Health Facilities Scotland

NHS National Services Scotland

Scottish Health Technical Memorandum 01-06

Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Unit Part A: Management

March 2023
Version 1.0

Contents

Disclaimer

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Executive summary

This guidance series Scottish Health Technical Memorandum (SHTM) 01-06 ‘Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units‘ (EDU).

SHTM 01-06 provides detailed guidance to assist in compliance with HFS guidance GUID 5013 ‘Requirements for compliant EDUs’ v2:2014 and replaces sections of SHTM 2030 (2001) related to Endoscope Washer Disinfectors (EWDs).

The SHTM 01-06 series comprises of five parts with the following titles:

- Part A – Management;
- Part B – General requirements for decontamination equipment and test equipment provision;
- Part C – Dry and wet leak testers and manual clean flushing unit equipment;
- Part D – Automated endoscope washer disinfectors;
- Part E – Storage cabinets and packing systems for containment of disinfected endoscopes.

SHTM 01-06 Part A focuses on the management of the decontamination process within the EDU and includes:

- reference to relevant regulations, standards and guidance;
- roles and responsibilities of staff in relation to endoscope decontamination;
- acquisition, repair, refurbishment and disposal of endoscopes and decontamination equipment and test equipment;
- health and safety;
- infection prevention and control;
- reporting of incidents and outbreaks.

1. Introduction

1.1 The SHTM 01-06 series aims to provide detailed guidance on the management, process and equipment elements for the implementation of HFS GUID 5013" Requirements for compliant Endoscope Decontamination Units" v2 (2014), which states all EDUs in NHSScotland should move towards the compliance requirements for facilities, equipment, management and process.

Scope of this guidance

1.2 This SHTM 01-06 series applies to flexible thermolabile endoscopes and TOE ultrasound probes.

Out of scope:

- rigid endoscopes and other devices that can withstand high temperature decontamination process;
- robotic devices unless recommended by the manufacturer;
- semi invasive ultrasound probes other than TOE ultrasound probes;
- other devices not recommended by the manufacturer.

Note 1.1: Refer to the Glossary in Appendix 1 for further definitions.

Structure of this guidance series

Part A

1.3 Part A focuses on the management of the decontamination process within the EDU including:

- relevant regulations and guidance;
- roles and responsibilities of staff in relation to endoscope decontamination;
- acquisition repair, refurbishment and disposal of endoscopes and decontamination equipment;
- health and safety;
- infection prevention and control;
- reporting of incidents and outbreaks.

1.4 Part A also introduces principles for the management of equipment used to leak test endoscopes and flushing units used to assist manual cleaning of endoscopes.

Part B

1.5 Part B covers general requirements applicable to decontamination equipment and test equipment provision.

Part C

1.6 Part C includes testing, use and maintenance of equipment for leak testing endoscopes, (dry or wet leak testers), and flushing equipment used to assist the manual cleaning process.

Part D

1.7 Part D covers specific requirements for automated EWDs including detailed specifications, services requirements, operation and validation. Water quality requirements for EWDs are also included.

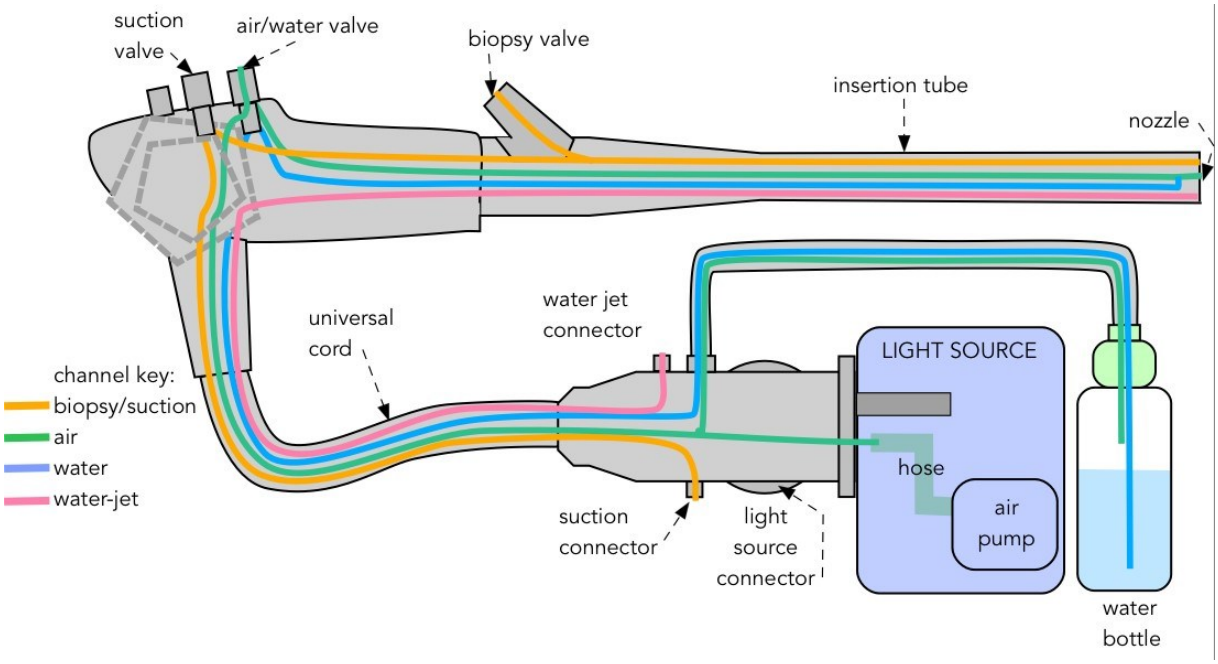
Part E

1.8 Part E covers specific requirements for installation and testing of storage cabinets as defined in the BS EN standard 16442: 2015. It introduces requirements for vacuum pack systems and pressure pack systems for containment of disinfected endoscopes.

Design of endoscopes

1.9 An endoscope is a flexible tube with a lens that connects to a light source and video processor (An example is shown in image 1.1). It can have a varying number and internal diameter of internal channels (that supply air, water and suction to the endoscope) or have no internal channels (known as non-lumen).

Image 1.1: A schematic of one possible configuration for the internal channels of a endoscope (Not to scale)



1.10 Endoscopes can be used in numerous areas of the body to carry out diagnostic procedures, including routine biopsies, or as a minimally invasive way of delivering some therapeutic treatments. A large range of endoscopes are used across a range of clinical specialities (table 1.1), in a variety of healthcare locations such as theatre, out-patient department/day bed unit, x-ray, accident & emergency, intensive care unit and in wards.

1.11 Flexible endoscopes present challenges to the decontamination process due to their variable length, the diameter of internal lumens and the materials used in their construction, which limit the maximum temperature (60°C approx.) they can be exposed to. Therefore, dedicated equipment, facilities and staff are required to clean and disinfect the endoscopes.

1.12 The level of decontamination required for a flexible thermolabile endoscope depends on the clinical procedure being performed. When access is via a natural opening, e.g. nose, mouth, etc., the endoscopes can be processed in an Endoscope Washer Disinfector (EWD) using detergent and high level disinfectant.

