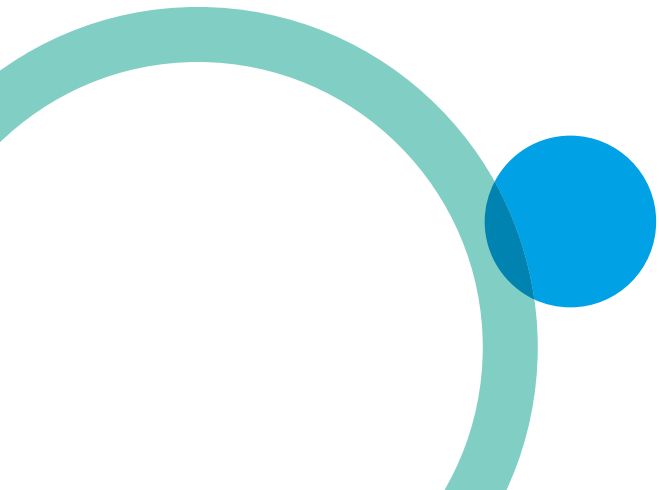
NHS National Services Scotland

Scottish Health Technical Memorandum 01-02.

Management, Operation and Testing of Laboratory Sterilizers and Washer Disinfectors.

Part A: Management and Operation.



June 2020

Contents

Executive summary.

The best practice guidance Scottish Health Technical Memorandum (SHTM) 01-02 Management, Operation and Testing of Laboratory Sterilizers and Washer Disinfectors (WDs) replaces some parts of SHTM 2010, SHTM 2030 and SHTM 2031 guidance published in 2001. SHTM 01-02:2020 provides a more detailed guidance to assist in the compliance with other relevant guidance such as HSE 'Safe working and prevention of infection in clinical laboratories and similar facilities: 2003' and 'Biological agents: Managing the risks in laboratories and healthcare premises: 2005'.

The SHTM 01-02:2020 series comprises four parts:

- Part A – Management and Operation;
- Part B – Test equipment / methods;
- Part C – Sterilization by steam;
- Part D – Automated cleaning and disinfection of laboratory equipment by use of a washer disinfector.

The SHTM 01-02 series covers best practice guidance on the cleaning and sterilization by use of a Laboratory WD and sterilizer. It covers standards, technical guidance, operational requirements, and testing and validation protocols used within the laboratory setting.

SHTM 01-02:2020 Part A content includes laboratory equipment and decontamination processes, general validation / periodic testing of decontamination equipment, health and safety, infection prevention and control, regulatory framework, incident reporting and distribution of safety alerts, functional roles and responsibilities and permit-to-work system and procurement. A glossary for the series is provided in Section 12.

1. Introduction.

1.1 As a result of the continuous evolution of technical advances in decontamination equipment since the publication of SHTMs 2010, 2030 and 2031 in 2001, it was proposed to revise the guidance for laboratory equipment and processes and for processing laboratory products and waste in a laboratory environment. This guidance has a new reference number SHTM 01-02 which will be composed of four parts.

SHTM 01-02 series scope

1.2 The SHTM 01-02:2020 series focus solely on the laboratory equipment used to process laboratory products and waste (for example, laboratory multi-cycle sterilizers and glassware washer disinfectors(WDS)) in a laboratory department.

The guidance given throughout this SHTM is designed to ensure that hazards are minimised and that decontamination procedures comply with the relevant legislation and established good practice.

Part A

Part A focuses on the management and operation of laboratory sterilizers and WDs in a laboratory environment. This applies to laboratory products and waste to be made safe for re-use and disposal.

Part B

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

Part C

Part C covers guidance on sterilization by steam employing a multi-cycle laboratory sterilizer and associated steam plant / integral steam generator.

Part D

Part D covers guidance on automated cleaning and disinfection of laboratory equipment by use of a washer disinfector.

Implementation of guidance

1.3 All healthcare providers engaged in the management of laboratory sterilizers and WDs will implement this document as required.

Who should use SHTM 01-02

1.4 SHTM 01-02:2020 is intended as a guide with the intended audience including, Laboratory Managers / Safety Managers, Decontamination Leads, Estates / Facilities personnel, Users responsible for the management of laboratory decontamination equipment, Waste Managers, technical personnel with appropriate training and experience such as Competent Person (Decontamination) (CP(D)),

Competent Person (Pressure Systems) (CP(PS)), Authorising Person (Decontamination) (AP(D)), Microbiologists (Decontamination) & Authorising Engineers (Decontamination) (AE(D)s).

