is to avoid migration of the medical devices and is a requirement of the HFS guidance ‘Requirements for compliant CDUs’ published 2016.

12.41 Records should be maintained for all the medical device sets (and supplementaries) for identifying:

- the decontamination 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;
- non-conformances.

12.42 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. The reunification of medical devices 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.

12.43 For those instruments, including delicate components such as electronic devices or imaging related markers, the use of single instrument identification may be of special value.

When marking is combined with properly managed decontamination procedures the individual instrument may be correctly identified as requiring a non-standard approach to washing, disinfection or sterilization.

12.44 Individual medical devices 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.

12.45 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 due to difficulty in streaming of non-marked instruments. Thus the use of larger sets which include supplementary instruments may mitigate this risk, particularly when combined with instrument marking, tracking and audit techniques.

Single-use medical devices

12.46 Single-use medical devices should be separated from reusable medical devices and disposed of at the end of the procedure. It is important that the single-use medical devices are not allowed to enter reusable medical device sets.

13. Disposal and metal recycling

13.1 Medical devices for recycling should be decontaminated before despatch to ensure they are safe to handle. The medical devices should be accompanied by a certificate stating the method by which they were decontaminated. Scrapped devices must not fall into the hands of those who may misuse them. Medical devices that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.

13.2 Disposal of medical devices should be in accordance with the Health Facilities Scotland guidance GUID 5008 ‘Guidance for Disposal and Recycling of Medical Devices’ published 2014. Also refer to HFS guidance Scottish Health Technical Note (SHTN) 3 published 2017.

14. Procurement of equipment

14.1 This section of the guidance provides advice on the specification, purchase and installation of equipment used for the decontamination of medical devices in Central Decontamination Units. Health Boards should use the NP143 framework for Decontamination equipment, accessories and maintenance when purchasing ultrasonic cleaners, washer-disinfectors and sterilizers etc.

Pre-purchase considerations

14.2 It is essential that the purchase of an item of decontamination equipment is planned correctly in order that the users predefined requirements are met. This section aims to help the purchaser with a step-by-step discussion of the issues to be included. As this section is designed to be universally applicable, it might be necessary to vary the procedure according to local circumstances or requirements.

Authorising Engineer (Decontamination) advice

14.3 The efficient completion of procurement documentation will require advice and assistance from the AE(D) as required.

14.4 Assistance can be sought in the following areas:

- determining initial User requirements;
- choosing and completing the relevant specification;
- determining throughput parameters;
- advising on relevant Performance Qualification (PQ);
- post-tender analysis;
- advising manufacturer/contractor on validation protocols;
- monitoring validation performance;
- auditing validation reports.

14.5 Adherence to engineering standards and quality systems ensures that decontamination equipment is manufactured, installed, validated and subject to the necessary periodic testing to establish the initial and then on-going satisfactory performance of the machine to ensure optimum decontamination of medical devices and safety of both operators and patients.

Specification preparation

14.6 The use of a specification will enable data provided by the tenderer on technical points as well as financial data to be compared. Not only will this enable the purchaser to confirm the acceptability of current services, spatial requirements and porterage, but also it will enable a like-for-like tender analysis to be made. Tender analysis will be best achieved by formalising tender comparison with respect to

performance and cost in all key areas. Qualifying statements by the tenderer should be taken into account. Their effect on tender content or eligibility should be assessed before making a choice.

Procurement of equipment – an overview of points to consider

14.7 Information required in the purchase of decontamination equipment, see Figure 9:

Questions	Comment
What type of load will be processed?	
What type of machine is required?	
Where will the machine be sited?	The location available for the equipment will have a significant influence on the type of machine that can be used.
What services are available?	Some decontamination equipment will require several of the following services: steam, electricity, water, compressed air, drainage, effluent handling, ventilation and bulk or integral storage/supply of chemical additives/sterilant gas supply. The manufacturers' data will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It might be necessary to plan for a new service, which would add greatly to the cost of the installation.
Who will operate the equipment?	Equipment located in a Central Decontamination Unit under the care of specially trained staff – whose sole or principal activity will be the operation of the machine – may be complex. Operators should thus be designated.
What capacity is required?	The likely daily and weekly workload, and the peak hourly workload, that the equipment will have to process should be established, then the number of machines required to process the workload should be calculated. Throughput figures for different manufacturers' machines and different models within any given range vary considerably.
What ancillary equipment will be	A sterilizer installation might require

