NHS National Services Scotland

Management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland

Scottish Health Technical Memorandum 01-05

SHTM 01-05 part A

part A - Management

Version 1 - April 2024

Contents

Executive Summary

The best practice guidance Scottish Health Technical Memorandum (SHTM) 01-05 management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland published in 2024 replaces relevant parts of SHTM 2010 relating to small steam sterilizers, SHTM 2030 for washer disinfectors (WD) and other previous dental decontamination guidance in NHSScotland.

In addition to Scottish Health Planning Note (SHPN) 13 part 2 'Decontamination Facilities: Local Decontamination Units' and 'Compliant Dental LDUs in Scotland' GUID 5005, SHTM 01-05 series will be the only guidance applicable for LDUs managed by NHS Health Boards, independent and private general dental services in Scotland.

The SHTM 01-05: 2024 series comprises three parts:

- **Part A - Management** - Focuses on the management of the decontamination process within the LDU and applies to dental instruments that are processed by the User or a third party to be made ready for use
- **Part B - Decontamination equipment/ test methods** - Covers decontamination equipment used to carry out processing of dental instruments. It details the maintenance, periodic testing, and test equipment requirements for decontamination equipment in line with the Chief Dental Officer (CDO) letter (2010) and current guidance
- **Part C - Process** - Provides practical guidance on the whole instrument decontamination process, presented in a form designed to be readily understandable by members of the dental team and has been written in collaboration with the Scottish Dental Clinical Effectiveness Programme (SDCEP)

SHTM 01-05 part A content includes regulatory framework and national requirements; staff training; health and safety; infection prevention and control; functional roles and responsibilities; documentation and traceability; reporting incidents outbreaks and distribution of safety alerts; repair, refurbishment, and quarantine of medical devices; disposal, decommissioning, and procurement. The Medical Device Regulations 2002 (MDR) and information provided by the medical device manufacturer for the processing of dental instruments are also considered in part A.

A glossary for part A is provided in Section 11.

1. Introduction

1.1. As a result of a continuous evolution of technical requirements since the publication of Scottish Health Technical Memorandum (SHTM) 2010, SHTM 2030 and SHTM 2031 and to facilitate greater alignment with similar guidance in UK administrations, it was proposed to revise the guidance for decontamination of dental instruments processed in a Local Decontamination Unit (LDU). This guidance has a new reference number, SHTM 01-05 and will consist of three parts.

1.2. This SHTM 01-05 series is aligned with the Medical Device Regulations 2002 (MDR) (Statutory Instruments (SI) 2002 No 618, as amended) (UK MDR 2002) and other guidance, such as, Scottish Health Planning Note (SHPN) 13 part 2 'Decontamination Facilities: Local Decontamination Units' and the 'Compliant Dental LDUs in Scotland' GUID 5005.

1.3. This SHTM 01-05 series is the only guidance applicable for LDUs managed by NHS Health Boards, independent and private general dental practices in Scotland. This guidance supersedes parts of SHTM 2010, SHTM 2030 and the Scottish Dental Clinical Effectiveness Programme (SDCEP) Decontamination into Practice series.

SHTM 01-05 series scope

1.4. This guidance is applicable for all general dental services that decontaminate their dental instruments in a LDU, for example NHS Health Boards, independent and private general dental practices in Scotland. The terminology 'dental instruments' is used in this guidance to cover medical devices, for example general dental and surgical instruments, handpieces and so on. Other medical devices such as dental chairs are not included in the scope. Each individual part of SHTM 01-05 as detailed below will be relevant to specific roles and responsibilities.

1.5. The type of instruments included in this document are dental instruments that are intended for reuse and require processing in line with manufacturer instructions, to take them from their state after clinical use to the state of being cleaned, disinfected, and sterilized, ready for their next use. Most dental instruments will be sterilized but not sterile when used. However, some instruments may need to be sterile at the point of use depending on their intended use or if advised by the manufacturer's instructions.

1.6. The following equipment may be used to process dental instruments in an LDU:

- benchtop, under-bench or standalone washer disinfector (WD)
- benchtop sterilizers type N, B or S (as per British Standards (BS) EN 13060:2014 + A1:2018)
- benchtop ultrasonic cleaner (UC) (pre-cleaner only)
- other related equipment, for example lubricator

Part A

1.7. Part A focuses on the management of the decontamination process within the LDU. This applies to dental instruments that are processed by the User or a third party to be made ready for use.

Part B

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

Part C

1.9. Part C covers guidance on the decontamination process, including elements of the dental instrument decontamination process applicable to the clinical environment.

Note 1: Dental services using equipment such as porous load sterilizers and pass-through WDs should refer to:

- SHTM 01-05:2024 parts A and C for the decontamination management and process
- SHTM 01-01:2018 parts B, C and D for guidance for decontamination equipment and testing. (part B of SHTM 01-05:2024 does not apply)

Creutzfeldt–Jakob Disease

1.10. LDUs process a wide range of dental instruments used in procedures which involve contact with low Creutzfeldt–Jakob Disease (CJD) transmission risk tissues in Primary Care dentistry. See the Gov.UK website for more details.

1.11. In the unlikely event that any dental instruments may make contact with medium or high CJD transmission risk tissues these instruments should be single-use. LDUs must not process single-use instruments that have been used on a patient and/ or outside the manufacturers' instructions, as stated in the Medicines and Healthcare products Regulatory Agency (MHRA) publication 'Single-use Medical Devices: Implications and Consequences of Reuse'. See MHRA for more details.

Note 2: In Scotland, endodontic files must be treated as single-use in compliance with the Chief Medical Officer's (CMO) letter CMO (2007) 5.

2. Regulatory framework and national requirements

2.1. This section clarifies the regulatory framework and technical requirements for Dental Local Decontamination Units (LDUs) processing dental instruments regarding the Medical Devices Regulations 2002 (MDR) (Statutory Instruments (SI) 2002 No 618, as amended) (UK MDR 2002), current best practice guidance and scope of activity.

2.2. From January 2020, the start of the EU-exit transition period, the MDR 2002 (SI 2002 No 618, as amended) (UK MDR 2002) as amended by the Medicines and Medical Devices Act, 2021, outlines the requirements for medicine and medical device manufacturers placing on the Great Britain market.

2.3. Although the BREXIT transition period has ended, Reusable Medical Devices (RMDs) may continue to use the Conformité Européene (CE) marking until 30th June 2028 (may be subject to change). However, the new United Kingdom Conformity Assessed (UKCA) mark (a new UK product marking) may also now be used for RMDs being placed on the UK market.