It will also be of interest to Infection Prevention & Control personnel (e.g. Infection Prevention & Control Nurse / Doctor / Manager), Architects, and Planners, Manufacturers / Suppliers, Procurement personnel and others in both the public and private sectors. Appropriate experience is required to understand and / or to implement the relevant parts of this guidance.

2. Regulatory framework.

2.1 The regulatory framework and guidance for laboratory decontamination in Scotland includes:

- MHRA 'Good Laboratory Practice (GLP) for safety tests on chemicals';
- Health & Safety Executive (HSE) documentation such as 'Safe working and prevention of infection in clinical laboratories and similar facilities' and 'Biological agents: Managing the risks in laboratories and healthcare premises';
- EU Waste Framework Directive;
- Scottish Health Technical Note 3 (SHTN 3) 'NHSScotland waste management guidance';
- Relevant International / European / British standards.

2.2 The guidance given throughout this SHTM is designed to ensure that hazards and risks are minimised and that decontamination procedures comply with the relevant legislation and established good practice.

2.3 The Health and Safety at Work etc. Act 1974 (the HSW Act) and its various Regulations, Guidance and Approved Codes of Practice (ACOPs) places responsibility on managers and staff for the application of health and safety in the workplace. Assistance and guidance will normally be available from local Health and Safety Services.

2.4 The Health and Safety at Work Act 1974 allows 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 and appropriate measures to tackle them. The HSW 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 00:2013 'Best practice guidance for healthcare engineering policies and principles' provides further advice in Section 3 on statutory requirements.

2.5 The HSW Act is supported by numerous sets of regulations. Some enhance and give substance to how general duties can be complied with and some are very prescriptive in how compliance will be achieved.

2.6 Many of the former require the preparation and implementation of identified controls from risk assessments. Examples would be 'The Management of Health and Safety at Work Regulations' 1999 and 'The Control of Substances Hazardous to Health Regulations (COSHH)' 2002.

2.7 Core to these regulations is the requirement placed on an employer to firstly identify hazards to which employees, or other persons, may be exposed to because of work activities, to judge the likelihood and consequences of such exposure and to identify and implement controls to either eliminate the risk or to control it as reasonably practicable. It is important that such risk assessments are recorded and done in conjunction with employees.

The following are examples of hazards and associated risks which are implicit in the practice of sterilization:

- the hazard of scalding from escaping steam;
- the high temperatures (up to 200 °C) at which sterilizers are operated;
- the stored energy hazards associated with the operation of pressure vessels contained within all steam sterilizers;
- the explosive hazards associated with the sterilization of fluids in sealed glass bottles;
- the infection hazard associated with the microbial pathogens that may be handled by personnel using certain laboratory sterilizers;
- the hazard of infection to patients and staff by the inadvertent release of an unsterile load due to the failure of a sterilization and quality control process;
- the hazards associated with the handling of heavy and hot loads while loading and unloading sterilizers.

2.8 Despite the best efforts of all concerned in a workplace, incidents can and do happen. Where such events occur, they must be reported via the organisations internal reporting systems. In these circumstances the events should be seen as an opportunity to learn and to review what went wrong and make the necessary adjustments to prevent recurrence.

Certain types of events may require to be reported to external agencies, and may include enforcement agencies.

2.9 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013.

Commonly known as RIDDOR, these regulations impose duties on persons in control of workplaces and on self-employed persons to report certain events. Harm such as death, specified injury, ill health or injury which causes an employee to be unfit for work for a period over 7 days;

Dangerous occurrences, a specific list of events where no harm has been caused to a person, but the potential was there. Managers of laboratory decontamination equipment should familiarise themselves with their organisation's arrangements for reporting incidents under RIDDOR. Advice on RIDDOR and how to make a report can be found at https://www.hse.gov.uk/riddor/.

Note: This part of SHTM 01-02 extensively references:

BS 2646-5:1993: Autoclaves for sterilization in laboratories. Methods of test for function and performance.

BS EN ISO 15883-1:2009+A1:2014: Washer-disinfectors. General requirements, terms and definitions and, tests.

BS EN ISO 15883-2:2009: Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

3. Quality Management - Medical Laboratories - (ISO 15189: 2012).

3.1 This international standard specifies requirements for competence and quality that are particular to medical laboratories. The quality of laboratory service is a major factor that affects the quality of health care. The clinical laboratory as a whole has to provide the best patient care promoting excellence.

