# Scottish Health Technical Memorandum 01-02

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

## Part C: Sterilization by steam

June 2020

# CONTENTS

**Page No.**

# 1. Introduction.

1.1 Scottish Health Technical Memorandum (SHTM) 01-02:2020 Part C presents best practice guidance on sterilization by steam for laboratory equipment. SHTM 01-02:2020 Part A Management should be used in conjunction with this guidance.

1.2 Part C of this SHTM is intended as a guide for management, for technical personnel with appropriate training and experience, and also for Users responsible for the management of laboratory decontamination equipment, Competent Person (Decontamination) (CP(D)), Competent Person (Pressure Systems) (CP(PS)), Authorising Person (Decontamination) (AP(D)), Authorising Engineers (Decontamination) (AE(D)), Validation Services Manager, Validation Engineers, Laboratory Managers / Safety Managers, Decontamination Leads, Estates / Facilities personnel, Waste Managers, Microbiologists, Infection Prevention & Control personnel, Manufacturers / Suppliers and Procurement personnel will also be required to make use of this guidance.

## Scope

1.3 This guidance covers

- steam sterilization equipment and steam plant to be used for the reprocessing of laboratory equipment (glassware) and waste (media);
- sterilization by steam including design and pre-purchase, operational requirements, testing and validation protocols when using steam for sterilization within a laboratory setting.

## Exclusions

1.4 Part C provides guidance for steam sterilizers for processing laboratory loads only and not intended for the processing of medical devices or medicinal products.

# 2. Laboratory sterilizer design and pre – purchase considerations.

2.1 This section discusses specifications for laboratory sterilizers used for the processing of materials and equipment to be used in laboratories.

## Process considerations

2.2 General information on the requirements for the four containment categories can be found in the HSE document ‘The Approved List of biological agents, Advisory Committee on Dangerous Pathogens’ 2013. Purchasers should note that the containment requirements have been given statutory force by the ‘Control of Substances Hazardous to Health Regulations, (COSHH)’ 2002.

2.3 The Management, Design and Operation of Microbiological Containment Laboratories (HSE 2001) state that sterilizers are required in a building with Containment Level 2 (CL2) and Containment Level 3 (CL3) laboratories.

2.4 Sufficient sterilizers should be installed to ensure that contaminated material can continue to be made safe if any sterilizer is removed from service or becomes unavailable due to breakdown.

2.5 A cycle for the make-safe of plastic discard and a cycle for the make-safe of contained fluid discard should be available at all times. The need for other cycles to be duplicated will depend on the nature and volume of the work being done in the laboratory.

2.6 Laboratory sterilizers intended to process discard material should be sited as close as possible to the area in which the discard is produced, to avoid contaminated material being transported through adjoining rooms. Laboratory sterilizers intended to process culture media should be directly accessible from the media preparation area.

2.7 A laboratory sterilizer may provide one or more operating cycles, each designed for processing a particular type of load. The number and nature of the operating cycles which can be supported by any particular machine will depend on details of its design and construction. It will depend in particular on the methods used to remove air from the chamber and load, the methods used for cooling and drying the load and the provision of thermal door locks. Purchasers should carefully consider which operating cycles they are likely to need in the future, so that the manufacturer can install the necessary hardware. Otherwise it may not be possible to add a new operating cycle to a sterilizer without expensive modification. It is not merely a matter of “reprogramming”.

2.8 The preferred type of laboratory sterilizer is a front-loading unit, recessed into a panel separating the loading area from the plant room. Such sterilizers are available with a wide range of chamber sizes and operating cycles, compliant with EN 285:2015.

2.9 Sterilizers with a door at each end are essential for CL4 laboratories, though they present special problems of installation and access for maintenance. Sterilizers

which form part of a barrier between rooms of different containment levels should be fitted with a barrier seal to prevent airflow around the door opening of the sterilizer.

2.10 Free-standing machines, with chambers up to 500 litres, are also available. They are either top-loading or front-loading. For top-loading sterilizers, where there may be difficulties in load handling and lifting and a hazard from hot surfaces, the practical limit is 250 litres.

2.11 Transportable sterilizers, which generate steam from an internal reservoir, may be appropriate for small laboratories.

## Design considerations

2.12 The following three considerations are crucial.

### Air removal

2.13 Laboratory sterilizers commonly employ one of two principles for removing air from the chamber, each of which can be implemented in several ways:

- **passive**: steam comes in at the top of the chamber and air is forced out at the bottom (downward displacement). This is the simpler (and cheaper) method, but only suitable for loads such as sealed bottles, which do not impede the removal of air from the chamber. (In certain machines, notably transportables, passive air removal may be by upward displacement);
- **active**: the chamber is subjected to successive pressure changes to draw air from the chamber. This is required for loads such as fabrics, glassware and other equipment where trapped air cannot reliably be removed by passive methods. The more difficult air is to remove; the more pressure pulses will be required. Active air removal is always faster than passive methods.

### Cooling and drying

2.14 Where necessary, one of three cooling methods may be used:

- **natural**: the load is allowed to cool naturally in the chamber until it reaches a safe temperature. This is the cheapest option and acceptable if lengthy cycle times are tolerable and the load is not likely to be damaged by remaining hot for long periods;
- **dry assisted**: either cold water is circulated through the jacket or through cooling coils, or air is circulated through the chamber (with or without pressure pulsing) to accelerate the cooling process. This is faster than natural cooling;
- **vacuum**: the chamber is evacuated to permit the remaining heat in the load to evaporate moisture, simultaneously cooling and drying the load. This is suitable for loads which trap moisture (in general these are the same as the loads which trap air).

### Thermal door locks

2.15 Laboratory sterilizers constructed to BS 2646-1:1993 will have one or two door locks designed to prevent the door from being opened until the load cools to a pre-set temperature.

2.16 All sterilizers will have an interlock that prevents the door from being opened until the temperature of any fluid in the chamber and load (including condensate) has fallen below the boiling point of water at local atmospheric pressure (100 °C at sea level).

2.17 Sterilizers designed to process discard and fluid loads (cycles for make-safe of discard in large containers, sterilization of culture media, and free steaming) will have an additional interlock (a “thermal door lock”) to ensure that the door cannot be opened until the temperature of fluid in sealed containers has fallen below 80 °C (see paragraph 2.27 ‘Thermal door-lock override’. for additional specifications). Note that this requirement will considerably lengthen the cycle time.

## Specification and contract

2.18 A specification should be completed as part of the procurement process and submitted as part of a legal contract between the purchaser and the manufacturer. It is essential that the procurement specification is prepared by a team of qualified and competent staff and that the AP(D) and AE(D) are consulted during this process.

### Preparing a specification

2.19 Sterilizers are covered by a number of European Regulations / Directives and are thus required to be in conformance. Manufacturers should provide certification to the purchaser that the particular design of the equipment is manufactured in conformity with all relevant EU standards, national guidance and regulations. Relevant Directives include but are not restricted to:

- Electromagnetic Compatibility Directive (2014/30/EU):
- Low Voltage Directive (2014/35/EU);
- Pressure Equipment Directive (2014/68/EU);
- Machinery Directive (2006/42/EC).

2.20 Purchasers should refer to NHS NSS National Procurement (NP) NP143/17 framework for Decontamination equipment, accessories and maintenance.

2.21 Sterilizers are required inside the building for CL2 laboratories and within the laboratory suite for CL3.

2.22 Laboratory sterilizers constructed in accordance with BS 2646-1:1993 will not be suitable for processing material infected with Hazard Group 3 pathogens unless provision is made to contain and sterilize all chamber effluents before disposal. Effluent retention provides operator safety by filtering all non-condensable gases through a 0.2-micron filter prior to exhaust, whilst returning liquids to the chamber for sterilization, ensuring that nothing is exhausted without first being either filtered or sterilized.

Such a sterilizer should not be operated without a full fault-and-effect analysis to ensure that the containment remains secure if a failure occurs. The advice of the Microbiologist (Decontamination), Laboratory Safety Officer, the AE(D) & the AP(D) should be sought before specifying a sterilizer for a CL3 laboratory.

2.23 BS 2646-1:1993 does not cover culture media preparators.

## Additional specifications

2.24 The following specifications are additional to those required by BS 2646-1:1993. Purchasers should ensure that they are agreed with the manufacturer before any contract is made.

### Instruments and controls

2.25 In addition to the requirements of BS 2646-1:1993 laboratory sterilizers for use in the NHS must have a temperature recorder and a pressure recorder, complying with the requirements of BS 3970-1:1990 and EN 285:2015.

2.26 A cycle counter complying with BS 3970-1:1990 will also be required.

### Thermal door-lock override

2.27 Where the sterilizer is provided with a thermal door lock designed to prevent the door being opened until the temperature of fluids in sealed containers has fallen to 80 °C. A means should be provided to override the lock during the cooling stage of the operating cycle. The override should only be used by trained personnel who require access to loads above 80 °C, which will not present an explosive hazard.

2.28 The override should meet the following specifications:

- the override switch is accessible only by means of a key, code or tool unique to the sterilizer;
- it operates only during the cooling stage of the cycle and causes the cooling stage to terminate;
- there is a visual indication that the override has been operated;
- the switch resets automatically when released;
- at the end of the cycle the door cannot be opened except by means of a key, code or tool.

2.29 Where the sterilizer is intended to be used exclusively for the make-safe of discard in small containers, compliance with paragraph 2.27 ‘Thermal door-lock override’ may be waived with the agreement of the laboratory safety officer. In this case, the switch should reset automatically whenever a different operating cycle is selected or whenever the power supply is interrupted.

### Load Temperature probe

2.30 The sterilizer should be fitted with a load-temperature probe within the chamber. This is a temperature sensor attached to a flexible sheathed (to prevent damage)

lead and designed to be inserted into load items (such as bottles) to monitor the temperature during an operating cycle.

### Steam generators

2.31 Where steam is supplied from a generator within the sterilizer (Types 2 and 3 of BS 2646-1:1993), condensate from the steam which comes into contact with any discard load should not be returned to the boiler.

2.32 Where the sterilizer chamber is used as a water reservoir (Type 4 of BS 2646-1:1993), the water should enter the chamber after the start of the cycle and be drained before the end of the cycle.

2.33 Water reservoirs may accumulate solidified agar and should de designed so that they can be cleaned easily.

2.34 Where steam is generated externally solely for use in the sterilizer, the generator should be supplied as an integral part of the sterilizer, with controls which comply with the 'Pressure Systems Safety Regulations (PSSR)' 2000.

### Chamber drain

2.35 The chamber drain should be designed to minimise the risk of blockage by solidified agar or similar material.

2.36 Where the temperature of the effluent is high, for example, for free steaming, means should be provided to prevent vapour being discharged into the plantroom or the loading area.

2.37 Condensate should be recovered wherever possible, including the steam distribution system, steam separators and chamber jacket, then returned to the steam generation plant, provided the quality of the feed water to the boiler is not compromised or the condensate is not corrosive.

2.38 All other effluent from a sterilizer is potentially contaminated and should be disposed of to the main drain. Effluent can originate from one or more of the following sources:

- air, condensate and steam from the chamber drain which can contain chemicals and microorganisms;
- discharge from a water – sealed vacuum pump, ejector or chamber vent, which can also contain microorganisms;
- water introduced to cool and dilute the discharge from the chamber;
- leaks from the chamber of steam, water or air could be contaminated;
- air filters designed to filter air entering or being extracted from the chamber should be fitted where appropriate & replaced at recommended intervals.

## Water services to the sterilizer

2.39 Where multiple units are installed, there should be adequate capacity to prevent starvation of services as a result of other equipment connected to common supplies. A cold water supply may be needed for equipment such as condensers, heat

exchangers and water-sealed vacuum pumps (feed water for steam generation is discussed in Section 4 'Steam plant'). Details of the water-quality requirements, the maximum pressure, minimum pressure and maximum flow rate should be obtained from the sterilizer manufacturer.

2.40 Backflow prevention devices should be provided on the water supply as required and need to comply with BS EN 1717:2000 and 'The Water Supply (Water Fittings) (Scotland) Byelaws' 2014.

2.41 The temperature of water used for sterilizers with vacuum systems should not exceed the value specified by the manufacturer. Higher water temperatures will reduce the efficiency of vacuum pumps and compromise the specified vacuum levels.

2.42 Performance will also deteriorate if the water is very hard or contains large quantities of solids in suspension. The hardness of the water should be in the range 0.7 – 2.0 $mmolL^{-1}$. Hardness values outside these limits may cause scaling and corrosion problems.

2.43 Water economy devices (for example, those that sense the temperature of cooling water and adjust the flow rate accordingly) should be fitted to reduce water consumption.

2.44 Chlorine and chlorides may cause corrosion of stainless steel in the presence of heat. Advice on maximum permissible levels should be obtained from the sterilizer manufacturer. EN 285:2015 also gives guidance on appropriate feedwater quality.

2.45 Further guidance on water supply is given in Scottish Health Technical Memorandum 04-01 – 'Water safety for healthcare premises' 2014.

### Non-hazardous effluents

2.46 As effluent from steam sterilizers and associated equipment is potentially contaminated it should be connected to the main drain in a manner which provides backflow protection and is consistent with 'Building (Scotland) Regulations' 2004 and 'Sewerage (Scotland) Act 1968' (as amended 2002).

2.47 Where a tank supplies water to a water-sealed vacuum pump or a water pump used for an ejector vacuum system, the overflow discharge from the tank should also include an air break.

**Note:** Steam safety valves

The Plant Room design should consider the safe discharge of vapour from the steam safety valves as fitted to the header, jacket and chamber of sterilizers to a safe exit, and from built in steam generators if fitted. Indication pipes or tails should be installed to ensure that leakage or discharge can be identified. The discharge points should be to outside of the building.

## Top-loading sterilizers

2.48 Top-loading sterilizers are difficult to load safely without the use of mechanical aids. Loading systems should be designed to protect the operator from the risk of injury caused by lifting and hot surfaces and should comply with the requirements of the 'Manual Handling Operations Regulations' 1992 (as amended) (MHOR) and the 'Lifting Operations and Lifting Equipment Regulations' 1998 (LOLER).

## Operating cycles

2.49 BS 2646-1:1993 recognises only three distinct operating cycles which it denotes as make-safe, liquids sterilization; and, equipment and glassware sterilization. The range of operating cycles recommended for NHS use, and the materials they are designed to process, are described below and specified in Table 1. Where the table gives a choice of sterilization temperatures, the highest temperature should normally be specified. If heat-sensitive loads are likely to be processed, then additional lower-temperature cycles may be required. The complete set of cycles to be provided on each machine, including any non- standard cycles not shown here, should be agreed with the manufacturer before the contract is placed. An automatic leak test should be provided for sterilizers with active air removal.

| Name of operating cycle | Thermal door lock (80 °C) | Air removal method | Cooling and drying method | Sterilization temperature (°C) | Hold times minutes (minimum) |
|---|---|---|---|---|---|
| Make safe of small plastic discard | Yes | Active | None / assisted | 134 | 3 |
| | | | | 126 | 10 |
| | | | | 121 | 15 |
| | | Passive | None / assisted | 134 | 3 |
| | | | | 126 | 10 |
| | | | | 121 | 15 |
| | | | | | |
| Make safe of contained fluid discard | Yes | Passive | Natural. | 121 | 15 |
| | | | Dry assisted. | 126 | 10 |
| | | | | 121 | 15 |
| | | | | | |
| Sterilization of culture media (pre-set cycle) | Yes | Passive | Natural | 121 | 15 |
| | | | | 115 | 30 |
| | | | Dry assisted | 121 | 15 |
| | | | | 115 | 30 |
| | | | Wet assisted | 121 | 15 |
| | | | | 115 | 30 |
| | | | | | |
| Sterilization of culture media (variable cycle) | Yes | Passive | Dry assisted | 102 – 121 | Up to 60 |
| | | | | | |
| Sterilization of fabrics | No | Active | Vacuum | 134 | 3 |
| | | | | 126 | 10 |
| | | | | 121 | 15 |
| | | | | | |
| Sterilization of glassware and equipment | No | Active | Vacuum | 134 | 3 |
| | | | | 126 | 10 |
| | | | | 121 | 15 |
| | | Passive | None | 134 | 3 |
| | | | | 126 | 10 |
| | | | | 121 | 15 |
| | | | | | |
| Free steaming (variable cycle) | Yes | Passive | Dry assisted | 102 – 104 | Up to 60 |
| | | | | | |

**Table 1: Operating cycles for laboratory sterilizers**

2.50 Operating cycles are normally automatic and pre-set and cannot be adjusted by the operator. For some processes, however, such as the sterilization of culture media and free steaming, it may be desirable to have a variable cycle with controls for adjusting the sterilization temperature and holding time within a pre-set range. This feature should normally be provided as a separate cycle.

### Make-safe of plastic discard

2.51 This cycle corresponds to the “make-safe” cycle specified in BS 2646-1:1993. It is designed to sterilize infected material held in plastic containers not exceeding 50 ml. Examples of such containers include Petri dishes, specimen bottles, and other small plastic items intended either for disposal or for reuse.

2.52 If the workload is heavy, an active air removal system is recommended to shorten the cycle time.

2.53 Discard boxes will be required.

### Make-safe of contained fluid discard

2.54 Although the containers would normally be unsealed, the limits on volume ensure that any fluid held in a sealed container does not present an explosion hazard when the door is opened at the end of the cycle.

2.55 Glass containers and larger plastic containers should be processed with the make-safe cycle for contained fluid discard. This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646-1:1993. It is designed to make-safe infected material in sealed glass containers of any size or sealed plastic containers of volume greater than 50 ml.

2.56 While essentially the same as the culture media cycle, a sterilization temperature of 121 °C is normally used to protect the glass.

2.57 Discard boxes as specified will be required.

### Sterilization of culture media

2.58 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646-1:1993. It is designed to sterilize culture media in open or sealed containers.

2.59 Since culture media are normally damaged by sterilization at 134 °C the maximum sterilization temperature is set at 121 °C.

2.60 A variable cycle, in which combinations of sterilization temperature and holding time can be set by the operator, may be desirable for certain products and, if required, should be specified as a separate cycle.

### Porous Load

2.61 This cycle is a variant of the “glassware and equipment” cycle specified in BS 2646-1:1993. It is designed to sterilize fabric materials such as towels, clothing, wrapped animal bedding, and other porous materials. The Porous Load cycle is also suitable for sterilizing empty glassware without caps and for disinfecting wrapped tubing and wrapped filters.

2.62 The cycle differs from the glassware and equipment cycle in that more pressure pulses will be required to remove air from the load.

### Sterilization of glassware and equipment

2.63 This cycle corresponds to the “glassware and equipment” cycle specified in BS 2646-1:1993. It is designed to sterilize clean, empty glassware (with loose caps) and equipment such as tubing and filters. Loads must not contain any fluids.

2.64 Some microbiological filter membranes may be damaged by the rapid fluctuations in pressure used by an active air-removal system, and it may be necessary to provide a separate filter cycle.

### Free steaming

2.65 This cycle is not specified in BS 2646-1:1993. It is designed to melt solidified agar by exposing it to steam near atmospheric pressure. It is normally a variable cycle. If the workload is heavy, this will not be a cost-effective way of using a sterilizer and a Köch steamer may be more suitable.

### Discard boxes

2.66 When a sterilizer intended for use with make-safe cycles is purchased, suitable boxes will need to be specified for receiving discard material, transporting it from the laboratory bench to the sterilizer, and containing the load during the sterilization process. Enough boxes to load the chamber fully should be provided.

2.67 The sterilizer manufacturer will have used a certain type of discard box in determining the cycle time. If other types are used for routine production, the cycle time may differ considerably.

2.68 The design of the box can greatly affect the overall cycle time, varying between 45 minutes and two hours when the process incorporates an active air-removal system; and, between two and six hours for processes based on passive displacement. Figure 1 illustrates a typical commercially available discard box.

2.69 The box should be designed to facilitate the removal of air from the load and the penetration of steam into the load.

2.70 The box material should be impervious, conduct heat well, be robust, resistant to puncturing, easily cleanable and able to withstand the sterilization process without damage. Stainless steel, aluminium and plastic are the most common materials:

- stainless steel, preferably coated with polytetrafluoroethylene (PTFE), is the material of choice. Its principal advantages are resistance to distortion at sterilization temperatures, good heat transfer and “non-stick” properties;
- aluminium is lighter than other metals but is prone to metal fatigue and cracking, and so has a shorter life expectancy;
- plastic boxes are cheaper than those made of metal but conduct heat poorly, increasing energy consumption and lengthening cycle times. Where inserts are used to segregate solid from liquid discard, a plastic box may distort and prevent the discard or insert from being withdrawn.

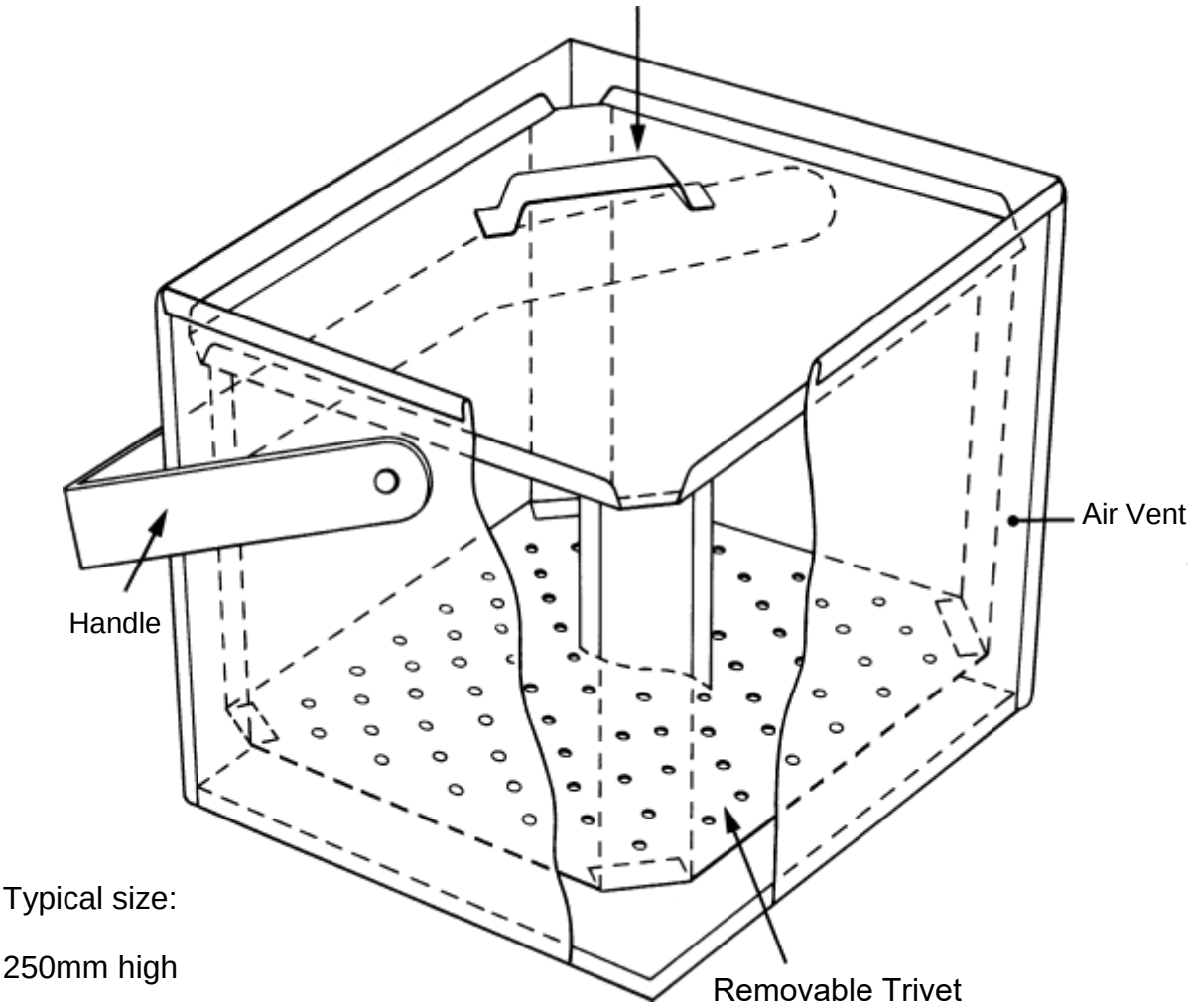
2.71 Where small discard is to be made safe, the box should contain a trivet to support the load before sterilization and allow any liquids to drain to the bottom of the box during the cycle. This will make it easier to separate solid and liquid residues for disposal.

