NSS Health Facilities Scotland

NHS National Services Scotland

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 A: Management

October 2022

CONTENTS

Executive summary

The best practice guidance Scottish Health Technical Memorandum (SHTM) 01-05 management, equipment and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland published in 2023 replaces all previous dental decontamination guidance in NHSScotland.

In addition to Scottish Health Planning Note (SHPN) 13 Part 2 'Decontamination Facilities: Local Decontamination Units' and 'Compliant Dental LDUs in Scotland' GUID 5005 v2, SHTM 01-05 series will be the only guidance applicable for local decontamination units (LDUs) managed by NHS Health Boards, independent and private general dental services in Scotland.

The SHTM 01-05: 2022 series comprises three parts:

- part A – Management;
- part B – Test equipment/methods;
- part C – Process.

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

A glossary for Part A is provided in **Section 11**.

1. Introduction

1.1 As a result of a continuous evolution of technical requirements since the publication of Scottish Health Technical Memoranda (SHTMs) 2010, 2030 and 2031 in 2001 and to facilitate greater alignment with similar guidance in UK administrations, it was proposed to revise the guidance for decontamination of dental instruments processed in a Local Decontamination Unit (LDU). This guidance has a new reference number, SHTM 01-05 and will consist of three parts.

1.2 This SHTM 01-05 series is aligned with the Medical Device Regulations 2002 (MDR) (SI 2002 No 618, as amended) (UK MDR 2002) and other guidance, such as, Scottish Health Planning Note (SHPN) 13 Part 2 'Decontamination Facilities: Local Decontamination Units' and the 'Compliant Dental LDUs in Scotland' GUID 5005 v2.

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

SHTM 01-05 series scope

1.4 This guidance is applicable for all general dental services that decontaminate their dental instruments in a LDU, for example NHS Health Boards, independent and private general dental practices in Scotland. The terminology 'dental instruments' is used in this guidance to cover medical devices, i.e. general dental and surgical instruments, handpieces etc. Other medical devices such as dental chairs will not be included in the scope.

1.5 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.

1.6 The following equipment may be used to process dental instruments in a local decontamination unit (LDU):

- Benchtop, underbench or standalone washer disinfector;
- Benchtop sterilizers type N, B or S (as per BS EN 13060 :2014 + A1 2018);
- Benchtop ultrasonic cleaner;
- other related equipment, e.g. lubricator.

Part A

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

Part B

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

Part C

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

Note: NHS Health Board dental services using equipment such as porous load sterilizers and pass-through washer disinfectors should refer to:

SHTM 01-05:2022 Parts A and C for the decontamination management and process.

SHTM 01-01:2018 Parts B, C & D for guidance for decontamination equipment and testing. (Part B of SHTM 01-05:2022 does not apply).

Creutzfeldt–Jakob Disease (CJD)

1.10 LDUs process a wide range of dental instruments used in procedures which involve contact with low Creutzfeldt–Jakob Disease (CJD) transmission risk tissues in Primary Care dentistry.

1.11 Any dental instruments which contact medium or high Creutzfeldt–Jakob Disease (CJD) transmission risk tissues should be single use. LDUs must not process single use instruments as stated in the MHRA alert DB (2006) 04 ‘Single-use Medical Devices: Implications and Consequences of Reuse’. Also in Scotland, endodontic files must be treated as single use in compliance with the Chief Medical Officer’s letter CMO (2007) 5.

2. Regulatory framework and national requirements

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

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

2.3 The BREXIT transition period continues until 30th June 2023 and after this date, the UKCA mark (a new UK product marking) will be used for all devices being placed on the Great Britain market.

2.4 All harmonised standards published in the UK, which conformed with the Directive 93/42/EEC and EU 2017/745 Article 8, continue to apply after 01.02.20 and until specifically replaced by UK or Scottish legislation as stated in the Medicines and Medical Devices Act, 2021.

2.5 Medicines & Healthcare products Regulatory Agency (MHRA) Regulating medical devices in the UK 2020**,** provides guidance for manufacturers placing a medical device on the Great Britain, Northern Ireland and European Union (EU) markets (www.gov.uk)

UK law and regulations

2.6 Medicines and Medical Devices Act 2021

Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

National Requirements

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

- premises;
- equipment;
- instruments;
- procedures.

