Scottish Health Technical Memorandum 2010

(Part 4 of 6)

Operational management

Sterilization

NHS in Scotland, HEEU, August 1999

Executive summary

SHTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the following types of sterilizer in use in the National Health Service:

a. clinical sterilizers:

   (i) high-temperature steam sterilizers used for processing porous loads (including instruments and utensils wrapped in porous materials);

   (ii) high-temperature steam sterilizers used for processing aqueous fluids in sealed containers;

   (iii) high-temperature steam sterilizers used for processing unwrapped solid instruments and utensils;

   (iv) dry-heat sterilizers (hot-air sterilizers);

   (v) low-temperature steam (LTS) disinfectors and low-temperature steam and formaldehyde (LTSF) sterilizers;

   (vi) ethylene oxide (EO) sterilizers;

NOTE: LTSF sterilizers are considered to be disinfectors.

b. laboratory sterilizers:

   (i) high-temperature steam sterilizers used with one or more specialised operating cycles;

   (ii) culture media preparators.

Users who wish to employ processes not included here bear the responsibility of ensuring that the validation procedures comply with the principles outlined in Part 3 of this SHTM and that the intended operating procedures will ensure an efficacious process for the different types of load.

This SHTM is intended primarily as a guide for technical personnel, whether specialists in sterilizers and sterilization procedures or those responsible for maintenance and testing. It is also intended for those responsible for the day-to-day running of sterilizers, and will also be of interest to microbiologists, infection control officers, supplies officers, architects, estates managers and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the level of provision of sterilizers, is given in SHPN 13; *Sterile services department*. Guidance for laboratory installations can be found in SHPN 15; *Accommodation for pathology services*.

Although this edition of SHTM 2010 reflects established sterilizer technology, it is recognised that considerable scope exists for the utilisation of emerging technology in the management of sterilizers. This will be kept under review with the aim of introducing recommendations for such technology at the earliest opportunity so that the procedures essential for the efficient, safe and effective operation of sterilizers can be optimised.

Most of the British Standards for sterilizers which were applicable at the time of HTM 10; *Sterilizers* (1980), have been either withdrawn or radically revised. Some of them, in turn, are being replaced by European Standards which will be published during the currency of this edition of SHTM 2010. Some of these European Standards support new European Union Directives on medical devices which are having a major impact on sterilization. Where practicable, the information in this SHTM has been aligned with existing or anticipated standards and advice is offered where no standard has yet been formulated.

The sterilizers described in this SHTM may not be suitable, without modification, for safely processing articles infected with Hazard Group 4 pathogens. Design considerations for sterilizers intended to process articles infected with such organisms are discussed in Part 2.

NOTE: Information about Hazard Groups may be found in the HSC document, 'Categorisation of pathogens according to hazard and categories of containment' (second edition 1990) compiled by the Advisory Committee on Dangerous Pathogens.

The agents associated with transmissible spongiform encephalopathies (TSEs) are unusually resistant to sterilization and cannot be reliably inactivated by the standard procedures described here. Advice on the sterilization of items contaminated with TSE agents can be found in Appendix 2.

NOTE: Information about TSEs may be found in the HSE document, 'Precautions for work with human and animal Transmissible Spongiform Encephalopathies', compiled by the Advisory Committee on Dangerous Pathogens.

This volume substantially revises previous editions of Part 4.

Contents

1. General

Introduction

1.1 This Part of SHTM 2010 covers the maintenance and operation of the various types of sterilizer used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in sterilization has long been inconsistent and occasionally ambiguous. This SHTM introduces a set of terms consistent with new European Standards (see paragraph 1.18) which, it is hoped, will in time be adopted by sterilization workers in the NHS. The Glossary contains definitions referred to in this Part.

1.3 The Reference section contains full references for all the documents referred to in this Part and for selected documents of which the reader should be aware.

Legal frameworks for sterilization

1.4 There are now two legal frameworks governing the manufacture of sterile products. The long-standing legislation on medicinal products has now joined by new European Union (EU) Directives on medical devices.

1.5 Users should be clear as to whether the load items they intend to process in a sterilizer are classified as medicinal products or medical devices. Definitions for both may be found in the Glossary. While the practical requirements have much in common, their implementation is very different.

1.6 For the guidance given in this SHTM, the various types of sterilizer are presumed to be used primarily as follows (though there are exceptions):

a. for **medicinal products**: fluid sterilizers, dry-heat sterilizers;

b. for **medical devices**: porous load sterilizers, sterilizers for unwrapped instruments and utensils, dry-heat sterilizers, LTS disinfectors, LTSF sterilizers, EO sterilizers.

NOTE: Despite their name, LTSF Sterilizers are disinfectors.

1.7 Where a sterilizer is purchased with the intention of processing both medicinal products and medical devices, users should ensure that the requirements for both types of product are met.