2.72 Discard should be enclosed when the box is being moved. Loose-fitting lids are satisfactory for transport within a laboratory. Alternatively, the discard material may be placed in a discard bag (see SAN (SC) 98/16) inside an open box, providing the neck of the bag is closed.

2.73 Whenever discard material is transported outside the laboratory suite, a sealed and locked lid should be fitted. Where the lid can affect the efficacy of the sterilization process, it should be opened or removed before the cycle begins and sterilized along with the box.

2.74 Bags, usually plastic, are available with identification markings for discard material. The bags are often manufactured in a material which will melt at 134 °C to assist air removal. Discard bags should always be contained in a discard box and opened wide before sterilization.

**Note**: SAN (SC) 98/16 relates specifically to sterilizer discard bags and should be taken into consideration.




Typical size:

250mm high

310mm x 310mm base

**Figure 1: An example of a laboratory discard container.**

# 3. Validation and verification of the laboratory sterilizer.

3.1 This section contains detailed procedures for tests specific to laboratory sterilizers and test schedules. The tests in this section apply to laboratory sterilizers equipped with one or more of the following operating cycles:

- make-safe of plastic discard;
- make-safe of contained fluid discard;
- sterilization of culture media (pre-set or variable cycle);
- disinfection of fabrics;
- sterilization of glassware and equipment;
- free steaming;
- culture media preparator.

3.2 Attention is drawn to the safety information presented in SHTM 01-02:2020 Part A. Unless specified, all tests should be performed at each of the sterilization temperatures available on the sterilizer.

3.3 Sterilization is a process whose efficacy cannot be verified retrospectively by inspection or testing of the product. For this reason, sterilization processes should be validated before use, the performance of the process should be monitored routinely, and the sterilization equipment should be maintained in accordance with the manufacturer's instructions for use.

3.4 Tests and checks should be carried out to ensure sterilizers are fit for purpose during the various stages of manufacture (type tests and work tests – see glossary in SHTM 01-02:2020 Part A), after delivery, during validation (Installation Qualification (IQ)), Operational Qualification (OQ) and Performance Qualification (PQ) and safety tests and periodically thereafter.

3.5 Standard EN 285:2015 Sterilization — 'Steam sterilizers — Large sterilizers' is an equipment standard giving manufacturers the basic requirements for steam processing equipment. The procedures to be performed by the manufacturer during type and works testing in order to confirm acceptable performance are defined in (clause 4, table 5) of EN 285:2015. Where factory acceptance testing is required, a protocol should be agreed in advance with the AE(D) prior to purchase and included in the procurement contract. The responsibility for performing type and works tests will normally rest with the manufacturer. The responsibility for testing once installed on-site is dependent upon contractual agreements and / or purchaser preferences and should be performed by qualified personnel.

3.6 IQ and OQ tests demonstrate compliance to the requested specification of the standards. Procedures performed upon installation ((IQ), (OQ) and (PQ)) are also defined in EN 285:2015 and EN ISO 17665 Part 1: 2006.

3.7 Advice should be sought from an AE(D) with respect to the status of the test procedures described in this guidance.

## Schedule of validation (IQ, OQ and PQ) tests

3.8 The contractor should carry out Installation Qualification (IQ) checks and tests before Operational Qualification (OQ) tests are performed; these may be witnessed or repeated by the CP(D) if required.

3.9 OQ tests and Performance Qualification (PQ) tests should be carried out by the CP(D).

3.10 PQ tests should be carried out after the IQ and OQ tests have been satisfactorily completed. PQ tests may be performed while the sensors used in the IQ and OQ tests are still in place and before the final vacuum leak test.

### Schedule of validation tests for laboratory sterilizers

3.11 A schedule for all validation tests is shown, see Table 2. The tests should be carried out with the equipment at normal working temperature, which may require a warm up cycle prior to testing.

| Test | IQ | OQ | PQ |
|---|---|---|---|
| Commissioning safety checks and tests | X | | |
| Physical steam quality tests (dryness, NCG, superheat) | X | | |
| Vacuum leak test | X | X | |
| Vacuum leak test (sensors connected) | | X | X |
| Verification of calibration* | X | X | |
| Automatic control test (for each cycle in use) | X | X | |
| Thermal Door override test (for each cycle in use) | X | X | |
| Chamber temperature profile | | X | |
| Tests for make safe of plastic discard<br><br>Thermometric test for a full load / production* (x2) | | X | X*** |
| Tests for make safe of Vacutainers**<br><br>Thermometric test for a full load* (x2) | | X | X*** |
| Tests for make safe of contained fluid discard<br><br>Thermometric test for a full load / production load*(x2) | | X | X*** |
| Tests for Porous Loads<br><br>Thermometric test for a small load test pack / production loaf (x2) | | X | X*** |
| Tests for sterilization of glassware and equipment (x2)<br><br>Thermometric test for a full load / production load | | X | X*** |
| Tests for free steaming (x2)<br><br>Thermometric test for a full load | | X | X*** |
| Vacuum leak test (sensors removed) | | X | XX |
| Sound pressure test | | X | |

**Table 2: Schedule of validation tests for laboratory sterilizers**

* Whichever is available to test

** Where programmed

***As applicable

## Installation checks

### Checks on ancillary equipment

3.12 Ancillary equipment should ideally be installed and commissioned before the validation procedure for the sterilizer begins. When the checks on ancillary equipment require a sterilizer to be in operation, the CP(D) should carry them out in co-operation with the contractor for the sterilizer.

3.13 The contractor responsible for the installation of sterilization equipment is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

3.14 Where factory acceptance testing is required, a protocol should be agreed in advance with the AE(D) and included in the procurement contract.

## Engineering services

3.15 Checks should be made on the following:

- that the engineering services are installed correctly, are adequate to meet the demands of the decontamination equipment, do not leak, and all necessary isolating valves or switches and test points have been installed and are working correctly;
- that drains remove effluent effectively when all plant in the vicinity, including the decontamination equipment, is connected and operating under full demand;
- that the water treatment plant (if fitted) operates correctly and that the quality of water supplied for each stage of the process is in accordance with the specification;
- that the water economy system (if fitted) operates correctly.

**Note:** Installation tests should determine and provide documented evidence that the porous load sterilizer is installed and configured to operate in a safe manner and is manufactured, installed and operates in accordance with BS EN 61010-2-040:2015.

3.16 Electrical equipment on the sterilization equipment should be checked to ensure it is correctly connected to the electrical service in accordance with BS 7671:2018 (IET Wiring Regulations). The following electrical tests should be carried out and certified:

- the manufacturer has supplied all the documents specified in the contract;
- the equipment has been supplied and installed in accordance with the contract;
- calibration verification certificates traceable to UKAS certification for the measuring instruments and controller(s) on the equipment have been supplied;
- no defects are apparent from a visual inspection of the equipment;
- all supports, bases and fixings are secure and without imposed strain from service connections;
- thermal insulation is in good condition and securely attached;
- security and settings of door safety switches are in compliance with data supplied by the manufacturer;
- keys, codes or tools required to operate locked controls and control over-rides have been supplied, operate correctly and only operate the control for which they are intended; and cannot unlock controls on other machines in the vicinity;
- load trolleys, load carriers and discard boxes are effective and safe in use;
- IT connections are made and connected for the sterilizer system and monitoring instrumentation onto the main server and available for back-up;
- security and settings of door safety switches are in compliance with data supplied by the manufacturer.

## Installation Qualification (IQ) tests

3.17 The Installation Qualification testing is a process of obtaining and documenting evidence that the equipment and ancillary services have been provided and installed in accordance with the specification supplied to the manufacturer.

After installation and when all commissioning and safety checks have been completed Installation Qualification tests should be carried out with an empty sterilizer and should consist of:

- an air leakage test;
- an automatic control test;
- verification of calibration
- These tests also form part of the OQ and are described in paragraph 3.18 ‘Operational Qualification (OQ) functional checks’.

## Operational Qualification (OQ) functional checks

3.18 During an operating cycle, with an empty chamber, checks should be made that the following recommendations are met (several cycles may be necessary to complete all the checks):

- the selection of automatic or manual control is by key code or tool;
- the selection of one control mode inactivates the other control mode;
- water, steam or compressed air cannot be admitted into the chamber when the equipment is under automatic control until the door is closed, locked and sealed;
- the operating cycle cannot start until the door is closed, locked and sealed;
- the cycle may be advanced sequentially under manual control – this function should be protected by password / code entry / key switch;
- the indicated and recorded values of cycle variables are within the limits specified by the manufacturer throughout the cycle;
- there are no leaks of water, steam aerosols, air, gas or effluent throughout the cycle;
- there is no evidence of interference to or from other equipment connected to the same services;
- operation and reading of all instruments appears to be satisfactory;
- the temperature of surfaces routinely handled by the operator does not exceed 43 °C;
- a means of diluting / reducing any high temperature effluent to <43 °C is required prior to discharge into any water company common drains.

3.19 At the end of the cycle, checks should be made that the following recommendations are met:

- the door opening system cannot be operated until the cycle has been completed;

- for sealed fluids cycles the door does not open if the temperature is above 80 °C;
- for plastic discard cycles or sealed fluids in plastic containers the door does not open if the temperature is above 90 °C;
- for systems incorporating one or more cycle stages at pressures 200 mbar above or below atmospheric pressure:
  - the door opening system cannot be operated until the chamber has been vented to atmosphere and the chamber pressure is within 200 mbar of atmospheric pressure;
  - the door retainers cannot be released until the seal between the door and chamber has been broken, and the chamber is effectively vented to atmospheric pressure.
- each door interlock system is fail-safe;
- failure of one interlock, or any one service, does not allow the door to be opened when conditions within the chamber would cause a hazard, for example pressure in excess of 200 mbar;
- the automatic controller has operated in accordance with the specification.

## Sterilizer response to external faults

3.20 The sterilizer should be checked to ensure it reacts correctly and safely, that is, it does not create a safety hazard or give a false indication of the satisfactory completion of a cycle, when exposed to a number of external fault conditions.

3.21 During each stage of an operating cycle, the response of the sterilizer to the following simulated faults (as appropriate to the type of machine) should be checked, ensuring that the cycle will fail in the event of each fault:

- operation of the emergency stop button;
- power failure;
- steam pressure too low;
- steam pressure too high;
- compressed air pressure too low;
- compressed air pressure too high;
- water service failure;
- communication failure.

## Performance Qualification (PQ) tests

3.22 Performance Qualification (PQ) is the process of obtaining and documenting evidence that the sterilizer will consistently provide reproducible results when operated in accordance with the pre-defined acceptance criteria within the process specification. PQ tests should be performed as part of the validation procedure, as part of any repeat validation procedure, and whenever the User judges that a new loading condition calls for a new PQ test. It is the responsibility of the User to set the

acceptance criteria to allow the steam processing equipment and sterilizer to be validated during PQ testing. Standard EN ISO 17665-1:2006 and technical specification CEN ISO/TS 17665-2:2009 describe how this should be carried out.

3.23 PQ tests (or commissioning tests providing PQ data) collect three different types of data, indicated, recorded and measured. The three sets of data serve different purposes and may require different tolerances:

- indicated data (electronic displays etc.) are available as a general guide to the User for monitoring production cycles during operation on all types of sterilizer;
- recorded data are available to the User for production cycles on most types of sterilizer and can be regarded as definitive proof for routine production control and product release;
- measured data obtained during OQ and PQ testing is regarded as definitive proof of sterilizer efficacy for the purposes of validation as they are more reliable than indicated or recorded values. The permitted tolerances should reflect this.

3.24 PQ data can be generated for single load conditions or conditions representative of pre-determined product families. Where the PQ data is to be used for loads requiring specific conditions (e.g. laboratory equipment (glassware) and waste (media) that would be damaged if the limits were broader) any recorded variation between cycles should be small and due to the performance limits of the sterilizer and the permitted tolerances should be tight. Replicated thermometric PQ tests should give some indication of acceptable variation.

3.25 Where the PQ data for a single loading condition is judged to be valid for a range of loading conditions (e.g. for a product family), the variation between cycles will contain a systematic variation related to the differing loading conditions, and the permitted tolerances will be greater. The choice of loading conditions for which the data is valid should take into account whether this greater tolerance is acceptable.

3.26 The extent of the PQ required will depend on the type of sterilizer and the nature of the load. The initial PQ load should be accurately documented to enable replication at yearly revalidation. Where a new load is not covered by an existing PQ report, full PQ tests should be conducted.

3.27 Users should adopt the following procedure for every sterilizer:

- establish a list of potential product families and their relationship to the validation loads (see CEN ISO/TS 17665-2: 2009 Chapters 6 and 9 and PD ISO/TS 17665-3:2013);
- establish a list of the different loading conditions to be processed in the sterilizer. Each production load should correspond to one of the listed loading conditions;
- determine whether each loading condition presents a greater or lesser challenge to the process than the small and full loads used in the thermometric tests carried out during validation;
- where the loading is a lesser challenge than the validation loads, the results of the validation tests may be used as PQ data;

- where the loading condition is a greater challenge than the validation loads, additional PQ tests should be carried out.

3.28 When setting the specifications for a new sterilizer, the User should ensure that details of the product families to be processed are identified, including weights. This will allow the manufacturer to assess whether their sterilizer is capable of processing the load during factory acceptance testing and prior to purchase.

3.29 In cases of doubt, advice should be sought from the AE(D).

## Sound power test

3.30 EN 285:2015 requires decontamination equipment manufacturers to carry out a sound power test as a type test if equipment produces noise (except alarms) at a level which could cause a hazard.

3.31 BS EN ISO 3746:2010 should be used for testing and calculation methods.

3.32 Noise emission tests shall be performed in normal use conditions with an empty sterilizer chamber. If the emission sound pressure level is required, it shall apply for the operator's position in front of the sterilizer at a distance of 1 m and a height of 1.6 m.

3.33 A failure of the sound pressure test need not be an indication that the machine is faulty. The problem may lie in the acoustic properties of the room in which the machine is installed.

### Results

3.34 The test should be considered satisfactory if the mean A-weighted sound pressure level does not exceed 70 dB (A).

**Note:** It is neither necessary nor practicable to repeat the sound pressure test on an installed machine.

## Thermometric tests for PQ

### Thermometric test for a full load (large volumes >100 ml / container) (PQ test)

3.35 Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.36 Fill nine one-litre bottles (or larger if it is the department standard processing load) with the test liquid. Insert a temperature sensor into each one, ensuring that the tops are sealed or unsealed as required. Unsealed bottles should be capped loosely to prevent coolant water entering the bottle.

3.37 If unsealed bottles are used, weigh each of them and note their masses ($M_1$) to an accuracy of 1 g.

3.38 Place three of the bottles in positions known to be the slowest to attain the sterilization temperature, three in positions known to be the fastest to attain the

sterilization temperature, and three in positions known to be the slowest to cool to 80 °C.

3.39 Load the remaining chamber space with one-litre bottles, filled either with water or a water-based medium, at the minimum spacing recommended by the manufacturer. Full load as specified by the laboratory.

3.40 Place a further temperature sensor in an active chamber discharge.

3.41 Connect a pressure sensor to the chamber.

3.42 Select the operating cycle:

- if a variable culture media cycle is being tested, set the sterilization temperature to 121 °C with a minimum holding time of 15 min;
- if a free steaming cycle is being tested, set the load temperature to 95-98 °C for a minimum of 15 min.

3.43 Start the cycle.

3.44 Measure the chamber pressure at the approximate mid-point of the holding time.

3.45 As soon as the cycle is complete, and before opening the door, observe and note the measured temperatures in the bottles.

3.46 Within 5 min of the end of the cycle, weigh any unsealed test bottles again and note their masses ($M_2$). For each bottle, calculate the percentage loss in mass from:

$$\text{percentage loss in mass} = 100 \times \frac{M_1 - M_2}{M_1}$$

3.47 The test should be considered satisfactory if the requirements listed in Table 1 are met and the loss of fluid in any unsealed bottles does not exceed 2 % by mass.

### Thermometric test for a small load (volumes <100ml / container) (PQ test)

3.48 Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.49 Fill nine 5-ml bijou bottles with 4 ml of test liquid. Insert a temperature sensor into each one, ensuring that the tops are sealed.

3.50 Distribute them among two wire baskets, one supported in the upper rear of the usable chamber space and the other in the lower front. Each should contain a total of 25 bijou bottles, so that three test bottles are in positions known to be the slowest to attain the sterilization temperature, three in positions known to be the fastest to attain the sterilization temperature, and three in positions known to be the slowest to cool to 80 °C.

3.51 If the sterilizer is not designed to process bottles of this size, the smallest size and number of containers recommended by the sterilizer manufacturer should be used.

3.52 Where the sterilizer is to be used to process one size of container only, the test load may be a single container of this size, filled with the nominal volume of test liquid and supported in a position known to be the slowest to attain the sterilization temperature.

3.53 Place a further temperature sensor in an active chamber discharge.

3.54 Connect a pressure sensor to the chamber.

3.55 Follow the procedure for the full-load test.

3.56 The test should be considered satisfactory if, except for the cycle time condition, the requirements listed in Table 1 are met.

## Automatic control test

### Introduction

3.57 The automatic control test is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the decontamination equipment.

3.58 It should be carried out once a week and is one of the tests for ensuring that the sterilizer continues to function correctly.

3.59 During the validation, yearly and quarterly test programmes the temperature and pressure sensors for subsequent thermometric tests should be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments, the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.

### Apparatus

3.60 For porous-load cycles place a test pack in the chamber, with the bottom of the pack supported 100–200 mm above the centre of the chamber base.

### Method

3.61 Select the operating cycle to be tested. This should normally be the highest temperature compatible with the load. Start the cycle.

3.62 Ensure that a Batch Processing Record (BPR) is made by the recording instrument fitted to the machine.

### Results

3.63 The test should be considered satisfactory if the following requirements are met:

- a visual display indicating “cycle complete” occurs;
- the values of the cycle variables, as indicated by the instruments on the machine and shown on the BPR, are within the limits established as giving satisfactory results either by the manufacturer or during PQ, during the whole of the operational cycle;
- during the plateau period determined from the recorded chamber temperature:
  - the indicated and recorded chamber temperatures are within the appropriate sterilization temperature band specified in Table 1;
  - the difference between the indicated, recorded and any other independent monitor chamber temperature does not exceed 2 ºC;
  - the difference between the indicated, recorded and any other independent monitor chamber pressure does not exceed 0.1 bar.
- during the holding time, any temperatures recorded in the load are within the appropriate sterilization temperature band specified in Table 1;
- the door cannot be opened until the cycle is complete;
- the person conducting the test does not observe any mechanical or other anomaly.

3.64 The sterilization conditions are specified by a sterilization temperature band, defined by a minimum acceptable temperature (sterilization temperature) and a maximum allowable temperature. These are listed in Table 1.

## Make-safe of plastic discard

3.65 Tests for make-safe plastic discard cycles material where no one item contains more than 50 ml of aqueous fluid.

3.66 Where required and by agreement with the laboratory safety officer, the User authorises the use of the sterilizer with the thermal door-lock override selected, tests should be conducted both with and without the override selected.

3.67 During testing containers should be held in the discard boxes recommended by the manufacturer. Discard boxes holding containers into which temperature sensors are to be inserted should not contain infected material.

**Note:** Material infected with Hazard Group 2 organisms may be used to make up other boxes in the test load. At no time should any material known to contain Hazard Group 3 or 4 organisms be used.

Information about Hazard Groups may be found in the HSE document ‘The Approved List of biological agents’ compiled by the Advisory Committee on Dangerous Pathogens 2013. Information on Containment levels can be found in HSE Document ‘Control of Substances Hazardous to Health Regulations’ 2002.

# Thermometric test methods

## Thermometric test for a full load

3.68 Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.69 Prepare sufficient Petri dishes to fill two discard boxes when the dishes are stacked vertically. Each dish should contain approximately 15 ml of agar gel.

3.70 Place one temperature sensor in the centre of each of six of the dishes. Put three of these test dishes in each box: one in the centre of the box, one-third from the bottom and one one-third from the top, supported by the remaining dishes. If only one box will fit in the chamber, put all six test dishes in the box, two at each position.

3.71 Put the two test boxes in opposite corners of the chamber. Load the remaining chamber space with boxes filled with discard material such that the spacing between boxes is in accordance with the minimum recommended by the manufacturer.

3.72 Place a further five temperature sensors in the following positions:

- one in an active chamber discharge;
- one in the chamber, alongside the sensing element of the load temperature probe, if it is fitted the load probe should be placed inserted down the corner of one discard box;
- one in the centre of the free space between the bottom of each test box and its trivet (if fitted). If the box does not have a trivet, the sensor should be placed in the free space between Petri dishes 15 mm above the centre of the bottom of the box;
- one in the chamber free space.

3.73 Connect a pressure sensor to the chamber.

3.74 Select and start the operating cycle.

3.75 The test should be considered satisfactory if the requirements listed in Table 1 are met, and the drain is not blocked with agar.

3.76 This test is not required if the sterilizer is designed to accommodate only one discard box. Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.77 Load the chamber with a single discard box filled with Petri dishes as described in the full-load test, with three temperature sensors located in the following positions:

- one in an active chamber discharge;
- one in the centre of a dish located one-third from the bottom of the box;
- one in the centre of a dish located in the approximate centre of the box.

3.78 Follow the procedure for the full-load test.

3.79 The test should be considered satisfactory if all but the cycle time conditions of the requirements for the full-load test are met.

## Thermometric testing: additional information

### Cycles for fluid loads

3.80 These tests apply to laboratory sterilizers with cycles designed to process fluid discard in glass containers and large plastic containers (>50 ml), culture media (pre-set or variable cycles) and for free steaming.

3.81 Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.82 Bottles into which temperature sensors are inserted should contain either the product the laboratory is processing or filled with water to the same volume as the load items the lab is processing.

3.83 All bottles should be filled to 80 % of their nominal capacity. The volumes of the fluid in each bottle should not vary from their mean by more than 5 %. At the start of the cycle the temperature of the fluid in each bottle should be 20 ±5 °C and the media preparation in the liquid form.