2.4. All harmonised standards published in the UK, which conformed with the Directive 93/42/EEC and European Union (EU) 2017/745 Article 8, continue to apply after 1 February 2020 and until specifically replaced by UK or Scottish legislation as stated in the Medicines and Medical Devices Act, 2021. These include but are not exclusive to British Standard (BS) EN 13060 (sterilizers) and BS EN ISO 15883 series (washer disinfectors (WDs)).

2.5. Medicines and Healthcare products Regulatory Agency (MHRA) Regulating medical devices in the UK 2020 provides guidance for manufacturers placing a medical device on the Great Britain, Northern Ireland, and EU markets. See Gov.UK website for more details.

UK law and regulations

2.6. Medicines and Medical Devices Act 2021 and Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

National Requirements

2.7. The National Health Service (General Dental Services) (Scotland) Regulations 2010, which came into force in July 2010. These require the LDU owner or legally responsible person to provide proper, sufficient, and safe:

- premises
- equipment

- instruments
- procedures

Associated NHSScotland standards and best practice guidance

- Scottish Health Technical Note (SHTN) 00-04: Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services, 2021. Health Facilities Scotland (HFS)
- Scottish Health Planning Note (SHPN) 13 part 2: Decontamination facilities: local decontamination units, 2008. Health Facilities Scotland (HFS)
- Compliant Dental Local Decontamination Units in Scotland: Version 2 - GUID 5005. HFS
- Guide to carriage of dangerous goods regulations with respect to used medical devices, 2013. - GUID 5006. HFS
- National Infection Prevention and Control Manual (NIPCM). Antimicrobial Resistance and Healthcare Associated Infection (ARHAI Scotland)
- Practice Support Manual (PSM), Scottish Dental Clinical Effectiveness Programme (SDCEP)

Quality Assurance

2.8. The "User" for all dental practices in Scotland is required to ensure that there is a quality assurance system in place. For NHS dental services this will be subject to a Combined Practice Inspection (CPI) carried out every 3 years by NHS Boards. Similarly, private dental practices in Scotland are subject to Healthcare Improvement Scotland (HIS) inspections every 3 years.

Note 3: The definition of 'User' can be found in Section 6 roles and responsibilities.

3. Health and safety

3.1. The standards of health and safety are delivered through a flexible, enabling system introduced in 1974 by the Health and Safety at Work Act etc.1974. Other legislation that follows this principal act can be found in Appendix 1.

3.2. The Health and Safety at Work Act etc.1974 leaves employers' freedom to decide how to control the risks which they identify, that is, to look at what the risks are and to take sensible measures to tackle them. The Act is part of criminal law, and enforcement is by the Health and Safety Executive (HSE) and Local Authority. Successful prosecution can result in fines or imprisonment. Scottish Health Technical Memorandum (SHTM) 00 'Best practice guidance for healthcare engineering Policies and principles', 2013 provides further advice in its Section 2 on statutory requirements.

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

3.4. Employees also have a responsibility for health and safety in the workplace:

- they must take reasonable care for the health and safety of themselves and of other persons who might be affected by what the employee does, or fails to do, at work
- they should attend health and safety training, and ensure they are aware of and comply with the Health and Safety at Work Act etc.1974 and the practice's policies on health and safety
- all staff have a responsibility for infection prevention and control and must comply with the National Infection Prevention and Control Manual (NIPCM).

4. Infection prevention and control in dentistry

4.1. Infection prevention and control in dental practice is aimed at minimising the risk of transmission of potentially infectious micro-organisms between individuals through the application of a range of infection prevention and control measures to prevent and control the occurrence of healthcare associated infections (HAIs). The primary sources of infective organisms are through secretions such as saliva, respiratory secretions, and blood.

4.2. Organisations and employers in dental practice all have a duty of care to their employees to ensure safe systems of work are in place in compliance with all applicable legislation. Practitioners must take accountability to ensure compliance with national standards and guidance and assessment of risk should be undertaken within the context of managing infectious agents. Practitioners should take appropriate precautions to protect patients, members of the dental team, and other contractors from the risk of infection during or associated with providing dental treatment. Practitioners must ensure their knowledge is up to date and that all staff are trained in infection prevention and control appropriate to their role in the practice. Failure to employ adequate methods of infection prevention and control could render a practitioner liable to a charge of serious professional misconduct by the General Dental Council (GDC).

4.3. The Hierarchy of Controls (HoC) are fundamental principles of risk assessment which if applied in order are used to identify the appropriate controls and should also be considered in controlling exposures to occupational hazards which include infection risks.

4.4. When applying infection, prevention and control (IPC) precautions at organisational, local and clinical level the HoC should be considered when applying Standard Infection Prevention and Control Precautions (SICPs) and Transmission Based Precautions (TBPs) recognising that the most effective method of control (elimination) is employed first.

4.5. This inherently results in safer control systems. It is recognised that elimination of risk may be challenging within health and care settings due to the nature of the services provided. Where that is not possible, all other controls must be considered in sequence. Personal protective equipment (PPE) is last in the HoC and may be the only mitigating control when caring for a service user. It is essential to ensure the safety of patients, practice staff and external personnel whether they attend on site or receive items dispatched to their premises.

4.6. SICPs should be applied at all times whether infection is known to be present or not. Elements of SICPs include hand hygiene, correct use of PPE, safe management of the care environment, patient equipment, waste management (including sharps), and safe management of blood and body fluids including spillages. These are detailed in Chapter 1 of the National Infection Prevention and Control Manual (NIPCM).

4.7. TBPs are not routinely required. However, an assessment of risk must be undertaken, and risks mitigated outlined under the hierarchy of controls. See the NIPCM website for more information.

4.8. A source for healthcare infection prevention and control guidance is available via the National Services Scotland (NSS) website on the Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) homepage. National Policies Guidance and Evidence provides relevant IPC evidence based best practice guidance within the NIPCM as well as the HAI compendium , that contains links to current national policy and guidance on HAI, antimicrobial prescribing and resistance, decontamination, built environment and other related topics.

4.9. The Practice Support Manual (PSM) is an online resource provided by the Scottish Dental Clinical Effectiveness Programme (SDCEP) that brings together information that is relevant to dental practice from current legislation, professional legislation, guidelines and expert opinion to achieve best practice and compliance.

4.10. Scottish Health Technical Memorandum (SHTM) 01-05:2024 part C covers all aspects of the dental instrument decontamination process.