needed?	ancillary equipment such as special ventilation, water treatment for steam generators, air compressors, preconditioning facilities, degassing facilities and gas disposal plants. A washer-disinfector might require ancillary equipment such as water softeners, deionization or reverse osmosis (RO) water treatment plants, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals. A decision on treatment should be based upon initial assessment of source water and historical reports and cost based upon risk analysis. In addition some machines will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product, and means for returning load carriers from the unloading side of the machine back to the loading side.
What standards or specifications are relevant?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine.
What type of contract?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine.
Which manufacturer?	Three or more manufacturers should be invited to tender for supplying the decontamination equipment. While no manufacturer should be excluded unnecessarily from the tendering process, they should not be invited to tender unless there is a realistic prospect of their being awarded the contract.
What installation and commissioning arrangements?	After delivery and installation, the decontamination equipment should be subjected to a formal documented programme of validation.
What arrangements are there for service and repair?	It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, that is, during the warranty

	period. A number of manufacturers also offer an extended warranty facility that, sometimes for an additional fee, provides an all-inclusive service and repair option.
What are the likely running costs?	Advice should be sought at the time of tender on the operational costs of the various machines that would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam etc.), consumable items (detergents, rinse aids etc.) and maintenance. This data should be used in the evaluation of the tender bids.

Figure 9: Questions to consider when procuring equipment

14.8 Consideration should be given to contingency plans for machine usage, and sufficient time should be included for testing, maintenance and service.

Thus, reliance on a single item of equipment is not advisable. It should be noted that the turnaround times can fluctuate based on the demand placed on the service.

General design considerations

14.9 All decontamination equipment and associated equipment is classed as work equipment and should comply with the Provision and Use of Work Equipment Regulations 1998 amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013.

Safety features

14.10 Safety features should be designed in accordance with the Standard code of practice for safety of machinery, PD 5304, and the European standards for the safety of electrical equipment, EN 61010-1: 2010 and EN 61010-2-040: 2015.

14.11 The design of the control system should ensure that the door cannot be opened until the cycle is complete. When a fault is indicated the door should only be able to be opened by a key code or tool, when the equipment is returned to a safe condition.

14.12 The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

14.13 All safety devices should be designed to fail in a manner that does not cause a safety hazard to personnel.

14.14 Any error in the control or indication system should not cause a safety hazard.

Instrumentation

14.15 Where an instrument can be adjusted the adjustment should require the use of a key code or tool that is not available to the Operator.

14.16 Where a fault is indicated as an error message shown on a visual display unit, it should be clearly distinguishable from normal messages, for example, by use of a different colour or larger size of text. The indication should remain displayed until acknowledged by the Operator.

14.17 Where required within the specification, the Contractor should be required to carry out adjustments to the instruments on site so that the accuracies specified at the sterilization temperature can be met with the plant running and under the conditions normally prevailing on site. Values should be recorded before and after adjustment.

Programmable electronic systems

14.18 Modern decontamination equipment frequently uses programmable electronic systems (PES) for control and data recording. Where such systems are used, they should be designed in accordance with the principles set out in the EN 61508: 2010 series "Functional safety of electrical/electronic/ programmable electronic safety-related systems" in safety related applications'.

14.19 Where a PES is used for control or monitoring of the process, the values of cycle variables critical to process performance and determined during validation should be documented in the validation report regardless of whether or not they are held in the PES memory. The version number of the software should be available for display when required.

14.20 Combined control and instrumentation systems that are wholly operated by means of PES should incorporate at least two timing systems, independent of each other, such that the timer used to control the holding time is verified by the other timer. Any future changes to software should be advised and agreed with the User prior to an upgrade in order that any revalidation requirements are addressed.

Invitation to tender

14.21 Once detailed specifications have been drawn up, manufacturers should undertake a mini competition for the supply and, if required, the installation of the decontamination equipment.

