Scottish Health Technical Memorandum 01-05

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

Part C: Process - Guidance on decontamination processes, including elements applicable to the dental environment.

October 2022

Contents

1. Introduction

As a result of a continuous evolution of technical requirements since the publication of SHTMs 2010, 2030 and 2031 in 2001 and to facilitate greater alignment with similar guidance in UK administrations, the guidance for decontamination of dental instruments processed in a Local Decontamination Unit (LDU) has been revised. This guidance has a new reference number, SHTM 01-05 and consists of 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 – Test equipment/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 guidance on the decontamination process, including elements of the dental instrument decontamination process applicable to the clinical environment.

The text of SHTM 01-05 Part C is based on and replaces the Scottish Dental Clinical Effectiveness Programme (SDCEP) *Decontamination Into Practice* guidance series. Completed in 2014, this comprised several documents that provided practical advice on the whole instrument decontamination process, presented in a form designed to be readily understandable by members of the dental team. The SDCEP guidance has been used extensively both within dental practices and as the basis for education and training to facilitate improvements in decontamination practice.

Building on the success of the SDCEP guidance series, SHTM 01-05 Part C presents in one document, practical advice on each aspect of decontamination within dental practice, which is up to date with current national standards and generic decontamination guidance. Reference to Parts A or B may be necessary for more detailed technical guidance. Environmental sustainability has been one of the considerations during the updating process. Certain points relevant to environmental sustainability are included.

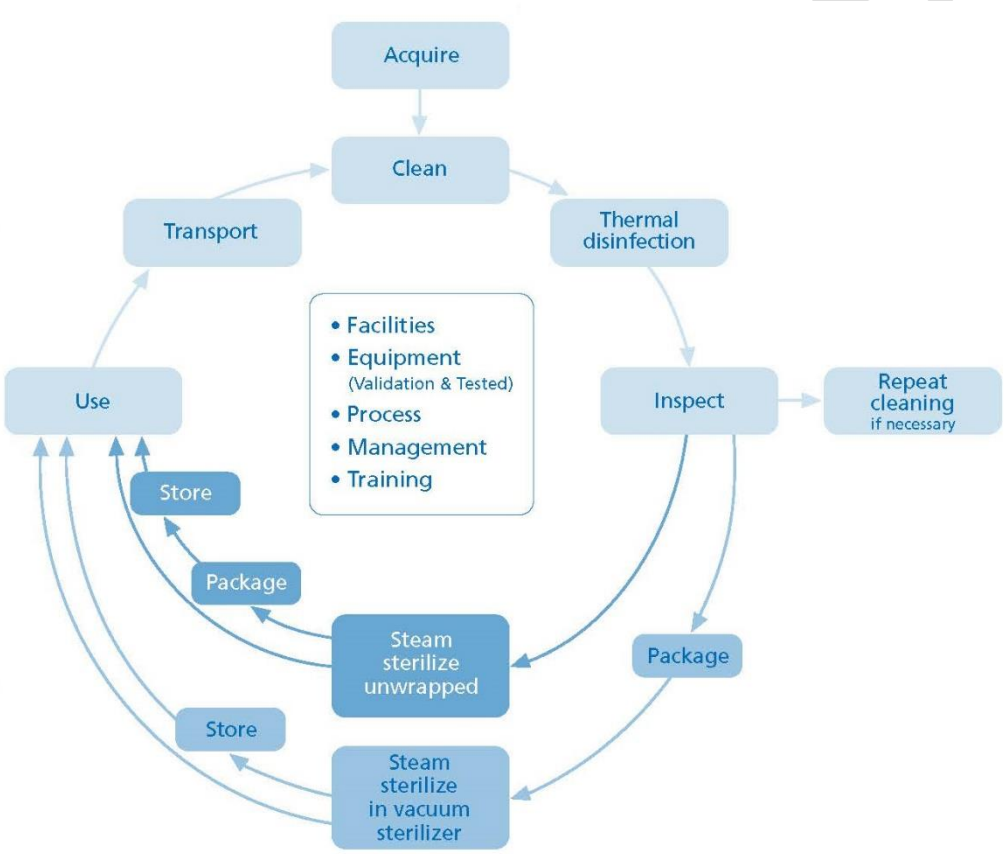
SHTM 01-05 has been developed by Health Facilities Scotland and Part C is the result of a collaboration with SDCEP.

Note that the extant guidance in Scotland is SHTM 01-05, published by NSS Health Facilities Scotland, and not HTM 01-05: Decontamination in primary care dental practices, published by the UK Department of Health.

1.1 Overview of Decontamination of Instruments

Decontamination is the process by which reusable items are rendered safe for further use on patients and safe for staff to handle. Decontamination is required to minimise the risk of transmission of infection between patients and between patients and staff. Decontamination of instruments (also known as processing) is a complex process that involves several stages, including cleaning, disinfection, inspection and sterilization. Figure 1.1 summarises how the individual stages ideally link together to complete the process of instrument decontamination.

Figure 1.1 Overview of instrument decontamination within a dental Local Decontamination Unit



Each stage of the process must be carried out correctly to ensure instruments are decontaminated effectively. Note that:

- disinfection after cleaning reduces the number of viable microorganisms on instruments making them safe to handle. It is not acceptable to use chemical disinfectants to disinfect instruments (unless this is specifically required by the manufacturer) and therefore thermal disinfection using a washer-disinfector (WD) is necessary.
- after sterilization, how instruments are stored before use depends on the type of sterilizer and the procedures the instruments are used for.

- some instruments cannot be steam sterilized. In these cases, decontaminate according to the manufacturers' instructions.
- if sending instruments for repair or disposal, ensure they are decontaminated first.

Ensuring effective decontamination of reusable instruments is complex and relies on the integration of several key elements:

- **facilities** for decontamination that are fit for purpose and well-organised and maintained;
- suitable **equipment** that is validated and undergoes periodic testing and maintenance to ensure it is functioning correctly;
- establishment of a standardised decontamination **process** that is followed;
- **management** of the process with suitable documentation to demonstrate, both to its staff and externally, that the practice meets national standards for decontamination in primary care, can consistently deliver these standards and can identify any improvements required;
- **training** of staff in all decontamination procedures used in the practice so that they know their roles and can carry out their duties effectively.

2. General considerations

2.1 Setting Up a Local Decontamination Unit

Within the Local Decontamination Unit (LDU) the decontamination process is carried out as a dirty-to-clean workflow. When setting up new premises or planning significant modification to existing premises, if space allows, a LDU separate from the patient treatment area(s) that comprises two rooms should be considered: one for dirty activity (the Wash Room) and one for clean activity (inspection, sterilization and wrapping instruments – the Sterilization Room).

A single room LDU is acceptable for general dental practice. In this situation, as the clean and dirty activity is undertaken in the same room, tight procedural control and careful consideration to workflow is required, i.e. incoming dirty instruments spatially segregated from outgoing clean, sterilized (or sterile) instruments is required.

A single room LDU preferably comprises a single run of sealed, easily cleaned worktops with the following items arranged in the order listed:

- a dedicated hand-washing facility with PPE storage;
- a setting-down area for dirty instruments;
- a washing sink with detergent for cleaning instruments;
- a setting-down area for washed instruments;
- an ultrasonic cleaner, if appropriate;
- a rinsing sink;
- a setting-down area for rinsed instruments;
- a lubricator, if required by the instrument manufacturer;
- an automated washer-disinfector (includes drying cycle);
- a setting-down area with task lighting and magnifier for inspection of all instruments;
- a lubricator, if required by the instrument manufacturer;
- an area for loading unwrapped instruments into trays or cassettes for sterilization or for pre-sterilization wrapping of instruments if using a vacuum sterilizer;
- a steam sterilizer;
- an area for set down and cooling following removal from the sterilizer, for wrapping or bagging instruments that have been sterilized unwrapped
- a lubricator, if required by the instrument manufacturer;
- an identifiable, dedicated, clean, rigid box with a lid to transport instruments to the clinical or storage area safely and securely.

Note: depending on the manufacturers' instructions items being processed may require lubrication pre washer-disinfector, and/or post washer-disinfector, and/or post Sterilization. In practice, one location may be sufficient for the lubrication of most, if not all, items processed in the LDU and an automatic lubricator is recommended at this location. For any further items that require lubrication elsewhere in the decontamination process, then lubrication canisters may suffice. Canisters, if used, must be clearly identified as Pre-Wash, Post-Wash, or Post Sterilized and are not interchangeable between areas.

- Ensure instrument storage is clean, orderly, enclosed (e.g. in trays, cassettes or pouches), and is not on open shelving.
    - Ideally, instruments are stored in an area that is separate from the decontamination unit, clinical areas, and is well lit, secure, dry and away from direct sunlight. (During surgery the formation of contaminated aerosols could contaminate processed instruments).
- Ensure storage is arranged so that sterile and sterilized instruments are stored separately and cannot be confused.
- Carry out the decontamination process as a dirty-to-clean workflow that ensures dirty instruments, splashes or aerosols generated during cleaning do not come into contact with clean instruments. This is a one-way process achieved by physical segregation of the dirty and clean activities, see Figure 2.1.

Figure 2.1 A dedicated decontamination unit

- Declutter the working environment, because irrespective of the specific layout, a tidy working environment makes carrying out decontamination easier.
- Within the decontamination unit, maintain air flow in a manner that will reduce the risk of carrying contaminants from the dirty area to the clean area. Do not use portable fans in the LDU and keep windows closed when the room is in use because rapid uncontrolled air circulation can spread contamination.
    - SHPN 13 Part 2 includes basic ventilation requirements for an LDU.
- Document the practice's arrangements for instrument decontamination. This could be a dedicated decontamination policy or part of the practice's infection control policy that provides details of the facilities, staff training, instrument transport within the practice, and written procedures for:
    - instrument segregation and transport to the LDU;

  - instrument cleaning and inspection;
  - instrument sterilization;
  - instrument and raw materials storage;
  - equipment use, testing and maintenance based on manufacturers' instructions;
  - management arrangements including action on decontamination failures.

- Draw up and follow a written waste disposal policy. For further information refer to the SDCEP Practice Support Manual.

Detailed information on planning a Local Decontamination Unit (LDU) is provided in Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Units (2008) and Decontamination - Compliant Dental Local Decontamination Units in Scotland (GUID 5005) (2019).

2.1.1 Health & Safety Requirements for Small Steam Sterilizers

The particular hazards associated with the use of steam sterilizers include scalds from steam or burns from hot metalwork (including instruments), explosive displacement of a door if not properly secured, and infection resulting from inadequate instrument processing. The Pressure Systems Safety Regulations 2000 (PSSR) covers the installation and use of steam sterilizers. As a legal requirement, each sterilizer must have:

  - a written scheme of examination;
  - a periodic examination of the pressure system;
  - third party liability insurance;
  - a record of repairs and maintenance of the pressure system.

- Following installation and before use, obtain a written scheme of examination for each sterilizer from the manufacturer, supplier or insurer that has been prepared by a Competent Person (Pressure Systems).
- Arrange for a Competent Person (Pressure Systems) to conduct safety examinations in accordance with the written scheme of examination for the sterilizer and retain a certificate as proof of each inspection. This examination is in addition to regular and routine maintenance.
- Obtain third-party liability insurance that specifically covers risks associated with the operation of pressure vessels. Such risks may not be covered by practice insurance.
- To comply with legislation, keep records of all examinations and repairs to the pressure system.

Your insurance company may provide details of Competent Persons (Pressure Systems), or advice can be sought from an Authorising Engineer (Decontamination). The Competent Person (Pressure Systems) can also advise how frequently the safety examination is required for each sterilizer (required at least once every 14

months but typically annually). The Health and Safety Executive leaflet Written schemes of examination provides further information.

2.1.2 Installation and Validation of Decontamination Equipment

Validation is the means by which the cleaning or sterilization processes are documented, tested and shown to be repeatable. This demonstrates that all items processed by these methods are reliably and consistently cleaned or sterilized using predetermined and reproducible conditions (see Section 5 for further details).

- Before using a washer-disinfector, ensure that it is installed and validated on site prior to use by a Competent Person (Decontamination) (CP(D)) in accordance with the SHTM 01-05 Part B and that an installation and validation report is issued.
    - If equipment is to be used prior to receipt of the validation report, confirmation should be sought from the manufacturer, supplier or installer (as appropriate) that the equipment is fit for use.
- If used, ensure ultrasonic cleaners are validated at installation to the requirements specified in SHTM 01-05 Part B.
- Ensure that your supplier installs and commissions a new sterilizer and that a Competent Person (Decontamination) validates the sterilization process for all specified loads before use as specified in SHTM 01-05 Part B.
- Keep records of installation and validation (e.g. in the equipment logbook) (see Section 5.2).