5. Reporting incidents, outbreaks, and distribution of safety alerts

Adverse incident reporting procedures

5.1. Any adverse incident in Scotland associated with the following:

- medical devices, such as dental instruments, syringes
- in vitro diagnostic devices (IVDs), such as implants
- estates and facilities, such as water
- social care equipment, such as equipment trolleys
- personal protective equipment (PPE), such as visors, FFP3 respirators, aprons should be reported locally to the NHS Board's adverse event reporting system and nationally to National Services Scotland (NSS) Incident Reporting Investigation Centre (IRIC). Any medical device or associated equipment involved in the adverse event or incident should be removed from use and placed in quarantine, as they may be required for examination and testing. It is essential that boards are aware of any known alerts, and these have been actioned appropriately. Please refer to NSS Health Facilities Incidents and Alerts for information on processes, current alerts and who your incidents and safety officer is.

Safety alerts

5.2. IRIC distributes safety alerts in Scotland using several formats:

- medical device alerts (MDA) deal with safety issues relevant to the medical devices. This format is published by the Medicines and Healthcare Products Regulatory Agency (MHRA) and UK devolved nations
- estates and facilities alerts (EFA) deal with safety issues related to health facilities and estates in Scotland
- safety action notice (SAN) safety issues which only affect Scotland

Note 4: many current alerts are available online, but copies of older alerts can still be requested. If you would like to request an older alert, or if you have a question about a safety alert, email nss.iric@nhs.scot or call 0131 275 7575.

5.3. Chief Executive Letter (CEL 43 2009) is updated by Addendum to CEL 43 2009 published on Nov 2013 which sets the requirement for Chief Executives to ensure the procedures of reporting incident to IRIC and cascading IRIC safety alert are extended to all contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients.

5.4. In dental practices, failure in processes in the management of correct decontamination of dental instruments and equipment can result in risk of exposure to an infectious agent. This

can lead to cross transmission or a near miss incident. Where there is a healthcare infection exposure incident or near miss, the incident should be assessed and reported in line with National Infection Prevention and Control Manual (NIPCM), Chapter 3 to Anti-microbial Resistance and Healthcare Associated Infection (ARHAI) Scotland.

6. Functional roles and responsibilities

Purpose/ Scope

6.1. This section is intended to define the roles and responsibilities of NHS Health Boards, independent and private general dental services in Scotland for staff decontaminating dental instruments in a Local Decontamination Unit (LDU) setting. It supersedes the defined roles and responsibilities in Scottish Health Technical Memorandum (SHTM) 2010 and SHTM 2030 published in 2001.

6.2. Some dental services may be unable to appoint all these responsible posts, and a local decision regarding them will need to be made. In some instances, it is likely that one individual may carry out two, or possibly more, of the following roles. All staff should be aware of each other's responsibilities.

Note 5: As per the government letter of 21 May 2018 from the Chief Nursing Officer (CNO) Division, the Cabinet Secretary for Health and Sport agreed that Decontamination Professionals would be formally recognised as coming under the Healthcare Science framework in Scotland from May 2018.

Principles

6.3. Staff undertaking decontamination and the management of decontamination should be able to demonstrate their competencies and training in the areas in accordance with their roles and responsibility:

- the roles and responsibilities of staff undertaking decontamination duties should be clearly defined and documented
- decontamination staff should, as part of their professional development, review their knowledge and skills and competency in line with the NHS Education for Scotland (NES) staff competencies as outlined in their 2022 publication 'Framework to support staff development in the decontamination of re-usable medical devices'
- staff undertaking decontamination duties should access training in section 6 of the above framework for courses and in-practice training which cover infection prevention and control, including decontamination
- at present there is no official requirement for a specific decontamination qualification. However, regarding continuing professional development (CPD), the General Dental Council (GDC) states: "Disinfection and decontamination: we recommend that you do at least five hours in each CPD cycle". See the GDC website for more information.
- persons carrying out periodic quarterly/ annual testing of decontamination equipment and possibly reviewing/ signing off reports require to be suitably qualified, for example City and Guilds certificate

- each NHS Health Board, independent and private general dental service should have a governance structure in place which supports the reporting and escalation of any failures to comply with this guidance document
- clinical staff should receive infection prevention and control training (including decontamination) during induction. This should be updated in line with the Personal Development Plan (PDP) requirements for their role. It is the Employers' responsibility to ensure all competencies are up to date
- non-clinical staff (for example receptionist/ cleaning contractors/ ancillary staff) should receive infection prevention and control training relevant to their role within the practice during induction. This should be updated regularly and documented in staff training records

Roles and Responsibilities generic to all dental services

6.4. The following roles are required to be in place as a minimum in all NHS Health Board, independent and private general dental services.

Executive Manager

6.5. 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, practice principal, or other person of similar authority.

Management

6.6. Management (for example Practice Principal) is defined as the owner, occupier, employer, general manager, chief executive, or other person who is ultimately accountable for the sole operation of its premises.

User

6.7. The User (for example Practice Manager or Practice Principal) is defined as the person designated by the Executive Manager to be responsible for the management of the process. The User is also responsible for the Operators. In primary care, the User could be a general practitioner, dentist, senior dental nurse, or other health professional.

The principal responsibilities of the User are as follows:

- to certify that the decontamination equipment is fit for use
- to hold all documentation relating to the decontamination equipment, including the names of other key personnel
- to ensure that decontamination equipment is subject to periodic testing and maintenance, (refer to SHTM 01-05 part B for details)

- to appoint operators where required and ensure that they are adequately trained
- to maintain production records
- to establish procedures for product release in line with the quality management system (QMS) where applicable
- to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice

Operator

6.8. The Operator (for example Dental Nurse, LDU Operator) is defined as a person with the authority to operate decontamination equipment in processing of medical devices. Duties can include:

- noting instrument readings
- replenishing consumables such as detergent
- simple housekeeping duties

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 2022 publication 'Framework to support staff development in the decontamination of re-usable medical devices'.

Competent Person (Pressure Systems)

6.9. The Competent Person (Pressure Systems) (CP(PS)) is defined in the Pressure Systems Safety Regulations (PSSR) 2000 and is a chartered engineer responsible for drawing up a written scheme of examination for the system for example porous load sterilizers. Most insurance companies maintain a technical division able to advise on appointing a CP(PS).

Roles and responsibilities specific to NHS Health Board dental services

Designated Person

6.10. The Designated Person is responsible for:

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

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

Decontamination Lead

6.11. Every healthcare organisation for example the NHS 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

Infection Control Doctor/ Microbiologist (Decontamination)

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

- providing general and impartial advice on all matters concerned with washing and disinfection
- arranging for the culturing of biological indicators used in microbiological tests
- auditing the documentation from all sterilizers and Washer Disinfectors (WDs) that have been tested by microbiological methods

Authorising Engineer (Decontamination)

6.13. 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 NHS Health Board documentation on validation.

The AE(D) is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties.