1.13 Where endoscopes are required to access a sterile body cavity via a surgical incision, rigid endoscopes that can be steam sterilized should be used whenever possible. Guidance for a low temperature sterilization method such as ethylene oxide (EO) or hydrogen peroxide (VH2O2) can be found in SHTM01-01-part E and is out with the scope of this guidance. Guidance for the decontamination of rigid endoscopes that can be processed through porous load sterilizers in Central Decontamination Units can be found in SHTM01-01 and is out with the scope of this guidance.

1.14 Where a sterile thermolabile flexible endoscope is required, they should undergo cleaning and high level disinfection in an EWD followed by sterilization using a low temperature sterilization method such as Ethylene Oxide (EO), or hydrogen peroxide (VH2O2). Examples of the type of clinical procedures requiring sterile endoscopes or high level disinfected endoscopes are shown in table 1.1.

Table 1.1: Decontamination status of endoscopes required for clinical use – High Level Disinfected (HLD) or sterile

Flexible Thermolabile Endoscope	Surgical or Medical Specialty	Decontamination state required
Bronchoscope	Respiratory	HLD only
Colonoscope	Gastroenterology	HLD only
Cystoscope	Urology	HLD only
Cystoscope Ureteroscope	Urology-urethra and bladder	HLD only
Duodenoscope	Gastroenterology/Hepatobiliary	HLD only
Endoscopic ultrasound	Respiratory/ Gastroenterology	HLD only
Flexible sigmoidoscope	Gastroenterology	HLD only
Gastroscope	Gastroenterology	HLD only
Hysteroscope	Gynaecology	HLD only
Intubating bronchoscope	Anaesthetics	HLD only
Laryngoscope	Ear, Nose and Throat	HLD only
Nasendoscope	Ear, Nose and Throat	HLD only
Small bowel enteroscope	Gastroenterology	HLD only
Intubating bronchoscope	Anaesthetics	HLD only
Laryngoscope	Ear, Nose and Throat	HLD only
Nasendoscope	Ear, Nose and Throat	HLD only
Small bowel enteroscope	Gastroenterology	HLD only
Choledochoscope	General surgery	Sterile

Flexible Thermolabile Endoscope	Surgical or Medical Specialty	Decontamination state required
Cystoscope	When used for examination or treatment other than the Urethra and Bladder	Sterile
Neuroscope	Neurosurgery	Sterile
Thoracoscope	General Surgery	Sterile
Cysto-nephroscope	Urology- surgical treatment of kidney	Sterile

TOE ultrasound probes

1.15 Transoesophageal Echocardiograph (TOE) ultrasound probes are used in cardiac clinics and theatres. They should be cleaned and disinfected using a high level chemical disinfectant prior to use, following manufacturers' decontamination instructions. TOE ultrasound probes are thermolabile and do not have any internal channels.

1.16 TOE ultrasound probes also pose additional difficulties to the decontamination process as the control handle and electrical connections cannot be immersed in fluid. Therefore, TOE ultrasound probe handles and electrical components (cable and plugs) will require manual cleaning and disinfection prior to any automated process.

1.17 Only Endoscope Washer Disinfectors (EWDs) that can be equipped with a device to protect the non-immersible parts of the TOE ultrasound probe (e.g. image 1.2), should be used where approved by the TOE ultrasound probe and EWD manufacturers.

Image 1.2: Example of a TOE ultrasound probe and its protective case

2. Regulatory framework and guidance

2.1 The current regulatory framework and guidance documents applicable to Endoscope decontamination services in NHS Scotland is illustrated, in image 2.1.

2.2 As the European Union Medical Device Regulation (EU) 2017/745 was not transposed into law prior to UK exit from the European Common Market on the 01/01/2021 the requirements of this regulation have not been implemented in Scotland. In 2021 the 'UK Medicines and Medical Devices Act 2021' became law. The Act states that The Medical Devices Regulations 2002 (SI 2002 No 618 Consumer Protection, as amended 92) applies in Scotland.

2.3 Manufacturers who intend to supply medical devices within Scotland need to be compliant with the following regulations:

- the Medical Devices Regulations 2002 (SI 2002 No 618, including amendments);
- the General Product Safety Regulations 2005.

2.4 The MHRA will continue to recognize European CE marking until 30 June 2023. From 1 July 2023, a UKCA mark will be required in order to place a medical device on the GB market. Further information for the legal framework, standards and national guidance can be found in SHTN 00-04 Management of medical devices and equipment in Scotland's Health and Social Care Services 2021.

2.5 HFS GUID 5013 v2 published 2014 sets the compliance requirements for Endoscope Decontamination Units within NHS Scotland.

2.6 A number of new or revised standards were released in 2021. Examples include, (Some new standards may include a new type of annex NZ):

- BS EN ISO 13485: 2016+A11:2021 Medical devices — Quality management systems — Requirements for regulatory purposes– Includes an annex NZ;
- BS EN ISO 17664-1: 2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices – does not have an annex NZ but does have annex ZA which refers to EU MDR 2017;
- BS EN ISO 15883-5: 2021 Washer-disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy- first release as a standard;
- BS ISO 20417: 2021 'Medical Devices. Information to be supplied by the manufacturer' – this introduced a new standard number.

Image 2.1: Regulatory framework and best practice guidance for endoscope decontamination

3. Functional responsibilities - roles and responsibilities in endoscope decontamination

Purpose/Scope

3.1 This section is intended to define the roles and responsibilities of NHS Scotland decontamination staff working in endoscope decontamination. 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 3.1: As per the Chief Nursing Officer Division, letter 'NHS Board Management of Infection Prevention and Control Services (IPCS) of 21 May 2018' 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

3.2 All staff undertaking decontamination and management of decontamination should be able to demonstrate the required level of training and competence for their roles and responsibility. Therefore:

- the roles and responsibilities of decontamination staff should be clearly defined and documented;
- decontamination staff should be encouraged to participate in a range of decontamination activities and be able to demonstrate their competency is in line with the NHS Education for Scotland (NES) 2016 publication 'Framework to support staff development in the decontamination of re-usable medical devices';
- each NHS Scotland Board should have a governance structure in place that supports the reporting and escalation of any failures to comply with this guidance document.

Management

3.3 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

3.4 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

3.5 The ICM is responsible for:

- co-ordination of prevention and control of infection throughout the Board area;
- delivery of the Board approved Infection Control Programme in conjunction with the Infection Control Committee and Infection Control Team;
- clear mechanisms for access to specialist infection control advice and support, including primary care (e.g. general medical practitioners);
- assessing the impact of all existing and new policies and plans on HAI, and making recommendations for change;
- challenging non-compliance with local and national protocols and guidance relating to prevention and control of infection, decontamination, antimicrobial prescribing and cleaning;
- the production of an annual report on the state of HAI, decontamination and cleaning in the organisation for which he/she is responsible, and releasing it publicly.

Decontamination Lead

3.6 Every healthcare organisation, (e.g. a 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

3.7 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 support the decontamination system.

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

3.8 The designated person is the person assuming responsibility for coordinating endoscope activity between the clinical areas, decontamination and the supply and purchase teams. The person fulfilling this role should also ensure that the inventory of endoscopes is proactively reviewed and managed in accordance with best practice decontamination guidance.

User

3.9 The User is defined as the person designated by the Executive Manager to be responsible for the management of the decontamination process. The User is also responsible for the EDU Operators. Within the endoscope decontamination process the User could be an EDU manager or Charge Nurse. The User should be suitably trained in decontamination principles and processes.