Associated NHSScotland Standards and Best Practice Guidance

2.8 SHPN 13 Part 2: Decontamination facilities: local decontamination units, 2008. Health Facilities Scotland (HFS).

Compliant Dental Local Decontamination Units in Scotland: Version 2 – GUID 5005. Health Facilities Scotland (HFS).

Guide to carriage of dangerous goods regulations with respect to used medical devices, 2013. – GUID 5006. Health Facilities Scotland (HFS).

National Infection Prevention and Control Manual (NIPCM). Health Protection Scotland (HPS).

Healthcare Associated Infection (HAI) standards, 2015. Healthcare Improvement Scotland (HIS).

Practice Support Manual, Scottish Dental Clinical Effectiveness Programme (SDCEP).www.psm.sdcep.org.uk

Quality Assurance

2.9 The quality assurance requirements need to be performed routinely by 'the User' as a part of the Combined Practice Inspection every 3 years. Healthcare Improvement Scotland (HIS) conducts inspections of private healthcare providers in Scotland, including private dental practices, while practices delivering NHS dentistry are inspected by local NHS Health Board s.

2.10 The definition of 'User' can be found in **Section 8** roles and responsibilities

3. Health and safety

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

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

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

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

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

4. Infection Prevention and Control in Dentistry

4.1 Infection prevention and control in dental practice is aimed at reducing the risk of transmission of potentially infective organisms between individuals and so prevent and control the occurrence of healthcare associated infections (HAIs). The primary sources of infective organisms are through secretions such as saliva,respiratory secretions and blood.

4.2 All dentists have a duty of care to take appropriate precautions to protect patients, members of the dental team, and other contractors from the risk of infection during or associated with providing dental treatment. Practitioners must ensure their knowledge is up to date and that all staff are trained in infection prevention and control appropriate to their role in the practice. Failure to employ adequate methods of infection prevention and control could render a practitioner liable to a charge of serious professional misconduct by the General Dental Council (GDC).

4.3 It is essential to ensure the safety of patients, practice staff and external personal, whether they attend on site or receive items dispatched to their premises. Standard Infection Control Precautions (SICPs) which cover a range of activities, including hand hygiene, environmental cleaning, waste management and instrument decontamination, should be followed at all times. These are detailed within chapter 1 of the National Infection Prevention and Control Manual (NIPCM). (http://www.nipcm.scot.nhs.uk).

4.4 A source for healthcare infection prevention and control guidance is available via the Heath Protection Scotland (HPS) website: The ‘Compendium of Healthcare Associated Infection Guidance’. This compendium contains links to current national policy and guidance on HAI, antimicrobial prescribing and resistance, decontamination and other related topics.

https://www.hps.scot.nhs.uk/web-resources-container/compendium-of-healthcare-associated-infection-guidance/.

4.5 The Practice Support Manual (PSM) is an online resource provided by the Scottish Dental Clinical Effectiveness Programme that includes advice for dental practices on a range on non-clinical topics, including instrument decontamination. The PSM includes template policies, procedures and checklists and can be found at www.psm.sdcep.org.uk.

4.6 SHTM 01-05:2022 Part C covers all aspects of the dental instrument decontamination process.

5. Reporting incidents, outbreaks and distribution of safety alerts

Adverse incident reporting procedures

5.1 Any incidents associated with dental instruments should be reported locally to the NHS Health Board 's adverse event reporting system and nationally to IRIC. Dental instruments which have been involved in an incident should be removed from use and placed in quarantine, as they may be required for examination and testing. More information on incident reporting can be found using this link:

http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/incident-reporting--what-happens-next/

Safety alerts

5.2 IRIC distributes safety alerts in Scotland using a number of formats:

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

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

6. Functional responsibilities - roles and responsibilities

Purpose/Scope

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

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

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

Principles

6.3 All staff undertaking decontamination and the management of decontamination should be able to demonstrate their competencies and training in the areas in accordance with their roles and responsibility;