3.84 The bottles may be either all sealed or all unsealed, according to the practice in the laboratory. Sealed and unsealed bottles should not be mixed in the same load.

### Revalidation Thermometric test for fluid loads

3.85 This test is not a substitute for a full PRQ test, but is used quarterly to check that the sterilization conditions continue to be met. Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.86 Prepare a production load known to present the greatest challenge to the operating cycle and for which there is a PQ report. (This will normally be the reference load used in the yearly PRQ tests). Place temperature sensors in the following positions:

- one in an active chamber discharge;
- one in a container known to be the slowest to attain the sterilization temperature;
- one in a container known to be slowest to cool to 80 °C.

3.87 Place the load in the chamber as described in the PQ report

3.88 Select the operating cycle as specified in the PQ report. Start the cycle.

3.89 The test should be considered satisfactory if the requirements listed in the PQ report are met.

## Sterilization of glassware and equipment

3.90 These tests for laboratory sterilizers with a cycle designed to sterilize empty glassware without caps and other non-porous equipment.

**Note:** If caps are fitted, air will not be removed, and the glassware should be classed as disinfected but not sterilized.

### Thermometric test for a full load

3.91 Temperatures and pressures should be recorded by independent measuring equipment as described in SHTM 01-02:2020 Part B.

3.92 Prepare a full load of empty clean glassware / equipment as routinely used by the laboratory. Distribute temperature sensors evenly throughout the load.

3.93 Place the load on the load carrier in the position usually used by the laboratory.

3.94 Place three further temperature sensors in the following positions:

- one in an active chamber discharge;
- one in the chamber located alongside the load temperature probe (if fitted);
- one in the upper chamber free space.

3.95 Connect a test pressure sensor to the chamber.

3.96 Select and start the operating cycle.

3.97 Measure the chamber pressure at the approximate mid-point of the holding time.

3.98 The test should be considered satisfactory if the temperature requirements listed in Table 1 are met, and the load is visibly dry.

### Thermal door-lock override test

3.99 A thermal door-lock is fitted to certain laboratory sterilizers to prevent the door from being opened until the temperature in the chamber and load falls below 80 °C. The override is intended for use by trained persons who wish to gain access at temperatures above 80 °C to loads which will not present an explosive hazard.

3.100 For this test the sterilizer chamber should be empty.

3.101 Select and start the operating cycle to be tested.

3.102 Attempt to select the thermal door-lock override during the heat-up, sterilization (holding time) and cooling stages.

3.103 The test should be considered satisfactory if the following requirements are met:

a. the override operates only during the cooling stage of the cycle and causes the cooling stage to terminate;

b. the override switch resets automatically when released;

c. the thermal door-lock override indicator is illuminated;

d. at the end of the cycle the door cannot be opened except by means of a key, code or tool which is unique to the sterilizer.

3.104 Where the sterilizer is intended to be used exclusively for make-safe of discard in small containers, compliance with (b) and (d) may be waived by agreement with the laboratory safety officer. In this case, the switch should reset automatically whenever a different operating cycle is selected or whenever the power supply is interrupted.

## Culture media preparator

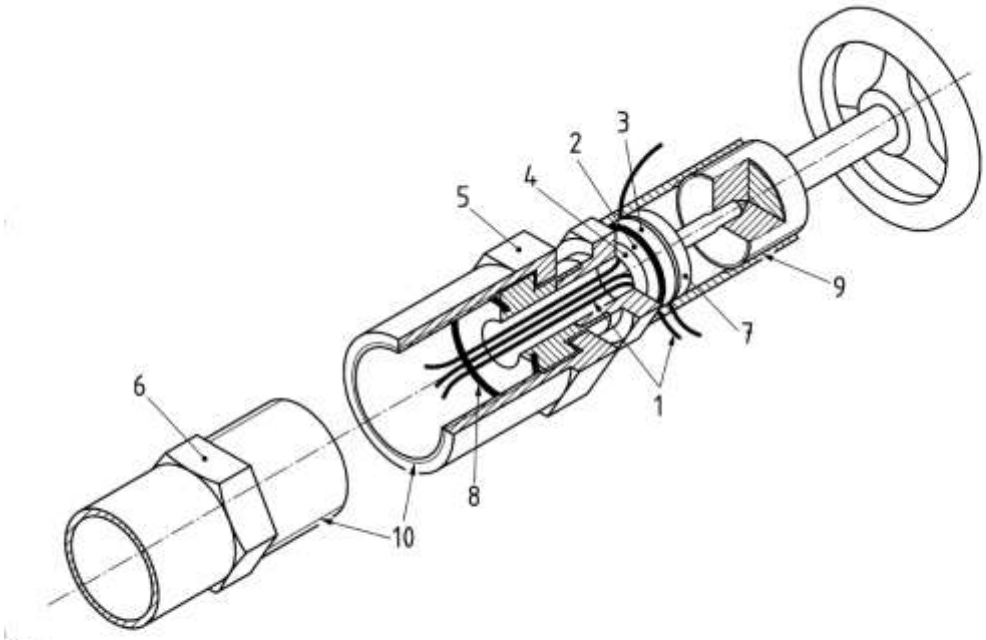
3.105 For these tests, the sterilizer vessel should be filled with water to the nominal capacity specified by the manufacturer.

## Schedule of periodic tests for laboratory sterilizers

3.106 Periodic tests should be carried out at daily, weekly, quarterly and yearly intervals, see Table 3. They are the shared responsibility of the CP(D) and the User. The tests should be carried out with the equipment at normal working temperature, which may require a warm-up run prior to testing.

| |
|---|
| **Daily test – Users** |
| **Weekly tests – Test person / Users** |
| **Quarterly tests – Test person** |
| **Yearly and revalidation tests – Test person** |
| During the holding time of the first production cycle of the day, observe and note the reading on the cycle counter, chamber temperature indicator and chamber pressure indicator, where a printout or paperless monitoring system is fitted this should be checked with the results recorded in the log book. |
| 1. Weekly safety checks<br>2. Vacuum leak test<br>3. Automatic control test*<br><br>*Rotated through all cycles used. |
| 1. Weekly safety checks<br>2. Vacuum leak test<br>3. Vacuum leak test (temperature and pressure sensors connected)<br>4. Automatic control test for each operating cycle<br>5. Verification of calibration of sterilizer instruments<br>6. Thermometric test for a discard cycle*<br>7. Thermometric test for a non-discard cycle**<br>8. Vacuum leak test (sensors removed)<br>9. Thermal door-lock override test<br><br>* to be rotated between fluids / plastics / vacutainers<br>** to be rotated between Porous Load / Glassware / Culture Media |
| 1. Yearly safety checks<br>2. Vacuum leak test<br>3. Vacuum leak test (temperature and pressure sensors connected)<br>4. Automatic control test for each cycle<br>5. Verification of calibration of sterilizer instruments<br>6. Thermometric tests for Plastic Discard<br>7. Thermometric cycle for Vacutainer Discard<br>8. Thermometric test for Fluid Discard<br>9. Thermometric test for Culture Media<br>10. Thermometric test for Porous Loads<br>11. Thermometric test for Glassware and Equipment<br>12. Thermometric test for free steaming<br>13. Tests for performance re-qualification as required by the User<br>14. Vacuum leak test (sensors removed)<br>15. Thermal door-lock override test<br><br>Performance Qualification tests will consist of a minimum of 2 cycles being run of either a full load or production load for each load type as per commissioning.<br>For thermometric tests full production loads should be used if available, if not available reference loads as described in Thermometric Tests for PQ section above should be used. |

**Table 3: Schedule of periodic tests for laboratory sterilizers**




**Key**

| | | | |
|---|---|---|---|
| 1 | temperature probes wire | 6 | adaptor |
| 2 | silicon rubber washer | 7 | metal thrust spigot |
| 3, 4 | metal thrust washer | 8 | O-ring |
| 5 | metal body | 9 | castellated to permit entry of leads |
| | | 10 | pipe thread ISO 228-G1 A |

**Figure 2: Typical sensor entry gland**

### Thermometric test for small load

3.107 This test is used to demonstrate that after the air removal stage of the operating cycle, sterilizing conditions are obtained within the chamber and standard test pack. The more air there is to remove, the more exacting will be the test; that is why the pack is used by itself in an otherwise empty chamber (that is, excluding a carriage etc.). The test pack should be supported 100–200 mm above the chamber base on a carrier with minimal thermal mass, i.e. DIN basket or small metal tray placed across the chamber rails.

3.108 This test should be carried out in accordance with EN 285:2015 clause 16.1. Figures 3 and 4 illustrate the position of the standard test pack in a porous load sterilizer with sensors fitted. The test pack position as shown can be utilized for the air detector function test and an automatic control test (ACT).

**Figure 3: A standard test pack positioned in the chamber on a basket or small tray**

**Figure 4: Three sensors in a standard test pack positioned 20 mm below centre, and equally spaced within a diameter of 45 mm**

**Notes** on the thermometric test procedures:

The thermometric test shall be conducted using the standard test pack as described in EN 285:2015.

The pack sheets shall be dried and allowed to normalize in a natural environment between 20 ºC and 30 ºC and humidity of 40 % to 60 %.

Prior to use the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C to 30 °C and 40 % to 60 % relative humidity before it is used for test purposes; pack temperature and humidity can be measured using a sword hygrometer.

The test pack shall be made up of plain cotton sheets, bleached and washed to remove soil and resin and approximately 900 mm x 1200 mm in size.

The sheets should be folded to approximately 220 mm x 300 mm and stacked to a height of 250 mm when compressed by hand. The sheets should be folded into 16 layers (folded 4 times). The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. This will usually utilize 30 sheets depending on their age and use.

The pack should weigh 7.0 kg ±0.14 kg.

When the weight of the sheets to form a stack of 250 mm exceeds 7.2 kg, then a new test pack should be used and the old ones discarded.

Test packs comprising different materials, sizes and weights can be used provided equivalence with the requirements for the test is met.

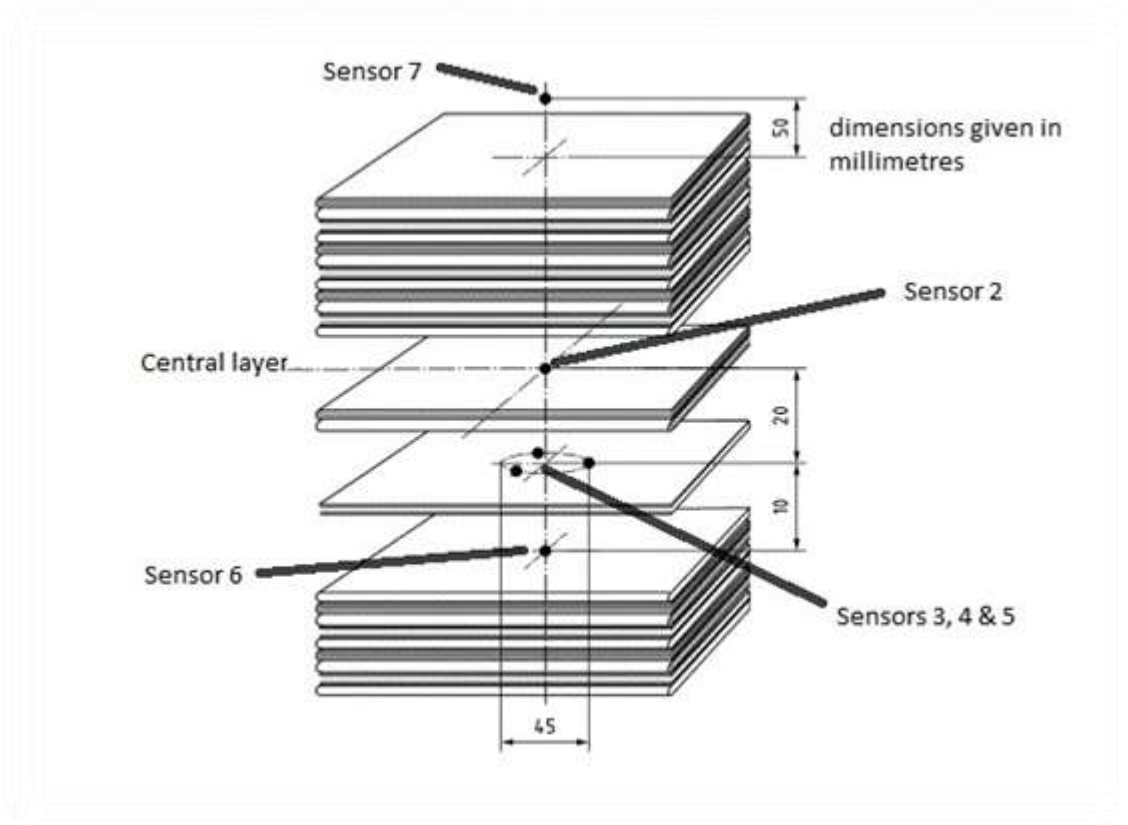



**Figure 5: Sensor positions in a standard test pack**

**Notes** on sensor positions:

Figure 3, 4 and 5 illustrate the position of the sensors within the standard test pack.

Sensor 1: Chamber drain / reference measurement point *

Sensor 2: Centre of test pack

Sensor 3, 4, 5: 20 mm below centre at 45 mm diameter spacing

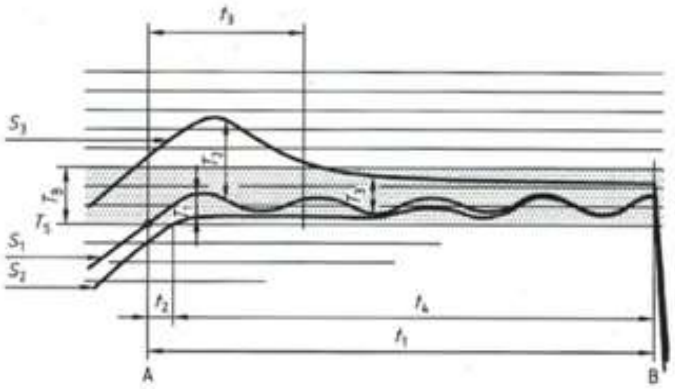
Sensor 6: 30 mm below centre of pack

Sensor 7: 50 mm above the test pack

**N.B.** Sensor 1 is not shown in Figure 5 as placed at drain.

## Thermometric testing: additional information

3.109 Figure 6 shows in schematic form the kind of data that is typically obtained in a thermometric test using measuring equipment as described in Section 2 'Decontamination Test Equipment' of SHTM 01-02:2020 Part B. In practice there may be more temperature traces depending on the number of sensors used. The detailed behaviour before and after the plateau period is dependent on the nature of the operating cycle and is not shown here.




**Key**

| | | | |
|---|---|---|---|
| *A* | start of plateau period | $S_1$ | trace of sensor 1 at the measurement reference point |
| *B* | end of plateau period | $S_2$ | trace of sensor 2 at the centre of the test pack |
| $T_s$ | sterilization temperature | $S_3$ | trace of sensor 7 located 50 mm above the test pack |
| $T_0$ | sterilization temperature band | $T_1$ | maximum difference between reference temperature and temperature in the test pack during holding time |
| $t_1$ | plateau period | $T_2$ | maximum difference between reference temperature and temperature above test pack within the first 60 s of plateau period |
| $t_2$ | equilibration time | $T_3$ | maximum difference between reference temperature and temperature above the test pack during the plateau period after the first 60 s |
| $t_3$ | 60 s | | |
| $t_4$ | holding time | | |

**Figure 6: Temperature and time tolerances during the small load thermometric test**

3.110 The equilibration time begins when the temperature in the reference point (that is, the point where the cycle control temperature sensor is situated) first attains the sterilization temperature. It ends when the holding time begins.

3.111 The holding time begins when the temperature in the part of the load that is the slowest to heat up first attains the sterilization temperature. It ends at the start of the drying stage, when the temperature in the coolest part of the chamber falls below the sterilization temperature.

3.112 The fluctuation in a trace over a given interval is ±T ºC if the difference between the maximum and minimum values is 2T °C.

3.113 The drift in a trace over a given interval is the change in the mean value of the trace over that interval.

3.114 The difference between two traces is the difference in their values at a given instant. A trace is said to be within T ºC of a given value or another trace if the difference between them at any instant over a given interval is no more than T.

## Results

3.115 The test should be considered satisfactory if the following requirements are met:

- the requirements of the automatic control test are met;
- during the plateau period the temperature measured above the test pack shall not exceed the temperature measured at the reference measurement point of the

sterilizer chamber by more than 5 °C for the first 60 s and 2 °C for the remaining period (see also Figure 6);

- the equilibration time shall not exceed 15 s for sterilizer chambers up to 800 litre usable space and 30 s for larger sterilizer chambers;
- throughout the holding time:
  - the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack, load and chamber, and the saturated steam temperature calculated from the time-averaged measured chamber pressure (see Appendix A) should be within the appropriate sterilization temperature band specified in Table 1, do not fluctuate by more than ±1 °C, and do not differ from one another by more than 2 ºC;
  - the indicated and recorded chamber temperatures are within 1 ºC of the temperature measured at the reference measurement point;
  - the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure.
- for sterilizers using vacuum as the sole method of drying;
  - the duration of the drying stage is not less than 3 minutes;
  - the chamber pressure at the end of the stage does not exceed 40 mbar absolute;
  - at the end of the cycle the sheets are sensibly dry.

## Weekly safety checks

3.116 The CP(D) should make the following safety checks before starting the sequence of weekly tests:

- examine the door seal;
- check the security and performance of door safety devices;
- check that safety valves or other pressure limiting devices are free to operate;
- make any other checks required by the competent person in connection with the written scheme of examination for the pressure vessel.

## Yearly safety checks

3.117 In order to ensure the safe functioning of the sterilizer, the CP(D) should conduct a sequence of safety checks before starting the yearly tests. The installation checks should be used as a basis for these but it will not be necessary to repeat them all. In selecting which checks to include in the yearly schedule consideration should be given to conditions that affect safety and to those that may have changed over the course of time. It will not be necessary, for example, to check again that the sterilizer has been supplied in accordance with the specification but it will be necessary to check that the engineering services remain adequate and are connected safely. The AP(D) should advise on which checks will need to be included with consultation, if necessary, with the AE(D).

**Notes** on safety checks:

When carrying out safety checks, it is important to ensure that a good housekeeping regime is in place on each individual sterilizer. This will include daily visual checks of instrumentation, doors, loading equipment, chamber rails, baffle plates and instrumentation. Any faults or concerns must be recorded in the log book, and reported / corrected immediately.

The yearly safety checks should include the following service failures as a minimum:

Steam supply;

Water supply;

Electrical power;

Emergency stop activation;

Air supply;

Air compressor(s);

Communication leads / network connection;

Door safety interlock for fluid cycles;

Door safety interlock override system;

All gauges fitted to the sterilizer, both on the front panel and in the plant room should be checked for correct functioning.

Check all pipework connections for leaks and damage and report any faults.

The weekly and quarterly test regimes can test any of the above on rotation to ensure that all the systems and failures set points are functioning correctly.

It is important to keep the sterilizer plant room clean and tidy with good task lighting and remove any debris and unwanted stored items.

# 4. Steam supply

4.1 There should be a continuous supply of saturated steam for steam sterilization.

4.2 There is a need to specify, for all processes, the quality of steam entering the sterilizer chamber and coming into contact with the load. This section defines a suitable specification for the steam supply.

4.3 The critical variables are the dryness of the steam (expressed as a dryness value), superheat and the level of non-condensable gases (expressed as a fraction by volume). Before a newly installed or replaced sterilizer is handed over to the User, the steam supply should be examined and tested.

4.4 Users should note that where the steam is supplied from the mains, quality can vary greatly during the course of a working day. In many hospitals, steam demand is greatest early in the morning when CDU, kitchens and laundries can start work at the same time. Care should be taken to sample the steam at times throughout a typical working day to gauge the likely range of steam quality. The trend towards 24-hour production may require different sampling patterns.

4.5 European Standard EN 285:2015: gives guidance on the chemical quality of steam.

## Operation and maintenance of steam generators

4.6 Users should ensure that operation and maintenance of the steam generator is carried out correctly, both to ensure safety and also to maintain the quality of the steam.

4.7 Steam generators are steam boilers and are subject to the ‘Pressure Systems Safety Regulations’ 2000 (as amended) and are subject to a written scheme of examination for pressure vessels.

4.8 Guidance on the design, maintenance, testing and operation of steam generators can be found in the Health and Safety Executive’s INDG436 – ‘Safe management of industrial steam and hot water boilers’.

4.9 The advice of the boiler manufacturer about water supply, water treatment, blowing down and other operational practices should be strictly observed.

**Note:** Failure to ensure adequate control of water quality and insufficient ‘blow-down’, can result in severe corrosion of steam generators leading to the collapse of internal components and potentially putting operators at risk.

### Steam quality – responsibilities

4.10 The AE(D) should be able to advise the User on all aspects of the production and use of steam for sterilization.

4.11 The User should, with advice:

- appreciate the nature of contaminants in steam supply (especially pyrogens), their possible adverse effects and their sources;
- be familiar with the current and impending standards on steam sterilization and their implications for steam quality;
- understand the difference between process steam, steam as defined in EN 285:2015: and the EN ISO 17665 series, and the appropriate applications of each;
- understand the rationale for the steam specification;
- understand the engineering principles required for the delivery of steam and how they might be realized for mains steam, dedicated steam generators and sterilizers with internal reservoirs;
- decide whether steam is required for any sterilizer unit and if so, what is the best means of achieving it;
- appoint a suitable laboratory and liaise with them regarding the analysis of steam condensate and feed water samples;
- arrange for the steam supply to be formally validated;
- on completion of the validation tests, confirm that the sterilizer is fit for use with the steam supply on the advice from the CP(D) and AE(D);
- arrange for periodic maintenance of any steam generating and distribution plant from the estates department or the plant directly under the User's control;
- arrange for periodic tests of the steam quality at intervals coinciding with periodic tests on the sterilizer with advice from the AP(D) and AE(D).

4.12 The CP(D) should: understand and be trained in the operation of the apparatus for taking samples of steam condensate for field analysis (see paragraph 4.143 'Sampling of water and steam – for field and laboratory analysis');

- be aware of the correct procedures for collecting, preserving and handling samples;
- be trained in the measurement of electrical conductivity of water samples using a portable meter;
- be trained and aware of the guidance in paragraphs 4.6 & 4.263 'Operation and maintenance of steam generators' if maintaining steam generators.

4.13 The Microbiologist should be able to advise on all microbiological aspects of steam in conjunction with the AE(D).

### How steam is made

4.14 Steam is generated initially by boiling water then maintaining a continued heat input to convert water into a gas. Boiling occurs at a temperature where evaporated water vapour has sufficient pressure to displace the water immediately below the surface to form bubbles of steam (at lower temperatures evaporation occurs only from the surface). The bursting of bubbles from the surface of the boiling water is accompanied by the ejection of small droplets of water. These droplets contain the same dissolved and suspended solids that are present in the water in the boiler. They are readily entrained in the flow of steam and can carry contaminants to the sterilizer. Even if the water droplets subsequently evaporate, the contaminants will still be present in the form of solid particles.

4.15 Therefore a crucial aspect of boiler design is to ensure the best possible separation and removal of such entrained moisture.