3.2 Accreditation means that medical laboratories have been assessed against internationally recognised standards to show their competence, impartiality and performance capacity. The reputation and competence of accrediting bodies are assurances of laboratories and accreditation gives international recognition.

ISO 15189:2012 should be consulted for essential requirements.

4. Overview of laboratory decontamination equipment and processes.

Laboratory sterilizers

4.1 Laboratory sterilizers are used for making-safe discard material, processing apparatus and materials to be used within clinical laboratories and sterilization of culture media / fluids. They are not intended for the sterilization of medical devices or medicinal products.

4.2 Laboratory sterilizers covered in this SHTM are designed for use only with high-temperature steam. No chemical sterilants are used.

4.3 Certain common laboratory operations may be carried out more economically with specialised machines designed for the purpose, and these are described below.

Sterilizers can be of the single door or pass through design depending upon the areas and hazards involved.

Operating cycles

4.4 Laboratory sterilizers are often required to process a wide range of materials and objects, and they are equipped with one or more operating cycles, each designed for a particular application. Different types of load require different operating cycles. Cycles are normally pre-set and proceed automatically once selected and started.

4.5 The range of cycles that a sterilizer can provide will depend on details of its construction. For example, the methods used to remove air from the chamber, the means employed to cool and dry the load, and the provision of safety features.

Note: The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

British Standards BS 2646-5:1993 permits 138 °C

4.6 Laboratory sterilizers may be equipped with one or more of the following operating cycles (however this is not an exhaustive list and other cycles may be required):

- make-safe of plastic discard;
- make-safe of contained fluid discard;
- sterilization of culture media;
- sterilization of fabrics;
- sterilization of glassware and equipment;
- free steaming;

- vacuum leak test (where vacuum systems are fitted).

4.7 Guidance on the specification of operating cycles is given in Part C of this SHTM 01-02:2020.

Load Types

Plastic Discard

4.8 Laboratory sterilizers using high-temperature steam can process laboratory waste containing less than 50 ml fluid per container in plastic containers, for example petri dishes / culture plates / plastic universal bottles. The cycle operates at a preferred sterilization temperature of 134 °C for a minimum of 3 minutes.

4.9 The cycle will have a phase to remove air from the load and either a vacuum or cooling phase post sterilization prior to door release at a maximum safe temperature of 90 °C.

4.10 The waste should be contained within specifically designed plastic discard sterilization containers which have been validated during the sterilizer commissioning, preferably not in discard bags. Air removal is the critical requirement for achieving a satisfactory cycle.

4.11 Ideally, the load probe should be placed in the slowest part of the load to achieve sterilization temperature, i.e. the bottom centre of the discard box. However, this is not practical due to the risk of probe entrapment in molten plastic. A discard box corner channel is a suitable alternative position, as long as the probe tip is at the base of the box where the fluid collects (SAN (SC) 02/18). Refer to SHTM 01-02:2020 Part C for more detail.

Clean Fluids / Media

4.12 Laboratory sterilizers using high-temperature steam can be used to process aqueous fluids in sealed containers (e.g. bottles) of either glass or plastic. They are operated at a preferred sterilization temperature of 121 °C for 15 minutes / F^0 15 unless the load being processed is sensitive to heat.

4.13 Fluids in glass containers can be hazardous. At a temperature of 121 °C the pressure inside a one-litre bottle having a normal fill of fluid is approximately 4 bar. If the door was opened at this temperature, and the load exposed to ambient air, the thermal stresses arising in the glass would crack the bottle and cause an explosion. A temperature of 80 °C is regarded as a safe maximum at which the door can be opened (even at this temperature the pressure inside a one-litre bottle is still 1.8 bar). Fluid sterilizers are fitted with a thermal door-lock to ensure that when glass containers are being processed, the door cannot be opened until the temperature inside all the containers has fallen below 80 °C. Failure to observe this requirement has led to serious accidents resulting from the explosion of glass containers. The sterilizer load probe should be put in a bottle with the same volume of fluid as the single largest item volume being processed.

4.14 Fluids in plastic containers present less of a hazard. Operating cycles for plastic containers allow the door to be opened when the temperature inside the containers falls below 90 °C.

Fabrics / Porous Load

4.15 Laboratory sterilizers using high-temperature steam can be used to process fabrics / porous loads, e.g. laboratory lab coats / wrapped pipette tips. The cycle can be operated at either a sterilization temperature of 134 °C for 3 minutes or 121 °C for 15 minutes.