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

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

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

Authorised Person (Decontamination)

6.14. The AP(D) should have technical knowledge and be appointed by the NHS 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.

6.15. The role of AP(D) is intended to provide the organisation with an individual who, as part of the local NHS Health 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 NHS Health Boards and is determined by the amount of decontamination equipment the individual will be responsible for. For example:

- in some organisations there are so few items of decontamination equipment in use that a service provided by a third party may be adequate
- in some organisations there is not enough decontamination equipment to warrant a full time AP(D). Here the role of the AP(D) would be one of several 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

6.16. In most organisations the role of AP(D) would only be one of several areas of similar responsibility for the individual(s) concerned. However, any additional responsibilities should not reduce the importance of the role nor impair the ability of the AP(D) to carry out his/her duties effectively. The AP(D) should report to the Designated Person.

The AP(D) will also be responsible for:

- the engineering management of reusable medical device decontamination equipment
- line management and/or appointment of the CP(D)
- the safe and effective systems of work for all installed decontamination equipment within their area of responsibility
- the acceptance criteria for operational and performance testing of all installed decontamination equipment
- liaison with the AE(D), Decontamination Lead and other decontamination stakeholders
- authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests

Competent Person (Decontamination)

6.17. The CP(D) is defined as a person designated by the AP(D) to carry out maintenance, validation, and periodic testing (quarterly/ annual) of decontamination equipment such as washer-disinfectors, and sterilizers.

Note 6: CP(D) was previously known as Test Person (Decontamination) or Maintenance Person (Decontamination)

The principal responsibilities of a CP(D) are:

- to carry out maintenance tasks
- to carry out repair work
- to conduct validation/ periodic tests, including preparation and issue of reports as specified in SHTM 01-05 part B and relevant European Standards
- to witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory, and should arrange for test loads to be supplied as required
- It is recommended that an individual CP(D) does not carry out all 3 quarterly tests and the (re)validation test on a particular piece of equipment in a calendar year

7. Documentation and traceability

Management of decontamination documentation

7.1. Policies, procedures, and records for all aspects of management of dental instruments and decontamination of dental instruments must be in place. Dental practices and Local Decontamination Units (LDUs) can obtain logbooks directly from the manufacturer for their decontamination equipment. Generic logbooks are available from Health Facilities Scotland (HFS). Logbooks for thermal washer disinfectors (WDs), ultrasonic cleaners (UCs), and sterilizers can be downloaded via the National Services Scotland (NSS) website.

Supplementary documents are also available online via Scottish Dental Clinical Effectiveness Programme (SDCEP's) Practice Support Manual (PSM). This series of documents are under Managing Decontamination in Dental Practice (MDDP) and consist of a checklist that can be used to review and record the current status of decontamination documentation and a collection of templates and checklists that dental services can adapt for their use.

Note 7: There is no requirement to use the MDDP documents. Instead, they are provided to illustrate what a dental service needs to include in its own quality management documentation.

Document retention

7.2. Dental and decontamination records, including equipment and process records should be held securely by the User for the period recommended by the Scottish Government in Scotland Government Records Management Health and Social Care Code of Practice (Scotland) 2020.

Section 3.2, (page 84) of the above Code of Practice indicates that records should be retained for the lifetime of the equipment plus 25 years afterwards.

7.3. Some types of printouts are known to fade quickly, therefore special action is required to preserve these records (for example photocopying, or electronic scanning) and it is acceptable to backup original paper records with electronic versions in this way.

Traceability

7.4. Where possible in day-to-day decontamination, dental instruments in a LDU should be traced through processing, which may include:

- operational cycles involved in processing a particular dental instrument, or set of dental instruments should be traceable

- record each process event either manually or on an IT system, including the cycle number (WD, Sterilizer and Ultrasonic Cleaner (UC) where used)
- alternatively recording by exception may be used after a risk assessment has been completed (for example the dental instruments rejected after unsatisfactory process stages recorded and details of the cycles used for ‘rework’)

8. Procurement of equipment

8.1. The National Procurement (NP)143 framework 'Decontamination Equipment and Associated Maintenance', should be used for decontamination equipment, and maintenance when purchasing ultrasonic cleaners (UCs), washer-disinfectors (WDs), and sterilizers and so on. NHS Health Boards requiring to purchase equipment via a tendering process should refer to Appendix 2.

8.2. In all cases sustainability should be assessed in line with the Scottish Government NHS Scotland Climate Emergency and Sustainability Strategy 2022-2026.

8.3. There is a need to reduce demand for resources and avoid generating waste. Dental services need to be aware of the way equipment/ dental instruments are procured with a more sustainable approach.

Maintenance, repair and quarantine of dental instruments and equipment

8.4. This section discusses the main points for consideration when sending dental instruments to a third party for maintenance or repair. More specifically, dental hand pieces which require to be maintained as per manufacturer's instructions to optimise their lifespan.

8.5. For more information on the management of dental instruments and equipment in Scotland refer to Scottish Health Technical Note (SHTN) 00-04 'Guidance on management of medical devices and equipment in Scotland healthcare and social services'.

Maintenance and repair

8.6. The dental service's decontamination policy should cover the provision of maintenance and repair of all dental instruments, including reconditioning and refurbishment. The service is responsible for ensuring that their dental instruments are maintained and repaired appropriately (for example dental handpieces).

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

8.8. The dental service is responsible for ensuring its dental instruments and equipment are maintained appropriately and included in the risk assessment process.

All staff should have access to and be aware of the local policy for equipment and instrument maintenance and repair schedules which may include:

- how dental instruments should be maintained and repaired, and by whom
- arrangements for maintenance and repair needs being included as part of the risk assessment process

- arrangements for the most suitable persons/ providers to carry out maintenance and repair tasks
- arrangements to ensure items subject to inspection, maintenance, repair, or disposal should be decontaminated beforehand
- the timescale for planned maintenance
- the timescale for repairs to be completed
- maintenance databases are validated for their intended use and functionality
- fitting spare parts in accordance with the manufacturer's specification
- the process in place to ensure that items subject to inspection, maintenance, repair are decontaminated beforehand
- a list of staff, contractors and CP(D) who are trained and competent to carry out dental instruments/ equipment repairs and maintenance where appropriate

Note 8: Any instruments or equipment that are beyond repair should be disposed of in accordance with section 10.

8.9. Dental instrument decontamination including maintenance and repair should be discussed and recorded at dental service staff meetings. A record of all dental instrument maintenance and repairs should be kept ensuring that the correct procedures are being adhered to. The management of dental instrument maintenance and repairs should be carried out by staff with appropriate knowledge and experience of dental instrument decontamination and use. The User is responsible for ensuring staff competencies remain current and up to date.