- the roles and responsibilities of decontamination staff should be clearly defined and documented;
- decontamination staff should be encouraged to get involved in decontamination activities to demonstrate their competency in line with the NHS Education for Scotland (NES) staff competencies as outlined in their 2016 publication 'Framework to support staff development in the decontamination of re-usable medical devices';
- decontamination staff should access training through section 63 courses and in-practice training which covers infection prevention and control, including decontamination;
- at present there is no official requirement for a specific decontamination qualification. However, the GDC states: "Disinfection and decontamination: we recommend that you do at least five hours in each CPD cycle";

  https://www.gdc-uk.org/education-cpd/cpd/recommended-cpd-topics
- persons carrying out testing of decontamination equipment and possibly reviewing/signing off reports require to be suitably qualified, e.g. City and Guilds certificate;

- each NHS Health Board , independent and private general dental service should have a governance structure in place which supports the reporting and escalation of any failures to comply with this guidance document;
- clinical-staff should receive infection prevention and control training (including decontamination) during induction. This should be updated annually and documented in staff training records;
- non-clinical staff (e.g. receptionist/cleaning contractors/ancillary staff) should receive infection prevention and control training relevant to their role within the practice during induction. This should be updated annually and documented in staff training records.

Roles and Responsibilities generic to all dental services

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

Executive Manager

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

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

Management (e.g. Practice Principle)

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

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

6.7 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 principal responsibilities of the User are as follows:

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

- to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

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

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

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

Competent Person (Pressure Systems)

6.9 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).

Roles and Responsibilities specific to NHS Health Board dental services

6.10 Some NHS Health Boards may be unable to appoint responsible posts listed 6.10 to 6.17, and a local decision regarding them will need to be made.

Designated Person

6.11 The Designated Person is responsible for:

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

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

Decontamination Lead

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

The Decontamination Lead is responsible for:

- providing effective and technically compliant decontamination services;
- implementing an operational policy for decontamination;

- ensuring that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment;
- monitoring the implementation of the operational policy for decontamination services; delegating specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

Infection Control Doctor/ Microbiologist (Decontamination)

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

Authorising Engineer (Decontamination)

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

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

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

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

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

Authorised Person (Decontamination)

6.15 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.

6.16 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.

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

The AP(D) will also be responsible for:

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

Competent Person (Decontamination)

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

The principal responsibilities of a CP(D) are:

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

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

7. Documentation and traceability

Management of decontamination documentation

7.1 Policies, procedures and records for all aspects of management of dental instruments and decontamination of dental instruments must be in place. Health Facilities Scotland (HFS) logbooks are available for thermal washer disinfectors, ultrasonic cleaners and sterilizers. They can be downloaded via (link to be added).

Documents are also available online via SDCEP's Practice Support Manual (www.psm.sdcep.org.uk). This series of documents are under Managing Decontamination in Dental Practice (MDDP) and consist of a checklist that can be used to review the current status of decontamination documentation and a collection of templates and forms that dental services can adapt for their use.

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

Document retention

7.2 All decontamination records, including equipment and process records are to be held securely by the User for a minimum period of 13 years.

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

Note: For more information, refer to The Consumer Protection Act 1987. (c.43), London: The Stationery Office Consumer Protection Act 1987 (legislation.gov.uk)

Traceability

7.4 Traceability is regarded as essential where there is a recognised risk of transmission of CJD which should not be the case for dental instruments being processed through an LDU. However, in day-to-day decontamination of dental instruments in a LDU instruments should be traced through processing:

- the methods, operational cycles and personnel involved in processing a particular dental instrument, or set of dental instruments should be traceable;
- record each process event either manually or on an IT system, including the cycle number (WD & Sterilizer) and the person responsible for carrying out each stage of the process;
- recording by exception may be used (i.e. the dental instruments rejected after unsatisfactory process stages recorded and details of the cycles used for 'rework').

8. Procurement of equipment

8.1 The National Procurement NP143 framework ‘Decontamination Equipment and Associated Maintenance, Accessories and Consumables’ should be used for decontamination equipment, accessories and maintenance when purchasing ultrasonic cleaners, washer-disinfectors and sterilizers etc. NHS Health Boards requiring to purchase equipment via a tendering process should refer to **Appendix 2.**

9. Maintenance, repair and quarantine of dental instruments.

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

9.2 For more information on the management of dental instruments and equipment in Scotland refer to Scottish Health Technical Note (SHTN) 00-04 'Guidance on management of medical devices and equipment in Scotland healthcare and social services' January 2020.