4.16 The cycle will have active air removal via negative and positive pulsing, and a vacuum dry phase to produce a dry load.

Glassware

4.17 Laboratory sterilizers using high-temperature steam can be used to process empty glassware and laboratory equipment. The cycle is generally operated at a sterilization temperature of 121 °C for 15 minutes.

4.18 The cycle will have air removal stage and a cooling / drying stage (depending upon type of sterilizer).

Free Steaming

4.19 Laboratory sterilizers using high-temperature steam can be used to reheat media prior to pouring.

4.20 The sterilizer load probe should be placed within a container of water, the same volume as the largest volume being heated.

4.21 The sterilizer door must not open until the load has cooled to 80 °C or less.

Culture media preparator

4.22 Many of the problems which relate to sterilizing culture media can be solved by the use of small sterilizers in which the media constituents are placed directly into the chamber, thus avoiding the use of glass containers and their attendant hazards.

4.23 The machine comprises two or three modules incorporated into a system designed to provide controlled preparation, sterilization, cooling and dispensing of culture media with a minimum of attention by the operator. The system may also include a module which automatically stacks the completed culture plates.

4.24 The sterilizer module is essentially a pressure-cooker in which water and dehydrated culture media are mixed, sterilized and then cooled to below 80 °C. This type of sterilizer is suitable for manufacturing batches of culture media in volumes between 1 and 20 litres.

Animal house sterilizer

4.25 The very wide range of materials and implements used in the care of laboratory animals is often catered for by specialised sterilizers with capacities as high as 10 m^3, which run several operating cycles. Examples of loads include bedding for discard, fresh bedding, feed bottles, food and water, cages, and tools and

implements for use by personnel in the animal house. In view of the specialised nature of these machines, no further information specific to animal house sterilizers is given in this SHTM. Users are advised to adapt the guidance on laboratory sterilizers to their circumstances in consultation with their Authorising Engineer (Decontamination).

Laboratory Washer Disinfectors (WDs)

4.26 Laboratory WDs are available to process a range of laboratory items. These items may include bottles and vials, either new or after previous use, intended for containing reagents, culture media, etc. and other laboratory equipment, predominantly glassware. The cycle can include a disinfection stage unless the WD has been designed for a particular application, e.g. animal cage processing.

4.27 Laboratory WDs, whether intended for use in a clinical laboratory or in the laboratory of a manufacturer of a medicinal product, can be equipped with one or more load carriers specific to the nature of the items to be processed.

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

Validation

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

5.2 Validation is applicable to a wide range of equipment used in the decontamination process. This includes water systems, clean steam generation plant, WDs, sterilizers and packaging systems. Specific validation requirements are given in Parts C and D of this SHTM 01-02:2020.

5.3 Quality management system standard BS EN ISO 15189:2012 states, “the organisation shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered”.

5.4 Validation should show the ability of these processes to achieve planned results consistently.

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

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

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

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

5.8 The organisation should document procedures for the validation of processes for decontamination. Processes for decontamination shall be validated prior to implementation and following product or process changes as appropriate.

5.9 Records of the results and conclusion of validation and necessary actions from the validation shall be maintained.

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

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

Installation qualification (IQ)

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

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

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

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

Operational qualification (OQ)

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

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

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

Performance qualification (PQ)

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

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

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

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

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

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

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

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

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

5.27 The AP(D) or User should forward the completed validation report to the AE(D) for audit. The AE(D) should issue a report of findings to the User and any other persons

as required within the organisation, the validation report should be returned to the User (via the AP(D) if local procedures dictate).

5.28 The AE(D) should certify that all necessary tests have been carried out and that the results were satisfactory.

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

Periodic testing of decontamination equipment

5.30 After validation the equipment should be subject to a schedule of periodic tests which may be daily, weekly, quarterly and yearly intervals. This provides evidence that the machine continues to operate within the limits established during commissioning. See relevant SHTM 01-02:2020 Parts C or D for periodic test frequencies of decontamination equipment.

5.31 The User is responsible for the completion of periodic tests.

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

5.33 Revalidation may also be required under the following examples:

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

- there have been parameter changes;
- a new packaging system has been introduced that may require alteration of the configuration of the machine to ensure attainment of process requirements.

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

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

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

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

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

5.39 The User has the ultimate responsibility to ensure that decontamination equipment is fit for use as per SHTM 01-02 Parts C & D as applicable.