Section 5 provides further information about validation.

2.2 Purchasing Dental Instruments

2.2.1 Purchasing Reusable Instruments

Failure to comply with manufacturers' instructions can adversely affect the safety of an instrument and affect product guarantees or warranties.

- Check the manufacturers' instructions **before** purchase to ensure that instruments are suitable, that is:
    - they are good quality and UKCA marked (CE acceptable for purchases up to 30 June 2023);
    - can be decontaminated with the equipment and facilities that you have available, giving preference to buying instruments that can be cleaned using an automated thermal washer-disinfector;
    - they can withstand the temperature and pressure applied during the steam sterilization cycle used in your sterilizer;
    - whether there is a limit to how many times an instrument can be sterilized (e.g. electrosurgery tips).

- If there are reusable instruments in use that cannot withstand cleaning in a washer-disinfector or steam sterilization, source alternatives which can be, or which are single use.

2.2.2 Purchasing Handpieces

- Check handpiece, WD and Sterilizer manufacturers' instructions to confirm that handpieces can be cleaned in your decontamination equipment and the correct procedure for doing this, see Figure 2.2. However, note that there is little published research to demonstrate the efficacy of the cleaning of the internal mechanism of handpieces by this method.

Figure 2.2 Example of a handpiece

2.3 Purchasing Decontamination Equipment

2.3.1 The NHSScotland National Contract for Decontamination Equipment

The NHSScotland National Procurement NP143 framework 'Decontamination Equipment and Associated Maintenance, Accessories and Consumables' was created following a period of equipment testing. The contract includes the purchase price of several washer-disinfectors, ultrasonic cleaners and small steam sterilizers for use in LDUs and gives details of the additional costs for installation, commissioning, testing and maintenance. A full support package which includes both the equipment and the additional costs is also listed.

Note that the current national contract does not include any Type S sterilizers (see Section 4.1.1). Further items are added periodically and, therefore, it is important to check the contract for the latest information.

Health Facilities Scotland and the Chief Dental Officer have recommended that all decontamination equipment (washer-disinfectors, ultrasonic cleaners and small steam sterilizers) is purchased using the national contract as a guide. Equipment purchased via the contract will meet the required specifications **provided that the additional installation, commissioning, testing and maintenance package is also purchased.** The suppliers listed within NP143 need to be contacted directly to purchase equipment.

- Consult the National Procurement NP143 framework to inform purchasing decisions and consider quoting it to the supplier when buying new equipment.
- Refer to the SHTM 01-05 Part A Appendix 2 ‘Procurement of equipment’ which includes a specification preparation and an overview of points to consider.

2.3.2 Purchasing a Washer-Disinfector

Different models of WDs are available that vary in size, design and capacity, a single door example is shown in Figure 2.3. Pass-through models have doors on two sides, which can facilitate the dirty-to-clean work-flow between the Wash Room and the Sterilization Room in a two room LDU.

- Refer to the SHTM 01-05 Part B Section 4 for washer-disinfector specification, performance requirements, design considerations, utilities (including water supply and quality, electrical supply, ventilation, drainage and supplies of process chemicals),
- Ensure cleaning recommendations from instrument manufacturers are in accordance with those of the washer-disinfector and detergent manufacturers.
- If any instruments you are considering buying cannot be satisfactorily decontaminated using a washer-disinfector, source alternatives that can be decontaminated using this method.

Figure 2.3 Under bench washer disinfector shown with door open.

2.3.3 Purchasing an Ultrasonic Cleaner

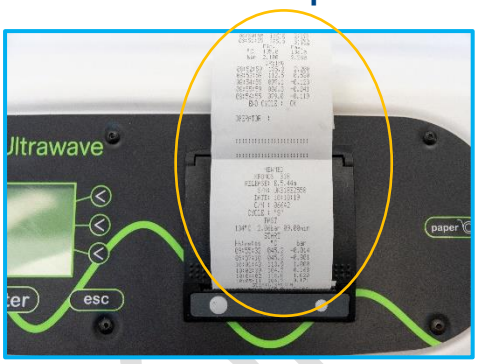
An Ultrasonic Cleaner (UC) within an LDU environment is usually a stand-alone ultrasonic bath, see example in Figure 2.4. Ultrasonic cleaners are not intended as a primary cleaning method routinely but may be used as a backup automated cleaning process in the event of washer-disinfector (WD) failure and as a cleaning process before cleaning and disinfection in a WD for dental instruments. Ultrasonic cleaners do not incorporate a disinfection stage.

- Refer to the SHTM 01-05 Part B Section 5 for general information about ultrasonic cleaners, including specification and process chemical compatibility.
- Before purchasing an ultrasonic cleaner ensure that the ultrasonic cleaner complies with the requirements of SHTM 01-05 Part B and has the following features:

Figure 2.4 Ultrasonic cleaner

- control of process variables such as time and temperature and preferably monitors for failure of ultrasonic activity;
- a lid with an interlock to prevent operation of the cleaner when the lid is open (ultrasonic cleaners must be operated with the lid closed);
- a choice of load carrier(s) appropriate to the nature of the devices to be processed;
- a chamber drain-tap to enable the chamber to be emptied;
- a printer or datalogger to give a retainable record of each cleaning cycle, see Figure 2.5.

Figure 2.5 Ultrasonic cleaner Printout slip



2.3.4 Purchasing Lubricators and Heat Sealers

Lubricators are mainly used during the reprocessing of dental handpieces. In some LDUs, a heat sealer is used to seal instruments into bags or pouches either before being sterilized, in a Vacuum Sterilizer, or after being sterilized, depending on whether the items are required to be sterile at the point of use or sterilized respectively.

- Refer to the SHTM 01-05 Part B Section 6 for information about lubricators (types and maintenance) and heat sealers (validation and maintenance and operation).

2.3.5 Purchasing a Small Steam Sterilizer

As discussed in Section 4.1.1, models of small steam sterilizer differ in the type of sterilization cycle they perform which dictates the types of load they can sterilize. The resource requirements (e.g. costs and time for testing, level of staff training) will differ significantly depending on the type of sterilizer. In 2017, the Scottish Health Technologies Group found no direct evidence to assess whether the provision of benchtop vacuum sterilizers to dental practices in Scotland would provide benefit in terms of increased patient safety to justify the additional cost. (Advice Statement 002/17). While more costly to purchase and maintain, use of a benchtop vacuum sterilizer enables instruments to be sealed inside a sterile barrier in which sterility is maintained after processing. Whatever type of sterilizer is chosen it is essential to follow manufacturers processing instructions for both sterilizer and instruments and this information should inform decisions about the purchase of a small steam sterilizer.

Figure 2.6 Benchtop Sterilizer 1

Figure 2.7 Benchtop Sterilizer 2

Before purchasing a small steam sterilizer, to ensure that it is suitable for use:

- Refer to the SHTM 01-05 Part B Section 7 for sterilizer specifications, performance requirements, design considerations, utilities (including water supply and quality, electrical supply, ventilation and drainage);
- Specify clearly to the supplier the type of loads that you intend to reprocess including:
    - the quantities of instruments you are likely to reprocess per load and per day;
    - instrument cassette/tray dimensions (if used);
    - whether the loads include solid or hollow instruments;
    - whether instruments will be wrapped or unwrapped.
- Ensure the sterilizer carries the UKCA mark (CE acceptable for purchases up to 30 June 2023). This indicates that the manufacturer claims compliance with the Essential Requirements of the Medical Device Directive.
- Ensure that the sterilizer complies with British Standards (BS EN 13060) and SHTM 01-05 Part B.
- Check with the supplier that:
    - they can install the sterilizer to be consistent with SHTM 01-05 Part B requirements and provide certification of this;
    - they will provide written operating instructions and training;
    - they provide a repair service and specify a response time and can provide, where necessary, replacement/loan equipment. (Before purchase the acceptability of the repair response time should be considered);
    - they can supply a contract for maintenance and testing in accordance with the manufacturers' instructions;
    - the sterilizer performs a cycle that can be validated (see Section 5).
- Ask the supplier to provide details in writing of:

- how many instrument trays, cassettes or racks the sterilizer can process in one cycle;
- how long a cycle takes;
- the number of different cycles the sterilizer can perform;
- dimensions of the chamber, useable chamber space and door orientation;
- a local servicing agent;
- the costs involved for installation, validation, periodic testing and maintenance;
- periodic tests, including whether the machine can perform these tests automatically and whether the User can perform them;
- how long the machine is out of action for maintenance (and how many times per year);
- the services required including electrical and plumbing requirements;
- any other specific requirements (e.g. water quality and quantity required per cycle);
- whether the machine has a printer installed or uses electronic data logging and capture. In the case of electronic data capture how and how long data is stored and how it can be retrieved for review and hardcopy printing. In addition what data is recorded and stored or printed during operating cycles. As a minimum the chamber temperature and pressure should be recorded along with the sterilization holding time;
- whether other attachments or accessories are required and whether they have been included in the costs.

2.4 Decontamination Staff

Appendix A details the roles and responsibilities of personnel necessary for validation and quality assurance. This includes both staff in the practice and external personnel.

Management (e.g. Practice Principal) should:

- Appoint a **User** as the named person responsible for appointing Operators and ensuring their competence, and for the day-to-day management of LDU equipment, its use, maintenance and testing, and relevant documentation.
    - In a dental practice, the User could be a suitably trained dentist, senior dental nurse, practice manager or other health professional.
- Appoint **Operators** to operate LDU equipment, including performing basic housekeeping duties.
- Maintain a list of roles and responsibilities for decontamination in the practice.

  - A template (Local Decontamination Unit Staff Roles and Responsibilities) is available in the SDCEP Practice Support Manual

- Ensure all members of staff who are directly involved in instrument decontamination comply with the practice infection prevention and control policy regarding hepatitis B vaccination status.

2.4.1 Training Staff

It is a requirement of the Provision and Use of Work Equipment Regulations 1998, HPS LDU Guidance and HFS GUID 5005 that all staff who manage, supervise or operate LDU equipment are trained in its use and maintenance. The practice owner (Management – see Appendix A) is responsible for ensuring that systems are in place for ongoing staff training.

- Train all staff in the basics of infection prevention and control procedures, including:
  - how infections are transmitted;
  - how to prevent transmission of infections;
  - what to do in the event of an accident or personal injury;
  - your practice policy on infection control.
- Train all members of staff involved in instrument decontamination in all stages of the process to ensure that they:
  - prepare properly for decontamination, including transporting contaminated instruments, disposing of single-use items correctly, recognising the range of reusable devices used in the practice, how to dismantle instruments where appropriate, and selecting the correct cleaning method for each instrument (see below and Section 3);
  - understand the key principles and importance of effective cleaning;
  - are able to use all cleaning methods and decontamination equipment in the practice properly and safely;
  - know what kind of sterilizers (vacuum/non-vacuum) are in the practice, what type of cycle is used in each sterilizer, and the loading configuration;
  - understand lubrication, inspection, wrapping and labelling;
  - know how to store instruments after sterilization;
  - understand record management;
  - understand the basis of and can perform periodic testing and housekeeping of the equipment and maintain accurate records (see Sections 5 and 6);
  - understand importance of reporting: equipment, instrumentation and decontamination failures and the process for doing so.
- Include new instruments in staff training.

- Record and retain details of all staff training and keep these up to date.

2.5 Standard Infection Control Precautions

The National Infection Prevention and Control Manual provides details of the Standard Infection Control Precautions (SICPs) to be followed to reduce the risk of transmission of infectious agents. These include hand hygiene and personal protective equipment.

2.5.1 Hand Hygiene

Effective hand hygiene is crucial for preventing the spread of infection.

- As gloves are not a substitute for hand hygiene, perform hand hygiene before and after using gloves.

Staff

- Keep nails short and clean. Do not wear artificial nails or extensions or nail varnish if working in the clinical environment, including the decontamination unit.
- Cover cuts and abrasions with waterproof dressings.
- Remove wrist and hand jewellery, including wrist watches, before working in the clinical environment or the decontamination unit. A plain metal finger ring or ring dosimeter (radiation ring) is permitted, but should be removed (or moved up) during hand hygiene to ensure the area under the ring is cleaned and dried thoroughly.