Maintenance and repair

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

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

9.5 The dental service is responsible for ensuring its dental instruments are maintained appropriately, which includes ensuring staff are appropriately trained and refreshed as necessary on:

- how dental instruments should be maintained and repaired, and by whom;
- arrangements for maintenance and repair needs being included as part of the risk assessment process;
- arrangements for the most suitable persons/providers to carry out the work;
- arrangements to ensure items subject to inspection, maintenance, repair or disposal should be decontaminated beforehand;
- the timescale for planned maintenance;
- the timescale for repairs to be completed;
- maintenance databases are validated for their intended use and functionality;
- fitting spare parts in accordance with the manufacturer's specification.

9.6 Dental instrument decontamination including maintenance and repair should be discussed and recorded at dental service staff meetings. A record of all dental instrument maintenance and repairs should be kept to ensure that the correct procedures being adhered to. The management of dental instrument maintenance and repairs should be carried out by staff with appropriate knowledge and experience of dental instrument decontamination and use.

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

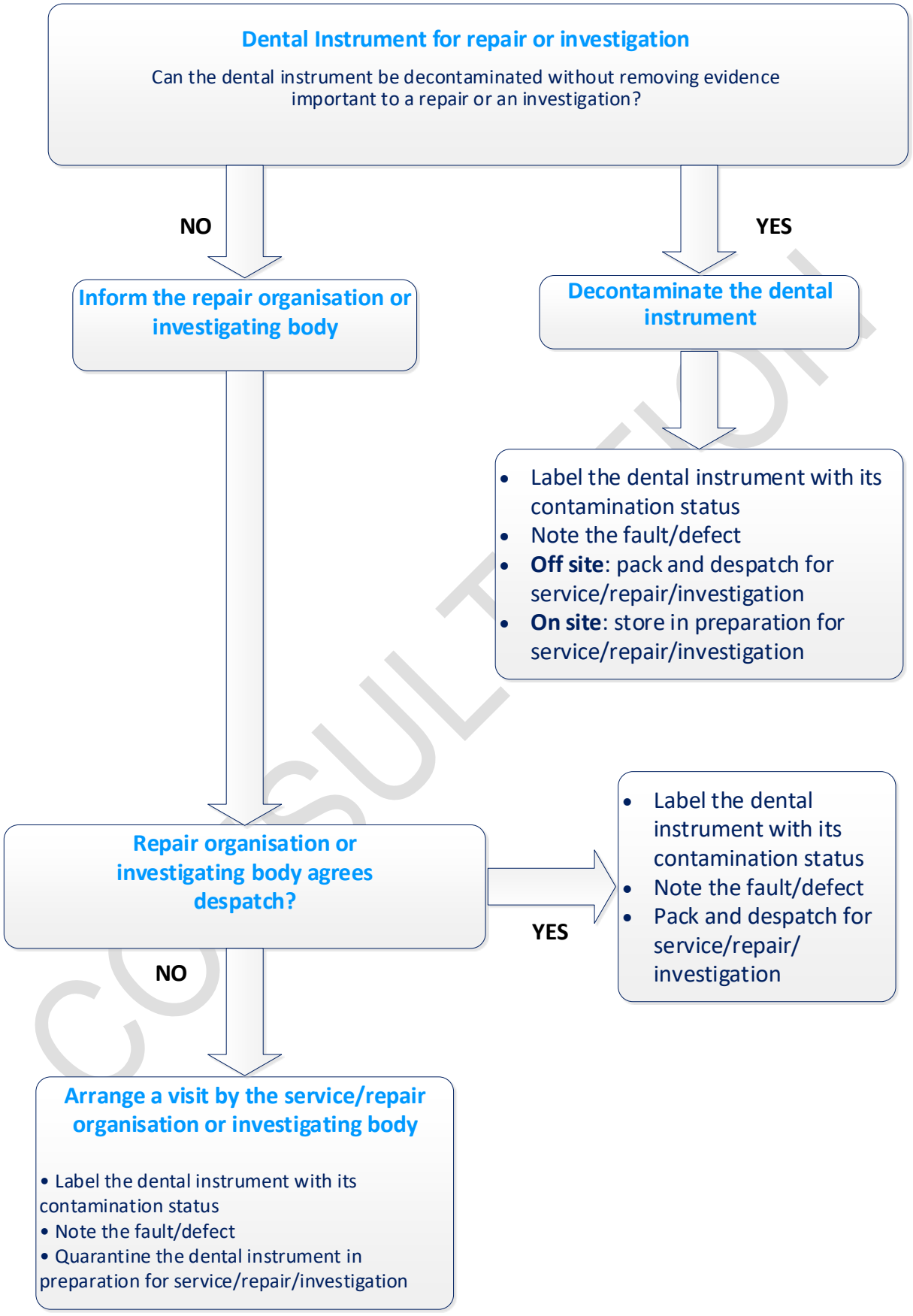
9.8 Ensure that dental instruments are regularly checked for functionality prior to use by the service user in line with the manufacturer's IFUs and throughout the expected lifetime of the dental instrument.