6. Waste Management.

6.1 Arrangements for handling and disposal of laboratory waste should be defined in local standard operating procedures (SOPs). All staff who have responsibility for waste should receive training on its safe handling and management. Guidance should be sought from the site-based or NHS Board Waste Management Officer to ensure compliance with local policies and SHTN 3: 2002 NHSScotland waste management guidance.

6.2 Every laboratory should have an administered policy for waste segregation and disposal in line with the laboratory classification. The employer should review and update this policy on a regular basis. All new members of staff should receive a copy of the current policy and all staff should receive information about any revision to it.

Segregation of waste

6.3 Staff should segregate equipment for reuse from disposable items. Waste should, as far as possible, be discarded 'dry'. Containers used for discarded material should have solid sides and bases, be made of metal or autoclavable plastic, and allow adequate steam penetration throughout the material within the container.

6.4 Infectious laboratory waste should be sealed in bags and / or boxes and clearly labelled identifying the source of the waste. Numbered identification tags available via the board procurement department should be used to label bags.

6.5 Infectious waste should be kept separate from all other wastes, including chemical wastes. The site or Health Board Waste Management Officer can provide advice on the specific packaging, labelling and disposal requirements for chemical waste and reference should be made to the hazard assessments in the Joint Agency Waste Classification Guidance WM3 v1.1:2018.

Containment levels 2 and 3 waste

6.6 Microbiological cultures from containment level (CL) 2 and 3 laboratories and all other potentially infected waste from CL3 laboratories should be sterilized before leaving the laboratory for final disposal. Such waste includes discarded bacterial cultures, tissue cultures and some specimens from immunology and other departments.

Hazard group 3 waste

6.7 If material is known or thought to contain hazard group 3, prion / TSE material, e.g. variant Creutzfeldt Jakob Disease, it should be disposed of in accordance with ACDP / SEAC guidance, 'Minimise transmission risk of CJD and vCJD in healthcare settings', Annex C.

Clinical waste

6.8 Blood specimens, swabs, infected tissue etc. (unless from patients infected with confirmed hazard group 3 agents) are considered to be clinical waste and must be sent to treatment / disposal facilities authorised to accept this waste. Not all facilities can accept this and guidance should be sought from the NHS Board Waste Management Officer.

Bulk fluid specimens

6.9 Bulk fluid specimens (e.g. 24-hour urine specimens in plastic containers) which are difficult to sterilize should be disposed of according to local policy, for example, in the sluice. Bulk liquid waste should not be sent for disposal in a free-flowing form and must be solidified using a gelling agent prior to disposal. Guidance should also be sought regarding the appropriate type of packaging used from the NHS Board Waste Management Officer and Dangerous Goods Safety Advisor (DGSA), who will be able to advise on the marking and suitability of packaging for liquid wastes. Most clinical waste packaging is not type-approved for liquids.

Waste for sterilization

6.10 Waste for sterilization **must** be suitably labelled before removal and be transported to the sterilizer in robust containers which would contain any accidental spillage. The sterilizer should be in the laboratory department and preferably in the laboratory for CL3 waste.

Contingency plans

6.11 Laboratories should have contingency plans for exceptional circumstances, such as sterilizer malfunction, specifying how waste should be stored and handled. Guidance should be sought from the site or Board Waste Management Officer. Guidance should also be sought from the clinical waste contractor who may require a separate collection for such waste to ensure that it is not mixed with other clinical waste produced by the site. Waste which is normally sterilized may only be treated in authorised facilities that have protocols in place to deal with this waste. This waste should not be shredded or macerated before treatment and may, subject to available facilities, require disposal by incineration. Such waste should not be allowed to accumulate for over 24 hours during the working week.

Sharps waste

6.12 All sharps should be discarded in an appropriate colour coded UN type approved sharps container; and must be disposed of in clinical waste facilities authorised to accept such waste. Sharps which have been in contact with containment level 2 or 3 microbiological cultures, e.g. broken petri dishes, should be sterilized before disposal. Refer to the National Infection Prevention and Control Manual (http://www.nipcm.scot.nhs.uk) for further guidance for safe use and disposal.

Registration of laboratory sterilizers in line with waste management licensing requirements.

6.13 Sites operating sterilizers which meet the requirements of Paragraph 28 Waste Management Licence Exemption are required to register the equipment with Scottish Environment Protection Agency (SEPA). The site should register for a Paragraph 28 Waste Management Licence Exemption, and it is not necessary to register each laboratory area separately. However, registrations will be required for each responsible party and if the facility or location is shared, for example, with a University, then all parties must register for the equipment they control. Registration may be made to SEPA online or using paper forms and are free of charge. All sterilizers used for waste on NHS sites will qualify for this registration requirement.