4.16 Priming is a related phenomenon where significant quantities of the boiler water can sporadically be carried over into the steam. This is often as a result of a sudden increase in the demand for steam, which reduces the pressure above the water and effectively lowers the boiling point, so increasing the violence of bubbling. Having a level of water in the boiler that is too high can also lead to priming. Priming should be reduced by standard good operating practice, such as running the boiler at or near its maximum permissible pressure, using pressure sustaining valves where demand causes a reduction in pressure in the distribution system and not in the boiler.

## Summary of requirements for steam

4.17 From the above considerations, the requirements for generating steam can be summarized as follows:

- the feed water should be as free as possible of contaminants, especially those specified for feedwater, see Table 5;
- the boiler should be designed to prevent water droplets being carried over into the steam;
- the boiler should be operated to prevent foaming and priming;
- the boiler and distribution system carrying steam from the boiler to the sterilizer should be resistant to corrosion;
- to minimise water carry over, the steam distribution system should be adequately serviced with appropriately designed steam traps;
- there should be a regime in place to routinely test the quality of the steam at the point of use;
- a risk assessment should determine corrective action in response to particulate test results that exceed specific levels;
- any changes to the method of steam generation, feed water chemical dosing and treatment regimes, and design of distribution system need to be clearly documented and monitored;

- a planned preventative maintenance regime should be in place to ensure the distribution system and components are functioning correctly.

The requirements in Table 4 should be met when measuring the quality of steam. The AE(D) can advise on the number of tests required and the actual test point depending on the steam distribution system, header design and numbers of sterilizers in the unit.

| | |
|---|---|
| Physical qualities | |
| Particulate qualities | |
| Silicate | ≤0.1 mg/L (corrosion) |
| Heavy metals | ≤0.1 mg/L (corrosion and load) |
| Cadmium | ≤0.005 mg/L (corrosion) |
| Lead | ≤0.05 mg/L (corrosion) |
| Chloride | ≤0.1 mg/L (corrosion), ≤0.5 mg/L (load) |
| Phosphate | ≤0.1 mg/L (corrosion and load) |
| Conductivity (at 25 °C) | ≤3 µS/cm (corrosion), ≤35 µS/cm (load) |
| pH | 5-7 (corrosion) |
| Hardness | ≤0.02 mmol/L (corrosion) |
| Appearance | Clear, colourless, no sediment (corrosion), clear and colourless (load) |
| Endotoxins | ≤0.25 EU/mL (load) |
| Ammonium | ≤0.2 mg/L (load) |
| Nitrate | ≤0.2 mg/L (load) |
| Sulphate | Ra (load) |
| Oxisable Sub | Ra (load) |
| Evap Residue | ≤30 mg/L (load) |
| Calcium & magnesium | Ra (load) |
| NOTE: This table is a combination of tables A1 (re: corrosion) and A2 (re: load) in CEN ISO/TS 17665 Part 2 2009. Compliance with this Table addresses the issues of equipment corrosion and load contamination. | |
| NOTE: Ra signifies methods and reagents specified in the European Pharmacopoeia | |

**Table 4: Suggested maximum values of contaminants in condensate collected according to the method described in EN 285:2015**

## Steam in practice

4.18 This section discusses the principles by which steam conforming to the steam specifications in Table 4 might be generated. It offers practical guidance on how to achieve steam standards for sterilizers supplied by mains steam systems, dedicated and integral clean steam generators.

4.19 A full costing analysis should be conducted when the relative merits of different steam supplies are being assessed. The cost of the testing required to demonstrate that a mains steam system can consistently produce steam might amount to a not insignificant fraction of the capital cost of a dedicated steam generator.

### Requirements for generating steam

4.20 A boiler system designed and operated to provide minimal carry-over of entrained water droplets will be able to maintain a low level of contaminants in the steam even where the quality of feedwater is poor.

4.21 Feedwater treatment might not be the decisive factor in the ability of a system to deliver steam. However, if the feed water is of low quality, even small deviations from optimum operating conditions might result in large amounts of contaminants being carried over and delivered to the sterilizer. The designer of a robust steam supply should ensure that all the above requirements are met.

| Determinant | Feed water |
|---|---|
| Residue on evaporation | ≤10 mg/l |
| Silicate | ≤1 mg/l |
| Iron | ≤0.2 mg/l |
| Cadmium[a] | ≤0.005 mg/l |
| Lead[a] | ≤0.05 mg/l |
| Rest of heavy metals except iron, cadmium, lead | ≤0.1 mg/l |
| Chloride[b] | ≤0.5 mg/l |
| Phosphate | ≤0.5 mg/l |
| Conductivity (at 20 °C) | ≤5 µS/cm |
| pH (20 °C) value | 5 – 7.5 |
| Appearance | Colourless clean without sediment |
| Hardness (Σ ions of alkaline earth) | ≤0.02 mmol/l |
| **NOTE:** Compliance can be tested in accordance with acknowledged analytical methods. | |
| [a] The limiting values meet the requirements for potable water. | |
| [b] Maximal chloride concentration in feed water influences corrosion in combination with high temperatures. | |
| [c] See European Pharmacopeia. | |
| **NOTE:** This table is identical to that published in EN285:2015 Annex B | |

**Table 5: Suggested maximum values of contaminants in feedwater**

## Engineering considerations

4.22 Steam is generally obtained from the hospital mains or dedicated steam generators; the requirements for steam quality at point of use are the same in either case.

4.23 In each case the delivery of high-quality steam depends on careful engineering.

### Capacity

4.24 The steam service should be designed to meet the maximum steam demand of the sterilizer(s) for short periods, while keeping the fall in pressure before the final pressure-reducing system to not more than 10 %. A single porous-load sterilizer of up to 600 L should use a boiler of at least 50 kW and storage to meet a peak demand of 125 kW for 15 min. The effect on the steam supply of the demands of other sterilizers and equipment connected to the distribution system should be carefully considered. In addition to traditional shell boilers, other options are available such as steam generators and steam / steam generators. Care should be taken when the option of generators is taken over shell boilers as water carry over can be a problem.

### Pipework

4.25 Except for vertical rises between floors, steam pipework should be designed so that any condensate flows by gravity in the same direction as the steam. This general principle applies equally to steam mains, branch connections and pipework on the sterilizer itself. Air vents and steam traps should be fitted at each vertical rise. Care should be taken to trap, drain and return any condensate which may be collected in pockets in the pipework. Dead-legs should be avoided.

4.26 The accumulation of condensate in the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate and correctly sized traps throughout the steam distribution system.

4.27 Figure 7 shows a suggested layout for the steam service in the Plant Room. The supply main should terminate in an adequately vented and trapped manifold not less than 150 mm nominal bore that is of adequate length for any future expansion. A vent with a cooling pot should be installed on the manifold upstream of the supply pipes to individual sterilizers. A pressure gauge should be fitted to the manifold. It is good practice to fit a pressure reducing valve (PRV) (and pressure gauges fitted either side to indicate the pressure drop), in the supply line to each sterilizer. The pressure reduction should not exceed 2:1 ratio at each stage of reduction.

4.28 The steam pressure to the manifold should be set within the acceptable range of supply pressure to the sterilizer as specified by the manufacturer. The line velocities should be kept below 25 metres/sec, to allow steam traps to remove entrained moisture effectively and to prevent condensate being drawn out of the condense lines and pockets.

4.29 If the sterilizer manufacturer has not already fitted them, an appropriate and correctly installed separator and steam trap should be fitted upstream of the sterilizer reducing valve. Advice should be sought from the AE(D) and CP(PS).

4.30 Three suitable test connections should be provided on the supply pipe to each sterilizer to permit the attachment of a needle valve, a pitot tube and a temperature sensor as shown in Figure 7. Safe access should be provided for the CP(D) to carry out steam quality tests including the provision of convenient cooling water and electrical supplies for test purposes.

4.31 Careful attention should be paid to the location of all pressure relief valves to ensure that the sterilizer is properly protected. Relief valves and their discharge pipes should be large enough to prevent the pressure in the supply pipe from the manifold rising to more than 10 % above the design pressure for the manifold.

4.32 The discharge pipe should terminate outside the building in a safe, visible position not affected by frost. Any rising discharge pipe should be fitted with a drain at the lowest point to prevent the accumulation of condensate. A tell-tale pipe of narrow bore should be connected to the drain point and should terminate inside the Plant Room for clear indication of condensate and pressure/valve problems.

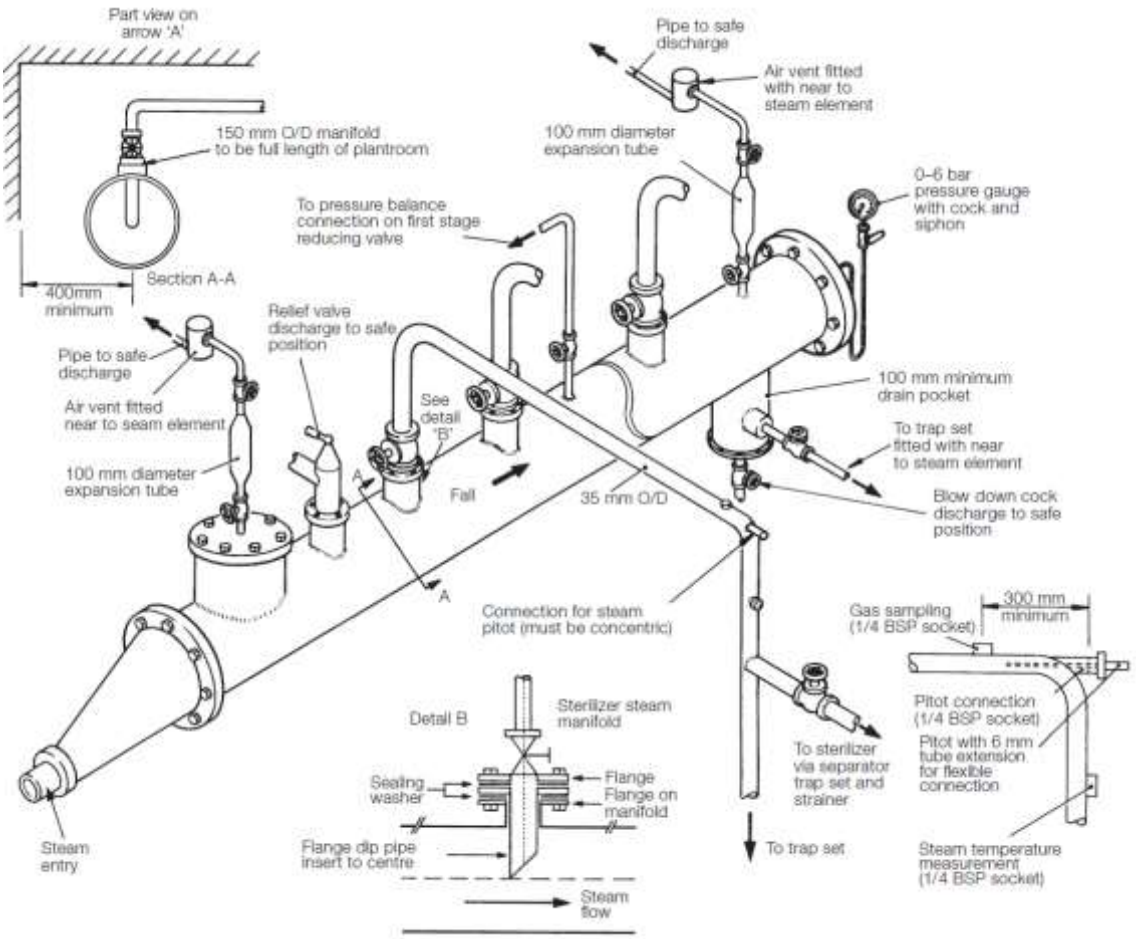



**Figure 7: Layout of Plant Room steam service (steam header)**

## Materials

4.33 To meet the purity standard for sterilizers, parts in contact with steam entering the chamber should be constructed from low-carbon or stabilized stainless steel. Check each manufacturer's specifications at the procurement stage.

## Dryness

4.34 Saturated steam is required for sterilization so that sufficient energy is transferred to the load upon condensation in order to achieve the required lethality. The dryness of the steam is therefore of vital importance; too little moisture carried in suspension may allow the steam to become superheated during expansion into the chamber and thus impair sterilization, while excess moisture may deliver insufficient energy to the surface of the load to be sterilized and additionally may cause damp or wet loads and uneven temperature distribution.

4.35 Steam dryness is traditionally characterised by a 'dryness fraction', but this is not appropriate for sterilizers because the method of measurement is difficult and requires a constant flow of steam. The low-volume sampling technique described in the steam dryness test (see paragraph 4.245 'Steam dryness test') cannot be regarded as measuring a true dryness fraction because the sample is taken from the centre of the steam supply pipe and condensate flowing along the pipe wall is not collected. Consequently, the term 'dryness value' is used, where 1.0 represents dry, saturated steam. The method is used to determine whether performance problems

could occur during testing and routine production. It is suitable for sterilizer installations because control valves and pipe services fitted to the sterilizer considerably reduce the amount of condensate entering the sterilizer chamber such that the sample has a similar amount of free condensate to the steam in the chamber.

4.36 European Standards require that sterilizers be designed to operate with steam having a dryness value of not less than 0.9 when measured in accordance with the steam dryness test described in paragraph 4.245 'Steam dryness test'. For metal loads, the dryness value should not be less than 0.95. In practice, problems are unlikely to occur if the pressure reduction through the final pressure reducing system is of the order of two to one.

4.37 Deviations from this specification are likely to cause the following problems:

- wet loads, resulting from too low a dryness value;
- superheating, resulting from either too high a dryness value before the pressure-reducing stage, or excessive pressure reduction through a valve or other restriction in the pipework (superheating may be severe if both conditions are present simultaneously);
- difficulties with operation of the pressure reducing system, resulting from a low pressure reduction ratio, water hammer, water logging, dirt and water carry-over.

### Excessive moisture

4.38 Possible causes of excessive moisture, where droplets of water are present in the steam and at the same temperature as that of the steam, are:

- steam pipes or manifolds might be incorrectly sloped and drained; insufficient trapping;
- incorrect traps fitted to the system, or malfunctioning traps;
- the sterilizer might be supplied from an inadequately drained and vented dead-leg rather than a live steam main and flow;
- the pipework between the boiler and the sterilizer might be insufficiently insulated, causing excessive condensation of the supply steam;
- the steam manifold might not be adequately served with appropriate steam traps and air vents to ensure optimum conditions at the sterilizer.

4.39 If wet steam continues to be a problem, "priming" might be occurring in the boiler, causing water droplets to be delivered in the steam. Modern, compact, and high-rated boilers and steam generators are particularly sensitive to the quality of feed-water treatment and are much more likely to prime than boilers of traditional design. Priming or foaming (which results in carryover of the boiler water) can be caused by any of the following:

- incorrect feed-water treatment;
- boiler water level being set too high;
- forcing a boiler which needs internal cleaning;

- violent boiling under fluctuating load conditions;
- a high level (typically 2000 ppm) of total dissolved solids (TDS).

4.40 The relationship between water injection timing and steam generation should also be checked in order to reduce water slugging of the system. Generators are designed for the water to be injected before the flame to protect the coils, hence if too much time lapse is present, water will carry over into the system.

### Superheating

4.41 Superheated steam is an unsuitable medium for moist heat sterilization and can cause failure to sterilize, scorching of textiles and paper, and rapid deterioration of rubber. Superheated steam behaves as a dry gas and can have a lower microbicidal effectiveness in comparison with saturated steam. Superheat conditions within the load and chamber may result from adiabatic expansion, exothermic reaction or both.

4.42 European Standards require that the superheat in free steam at atmospheric pressure should not exceed 25 ºC when measured by the superheat test.

4.43 Superheated steam is uncommon and can be difficult to identify. A failed process indicator is one sign while charring of wrapping materials is another. Thermometric tests may also provide evidence of superheated steam. One possible cause of superheated steam is an excessive reduction in pressure through a throttling device, such as a pressure reducing system or a partially closed main steam valve. In this case superheating arises from adiabatic expansion, and is usually the result of an excessive reduction in pressure through a throttling device or torturous pipework and joints, a pressure reducing system or a partially closed main steam valve.

4.44 Superheat can also occur if the steam is admitted into the chamber with excessive velocity. This problem is usually detected and overcome during commissioning by fitting a throttling device in or over the steam inlet port with some modifications to the baffle plate assembly. Superheating may also arise if the pressure is unusually high before the throttling device. This superheat can sometimes be avoided by measures that reduce the dryness value of the steam at the inlet to the sterilizer pressure reducing system. The reduced pressure ratio will minimise the effect of the expansion through it.

4.45 Another possibility is superheating from exothermic reaction, which can occur as a result of rehydration of exceptionally dry (hygroscopic) material. In these circumstances, the superheating can persist for the entire holding time with consequential risk of a failure to sterilize. It is usually associated with certain textiles, particularly those incorporating cellulosic materials (such as cotton or paper), which have become excessively dry before sterilization. It can occur during periods of very cold, dry weather especially where the materials to be sterilized are kept in rooms that are heated and mechanically ventilated without humidification.

4.46 This is one reason for airing the standard test pack between successive tests.

## Non-Condensable Gases

4.47 Non-Condensable Gases (NCGs) are defined as gases that cannot be liquefied by compression under the range of conditions of temperature and pressure used during the sterilization process. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process, can cause chamber overheat and can lead to inconsistencies in the performance of air detectors. The major NCGs are air and carbon dioxide.

4.48 European Standards require that sterilizers be designed to operate with steam having a fraction of NCGs not exceeding 3.5 % by volume of gases to steam that has been condensed when measured by the method described in the non-condensable gas test (see paragraph 4.220 'Non-condensable gas test').

4.49 The main source of NCGs in the steam supply is the boiler feed-water, and the level will be greatly influenced by the water treatment employed. In some cases, a study by a water treatment specialist will be necessary. The study should cover analysis of the water, venting and the blow-down regime required in order to ensure protection of the boiler against corrosion whilst minimizing the entrainment of NCGs in the steam supply.

4.50 If anti-foaming agents and oxygen-scavenging agents (such as sodium sulphite) are used, checks should be made to ensure that the dosages are accurate.

4.51 Water-softening treatment can be employed to prevent the formation of scale.

4.52 A base-exchange softener will reduce limescale but will also produce bicarbonate ions, which will break down into carbon dioxide in the boiler and give rise to an increase in NCG levels. The water supply should be tested prior to installation.

4.53 In order to drive off dissolved air, carbon dioxide and other NCGs in the boiler, feed-water should be degassed before use by heating in a vented tank (a hot well). This will also break down bicarbonate ions, driving off further carbon dioxide. For the degassing to be effective, the temperature of the feed-water should not fall below 80 ºC at any time. The following measures should be adopted:

- pipework returning condensate to the hot well should be well lagged to keep the condensate hot;
- the amount of cold makeup water in the hot well should at no time exceed 15 % (the rest being returned condensate), since new water will both lower the temperature and introduce further NCGs;
- the water in the hot well should be kept well mixed.

4.54 This may be achieved by locating the feed-water inlet on the opposite side of the tank from the outlet and by arranging for the feedwater to be "sparged" from the inlet through a number of small openings. The mean temperature of the hot well should be maintained at 80 ºC to reduce the potential of dissolved gases being present in the system.

4.55 In very hard water areas the level of NCGs may still be high despite these measures. Where this is the case, the feed-water should undergo de-alkalization treatment and

the high temperatures in the hot well should be maintained. Treatment with filming amines is not permitted for sterilization applications.

4.56 Users should note that, even with a well-designed system, the level of NCGs can be affected by competing demands on the steam service. For example, where a central steam boiler supplies both a sterilizer unit and a laundry through the same distribution system, the level of NCGs in the steam at the sterilizer may rise when the laundry demand is high. This is the result of an influx of cold makeup water into the hot well. Paradoxically, in some installations the NCG level may also rise when steam demand is low. In this case, NCGs that would normally be removed by the laundry are being carried through to the sterilizer.

4.57 Some other causes of the of NCGs in the steam are as follows:

- the boiler might be priming (see paragraph 4.34 'Dryness');
- air might be being drawn into the system either through the boiler's feed-pump glands or through a leak in the steam pipework between the boiler and the sterilizer;
- steam pipework might be inadequately vented;
- hot well temperature too low;
- insufficient trapping in system or malfunctioning traps;
- where NCGs are found in the sterilizer chamber during a production cycle;
- there might be an air leak into the chamber;
    - packaging materials, for example, certain boxes, inks, adhesives, labels or trays might be liberating gases.

## Contamination in steam supplies

4.58 Recent years have seen a growing awareness of the need to monitor, test, report and improve the quality of steam used for sterilization, due in part to regulatory requirements.

4.59 This section discusses the adverse effects that impurities in the steam supply can have on equipment and the sterilizer itself. It identifies the products most likely to be susceptible to contamination and reviews the means by which various contaminants find their way into steam for sterilization.

### Why does contamination matter?

4.60 Quality assurance - the manufacture and the quality of the steam used in sterilization should be known and controlled. There are a number of specific contaminants known to have adverse effects and whose presence in steam is therefore undesirable.

### Adverse effects on materials

4.61 Contaminants in steam can have a damaging effect on the materials of load items and the sterilizer.

4.62 Reactive contaminants in the steam can cause corrosion or otherwise impair the longevity or function of the product. Reactions can occur when contaminants interact with the product directly or indirectly (by interacting with materials that will subsequently come into contact with the product).

4.63 The steam also comes into direct contact with the internal surfaces of the sterilizer pressure vessel and associated equipment and instrumentation. Contaminants within the steam can react with the materials of construction and cause corrosion of the equipment or otherwise impair its longevity or function.

4.64 The reaction of steam with surfaces is affected by its pH. In general, steam of a low pH (acidic) will react with and dissolve metals. A pH of approximately 7 (neutral) is ideal and deviation towards alkaline (for example to pH 8) is acceptable.

4.65 Contaminants of concern include the following:

- alkaline earth metals cause “hardness” which can lead to build-up of limescale on load items in the sterilizer chamber and in pipework. Most problems are caused by calcium and magnesium and, to a lesser extent, strontium;
- iron, whether in metallic or ionic form, is corrosive to stainless steel;
- chlorides in the presence of oxygen lead to pitting corrosion and (to a lesser extent) crevice corrosion in stainless steel. The effects can be controlled by limiting the amount of oxygen in the feed water (see Figure 8);
- phosphates and silicates act to concentrate chloride ions and so promote their corrosive effects. Silicates may also cause colour changes in some instrumentation although this is often only cosmetic.

4.66 The materials used in the construction of load items and of the sterilizer itself will determine which contaminants are of greatest importance in each case. EN 285:2015, the European Standard for sterilizers, offers guidance on materials for construction suitable for all steam sterilizers.

4.67 Steam sampling systems should be constructed of materials that will not react with, and hence contaminate, the sample being collected.

### Products vulnerable to steam – borne contamination

4.68 Any product can become contaminated if it comes into contact with the steam supplied to sterilizers. Contaminants in the steam are deposited on the product as the steam condenses during the heating-up stage. The amount of steam condensing, and hence the amount of contamination deposited, is proportional to the heat capacity of the load item, which in turn is proportional to its mass and the specific heat capacity of the material from which it is made. A massive metal item will therefore receive much more contamination than a light plastic item of similar size and shape heated to the same temperature.