Medicinal products

1.8 The manufacture and supply of medicinal products are controlled by a large body of legislation stemming from the EU Directives on medicinal products and enacted by the UK Medicines Acts and numerous Regulations. Further details can be found in Part 1 of this SHTM.

1.9 The requirements for the manufacture of medicinal products are set out in the 'Guide to good manufacturing practice for medicinal products' published in volume IV of, 'The rules governing medicinal products in the European Community'. This document is referred to as the "GGMP" in this SHTM.

1.10 The GGMP contains an Annex on the 'Manufacture of sterile medicinal products' which has considerable implications for the operation of sterilizers. Users considering using a sterilizer for the processing of medicinal products should consult the GGMP at an early stage.

1.11 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) whose address may be found in Appendix 1.

Medical devices

1.12 Part 1 of this SHTM discusses the three EU Directives on the manufacture and supply of medical devices, active implantable medical devices and in-vitro diagnostic medical devices. The first two directives are implemented in the UK by The Active Medical Devices Regulations 1992 and The Medical Devices Regulations 1994. General guidance on these directives and regulations may be found in MDA Directives Bulletin 8.

1.13 Annex I of the Medical Devices Directive lists a number of "essential requirements", among which the following are relevant to sterilization:

a. Section 7.2 requires that devices are "designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product." This has implications for the quality of steam used in sterilization processes, and for the efficacy of removal of gas residuals in LTSF and EO sterilization.

b. Sections 8.3 and 8.4 require that devices delivered in a sterile state:

   (i) "must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened";

   (ii) "must have been manufactured and sterilized by an appropriate, validated method".

c. Section 8.7 requires that the "packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition".

d. Section 13.3 sets out the requirements for the labelling of sterile packs.

e. Section 13.6 sets out requirements for the instructions for use which must accompany each device, including instructions in the event of the sterile pack being damaged.

1.14 Requirements for active implantable medical devices are similar, and users should consult the appropriate Directive and Regulations for details.

1.15 It is likely that all or most products for clinical use that are not classified as medicinal products will be classified as medical devices. Whether such medical devices are subject to the Regulations is a complex issue turning on the relationship between the producer and the end-user of the devices and is discussed in MDA Directives Bulletin 18.

1.16 Certain sterilizers used in a "medical environment" are regarded as "accessories" to medical devices, with the consequence that they are to be treated as medical devices in their own right. These machines, which are often (but not necessarily) transportable sterilizers designed for processing unwrapped instruments and utensils, are intended by their manufacturer for use with specific medical devices (such as surgical instruments or endoscopes) in accordance with the manufacturer's instructions for such devices.

1.17 The European Committee for Standardisation (Comité Européen de Normalisation, CEN) has prepared a number of European Standards on the manufacture of medical devices. These are known as "harmonised" standards. Compliance with a harmonised standard is considered to bring with it a legal presumption of compliance with the essential requirements of the Directive it supports. Official notification of European Standards supporting EU Directives is published in the *Official Journal of the European Communities* and in the London, Edinburgh and Belfast Gazettes. European Standards are published in the UK by the British Standards Institution with "BS EN" prefixes.

1.18 Although compliance with a harmonised standard is not the only way of complying with the directives, it is the simplest. Purchasers intending to process sterile medical devices in compliance with the directives should therefore ensure that their processes conform with one of the harmonised standards. The following harmonised standards on the validation and control of sterilization processes are discussed in this Part of this SHTM:

a. EN 556 covering the requirements for a medical device to be labelled "sterile";

b. EN 554 covering sterilization by "moist heat" (ie. steam);

c. EN 550 covering sterilization by ethylene oxide.

1.19 These standards are themselves supported by the following standards for the specification of sterilizers which are discussed in Part 2 of this SHTM:

a. EN 285 covering “large” porous load sterilizers;

b. EN 1422 covering ethylene oxide sterilizers.

1.20 There are no European Standards, as yet, for fluid sterilizers, sterilizers for unwrapped instruments and utensils, dry-heat sterilizers, low-temperature steam disinfectors, low-temperature steam and formaldehyde sterilizers or laboratory sterilizers. CEN technical committee TC102 is developing standards for “small” steam sterilizers which will cover certain porous load sterilizers and also sterilizers for unwrapped instruments and utensils. A list of European Standards specific to sterilization is given in the Reference section.

1.21 This edition of SHTM 2010 has been written while the new standards are in the course of development. While the guidance given here is designed to be broadly consistent with the emerging standards, SHTM 2010 should not be regarded as a substitute for the standards themselves when ascertaining compliance with EU Directives and the UK Regulations that implement them.