Facilities and procedures

- Ensure that there is a dedicated sink for hand washing in the decontamination unit and that the sink:
    - does not have a plug or an overflow and is fitted with a remote running trap (i.e. the U bend is not directly under the plughole);
    - has an electronic sensor-operated or elbow/wrist lever-operated mixer tap;
    - has a tap that runs into the sink basin and not straight down the drain to avoid aerosol from the drainage system splashing back onto the user.

Figure 2.8 A wall-mounted soap dispenser

- Use wall-mounted non-antimicrobial liquid soap dispensers with disposable cartridges and ensure the nozzle is kept clean. Recycle used plastic. (see Figure 2.8)

- Do not use refillable containers as bacteria can multiply within many of these products and are therefore a potential source of contamination.
- Document the practice's policy and procedures for when and how to use non-antibacterial liquid soap and alcohol-based hand rubs/gels to perform hand hygiene, and ensure that staff follow these procedures.
- Apply non-antimicrobial liquid soap to wet hands to reduce the risk of irritation and wash all surfaces of the hands thoroughly before rinsing under running water.
- Do not use bar soap.
- Do not use scrub or nail brushes because these can cause abrasion of the skin and can be a source of infection.
- Use disposable paper towels to pat hands dry thoroughly after hand washing; avoid rubbing which may lead to skin irritation/damage.
- Discard paper hand towels in foot-operated or sensor-operated waste bins.
- Use an emollient hand cream during and after work to counteract dryness but, do not use hand cream under gloves because, this can encourage growth of microorganisms. Do not use refillable dispensers or provide communal tubs of hand cream.
- Alcohol-based hand rubs/gels formulated for use without water can be used on visibly clean hands following manufacturers' instructions.
    - Follow local infection control guidance or manufacturers' instructions on the maximum number of applications of alcohol-based hand rubs/gels that can be used on physically clean hands before hand washing is required. Be aware that build-up of product on the hands occurs with repeated application.
- Do not use alcohol-impregnated wipes as a substitute for alcohol-based hand rubs/gels.

The National Infection Prevention and Control Manual includes step-by-step illustrated guides for hand washing and use of alcohol-based hand rubs.

Moving from dirty to clean areas

- During the decontamination process, change PPE and clean hands between dirty and clean activities.

2.5.2 Personal protective equipment (PPE)

PPE provides a protective barrier against the spread of infections through contact with blood or body fluids either directly or via splatter or aerosol spray.

- For instrument cleaning, wear PPE that is appropriate to the cleaning method. For example, household gloves, facemasks, eye protection, and plastic disposable aprons are required for manual cleaning.
- Include this information in the practice's COSHH assessment of blood, saliva and other biological materials.
- Wash household gloves with detergent and hot water and dry after each use to remove visible soil.
- Inspect these gloves for damage prior to use.
- Replace these gloves if damaged or, if soil cannot be removed.
- Otherwise, wear fresh disposable gloves when
    - handling instruments that have been cleaned prior to sterilization
    - handling unwrapped or wrapped instruments after sterilization prior to storage or use
    - handling packs of sterile or sterilized instruments
    - loading the WD
- Ensure your local infection control or decontamination policy specifies when PPE is to be worn and changed.

Figure 2.9 Personal protective equipment

Figure 2.10 PPE – household gloves

3. Cleaning of Dental Instruments

Effective cleaning is fundamental within the decontamination process and is essential to enable the subsequent disinfection and sterilization of instruments to be carried out reliably (see Figure 3.2 as an example of soiled dental instrument). Any organic material, including prions, or adherent dental materials left on instruments can inhibit these processes. This can also cause corrosion of instruments or impair their function and might lead to transmission of infection from one patient to another.

Figure 3.1 A soiled dental instrument

F3.1 Before Cleaning

General considerations, including LDU setup, staffing and staff training, procurement and SICPs, are described in Section 2.

3.1.1 During treatment

- Keep your standard kits to a minimum. Do not set out instruments you do not need.
- Regard all instruments set out for each patient as contaminated after the treatment, whether or not they have been used.
- When working with substances that can harden on instruments (e.g. cements), wipe reusable instruments immediately with a lint free swab.
    - To avoid risk of sharps injuries, it is the clinician's responsibility to ensure that residues are removed from sharp hand instruments used in the patient's mouth, such as scalers.

3.1.2 Segregating Instruments and transport to the LDU

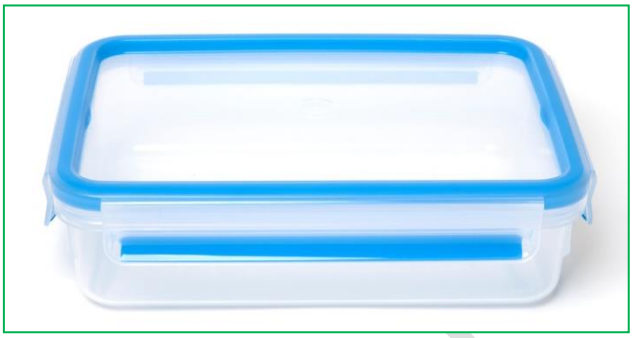
A used dental kit (see figure 3.2) contains a wide variety of instruments and contaminated material.

Figure 3.2 Used dental kit

- Following clinical procedures, segregate disposable and reusable items.
- Dispose of all single use instruments and disposable items in the clinical area.
- Place reusable items in the appropriate transport container to be transferred to the LDU for decontamination.

- Transport instruments to the LDU as soon as possible so that decontamination can begin with minimum delay.
- Use a dedicated rigid, durable, leak-proof container that has a tight-fitting lid and is easy to clean and disinfect, see Figure 3.3
- Ensure that containers for transporting dirty instruments are clearly distinguishable from those used for clean instruments, for example, by colour coding or containers of different sizes.
- Ideally, clean containers in a washer-disinfector (WD). If this is not possible, clean with a fresh detergent solution, rinse and dry. Do not use bleach or hypochlorite solution because residues might damage the instruments.

Figure 3.3 Instrument transport container



More detailed advice on transporting instruments is provided within Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management (2007) and Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Units (2008).

3.1.3 Items for Disposal and Waste Streams

Figure 3.4 shows the symbol that identifies single-use items. This symbol indicates that the device is disposable and not intended to be reprocessed for use on the same or another patient. This will appear on packaging as in Figure 3.5 and 3.5 but might not be present on individual items.

Figure 3.4 Symbol for Single-use item

Figures 3.5 Single-use item symbol shown on rigid packaging

Figure 3.6 Single-use item symbol shown on flexible packaging

- Always check packaging for the single-use symbol before use and note that it might be difficult to see.

- Use single-use instruments only on an individual patient during a single procedure and then discard. The re-use of a single-use device has legal and professional practice implications. Anyone who reprocesses or re-uses a device intended for use on a single occasion bears full responsibility for its safety and effectiveness.

Health Facilities Scotland (HFS) has provided guidance for NHSScotland on waste management in Scottish Health Technical Note 3, including an overview of best practice, policy and procedures. Healthcare waste (including clinical waste) is categorised as a type of special waste and an additional colour-coded stream (Red) has been introduced for individual potentially toxic products (e.g. dental radiography chemicals, amalgam and amalgam-filled teeth) that require specialised disposal. These regulations specify the labelling and paperwork associated with clinical waste.

Figure 3.7 Waste Containers

- Ensure that appropriate waste containers are available for all types of waste (i.e. paper, plastic or special waste, including sharps). See Figure 3.7.
- Assemble all colour-coded waste-disposal containers correctly before use and ensure the lids are firmly clicked into place.
    - Some sharps injuries are caused by containers separating when in use.
- Check with your local waste contractor to ensure that all your colour-coded waste containers and labels comply with the latest HFS guidance.
- Dispose of single-use items according to their category (as outlined in your waste disposal policy).

Figure 3.8 Hand files

Figure 3.9 Endo rotary files

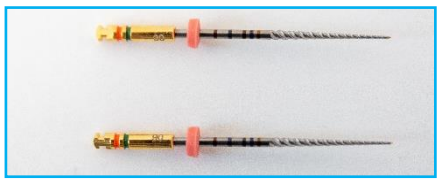


Figure 3.10 Local Anaesthetic cartridge and needle

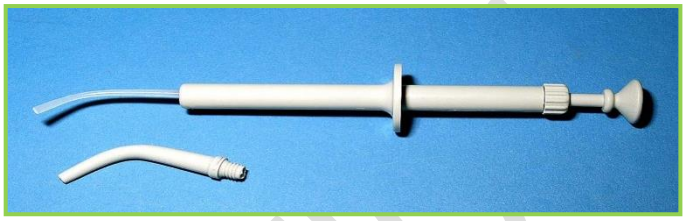
- Identify and dispose of single-use sharps, matrix bands, used and partly used local anaesthetic cartridges in Yellow Stream waste-disposal containers close to the point of use.
- Dispose of amalgam and extracted teeth without amalgam into a designated Red Stream waste-disposal container that is clearly labelled for amalgam waste.

- Dispose of extracted teeth containing amalgam into a separate Red Stream container that is clearly labelled for extracted teeth with amalgam.
- Do not fill colour-coded waste-disposal containers above the specified level.
- Avoid disposing of uncontaminated waste items in specialised waste streams.

3.1.4 Reusable instruments

- Decontaminate all reusable instruments according to manufacturers' instructions. Some instruments will require to be dismantled before cleaning (figure 3.11)

Figure 3.11 Dismantled instrument



- Unless manufacturers' instructions state otherwise, clean reusable instruments in a washer-disinfector following manufacturers' instructions.
    - For heavily soiled instruments, pre-cleaning might be necessary by submerging instruments in cold water (the use of hot water above 45oC can coagulate dental debris fixing it to instrument surfaces making cleaning more difficult).
- Identify reusable items that cannot be immersed in aqueous solution or processed in a washer-disinfector and clean them according to manufacturers' instructions Figure 3.12.
- Maintain a list of instruments to be cleaned by each method.

Figure 3.12 Instrument unsuitable for immersion

3.1.5 Dental handpieces

- Follow the handpiece manufacturers' recommendations for lubrication.
    - Cleaning in a WD might remove all lubricant during the cleaning cycle and therefore handpieces might require further lubrication after cleaning.
    - Some manufacturers recommend that handpieces are lubricated before cleaning, after cleaning and in some cases after sterilization.
    - If carrying out lubrication manually, use separate designated 'pre-wash', 'post-wash' and 'post-sterilizer' canisters of lubricant, labelled

accordingly. Ensure canisters are shaken well before use and that excess lubricant is allowed to drain by standing the handpieces upright.

- Consider the use of automated handpiece lubrication equipment.
    - These machines are not validated for cleaning and do not disinfect. However, their use may prolong handpiece life and can be particularly useful after handpieces are cleaned in a washer-disinfector.
    - Further information about lubricators is provided in SHTM 01-05 Part B Section 6.

3.2 Washer-disinfector cleaning

Use of a washer-disinfector (WD) is a requirement for compliant reprocessing of dental instruments in a LDU [Compliant Dental Local Decontamination Units in Scotland (GUID 5005) (2019]. Using a WD is the preferred method for cleaning dental instruments because it offers the best option for the control and reproducibility of cleaning, and the cleaning process can be validated. WDs are used to carry out the processes of cleaning and disinfection consecutively. A typical WD cycle for instruments includes the following five stages:

Pre-wash Removes 'difficult' gross contamination, including blood, tissue debris, bone fragments and other fluid and solid debris. Latest standards indicate that a water temperature of less than 45°C prevents protein coagulation and fixing of soil to the instrument.

Wash Removes any remaining soil. Mechanical and chemical processes loosen and break up contamination adhering to the instrument surface. Detergents used in this process must be specified by the manufacturer as suitable for use in a WD.

Rinse Removes detergent used during the cleaning process. This stage can contain several sub-stages. It is important to use water of suitable quality.

Thermal disinfection The temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time: for example, 80˚C for 10 minutes, or 90˚C for 1 minute.

Drying Purges the load and chamber with heated air to remove residual moisture.

The cycle time depends on the model of the WD.

It is essential that each WD is correctly:

- Installed;
- Validated;
- Operated;
- Maintained;

  - Periodically tested.

to ensure it is safe, is cleaning dental instruments effectively and to protect your rights should any clinical or decontamination equipment failures occur.