4.69 The amount of contamination remaining at the end of the cycle will depend on how much condensate is retained at the surface of the product. Where condensate can drain freely from unwrapped items, a small fraction of the deposited contaminants will be held in a thin film of water and the total amount remaining when the film is evaporated will be proportional to the exposed surface area of the item. Where

condensate is trapped in cavities or held in the packaging close to the surface, the amount of contamination retained will be proportionally greater.

4.70 Whether such contamination has any adverse effect depends upon the nature and intended use of the product.

### Sources of contamination

4.71 contaminants delivered to the sterilizer in steam can arise from a number of sources:

- contaminants present in the public water supply from which the steam is generated;
- contaminants arising from treatment of the boiler feedwater;
- possible contaminants arising in the distribution system carrying steam to the sterilizer

### Public water supply

4.72 While the quality of mains water can differ considerably due to location and water source, it can normally be relied upon to meet the minimum standards set out in 'The Public Water Supplies (Scotland) Regulations' 2014 i.e. the potable water standards. These standards specify more than 50 limits for a wide range of impurities including dissolved minerals, organic compounds and microorganisms.

4.73 To assess the need for water treatment, Users should obtain an analysis of the mains water from the supply company over a 12-month period and analyse this data for any periodic trends. Under 'The Public Water Supplies (Scotland) Regulations' 2014 such an analysis should be supplied to customers on request.

4.74 Water drawn from the public supply may contain significant concentrations of the salts of the alkaline earth metals (chiefly calcium and magnesium) giving 'hard water' and may also have traces of other contaminants that need to be removed, to ensure water of the desired quality.

4.75 Most water companies use chlorine as a means of microbiological control but by the time the water reaches the point of use the disinfection effect of the chlorine can be largely lost. Therefore, water taken from the mains, and subsequently kept in storage tanks before use, can have significantly higher microbial counts than the original mains water. In the summer months counts greater than 100 CFU/ml are not uncommon. This is of particular concern for sterilization since some 98 % of the bacteria found in water supplies are reported to be Gram-negative bacteria, which are the predominant source of pyrogens. Further guidance for the maintenance of water systems within healthcare premises can be found in Scottish Health Technical Memorandum (SHTM) 04-01:2014.

4.76 There are no requirements for suppliers to measure or control the level of pyrogens in mains water. The level of total dissolved solids (TDS) in the boiler water is another important factor both in the prevention of foaming (see paragraph 4.14 'How steam is made') and for the contaminants that may be present in the entrained water droplets. If steam is to be produced, TDS levels should be below 2000 ppm.

4.77 While some control of TDS concentration can be exercised by appropriate feed water treatments, the boiler usually has a “blowdown” facility to allow accumulated sludge to be expelled from the bottom of the vessel. The water level gauge and TDS sensor element should also be blown down at regular intervals.

4.78 Filming amines, which are often added to feed water to prevent corrosion of condensate return pipes, are toxic and are not acceptable for boilers supplying steam for sterilizers.

4.79 There are no controls; however, on the amounts of atmospheric gases such as air (the principal non-condensable gas that can impede steam sterilization), carbon dioxide and oxygen are important contributors to corrosion in boiler systems.

### Water treatment options

4.80 Although the stated water quality can be relied on most of the time, gross contamination of water supplies may occasionally occur due to engineering works and treatment failures.

4.81 Although the stated water quality can be relied on most of the time, gross contamination of water supplies may occasionally occur due to engineering works and treatment failures.

4.82 Further contaminants can be introduced either deliberately or inadvertently as a result of treatments applied to mains water before it can be used as boiler feedwater.

4.83 Base-exchange water softeners remove calcium and magnesium ions from the water and replace them with sodium ions. (see paragraph 4.104 ‘Steam from a dedicated generator’). Sodium levels will therefore be raised in mains water softened by this method. The use of brine to regenerate the ion exchange beds can temporarily raise the level of chloride.

4.84 Bacterial growth can occur in water softening, deionisation or reverse osmosis plant unless the manufacturer’s operating and maintenance procedures are strictly adhered to.

4.85 While bacteria will not survive the steam generating process, the pyrogens they produce could be delivered to the sterilizer.

4.86 Any chemicals added to the boiler water can be carried into the steam as contaminants either in droplets of water entrained in the steam during the evaporative process or as volatile components present as gases. Treatment with filming amines is not permitted for sterilization applications and other corrosion inhibitors and chemicals, used to prevent corrosion in steam systems and boilers, should only be used in concentrations that are proven not to pose a risk to sterilizing equipment and loads they are in contact with. Concentrations of such chemicals should be carefully monitored to ensure that safe limits are not exceeded.

**Note:** Any significant alterations to the chemical dosing regimen used to treat the feedwater supply for the sterilizer steam supplies should be clearly documented with quantities, dates and chemicals and a further testing of the steam quality may be required. Advice should be sought from the AE(D).

### Steam distribution system

4.87 The distribution system also influences the quality of steam delivered to the sterilizer. The design of distribution systems suitable for the delivery of dry, saturated steam is considered in paragraph 4.1 ‘Steam supply’.

4.88 A purpose-built distribution system for steam for sterilization would normally be constructed of stainless steel. However, when a large conventional installation has been in use for a number of months, a hard protective layer of oxide (magnetite ($Fe_3O_4$)) may have formed on the inside of the steam pipes.

4.89 Providing the steam condensate is neutral or alkaline, this coat will remain intact and permit the use of the pipework for the distribution of steam. Acidic condensate in the presence of moist air, however, can break down the layer, leading to corrosion, which may then be shed as contaminating particles.

4.90 This substance forms fine particulates that are not readily removed by the strainers normally installed in steam services. This can occasionally be seen as black or reddish-brown discoloration of packaging material.

4.91 The hydrogen liberated by the formation of magnetite (400 ml for each gram of iron) can also contribute appreciably to the amount of non-condensable gases in the steam delivered to the sterilizer, especially in new installations with long pipe runs.

4.92 It is important that the distribution system is free of dead-legs and other places where condensate may become trapped otherwise contamination as rust is likely to arise at points where water can collect, such as dead-legs, gauges and poorly maintained traps. This can be shed into the steam as rust particles. During periods when the steam supply is off, such accumulation of water may also become a focus of microbial growth and the formation of biofilms, which periodically generate high levels of contamination as they slough off.

4.93 Other key points for a distribution system suitable for steam include:

- correctly sized automatic air vents throughout the pipework distribution system to minimise the amount of air and other non-condensable gases delivered to the sterilizer;
- properly sized and selected steam traps to remove condensate and air (if designed to do so);
- steam pipeline velocities kept below 25 $ms^{-1}$ to allow steam traps to remove entrained moisture effectively and to prevent condensate being drawn out of them;
- steam separators near the steam take-off on boiler plant prone to generating wet steam;
- strainers to protect control valves, steam traps etc.

### Assurance of the steam quality

4.94 Where a mains steam supply is found to be capable of meeting the steam specification, Users should assess whether the steam quality can be maintained under all operating conditions. There are several points to consider:

- programme testing of the steam at the sterilizer will provide assurance that the steam specification is consistently met;
- competing demands on the steam service from other units in the hospital can degrade the steam quality at the sterilizer;
- steam quality is apt to vary through the year as the boiler room responds to changing seasonal demands;
- an otherwise effective steam supply can quickly deteriorate if appropriate periodic maintenance is not carried out;
- arrangements should be made for the User to be warned of imminent engineering modifications, maintenance and changes in steam generation, distribution and operating practice. If changes are likely to be made without the User's knowledge, the supply cannot be considered a reliable source of steam.

### Steam from the mains steam supply

4.95 Experienced and monitored tests have shown that steam can be obtained from well designed, constructed and operated conventional boilers and distribution systems of the type found in most hospitals. If steam from this source is chosen, it is essential to demonstrate compliance and identify maintenance and boiler treatment regimens necessary for reproducibility.

4.96 Where a central supply does not deliver steam of acceptable standard, it is possible that the quality might be sufficiently improved by changes in operating practice and relatively minor engineering modifications. However, it is unlikely to be economical to embark on extensive remedial works such as the introduction of new feed water treatment plant or the replacement of distribution pipework. It might be more cost effective to install a dedicated steam generator solely to supply sterilizers (see paragraph 4.104 'Steam from a dedicated generator').

### Boiler design and operation

4.97 The first step in assessing whether steam can be supplied from the mains is to examine the design and operation of the boiler plant.

4.98 An important consideration is the proportion of boiler feed water that is fresh "makeup" water rather than steam condensate returned from the distribution system. In most large hospitals, where steam is supplied centrally, only a small fraction of the steam demand is due to sterilizers (which discharge most of their condensate to waste) and therefore the bulk of the condensate is returned to the boiler. This makes it more feasible to control the level of contaminants in the boiler. While the nature of the feedwater treatment is also of importance, the requirements for steam for sterilization are unlikely to be achieved if the proportion of makeup feedwater exceeds 15 %.

4.99 The level of total dissolved solids (TDS) in the boiler water is an important factor both in the prevention of foaming (see paragraph 4.14 'How steam is made') and for the contaminants that might be present in the entrained water droplets. If steam is to be produced, TDS levels should be below 2000 ppm. While some control of TDS concentration can be exercised by appropriate feedwater treatments, the boiler usually has a "blowdown" facility to allow accumulated sludge to be expelled from the bottom of the vessel. The water level gauge and TDS sensor element should also be blown down at regular intervals.

4.100 Filming amines, which are often added to feed water to prevent corrosion of condensate return pipes, are toxic and are not acceptable for boilers supplying steam for sterilizers. If it is not possible for the boiler to be operated without filming amines, another source of steam should be found.

4.101 While the boiler is unlikely to have been designed with the requirements of steam for sterilizers in mind, it should nonetheless have some means of preventing water being carried over into the steam. The chief precaution against carry-over is good practice in operating the boiler so that foaming and priming do not occur. Discussion with boiler-room staff will ascertain the degree to which operating procedures are successful in this regard.

4.102 Steam sampling points on the boiler are desirable and should be installed if they are not already fitted.

4.103 As the operational management of the steam supply will normally be outside the User's control, the User should consult with the AP(D) to ensure that the boiler-room staff is aware of the principles of saturated steam for sterilization and that the necessary assurances will be met. The appointment of suitably qualified and trained boiler-room staff is an essential part of this process.

### Steam from a dedicated generator

4.104 A dedicated steam generator, whether supplying one or several sterilizers, should be used where steam cannot be reliably obtained from the mains supply or for new installations. Since the bulk of the condensate from sterilizers is discharged to waste and not returned to the boiler, such generators might have to run on practically 100 % makeup feedwater.

4.105 A dedicated system should therefore:

- minimise the amount of non-condensable gases and other contaminants in the boiler feedwater;
- prevent liquid water leaving the boiler and being delivered in the steam;
- prevent microbial growth in any storage tank or pipework;
- be constructed from materials resistant to corrosion and particle shedding, such as low carbon stainless steel (type 316L).

4.106 The capacity of the generator should be sufficient to meet both maximum and minimum demands while still maintaining the requirements for dryness and non-condensable gases specified in paragraph 4.47 'Non-condensable gases'.

4.107 Steam sampling points should be fitted between dedicated generators and the sterilizer entry point so that steam quality tests can be performed.

### Moisture separation

4.108 A steam generator should allow the entrained water droplets to be separated from the steam before it is delivered to the sterilizer. The baffles used in some conventional boilers are not normally adequate for this purpose, but good results have been obtained using cyclonic separators, which essentially spin-dry the steam by causing it to rotate at high speeds. Experience has shown that the fitment of a large plate type separator fitted in the main steam line can safely remove water carryover from the distribution system prior to the header. This will protect the loads as processed in the porous-load sterilizers.

4.109 The manufacturer will have measured the efficiency of moisture removal by spiking the feedwater with high levels of endotoxin (at least 103 EU/mL) and testing samples of the steam for endotoxin levels by means of the LAL (limulus amoebocyte lysate) test. This work should be undertaken only by personnel with appropriate training and experience. Tests on an experimental steam generator have shown that reduction factors greater than 105 can be consistently achieved.

4.110 Adequate moisture removal should be maintained over the entire range of steam demand, typically up to 200 $kgh^{-1}$ for each sterilizer.

### Heating of steam generators

4.111 A single 600 L porous-load sterilizer requires a steam generator capable of converting energy at a rate of up to 50 kW. A group of sterilizers will require a proportionately higher heating power. Steam demand for peak and average flows should be obtained from the sterilizer manufacturers, and peak demands utilized for sizing the steam generators and distribution system.

4.112 Where existing sterilizers are supplied from a central boiler, the ideal solution is to install a generator heated by mains steam. The steam generator is then effectively a steam-to-steam calorifier in which the mains steam is used only to heat the feed water and does not come into contact with the steam for the sterilizer.

4.113 Primary steam requirements for this type of calorifier will normally be 300 $kgh^{-1}$ for each sterilizer at a minimum pressure of 10 bar and operating on 100 % condensate return. Where mains steam is not available, a small packaged boiler might be a convenient source of steam for heating, but should not itself be regarded as a source of steam.

4.114 Generators might be heated by electricity, but size for size, an electrically heated generator cannot match a steam-to-steam generator for heating power. The pressure in the boiler cannot be maintained at a high enough level to ensure adequate removal of droplets by the cyclonic method described above. Gas-fired heating is not recommended for stainless steel boilers.

### Materials of the steam generator and associated pipework

4.115 The boiler and other parts of the generator that come into contact with feedwater or steam should be constructed of corrosion-resistant stainless steel (such as low-carbon 316L grade).

4.116 Pipework connecting the steam generator to the sterilizer should be also constructed in stainless steel. Since the generator can be sited close to the sterilizer, it is a false economy to re-use existing sections of the steam supply system.

4.117 While existing sterilizers should not be harmed by a carefully-designed steam system, steam-contact surfaces of iron, mild steel or copper should be avoided in new machines. In most cases this will require contact surfaces to be fabricated in stainless steel as specified in EN 285:2015.

### Steam generator feed water treatment

4.118 As there is no return of chamber condensate from the sterilizer, the quality of feed water is crucial to the performance of a steam generator / boiler. It is especially critical for those generators that operate on a straight-through principle and have no reservoir of water within the boiler.

4.119 Water drawn from the public supply might be hard, that is, containing significant concentrations of the salts of the alkaline earth metals (chiefly calcium and magnesium) and might also have traces of other contaminants that need to be removed. To assess the need for water treatment, Users should obtain an analysis of the mains water from the supply company providing a trend over a 12-month period. Under 'The Public Water Supplies (Scotland) Regulations' 2014, such an analysis should be supplied to customers on request.

4.120 Although the stated water quality can be relied on most of the time, gross contamination of water supplies might occasionally occur due to engineering works and treatment failures.

4.121 Full water treatment consists of three stages:

- softening (to remove scale-forming contaminants that might harm the boiler);
- purification (to remove other undesirable contaminants);
- degassing (to remove corrosive and non-condensable gases).

4.122 The need for softening treatment will depend on the hardness of the local water supply. Where the water is soft it might be possible to achieve the steam requirements without further treatment. In such cases, Users should be aware that the quality of the steam will vary with the quality of the water supply, and that the quality of the steam should be frequently monitored to ensure that the steam specification is maintained.

4.123 In hard-water areas a base-exchange softening plant will normally be required. In this process calcium and magnesium ions are exchanged for sodium ions in a zeolite column (permutit process). The columns are periodically regenerated by flushing with brine (sodium chloride). The flushing should be carried out in accordance with

the manufacturer's instructions to prevent chloride ions being introduced into the softened water.

4.124 Microbial growth might occur in the columns unless the equipment is correctly operated and scrupulously maintained.

4.125 Steam generators that are highly efficient at removing water droplets might be able to attain steam standards without the need for further purification of the feed water, but this can only be determined by experiment. Users could consider installing specifically designed feed water purification plant that suits the needs of the site.

4.126 Purification might be achieved by either reverse osmosis or deionisation. In reverse osmosis (RO), water is forced through a semi-permeable membrane, which filters out contaminants to a high degree of efficiency. In deionisation (DI), ions and charged particles are removed either by electric fields or by ion exchange in resin beds. Although RO cannot normally attain the degree of purity possible with DI methods, it is more than adequate for feed water intended for purpose-built steam generators. Moreover:

- RO is cheaper to install and to run than DI;
- RO removes particulate matter, organic molecules and pyrogens that DI cannot;
- RO water is less corrosive to steel and copper than DI water;
- maintenance requirements are less demanding than for DI units.

4.127 When seeking quotations for the supply of water purification plant, the User should ensure that the manufacturer is aware of the intended use of the purified water, and should establish that it will not be corrosive to the materials of the steam generator.

4.128 Further treatment of the feedwater to remove dissolved gases should be carried out. This is usually achieved by pre-heating the water in a "hot well" maintained at temperatures of 80–90 ºC (at atmospheric pressure) to drive dissolved gases out of solution. The hot well is often provided by the manufacturer of the steam generator as an integral part of the unit.

4.129 A schematic illustration of a complete water treatment system is shown in Figure 8.

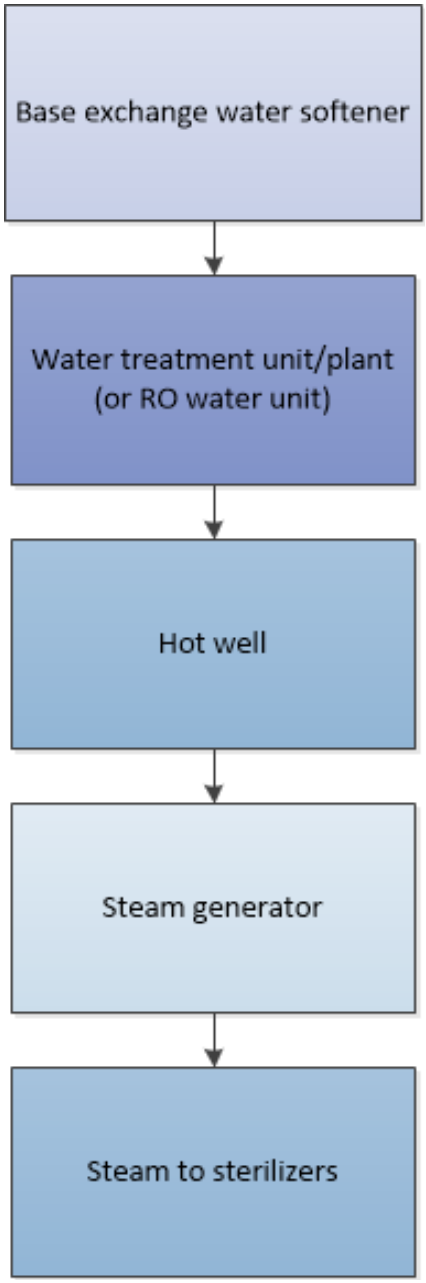



**Figure 8: Typical feed water treatment for a steam generator**

## Steam supply testing for compliance

4.130 This section discusses the testing regimes necessary for the initial validation of a steam supply for sterilization and for subsequent periodic testing. Methods for taking steam samples are given in this section and their analysis is discussed in paragraph 4.207 'Analysis of steam condensate samples'. Further information on steam, steam generators and their management can be found in this section.

### Where to take samples

4.131 To ensure a thorough quality assessment of the steam supply, water and steam samples should ideally be taken throughout the steam generating and distribution system, as required, from the incoming water to steam at the point of use – the sterilizer supply. Such an extensive testing regime used throughout the whole

generation and distribution system is rarely required in practice. Examples of points at which samples may be taken include:

- mains water, which after suitable treatment will be used as feedwater to the boiler;
- treated water, which may include one or more distinct treatment stages. Samples should be taken from the inlet and outlet pipes as close as possible to the treatment plant. To monitor the various stages of water treatment, samples should be taken after each stage;
- feedwater, the water admitted to the boiler from the hot well without any dosing treatments admitted simultaneously or separately to the boiler;
- boiler water, the water in the boiler prior to blow-down;
- boiler steam, the steam leaving the boiler;
- steam for use in the sterilizer, the steam delivered to the sterilizer, sampled at the steam service pipe.

4.132 Testing of the total system can be costly and may only be required where major problems are experienced.

4.133 The sampling points should be chosen so that the samples obtained will allow the identification and quantification of any significant changes in contamination levels at each stage in the process; e.g. sampling before and after a base-exchange water softener may reveal an increase in bacterial endotoxin levels from a contaminated ion exchange column. A full set of sampling points at strategic locations will allow such problems to be investigated with a minimum of disruption, even though most of them will rarely be used in routine operation.

4.134 The design and construction of the system will determine how many sampling points would be of value. For a mains system supplying a large hospital all the above points may be desirable. For a sterilizer with an adjacent, dedicated steam generator supplied from a simple treatment plant, fewer would be needed.

### Validation and periodic testing of the steam supply

4.135 Validation tests should normally be carried out on the following occasions:

- on initial validation of the steam-raising and distribution plant;
- on initial validation of the sterilizers served by the steam plant;
- on yearly testing or revalidation of the sterilizers;
- when there is operational evidence that the steam quality may have deteriorated;
- after any significant modification of the steam plant or its operation.

4.136 Periodic conductivity tests should be carried out during quarterly testing of the sterilizers.

4.137 As a minimum, samples for validation should include the feedwater and the steam for use in the sterilizer. Testing the steam without testing the water from which it is raised can lead to a false sense of security.

4.138 For example, high levels of pyrogens in the feed water will not necessarily produce contamination in the steam when the boiler is operating under loads that do not induce carry-over or priming. But during normal operation this could occur and contamination in the feedwater would require urgent investigation and remedial action.

4.139 Once a steam supply has been validated, periodic testing of steam quality will be necessary. Quarterly testing of electrical conductivity is recommended (see paragraph 4.277 'Field test for pH and electrical conductivity'), but the frequency will depend upon the particular application and the consistency of control established from historical data. Other tests might be necessary if one or more of the possible contaminants is critical for the process or product.

4.140 Formal validation should be carried out once the User is satisfied that the chosen system is capable of supplying steam and boiler-operating procedures have been established. Much exploratory testing may be required before this point is reached.

4.141 The AP(D) and CP(D) could consult boiler room records to establish how the demand on the boiler varies through a typical working day (in a large hospital sterilizers are likely to contribute only a small fraction of this load). The object is to ensure that times of highest and lowest demand can be reliably identified so that representative steam samples can be taken.

4.142 It may take several minutes for steam produced in the boiler to arrive at the sterilizer due to the large amount of steam contained within a mains distribution system. This means that the steam quality at the sterilizer might not be representative of the quality at the boiler. In particular, the steam in the pipes may have been generated at a time of less extreme demand and therefore be of higher quality, although if it has been standing in the pipes it is more likely to have been contaminated by the distribution system. CP(D)s should therefore ensure that the steam sample was generated when the boiler was operating at the appropriate level of demand, for example, by flushing the plant room manifold pipework with fresh steam immediately before samples are taken. In practice, the samples should be satisfactory if the boiler demand has been steady for several minutes and remains steady while the flushing takes place and the samples are taken.

### Sampling of water and steam – for field and laboratory analysis

4.143 This section discusses methods for taking water and steam samples for both field and laboratory analysis and provides background information on interpreting the results of some of the steam tests and explain the relationships between them.

4.144 Two samples each of feed water and / or steam at the sterilizer should be taken:

- at a time of highest demand;
- at a time of lowest demand.

4.145 Samples should consistent of:

- a full set of duplicate samples for laboratory analysis as described in paragraph 4.191 'Method of steam sampling for laboratory analysis';

- a field sample as described in paragraph 4.143 ‘Sampling of water and steam – for field and laboratory analysis’.