14.22 Prospective contractors should be given the following information:

- that each machine will be subject to a validation process;
- that unless otherwise specified, the installation checks and tests specified in the validation process should be satisfactorily completed before the machine can be accepted;
- whether the factory/works tests (optional, only carried out in special circumstances), site visits or installation checks and tests are to be witnessed by

the appropriately-qualified purchaser's representative (normally the AE(D), AP(D) or CP(D));

- the date by which all services will be available;
- the date by which the validation process is expected to be completed.

Contract

14.23 Advice from NSS should be obtained as part of this process and Health Boards should use the NP143 framework for Decontamination equipment, accessories and maintenance. Equipment purchased from the NP143 framework for Decontamination equipment, accessories and maintenance have had compliance with type test data, validation and commissioning reports and qualification reports reviewed by AE(D)s and a Pass/Fail allocated. The framework is awarded on National Procurement's standard terms and conditions of contract for the purchase of goods and service. Health Boards should ensure that all orders reference the NP143 contract reference on all purchase orders.

14.24 Alternative forms of contract could be used dependent on the Health Board's policy and procedures for purchase of equipment not available on the framework.

Delivery

14.25 Decontamination equipment for a particular scheme should not be ordered and stored on site for long periods prior to installation, validation or operation. Disregard of this recommendation can invalidate the manufacturer's warranty and cause deterioration of the machine prior to installation or routine use. Where a long delay is unavoidable, conditions for storage should be agreed with the manufacturer.

14.26 The contractual terms of the warranty should be clearly defined between purchaser and manufacturer at time of procurement. This agreement should confirm terms, conditions, service requirements and exact dates for commencement and conclusion of the warranty.

Engineering services

14.27 Decontamination equipment installation will require one or more external services including steam, electricity, hot and cold water, compressed air, ballast air, drainage, ventilation and purified water. The manufacturer should make clear at an early stage which services will be needed and the detailed requirements for each. Consult Scottish Health Planning Note (SHPN) 13 Part 1: 2011.

15. Glossary

15.1 **Absolute pressure** - pressure for which the zero value is associated with absolute vacuum. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.2 **Accessory for a medical device** means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s). [SOURCE: Regulation (EU) 2017/745 article 2 – (2)]

15.3 **Active ingredient** - chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.4 **Aeration** - part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.5 **Air detector** - device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.6 **Aseptic presentation** - transfer of the sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.7 **Automatic controller** - device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.8 **A_0** - measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.9 **Bioburden** - population of viable microorganisms on or in a product and/or sterile barrier system. [SOURCE: EN ISO 11737-1: 2018 section 3 definitions]

15.10 **Biological indicator** - test system containing viable microorganisms providing a defined resistance to a specified sterilization process. [SOURCE: EN ISO 11138-1: 2017 section 3 definitions]

15.11 **Clean** - visually free of soil and below specified levels of analytes. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.12 **Cleaning** - removal of contaminants to the extent necessary for further processing or for intended use. Note: Cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or

automated process that prepares the items for safe handling and/or further processing. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.13 **Cleaning agent** - physical or chemical entity, or combination of entities, having activity to render an item clean. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.14 **Chemical indicator non-biological indicator** - test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process [SOURCE: EN ISO 17665: 2006 section 3 definitions]

15.15 **Conditioning** - treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.16 **Cycle complete** - message from the automatic controller that the operating cycle has ended successfully. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.17 **Decontamination** – refer to definitions for “processing” and “reprocessing”.

15.18 **Disinfection** - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.19 **Endotoxin** - lipopolysaccharide component of the cell wall of Gram-negative bacteria that is heat stable and elicits a variety of inflammatory responses in animals and humans. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.20 **EO-cartridge** - hermetically sealed container that holds a predetermined weight of ethylene oxide (EO) for single use. Note 1 to entry: The EO-cartridge is designed to be used in low volume chambers and/or to be activated while in the flexible sterilization bag, releasing EO. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.21 F_0 **value** - measure of microbiological lethality delivered by a moist heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 121.1 °C with reference to microorganisms with a *z* value of 10 K. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.22 **Flexible sterilization bag** - <EO-sterilization> container constructed from a malleable membrane that acts as the sterilization chamber. Note 1 to entry: The material from which the flexible sterilization bag is manufactured can be either permeable or impermeable to EO gas. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.23 **Gas concentration** - weight of a specific gas in a given volume. Note 1 to entry: Concentration can be expressed as mg/l or g/m3. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.24 **Implantable medical device** - medical device which can only be removed by medical or surgical intervention and which is intended to:

— be totally or partially introduced into the human body or a natural orifice, or
— replace an epithelial surface or the surface of the eye, and
— remain after the procedure for at least 30 days
[SOURCE: EN ISO 13485: 2016 section 3 definitions]

15.25 **Installation Qualification (IQ)** - is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. [SOURCE: EN 285: 2015]

15.26 **Instructions for use** - means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. [SOURCE: Regulation (EU) 2017/745 article 2 – (14)]

15.27 **Invasive device** - means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. [SOURCE: Regulation (EU) 2017/745 article 2 – (6)]

15.28 **Labelling** - label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. [SOURCE: EN ISO 13485: 2016 section 3 definitions]

15.29 **Life-cycle** - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: EN ISO 13485: 2016 section 3 definitions]

15.30 **Load** - product, equipment, or materials to be processed together within an operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.31 **Load configuration** - distribution and orientation of a load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.32 **Lumen device** - item that consists of tube(s) or pipe(s). [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.33 **Manual cleaning** - Manual cleaning -removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.34 **Medical device** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [SOURCE: Regulation (EU) 2017/745 article 2 – (1)]

Note: The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

15.35 **Microbial barrier** - property of a sterile barrier system to minimize the risk of ingress of microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.36 **Microbial contamination** - presence of unintended bacteria, fungi, protozoa, or viruses. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.37 **Moist heat** - thermal energy in the presence of moisture released by gaseous or liquid water. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.38 **Non-condensable gas** - air and/or other gas which will not liquefy under the conditions of saturated steam sterilization processes. [SOURCE: EN 285: 2015]

15.39 **Operating cycle** - complete set of stages of a process that is carried out, in a specified sequence. Note 1 to entry: Loading and unloading are not part of the operating cycle. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.40 **Operational Qualification (OQ)** - is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures. [SOURCE: EN 285: 2015]

15.41 **Overkill approach** - method of defining a sterilization process that achieves a maximal sterility assurance level (SAL) for product substantially less than 10^{-6}. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.42 **Packaging system** – combination of the sterile barrier system and protective packaging. [SOURCE: EN 11607-1: 2017]

15.43 **Performance Qualification (PQ)** - is defined as the process of obtaining and documenting PQ evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

15.44 **Periodic testing** - is a series of tests carried out at daily, weekly, quarterly and yearly intervals.

15.45 **Powered device** - <washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments. Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air. EXAMPLE Dental hand pieces, orthopaedic saws, drills. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.46 **Preconditioning** - treatment of product, prior to the operating cycle, to attain specified values for temperature, relative humidity, and/or other process variables. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.47 **Process chemical** - formulation of chemical compounds intended for use in a washer-disinfector.

Note: Process chemicals include for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners. [SOURCE: EN ISO 15883-1: 2014 section 3 definitions]

15.48 **Processing** - activity to prepare a new or used healthcare product for its intended use. Note processing includes cleaning, disinfection and sterilization (if necessary and applicable). A healthcare product refers to a medical device. [SOURCE: EN ISO 17664: 2017 (published 25 October 2017) section 3 definitions]

15.49 **Processor** - organization and/or individual with the responsibility for carrying out actions necessary to prepare a new or reusable healthcare product for its intended use. Note a healthcare product refers to a medical device. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.50 **Process challenge device PCD** - item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. [SOURCE: EN ISO 11138-1: 2017 section 3 definitions]

15.51 **Product family** - group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.52 **Protective packaging** – configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use. [SOURCE: EN 11607-1: 2017]

15.53 **Reference load** - specified load created to represent combinations of items that provide defined challenge(s) to a process. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.54 **Relative humidity** - measure of water vapour in the air expressed as a percentage of the maximum for a given temperature. Note 1 to entry: It is expressed as a percent. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.55 **Reprocessing** - means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device. [SOURCE: Regulation (EU) 2017/745 article 2 – (39)]

15.56 **Reusable medical device** - medical device designated or intended by the manufacturer as suitable for processing and reuse. Note: This is not a medical device that is designated or intended by the manufacturer for single-use only. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.57 **Reusable surgical instrument** means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the

manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out. [SOURCE: Regulation (EU) 2017/745 Annex VIII chapter 1, 2.3]