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

8.11. Ensure that dental instruments are regularly checked for functionality prior to use by the service user in line with the manufacturer's IFUs and throughout the expected lifetime of the dental instrument.

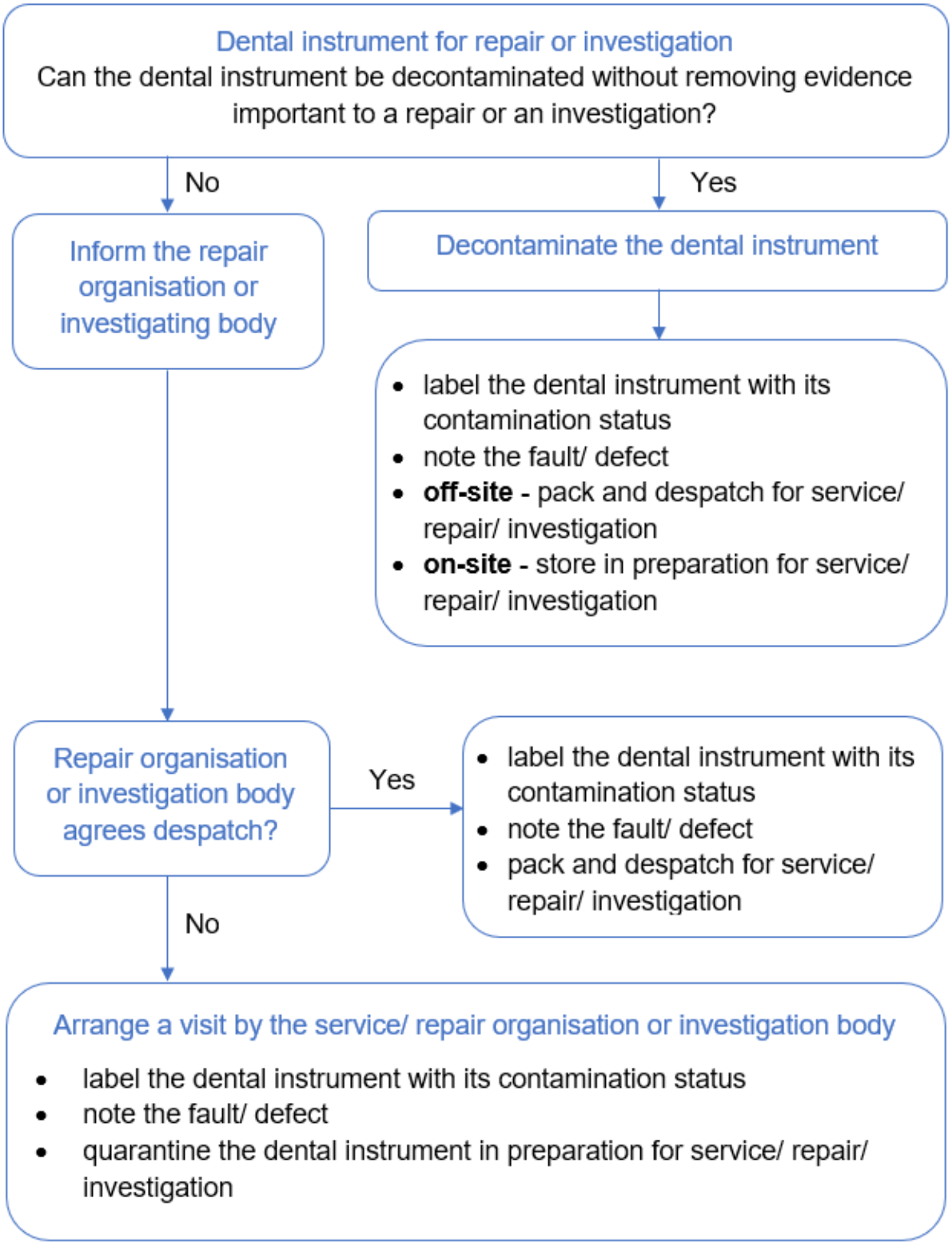
8.12. If using a third-party organisation, ensure there is an agreed specification regarding the level and extent of work to be undertaken and the quality of replacement items.

Sending dental instruments for repair or refurbishment

8.13. Ensure that the dental instrument is decontaminated to an appropriate level before despatch, packed securely and accompanied by a certificate stating the decontamination method used, see Figure 8.1. The decontamination process should not cause further damage. However, the emphasis should always be on presenting a dental instrument which is as safe as possible to handle on receipt. Consult the repair organisation or investigating body (refer to Section 5) if there is any doubt. As a minimum, the external surfaces should

be wiped clean, the device packaged securely, and a full explanation given on the accompanying decontamination certificate. Consult Health Facilities Scotland (HFS) 2013 guidance GUID 5006 'Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices'.

Figure 8.1 - Assessing actions for repairing the dental instrument



Quarantine of dental instruments

8.14. Dental instruments that are worn, damaged, or require a scheduled service should be quarantined pending the repair, replacement, or service.

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

9. Disposal and decommissioning

9.1. Where required by the terms of the waste disposal contract, dental instruments at the end of life that are to be recycled may or may not be decontaminated before despatch (such as if single-use the instruments may not be processed). If required to be decontaminated to make them safe to handle, the dental instruments should be accompanied by a certificate stating the method by which they were decontaminated. The correct contract should be put in place for the waste produced.

9.2. Scrapped dental instruments must not fall into the hands of those who may misuse them. Dental instruments that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.

9.3. Disposal of dental instruments should be in accordance with Health Facilities Scotland (HFS) guidance HFS guidance Scottish Health Technical Note (SHTN) 03-01 'NHSScotland Waste Management Guidance'.

Global Citizenship Programme

9.4. Organisations may choose, in accordance with their local policy, to offer or sell unused or unwanted equipment (such as dental instruments/ decontamination equipment) or to pass it to other countries, must follow various guidance such as SHTN 00-04, and see Scotland Global Citizenship Programme information via the Scottish Global Health Coordination Unit website.