4.146 Where more than one sterilizer is supplied from the same steam manifold, steam samples should be taken at the sterilizer furthest downstream from the boiler. It is not necessary to sample the steam at each sterilizer.

4.147 Samples should be given a full laboratory analysis (see paragraph 4.186 ‘Sampling for laboratory analysis’). The field sample should be tested for electrical conductivity on site as described in paragraph 4.159 ‘Field tests for steam - conductivity and pH measurements’.

4.148 If the steam samples fail the test, the feedwater analysis should be examined to determine whether the failure could be remedied by a simple adjustment of the treatment regime. If not, further samples may need to be taken at points other than those mentioned in paragraph 4.131 ‘Where to take samples’ to establish where the problem originates.

4.149 When validation has been completed successfully, the mains supply may be used as a source of steam for sterilization, although Users should proceed with caution until sufficient experience has been gained to build confidence in the system. During the first year of steam operation, the validation tests should be repeated at intervals chosen to coincide with the peak variations in seasonal demand. This will provide further assurance that the system is capable of meeting the steam specification under all normal operating conditions. If any tests fail during this period, corrective action should be taken and the tests repeated.

### Sampling points

4.150 Sampling is required in each part of the system where the composition of the water or steam may need to be confirmed, or where changes in composition may need to be determined. Sampling points should be designed and constructed to ensure that:

- the sample taken is as nearly as possible representative of the water or steam in that section of the system;
- the sample can be taken without contaminating it;
- the sample can be taken safely.

4.151 When possible, samples should be taken from flowing rather than static parts of the system. For example, in sampling a tank the samples are best taken from the inflow or outflow pipes rather than the static reservoir.

4.152 Where boiler water is to be sampled, the position of the sampling point should be chosen with care, giving consideration to the fact that the composition of water can vary considerably at different locations in the boiler. For boilers with forced circulation the sampling point is best located on the discharge side of the pump.

4.153 It is good practice to install coolers to ensure that representative boiler water samples can be taken safely.

4.154 Guidance on the design and construction of sampling points is given in BS 6068-6.7:1994, BS EN ISO 5667-7:1993.

4.155 Two samples each of both feedwater and steam at the sterilizer should be taken under conditions of highest demand.

4.156 Samples should consist of:

- a full set of duplicate samples for laboratory analysis as described in paragraph 4.186 ‘Sampling for laboratory analysis’;
- a field sample as described in paragraph 4.176 ‘Apparatus for collecting steam sample during field analysis’.

4.157 Where more than one sterilizer is supplied from the same steam generator, steam samples should be taken at the sterilizer furthest downstream. It is not necessary to sample the steam at each sterilizer.

4.158 Samples should be given a full laboratory analysis, see paragraph 4.191 ‘Method of steam sampling for laboratory analysis’. The field sample should be tested for electrical conductivity on site as described in paragraph 4.176 ‘Apparatus for collecting steam sample during field analysis’.

## Field tests for steam – conductivity and pH measurements

4.159 This section contains procedures for the testing of steam condensate samples. It should not be used for samples intended to be sent for laboratory analysis.

4.160 Periodic testing of the steam supply should be carried out quarterly to coincide with the quarterly tests scheduled for the sterilizer. Periodic testing of the feedwater is not necessary.

4.161 The test should consist of a conductivity measurement of a field sample (see paragraph 4.277 ‘Field test for pH and electrical conductivity’), and the conductivity value should remain below the limit established during validation. Failure of the periodic test (i.e. the conductivity measurement is above the validation level) requires further investigation, normally by a full laboratory analysis of both feedwater and steam. Revalidation should be carried out once a year, to coincide with the yearly testing of the sterilizer.

4.162 Additional tests may be required if problems are experienced with steam quality / contaminants. The advice of the AE(D) should be sought as to frequency of testing required in that case.

### Dedicated steam generator

4.163 A dedicated steam generator supplying one or more sterilizers may not suffer competing demands from other equipment and may be more likely to be within the User’s control. Consistency of steam quality may therefore be demonstrated more readily than for a mains steam supply.

### Validation / Re-validation tests

4.164 Validation can normally be carried out as soon as the Contractor has installed the equipment and completed their own installation tests.

4.165 The AP(D) and CP(D) should first establish when the steam generator will be subject to the highest and lowest demand. Depending on the design of the steam plant, it is possible for either to constitute the worst-case conditions for carry-over of moisture. For example, a large plant designed to supply several sterilizers and relying on a cyclonic separator for removal of entrained water droplets may be inefficient at the lower velocities generated by a single sterilizer on light load.

4.166 The highest demand on the boiler usually occurs when all sterilizers are operating simultaneously. However, the period of peak demand (steam admission into the chamber) is brief, and it is difficult to synchronize the operating cycles so that the peaks coincide for long enough to allow a sample to be taken. The peak demand of any sterilizer is usually at the steam admittance point at the end of the deepest pulse stage.

4.167 An alternative method is to vent steam from the relief valve on the plantroom manifold. Users should first ensure that the steam will be discharged to a safe position outside the building. The relief valve is designed to limit pressure in the system and therefore this action creates a demand on the boiler that is greater than the maximum demand of the sterilizers. If steam samples collected under these conditions comply with steam specification, it can be assumed that the generator will cope with the demand of the sterilizers. If not, the generator may still comply if loaded normally, and further testing will be required.

4.168 A third possibility is to install a discharge valve on the steam manifold designed to simulate the peak demand of all sterilizers operating at the same time.

4.169 The amount of steam contained within the distribution system will be small, the steam produced in the boiler will arrive at the sterilizer almost instantly, and the steam sample collected can be assumed to be representative of that created in the boiler.

4.170 Two samples each of both feed water and steam at the sterilizer should be taken under conditions of highest demand.

4.171 Samples should consist of:

- a full set of duplicate samples for laboratory analysis as described in paragraph 4.191 ‘Method of steam sampling for laboratory analysis’;
- a field sample as described in paragraph 4.180 ‘Method for collecting the steam sample during field analysis’.

4.172 Where more than one sterilizer is supplied from the same steam generator, steam samples should be taken at the sterilizer furthest downstream. It is not necessary to sample the steam at each sterilizer.

4.173 Samples should be given a full laboratory analysis (see paragraph 4.207 ‘Analysis of steam condensate samples’). The field sample should be tested for electrical

conductivity on site as described in paragraph 4.277 ‘Field test for pH and electrical conductivity’.

### Periodic tests

4.174 Periodic testing of the steam supply should be carried out quarterly to coincide with the quarterly tests scheduled for the sterilizer. Periodic testing of the feed water is not necessary. The test should consist of a conductivity measurement of a field sample (see paragraph 4.277 ‘Field test for pH and electrical conductivity’), and the conductivity value should remain below the limit established during validation. Failure of the periodic test (i.e. the conductivity measurement is above the validation level) requires further investigation, normally by a full laboratory analysis of both feed water and steam.

4.175 Re-validation should be carried out once a year, to coincide with the yearly testing of the sterilizer.

**Note:** Commercial test equipment is available to undertake these tests that will give a consistent result and offer a practical solution on site for use by the CP(D).

### Apparatus for collecting steam sample during field analysis

4.176 Figure 9 shows the apparatus connected to a pitot tube identical to the one specified for the steam quality tests in paragraph 4.216 ‘Physical steam quality tests’. The pitot is fitted to the steam supply pipe near the sterilizer. This standard pitot is not suitable for laboratory samples. Sampling equipment is now readily available to purchase. Figure 10 shows an alternative pitot that may be used for all steam testing. If this pitot is used for field samples or the tests in paragraph 4.216 ‘Physical steam quality tests’, the ball valve, nipple and socket should be removed.

4.177 Steam is led through a length of polypropylene tubing and condensed as it passes through a bath of cold or iced water.

4.178 This apparatus is suitable for use for samples that are to be analysed immediately, such as for periodic tests for electrical conductivity. It is not suitable for samples intended for more sensitive analysis in the laboratory. It is also unsuitable for taking samples for pyrogen testing.

4.179 Steam pipework and sampling apparatus will be hot and adequate precautions should be taken against getting burnt. Thermal gloves and safety glasses should be worn.

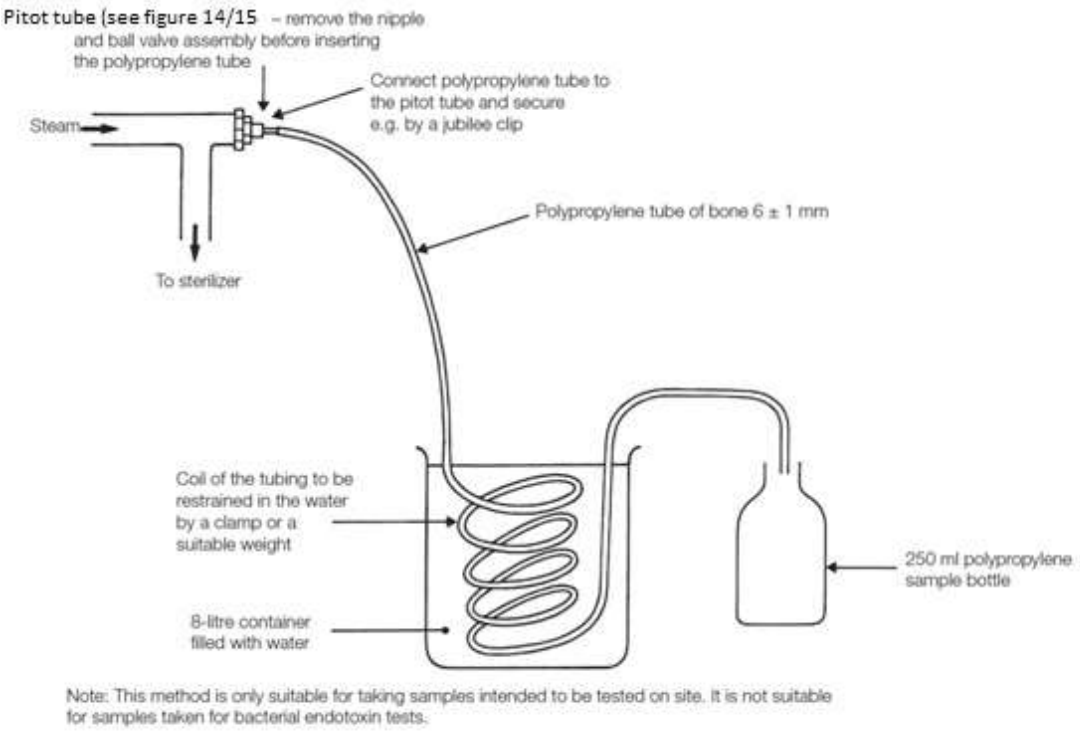



**Figure 9: Steam sampling system for field analysis**

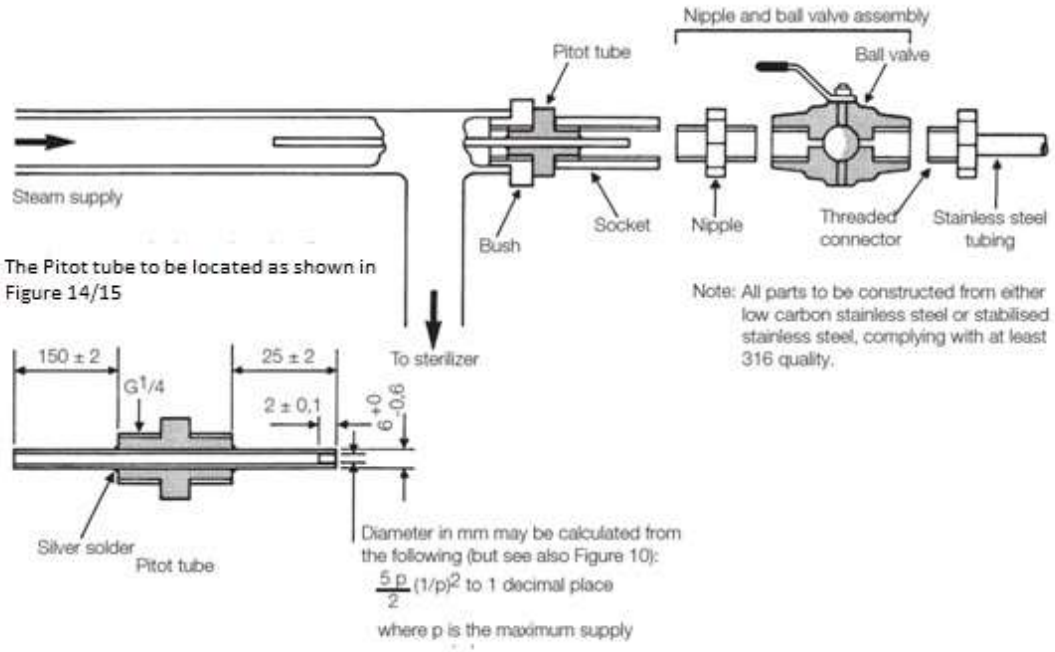



**Figure 10: Typical pilot sampling tube assembly**

### Method for collecting the steam sample during field analysis

4.180 Use new polypropylene tubes for each test or series of tests. Clean the polypropylene sample bottle by rinsing well with distilled water. Detergents should not be used. Leave them to dry.

4.181 If the pitot is not already fitted, isolate the steam supply and vent the pipe of pressure. Fit the pitot tube into the pipe and secure the polypropylene tube to it with a clip.

4.182 Restore the steam supply and allow steam to vent through the polypropylene tube for at least 5 min to restore the steam service to its stable operating temperature. Ensure that the condensate drains freely. Close the steam valve.

4.183 Coil part of the tube into a sufficient number of coils to ensure condensation of steam, place it in the 8 L container and retain it in place. Fill the container with enough cold water (add ice if required) to immerse the coils.

4.184 Open the steam valve. The steam will condense in the coils and condensate will emerge from the end of the tube. Allow the first 50 mL of condensate to discharge to waste and then collect approximately 250 mL in the sample bottle.

4.185 Seal and label the bottle. The electrical conductivity should be measured promptly as described in paragraph 4.277 ‘Field test for pH and electrical conductivity’.

### Sampling for laboratory analysis

4.186 This method is suitable for taking all required samples, including those to be subjected to full laboratory analysis and the test for pyrogens.

The tests for chemical purity and the test for bacterial endotoxins are derived from the tests for “Water for Injections” in the BP.

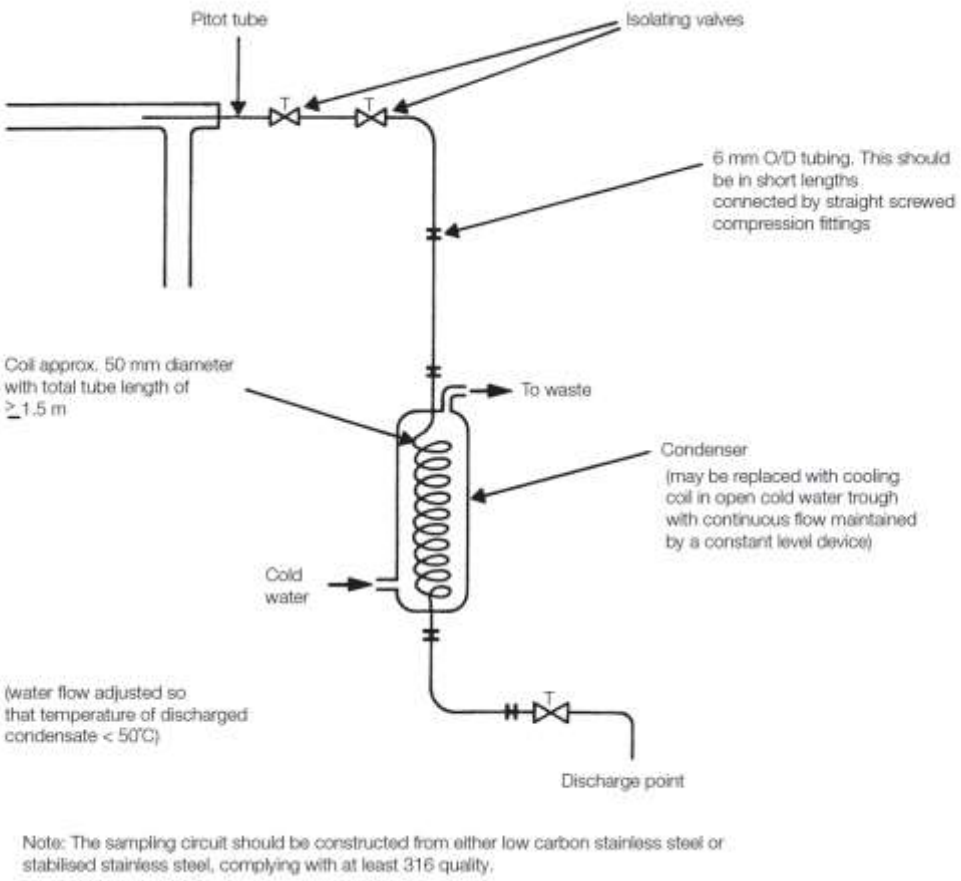



**Figure 11: Steam sampling system for laboratory analysis**

## Apparatus – steam sampling for laboratory analysis

4.187 The is shown in Figure 11. All components, including the condenser and valves should be constructed in 316L stainless steel. The tubing is made in short sections connected by compression joints to form the required length and configuration. The sections are short enough to allow each element to be thoroughly cleaned, sterilized and depyrogenated before next use.

4.188 The standard pitot used with the field sampling apparatus described above is not designed to take compression fittings and so cannot be used with this apparatus. It should be replaced with the modified pitot and ball valve shown in Figure 10.

4.189 The apparatus is suitable for taking samples for all the determinants of interest. It may be used for steam condensate or water samples throughout the steam-raising system.

4.190 In theory there is a risk of some contamination of the sample from metals that could be extracted from the stainless steel, but the grade of steel chosen is no more reactive than those used in the construction of steam pipes and equipment. If, for whatever reason, the steam reacts with the sampling apparatus, it will also have reacted with the installed system.

## Method of steam sampling for laboratory analysis

4.191 Clean and prepare sample bottles and stainless steel components according to the instructions from the receiving laboratory. All the stainless steel components should

be depyrogenated by processing in a dry-heat sterilizer at a sterilization temperature of 180 °C for 3 hours. If a suitable oven is available, they may alternatively be baked at 250 °C for 30 minutes (dry-heat sterilizers cannot attain this temperature). Normally, two sets will be used for steam samples and one for control samples. Ensure that the bottles are labelled as described in paragraph 4.194 'Handling of samples for laboratory analysis'.

4.192 Open the valve on the pitot and allow steam to vent through the cooler for at least 5 minutes before turning on the cooling water. The steam will condense in the coil and condensate will emerge from the end of the tube. Allow the first 50 mL of condensate to discharge to waste and then collect samples in the first two sets of bottles.

4.193 Fill the third set of bottles with Water for Injection BP and preserve and analyse this in the same manner as the two sets of steam samples.

**Note:** These negative control samples provided evidence that the choice of container, cleaning system and preservative is appropriate.

### Handling of samples for laboratory analysis

4.194 It is important that the physical, chemical and biological properties of water and steam samples remain stable from when they are sampled until they arrive at the laboratory for analysis. The conditions in which the sample should be kept are determined by the contaminants for which the water is to be tested. The material of the sample container is also important since it may interact with substances in the water; plastic is suitable for some parameters, glass for others.

4.195 General guidance on these points is given below; more specific advice is in BS EN ISO 5667-3:2018. The laboratory carrying out the analysis will normally provide all the necessary containers, preservatives and labels with full instructions for their use.

### Sample containers

**Note:** For advice, consult the laboratory carrying out the analysis prior to testing.

4.196 There is no single material suitable for containing samples with all relevant contaminants. Containers may be made from polyethylene, polystyrene, polypropylene, glass or borosilicate glass. The receiving laboratory will normally supply the appropriate containers, with full instructions for their use.

4.197 Each type of container requires a different cleaning procedure to ensure samples are not contaminated by residues. The instructions from the receiving laboratory should be followed.

4.198 The laboratory's instructions on filling and closing the bottles should be followed. Most bottles should be filled to the brim and then stoppered or capped to ensure that as little air as possible remains above the sample. A small air space should be left above samples to be frozen.

## Identification of samples

4.199 Each container should be unambiguously labelled with a water-resistant label at the time of sampling. The laboratory will supply suitable labels and instructions. The information to be recorded should include:

- the establishment at which the sample was taken;
- the date and time at which the sample was taken;
- the name of the person taking the sample;
- clear identification of hazardous materials present (for example, acids used as a preservative); and either;
- an unambiguous reference number for contemporaneous notes of the information in the following bullet points; or
- the sampling point;
- the nature of the sample (for example condensed steam);
- the determinant(s) for which the sample is to be analysed;
- any preservative treatment;
- notes on any observations pertinent to the analysis, such as an event not in accordance with the sampling procedure that might affect the analysis.

## Sample preservation

4.200 The purpose of preservation is to maintain the concentration and state of the contaminant of interest unchanged from when the sample was taken to arrival at the laboratory.

4.201 There are many possible interactions that would adversely affect the sample. The contaminant of interest might:

- polymerise or, if already a polymer, depolymerise;
- react with other constituents of the sample;
- react with atmospheric oxygen or carbon dioxide becoming dissolved in the sample;
- be consumed, modified or be produced in higher concentrations by microorganisms growing in the sample;
- react with, or be adsorbed or absorbed by, the material of which the container is constructed.

4.202 The sample and the extent and nature of any contaminants present, will determine which reactions and changes may occur. The more contaminated a sample, the more likely it is that changes will occur. In addition, the temperature during transport and storage, exposure to light, the container material and any special precautions used in its preparation, and the elapsed time before analysis, will all affect reactions and changes.

4.203 While it is desirable for all samples to be cooled (normally at 2–5 ºC), some will require the addition of an acid preservative and others will need to be frozen. The receiving laboratory will specify the preservative treatment for each container and supply suitable reagents where necessary.

4.204 Few preservative treatments for the contaminants specified for steam are valid for more than 24 hours and some for a much shorter time. Prompt despatch and analysis are therefore essential.

### Packaging and transport

4.205 The samples should be packaged securely in containers providing suitable protection from breakage or external contamination during transport. The containers should be kept as cool as possible during transport. For transporting small quantities of samples, domestic cool boxes provide suitable protection and cooling.

4.206 The transport container should be accompanied by a list of the samples being sent. A duplicate of this list should be retained by the AP(D) and / or User. The list should be sufficiently comprehensive to allow confirmation of the identity of each sample in the consignment.

### Analysis of steam condensate samples

4.207 This section discusses the means by which a sample of steam condensate may be analysed for compliance with the steam specification. The tests are equally suitable for testing samples of steam or water from elsewhere in the steam supply system, provided the limitations of the pharmacopoeia tests are understood.

4.208 To determine whether a steam sample conforms with the steam specification, it is necessary to carry out tests for all the determinants listed in Table 5.