3.10 The principal responsibilities of the User are:

- certifying that the decontamination equipment is fit for use;
- holding all documentation relating to the decontamination equipment, including the names of other key personnel;
- ensuring that decontamination equipment is subject to periodic testing and maintenance;
- appointing operators where required and ensure that they are adequately trained;
- maintaining production records;
- establishing procedures for product release in line with the quality management system where applicable;
- ensuring 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)

3.11 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 NHS Scotland healthcare facilities. The principal responsibilities of the AE(D) are:

- 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;
- audit reports on validation, revalidation, and yearly tests submitted by the AP(D) or User;
- advise decontamination management and operational decontamination staff on programmes of periodic tests and periodic maintenance;
- 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)

3.12 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.

3.13 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 Board's 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.

3.14 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.

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

- the engineering management of reusable endoscope decontamination equipment;
- line management and/or appointment of The Competent Person (Decontamination) (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)

3.16 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 decontamination equipment, including Endoscope Washer Disinfectors and endoscope storage cabinets/systems.

3.17 The principal responsibilities of a CP(D) are to:

- carry out maintenance tasks;
- carry out repair work;
- conduct validation tests and periodic tests as specified in Scottish Health Technical Memoranda (SHTMs) and relevant European standards;
- 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.

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

Infection Control Doctor/ Microbiologist (Decontamination)

3.19 The Infection Control Doctor/ Consultant Microbiologist with responsibility for Decontamination is defined as a person designated by executive management to advise the User on all clinical infection control and microbiology aspects of the decontamination of endoscopes including water test and disinfection efficacy test results.

Operator

3.20 The Operator is defined as a person with the authority to operate decontamination equipment in processing of endoscopes.

3.21 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’.

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

4. Operational management

Quality Management Systems

4.1 Endoscope decontamination should be a controlled process carried out after each clinical procedure using a validated method in accordance with the endoscope manufacturer's instructions.

4.2 A Quality Management Systems (QMS) as specified in the compliance document GUID 5013 v2: 2014 for Endoscope Decontamination Units (EDU) should be in place. Documented evidence for management of the decontamination processes, validation and testing of all decontamination equipment, maintenance of the EDU facilities and staff training should be in place.

4.3 The QMS should be inclusive of national guidance, applicable national and international standards. The Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy subgroup document 'Minimise transmission risk of CJD and vCJD in healthcare settings prevention of CJD and vCJD (2017) should be considered.

4.4 The Endoscope Decontamination Unit (EDU) Manager should ensure the EDU is managed in line with a Decontamination policy, procedures and records that comply with current guidance.

Note 4.1: The National Services Scotland publication 'Endoscope Decontamination Documentation system' (EDDS) 2017 is intended to assist Health Boards' to operate compliant EDUs that provide timely supply of safe, reliable and effectively decontaminated endoscopes.

4.5 A master list of flexible endoscopes and their accessories detailing their specific decontamination requirements should be generated (by the User in consultation with the Infection Prevention and Control team), maintained and followed.

4.6 The master list should consider endoscopes with and without lumens. The clinical requirement for high level disinfection and/or sterilisation of each endoscope depending on its use should be defined in the master list.

4.7 Procedures for handling complaints from service users, managing non-conformances, and undertaking an internal audit program should be in place.

4.8 Staff should be aware of the legislation and guidance related to their work activity. Relevant Information on medical devices, including, acquisition, use, decontamination and eventual disposal should be accessible to all staff who may need the information.

4.9 Where processed endoscopes are supplied by the EDU to other legal entities the quality management system should be certified to the BS EN ISO 13485:2016+A11:2021 by a UK Approved Body.

4.10 Consideration must be given to the security of endoscopes throughout the decontamination process, including during transport and storage.

4.11 The Health Boards' management system should cover the provision of maintenance and repair of all equipment including endoscopes and TOE ultrasound probes, including reconditioning and refurbishment. The organisation is responsible for ensuring that all equipment and devices are maintained and repaired appropriately. Scottish Health Technical Note (SHTN) 00-04: 2021 'Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services' should be consulted.

4.12 The frequency and type of Planned Preventive Maintenance (PPM) for decontamination equipment should be specified, in line with the manufacturer's instructions for use while taking account of the expected level of usage and the environment in which it will be used. Further guidance on PPM can be found in Part B of this SHTM.

4.13 To ensure that the correct procedures are in place and being adhered to, audits should be undertaken on all elements of maintenance and repair including, keeping of records. Audits should be carried out by staff with appropriate knowledge and experience of managing endoscope decontamination.

4.14 Health Boards should also ensure that a method for obtaining regular feedback on the repair and maintenance process for equipment or devices is in place and accessible by service users. This should include the reporting of apparently minor non-conformances, that could lead to a major failure if not remedied.

4.15 Ensure that devices are checked for functionality in line with the manufacturer's instructions for use, throughout the expected lifetime of the equipment or device.

4.16 An annual management review should be conducted. This should ensure that necessary resources and information are available to:

- support the decontamination process;
- meet current and future demand;
- ensure that the decontamination procedures are effective;
- that equipment and facilities comply with current guidance;
- that staff are trained.

Risk management

4.17 Procedures should be in place to identify hazards associated with the decontamination process. A risk management system provides a framework for the systematic assessment and investigation of risk that can be estimated and evaluated. Standard BS EN 14971:2019 'Medical devices–application of risk management to medical devices' provides such a framework.

Traceability system

4.18 An automated or manual tracking and traceability system capable of capturing all endoscopes, staff and equipment should be in use throughout all stages of the decontamination process. The tracking system should also have the capability of

tracing endoscopes to the patients on whom they are used as required in the Scottish Government letter NHS MEL (1999) 65.

4.19 A procedure should also be in place for tracking and tracing endoscopes being sent for repair or servicing and return of the endoscope back into service. Loan endoscopes should also be considered. Sample procedures can be found in the SHPN 13 part 3: 2010 and EDDS 2017.

Note 4.2: Consideration should be given to the integration of specific endoscope track and trace systems with existing track and trace systems in use in other decontamination areas.

Staff training

4.20 All staff processing endoscopes should have their roles and responsibilities clearly defined.

4.21 A documented training scheme is required and training records and a skills register kept for each individual. These records should, identify that staff have the required competency to carry out their assigned duties.

4.22 All staff working within the EDU require initial and regular ongoing training and approved competency assessments should be carried out at least annually. Additional resources to allow training to support cross-site working should also be considered.

4.23 Training can be provided by the endoscope and equipment manufacturers, external training and educational establishments and in house.

4.24 NHS Education for Scotland (NES) ‘Framework to support staff development in decontamination of reusable medical devices’ is available on ‘Turas Learn’. This framework has been developed to support staff who undertake, manage or are responsible for decontamination activities endoscopy decontamination units throughout Scotland.

4.25 This framework provides detail of each career framework level, level attributes and examples of job roles and titles in relation to decontamination activities.

5. Decontamination process - Overview

5.1 After each clinical procedure, flexible endoscopes should be decontaminated, in a controlled manner using a validated method. The endoscopes and endoscope decontamination equipment manufacturers' instructions for use should be requested and followed.