More detailed technical guidance about washer-disinfectors is provided in SHTM 01-05 Part B.

- Install and validate each washer-disinfector in accordance with the current technical guidance (SHTM 01-05 Part B).
- Ensure periodic testing, maintenance and operation of each washer-disinfector is in accordance with the manufacturers' instructions.
- Ensure staff are trained in the operation of the washer-disinfectors, including testing.
- Keep the logbook near the WD so that routine information can be recorded easily. Include in the logbook:
  - results of periodic testing;
  - a record of any cycle that fails and actions taken, including what was done with the load;
  - a record of all maintenance, repairs or modifications;
  - installation, commissioning and validation tests and checks.

Section 5.2 lists other items that must be kept either within the logbook or elsewhere in the practice.

- Retain the logbook for inspection.
  - Refer to SHTM 01-05 Part A for retention periods.

Section 5 provides an overview of the installation, validation, testing, housekeeping and maintenance of washer-disinfectors.

3.2.1 Using a washer-disinfector

Using a WD requires several resources, including:

  - appropriate staff training in operating the WD (e.g. on installation);
  - adequate space and provision of utilities (drainage, water, electricity);
  - compatible instruments and tray systems;
  - a sufficient quantity of instruments.

Tray or cassette systems (see Figure 3.13) for cleaning dental instruments in WDs are recommended. Their use can minimise instrument handling and the risk of sharps injuries.

- Obtain recommendations from the WD manufacturer for the most efficient design and size of trays for use in your washer-disinfector and sterilizer.
    - Instruments must be loaded correctly to ensure adequate cleaning. This will be determined at installation and validation. The design of trays and cassettes must ensure, once loaded, instrument surfaces are not occluded thereby preventing effective cleaning and sterilization. This will be determined at installation and validation.

Figure 3.13 A cassette used in a washer-disinfector and a sterilizer

- Use a suitable quality of water for rinsing instruments that is as recommended in the WD manufacturers' instructions.
- Follow the practice's written procedure for the correct operation of the washer-disinfector that is based on the manufacturers' instructions.
- Train staff in the correct operation of a WD, including how to perform housekeeping checks and periodic tests specified by the manufacturer. An overview of routine testing, including daily tests, is given in Section 5.
- It is crucial to load a WD correctly because incorrectly loaded instruments will not be cleaned effectively. Therefore, follow an instrument loading procedure that has been shown at validation to achieve effective cleaning in the WD.
- Use the same detergent as was used for validation.
    - If a different detergent is used, the washer-disinfector will need to be re-validated.
- In general:
    - do not overload instrument carriers or overlap instruments;
    - open instrument hinges and joints fully;
    - use appropriate instrument carriers and trays for use in the WD.
- Follow the WD manufacturers' instructions for cleaning handpieces.
- Record whether each cycle was satisfactory (e.g. check and sign printouts and keep them as a record).
    - Printouts can be scanned in batches to store electronically.
- After processing in a WD, inspect instruments for cleanliness and, where possible, check functionality as described in Section 3.5, before sterilization.

3.3 Ultrasonic Cleaning

Use of a washer-disinfector (WD) is a requirement for compliant reprocessing of dental instruments in a LDU. Although not an essential requirement, an ultrasonic cleaner can be useful for removal of debris prior to processing in a WD, particularly from instruments with hinges and/or intricate parts. Ultrasonic cleaning may also be used as a backup automated cleaning process in the event of WD failure. It is essential that ultrasonic cleaners are shown to be effective through regular testing and maintenance.

- To enable consistent cleaning of instruments, follow the manufacturers' operating instructions and ensure all staff use a specified and documented operating procedure (see Section 3.3.1).
- Do not use ultrasonic cleaners to clean dental handpieces.
- Test your ultrasonic cleaner as specified in the manufacturers' instructions to ensure that it is fully functional (see Section 5).
- Keep the logbook near the ultrasonic cleaner so that routine information can be recorded easily. Include in the logbook:
    - a record of water changes;
    - results of periodic testing;
    - a record of any cycle that fails and actions taken, including what was done with the load;
    - a record of all maintenance, repairs or modifications.

Section 5.2 lists other items that must be kept either within the logbook or elsewhere in the practice.

- Retain the logbook for inspection.
    - Refer to SHTM 01-05 Part A for retention periods

Section 5 provides an overview of the installation, validation, testing, housekeeping and maintenance of ultrasonic cleaners.

3.3.1 Ultrasonic Cleaning Procedure

- Follow the practice's written procedure for the correct operation of the ultrasonic cleaner that is based on the manufacturers' instructions and follow the points outlined below regarding filling and emptying the cleaner.
- Fill the ultrasonic cleaner tank with cleaning solution approved by the ultrasonic cleaner and instrument manufacturers and at the concentration specified by the cleaning solution manufacturer.
- Run the ultrasonic cleaner while filled with the cleaning solution but without a load for the manufacturers' specified time to de-gas the solution on start-up and on subsequent re-fillings.
- Ensure that joints or hinges are opened fully and instruments that need taking apart are fully disassembled before they are immersed in the solution.

- Place instruments in a suspended basket and fully immerse in the cleaning solution ensuring that all surfaces are in contact with the solution.
- Do not overload the basket or overlap instruments because this results in poor cleaning and can cause wear to the instruments.
- Do not place instruments on the floor of the ultrasonic cleaner because this results in poor cleaning and excessive instrument movement, which can damage the instruments.
- To avoid damage to delicate instruments, a modified basket or tray system might also be necessary.
- Close the lid and do not open until the cycle is complete.
- Select the correct cycle settings for the validated cleaning procedure and start the cleaning cycle.
- After the cycle is complete, raise the basket of instruments and allow to drain before rinsing.
- Change the solution when it becomes visibly contaminated or otherwise every 4 hours because the build-up of debris will reduce the effectiveness of cleaning. Keep a record of each change of solution. Ensure staff are aware of the need to assess when a change of solution is necessary.
- Rinse out the tank after emptying the solution to remove soil before refilling.
- Drain, clean with a neutral detergent solution, rinse and dry the cleaner when not in use (e.g. overnight).
- Record whether each cycle was satisfactory (e.g. check and sign printouts and keep them as a record).
    - Printouts can be scanned in batches to store electronically.
- If, due to WD failure, ultrasonic cleaning is used as a back-up cleaning process, rinse dry and inspect instruments prior to sterilization as described in Section 3.5.

3.4 Manual Cleaning

Manual cleaning of dental instruments cannot be validated because it is difficult to ensure that it is carried out effectively on each occasion. Compared with other cleaning methods, manual cleaning presents a greater risk of sharps injury to staff. Consequently, a washer-disinfector should be used to clean all items where manufacturers' instructions allow. However, despite the limitations of manual cleaning, it is important for each practice to have the facilities, documented procedures and trained staff to carry out manual cleaning as a backup for when other methods fail, are unavailable during maintenance or are not appropriate. For instruments known to be difficult to clean, soaking or manual cleaning prior to an automatic washer-disinfector process might be useful to improve the efficacy of the cleaning process.

Manual cleaning procedures must have systems in place to avoid recontamination of clean instruments.

- Put in place an effective system for manual cleaning, as outlined below, and ensure all staff are trained to follow an agreed, written procedure.
- Soak in cold water and/or use manual cleaning only when it is required by the instrument manufacturers' instructions, for instruments known to be difficult to clean or when the WD fails.

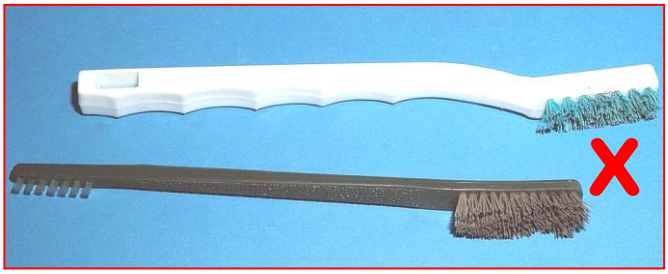
3.4.1 Workflow and Facilities

- Maintain a dirty-to-clean workflow throughout the cleaning procedure.
    - Use two sinks: one for manual cleaning and one for rinsing.
- Always use detergents specifically formulated for manual cleaning of instruments according to manufacturers' instructions.
    - NB: do not use chlorhexidine handscrub, washing-up liquid, cleaning creams or soap. Chlorhexidine in particular makes proteins stick to steel.
- Use appropriate PPE to avoid skin contact. Refer to the detergent manufacturers' instructions regarding hazards.

3.4.2 Manual Cleaning Procedure

- Wear the correct PPE for manual cleaning: household gloves, facemasks/eye protection and plastic disposable aprons.
- Measure the volume of water and detergent to achieve the exact concentration specified by the detergent manufacturer. A line painted on the sink is useful to indicate the required volume of water.
- Using a thermometer, monitor the temperature of the water throughout the cleaning procedure to ensure the temperature is maintained within the range recommended by the detergent manufacturer.
- Where manufacturers' instructions permit, fully submerge items to be cleaned in the detergent solution.
- Scrub instruments using long-handled brushes with soft plastic bristles. To minimise aerosol risk, do not scrub under running water.
- Following cleaning, drain the water, avoiding splashing.
- If the water is heavily soiled, repeat the cleaning procedure.
- Wash brushes with detergent and hot water after each use to remove visible soil and store dry and head up.
- Replace brushes when worn or if soil cannot be removed – see Fig. 3.14.

Figure 3.14 Worn/soiled brushes



3.4.3 Avoiding Instrument Damage

Most dental instruments are made of high-quality materials designed to minimise corrosion if reprocessed correctly. The corrosion resistance is based on their alloy composition and structure, which forms a protective layer on the surface. The ability of the instruments to resist corrosion depends on the quality and thickness of this layer. It is important to avoid damage to the protective layer during cleaning.

- Avoid the use of wire brushes as this can compromise the protective layer and increase the chance of breakage.
- Remove from use any instruments that have rust spots. On no account use wire brushes to remove rust spots.
- Do not use wire pot scourers to clean instruments because these will damage the surface of instruments.
- Avoid contact with chemicals that could damage instruments.
- If manual cleaning is used either as a back-up process due to WD failure or for items that cannot be processed by an automated method, rinse, dry and inspect instruments before sterilization as described in Section 3.5.

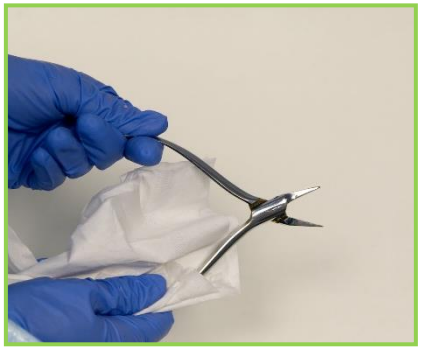
3.5 After Cleaning

Instruments processed in a washer-disinfector do not need to be rinsed and dried as this is part of this automated process. However, after cleaning either manually or in an ultrasonic cleaner, instruments must be rinsed thoroughly to remove residual soil and detergents and then dried thoroughly. Instruments must not be allowed to air dry as inadequate drying might enable moisture to be trapped, promoting corrosion and/or microbial growth.

3.5.1 Rinsing and Drying of Instruments after Cleaning

- Ensure staff are trained in how to rinse, dry and inspect instruments in accordance with the manufacturers' instructions.
- Immerse clean instruments in clean water in a separate sink dedicated for rinsing instruments. Preferably, use the same quality of water for rinsing as is used for sterilization. However, it is acceptable to use freshly drawn soft tap water. In hard-water areas, use purified water for rinsing.
- Use disposable, lint free towels to dry instruments immediately after rinsing, see Figure 3.15.

Figure 3.15 Drying instruments



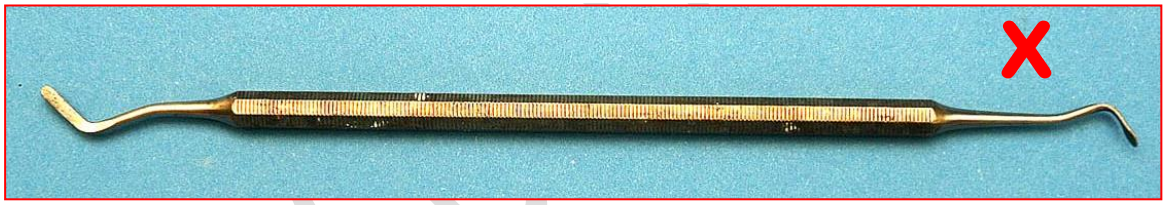
3.5.2 Inspection and Care of Instruments before Sterilizing

All instruments that have been through any cleaning procedure, including processing by a washer-disinfector, need to be inspected to ensure they are clean, functional and in good condition. Using an illuminated magnifier (Figure 3.16) is recommended because it makes it much easier to see residual contamination, debris or damage.