7. Infection prevention and control.

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

Infection Prevention and Control Teams (IPCTs)

7.2 IPCTs can give advice on:

- local policies on recommended disinfectants, their application, use, storage and disposal;
- risk assessments for procedures used in the reprocessing of medical devices;
- spillage procedures;
- environmental audits using national/local audit tools;
- guidance on many of these items can be found in the National Infection Prevention and Control Manual. (http://www.nipcm.scot.nhs.uk).

7.3 A source for healthcare guidance is the compendium of Healthcare Associated Infection Guidance. https://www.hps.scot.nhs.uk/web-resources-container/compendium-of-healthcare-associated-infection-guidance/

8. Reporting incidents and distribution of safety alerts.

Adverse incident reporting procedures

8.1 You need to inform IRIC if something goes wrong with medical devices, social care equipment and / or the estates and facilities you use. This is called an adverse incident and should be reported to IRIC via this link:

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

Too many incidents go unreported, but by telling IRIC about an incident, or even a near miss, you can help avoid potential harm.

All reports received by IRIC are added to their database and live data trending system. This helps identify and prevent recurring equipment issues. Information about IRIC's trending system can be found via this link:

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

Some incidents are serious enough to warrant immediate investigation before waiting for a trend to develop. In this instance, IRIC's triage process helps to identify these incidents.

Please note that you also need to report the incident on your local adverse event management system, usually via a Datix system. This will inform your employer that something has gone wrong at one of their facilities.

Use the link below to access information about what happens when you report an incident to IRIC, quarantining equipment involved in incidents or how to complete a Contamination Status Certificate:

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

IRIC Safety Alerts

8.2 IRIC has the remit to send safety alerts to all NHS boards and local authorities in Scotland. These safety alerts, which include Medical Device Alerts (MDA), Estates and Facilities Alerts (EFA) and Safety Action Notices (SAN), highlight new risks or tell you how to manage existing risks in the light of new information. These alerts also give you general guidance on managing risks along with details of where to go for more information and support. Equipment Coordinators are responsible for distributing safety alerts in their organisation such as:

Medical device alerts (MDA) tell you about any safety issues to do with the medical devices you use. IRIC help produce MDAs in partnership with the Medicines and

Healthcare Products Regulatory Agency (MHRA) and our counterparts in Wales and Northern Ireland.

Estates and facilities alerts (EFA) tell you about safety issues to do with health facilities and estates in Scotland. IRIC publish EFAs in partnership with NHS Improvement and our counterparts in Wales and Northern Ireland.

Safety action notice (SAN) tell you about safety issues which only affect Scotland and IRIC also use this format to publish Scottish versions of equipment-related Patient Safety Alerts (PSA) which are published in England by NHS Improvement.

For more information about safety alerts and access to the alerts online click on the link below:

http://www.hfs.scot.nhs.uk/services/iric-safety-alerts/

9. Functional responsibilities - roles and responsibilities.

Purpose / Scope

9.1 This section is intended to define the roles and responsibilities of NHSScotland decontamination staff working in medical laboratories. It supersedes the defined roles and responsibilities in Scottish Health Technical Memorandum (SHTM) 2010 and SHTM 2030 published in 2001 and the interim HFS guidance GUID 5015 published in 2017.

Principles

- staff undertaking laboratory processes and management of the laboratory process should be able to demonstrate their competencies and training in the areas in accordance with their roles and responsibility;
- the roles and responsibilities of laboratory staff should be clearly defined and documented;
- each NHSScotland Board should have a governance structure in place which supports the reporting and escalation of any failures to comply with this guidance document.

Management – definition

9.2 Management of a healthcare organisation performing decontamination is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises, including decontamination.

Executive Manager

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

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

Laboratory Safety Manager / Officer

9.4 The Laboratory Safety Manager / Officer serves as a resource for ensuring safe practices in the area as well as serves as a role model for safety. Larger laboratories may have more than one safety manager / officer if needed in order to fulfil all duties. In some areas, the Principal Investigator (PI) acts as the safety manager / officer.