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

Sending dental instruments for repair or refurbishment

9.10 Ensure that the dental instrument is decontaminated to an appropriate level before despatch, packed securely and accompanied by a decontamination certificate stating the method used, see **Figure1**. The decontamination process should not cause further damage. However, the emphasis should always be on presenting a dental instrument which is as safe as possible to handle on receipt. Consult the repair organisation or investigating body (refer to **Section 5**) if there is any doubt. As a minimum, the external surfaces should be wiped clean, the device packaged securely and a full explanation given on the accompanying decontamination certificate. Consult HFS 2013 guidance GUID 5006 'Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices'.

Figure 1: Assessing actions for repairing the dental instrument



Quarantine of dental instruments

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

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

10. Disposal and decommissioning

10.1 Dental instruments for recycling should be decontaminated before despatch to ensure they are safe to handle. The dental instruments should be accompanied by a certificate stating the method by which they were decontaminated.

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

10.3 Disposal of dental instruments should be in accordance with the Health Facilities Scotland (HFS) guidance GUID 5008 'Guidance for Disposal and Recycling of Medical Devices' 2014. Also refer to HFS guidance Scottish Health Technical Note (SHTN) 3 'Management and disposal of clinical waste' 2017.

Global Citizenship Programme

10.4 Organisations may choose, in accordance with their local policy, to offer or sell unused or unwanted equipment (e.g. dental instruments/decontamination equipment) or to pass it to Developing Countries (see Scotland Global Citizenship Programme information).

10.5 Scottish Global Health Coordination Unit at https://www.scottishglobalhealth.org/

Glossary – specific to Part A

Decontamination – refer to definitions for 'processing'.

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

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

[SOURCE: EN ISO 13485: 2016 section 3 definitions]

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

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

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

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

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

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

Performance Qualification (PQ) - is defined as the process of obtaining and documenting PQ evidence that the equipment, as installed and operated in

accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

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

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

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

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

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

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

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

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

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

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

ACRONYMS

AE(D)	**–**	**Authorising Engineer (Decontamination)**
AP(D)	**–**	**Authorised Person (Decontamination)**
CP(D)	**–**	**Competent Person (Decontamination)**
CJD	**–**	**Creutzfeldt Jakob Disease**
EU	**–**	**European Union**
HAI	**–**	**Healthcare Associated Infection**
IFU	**–**	**Instructions for Use**
LDU	**–**	**Local Decontamination Unit**
SHPN	**–**	**Scottish Health Planning Note**
SHTM	**–**	**Scottish Health Technical Memorandum**
SICPs	**–**	**Standard Infection Control Precautions**
TSE	**–**	**Transmissible Spongiform Encephalopathy**
vCJD	**–**	**variant Creutzfeldt Jakob Disease**

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Appendix 1 Health and Safety legislation