Appendix A Health and safety legislation

A.1 The standards of health and safety are delivered through a flexible enabling system introduced in 1974 by the Health and Safety at Work Act etc.1974. Other legislation that follows this principal act includes:

- Confined Spaces Regulations 1997
- The Carriage of Dangerous Goods and Use of Transportable Pressure; Equipment Regulations 2004
- Control of Noise at Work Regulations 2005
- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- Controlled Waste Regulations 1992. SI 1992 No 588
- Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002
- Disability Discrimination Act 1995 and amendments 2005
- Electricity at Work Regulations 1989
- Electricity Safety, Quality and Continuity Regulations 2002
- Electrical Equipment (Safety) Regulations 1994
- Electromagnetic Compatibility Regulations 1992
- Employers Liability (Compulsory Insurance) Regulations 1998
- Environment Protection Act 1990
- Furniture and Furnishings (Fire) (Safety) Regulations 1988
- Gas Appliances (Safety) Regulations 1995
- Gas Safety (Installation and Use) Regulations 1998
- Health and Safety (Display Screen Equipment) Regulations 1992
- Health and Safety (Safety Signs and Signals) Regulations 1996
- Health and Safety Executive (HSE) Approved Code of Practice (ACoP) L8 Legionnaires' disease - The control of legionella bacteria in water systems
- HSE Technical guidance HSG 274 Part 2 Legionnaires' disease - The control of legionella bacteria in hot and cold-water systems
- Low Voltage Electrical Regulations 1997. HMSO, 1997
- (the) Management of Health and Safety at Work Regulations 1999
- Manual Handling Operations Regulations 1992
- Personal Protective Equipment Regulations 2002
- Plugs and Sockets etc. (Safety) Regulations 1994
- Pollution Prevention and Control (Scotland) Regulations 2000
- Pressure Equipment Regulations 1999

- Pressure Systems Safety Regulations 2000
- (the) Provision and Use of Work Equipment Regulations 1998
- Producer Responsibility Obligations (Packaging Waste) Regulations 2005
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations;1995 (RIDDOR 95)
- (the) Regulatory Reform (Fire Safety) Order 2005
- Simple Pressure Vessels (Safety) Regulations 1991
- (the) Special Waste Regulations 1996
- Supply of Machinery (Safety) Regulations 1992

Appendix B Procurement of equipment

Pre-purchase considerations

B.1 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.

B.2 The efficient completion of procurement documentation will require advice and assistance from the Authorising Engineer (Decontamination) (AE(D)) as required.

B.3 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

B.4 Adherence to engineering standards and quality systems ensures that decontamination equipment is manufactured, installed, validated and subject to the necessary periodic testing to establish the initial and then ongoing satisfactory performance of the machine to ensure optimum decontamination of medical devices and safety of both operators and patients.

Specification preparation

B.5 The use of a specification will enable data provided by the tenderer on technical points as well as financial data to be compared. Not only will this enable the purchaser to confirm the acceptability of current services, spatial requirements, and porterage, but also it will enable a like-for-like tender analysis to be made. Tender analysis will be best achieved by formalising tender comparison with respect to performance and cost in all key areas. Qualifying statements by the tenderer should be taken into account. Their effect on tender content or eligibility should be assessed before making a choice.

Procurement of equipment - an overview of points to consider

B.6 Information required in the purchase of decontamination equipment, see Table B.1

Table B.1: Questions to consider when procuring equipment

Questions	Comment
What type of load will be processed?	Examples - Lumened instruments, packed/ non-packaged (vacuum/ non-vacuum.)
What type of machine is required?	Examples - Under-bench, standalone, pass-through.
Where will the machine be sited?	The location available for the equipment will have a significant influence on the type of machine that can be used.
What services are available?	Some decontamination equipment will require several of the following services: steam, electricity, water, compressed air, drainage, effluent handling, ventilation and bulk or integral storage/ supply of chemical additives/ sterilant gas supply. The manufacturers' data will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It might be necessary to plan for a new service, which would add greatly to the cost of the installation.
Who will operate the equipment?	Equipment located in a Local Decontamination Unit (LDU) under the care of dental nurse or LDU operators.
What capacity is required?	The likely daily and weekly workload, and the peak hourly workload, that the equipment will have to process should be established, then the number of machines required to process the workload should be calculated. Throughput figures for different manufacturers' machines and different models within any given range vary considerably.
What ancillary equipment will be needed?	A sterilizer installation might require ancillary equipment such as special ventilation, water treatment for steam generators, air compressors, preconditioning facilities, degassing facilities, and gas disposal plants. A washer-disinfector might require ancillary equipment such as water softeners, deionization, or reverse osmosis (RO) water treatment plants, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals. A

Questions	Comment
	decision on treatment should be based upon an initial assessment of source water and historical reports and cost based upon risk analysis. In addition, some machines will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product, and means for returning load carriers from the unloading side of the machine back to the loading side.

B.7 Consideration should be given to contingency plans for machine usage, and sufficient time should be included for testing, maintenance, and service.

B.8 Thus, reliance on a single item of equipment is not advisable. It should be noted that the turnaround times can fluctuate based on the demand placed on the service.

General design considerations

B.9 All decontamination equipment and associated equipment is classed as work equipment and should comply with but not exclusive to the Provision and Use of Work Equipment Regulations 1998 amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013, Pressure Systems Safety Regulations (PSSR) 2000.

Safety features

B.10 Safety features should be designed in accordance with the Guidance on safe use of machinery, PD 5304:2019, and the European standards for the safety of electrical equipment, BS EN 61010-1: 2010+A1:2019 and BS EN IEC 61010-2-040:2021.

B.11 The design of the control system should ensure that the door cannot be opened until the cycle is complete. When a fault is indicated the door should only be able to be opened by a key code or tool, when the equipment is returned to a safe condition.

B.12 The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

B.13 All safety devices should be designed to fail in a manner that does not cause a safety hazard to personnel.

B.14 Any error in the control or indication system should not cause a safety hazard.

Decontamination equipment

B.15 Where a piece of decontamination equipment can be adjusted, the adjustment should require the use of a key code or tool that is not available to the Operator.

B.16 Where a fault is indicated as an error message shown on a visual display unit, it should be clearly distinguishable from normal messages, for example, by use of a different colour or larger size of text. The indication should remain displayed until acknowledged by the Operator.

B.17 Where required within the specification, the Contractor should be required to carry out adjustments to the decontamination equipment on site so that the accuracies specified for chemical dosing, and disinfection temperatures can be met with the plant running and under the conditions normally prevailing on site. Values should be recorded before and after adjustment.

Programmable electronic systems

B.18 Modern decontamination equipment frequently uses programmable electronic systems (PES) for control and data recording. Where such systems are used, they should be designed in accordance with the principles set out in the BS EN 61508: 2010 series 'Functional safety of electrical/ electronic/ programmable electronic safety-related systems' in safety related applications.

B.19 Where a PES is used for control or monitoring of the process, the values of cycle variables critical to process performance determined during validation, should be documented in the validation report, regardless of even if they are held in the PES memory. The version number of the software should be available for display when required.