4.209 Laboratories invited to carry out these tests should be accredited to BS EN ISO/IEC 17025:2017.

4.210 Tests should be performed as defined in the European Pharmacopoeia.

### Reporting of laboratory results

4.211 The report obtained from the laboratory for each test should contain the following information:

- the exact identity of the water sample;
- the date and time the sample was received;
- the date and time at which the test was commenced;
- the storage conditions if the above two points are not the same;
- the determinant for which the sample was analysed;
- for non-quantitative tests, a statement as to whether the result complies with specification;
- for quantitative tests:
  - the numerical value expressed in the unit specified for each of the duplicate determinations;

  - the mean of the results of the duplicate determinations and the uncertainty that might be associated with the final result;
- a description of any pre-treatment of the sample;
- a description of the method used, including reference to specific items of equipment, calibration standards, etc.;
- any deviations from the method or other facts that might reasonably be expected to influence the result obtained. These should be signed both by the analyst responsible for carrying out the determinations and the analyst or quality controller responsible for checking the report.

4.212 For any given determinant there will usually be several methods that are suitable and cover the range of concentrations of interest. The choice of method should be determined by factors including availability of equipment, previous experience with the method, cost, and sensitivity to interfering substances that might be present. Consideration should be given to:

- the limit of detection, which should be lower than the specified limit for the contaminant;
- the accuracy of the method, which is of particular importance in observing changes in quality;
- the likely presence of interfering substances in the samples to be tested.

4.213 There are several ways in which numerical results from any given analysis may be presented. The User should specify that the results are quoted in the units used in the specification in CEN ISO/TS 17665-2:2009 so that the sample can readily be compared with the specification.

4.214 The following sections give background information on interpreting the results of some of the steam tests and explain the relationships between them.

4.215 The requirements for steam are stated in Table 5 ‘Specification for contaminants in condensate collected according to the method described in BS EN 285:2015.

## Physical steam quality tests

4.216 A continuous supply of saturated steam is required for steam sterilization. Too high a level of non-condensable gases will prevent the attainment of sterilizing conditions; too little moisture carried in suspension can allow the steam to become superheated during expansion into the chamber, while excess moisture can cause damp loads.

4.217 For all physical steam quality tests, the steam should be sampled from the steam service pipe to each sterilizer. The measurements are taken during a period of maximum steam demand, when steam is first admitted to the sterilizer chamber.

4.218 Silicone rubber tubing is porous to steam and should not be used to carry steam in these tests.

**Note:** Steam pipework and sampling apparatus will be hot, and adequate precautions should be taken against getting burnt. Thermal gloves and safety glasses should be worn.

### Non-condensable gas test

4.219 This test is used to demonstrate that the level of non-condensable gases in the steam will not prevent the attainment of sterilization conditions in any part of the load. Possible sources of non-condensable gases are discussed in paragraph 4.47 'Non-condensable gases'. The method described should not be regarded as measuring the exact level of non-condensable gas, but as a method by which the provision of acceptable steam quality can be demonstrated.

### Apparatus for the non-condensable gas test

4.220 The apparatus is shown and described in Figure 12. All sizes are nominal. Alternative commercially-available versions of this may be used (See note below). Robust apparatus should lead to consistent result-gathering. When using commercially available test units, correlation between the standard method and the alternative method should be established. For example, it may be necessary to ensure that the temperature in the container remains above 65 ºC during the test in order to avoid dissolution of carbon dioxide. The flow rate may also need to be adjusted to ensure that 200 mL of condensate is collected over the whole of the air-removal stage.

**Note:** The equipment shown in Figure 12 is the standard method for collecting non-condensable gases. Commercially available alternative test units which are more easily transported and safer to connect to the steam system may be used provided the correlation between results from the alternative and standard method is established.

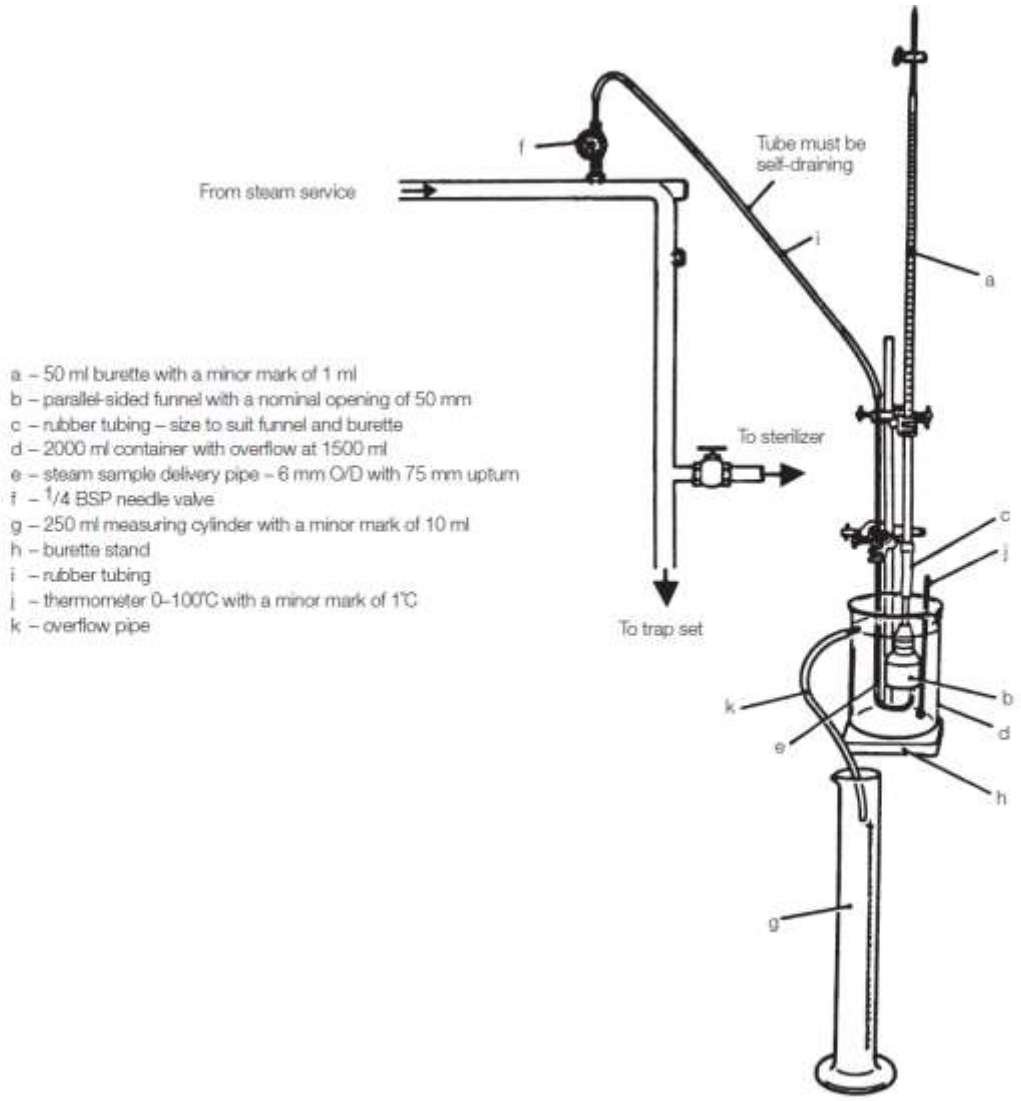



**Figure 12: Apparatus for non-condensable gas test**

## Method for the non-condensable gas test

4.221 Connect the needle valve to the steam service pipe as shown in Figure 12. When performing this test, the pitot tube used for the superheat and dryness tests should not be connected.

4.222 Assemble the apparatus so that condensate will drain freely from the long rubber tube into the sampling pipe. Copper or stainless steel tubing may also be used.

4.223 Fill the container with degassed cold water, preferably condensate, until it overflows. Fill the burette and funnel with cold water, invert them and place them in the container. Draw out any air that has collected in the burette.

4.224 With the steam sampling pipe out of the container, open the needle valve and allow steam to purge the air from the pipe. Place the pipe in the container, locate the end within the funnel, and add more cold water until it flows through the overflow pipe.

4.225 Place the empty measuring cylinder under the container overflow.

4.226 Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard. Ensure that all the steam is discharged into the funnel and does not bubble out into the container. Record the setting of the needle valve. Close the valve.

4.227 Draw out any air present in the burette; ensure that the container is topped up with cold water and that the measuring cylinder is empty.

4.228 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

4.229 When the steam supply to the chamber first opens, open the needle valve to the previously recorded setting, allowing a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard.

4.230 Allow the steam sample to condense in the funnel. Any non-condensable gases will rise to the top of the burette. Overspill formed by the condensate and the water displaced by the gases will collect in the measuring cylinder.

4.231 When the temperature of the water in the container reaches 70–75 °C, close the needle valve. Record the volume of gas collected in the burette ($V_b$) and the volume of water collected in the measuring cylinder ($V_c$).

4.232 Calculate the fraction of non-condensable gases as a percentage as follows:

$$\text{Fraction of non-condensable gases} = 100 \times \frac{V_b}{(V_c - V_b)}$$

### Results from the non-condensable gas test

4.233 The test should be carried out twice further to check consistency. If the results of the three tests differ significantly, the cause should be investigated before proceeding further.

4.234 The test should be considered satisfactory if the maximum result of the 3 tests of the fraction of non-condensable gases does not exceed 3.5 %.

### Steam superheat test

4.235 This test is used to demonstrate that the amount of moisture in suspension with steam from the service supply is sufficient to prevent the steam from becoming superheated during expansion into the chamber. The test assumes that the steam supply pressure is nominally 4.0 bar gauge. If the supply pressure differs from this, it might be necessary to amend the acceptance criteria accordingly.

4.236 The method described here uses a low-volume sample, continuously taken from the centre of the steam service pipe. The level of superheat determined by this method cannot be regarded as indicative of the true condition of the steam in the pipe, since condensate flowing along the inner surface is not collected. However, devices designed to separate free condensate are incorporated into the steam delivery system to the chamber, and therefore the level determined by this method is representative of steam conditions likely to prevail within the chamber during the plateau period.

4.237 This test should normally follow a satisfactory test for non-condensable gases.

### Apparatus for the steam superheat test

4.238 A pitot tube is shown in Figure 12. The rest of the apparatus is shown and described in Figure 13.

### Method

4.239 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 12.

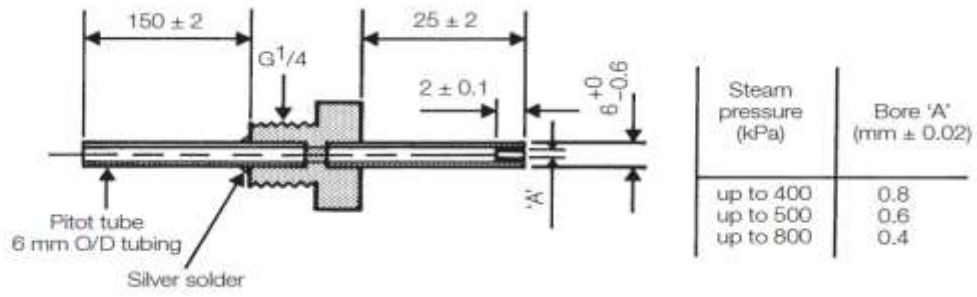



**Figure 13: Pitot tube**

4.240 Fit the sensor entry gland Figure 2 to the steam service pipe. Insert one of the sensors through the gland and position it on the axis of the pipe.

4.241 Insert the second sensor through the gland in the expansion tube and position it on the axis of the pipe. Wrap lagging around the expansion tube. Push the tube onto the pitot tube as shown in Figure 14.

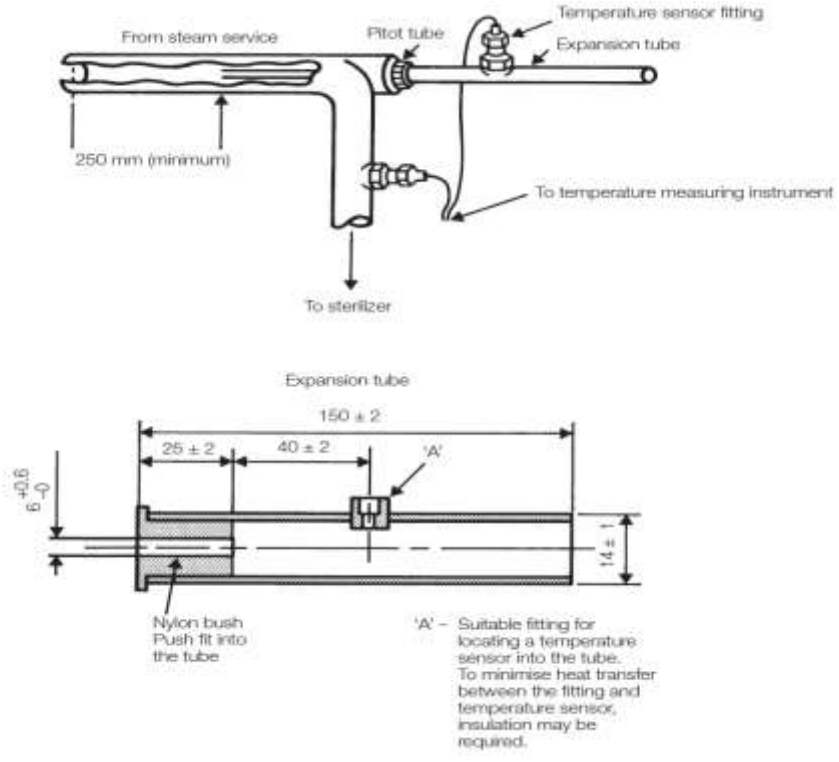



**Figure 14: Apparatus for superheat test**

4.242 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

4.243 From the measured temperatures, record the temperature in the steam service pipe (for use in the dryness test) and in the expansion tube (T) when the steam supply to the chamber first opens. Calculate the superheat in °C from the following equation:

$$\text{Superheat} = T - T_0$$

Where $T_0$ is the boiling point of water at local atmospheric pressure.

### Results of the steam superheat test

4.244 The test should be considered satisfactory if:

- the superheat measured in the expansion tube does not exceed 25 ºC;
- the temperature measured in the steam pipe did not differ by more than 3 °C from that measured in the steam pipe during the steam quality, dryness test.

**Note:** This temperature is a parameter from which the variability of the steam pressure between sequential cycles can be assessed. A higher temperature difference can cause operational problems from the moisture content in the steam.

### Steam dryness test

4.245 The accurate measurement of the percentage of moisture content in the steam is difficult, and the traditional methods, where constant steam flow is required, are not suitable for sterilizers. This test should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated. Possible sources of excessive moisture are discussed in paragraph 4.34 ‘Dryness’.

4.246 The test is carried out immediately after the superheat test.

### Apparatus for the steam dryness test

4.247 A pitot tube is shown in Figure 13. The apparatus is shown and described in Figure 15. All sizes are nominal.

4.248 A laboratory balance capable of weighing a load up to 2 kg with an accuracy of 0.1 g or better.

### Method

4.249 If it is not already fitted, fit the pitot tube concentrically within the steam service pipe as shown in Figure 15.

4.250 If it is not already fitted, fit the sensor entry gland to the steam service pipe. Insert a temperature sensor through the gland and position it on the axis of the pipe.

4.251 Connect the rubber tube to the longer of the pipes in the stopper, place the stopper in the neck of the vacuum flask, weigh the whole assembly and record the mass ($M_1$).

4.252 Remove stopper and tube assembly and pour 650 ±50 ml of cold water (below 27 ºC) into the flask. Replace the stopper and tube assembly, weigh the flask and record the mass ($M_2$).

4.253 Support the flask close to the pitot and ensure that the rubber tube and flask are protected from excess heat and draughts. Do not connect it to the pitot tube yet.

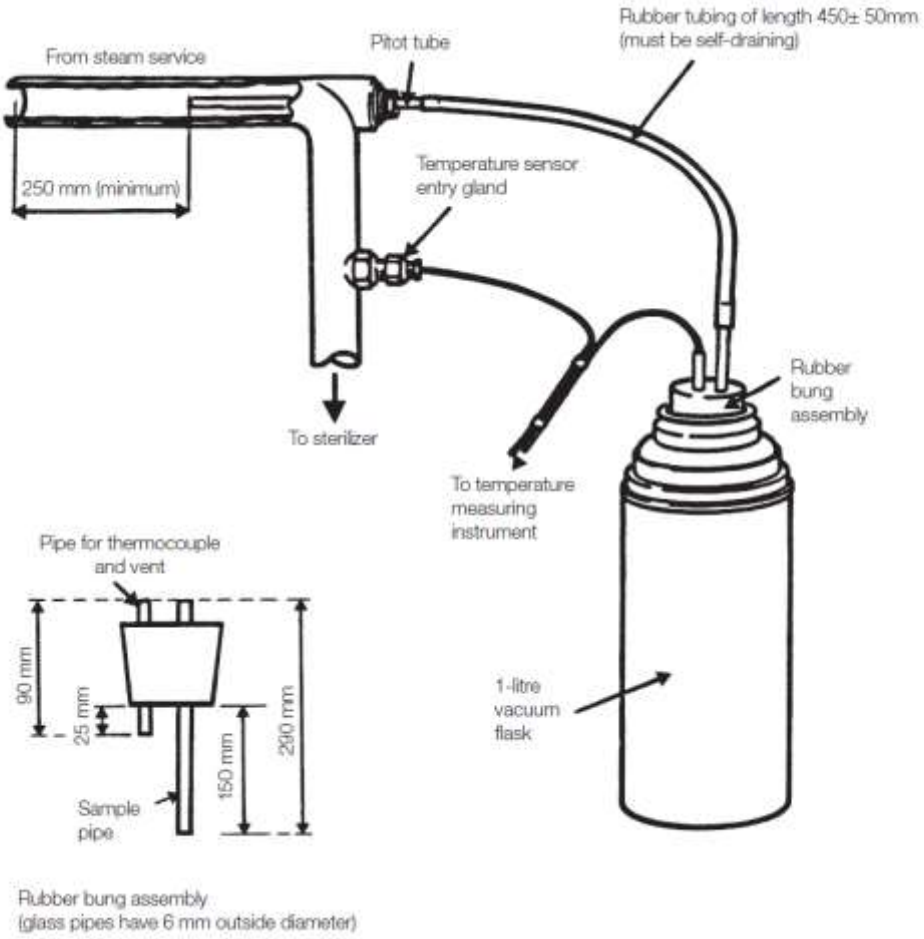



**Figure 15: Apparatus for steam dryness test**

4.254 Introduce the second temperature sensor through the shorter of the two pipes in the stopper and into the water in the flask. Record the temperature of the water in the flask ($T_0$).

4.255 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

4.256 When the steam supply to the chamber first opens, connect the rubber tube to the pitot discharge and wrap lagging around it. Arrange the rubber tube to permit condensate to drain freely into the flask. Record the temperature in the steam service pipe ($T_0$).

4.257 When the temperature of the water in the flask is approximately 80 °C, disconnect the rubber tube from the pitot, agitate the flask so that the contents are thoroughly mixed and record the temperature of the water ($T_1$).

4.258 Weigh the flask and stopper assembly and record the mass ($M_3$).

4.259 The initial mass of water in the flask is given by $M_w = M_2 – M_1$

4.260 The mass of condensate collected is given by $M_c = M_3 – M_2$

4.261 Calculate the dryness value of the steam from the following equation:

$$D = \frac{(T_1-T_0)(4.18M_W+0.24)}{LM_c} - \frac{4.18(T_S-T_1)}{L}$$

Where:

$T_0$ = initial temperature of the water in the flask (°C);

$T_1$ = final temperature of the water and condensate in the flask (°C);

$T_S$ = average temperature of the steam delivered to the sterilizer (°C);

$M_w$ = initial mass of the water in the flask (kg);

$M_c$ = mass of condensate collected (kg);

L = latent heat of dry saturated steam at temperature $T_S$ (kJ $kg^{-1}$);

0.24 kJ $kg^{-1}$ = Effective heat capacity of the apparatus.

### Results of the steam dryness test

4.262 The test should be repeated 3 times and considered satisfactory if the following requirements are met:

- the dryness value is not less than 0.95 unless only textile loads are being processed, in which case 0.90 is permissible;
- throughout the operating cycle, the temperature measured in the steam service pipe is within 3 °C of that measured during the superheat test.

## Operation and maintenance of steam generators

4.263 Steam generators are steam boilers and are subject to the ‘Pressure Systems Safety Regulations (PSSR)’ 2000.

4.264 Users should ensure that operation and maintenance of the generator is carried out correctly, both to ensure safety and also to maintain the quality of the steam.

4.265 Steam generators are subject to a written scheme of examination for pressure vessels.

4.266 Guidance on the design, maintenance, testing and operation of steam generators can be found in the Health and Safety Executive’s INDG436 – ‘Safe management of industrial steam and hot water boilers’.

4.267 The advice of the boiler manufacturer about water supply, water treatment, blowing down and other operational practices should be strictly observed.

4.268 Failure to provide adequate supervision, with consequential inadequate control of water quality and insufficient blow-down, has resulted in such severe corrosion of steam generators that in some cases internal parts have collapsed and operators have been put in danger.

### Operation

4.269 A risk assessment should be undertaken to establish the level of supervision required. While it is not acceptable for steam generators to be left continuously unattended, it is not necessary for an operator to be present at all times. The amount and frequency of attention necessary in each case will depend largely on the nature of the water supply, water treatment arrangements and the intensity of use. The operator, who can also be the sterilizer operator, should be adequately trained.

### Maintenance

4.270 Because there is little condensate return to these steam generators, their feed water is usually almost 100 % make-up, and as a result the concentrations of dissolved and suspended solids in the boiler water quickly build up to very high levels. Such boilers are provided with a “blow down” facility to expel deposits of sludge from the bottom of the boiler. It is essential that an effective blow-down regime is established and adhered to. There are three possibilities:

- continuous blow-down – sludge is expelled continuously;
- automatic intermittent blow-down – sludge is expelled automatically under the control of a timer or conductivity device;
- manual intermittent blow-down – sludge is expelled manually under the control of the operator.

4.271 With manual blow-down there is a risk of affecting the steam quality if this is undertaken at a time when there is a high demand for steam. For this reason, manual blow-down should be undertaken at times of light load, preferably when none of the sterilizers are operating. Continuous and automatic blow-down systems should be carefully managed to ensure they do not affect steam quality.

4.272 Guidance on blow-down can be found in the Health and Safety Executive’s INDG436 ‘Safe management of industrial steam and hot water boilers’.

4.273 Generator vessels constructed from stainless steel will be subject to the same risk of stress-corrosion cracking encountered in stainless steel sterilizer chambers. To minimize the risk, the manufacturer’s guidance on feed water quality should be followed.

4.274 A record of all tests and maintenance should be kept in the machine’s plant history file.

## Testing steam condensate samples

4.275 This section contains procedures for the testing of steam condensate samples. The tests for chemical purity and the test for bacterial endotoxins are derived from the tests for “Water for Injections” in the BP. A procedure for the field measurement of electrical conductivity is also given.

### Laboratory tests for chemical purity

4.276 Tests should be performed as defined in the European Pharmacopoeia.

### Field test for pH and electrical conductivity

4.277 The only tests of steam condensate or feed water that can be reliably carried out on site are tests for electrical conductivity and pH.

4.278 A portable conductivity meter is required, accurate to 1 % over a range that includes 1–30 µS $cm^{-1}$ with a resolution of 0.1 µS $cm^{-1}$. It should be temperature-compensated over the range 0–40 °C so that it gives readings standardised to 25 °C. The instrument should be designed to measure the conductivity of very pure water.