Figure 3.16 An illuminated magnifier

- Inspect instruments for any visible soiling such as blood or dental cements. If there is any residual contamination, reject the instrument and return it to the beginning of the cleaning process.
    - It is especially important to check joints, hinges or the serrated surfaces of jaws, which are difficult to clean.
- Check all instruments to ensure that they are in good working order.
- Dispose of instruments that are blunt, bent or damaged or show any signs of pitting or other corrosion (Figure 3.17).

Figure 3.17 A corroded instrument



- Send broken or damaged instruments that have been decontaminated for repair and include decontamination certification.
- Lubricate the joints and hinges of instruments before sterilizing to prevent seizing and corrosion. Use a lubricant recommended by the instrument manufacturer that is suitable for sterilization.

3.5.3 Handpiece Care

Handpiece lubrication is part of good handpiece maintenance. Inadequate lubrication can lead to unnecessary damage to the internal mechanism.

- Lubricate handpieces according to the manufacturers' instructions. Some manufacturers recommend that handpieces are lubricated before cleaning, after cleaning and in some cases after sterilization.
- If carrying out lubrication manually, use separate designated 'pre-wash', 'post-wash and 'post-sterilizer' canisters of lubricant, labelled accordingly. Ensure canisters are shaken well before use and that excess lubricant is allowed to drain by standing the handpieces upright.

- Consider the use of automated handpiece lubrication equipment. These machines are not validated for cleaning and do not disinfect. However, their use may prolong handpiece life and can be particularly useful after handpieces are cleaned in a washer-disinfector.

The cleaning process is now complete, and the dry instruments are ready for sterilization (see Section 4).

3.5.4 Protocol for End of Day processing of Instruments

- Fully decontaminate instruments as soon as possible after use because if soiled instruments are left to dry then they become more difficult to clean and more likely to corrode. However, if a patient is seen late or out of normal working hours, clean and dry instruments at the end of the treatment session. If instruments are not to be sterilized, clearly label them as unsafe for handling or use and reprocess them through the full decontamination cycle the next working day.
- Put together written policies for staff regarding out-of-hours use of instruments and ensure the details of these policies are included in staff training.

4. Sterilization of Dental Instruments

4.1 Sterilization in the Dental Practice

Sterilization is an essential step in the reprocessing of reusable dental instruments that have become contaminated, or are potentially contaminated, with saliva, blood or other biological fluids. This includes dental handpieces. The aim of sterilization is to break the chain of potential cross-infection between patients by killing micro-organisms, including spores. However, prion proteins are not fully deactivated by the sterilization process. Therefore, effective instrument cleaning is particularly important to physically remove contamination, including prion proteins, prior to sterilization and reduce the risk of cross infection.

Sterilization using a steam sterilizer is recommended as the most efficient, cost effective and safe method of sterilizing dental instruments in primary care dental practices. The sterilization process must be validated to ensure that instruments are reliably and consistently sterilized using predetermined and reproducible conditions (See Section 5).

To kill microorganisms, the instruments need to be exposed to steam (moist heat) at a specified temperature for a specific holding time. Although other options exist, the preferred temperature-pressure-time relationship for all small steam sterilizers is 134–137°C, 2.1–2.25 bar gauge pressure for at least a three-minute holding time.

It is preferable to use reusable instruments that can withstand both an automated cleaning/disinfection process and steam sterilization or to use single-use instruments if a reusable instrument cannot be sourced. Reusable instruments that cannot withstand steam sterilization must be decontaminated as recommended by the instrument manufacturer.

4.1.1 Sterilization Cycles in Small Steam Sterilizers

The sterilization cycle in a small steam sterilizer is a pre-programmed sequence of operating stages. There are three types of sterilization cycle, Type N, Type B and Type S. These cycles differ in the way air is removed, the types of load they can sterilize, and whether or not items can be wrapped during sterilization. Table 4.1 summarizes the features associated with each type of cycle.

Table 4.1 Types of sterilization cycle in small steam sterilizers

Cycle type	Method of air removal	Type of load	Comments	Alternative names for sterilizers that can perform these cycles
N	Passive air removal from the sterilizer chamber (gravity displacement) by steam	Unwrapped, solid items	Simplest type of cycle. Cannot assure sterilization of hollow instruments or those with lumens which may trap air pockets preventing penetration of steam Not suitable for wrapped loads (e.g. items in pouches) Produces a 'sterilized' rather than a 'sterile' product, i.e. the product does not remain sterile beyond the end of the sterilization cycle and the door is opened.	Type N: Non-vacuum, Gravity Displacement,
B	Active (forced) air removal using a vacuum pump	Wrapped or unwrapped solid items Wrapped or unwrapped hollow items	Has the widest range of applications. Can be used for the sterilization of lumened instruments as specified by the manufacturer. A post-sterilization drying stage is essential for wrapped items. This increases the total cycle time. Due to the method of air removal and the additional periodic testing required, sterilizers capable of Type B cycles are relatively more expensive to purchase and maintain. However, they offer the advantage that they can be used to produce sterile wrapped instruments which can then be stored for long periods in a sterile state.	Type B: Vacuum Sterilizer
S	Active (forced) air removal by, for example, steam pulsing	Only suitable for the types of loads specified by the sterilizer manufacturer	Some but not all sterilizers designed to perform Type S cycles can sterilize wrapped and/or hollow items. A type S cycle is only compatible with sterilization of unwrapped, wrapped or hollow items if the sterilizer manufacturer specifies that this is the case. Some have rapid cycle times but a post-sterilization drying stage is essential for wrapped items. This increases the total cycle time. Some sterilizers have instrument cassettes that allow transport of sterile instruments. Sterilizers capable of Type S cycles are relatively more expensive to purchase and maintain. With this in mind care should be taken	Type S

			when considering the purchase of a type S sterilizer to make sure it will have wide applicability for the range of instruments which will need processing in the dental practice	

As some sterilizers can perform more than one type of sterilization cycle, it is more correct to refer to the type of cycle performed rather than the type of machine. However, the following terms are often used for convenience:

- Non-vacuum sterilizer or Type N sterilizer.
- Vacuum sterilizer or Type B sterilizer.

This guidance describes the sterilization of unwrapped instruments in any type of sterilizer and wrapped instruments in a vacuum sterilizer, but not specifically a Type S sterilizer. This is because the various makes of Type S sterilizers differ in the type of load they can be used for and some may not be suitable for sterilizing wrapped instruments. Refer to the manufacturers' instructions for advice on the use of Type S sterilizers.

4.1.2 Sterilized versus Sterile

Instruments are regarded as **sterilized** when they

- have been cleaned, inspected and have undergone sterilization unwrapped (in any type of sterilizer) and are stored in a manner designed to limit environmental recontamination. However, by undergoing the sterilization process, the chain of potential microbial cross-infection between patients is broken.

Instruments are considered to be **sterile** when they

- have been cleaned, inspected and then wrapped and sealed in a sterile barrier system (e.g. sterilization pouch) before being sterilized in a sterilizer designed to process wrapped instruments (e.g. a vacuum sterilizer); to maintain sterility, these instruments must be stored with the wrapping intact until immediately before use;

or

- are bought as sterile single-use items and used in accordance with manufacturers' instructions. (i.e. used immediately on removal from the sterile pack and used only once).

As noted in SHTM 01-05 Part A, instruments used for surgical or implant procedures must be sterile at the point of use. The type of instruments included in this document are dental instruments that are intended for reuse and require processing 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 must be sterile at the point of use e.g. instruments used for dental implant or graft procedures.

4.1.3 Sterilization of Dental Handpieces

It is best practice to follow manufacturers' instructions for handpiece cleaning. After cleaning it is then essential to sterilize handpieces in a steam sterilizer. Although the effectiveness of sterilization of the internal structures is unclear, processing in a sterilizer ensures that the external surfaces are sterilized and may also contribute to risk reduction through further thermal disinfection of the internal structures.

- When purchasing new handpieces, ensure that they can withstand thermal disinfection and steam sterilization.
- Always process dental handpieces in a steam sterilizer as part of their decontamination.
- Follow the handpiece manufacturers' decontamination instructions.
- If necessary, contact the handpiece manufacturer to request clarification of their instructions.
- Lubricate handpieces before and/or after sterilization as recommended by the manufacturer. If lubrication is required both before and after sterilization, use separate designated 'post-wash' and 'post-sterilizer' canisters of lubricant, labelled accordingly and located at the correct position within the decontamination workflow (see Section 2.1).
    - Automated lubricators can be used to lubricate handpieces. These machines are not validated for cleaning and do not disinfect. However, their use may prolong handpiece life and can be particularly useful when handpieces are cleaned in a washer-disinfector (see Section 3.5.3).

4.1.4 Testing and Maintenance of Small Steam Sterilizers

- Ensure that each sterilizer is subject to a documented, planned maintenance programme and periodic testing schedule (see Section 5), for example, through a service contract with your supplier or Competent Person (Decontamination), previously known as either Test Person (Sterilizers) and/or Maintenance Person (Sterilizers).
- Record in the logbook details of all testing and maintenance carried out on each sterilizer.

Section 5 provides an overview of the installation, validation, testing, housekeeping and maintenance of sterilizers.

4.1.5 Cleanliness of Instruments

Contamination of instruments with residual tissue, body fluids, oil or other deposits such as cements can prevent the direct contact between the steam and surfaces of the instruments that is necessary for effective sterilization. Also, any deposits left on instruments before sterilization might become fixed to the instruments making them more difficult to remove later. These deposits can also enter the water in the sterilizer reservoir and encourage growth of microorganisms or accumulation of endotoxins, which could contaminate instruments processed subsequently.

- Ensure all items to be sterilized are clean and dry before placing them in the sterilizer chamber (see Section 3).

4.1.6 Loading of Instruments

Air removal might be impeded if instruments are not loaded correctly and steam may not contact every surface of every instrument. This steam contact is essential for sterilization to occur. See Figures 4.1 and 4.2.

- Load the sterilizer according to the manufacturers' instructions and as specified at validation.
- Ensure instruments do not overlap.
- Open hinged instruments to expose all of the surface area to the steam.
- Place instruments on perforated trays, cassettes or racks that have been validated for use with the selected sterilization cycle.
- Do not overload the sterilizer chamber or individual trays or containers with instruments.

Figure 4.1 Correct loading of instruments for sterilization

Figure 4.2 Incorrect loading of instruments for sterilization

4.1.7 Water for Use in Steam Sterilizers

Water used for sterilization must be essentially free of chemicals and endotoxins. In MDA DB2002(06), the MHRA recommends Sterile Water for Irrigation BP, though other forms of purified water of equivalent specification can be used, for example certain freshly drawn reverse osmosis (RO) or freshly prepared distilled waters. The use of tap water is not acceptable as this can lead to a build-up of contaminants that can be harmful and/or might damage the sterilizer.

- Fill the empty sterilizer reservoir with water of suitable quality. Do not use tap water.
- Change the water at least once per day or sooner if the chamber water is visibly coloured or cloudy and always drain the reservoir at the end of the day. Record when each water change is done.
- If considering purchasing a water purification system to produce distilled or reverse osmosis water within the practice, first seek advice from an Authorising Engineer (Decontamination).

4.1.8 Sterilizer Logbook and Record Keeping

The logbook provides a permanent record of the complete history of the sterilizer.

- Keep the logbook near the sterilizer so that routine information can be recorded easily. Include in the logbook:
    - results of periodic testing;
    - a record of reservoir water changes;
    - a record of any cycle that fails and actions taken, including what was done with the unsterilized load;
    - a record of all maintenance, repairs or modifications.

  Other items that must be kept either within the logbook or elsewhere in the practice include:
    - a list of roles and responsibilities for decontamination;
    - installation, commissioning and validation tests and checks;
    - the written scheme of examination under the Pressure Systems Safety Regulations 2000 (PSSR) (see Section 2.1.1);
    - a record of inspection under the scheme of examination.
- Retain the logbook for inspection.
    - Refer to SHTM 01-05 Part A for retention periods.