Note 5.1: For decontamination of TOE ultrasound probes ref to 5.25 and National Services Scotland's Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes HPS/HFS 2017.

This SHTM 01-06 series describes decontamination within an Endoscope Decontamination Unit only.

Note 5.2: The decontamination process includes initial treatment at the point of use in the clinical area and clinical considerations concerning the processed endoscope.

5.2 Flexible endoscopes and any reusable accessories should be kept together as a set and handled with care at all times, including throughout the decontamination process.

5.3 The following standards provide the list of information to be supplied by the manufacturers:

- BS EN ISO 17664-1: 2021 'Processing of healthcare products. Information to be provided by the medical device manufacturer for the processing of medical devices – Critical and semi critical medical devices';
- BS ISO 20417: 2021 'Medical Devices. Information to be supplied by the manufacturer'.

Initial treatment at the point of use in the clinical area

5.4 An initial treatment at point of use of the endoscope should be carried out in the clinical area. This initial treatment should:

- in line with the manufacturers' IFUs;
- occur immediately after use and prior to transfer to the EDU;
- include the removal of gross contamination from the endoscopes external surface and flushing of all channels;
- be carried out by trained staff.

5.5 Where there is a delay in returning a used endoscope to the EDU (out of hours use) a procedure should be in place to enable staff to carry out the initial manual cleaning of the endoscope. This will include staff training in the manual cleaning process and a method of keeping the endoscope moist to prevent drying of any residual contamination on endoscopes internal or external surfaces. Any endoscopes used out of hours should be placed in a suitable covered tray, clearly marked as 'used or contaminated' (this can be indicated by colour coded lids/covers etc) and held securely in a locked room or cabinet until collection or delivery to the EDU.

Note 5.3: During the initial treatment in the clinical area ensure that particular attention is paid to endoscopes with elevator wires and accessory channels (e.g. Duodenoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures).

5.6 All single use devices used in the clinical area should be disposed of prior to transportation to the EDU.

Transport to the EDU

5.7 Used endoscopes and their associated set of reusable valves (where used) should:

- be transported to the EDU as a set as soon as practicably possible;
- be transported safely and securely in dedicated covered transportation containers and/or trolleys;
- be transported to the EDU in a containment system which will prevent drying of residual contamination on endoscope surfaces;
- clearly state the decontamination state of the endoscope (e.g. contaminated), labelling or colour coding of transportation containers can be used.

Note 5.4: Endoscopes and any associated accessories (reusable valves and buttons) exposed to the clinical environment (i.e. connected to the endoscope system and electronically tracked to the patient) should be returned to the EDU for processing, even if the patient procedure is stopped prior to insertion of the endoscope.

A process should be in place to prevent contaminated endoscopes being used in error. Contaminated endoscopes should not be stored and or transported in the same trolley or container as clean processed endoscopes.

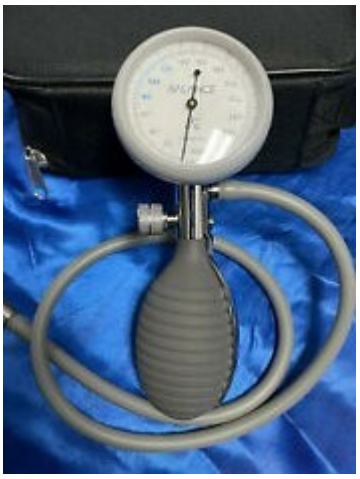
Processing in the EDU

5.8 On arrival at the EDU the endoscope should be checked into the EDU tracking system.

Dry leak testing and/or wet leak testing

5.9 A manufacturer specified leak test of the endoscope (using a Wet leak tester or a Dry leak tester as specified) should be carried out prior to the manual clean. The requirements for testing and maintenance of both types of leak testers can be found in SHTM01-06 Part C. A visual inspection of the endoscope for damage should be carried out in conjunction with the leak test. image 5.1 shows an example of a dry leak tester.

Image 5.1: Example of dry leak tester



Manual cleaning

5.10 Manual cleaning of the endoscope should be carried out as soon as possible and prior to processing in an EWD. Particular attention is required where endoscopes have elevator wires and accessory channels (e.g. Duodenoscopes used in ERCP procedures). Ensure that manufacturers' decontamination instructions compliant with BS EN ISO 17664:2021 are available for use and followed.

5.11 Only manual cleaning detergents and accessories specified by the endoscope manufacturer should be used to clean and rinse the exterior, internal lumens (if present) and any reusable valves and buttons of all endoscopes. Single use cleaning cloths and channel cleaning brushes should be used.

5.12 In addition to manual cleaning and rinsing of endoscope lumens with brushes and syringes manual clean flushing units (an example is shown in image 5.2) can be used:

- as an alternative to single use syringes for flushing internal lumens;
- after brushing;
- prior to processing in an EWD;
- further details for maintenance and testing of these devices can be found in part C of this SHTM.

Image 5.2: Example of manual clean flushing unit used during the manual cleaning process

Automated cleaning and disinfection via an Endoscope Washer Disinfector

5.13 Automated cleaning and disinfection should be carried out in an Endoscope Washer Disinfector (EWD) validated in line with the requirements of BS EN ISO 15883-1:2014 and BS EN ISO 15883-4: 2018 and part D of SHTM 01-06. Records of all EWD cycles should be maintained for the required retention period of 13 years. This can be by paper or electronic means. As most decontamination equipment includes an Information Management System (IMS) with the capability to record and download data, the preference is for an electronic record to be kept. It is therefore preferable if the User and manufacturer can agree on a method that the User can use to access any required data.

Inspection

5.14 After completion of a satisfactory EWD cycle endoscopes should be inspected for cleanliness and damage then if not required for immediate use they should be dried prior to storage.

Storage in a storage cabinet

5.15 The endoscope storage time for any given make of storage cabinet should be validated in line with BS EN ISO 16442: 2015 and the requirements in Part E of this SHTM (01-06) series.

5.16 Cleaned disinfected endoscopes removed from storage cabinets should be inspected for damage and expiry time before each patient procedure.

Endoscope contained in a packing system

5.17 Where disinfected endoscopes are vacuum packed, or pressure-packed for long-term storage, the shelf life specified for endoscopes in the packing system should be defined and validated. Additional information on the requirements for a range of vacuum and pressure pack systems can be found in Part E of SHTM 01-06.

Product release from the EDU

5.18 The documented release criteria should be in place and met for all processed endoscopes before they are released for use. This should include specific release criteria for endoscopes processed in an EWD, removal from storage cabinets, or after being vacuum packed, or pressure packed.

5.19 The integrity of any packaging should be checked and product label details should be confirmed as satisfactory and include:

- expiry date and or time;
- the endoscope type;
- the endoscope decontamination state.

Transport to clinical area

5.20 Where processed endoscopes are transferred from the EDU storage cabinets to storage cabinets in clinical areas, the total time in storage should not exceed the cabinet manufacturers validated storage period.

5.21 A procedure should be available in the clinical area to confirm the decontamination state of the endoscope, the integrity of any packaging, the expiry date and/or time of packaged endoscopes to ensure they are not used after their validated storage period.

5.22 Verification of an endoscopes functionality is determined by clinical staff when connected to its recommended light source/video processor before the patients' procedure.