4.279 A portable pH meter will be required, accurate to 1 % over a range that includes 5–7 with a resolution of 0.1 pH units. It should be temperature compensated over the range 0–40 °C so that it gives readings standardised to 25 °C. The instrument should be designed to measure the conductivity of very pure water.

4.280 Commercially available meters usually have temperature compensation set at 2 % per °C either as standard or as a default value. The compensation effect is often User-adjustable over the range 0–5 % per °C, but unless there are unusual local circumstances (such as a particularly ubiquitous contaminant), the temperature compensation value should be set at 2 % per °C.

4.281 Several standard pH and conductivity reference solutions are also required, preferably with pH and conductivity values that bracket the expected value. A range of such reference solutions, including pure water reference solutions (also known as absolute water) is available commercially, standardised at 25 °C and traceable to national standard reference materials. The reference solutions should be allowed to equilibrate to room temperature in the area in which the tests will be conducted.

4.282 Determine steam condensate pH using a suitably calibrated pH meter.

4.283 Wash the meter probe with purified water BP or with the sample water. Measure the conductivity and pH of the reference solutions. Use the results to calibrate the meter in accordance with the manufacturer’s instructions.

4.284 Measure the temperature of the sample. For effective temperature compensation, this test is best carried out with both sample and reference solutions near a temperature of 25 °C. If the sample is hotter, allow it to cool until the temperature is approximately 25 °C.

4.285 Wash the meter probe either with purified water BP. Measure the conductivity of the sample.

4.286 The test should be considered satisfactory if the measured conductivity:

- does not exceed the value specified for steam in Table 5;
- is consistent within experimental errors with the value measured during validation.

4.287 If the conductivity has risen substantially from the value determined during validation, the cause should be identified and corrected.

### Drainage requirements

4.288 Trapped and vented, sealed to main drain. No open gulleys.

# 5. Operational Management

## Record-keeping

5.1 Complete and accurate records are an essential element in ensuring the safe and efficient functioning of sterilizers and compliance with regulatory requirements. Where electronic tracking systems (preferably compatible with GSI) are used to retain data, a routine audit should be carried out on databases to ensure information is securely stored and available to be easily retrieved where required.

5.2 The following principles, for quality control of sterilization processes. Records should:

- be original (not a transcription), indelible, legible and dated;
- be made concurrently with the performance of each operation and test;
- identify the person recording the data as well as the person checking the data or authorizing continuation of processing;
- be detailed enough to allow a clear reconstruction and understanding of all relevant procedures performed;
- allow tracing of all successive steps and identify the interrelationships of dependent procedures, products and waste materials;
- be maintained in an orderly fashion permitting the retrieval of data for a period consistent with dating periods (shelf life) and legal requirements;
- indicate that processing and testing were carried out in accordance with procedures established and approved by management;
- if necessary, allow a prompt and complete recall of any particular batch;
- show the lot numbers of materials used for making up specified batches of products.

5.3 The system recommended in this guidance requires two sets of records to be kept for each sterilizer:

- a plant history file;
- a sterilizer process log.

5.4 The sterilizer records are the responsibility of the User. They should be made available to any other personnel who need to use them. This will include the AE(D), AP(D), CP(D), CP(PS), the Microbiologist and Infection Control.

### Sterilizer plant history file

5.5 The plant history file contains engineering records of the sterilizer installation. It should be kept throughout the life of the sterilizer. Examples, of the information that should be kept in the plant history file include:

- identification of the sterilizer;

- names, addresses and telephone numbers of the sterilizer manufacturer, owner and key personnel (User, AE(D), AP(D), CP(D), CP(PS), Microbiologist);
- dates of installation and commissioning;
- validation procedures;
- validation reports (including PQ reports for each loading condition);
- copies of validation summary sheets;
- copy of any maintenance contract;
- planned maintenance programme including detailed procedures for all maintenance tasks;
- records of maintenance, both scheduled and unscheduled, sufficient to show that all examinations, tests and checks have been carried out;
- manuals supplied by the manufacturer;
- documentation for any software used for control or instrumentation (including the name of an agent where the source codes may be obtained should the manufacturer cease trading);
- the written scheme of examination for any pressure vessel;
- reports by the CP(PS) in respect of pressure systems;
- data from periodic tests carried out by the CP(D);
- copies of data from the periodic tests carried out by the User (kept in the sterilizer process log);
- records of any defects found on the sterilizer and corrective action taken;
- records of any modification made to the sterilizer;
- references to the plant history files for the test instruments used in the validation and periodic tests;
- specifications for the operating cycles;
- sterilizer capacity, chamber size in litres;
- control system fitted and software serial code and version number;
- recorder/independent monitor fitted, make model and type and software serial code and version number;
- any IT systems fitted or tracking system details;
- last test date, whether annual or quarterly thermometric test.

### Sterilizer process log book

5.6 The sterilizer process log book contains information required for routine operation of the sterilizer and records relevant to each cycle. It should contain the following information:

- identification of the sterilizer;
- names, addresses and telephone numbers of the sterilizer manufacturer, owner and key personnel (User, AE(D), AP(D), CP(D), CP(PS), Microbiologist);
- names of authorised Operators;
- written procedures for all duties to be carried out by the Operators;
- full operating instructions;
- copies of validation summary sheets (see Section 3 'Validation and verification of the laboratory sterilizer');
- data from the periodic tests carried out by the User;
- records of routine housekeeping carried out by the User (see paragraph 5.14 'Planned maintenance programme');
- specifications for the operating cycles for which the sterilizer has been validated, defined by the settings for the cycle variables;
- specifications for the loading conditions for which the sterilizer has been validated, defined by the nature and number of load items, items of chamber furniture, and their distribution within the chamber.

5.7 The following information should be noted for each batch processed by the sterilizer:

- the name of the Operator;
- the date and time of the start of the cycle;
- the cycle number;
- a reference to the loading condition;
- a reference to the operating cycle;
- a specification of any preconditioning, conditioning or degassing process;
- reference number of the Master Processing Record (MPR);
- values of cycle variables needing observation and noted by the Operator during the cycle;
- confirm whether or not the cycle was satisfactory;
- sterilizer identification;
- batch number.

5.8 The Batch Processing Record (BPR) for each cycle should be filed in such a way that it can be readily retrieved for inspection. Before filing it should be clearly marked with the following:

- sterilizer identification;

- date;
- cycle number;
- batch number;
- reference number of the MPR;
- confirm whether or not the cycle was satisfactory.

## Maintenance

5.9 Means of ensuring that a sterilizer is fit for its intended purpose will include the validation and testing programme specified in Section 3 'Validation and verification of the laboratory sterilizer', and also the programme of planned maintenance as described in this section.

5.10 The philosophy of maintenance and testing embodies two main principles to ensure that the required standards of performance and safety are met and maintained:

- all sterilizers are subject to a carefully planned programme of tests to monitor their performance;
- all sterilizers are subjected to a planned programme of preventative maintenance.

5.11 The sterilizer manufacturer defines the maintenance requirements in their instructions for use. Health Board expertise on the maintenance of sterilizers is available at three levels:

- the AP(D);
- the CP(D);
- the AE(D).

5.12 Refer to SHTM 01-02 Part A for roles and responsibilities which describes these three roles.

5.13 The testing of sterilizers is dealt with in Section 3 'Validation and verification of the laboratory sterilizer.'

## Planned maintenance (PM) programme

5.14 The planned maintenance programme should be designed according to the following principles:

- all parts of the sterilizer that are vital to correct functioning or safety should be tested at weekly intervals, meaning:
  - there is no need to test components individually in those cases where any malfunction will be revealed by the periodic tests outlined in Section 3 'Validation and verification of the laboratory sterilizer', for weekly or more frequent intervals;

  - where the correct functioning of important components is not necessarily verified by the periodic tests prescribed for the sterilizer, those components should be individually tested each week and reference to testing them should be included in the schedules of maintenance tasks. This applies, for example, to door interlocks that might only have their safety function activated when there is an abnormal condition;

- the maintenance programme should include, at appropriate intervals, those tasks such as lubrication and occasional dismantling of particular components (such as pumps) necessitated by normal good practice, manufacturer's advice and experience. Apart from those tasks, the maintenance programme should concentrate on verifying the condition of the sterilizer and its components by means of testing and examination without dismantling. Parts that are working correctly should not be touched unnecessarily;
- maintenance should be carried out under a quality system such as BS EN ISO 9001:2015. Spares fitted to sterilizers constructed under a quality system should be sourced from a similarly approved quality system.

### Design of planned maintenance (PM) programme

5.15 The PM programme recommended by the manufacturer should be used when it is available. The maintenance programme can be modified subsequently to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.

5.16 If no PM programme is available from the manufacturer, a maintenance programme should be drawn up in consultation with the AE(D), the AP(D) and CP(D).

5.17 Although the manufacturer can carry out certain inspection and maintenance procedures under the terms of the warranty, these might not constitute a full PM programme. The User should therefore ensure that the complete PM programme is carried out by the CP(D) (who can be an employee of the manufacturer) during the warranty period. The User should also implement any reasonable instructions given by the manufacturer during this period. Failure to carry out maintenance tasks and periodic tests could affect safety. It could also allow a contractor to place some, if not all, liability on to management. Where maintenance is carried out under a lump sum term contract, such failure is tantamount to a breach of contract and can give the contractor cause to terminate the contract, if desired.

5.18 A set of procedures should be developed for each model of sterilizer, each containing full instructions for a particular maintenance task.

5.19 The frequency with which each task will need to be carried out will depend, in part, on the usage level for the machine and also on the quality of the water / steam supplied to the machine. It might be necessary to adjust the programme so that work is carried out more frequently on machines that are heavily used and /or are supplied with hard water.

5.20 It is important that maintenance is planned so that the machine is out of service as little as possible. Maintenance should, where practicable, be scheduled to precede the periodic tests immediately as specified in Section 3 'Validation and verification of the laboratory sterilizer.'

5.21 Systematic records should be kept of all maintenance work undertaken both to demonstrate that the work has been carried out and also to facilitate a periodic review of the PM programme.

5.22 Maintenance and facilities management software packages can be used to maintain a full technical and financial history of the equipment.

### Review of a PM programme

5.23 The PM programme should be reviewed, either within a routine internal / external audit process or as part of the AE(D) assessment, at least annually, to ensure that the equipment is being fully maintained but without any unnecessary maintenance activity.

5.24 The review should aim to identify:

- the adequacy of maintenance records and compliance with the PM programme;
- any emerging defects;
- any changes required to the PM programme;
- any changes required to any maintenance procedure;
- any additional training required by maintenance personnel.

5.25 Proposed changes to the PM programme should be made in consultation with the manufacturer wherever possible.

### Modifications to sterilizer

5.26 Occasionally, modifications to the machine might be recommended by the manufacturer or by NHSScotland for reasons of efficacy and safety. The User should arrange for such modifications to be carried out within a reasonable period, normally coinciding with a scheduled maintenance session. The AE(D) should advise whether any revalidation is required depending on the nature of the modification.

### Warranty period

5.27 After the purchase of a new machine, the manufacturer can carry out certain inspection and maintenance procedures under the terms of the warranty. This might not be a full PM programme. If so, the User should ensure that the complete PM programme is carried out by the CP(D) during the warranty period.

The User should also follow any reasonable instructions from the manufacturer during the warranty period.

**Note:** Agreement must be established with the manufacturer and the User to establish the start date of the warranty period and a clear time of completion.

### Routine housekeeping

5.28 Certain maintenance tasks can be carried out by the User, or by the Operator under the User's supervision, and should be recorded in the sterilizer log. Examples of such tasks include:

- cleaning the strainer fitted in the opening to the chamber discharge line;
- wiping the door seal and inspecting it for damage;
- carrying out any door safety checks;
- weekly cleaning of chamber in accordance with manufacturer's instructions;
- visual checks that gauges and instrumentation are functioning correctly;
- checking loading equipment and locking mechanisms;
- checking clock times and cycle numbers agree and are correct.

### Pressure Systems Safety Regulations

5.29 Requirements of the 'Pressure Systems Safety Regulations' 2000 should be met. Advice should be sought from the CP(PS). The CP(PS) has three principal duties under the Regulations:

- advising on the scoped of the written scheme of examination for each pressure vessel;
- drawing up the written scheme of examination or certifying the scheme as being suitable;
- carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

5.30 The User should cooperate closely with the CP(PS) to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes. The written scheme may require certain examinations to be carried out more frequently than recommended by the manufacturer. Each scheme should include detailed procedures and frequency of examination and be regularly reviewed and updated.

### Features requiring special attention Chambers

5.31 Chambers should be maintained in good condition following manufacturer's instructions.

### Airtightness of the chamber

5.32 Airtightness of the chamber is of fundamental importance to the correct functioning of sterilizers. The door seal is the major potential source of leakage and should receive careful attention as advised by the manufacturer. The working life of door seals varies widely and it is essential that all seals are cleaned regularly. Door seals should be renewed with spares approved by the manufacturer at recommended intervals, or when there is any evidence of damage or deterioration.

5.33 Leaks may also occur in the following places:

- joints in pipework;
- connections to gauges;
- blanked-off connections for test gauges;
- entry points for temperature and pressure sensors (whether in use or blanked off);
- glands and seats of valves;
- cracks in chamber welds or platework;
- pinholes in pipework and fittings;
- holes in condenser tubes.

### Ancillary equipment

5.34 Ancillary equipment used in conjunction with the sterilizer should also be subject to planned maintenance in accordance with the manufacturer's instructions.

5.35 Where the maintenance of ancillary equipment is not the responsibility of the User, arrangements should be made to give the User reasonable notice of all periods of maintenance (whether scheduled or not) and of impending modifications to any part of the equipment. The User should also have access to maintenance records.

5.36 Examples of ancillary equipment include:

- all engineering services to the sterilizer, especially steam;
- dedicated steam generators (see paragraph 4.104 'Steam from a dedicated generator');
- sterilizer furniture (loading cart, racks and automatic loading equipment);
- room ventilation and local exhaust ventilation (see Scottish Health Technical Memorandum 03-01: 2014 'Ventilation for healthcare premises');
- Personal Protective Equipment (PPE);
- air compressors and potable water pumps.

5.37 Consideration should be given to the introduction of a permit to work system for the maintenance of ancillary equipment.

### Sterilizer Instruments

5.38 Instruments fitted to sterilizers should be maintained and calibrated in accordance with the manufacturer's instructions. Calibration should be verified at the normal sterilization temperature and pressure and at stable ambient temperatures. Any instrument found to read seriously in error or which is inconsistent, i.e. will not repeat satisfactorily, should be discarded, or repaired by the makers if practical and economical to do so. Instruments which do repeat satisfactorily but read slightly in error should be checked for zero and span; and, then adjusted to read correctly by a CP(D).

5.39 An instrument case should never be left open; broken glass should be replaced promptly.

5.40 The recorder/independent monitoring system is an essential monitor of the general functioning and performance of a sterilizer. Temperature measuring systems are subject to both inherent calibration errors and loss of calibration with use. As a consequence, temperatures read from a recorder/independent monitor should be regarded with caution and interpreted from knowledge of the characteristics of the particular recording system, the load and previous records.

5.41 It is essential that calibrated instruments and independent monitoring system are not adjusted unless absolutely necessary – any adjustments to be made by trained, competent staff in accordance with manufacturer's instructions using reference equipment having calibration traceable to the National Standard, and detail of adjustments recorded i.e. before (as found) / after readings. This is applicable to any process critical measurement e.g.; temperature, pressure, time.

5.42 Persons who change charts, print rolls and other consumables on recording instruments should be trained, made fully aware of the delicate nature of the instruments and authorised by the User.

### Returning a sterilizer to service

5.43 The User, with the assistance of the AE(D) and AP(D), should prepare an operational procedure for the return to service of a sterilizer after maintenance or testing. The procedure should include safety checks and some or all of the re-validation (yearly) tests specified in Section 3 'Validation and verification of the laboratory sterilizer.'

5.44 The CP(D) should certify that the work has been completed and that the sterilizer is safe to use. (See guidance on permits-to-work found in SHTM 01-02: 2020 Part A 'Permit-to-work system'.

5.45 The User should ensure that a sterilizer is not used for production until all required maintenance has been successfully completed.

### Door interlocks

5.46 Maintenance and inspection of door safety devices and door interlocking and chamber sealing systems should be carried out in accordance with the manufacturer's written instructions.

5.47 Security and settings of door safety switches and interlocks should be checked at the frequency recommended in the manufacturer's maintenance instructions or in Section 3, 'Validation and verification of the laboratory sterilizer.' The setting should be within the limits specified by the manufacturer.

# Appendix A: Saturated Steam Tables.

A.1 Saturated steam tables calculated according to EN 285:2015 clause 8.2.1.2.3; and, CEN ISO/TS 17665-2 2009 Annex C:

Equation: $T = 42.6776 + \left[-\frac{3.89}{(\log_e P - 9.48654)}\right] - 273.27$

Where:

T is the theoretical steam temperature, in degrees centigrade (°C);

P is the measured pressure, in mega Pascals (MPa);

$\log_e$ denotes natural logarithm (written as 'ln' in Standards)

−273.27 °C is used for the value of absolute zero (0 K) for derivation of Table A.1 and A.2

*Linear interpolation between data points may be used to derive intermediate values.*

## MEASURED PRESSURE → TEMPERATURE

| Measured Pressure (mbarA) | MPa | Temp (°C) |
|---|---|---|
| 1000 | 0.1 | 99.6 |
| 1050 | 0.105 | 101 |
| 1100 | 0.11 | 102.3 |
| 1150 | 0.115 | 103.6 |
| 1200 | 0.12 | 104.8 |
| 1250 | 0.125 | 106 |
| 1300 | 0.13 | 107.1 |
| 1350 | 0.135 | 108. |
| 1400 | 0.14 | 109.3 |
| 1450 | 0.145 | 110.3 |
| 1500 | 0.15 | 111.4 |
| 1550 | 0.155 | 112.4 |
| 1600 | 0.16 | 113.3 |
| 1650 | 0.165 | 114.2 |
| 1700 | 0.17 | 115.2 |
| 1750 | 0.175 | 116.1 |
| 1800 | 0.18 | 116.9 |
| 1850 | 0.1815 | 117.8 |
| 1900 | 0.19 | 118.6 |
| 1950 | 0.195 | 119.4 |
| 2000 | 0.2 | 120.2 |
| 2050 | 0.205 | 121 |
| 2100 | 0.21 | 121.8 |
| 2150 | 0.215 | 122.5 |
| 2200 | 0.22 | 123.3 |
| 2250 | 0.225 | 124 |
| 2300 | 0.23 | 124.7 |
| 2350 | 0.235 | 125.4 |
| 2400 | 0.24 | 126.1 |
| 2450 | 0.245 | 126.8 |
| 2500 | 0.25 | 127.4 |
| 2550 | 0.255 | 128.1 |
| 2600 | 0.26 | 128.7 |
| 2650 | 0.265 | 129.4 |
| 2700 | 0.27 | 130 |
| 2750 | 0.275 | 130.6 |
| 2800 | 0.28 | 131.2 |
| 2850 | 0.285 | 131.8 |
| 2900 | 0.29 | 132.4 |
| 2950 | 0.295 | 133 |
| 3000 | 0.3 | 133.5 |
| 3050 | 0.305 | 134.1 |
| 3100 | 0.31 | 134.7 |
| 3150 | 0.315 | 135.2 |
| 3200 | 0.32 | 135.7 |
| 3250 | 0.325 | 136.3 |
| 3300 | 0.33 | 136.8 |
| 3350 | 0.335 | 137.3 |
| 3400 | 0.34 | 137.8 |

| | | |
|---|---|---|
| 3450 | 0.345 | 138.4 |
| 3500 | 0.35 | 138.9 |
| 3550 | 0.355 | 139.4 |
| 3600 | 0.36 | 139.9 |

**Table A1**

A.2 Saturated steam tables calculated according to inverse equation EN 285:2015 clause 8.2.1.2.3, and CEN ISO/TS 17665-2:2009 Annex C:

## MEASURED PRESSURE → TEMPERATURE

| Measured Temperature (°C) | MPa | mbarA |
|---|---|---|
| 100 | 0.1014 | 1014 |
| 101 | 0.1051 | 1051 |
| 103 | 0.1128 | 1128 |
| 104 | 0.1168 | 1168 |
| 105 | 0.1209 | 1209 |
| 106 | 0.1251 | 1251 |
| 107 | 0.1295 | 1295 |
| 108 | 0.134 | 1340 |
| 109 | 0.1386 | 1386 |
| 110 | 0.1433 | 1433 |
| 111 | 0.1482 | 1482 |
| 112 | 0.1532 | 1532 |
| 113 | 0.1584 | 1584 |
| 114 | 0.1637 | 1637 |
| 115 | 0.1691 | 1691 |
| 116 | 0.1747 | 1747 |
| 117 | 0.1804 | 1804 |
| 118 | 0.1863 | 1863 |
| 119 | 0.1924 | 1924 |
| 120 | 0.1986 | 1986 |
| 121 | 0.2049 | 2049 |
| 122 | 0.2115 | 2115 |
| 123 | 0.2182 | 2182 |
| 124 | 0.2251 | 2251 |
| 125 | 0.2321 | 2321 |
| 126 | 0.2393 | 2393 |
| 127 | 0.2468 | 2468 |
| 128 | 0.2544 | 2544 |
| 129 | 0.2622 | 2622 |
| 130 | 0.2702 | 2702 |
| 131 | 0.2783 | 2783 |
| 134 | 0.3041 | 3041 |
| 135 | 0.3131 | 3131 |
| 136 | 0.3224 | 3224 |
| 137 | 0.3318 | 3318 |
| 138 | 0.3415 | 3415 |
| 139 | 0.3514 | 3514 |
| 140 | 0.3615 | 3615 |

**Table A2**

# References

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

## Standards/test specifications

**EN ISO 17665 - 1:2006** Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices.

**CEN ISO/TS 17665 - 2:2009** Sterilization of health care products. Moist heat. Guidance on the application of ISO 17665-1 CEN.

**PD ISO/ TS 17665 - 3:2013** Sterilization of health care products. Moist heat. Guidance on the designation of a medical device to a product family and processing category for steam sterilization. CEN.

**EN 285:2015:2006+A2:2015** Sterilization. Steam sterilizers. Large sterilizers. CEN.

**BS 2646-1:1993** Autoclaves for sterilization in laboratories. Specification for design, construction, safety and performance.

**BS EN 61010-2-040:2015** Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.

**BS 7671:2018** Requirements for Electrical Installations. IET Wiring Regulations.

**BS EN 1717:2000** Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow.

**BS EN ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories.

**BS 2646-1:1993** Autoclaves for sterilization in laboratories. Specification for design, construction, safety and performance.

**BS EN ISO 5667-3:2018** Water quality. Sampling. Preservation and handling of water samples.

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**BS 3970-1:1990** Sterilizing and disinfecting equipment for medical products. Specification for general requirements.

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Pressure Equipment Directive (2014/68/EU).

Machinery Directive (2006/42/EC.

## Scottish Water Regulations

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https://www.scottishwater.co.uk/byelaws

**The Public Water Supplies (Scotland) Regulations, 2014.**

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## Miscellaneous

**SAN (SC) 98/16 Sterilization of hospital laboratory waste: failure to achieve required conditions.**

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https://www.nhsscotlandprocurement.scot.nhs.uk/

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