Responsibilities of a Laboratory Safety Manager / Officer are:

- to assist in the yearly maintenance of the area's Chemical Hygiene Plan or Safety Plan;
- to write and the annual maintenance of specific standard operating procedures (SOPs);
- to maintain records for your area regarding safety training, area specific training procedures and safety equipment (for instance, eyewash) testing;
- to know the proper steps for reporting incidents;
- to be familiar with emergency procedure information (what to do, where to go, etc.);
- to be able to identify safety showers, eye washes, first aid, fire extinguishers, etc. in each area and ensuring every new member learns where these are located;
- to ensure the maintenance of group safety equipment such as spill control kits, first aid kits, and eyewash facilities;
- to be familiar with hazardous waste requirements and storage. Assist in ensuring that area waste is being collected and tagged properly;
- to adhere, as part of the role model position, to all Personal Protective Equipment (PPE) and other safety requirements, setting a good example for their peers and be encouraged to seek assistance from their PI if a researcher ignores these requirements;
- to ensure that the Monthly Quick Checks are being done in the area.

Decontamination Lead

9.5 Every healthcare organisation e.g. 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 policy;
- 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.

The Health Boards will decide on the need for this role.

Designated Person

9.6 The Designated Person is responsible for:

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

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

User

9.7 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 the acute sector, the User could be a Laboratory Manager.

The principal responsibilities of the User are:

- 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.

Waste Management Officer

9.8 Waste management officers organise and manage waste disposal. It is the responsibility of the waste management officer to ensure the disposal of waste is safe, with due consideration for the health and safety of staff and the environment and while conforming to government regulations.

The principal responsibilities of the waste management officer are:

- oversee waste management scheme and internal policy;
- supervise the transportation of waste to ensure that it takes place efficiently without contaminating air, land or water sources;

- assist with the development, promotion and implementation of new waste disposal schemes;
- ensure compliance with current legislation in the transportation, handling and disposal of waste;
- formulate and control the budget for waste disposal;
- monitor the quality and performance of waste services, including contract management of external providers;
- aim to meet waste reduction and recycling targets.

Authorising Engineer (Decontamination) (AE(D))

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

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

The AE(D) should provide professional and technical advice to the AP(D)s, CP(D)s, 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:

- 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) (AP(D))

9.10 The AP(D) should have technical knowledge and be appointed by the Health Board 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 AP(D) should be able to undertake their role in a safe and effective manner.

The role of AP(D) is intended to provide the organisation with an individual who, as part of the local 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 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 principal responsibilities of the AP(D) are:

- 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) (CP(D))

9.11 The 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 WDs.

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 SHTMs and relevant European standards;
- to witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory, and should arrange for test loads to be supplied as required.

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

Infection Control Doctor / Microbiologist (Decontamination)

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

Operator

9.13 The Operator is defined as a person with the authority to operate decontamination equipment.

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.

Competent Person (Pressure Systems) [CP(PS)]

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

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

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

10. Permit-to-work system.

10.1 In order to address concerns with regard to situations where equipment is taken out of use and returned into use without the mutual agreement of the technical staff and Users, the laboratory should operate a ‘permit-to-work’ system to ensure that equipment such as washer disinfectors (WDs) and sterilizers are declared safe to undertake repairs, maintenance and validation and that personnel working on them have documented authority to do so.

10.2 The permit system should be introduced for all decontamination equipment that is used in the laboratory.

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

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

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

10.6 The AE(D) under authorised delegation, should sign the initial permit to use the equipment after installation and validation testing (or revalidation testing for existing equipment that has been reinstalled). The User should sign the permit to accept the equipment into use.

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

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

10.9 The AE(D) should formally audit the permit system records with the AP(D) at periodic intervals.

11. Procurement of equipment.

11.1 This section of the guidance provides advice on the specification, purchase and installation of sterilizers and washer disinfectors (WDs) used in Laboratories. Health Boards should use the NP143 17 framework for Decontamination equipment, accessories and maintenance when purchasing laboratory sterilizers, etc.

Pre-purchase considerations

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

Specialist advice

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

11.4 Assistance can be sought in the following areas:

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

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

Specification preparation

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

Procurement of equipment – an overview

11.7 Information required in the purchase of decontamination equipment:

Questions	Comment
What type of load will be processed?	
What type of machine is required? Single or double door (pass through) design?	
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, and ventilation. 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?	Operators should be designated as per 9.14.
What capacity is required?	The likely daily and weekly 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. A WD might require ancillary equipment such as water softeners, deionisation or reverse osmosis (RO) water treatment plants, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals. A decision on treatment should be based upon