Sterilization of Endoscopes

5.23 It should be noted that some endoscopes are required to be sterile at the point of use if introduced through a surgical incision (e.g. Choledochoscopes).

5.24 When required sterile endoscopes should be processed in a EWD prior to sterilization. Only low temperature sterilizing agents approved by the endoscope manufacturer should be used e.g. Ethylene Oxide (EO). Endoscopes should be processed through the EDU then transported as directed by the organisation carrying out sterilization of the endoscope. Guidance for sterilization methods can be found in SHTM 01-01: 2018 Parts E and F.

TOE ultrasound probe decontamination process

5.25 For departments using an EWD for the decontamination of TOE ultrasound probes, local procedures should be in place for their initial treatment prior to transportation to the EDU. This should be agreed with the Decontamination Lead and the Infection Prevention and Control Team.

5.26 A Standard Operational Procedure (SOP) for transport should be in place and followed. This will ensure the appropriate steps are taken for transport to and from the Endoscopy Decontamination Unit (EDU) where the TOE ultrasound probe will be reprocessed by trained decontamination staff. Further guidance for decontamination of ultrasound probes can be found in the NSS document 'Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes': 2017.

5.27 Manual cleaning, and disinfection of the non-immersible parts (e.g. handles and electrical connectors) of TOE ultrasound probes should take place prior to processing in an EWD compliant with the BS EN 15883 series of standards and follow the TOE ultrasound probe manufacturers' instructions.

5.28 Where an EWD requires modification to accommodate TOE ultrasound probes, this should only be undertaken following approval of both the TOE ultrasound probe and EWD manufacturers to ensure warranties are not compromised.

5.29 Areas using an EWD for reprocessing TOE ultrasound probes must have a validated process in place to assure chemical high level disinfection has been achieved.

5.30 The EWD product release procedure should be followed before the TOE ultrasound probe is returned to the clinical area for storage or use. An SOP for storage of TOE ultrasound probes should be in place and followed.

6. Health and safety

6.1 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.

6.2 The standards of health and safety are delivered through a flexible enabling system introduced by the Health and Safety at Work Act 1974. This Act gives 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.

6.3 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 section 3 on statutory requirements provides further guidance.

7. Infection prevention and control

7.1 All organisations should include endoscope decontamination in the Board's Healthcare Associated Infection governance structure. This may include an Area Infection Control Committee and an Infection Prevention and Control Senior Management Team (IPCSMT), who have oversight of decontamination processes.

7.2 The IPCSMT should be consulted if necessary during every stage of:

- planning;
- specification;
- procurement;
- installation;
- validation and;
- use of facilities and patient use equipment.

7.3 The detailed agenda for endoscope decontamination may be devolved to a stand-alone decontamination sub-group within the organisation, Clinical Governance structure, or form part of the IPCSMT agenda. Consult the National Infection Prevention and Control Manual (NIPCM) 2022.

7.4 Infection Prevention and Control Teams (IPCTs) also give advice on:

- local policies for EWD manufacturers validated disinfectants, their application, use, storage and disposal;
- risk assessments for procedures used in the reprocessing of Endoscopes;
- spillage procedures (blood and body fluids);
- built environment audits using national/local audit tools;
- assessing the infection risk of new and novel invasive endoscopes.

7.5 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'.

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

7.7 Management and disposal of clinical waste should be in line with Scottish Health Technical Note (SHTN) 3: 2015.

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

7.8 The Creutzfeldt-Jakob Disease (CJD) risk categorisation, and deadlines for compliance were amended in HDL (2003) 42 and updated in response to the

Advisory Committee on Dangerous Pathogens (ACDP) guidance 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection' (Annex A.1 and Annex F 2015).

Where an endoscope has been out of use for more than a few months it is recommended that it is returned to the manufacturer for service and a check of handling characteristics before returning to use.

7.9 Annex F of the Advisory Committee on Dangerous Pathogens (ACDP) guidance provides specific advice for the management of instruments used in all types of endoscopic procedures. This advice differs depending on:

- the type of CJD that a patient has been diagnosed with, or for;
- which symptoms are being investigated;
- an increased risk of developing disease has been identified.

7.10 In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes used in all patients with definite, probable or possible CJD/vCJD diagnoses, and in those identified as "at increased risk" of developing CJD/vCJD, are recommended.

7.11 For all other routine endoscopic procedures, the normal decontamination process should be followed.

7.12 Where endoscopes are placed into quarantine on or after 1 January 2010, and not used to treat one of the patient categories described at paragraphs F21 to F24 of the ACDP guidance, the requirements for decontamination or disposal of the endoscope should be reviewed considering the following:

- was the endoscope properly decontaminated using a validated process prior to quarantine?
- are tracking and traceability records available that demonstrate decontamination with a validated process?
- has the endoscope been stored in a storage cabinet or dried and stored vertically, (not coiled up in a transportation case)?

If all the above are met, the endoscope can be returned to use.

7.13 Where a patient is known to be at risk from or has been confirmed as having vCJD/CJD and the procedure involve contact with olfactory epithelium the endoscope should be processed on its own using a validated EWD cycle and then quarantined for use on the same patient or until a definitive diagnosis is obtained.

8. Reporting of adverse events & distribution of safety alerts

Introduction

8.1 All adverse events, should be managed effectively through reporting, review and improvement planning. The 'National Framework for Learning from Adverse Events' published by Healthcare Improvement Scotland 2019 supports NHS boards to standardise processes of managing adverse events across all care settings in Scotland.

How incidents should be reported

8.2 All adverse events should be reported within the Health Board incident management system (e.g. Datix). Where there has been an equipment or medical device failure, a complaint should also be raised with the equipment supplier/manufacturer. If this does not resolve the issue and the equipment was purchased through a National framework the NP Customer complaint team should be informed.

Reporting adverse events to IRIC

8.3 Any adverse events involving medical devices and patient use equipment, should also be reported to the Incident Reporting and Investigation Centre (IRIC). This includes near misses, as reporting a near miss can be the most effective way to prevent an adverse incident from happening. The forms required can be found on the IRIC website.

8.4 Where there is a healthcare infection exposure incident, the incident should be assessed and reported in line with the 2022 National Infection Prevention and Control Manual, Chapter 3 to Anti-microbial Resistance and Healthcare Associated Infection (ARHAI) Scotland.

Safety Alerts

8.5 Safety alerts are received from various organisations including from IRIC. IRIC has a partnership arrangement with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the other devolved administrations for drafting, publishing and cascading Device Safety Information, Field Safety Notices and National Patient Safety Alerts.

8.6 Organisations should ensure Equipment Co-ordinators (EC) are in place, are supported strategically, and that there is continuity of cover. Where staff are unclear on the required action in a safety alerts, they should contact their EC in the first instance. Safety alerts should be cascaded to the NHS Boards via the Equipment Coordinators who should then inform any affected services.

9. Acquisition of endoscopes, decontamination equipment and test equipment

User requirements

9.1 Specifications for the procurement of endoscopes, accessories and endoscope reprocessing equipment should be set in a User Requirement Brief (URB). These specifications should be agreed with the Endoscope Decontamination Unit (EDU) management and when purchasing endoscopes, in consultation with the Clinical Lead. Further guidance can be found in SHTN 00-04 Management of medical devices and equipment in Scotland's Health and Social Care Services 2021 and part B of this SHTM.