Section 5 provides an overview of the installation, validation, testing, housekeeping and maintenance of washer-disinfectors.

4.2 General Sterilization Procedure

The key consideration when determining sterilization operating procedures is the type of sterilizer and sterilization cycle that is being used because this dictates whether or not the instruments can be wrapped before sterilization. Instruments can only be wrapped before sterilization if using a vacuum (or compatible Type S) sterilizer designed for wrapped instruments.

Some procedures are common to all sterilizers and are described in this Section. Specific procedures for sterilizing unwrapped and wrapped instruments are then described in Section 4.3 and 4.4 respectively.

- Have in place a written sterilization procedure that is based on manufacturers' instructions and that includes loading, choice of sterilization cycle, procedure after sterilization and record keeping and ensure that all staff follow this written procedure.
- On each day that the sterilizer is used, carry out the daily housekeeping checks and daily tests (see Section 5).
- Ensure that maintenance and testing records for all sterilizers in use are up to date and satisfactory (see Section 5).

4.2.1 Before Sterilization

- Change your gloves and plastic apron before handling the cleaned instruments, remembering to wash your hands or use alcohol rub on visibly clean hands before putting on new gloves.
- If moving cleaned instruments to a sterilizer in another room, use a dedicated, clean, rigid, labelled container with a lid.
- Transfer instruments to the sterilizer as soon as possible after cleaning, thermal disinfection if a washer-disinfector is used, drying and inspection for cleanliness and functionality. Only wrap instruments before sterilization if using a vacuum sterilizer.
- Load instruments correctly (see Section 4.1.6). For specific advice about unwrapped and wrapped instruments refer to Sections 4.3 and 4.4.
- Check that there is sufficient water in the reservoir (see Section 4.1.7).
- Close the door and lock as per manufacturers' instructions.
- Ensure that the correct sterilization cycle is selected and start the cycle.
- If instruments are not to be sterilized at the end of the day, clean and dry them, clearly label them as unsafe for handling or use and reprocess them through the full decontamination cycle the next working day.

4.2.2 After Sterilization

- Check that the sterilizer indicates that the cycle was satisfactory.
- Using the data logger or printout fitted to the sterilizer, confirm that the required temperature was held (usually 134–137°C for at least 3 minutes) and, if recorded, that the required pressure was attained (usually 2.1–2.25 bar) during the cycle.
- Record that the cycle was satisfactory.
    - If using a printer sign and retain it as a record. Some practices choose to keep an electronic record by scanning signed printouts in batches, thus avoiding the need to store large quantities of printouts.
    - If using a data logger ensure that the data is downloaded and checked at least weekly.

Figure 4.3 Using a tray lifter to unload instruments

- Use special tray lifters or heatproof gloves to carefully unload the sterilizer, see Figure 4.3.
- For instruments sterilized wrapped, check each package remains sealed and is intact and satisfactory (as detailed in Section 4.4).
- If any of the above cycle conditions is not achieved or there is a problem with instruments unloaded from the sterilizer, ensure that the details are recorded, notify the User and reprocess the instruments from the start of the decontamination cycle (cleaning, thermal disinfection if available, and sterilization).

4.2.3 At the End of the Day

- Follow the manufacturers' instructions to drain and clean the chamber and reservoir at the end of each day and leave dry.

4.3 Unwrapped Instruments (All types of sterilizer)

If using a non-vacuum sterilizer, the instruments must be processed unwrapped.

Instruments processed unwrapped are classified as 'sterilized' and are not sterile (see Section 4.1.2).

Solid instruments can be sterilized unwrapped in any type of sterilizer. The sterilization of hollow or lumened instruments can only be achieved if they are cleaned effectively and a vacuum (or a compatible Type S) sterilizer is used (see Table 4.1.1).

- When processing instruments using a non-vacuum sterilizer, ensure that the instruments are unwrapped.
    - Note that the sterilization of the internal surfaces of instruments with lumens processed in a non-vacuum sterilizer cannot be guaranteed.
    - Refer to Section 4.1.3 regarding the sterilization of dental handpieces.
- If possible, process instruments using a sterilization cycle with a drying stage.
- When using a vacuum sterilizer, if the load includes hollow or lumened instruments, ensure that a drying stage is included.

4.3.1 Handling and Storage of Unwrapped Instruments Immediately After Sterilization

Instruments that have been sterilized unwrapped are designated as 'sterilized only' (see Section 4.1.2). It is currently acceptable for instruments sterilized unwrapped to be kept for later use. However, they must be:

- dry – it is very important that instruments are completely dry when stored because dampness encourages growth of microorganisms and corrosion of instruments;
- protected from contamination;
- stored correctly - note that storage of loose unwrapped instruments is unacceptable.

Figure 4.4 Unacceptable storage of loose unwrapped instruments

- Clean hands and put on clean gloves and a clean apron before handling unwrapped instruments that have been removed from the sterilizer. Take additional precautions if the instruments are still hot.

- Examine newly sterilized instruments visually for dryness. Ideally the instruments will be dry on removal from the sterilizer but, if a drying cycle has not been used, manual drying using disposable, lint free wipes may be necessary.
- Do not leave sterilized instruments exposed in the clinical environment.
- Store instruments individually or in sets in clean, dry conditions and in a manner that prevents recontamination (see Figures 4.5 and 4.6)
    - Instruments can be placed in covered trays, cassettes or clip-in trays in enclosed boxes or cupboards in a rack system or alternatively, instruments can be sealed clean, single-use, sterilization grade wrapping material or self-seal sterilization bags/pouches, though the latter may generate considerable quantities of waste.

Figure 4.5 Example of correct storage of instruments

- When labelling wrapped instruments, write on the labels before attaching them to the wrapping. Do not write on the wrapping directly with ballpoint or felt pen as this might damage it.
- Store instruments in clean enclosed cupboards, drawers or boxes in an orderly manner that avoids damaging the wrapping .
- Do not store any instruments on open shelving or on work surfaces in clinical areas.
- Use a first-in, first-out stock rotation to minimise the duration of storage. Whilst maximum storage times are not specified in Scotland, storage conditions and stock rotation are important.

Figure 4.6 Example of correct drawer storage of instruments

4.4 Wrapped Instruments (Vacuum sterilizers)

Instruments can only be processed wrapped in a vacuum (or a compatible Type S) sterilizer that is designed for wrapped instruments. If using a non-vacuum sterilizer, refer to Section 4.3.

As wrapping and labelling are part of the validation process, the sterilizer should be re-validated when introducing new wrapping and labelling. Wrapping materials are

often called sterile barrier systems (SBS) and would include sterilization pouches and bags.

- If wrapping instruments prior to sterilization in a vacuum sterilizer, (see Figure 4.7) ensure that:
    - the wrapping material manufacturers' instructions are followed;
    - the wrapping materials are compatible with the steam sterilization process (in dental practices, self-seal sterilization pouches are typically used);
    - only a single layer of wrapping material is used;
    - instruments are allowed to cool before handling and wrapping;
    - each instrument is wrapped separately or as a set of instruments for a single treatment held in a cassette that prevents them overlapping;
    - the correct size of pouch is used (i.e. only slightly larger than the contents);
    - the method of sealing preserves the microbial barrier properties of the wrapping and enables the pack to be opened aseptically (e.g. self-seal or fold three times and apply autoclave tape).
    - pouches and bags will only retain their microbial protective properties when dry. If wet when removed from the sterilizer the contents cannot be guaranteed as sterile and there is a high risk that microbial recontamination will occur if they remain wet.

Figure 4.7 Wrapped instruments

- Attach a pre-written or pre-printed adhesive label to each pack that includes the word 'Sterile', the process date, the sterilizer identification and cycle number. Do not write on the label after attaching it to the wrapping and do not write directly onto the wrapping with a ballpoint or felt pen as this might damage it.
- Use a chemical process indicator that is either printed on the pouch or available as a label or tape.
    - Note that this does not indicate sterility but simply distinguishes items that have been exposed to a sterilization process from those that have not.
- Ensure that the selected sterilization cycle includes a drying stage.
    - It is essential to dry the load before the sterilizer chamber is opened otherwise the wrapped instruments will not remain sterile.

4.4.1 Handling and Storage of Wrapped Instruments Immediately After Sterilization

Careful handling and storage of sterilized packs will ensure that the contents remain sterile until the pack is opened.

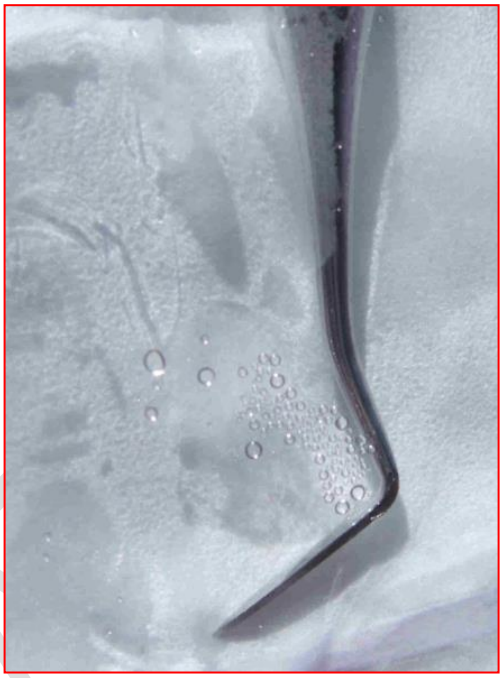
- Check the wrapping material for dampness, tears, broken seals or any other damage and that the label is intact and the details are legible.
    - It is very important that instruments are completely dry when stored because dampness encourages growth of microorganisms and corrosion of instruments.
- Handle packs carefully so that they are not dropped or damaged.
- Do not place newly sterilized wrapped instrument packs on cool or solid surfaces because these items are cooling fast and are in a vulnerable state as the warm vapour leaving the pack can condense to form ‘dew’ that wets the wrapping materials.
- If a wrapped item or pack is wet, is dropped on the floor, is torn or has broken seals, it is no longer sterile. Unwrap the instruments and return them to the start of decontamination process.
- If wrapped sterile instrument packs are to be stored for some time, confirm that the process date is marked clearly on the wrapping to enable stock rotation.
- Check that the chemical process indicator has changed colour correctly. If it has not, investigate the problem, assess the disruption to the decontamination process and reprocess the instruments from the start of the decontamination cycle.
- Store wrapped instruments (sterile at point of use) separate from sterilized instruments, in clean, enclosed cupboards, drawers or boxes in an orderly manner that avoids damaging the wrapping (i.e. dry with little variation in temperature and minimal handling).
- Do not store instruments on open shelving or on work surfaces in clinical areas.
- Use a first-in, first-out stock rotation to minimise the duration of storage of sterile instruments.

4.5 Instrument Inspection

- Ensure hands are clean and dry when handling instrument packs.
- Check each pack is satisfactory before use. Do not use the instrument(s) if either:
    - the wrapping or seals are damaged;
    - the pack is moist (see figure 4.8);
    - the pack has labelling that is damaged or incorrect;
    - the pack has a process indicator that has not changed colour correctly; or
    - the instruments are visibly soiled.

  Instead, open the pack and return the instrument(s) to the start of the decontamination process.
- If an instrument appears damaged, remove it from use.

Figure 4.8 Condensation within an instrument pack



5. Validation, Periodic Testing and Maintenance

5.1 Overview

Validation is a documented procedure used to show that the decontamination process will repeatedly and consistently take place to a satisfactory standard when defined operating conditions are used. Validation comprises a series of specified checks and tests that are performed by a Competent Person (Decontamination) (CP(D)) as specified in SHTM 01-05 Part B. These checks and tests are carried out after installation of new equipment as part of commissioning. Thereafter, validation checks and tests are carried out at least annually, which is referred to as revalidation.

Before installation, it is helpful to contact the manufacturer to obtain drawings and layouts to prepare the site for installation of your machine correctly to conform to specifications. Particular attention should be paid to the power supply (WD and sterilizer) and drainage requirements (WD) and that these services are close to the point of installation. Attention should also be paid to any other specific services which may be needed to operate the proposed equipment. On delivery of the equipment, the supplier is expected to install and validate as specified in SHTM 01-05 to establish that the equipment:

- has been provided and installed correctly;
- is safe to operate;
- performs correctly (i.e. according to the purchase specification);
- does not interfere with other equipment;
- is satisfactorily linked to all connected services.