B.20 Combined control and instrumentation systems that are wholly operated by means of PES should incorporate into at least two-timing systems, independent of each other, such that the timer used to control the holding time is verified by the other timer. Any future changes to software should be advised and agreed with the User prior to an upgrade, in order that any revalidation requirements are addressed.

Invitation to tender

B.21 Once detailed specifications have been drawn up, manufacturers should be invited to contribute to a mini competition for the supply and the installation of the decontamination equipment.

B.22 Prospective contractors should be given the following information:

- that each machine will be subject to a validation process

- that unless otherwise specified, the installation checks and tests specified in the validation process should be satisfactorily completed before the machine can be accepted
- whether the factory/works tests (optional, only carried out in special circumstances), site visits or installation checks and tests are to be witnessed by the appropriately qualified purchaser's representative (normally the AE(D), Authorising Person (Decontamination) (AP(D)) or Competent Person Decontamination (CP(D))
- the date by which all services will be available
- the date by which the validation process is expected to be completed

Contract

B.23 Advice from National Services Scotland (NSS) should be obtained as part of this process and NHSScotland dental services should use the National Procurement (NP) framework 143 for Decontamination equipment, accessories, and maintenance. The principal objective of this Framework is to provide a route to market for all NHSScotland decontamination capital equipment requirements and provide Dental Contractors, who treat NHS patients, with access to compliant decontamination equipment.

B.24 Equipment purchased from the NP143 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 NP standard terms and conditions of contract for the purchase of goods and service. Dental Services should ensure that all orders reference the NP143 contract reference on all purchase orders.

B.25 User will also assess:

- the suitability of equipment for decontamination within the practice's current protocol and national guidance is assessed through communication with supplier/ manufacturers' representatives or specialist bodies who can provide this information
- specialists are consulted where necessary (for example Antimicrobial Resistance and Healthcare Associated Infection (ARHAI Scotland) for infection, prevention and control (IPC) component for decontamination and Health Facilities Scotland (HFS) for decontamination technical)

Alternative forms of contract could be used dependent on the dental service policy and procedures for purchase of equipment not available on the NP143 framework.

Delivery

B.26 Decontamination equipment for a particular scheme should not be ordered and stored on site for prolonged 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.

B.27 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

B.28 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 at an early stage which services will be needed and the detailed requirements for each. Consult Scottish Health Planning Note (SHPN) 13 part 2 ‘Decontamination Facilities: Local Decontamination Units’: 2008.

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.

Government publications

- **Government letter of 21 May 2018** Chief Nursing Officer Division, Karen Stewart Healthcare Science Officer - Decontamination Professionals - Healthcare Science framework
- **Scottish Executive Health Department (SEHD)/ Chief Medical Officer's (CMO) (2007) 5, Important Advice for Dentists on Re-use of Endodontic Devices and Variant Creutzfeldt-Jacob Disease (vCJD)**, Scottish Executive Health Department 19 April 2007
- **The National Health Service (General Dental Services) (Scotland) Regulations 2010**, SSI 2010 No 208, 2 July 2010
- **Creutzfeldt-Jakob disease (CJD)**: guidance, data and analysis in Primary Care dentistry
- **Chief Executive Letter (CEL 43 2009):** Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities
- **Addendum to Chief Executive Letter (CEL 43 2009):** Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

Regulation

- **Council Directive 93/42/EEC** concerning medical devices
- **The Medical Devices Regulations 2002** (SI 2002 No 618, as amended) (UK MDR 2002)
- **Medicines and Medical Devices Act 2021**

European Standards/ Test specifications

- **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. BSI
- **BS EN ISO 17664-2:2021** Processing of healthcare products – Information to be provided by the medical device manufacturer for the processing of medical devices – Non-critical medical devices. BSI
- **BS EN 13060 :2014 + A1 2018** Small steam sterilizers, BSI
- **BS EN ISO 13485: 2016+A11:2021** Medical Devices. Quality management systems. Requirements for regulatory purposes. CEN
- **BS EN ISO 11139: 2018** Sterilization of health care products - Vocabulary - Terms used in sterilization and related equipment and process standards. CEN

- **BS EN 61010-1:2010+A1:2019** Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements. BSI
- **BS EN IEC 61010-2-040:2021** Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials. BSI
- **BS EN 61508: 2010** series Functional safety of electrical/ electronic/ programmable electronic safety-related systems. Requirements for electrical/ electronic/ programmable electronic safety-related systems. BSI
- **PD 5304:2019** Guidance on safe use of machinery. BSI

Health Facilities Scotland publications

- **Scottish Health Technical Memorandum (SHTM) 01-05 part B**: Decontamination equipment / test methods, Health Facilities Scotland, 2024
- **SHTM 01-05 part C**: Process, Health Facilities Scotland, 2024
- **SHTM 01-01** Decontamination of medical devices in a Central Decontamination Unit - part B: Test equipment/methods, 2018
- **SHTM 01-01** Decontamination of medical devices in a Central Decontamination Unit - part C: Sterilization by steam equipment/methods, 2018
- **SHTM 01-01** Decontamination of medical devices in a Central Decontamination Unit - part D: Automated cleaning and disinfection equipment, 2018
- **SHPN 13 part 2** Decontamination Facilities: Local Decontamination Units, Health Facilities Scotland, 2008
- **SHTM 2031**: Clean steam for sterilization, Health Facilities Scotland, 2001
- **Compliant Dental Local Decontamination Units in Scotland – GUID 5005**, November 2019
- **SHTM 00** Best practice guidance for healthcare engineering Policies and principles - Health Facilities Scotland, 2013
- **Scottish Health Technical Note (SHTN) 03-01**: NHSScotland Waste Management Guidance, Health Facilities Scotland 2023.
- **Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices GUID 5006**, Health Facilities Scotland, 2013
- **SHTN 00-04** Guidance on management of medical devices and equipment in Scotland healthcare and social services. Health Facilities Scotland, 2021

Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) publications

- National Infection Prevention and Control Manual. ARHAI Scotland, [Accessed July 2023]
- HAI Compendium Guidance and Resources. ARHAI, updated real time. [Accessed October 2023]

Healthcare Improvement Scotland publications

- Infection prevention and control standards, May 2022. Healthcare Improvement Scotland (HIS)

NHS Education for Scotland (NES) publications

- **Scottish Dental Clinical Effectiveness Programme - Decontamination into Practice** - Dental Clinical Guidance 2016
- Framework to support staff development in the decontamination of reusable medical devices - updated (Version 2 updated 1/2/22)
- **Practice Support Manual (PSM)**, Scottish Dental Clinical Effectiveness Programme https://www.psm.sdcep.org.uk/

Other publications

- **NP143/17** Decontamination Equipment and Associated Maintenance
- National Services Scotland Accessories and Consumables.