Note 9.1: If part of a new build/refurbishment project - the board project team may go through multiple iterations of layout design before arriving at an agreed layout on a 1:200 scale drawing of the EDU department. More detailed drawings 1:50 scale listing equipment will also be prepared and require to be agreed.

The layout of an Endoscope Decontamination Unit should be in line with SHPN 13 Part 3: 2010 as cited in compliance document GUID 5013:2014.

Prior to agreeing the final design consideration should be given to the type(s) of EWD, storage and ancillary equipment likely to be considered for procurement and their service, engineering and spatial requirements.

Board approved drawings should be used when consulting with suppliers of decontamination equipment such as storage cabinets and endoscope washer disinfectors etc.

Endoscopes

9.2 It should be established during purchasing which Product Families' categories (as described in BS EN 15883 Part 4: 2018 Annex H) are applicable. Confirmation that these Product Families can be decontaminated by the available or proposed decontamination equipment and process should be obtained from the decontamination equipment and endoscope manufacturers'.

9.3 The endoscope manufacturer's Instructions for Use (IFU) for any accessories and components required to decontaminate a specific endoscope (e.g. endoscope washer disinfector (EWD) connectors) should be reviewed. This being done for compliance with the BS EN ISO 17664-1: 2021 'Processing of health care products information to be provided by the medical device manufacturer for the processing of medical devices—critical and semi critical medical devices'.

9.4 MDA DB2002(05) states that where possible single use devices such as biopsy caps and cleaning brushes etc. should be used. Alternately re-usable accessories that are capable of being sterilised by steam may be substituted if approved by the endoscope manufacturer.

Decontamination equipment

9.5 When inviting tenders and issuing a contract for EWDs and associated equipment. Where possible Health Boards (HB) should procure new EWDs under the terms of the NP143 framework for decontamination equipment, accessories and maintenance.

Test equipment for testing decontamination equipment or testing endoscopes

9.6 Refer to the test equipment section in Part B of SHTM 01-06 to determine the required capability of the relevant test equipment.

Pre-purchase considerations

9.7 It is essential that the purchase of an item of decontamination equipment is planned correctly in order that the User's pre-defined 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.

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

9.9 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.

9.10 Adherence to engineering standards and quality systems can ensure that decontamination equipment is manufactured, installed, validated and tested to establish initial and ongoing satisfactory performance of the equipment. This will ensure optimum decontamination of endoscopes and the safety of both operators and patients.

Specification preparation

9.11 The use of a specification that includes all essential performance requirements including technical and financial data for all key areas will:

- enable a like-for-like tender analysis to be made;

- enable the purchaser to confirm the acceptability of current service provision, spatial requirements and porterage.

9.12 Qualifying statements by the tenderer should be taken into account and their effect on tender content or eligibility should be assessed before making a choice. Further guidance for decontamination equipment specifications applicable to specific devices and equipment can be found in the relevant parts of SHTM 01-6.

Note 9.2: Some decontamination equipment at the time of publication were described by standards e.g. endoscope washer disinfectors by BS EN ISO 15883-4: 2018 or endoscope storage cabinets by BS EN 16442: 2015. Other decontamination equipment such as vacuum pack systems or pressure pack systems were not described by standards at the time of publication of the SHTM01-06 series. In these cases, specification preparation is informed by this best practice guidance.

Workload and throughput requirements

9.13 The throughput requirements of the EDU equipment should be based on the number and type of endoscopes required by the clinical services supplied. Consideration should be given to future changes to or expansion of clinical services warranting procurement of new types of or additional endoscopes resulting in increase in EDU workload.

9.14 The capacity of the EWD and storage systems should be assessed on the number of endoscopes or TOE ultrasound probes that can be processed in a single load and the required throughput time. Further guidance on the planning and selection of associated equipment, facilities and EWD sizing requirements can be found in Scottish Health Planning Note (SHPN) 13 part 3: 2010 - 'Decontamination Facilities: Endoscope Decontamination Units'. Packing systems have been introduced widely since production of the planning note. Consideration of capacity requirements for these systems should also consider their location within an EDU and also identify where packed product is to be located (suitable shelve arrangements) prior to use.

Note 9.3: As turnaround times can fluctuate based on the demand placed on the service, the period of maximum demand should be used to calculate the capacity requirements. Where possible any additional future service requirements should also be included in the calculations. Any contingency plan should also allow for any catastrophic failure of facilities, equipment or critical services. Reliance on a single item of equipment is not advisable.

Procurement of equipment – an overview of points to consider

9.15 Information required in the purchase of decontamination equipment, see table 9.1.

Table 9.1: Questions to consider when procuring equipment

Questions	Comment
What type of load will be processed?	Endoscopes only or endoscopes and TOE ultrasound probes. TOE ultrasound probes require additional equipment to protect non immersible parts during decontamination. This may require additional space and impact on the design of EWD required.

Questions	Comment
What type of equipment is required?	Consider the following items. Dry and wet leak testers, manual clean flushing units, EWD, Storage cabinets, hubs or baskets, vacuum pack systems and pressure pack systems.
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. For example, some EWDs require installation of compressors. Refer to SHPN 13 Part3: 2010.
What services are available?	Some decontamination equipment will require several of the following services: electricity, water (potable and RO), compressed air, drainage, effluent handling, ventilation and bulk or integral storage/supply of chemical additives. 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. Consideration should be given to local regulations regarding discharge into the public sewer system (hot water, process chemicals) It might be necessary to plan for a new service, which would add greatly to the cost of the installation. Refer to SHPN 13 Part3: 2010.
Who will operate the equipment?	Equipment located in an Endoscope Decontamination Unit should be under the care of specially trained staff – whose principal activity will be the operation of the EDU equipment and process. As they may be complex Operators should be designated.
What capacity is required?	As throughput figures for different manufacturers' machines and different models within any given range can vary considerably the 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 can be calculated. Consideration of future expansion of clinical services should be made in order to future proof provision. Refer to SHPN 13 Part3: 2010.
What ancillary equipment will be needed?	An Endoscope Washer-Disinfector may require ancillary equipment such as water softeners, Reverse Osmosis (RO) water treatment plants, air compressors, extract ventilation (with or without condensers), and dispensing facilities for process chemicals. A decision on water treatment should be based upon initial assessment of source water and historical reports and cost based upon risk analysis. Refer to SHPN 13 Part3: 2010.
What standards or specifications are relevant?	The specification should include reference to relevant standards and minimal requirements of local guidance and policy. SHTM 01-06 identifies the relevant standards, Manufacturers' specifications and Type test data should be made available as part of this tender process.
What type of contract?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the equipment as applicable.
Which manufacturer?	Three or more manufacturers should be invited to tender for the decontamination equipment contract. No manufacturer should be excluded unnecessarily from the tendering process.

Questions	Comment
What installation and commissioning arrangements are required?	The decontamination equipment should be subjected to a formal documented programme of validation which includes the delivery and installation. Consideration must be given to services provision and who is responsible for providing all required services to the point of connection. This may be by means of a separate building services contractor.
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. Manufacturers may also offer an extended warranty facility that provides an all-inclusive service and repair option. Manufacturers may provide a list of essential spare parts that need to be held in stock and require additional funds.
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.

9.16 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.

Invitation to tender

9.17 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.