15.58 **Seal** - <packaging> result of joining surfaces together by fusion to form a microbial barrier. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.59 **Seal integrity** - <packaging> characteristics of a seal to minimize the risk of ingress of microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.60 **Self-contained biological indicator** - biological indicator presented in such a way that the primary package, intended for incubation, contains the incubation medium required for recovery of the test organism [SOURCE: EN ISO 11138-1: 2017 section 3 definitions]

15.61 **Service life** - number of processing cycles and/or life-time that a medical device can be subjected to and remain suitable and safe for its intended use. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.62 **Single-use medical device** - medical device designated or intended by the manufacturer for one-time use only. Note: A single-use medical device is not intended to be further processed and used again. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.63 **Single-use device** means a device that is intended to be used on one individual during a single procedure. [SOURCE: Regulation (EU) 2017/745 article 2 – (8)]

15.64 **Single patient use** - means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use. [SOURCE: Ref Page 14 – MHRA Single-use medical devices: implications and consequences of reuse December 2013]

15.65 **Sterilant** - chemical or combination of chemicals used to generate a sterilizing agent. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.66 **Sterile** - free from viable microorganisms. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.67 **Sterile barrier system** - minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the *sterile product* at the point of use**.** [SOURCE: EN ISO 11737-1: 2018 section 3 definitions]

15.68 **Sterile field** - area created by sterile surgical drape material where aseptic technique is practised NOTE A sterile field can be practised e.g. on a back table. [SOURCE: EN ISO 13795: 2013 section 3 definitions]

15.69 **Sterile medical device** - medical device intended to meet the requirements for sterility. [SOURCE: EN ISO 13485: 2016 section 3 definitions]

15.70 **Sterility assurance level SAL** - probability of a single viable microorganism occurring on an item after sterilization. Note 1 to entry: It is expressed as the negative exponent to the base 10. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.71 **Sterilization** - process used to render product free from viable microorganisms.
Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero [SOURCE: EN ISO 17664: 2017 section 3 definitions]

15.72 **Type tests** - is a series of tests conducted by the manufacturer to establish the working data for decontamination equipment. E.g. **type test** in EN 285: 2015 is a series of checks and tests for a particular design of sterilizer and **type test** in EN 15883-1: 2014 is a test programme to verify conformity of a washer-disinfector type to this standard and establish data for reference in subsequent tests.

15.73 **Unique Device Identifier** (UDI) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. [SOURCE: Regulation (EU) 2017/745 article 2 – (15)]

15.74 **Usable chamber space** - specified geometry within the chamber that is available to accept the load. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.75 **Validation** - is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

15.76 **Washing** - removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary [SOURCE: EN ISO 15883-1: 2014 section 3 definitions].

15.77 **Washer-disinfector WD** - equipment designed to clean and disinfect product. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

15.78 **Works tests** - series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified [SOURCE: EN 285: 2015].

ACRONYMS

ACDP	**–**	**Advisory Committee on Dangerous Pathogens**
AE(D)	**–**	**Authorising Engineer (Decontamination)**
AP(D)	**–**	**Authorized Person (Decontamination)**
CDU	**–**	**Central Decontamination Unit**
CP(D)	**–**	**Competent Person (Decontamination)**
CJD	**–**	**Creutzfeldt Jakob Disease**
EU	**–**	**European Union**
GSPRs	**–**	**General Safety and Performance Requirements**

GTR	**–**	**Glennie Technical Requirements**
HAI	**–**	**Healthcare Associated Infection**
HDL	**–**	**Health Department Letter**
IFU	**–**	**Instructions For Use**
IQ	**–**	**Installation Qualification**
OQ	**–**	**Operational Qualification**
PCD	**–**	**Process Challenge Device**
PQ	**–**	**Performance Qualification**
RMD	**–**	**Reusable Medical Device**
SHPN	**–**	**Scottish Health Planning Note**
SHTM	**–**	**Scottish Health Technical Memorandum**
SICP	**–**	**Standard Infection Control Precautions**
TSE	**–**	**Transmissible Spongiform Encephalopathy**
UDI	**–**	**Unique Device Identifier**
vCJD	**–**	**variant Creutzfeldt Jakob Disease**