In addition to validation, satisfactory **periodic testing** is necessary to provide ongoing reassurance that the equipment is performing consistently as specified at validation. Daily and weekly periodic tests will normally be carried out by practice personnel to ensure there is no variation in performance between the other periodic tests that are performed by a Competent Person (Decontamination) (CP(D)). The legal requirement is to carry out periodic testing as specified in the manufacturers' instructions.

Following a planned **maintenance** programme also helps preserve performance and prevent breakdowns.

As decontamination is a highly technical activity, on occasion it may be necessary to consult an Authorising Engineer (Decontamination) for specific advice concerning validation, periodic testing, maintenance and operational management as detailed in SHTM 01-05 (Parts A and B). The Authorising Engineer (Decontamination) service for NHSScotland is provided by Health Facilities Scotland (see Appendix B). Note

that at time of writing, there are relatively few of these specialists to advise both secondary and primary care services.

For each item of decontamination equipment, it is essential to obtain a written test schedule from a Competent Person (Decontamination), an Authorised Person (Decontamination) or an Authorising Engineer (Decontamination).

5.2 Logbooks and Record Keeping

A logbook is required for each item of decontamination equipment as a permanent record of the complete history of the equipment, including periodic testing, failed cycles, faults and maintenance. The logbook could provide useful evidence in the event of an adverse incident. Examples of pages of a logbooks are given in Appendix C. Logbooks may be supplied by the equipment manufacturer or supplier and are also available from Health Facilities Scotland. A secure digital format for logbook records is also acceptable. If digital records are retained then an IT backup procedure must be specified and followed to ensure data integrity, longevity and security. SHTM01-05 Part A section 7.2 states LDU records should be held for a minimum of 13 years and SHTM01-05 Part A section 7.3 advises that for records, such as printouts, that may fade over time, then special action is required to preserve them (e.g. photocopying or electronic scanning).

- Keep the logbook near the equipment so that routine information can be recorded easily. For details of what to include in logbooks for specific types of equipment, refer to Sections 3.2 (washer-disinfectors), 3.3 (ultrasonic cleaners) and 4.1.8 (sterilizers).

  Other items that must be kept either within the logbook or elsewhere in the practice include:

    - a list of roles and responsibilities for decontamination;
    - installation, commissioning and validation tests and checks.
- Retain each logbook for inspection.
    - Refer to SHTM 01-05 Part A for retention periods.

5.3 Washer-disinfector periodic testing

Daily and weekly testing will normally be carried out by practice personnel to ensure there is no variation in performance between the other periodic tests that are performed by a Competent Person (Decontamination) (CP(D)). The legal requirement is to carry out periodic tests as specified in the manufacturers' instructions.

5.3.1 Washer-disinfector daily housekeeping checks and periodic tests

Daily tests usually involve:

- inspecting instruments visually for cleaning efficacy, using a magnifier to help;

  - conducting an automatic control test (see below).

General housekeeping as specified by the WD manufacturer is also required each day and usually involves:

  - checking the spray arm for rotation;
  - checking the spray nozzles for blockage;
  - removing and cleaning strainers and filters.

Additional weekly tests may include:

  - conducting an automatic control test (see below);
  - cleaning efficacy test.

- Carry out daily and weekly tests as per manufacturers' instructions.
- Record the outcome of these tests in the WD logbook.
- If the WD fails to perform to set parameters, contact an engineer immediately.
- Arrange for a Competent Person (Decontamination), (CP(D)) to carry out quarterly (if specified by the manufacturer) and annual tests (e.g. through purchase of a full support package via the NHSScotland contract or by arrangement with a contractor).

5.3.2 Washer-disinfector automatic control test

This is a test for ensuring that the WD continues to function correctly and involves checking readings and timings during a normal cycle. Printers or data loggers record this information, give notice if a cycle has failed and can also be referred to for test information.

Procedure for daily and weekly tests or as recommended by the Manufacturer.

- Place a normal standard load, typical of that used throughout the day, in the chamber of the WD.
- Select the operating cycle to be tested.
- Start the cycle.
- Check the printout or data logger to ensure that the following criteria are met.
  - A visual display indicating 'cycle complete' occurs;
  - During the whole cycle the variables indicated on the WD or on the printout are within the limits established as satisfactory by the manufacturer or set during validation;
  - During the disinfection hold period, the temperature and time are within the range specified by the manufacturer or established at validation. This is to ensure that the load is maintained at temperatures within the disinfection temperature band for the time specified in SHTM 01-05;
  - The door cannot be opened until the cycle is complete;

  - The person conducting the test does not observe any mechanical or other anomaly.

- Refer to the logbook to identify what parameters should be recorded for daily and weekly tests.
- Record the outcome of the test in the WD logbook. If any of these criteria are not met, record the test as a fail and do not use the WD until the fault has been resolved. In this case, return any instruments that were loaded in the WD to the start of the decontamination process.

5.3.3 Washer-disinfector cleaning efficacy testing or as recommended by the Manufacturer.

Cleaning efficacy tests are used to demonstrate the ability of the WD to remove soiling and contamination. The result should be recorded in the logbook. Methods to determine whether instruments are being cleaned effectively include:

  - daily visual inspection;
  - weekly residual protein detection, which involves a test for residual protein on instruments. A variety of methods are available. Follow manufacturers' instructions;
  - a quarterly or annual chemical test which involves removal of artificial soil from a test device designed for use in WDs.

SHTM 01-05 Part B provides details of these tests.

5.4 Washer-disinfector maintenance

A planned programme of preventative maintenance carried out by a qualified maintenance person aims to minimise equipment failure.

- Obtain a maintenance contract to carry out the programme of preventative maintenance tasks as specified in the manufacturers' instructions.
- Ensure details of all maintenance work are recorded in the equipment logbook, including problems, faults, preventative and corrective actions.

5.5 Ultrasonic cleaner periodic testing

Foil ablation testing has been used to test the ultrasonic activity of ultrasonic cleaners. This involves reviewing the erosion pattern which is created on aluminium foil exposed in the cleaner tank for a short period. Although practice staff can perform this test, it would usually be carried out quarterly by a Competent Person (Decontamination). Electronic testing is now more commonly used by engineers to monitor the efficiency and operating frequency of ultrasonic cleaners. Other acceptable tests methods may also be available.

Cleaning efficacy testing is likely to be recommended by the manufacturer to determine whether the ultrasonic cleaner is functioning correctly. This may involve a

test for residual protein on instruments and/or a soil test involving removal of artificial soil from a test device.

When in use, daily tests are as recommended by the ultrasonic cleaner manufacturer and usually involve:

  - automatic control test (i.e. cycle completed with correct temperature and time);
  - inspecting instruments visually for cleaning efficacy, using a magnifier to help.

General housekeeping as specified by the ultrasonic cleaner manufacturer is also required each day and usually involves:

  - removing, cleaning and replacement of strainers and filters;
  - draining and rinsing the bath after morning and afternoon sessions or more frequently when solution is visibly contaminated;
  - leaving the ultrasonic tank clean and dry when not in use to ensure that the surfaces are undamaged and the inlets and drains are free from obstructions.

Additional weekly tests include:

  - cleaning efficacy test using a method as specified by the ultrasonic cleaner manufacturer.

- Carry out daily and weekly tests as per the manufacturers' instructions.
- If the ultrasonic cleaner fails to perform to set parameters, contact an engineer and do not use the machine until the fault has been found and rectified.
- Record the outcome of these tests in the ultrasonic cleaner logbook.

5.6 Ultrasonic cleaner maintenance

- Ensure regular checks of electrical safety are made and keep a record of these checks.

5.7 Small steam sterilizer periodic testing

Periodic tests need to be carried out regularly to confirm that during each sterilization cycle the sterilizer reproduces the operating conditions that were previously established as effective for sterilization These operating conditions include the choice of sterilization cycle, the nature of the load, the loading pattern, wrapping, trays or containers and labelling.

For sterilizers, the legal requirement is to carry out periodic tests as specified in the manufacturers' instructions. Daily and weekly tests will normally be carried out by practice personnel and are described below. Quarterly (if specified by the manufacturer) and yearly (also known as annual revalidation) tests require specialist

equipment and are performed by external personnel [a Competent Person (Decontamination)] (e.g. arranged through purchase of a full support package via the NHSScotland contract or by arrangement with a contractor). If the manufacturers' instructions are not available, periodic testing as recommended within SHTM 01-05 Part B is necessary.

Table 2 lists the periodic tests that SHTM 01-05 Part B describe in detail for the various types of steam sterilizers. For specific guidance on testing and maintenance of Type S sterilizers, refer to the manufacturers' instructions.

There is no practical way of determining that items processed in a steam sterilizer have been sterilized. Instead with satisfactory periodic testing established, checking after each sterilization cycle that the required temperature was held (usually 134–137°C for at least 3 minutes) and, if recorded, that the required pressure was attained (usually 2.1–2.25 bar) during the cycle is an acceptable way of verifying that the load is fit for use – a method known as parametric release.

5.7.1 Sterilizer daily housekeeping checks and periodic tests

At the start of each day:

- Wipe the door seal with a clean, disposable, damp, lint free cloth;
- Check that the chamber and shelves are clean;
- Refill the reservoir with suitable quality water (see Section 4.1.7);
- When switching the power on, check that the ventilation louvres are not covered to avoid overheating;
- If recommended by the sterilizer manufacturer, preheat the sterilizer chamber before performing daily tests;
- Conduct an automatic control test (see below);
- Carry out any other daily checks and tests recommended by the sterilizer manufacturer;
- Record completion of the daily checks and tests in the sterilizer logbook;
- If the sterilizer fails to perform to set parameters, contact an engineer immediately and do not use the machine until the fault has been found and rectified.
- .

At the end of the day, ensure that the reservoir is drained and dried.

5.7.2 Sterilizer weekly checks and periodic tests

In addition to the daily checks and tests:

- Examine the door seal for signs of wear or damage;

- Examine the security and performance of the door safety features including the hinges and the locking mechanism as detailed in the manufacturers' instructions;
- If a fault is detected in the door seal or safety features, ensure this is corrected before carrying out weekly tests or using the sterilizer;
- Carry out any other weekly checks and tests recommended by the sterilizer manufacturer;
- Record completion of the weekly checks and tests in the sterilizer logbook;
- If the sterilizer fails to perform to set parameters, contact an engineer immediately and do not use the machine until the fault has been found and rectified.

5.7.3 Automatic control test for all sterilizers

The automatic controller is the device within the sterilizer that controls the sterilization cycle. To be sure that it is working, an automatic control test is carried out every day, or as recommended by the manufacturer either, using the sterilization cycle parameter values recorded on the printout or electronic data logger.

The Automatic Control Test can be done when sterilizing a standard load, unless also carrying out a steam penetration test for a vacuum sterilizer (see Section 5.7.4) at the same time. This is usually the first cycle of the day.

Automatic control test using a recorder

This test is carried out once per day on a sterilizer fitted with a suitable recorder (i.e. a printer or electronic data logger). The check of the automatic control test on a sterilizer with a recorder should be carried out at least weekly and recorded in the logbook.

- Run a sterilization cycle with a standard load or an empty chamber (the chamber must be empty if also carrying out a steam penetration test in a vacuum sterilizer).
- At the end of the cycle, check the printout (see figure 5.1) or data logger to ensure that the recorded cycle parameters (temperature, pressure, hold time) are within the specified range for the cycle and comparable to the values obtained at validation.
- Keep a record of the recorded values for temperature, pressure and hold time.

Figure 5.1 Automatic control test using a recorder printout

- If the automatic control test is unsatisfactory (i.e. the recorded temperature, pressure or hold time are not within the specified range for the cycle), record the test as a fail and do not use the sterilizer until the fault has been resolved.
    - In this case, return any instruments that were loaded in the sterilizer to the start of the decontamination process.

- Sign the logbook.

Manual automatic control test

This test would be required for a sterilizer without a suitable printer or data logger fitted. As all sterilizers should now have a suitable printer or data logger fitted, the manual automatic control test has not been described here.

5.7.4 Steam penetration test for vacuum sterilizers

This test is carried out in vacuum sterilizers designed to sterilize wrapped instruments. It is intended to show that steam will rapidly and evenly penetrate a test device that is similar to the intended load.