9.18 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

9.19 Advice from NSS should be obtained as part of this process. Where possible Health Boards (HB) should procure new EWDs contracts under the terms of the NP143 framework for decontamination equipment, accessories and maintenance

accessories, installation services, testing services and maintenance contracts. Equipment purchased from the NP143/21 framework 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 NP143/21 contract reference on all purchase orders. 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

9.20 Decontamination equipment for a particular scheme should not be ordered and stored on site for long periods prior to installation, validation or operation. Disregarding 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. It is advisable to conduct a site audit prior to procurement to ensure that there is free access from the point of delivery to the point of installation of the packaged equipment.

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

Engineering services

9.22 Decontamination equipment installation will require one or more external services, electricity, hot and cold water, compressed air, drainage, ventilation and purified water. The manufacturer should make clear in the tender support documentation which services will be needed and the detailed requirements for each. Provision of additional services after purchasing will add cost. Consult Scottish Health Planning Note (SHPN) 13 Part 3: 2010.

10. Repair, refurbishment and disposal

Repair and refurbishment

10.1 Repair work may be carried out by appropriately trained personnel under the original manufacturer/supplier or its agent, by a third party repair organisation, or in-house within the organisation. If a third party organisation is used ensure there is an agreed specification regarding the level and extent of work to be undertaken and the quality of replacement items.

10.2 The use of the manufacturers personnel and Original Equipment Manufacturer (OEM) parts may be required to fulfil the requirements of the manufacturers' warranty. Further guidance is available in 'Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services' SHTN 00-04: 2021 and The Medicines and Healthcare Regulatory Agency (MHRA) produced 'Managing Medical Devices' April 2015 also gives recommendations on maintenance and repair.

10.3 A number of considerations should be made when drafting the initial specification and appointing repair and maintenance organisations, see table 10.1. These considerations will vary depending on what is being repaired/refurbished/disposed i.e. an endoscope, decontamination equipment or test equipment.

Table 10.1: Questions to consider when appointing repair and maintenance organisations

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?	This consideration should be made during the planning stage prior to procurement
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 endoscopes BS EN ISO 13485 might be required. As a minimum BS EN ISO 9001 should be expected as an indication of reliability and consistency.

Question	Note
Does the preferred supplier have a proven track record? Do you already have a good working relationship?	Citations from existing customers and on-line recommendations may be consulted.
Does the preferred supplier have adequate indemnity insurance?	

Sending endoscopes/TOE ultrasound probe for repair or refurbishment

10.4 Ensure that the endoscope/TOE ultrasound probe is decontaminated to an appropriate level. As a minimum, the external surfaces should be wiped clean, the device packaged securely and a full explanation of the decontamination status given on the accompanying decontamination certificate. The User has responsibility and liability for ensuring the decontamination certificate is valid. This relates to the Health and Safety of the service personnel who will carry out the work. Used endoscopes may be contaminated with pathogenic microorganisms.

10.5 The decontamination process should not cause further damage. However, the emphasis should always be on presenting an endoscope which is as safe as possible to handle on receipt. Consult SHTN 00-04: 2021 and the repair organisation or investigating body if there is any doubt.

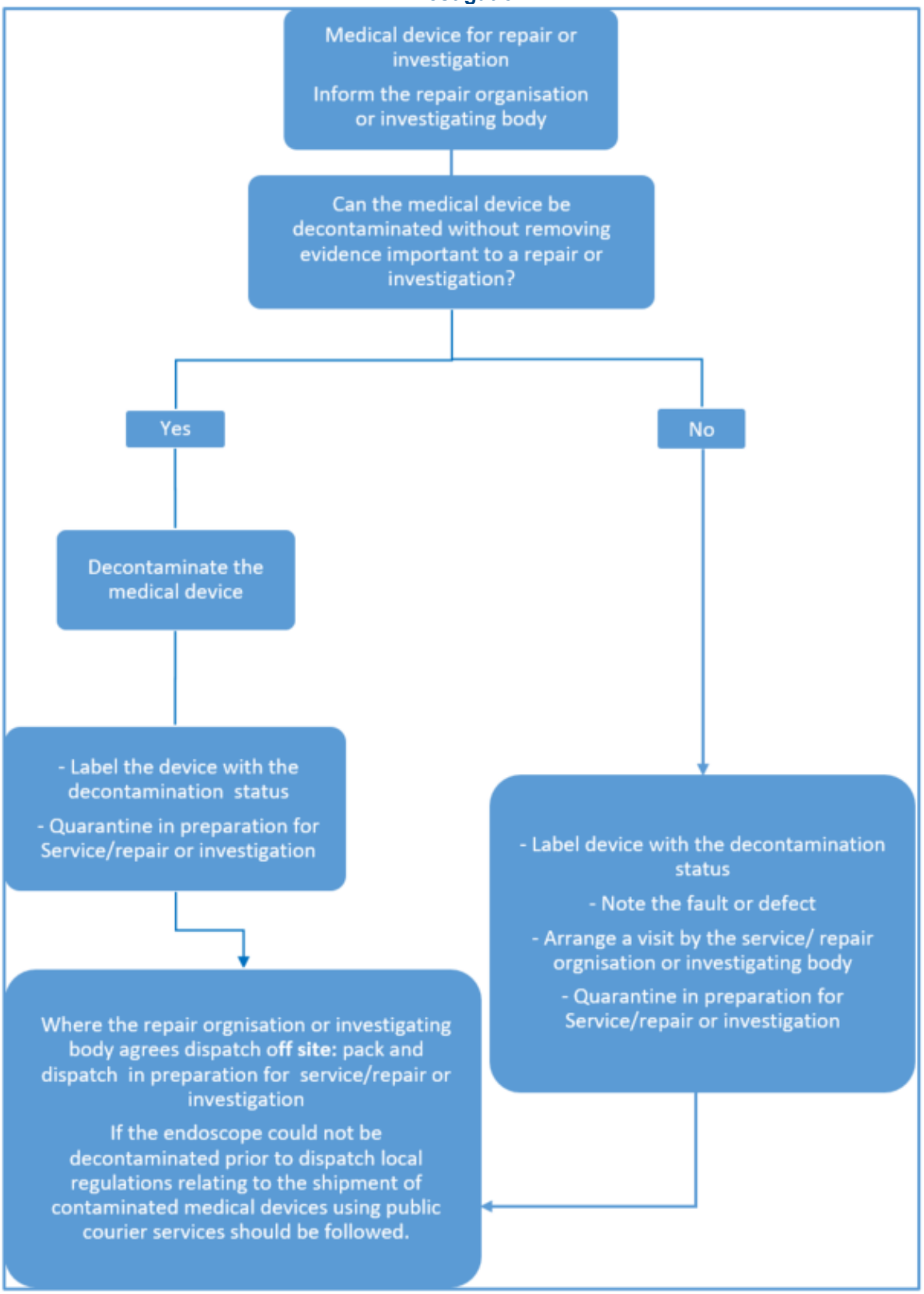
Quarantine of endoscopes/TOE ultrasound probes

10.6 Endoscopes/TOE ultrasound probes that are worn, damaged, or require a scheduled service should be quarantined pending repair, replacement or service. Quarantine areas should be clearly marked as such to prevent any confusion as to their intended use, that is storing non-conforming product or devices (Refer to the process in image 10.1).