HSE (Health and Safety Executive) guidance

- HSE Guidance.
- **Health and Safety at Work etc. Act 1974**, SI 1974 c 37
- **Management of Health and Safety at Work Regulations 1999**, SI 1999 No. 3242 (Amendment Regulations 2006)
- Provision and Use of Work Equipment Regulations 1998 **amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002**
- **The Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013**. Machinery Directive 2006/42/EC
- **The Pressure Systems Safety Regulations 2000** (PSSR)
- Scottish Global Health Coordination Unit. NHS Scotland.

Glossary (specific to Part A)

Decontamination – refer to definitions for 'processing.'

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

- be totally or partially introduced into the human body or a natural orifice
- replace an epithelial surface or the surface of the eye
- remain after the procedure for at least 30 days

[SOURCE: BS EN ISO 13485: 2016+A11:2021 section 3 definitions]

Instructions for use (IFU) - 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)]

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 sterilization 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)]

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

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: BS EN ISO 17664-1:2021 section 3 definitions].

Reusable medical device (RMD) - medical device designated or intended by the manufacturer as suitable for processing and reuse. Note: This is not a medical device that is designated or intended by the manufacturer for single-use only. [SOURCE: BS EN ISO 17664-1:2021 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)]

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

Sterilized – condition of a product that has been exposed to a sterilization process in its sterilized barrier system [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Sterile medical device - medical device intended to meet the requirements for sterility. [SOURCE: BS EN ISO 13485: 2016+A11:2021 section 3 definitions]

Sterilization - process used to render product free from viable microorganisms.

Note 9: 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: BS EN ISO 17664-1:2021 section 3 definitions]

Small steam sterilizer - steam sterilizer which has a chamber volume of less than 60 litres and is unable to accommodate a sterilization module. [SOURCE: BS EN 13060: 2014 + A1:2018 section 3 Terms and definitions]

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

Abbreviations (used in SHTM 01-05)

AC:	alternating current
ACDP:	Advisory Committee on Dangerous Pathogens
AC/hr:	Air Changes/per hour
ACoP:	Approved Code of Practice
ACT:	Automatic Control Test
A/D:	Air Detector
ADR:	Agreement concerning the international carriage of Dangerous goods by Road
AE(D):	Authorising Engineer (Decontamination)
AHD:	Alternative hollow device
AP(D):	Authorized Person (Decontamination)
APIS:	Alternative Porous Indicator System
ARHAI:	Antimicrobial Resistance and Healthcare Associated Infection
BPR:	Batch Processing Record
BS:	British Standard
$CaCO_3$:	Calcium Carbonate
CDO:	Chief Dental Officer
CE:	Conformité Européene
CEL:	Chief Executive Letter
CJD:	Creutzfeldt Jakob Disease
Cl:	Chloride
CMO:	Chief Medical Officer
CNO:	Chief Nursing Officer
COSHH:	Control of Substances Hazardous to Health
CPD:	Continuing Professional Development
CP(D):	Competent Person (Decontamination)
CPI:	Combined Practice Inspection
CP(PS):	Competent Person (Pressure Systems)

DB:	Device Bulletin
DC:	Direct Current
DI:	Deionised
DoH:	Department of Health
DSEAR:	Dangerous Substances and Explosive Atmospheres Regulations
EDTA:	Ethylene Diamine Tetra-Acetic acid
EFA:	Estates and Facilities Alerts
EPA:	Efficient Particulate Air
EU:	European Union
GDC:	General Dental Council
GDP:	General dental practitioners
HAI:	Healthcare Associated Infection
HDL:	Health Department Letter
HEPA:	High Efficiency Particulate Air
HFS:	Health Facilities Scotland
HIS:	Healthcare Improvement Scotland
HoC:	Hierarchy of Controls
HSE:	Health and Safety Executive
HTM:	Health Technical Memorandum, Department of Health, England
IFU:	Instructions for Use
IHEEM:	Institute of Healthcare Engineering and Estate Management
IPC:	Infection, Prevention and Control
IQ:	Installation Qualification
IRIC:	Incident Reporting Investigation Centre
ISE:	Ion-Selective Electrodes
IVD:	in vitro diagnostic device
kVA:	kilovolt-ampere
kW:	kilowatt
LDU:	Local Decontamination Unit

MDA:	Medical Device Alerts
MDDP:	Managing Decontamination in Dental Practice
MDR:	Medical Device Regulations
MHRA:	Medicines and Healthcare products Regulatory Agency
mg/L:	milligrams per litre
MPR:	Master Processing Record
ncg:	non-condensable gas
NES:	NHS Education for Scotland
NIPCM:	National Infection Prevention and Control Manual
NIST:	National Institute of Standards and Technology
NP:	National Procurement
NSS:	National Services Scotland
OEM:	Original equipment manufacturer
OQ:	Operational Qualification
PCD:	Process Challenge Device
PDP:	Personal Development Plan
PES:	Programmable Electronic Systems
pH:	potential of Hydrogen
PPE:	Personal protective equipment
ppm:	parts per million
PPM:	Planned Preventative Maintenance
PQ:	Performance Qualification
PRQ:	Performance Requalification Test
PSM:	Practice Support Manual
PSSR:	Pressure Systems Safety Regulations
QIiPT:	Quality Improvement in-Practice Training
QMS:	Quality Management System
RH:	Relative Humidity
RHD:	Reference Hollow Device

RIDDOR:	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
RMD:	Reusable Medical Device
RO:	Reverse Osmosis
RPD:	Reference Porous Device
SAL:	Sterility Assurance Level
SAN:	Safety Action Notice
SBS:	sterile barrier systems
SDCEP:	Scottish Dental Clinical Effectiveness Programme
SEHD:	Scottish Executive Health Department
SGHD:	Scottish Government Health Department
SHPN:	Scottish Health Planning Note
SHTG:	Scottish Health Technologies Group
SHTM:	Scottish Health Technical Memorandum
SHTN:	Scottish Health Technical Note
SICPs:	Standard Infection Control Precautions
SOP:	Standard Operating Procedure
TBP:	Transmission Based Precautions
TDS:	Total Dissolved Solids
TSE:	Transmissible Spongiform Encephalopathy
TVC:	Total Viable Count
UC:	Ultrasonic Cleaner
UDI:	Unique Device Identifier
UKCA:	United Kingdom Conformity Assessed
vCJD:	variant Creutzfeldt Jakob Disease
WD:	Washer Disinfector
WRAS:	Water Regulations Advisory Scheme
ºC:	Degrees Celsius
µS/cm:	microsiemens per centimetre