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

- confined Spaces Regulations 1997;
- the Carriage of Dangerous Goods and Use of Transportable Pressure; Equipment Regulations 2004;
- control of Noise at Work Regulations 2005;
- control of Substances Hazardous to Health (COSHH) Regulations 2002;
- controlled Waste Regulations 1992. SI 1992 No 588;
- dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002;
- disability Discrimination Act 1995 and amendments 2005;
- electricity at Work Regulations 1989;
- electricity Safety, Quality and Continuity Regulations 2002;
- electrical Equipment (Safety) Regulations 1994;
- electromagnetic Compatibility Regulations 1992;
- employers Liability (Compulsory Insurance) Regulations 1998;
- environment Protection Act 1990;
- furniture and Furnishings (Fire) (Safety) Regulations 1988;
- gas Appliances (Safety) Regulations 1995;
- gas Safety (Installation and Use) Regulations 1998;
- health and Safety (Display Screen Equipment) Regulations 1992;
- health and Safety (Safety Signs and Signals) Regulations 1996;
- HSE Approved Code of Practice (ACoP) L8 Legionnaires' disease - The control of legionella bacteria in water systems;
- HSE Technical guidance HSG 274 Part 2 Legionnaires' disease - The control of legionella bacteria in hot and cold water systems;
- low Voltage Electrical Regulations 1997. HMSO, 1997;
- (the) Management of Health and Safety at Work Regulations 1999;
- manual Handling Operations Regulations 1992;
- personal Protective Equipment Regulations 2002;
- plugs and Sockets etc. (Safety) Regulations 1994;
- pollution Prevention and Control (Scotland) Regulations 2000;
- pressure Equipment Regulations 1999;
- pressure Systems Safety Regulations 2000;

- (the) Provision and Use of Work Equipment Regulations 1998;
- producer Responsibility Obligations (Packaging Waste) Regulations 2005;
- reporting of Injuries, Diseases and Dangerous Occurrences Regulations;1995 (RIDDOR 95);
- (the) Regulatory Reform (Fire Safety) Order 2005;
- simple Pressure Vessels (Safety) Regulations 1991;
- (the) Special Waste Regulations 1996;
- supply of Machinery (Safety) Regulations 1992.

Appendix 2 Procurement of Equipment

Pre-purchase considerations

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

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

Assistance can be sought in the following areas:

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

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

Specification preparation

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

Procurement of equipment – an overview of points to consider

Information required in the purchase of decontamination equipment, see **Figure 2:**

Figure 2: Questions to consider when procuring equipment

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

What standards or specifications are relevant?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine, e.g. BS EN 13060 2014 + A1 2018 for sterilizers, EN ISO 15883 series for washer disinfectors.
What type of contract?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine.
Which manufacturer?	Three or more manufacturers should be invited to tender for supplying the decontamination equipment. While no manufacturer should be excluded unnecessarily from the tendering process, they should not be invited to tender unless there is a realistic prospect of their being awarded the contract.
What installation and commissioning arrangements?	After delivery and installation, the decontamination equipment should be subjected to a formal documented programme of validation.
What arrangements are there for service and repair?	It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, that is, during the warranty period. A number of manufacturers also offer an extended warranty facility that, sometimes for an additional fee, provides an all-inclusive service and repair option.
What are the likely running costs?	Advice should be sought at the time of tender on the operational costs of the various machines that would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam etc.), consumable items (detergents, rinse aids etc.) and maintenance. This data should be used in the evaluation of the tender bids.

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

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

General design considerations

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

Safety features

Safety features should be designed in accordance with the Standard code of practice for safety of machinery, PD 5304, and the European standards for the safety of electrical equipment, EN 61010-1: 2010+A1:2019 and EN 61010-2-040: 2015.

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

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

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

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

Decontamination equipment

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

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

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

Programmable electronic systems

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

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

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

Invitation to tender

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

Prospective contractors should be given the following information:

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

Contract

Advice from NSS should be obtained as part of this process and dental services should use the National Procurement (NP) framework 143 for Decontamination equipment, accessories and maintenance. Equipment purchased from the NP143 framework have had compliance with type test data, validation and commissioning reports and qualification reports reviewed by AE(D)s and a Pass/Fail allocated. The framework is awarded on National Procurement's standard terms and conditions of contract for the purchase of goods and service. Dental Services should ensure that all orders reference the NP143 contract reference on all purchase orders.

Alternative forms of contract could be used dependent on the dental service policy and procedures for purchase of equipment not available on the NP 143 framework.

Delivery

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

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

Engineering services

Decontamination equipment installation will require one or more external services, electricity, hot and cold water, compressed air, drainage, ventilation and purified water. The manufacturer should make clear at an early stage which services will be needed and the detailed requirements for each. Consult Scottish Health Planning Note (SHPN) 13 Part 2 'Decontamination Facilities: Local Decontamination Units': 2008.