- Refer to the sterilizer manufacturers' instructions for the recommended test device and indicator (e.g. Bowie-Dick).
- At the start of the day, select the usual sterilization cycle and perform the test with the chamber empty apart from the test device, following the test device manufacturers' instruction. The Sterilizer and/or test device manufacturers may recommend running a warm-up cycle prior to this steam penetration test.
- Record whether the test was a pass or a fail in the sterilizer logbook.
- If the steam penetration test result is unsatisfactory, repeat the test. A second unsatisfactory test result confirms that there is a fault. Arrange for a Competent Person (Decontamination) to investigate and do not use the sterilizer to sterilize instruments until the fault has been resolved.

5.7.5 Air leakage test for vacuum sterilizers or as recommended by the manufacturer.

If air leaks into the sterilizer chamber at a higher rate than specified by the manufacturer, it might interfere with the penetration of steam into the load and, as the air will not have passed through the bacteria retentive filter, there is a risk of recontaminating the load. An air leakage test involves removing air from the chamber, isolating the chamber and monitoring the pressure for a period of time. Air leakage will cause an increase in the chamber pressure.

- If an automatic test is available, carry out an air leakage test according to the manufacturers' instructions once per week.

  - It is preferable to have a sterilizer that is capable of performing an automatic test because otherwise a Competent Person (Decontamination) is required to perform a weekly manual test.
  - Note that some manufacturers specify that an air leakage test is carried out each day before the steam penetration test.
- Record the results in the sterilizer logbook.

5.7.6 Automatic air detection system function test for vacuum sterilizers or as recommended by the manufacturer.

Sterilizers that actively remove air from the load before sterilization (e.g. using a vacuum pump) are fitted with a means of detecting whether any residual air present in the chamber is sufficient to impair sterilization during each cycle. A test is performed each week to check that the air detector is functioning correctly. The details of the test vary between different makes of sterilizer. If the User cannot perform this test, it will require a Competent Person (Decontamination) to visit weekly to perform the test. This will add significantly to your costs so check this before purchase.

- Carry out an automatic air detection system function test as specified in the manufacturers' instructions once per week.
- Record the results in the sterilizer logbook.

5.8 Maintenance of small steam sterilizers

A planned programme of preventive maintenance is also required for each sterilizer. Maintenance work is carried out by a qualified maintenance person. In some cases, when parts (e.g. temperature probes) are changed, it is necessary to have the sterilization cycle revalidated.

- Obtain a maintenance contract to carry out the programme of preventative maintenance tasks as specified in the manufacturers' instructions.
- If the manufacturers' programme of maintenance is not available, consult the Competent Person (Decontamination) (who might be an employee of the supplier or manufacturer), an Authorised Person (Decontamination) or an Authorising Engineer (Decontamination) to devise a suitable programme.
- Ensure details of all maintenance work are recorded in the sterilizer logbook, including problems, faults, preventative and corrective actions.
- If any maintenance or modification work is carried out to the pressure system, seek the advice of a Competent Person (Pressure Systems) before using the sterilizer.

Table 5.1 Periodic tests for small steam sterilizers

This table is included for information and will be of use if the Manufacturers' instructions are not available.

Tests	Performed by	Sterilizer Type Non-vacuum /N	Vacuum /B	S
Daily tests				
Automatic control test	User	✓	✓	✓
Steam penetration test	User		✓	✓
Weekly tests				
Weekly safety checks (door seal and lock)	User	✓	✓	✓
Air leakage test§	User*		✓	✓
Air detection system function test	User*		✓	✓
Quarterly tests				
Automatic control test	CP(D)	✓	✓	✓
Air leakage test	CP(D)		✓	✓
Verification of calibration of sterilizer instruments	CP(D)	✓	✓	✓
Thermometric test for a small load	CP(D)	✓	✓	✓
Yearly and revalidation tests				
Yearly safety checks	CP(D)	✓	✓	✓
Air detector performance test – small load	CP(D)		✓	✓
Air detector performance test – full load	CP(D)		✓	✓
Thermometric test – small load (Porous load)	CP(D)		✓	✓
Thermometric test – full load (Solid load)	CP(D)	✓		
Thermometric test - full load (Porous load)	CP(D)		✓	✓
Load dryness (Solid load)	CP(D)	✓		
Load dryness (Porous load)	CP(D)		✓	✓
Overheat cut-out	CP(D)	✓	✓	✓
Performance Qualification (PRQ) test	CP(D)	✓	✓	✓
Steam superheat test	CP(D)		✓	✓
Steam dryness test	CP(D)		✓	✓

* The user may perform these tests with the prior agreement of the Competent Person (Decontamination) or an Authorising Engineer (Decontamination) (AE(D))

§ Some manufacturers recommend a daily (rather than a weekly) air leakage test.
CP(D) = Competent Person (Decontamination)

The information in this table is based on SHTM 01-05 Part B (Table 7 and Appendix D). Refer to the manufacturers' instructions for guidance on Type S sterilizers.

6. Management of Decontamination in Dental Practice

Figure 6.1. Management of Decontamination in Dental Practice

As discussed in Section 1.1, ensuring effective decontamination of reusable instruments is complex and relies on having the correct facilities, equipment, a standardised process and trained staff. In addition, an effective system for management of the process is necessary to enable the practice to demonstrate, both to its staff and externally, that it meets national standards for decontamination in primary care, can consistently deliver these standards and can identify any improvements required. This includes:

- documenting how the practice sets out to achieve effective decontamination in the form of policy statements and procedures for each part of the process;
- recording and retaining relevant information to show that each part of the process has been effective;
- regular audit and review to monitor whether processes are up to date, are being followed and to implement any changes required.

Policies and procedures are living documents and should be reviewed periodically to ensure they reflect current best practice and operational activities within the practice. Such documents should have revision identifiers which should include any code/ revision numbers and revision dates and should include a brief section showing when they were revised, by whom and a very brief description of what has changed.

The requirements for decontamination management are detailed in SHTM 01-05 Part A and many of these requirements are specified within the NHSScotland Combined Practice Inspection for dental practices.

SDCEP provides within its Practice Support Manual a suite of template documents entitled Managing Decontamination in Dental Practice (MDDP), which has been developed specifically for the needs of dental practices following a review of earlier generic approaches to decontamination management. MDDP aims to help dental practices create the documentation that underpins a decontamination management system by supplementing the documents that the practice already has.

There is considerable overlap between decontamination management and general health and safety management within a dental practice. Consequently, some of the documentation is common to both of these activities.

MDDP comprises a checklist for reviewing the current status of decontamination documentation and a collection of templates and forms that the practice can adapt for its own use as required. These documents are all available online at www.psm.sdcep.org.uk.

Note that there is no requirement to use the MDDP documents. Instead, they are provided to illustrate what a practice needs to include in its own documentation.

For further advice on requirements for decontamination management, refer to Compliant Dental Local Decontamination Units in Scotland (GUID 5005) (2019)

6.1 How to Use MDDP

The MDDP Checklist, templates and forms are all available online via SDCEP's Practice Support Manual (http://www.psm.sdcep.org.uk/www.psm.sdcep.org.uk).

Many of the MDDP documents are templates for policies and procedures.

- A policy states what the practice sets out to do.
- A procedure is a more detailed guide for what to do to put the policy into practice.

While for most activities both a policy statement and procedure are appropriate, for some either a policy or procedure is sufficient.

- To begin using MDDP to develop your decontamination management system, first familiarise yourself with the MDDP Checklist and the template documents cited in it.
- Use the MDDP Checklist to note which items are included in your current documentation.

If you already have similar documents in use in your practice:

- Refer to the documents cited in the MDDP Checklist to confirm whether you have included all the necessary elements to cover the processes, equipment and products used for decontamination;
- Update your documents as necessary.

If you are just at the stage of setting up your decontamination management system:

- Use the MDDP Checklist as the basis for compiling the necessary documents and establishing processes.

Practices are likely to differ in the way that they store documentation (e.g. electronically or printed). It is recommended that some items, such as certain procedures, are readily available for staff to consult routinely.

By using the MDDP documents as described, you should find that when a practice inspection approaches, it is more straightforward to produce the necessary documentation to demonstrate that you are achieving the national standards for decontamination as expected of a modern primary care dental practice.

Appendix A Key roles in a decontamination service

A comprehensive description of the roles and responsibilities of all personnel involved in decontaminating dental instruments in a Local Decontamination Unit setting is provided in SHTM 01-05 Part A Section 6.

The roles and responsibilities of staff within a dental practice or who may occasionally attend or be contacted for validation and quality assurance purposes are also provided here.

Management (e.g. Practice Principal)

Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately legally and professionally accountable for the sole operation of its premises.

User (e.g. Practice Manager or Practice Principal)

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

The principle responsibilities of the User are as follows:

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

Operator (e.g. Dental Nurse, LDU Operator)

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

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

Competent Person (Decontamination)

The Competent Person (Decontamination) (CP(D)) [in previous guidance referred to as the Test Person (Sterilizers)] is defined as a person designated by the Authorised Person (Decontamination) (AP(D)) to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilizers.

The principal responsibilities of a CP(D) are:

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

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

Competent Person (Pressure Systems)

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

Authorising Engineer (Decontamination)

The Institute of Healthcare Engineering and Estate Management (IHEEM) maintain a list of AE(D)s registered by IHEEM. This can be found on-line on the IHEEM website. Health Facilities Scotland employ IHEEM registered AE(D)s to provide advice to the Scottish Health Care Service.

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 (specific to NHS Boards, see Part A for further details), 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;
- to advise and provide support to decontamination management and operational decontamination staff on fault finding in the event of a process failure or failure of tests for which the Use is responsible.

Authorised Person (Decontamination)

The Authorised Person (Decontamination) (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.

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 a number of areas of similar responsibility for the individual(s) concerned. However, any additional responsibilities should not reduce the importance of the role nor impair the ability of the AP(D) to carry out his/her duties effectively;
- larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role;
- some organisations may wish to consider the appointment of more than one AP(D) to ensure that appropriate cover is provided. In these circumstances the

organisation should appoint a senior AP(D). Even where estates roles are contracted out, it is recommended that the AP(D) function remains the responsibility of the healthcare organisation.

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

The AP(D) will also be responsible for:

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

Appendix B Useful Sources of information

Health Facilities Scotland (HFS) is a division of NHS National Services Scotland (NSS) and provides operational guidance to NHSScotland bodies on a range of healthcare facilities topics.

Email: nss.hfsenquiries@nhs.net
Website: www.hfs.scot.nhs.uk

The HFS Decontamination Team leads the national decontamination agenda for reusable medical devices, including dental instruments, by standard setting, providing guidance and advice, audit, monitoring and support training programmes. HFS also provides validation and authorising engineering services for decontamination equipment.

HFS Decontamination Team
E-mail: nss.hfsdeconteam@nhs.net

The HFS Incident Reporting and Investigation Centre (IRIC) is Scotland's specialist national safety and risk management unit, which aims to improve the safety of equipment and facilities in Scotland's health and social care services. If you work at a local authority or health board in Scotland, you can report adverse

incidents and near-misses involving medical devices, in-vitro diagnostic medical devices, estates, facilities, social care equipment and personal protective equipment (PPE). Please note you need to register for a log in before you can use this service.

Website: www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/

NHS Education for Scotland (NES) develops and provides education and training for those who work in NHSScotland. The **Scottish Dental Clinical Effectiveness Programme** operates within the NES to provide user-friendly evidence-based guidance for the dental profession. This included the *Decontamination Into Practice* guidance series, which has been updated to create SHTM 01-05 Part C.

Website: www.sdcep.org.uk

NES supports improvements in decontamination in dental practices through a variety of educational activities, including continuing professional development courses, online e-Learning modules, on-site training and user-friendly guidance. NES has a **Quality Improvement in-Practice Training (**QIiPT) team that provides decontamination training either on-site or remotely. The primary aim of these training sessions is to enable the practice to look at its existing processes and to consider any changes required for improvement. Formulating an agreed action plan that details timescales and responsibilities is an essential component of the training.

Further details about the in-practice training and other decontamination support provided by NES are provided at: Quality Improvement in Practice Training : Infection Control and Decontamination | Turas | Learn (nhs.scot)

Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland within NHS National Services Scotland provides the National Infection Prevention and Control Manual which covers application of Standard Infection Control Precautions (SICPs) including:

- Hand Hygiene
- Control of the Environment
- Management of Blood and Body Fluid Spillages
- Occupational Exposure Management, including Sharps
- Personal Protective Equipment

This information is regularly updated based on new developments and evidence.

Appendix C Examples of logbook test record pages

To be confirmed after consultation and before publication.