	initial assessment of source water and historical reports and cost based upon risk analysis. In addition, some machines will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product, and means for returning load carriers from the unloading side of the machine back to the loading side.
What standards or specifications are relevant?	Most items of decontamination equipment will be constructed to a British, European standard and International Standards as applicable.
What type of contract?	Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine.
Which manufacturer?	Three or more manufacturers should be invited to tender for supplying the decontamination equipment. While no manufacturer should be excluded unnecessarily from the tendering process, they should not be invited to tender unless there is a realistic prospect of their being awarded the contract.
What installation and commissioning arrangements?	After delivery and installation, the decontamination equipment should be subjected to a formal documented programme of validation.
What arrangements are there for service and repair?	It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, that is, during the warranty period. A number of manufacturers also offer an extended warranty facility that, sometimes for an additional fee, provides an all-inclusive service and repair option.
What are the likely running costs?	Advice should be sought at the time of tender on the operational costs of the various machines that would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam, etc.), consumable items (detergents, rinse aids, etc.) and maintenance. This data should be used in the evaluation of the tender bids.

Figure 1: Questions to consider when procuring equipment

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

Thus, reliance on a single item of equipment is not advisable.

General design considerations

11.9 All decontamination equipment and associated equipment is classed as work equipment and should comply with the Provision and Use of Work Equipment Regulations 1998 amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002 and the Health and Safety (Miscellaneous Repeals, Revocations and Amendments) Regulations 2013, Machinery Directive 2006/42/EC.

Such equipment should be CE marked.

Safety features

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

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

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

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

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

Instrumentation

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

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

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

Programmable electronic systems

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

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

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

Invitation to tender

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

11.22 Prospective contractors should be given the following information:

- that each machine will be subject to a validation process as described in the validation and verification Section 5 (see 'Validation / periodic testing of equipment used in the decontamination 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

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

11.24 Alternative forms of contract could be used dependent on Health Board policy and procedures for purchase of equipment not available on the framework. For example, MF / 1 (available from the Institution of Electrical Engineers, the Institution of Mechanical Engineers or the Association of Consulting Engineers) or the Joint Contracts Tribunal (JCT) suite of documents (available from RIBA Publications).

Purchasers using other forms of contract are strongly advised to seek legal advice, from the Central Legal Office (CLO) especially where a contract proposed by the prospective contractor is being considered.

Delivery

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

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

Engineering services

11.27 Decontamination equipment installation will require one or more external services including steam, electricity, hot and cold water, compressed air, ballast air, drainage, ventilation and purified water. The manufacturer should make clear at an early stage which services will be needed and the detailed requirements for each.

12. Glossary.

12.1 **Cleaning** - removal of contaminants to the extent necessary for further processing or for intended use. Note: Cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) by a manual or automated process that prepares the items for safe handling and / or further processing.

[SOURCE: ISO 17664:2017 section 3 definitions]

12.2 **Disinfection** - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose.

[SOURCE: ISO 17664:2017 section 3 definitions]

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

[SOURCE: EN 285:2015]

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

[SOURCE: EN 285:2015]

12.5 **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.

[SOURCE: EN 285:2015]

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

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

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

12.8 **Service life** - number of processing cycles and / or life-time that a piece of equipment can be subjected to and remain suitable and safe for its intended use.

[SOURCE: ISO 17664:2017 section 3 definitions]

12.9 **Sterile** - free from viable microorganisms.

[SOURCE: EN ISO 17664:2017 section 3 definitions]

12.10 **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]

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

12.12 **Validation** - confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

[SOURCE: EN ISO 17664:2017 section 3 definitions]

12.13 **Works tests** - series of tests performed during or after manufacture to demonstrate compliance of equipment with the requirements of the test specified.

[SOURCE: EN 285:2015].

ACRONYMS

ACDP	Advisory Committee on Dangerous Pathogens
AE(D)	Authorising Engineer (Decontamination)
AP(D)	Authorised Person (Decontamination)
CP(D)	Competent Person (Decontamination)
CJD	Creutzfeldt Jakob Disease
DGSA	Dangerous Goods Safety Advisor
EU	European Union
GSPRs	General Safety and Performance Requirements
HAI	Healthcare Associated Infection
HDL	Health Department Letter
IQ	Installation Qualification
OQ	Operational Qualification
PCD	Process Challenge Device
PQ	Performance Qualification
SHPN	Scottish Health Planning Note
SHTM	Scottish Health Technical Memorandum
SICP	Standard Infection Control Precautions
TSE	Transmissible Spongiform Encephalopathy
vCJD	variant Creutzfeldt Jakob Disease

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

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