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Appendix

Working group looking at medical devices potentially contaminated with Transmissible Spongiform Encephalopathy (TSE) infectivity

Background

In late 1999 a Scottish Executive Health Department Working Group, chaired by Dr D Old, (the 'Old' working group (WG)) commissioned a review to assess decontamination practice in a sample of healthcare premises in Scotland. The stimulus for the establishment of the WG and the subsequent review was concern about the potential risk of person-to-person transmission of vCJD via re-usable surgical instruments. The findings of the review (Managing the risk of healthcare associated infection in NHSScotland) were included in the report of the WG published with (HDL(2001)10). Whilst examples of good practice and appropriate equipment and facilities were observed, there were many examples where these were unacceptably poor.

As a result of the recommendations of the 'Old' WG a further WG was established, the "Glennie Group" and its programme looked at reducing the potential risk of person to person transmission of vCJD via surgical instruments in those clinical services that present the highest theoretical risk.

Included in the Glennie WG remit was the development of a framework for change, specifically related to the technical and operational standards required. Technical requirements for the reprocessing of devices according to the potential risk for transmission of CJD for the particular procedure for which they were used, were specified in the Glennie WG Report [HDL(2001)66] and deadlines were set to achieve compliance.

In order to further improve the decontamination process HFS published 'Requirements for compliant CDUs' in 2016. This is listed in the government endorsed 'Compendium of Healthcare Associated Infection Guidance' published by HPS June 2018.

Human prion diseases (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 commonest 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.

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.

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 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 medical devices decontamination for all patients.

Prion proteins, high risk tissues, high risk patients and decontamination processes

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 (Taylor 2004) 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.

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).

This SHTM supports staff involved in all elements of medical device decontamination 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 especially in confirmed or at-risk cases.

Guidance on the relative risk of different body tissues can be found in Figure 6 in this SHTM and ACDP-TSE Subgroup's Annex A1. Patient risk assessment and procedures can be found in Annex J.

As information in these areas is constantly updated it is prudent to check for recent guidance updates.

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

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.

This advice applies to:

patients with probable or confirmed CJD;

those for whom CJD is being considered as a differential diagnosis; and

around 5000 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'. 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). 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.

Implication of Appendix III study (source DOH vCJD latest handling 12-8/16)

In August 2016 PHE published their third study, which investigated appendix tissue from the UK for presence of prion protein. This was the latest in a series of studies undertaken to try to estimate the prevalence of the abnormal protein in the UK population. The two earlier studies showed that one in every few thousand appendices removed from people during the period when BSE was most common in the UK contained the abnormal protein linked to vCJD.

The first two studies concentrated largely on the population born between 1961 and 1985; this cohort of people is known to have been exposed to BSE. The second study was published in 2013. It found that of the 32,441 samples tested, 16 tested positive for abnormal prion proteins. This was interpreted as meaning that around 1 in 2,000 of the UK population exposed to BSE may be carrying the vCJD/BSE prion.

A further study was carried out to test appendices taken from individuals not previously thought to have had significant exposure to BSE, i.e.:

- stored appendices removed during operations carried out prior to 1980 (i.e. well before any large-scale incidence of BSE became apparent);

- appendices taken from patients born after 1st January 1996 (the year by which measures to remove BSE from the food chain were fully in place).

This latest study has found that:

- 2 positive samples were found from 14,692 appendices collected during 1970-79 (i.e. about 1 in 7,000); and
- 5 positive samples of 14,824 taken from patients born in 1996 or later (i.e. about 1 in 3,000).

If the two groups (before 1980 and after 1996) in the third study are combined, the prevalence estimate for these groups is roughly 1:4200 (240 per million). This estimate is not statistically different from previous studies, such as the second study, which estimated a prevalence of 1:2000. The link between abnormal prion proteins and vCJD is not fully understood, and even if these proteins are found, there is no suggestion that people will go on to develop vCJD. None of the positive samples from the third study were from appendices removed before 1978 or from patients born after 2000.

Some interpretations of the third study results complicate the use of any specific cut-off date to define a low-risk population cohort (e.g. “born after 1996”). Differences in interpretation therefore have some practical implications for risk management, which will need to be considered further by ACDP.