Disposal

10.7 Disposal of endoscopes/TOE ultrasound probes should also be in accordance with the Health Facilities Scotland guidance Scottish Health Technical Note (SHTN) 3 series, parts A-D and SHTN 00-04: 2021 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services.

Image 10.1: Process to consider in sending the medical device for service/repair or investigation



Appendix 1: Glossary of terms used in SHTM 01-06 parts A-E

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

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]

Analyte - chemical substance that is the subject of chemical analysis. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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

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]

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

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]

Block - <endoscope> group of channels comprising part of an endoscope with specified lengths, diameters, and interconnections. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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

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 an endoscope 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]

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]

Channel separator - <endoscope> device used to keep apart interconnected fluid pathways. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

EXAMPLE A device inserted in a trumpet valve cylinder where multiple channels meet in order to separate the air and water pathways in the air/water valve assembly.

Chemical disinfection - disinfection achieved by the action of one or more chemicals [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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]

Controllable portion - part of the insertion portion of an endoscope or endotherapy device whose motion is intended to be remotely controlled by the user [SOURCE: ISO 8600-1: 2015 section 3 definitions]

Clinical use - use of a health care product during a procedure on a patient. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Critical medical device - a medical device that enters normally sterile parts of the human body [SOURCE: BS EN ISO 17664-1:2021]

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

Decontamination – refer to definitions for “processing” and “reprocessing”

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 and EN ISO 11139: 2018 section 3 definitions]

Distal - any location of that portion of an endoscope or endotherapy device which is farther from the user than some referenced point [SOURCE: ISO 8600-1: 2015 section 3 definitions]

Endoscope - medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis, or therapy [SOURCE: ISO 8600-1: 2015 section 3 definitions] Note 1: Endoscopes may be of rigid or flexible type; all types may have different image pickup systems (e.g. via lenses or ultrasonic sensors) and different image-transmitting systems (e.g. optical, via lenses, or fibre bundles, or electrical).

Endoscope connector - device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Endoscope leak test - set of actions to identify a loss of integrity [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Endoscope port - part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Endoscope product family - group of endoscopes with comparable design, including the number, construction, and purpose of the different endoscope channels [SOURCE: EN ISO 11139: 2018 section 3 definitions] item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels Note 1 to entry: Elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

Endoscope type test group - Endoscopes for which the general channel design and specific characteristics affecting the flow conditions in the endoscope are similar [SOURCE: EN ISO 11139: 2018 section 3 definitions] Note 1 to entry: The general channel design includes lengths and diameters. Characteristics affecting the flow conditions in the endoscope are, for example, connectors, channel separators, port closures, return valves. Note 2 to entry: Similar implies that small variations can be possible. Endoscopes that show small variations in channel specifications that do not lead to a significant variation in the flow and pressure characteristic through the channels could be in the same endoscope type test group.

Endoscope washer-disinfector - washer-disinfector intended to clean and disinfect loads comprising flexible endoscopes [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Endoscope surrogate device - Item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in an endoscope [SOURCE: EN 16442: 2015 section 3 definitions] Note 1 to entry: Construction elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

Endotoxin - lipopolysaccharide component of the cell walls 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]

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]

Facultative organism - microorganism capable of both aerobic and anaerobic metabolism [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Flexible endoscope (endotherapy device) - endoscope or endotherapy device whose insertion portion is intended to conform to natural or surgically created body cavities or instrument channels [SOURCE: ISO 8600-1: 2015 section 3 definitions]

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]

Fitting/connector for liquid or gaseous media - port for input/injection or output/suction of liquid or gaseous media on endoscopes or endotherapy devices [SOURCE: ISO 8600-1: 2015 section 3 definitions]

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]

Insertion portion - insertion tube - portion of an endoscope or endotherapy device which is intended to be inserted into a natural or surgically created body opening or which is intended to be inserted into the instrument channel of an endoscope or endotherapy device [SOURCE: ISO 8600-1: 2015 section 3 definitions]

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]

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)]

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)]

Irrigation plan - <endoscope washer-disinfector> stipulated direction of flow of process fluids through the specified channels of an endoscope [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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

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]

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

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

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

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]

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 endoscope as used in the SHTM 01-06 series only applies to those processed through an EDU.

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

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

Obstruction - <endoscope channel> partial or complete blockage [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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]

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]

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]

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

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

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

Port closure - endoscope device used to close an endoscope port during processing in order to maintain the flow of process fluids throughout the length of the endoscope [SOURCE: EN ISO 11139: 2018 section 3 definitions]

EXAMPLE to close the suction valve port.

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]

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]

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]

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]

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 an Endoscope. [SOURCE: EN ISO 17664: 2017 section 3 definitions]

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]

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]

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]

Proximal - any location of that portion of an endoscope or endotherapy device which is closer to the user than some referenced point [SOURCE: ISO 8600-1: 2015 section 3 definitions]

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]

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]

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)]

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

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]

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

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

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]

Semi Critical medical device - a medical device that comes into contact with mucous membranes or non-intact skin) [SOURCE: BS EN ISO 17664-1:2021]

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

Simulated use - use that mimics the intended use of the medical device. [SOURCE: BS EN ISO 15883-5: 2021 definitions 3.9]

Single-use medical device - designated or intended by the manufacturer for onetime 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]

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)]

Single patient use - means the 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 devices: implications and consequences of reuse December 2013]

Soil - natural or artificial contamination on a device or surface following its use or simulated use [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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

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

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]

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]

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

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]

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]

Storage cabinet - <endoscope> equipment that maintains the microbiological quality of processed thermolabile endoscopes [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Storage cabinet - equipment controlled by an automatic control system that maintains the microbiological quality of processed thermolabile endoscope [SOURCE: EN 16442: 2015 section 3 definitions]

Storage cycle - time between connecting and disconnecting the endoscope(s) inside the storage cabinet. [SOURCE: EN 16442: 2015 section 3 definitions] Note 1 to entry: A storage cycle can include a drying phase.

Surrogate product - item designed to represent product in process simulations and which is comparable with the actual product. [SOURCE: ISO 11139:2018, 3.291]

Test soil - formulation designed for use as a substitute for a contaminant or debris found on a device after use [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Thermolabile - readily damaged by heat [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Type test - technical operation to verify conformity of an equipment type to a standard or specification, and to establish data for reference in subsequent tests [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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)]

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.

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].

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

Works test - series of technical operations performed prior to delivery to demonstrate compliance of a piece of equipment with its specification. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Appendix 2: Acronyms/Abbreviations

ACDP – Advisory Committee on Dangerous Pathogens

AE(D) – Authorising Engineer (Decontamination)

AP(D) – Authorized Person (Decontamination)

EDU – Endoscope 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

Appendix 3: References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current versions of any references.

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Act & Regulations

Medicines and Medical Devices Act 2021.

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Standards/Test specifications

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BS EN ISO 868-3: 2017 Packaging for terminally sterilized medical devices. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) Requirements and test methods. BSI.

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BS EN ISO 11607-2: 2020 Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes. BSI.

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BS 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 Endoscopes. BSI.

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prEN 17180: Dec 2017 Sterilizers for medical purposes – Low temperature vaporized hydrogen peroxide sterilizers – Requirements and testing. CEN.

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