1.22 Guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency (MDA) whose address may be found in Appendix 1.

Quality systems

1.23 The European Standards referred to in this SHTM may be used alongside a quality system for the supply of sterile medical devices based upon the EN ISO 9000 series:

a. EN ISO 9001 and 9002 (formerly EN 29001 and 29002) describe the basic requirements for a quality system;

b. EN 46001 and 46002 describe particular requirements for the suppliers of medical devices.

1.24 Written procedures for the procurement, validation and management of sterilizers designed to support a quality system for the production of sterile goods will be found in Part 6, which should be obtained from the Stationery Office. Further guidance may be found in the ‘Guide to good manufacturing practice for National Health Service sterile services departments’ published by the Institute of Sterile Services Management and issued to the NHS as EL89(P)136.

Personnel

1.25 The following personnel are referred to in this Part of SHTM 2010. Further information, including qualifications and areas of responsibility, can be found in Part 1.

1.26 **Management** is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the sterilizer is employed.

1.27 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small, autonomous installations the user may take on this function.

1.28 The **User** is defined as the person designated by Management to be responsible for the management of the sterilizer.

1.29 In a hospital the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the Production Manager (see paragraph 1.37) in charge of the entire manufacturing process.

1.30 The **Competent Person (Pressure Vessels)** is defined as a person or organisation designated by Management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems and Transportable Gas Containers Regulations 1989 (see Part 1). The shorter term “Competent Person” is used in this SHTM.

1.31 The **Authorised Person (Sterilizers)** is defined as a person designated by Management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “Authorised Person” is used in this SHTM.

1.32 The Institute of Healthcare Engineering and Estate Management (formerly the Institute of Hospital Engineering) is the registration authority for Authorised Persons. The address is given in Appendix 1.

1.33 Guidance on the appointment of an Authorised Person is given in Appendix 4.

1.34 The **Test Person (Sterilizers)** is defined as a person designated by Management to carry out validation and periodic testing of sterilizers. The shorter term “Test Person” is used in this SHTM.

1.35 The **Maintenance Person (Sterilizers)** is defined as a person designated by Management to carry out maintenance duties on sterilizers. The shorter term “Maintenance Person” is used in this SHTM. See paragraphs 4.5 – 4.8 for more information.

1.36 The **Microbiologist (Sterilizers)** is defined as a person designated by Management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. The shorter term “Microbiologist” is used in this SHTM.

1.37 The **Production Manager** is defined as a person designated by Management to be responsible for the production of medicinal products.

1.38 The **Quality Controller** is defined as a person designated by Management to be responsible for quality control of medicinal products with authority to establish, verify and implement all quality control and quality assurance procedures. (A similar role may be defined for the manufacture of medical devices, but this is rarely the practice in hospitals.)

1.39 The **Laboratory Safety Officer** is defined as a person designated by Management to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety issues, and ensuring compliance with safety legislation and guidelines.

1.40 An **operator** is defined as any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties.

1.41 The **manufacturer** is defined as a person or organisation responsible for the manufacture of a sterilizer.

1.42 The **contractor** is defined as a person or organisation designated by Management to be responsible for the supply and installation of the sterilizer, and for the conduct of the installation checks and tests. The contractor is commonly the manufacturer of the sterilizer.

Safety

1.44 Guidance on the safe operation of the various types of sterilizer is given in Chapters 5 to 12. Guidance on safe practices in the testing of sterilizers is given in Part 3 of this SHTM.

1.45 Low-temperature steam and formaldehyde (LTSF) sterilizers and ethylene oxide (EO) sterilizers both use toxic gases in the sterilization process. Occupational exposure to formaldehyde and EO is controlled by the Control of Substances Hazardous to Health Regulations 1994. Maximum exposure limits are set out in the annual Guidance Note EH40, ‘Occupational exposure limits’, published by the Health and Safety Executive (see Reference section). At the time of writing (1998) the limits are as shown in Table 1. These limits are statutory maxima but should not be regarded as

representing a safe working exposure; employers have a legal obligation to ensure that the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

Table 1: Maximum exposure limits for atmospheric formaldehyde and ethylene oxide

Gas	Short-term maximum exposure limit		Long-term maximum exposure limit	
	[ppm]	[mg m^{-3}]	[ppm]	[mg m^{-3}]
Formaldehyde	2	2.5	2	2.5
Ethylene oxide	–	–	5	9.2

The short-term maximum exposure limit (STMEL) is the average exposure over any 15-min period.

The long-term maximum exposure limit (LTMEL) is the exposure over any 24-h period expressed as a single uniform exposure over an 8-h period.

COSHH does not specify a STMEL for EO. In the above table the STMEL is deemed to be three times the LTMEL in accordance with the recommendations of the Health and Safety Executive.

Source: COSHH Regulations 1999, HSE Guidance Note EH40 (1999).

1.46 The COSHH Regulations 1999 also introduce new controls on biological agents which are of relevance to users of laboratory sterilizers.

2. Operational management – an overview

Introduction

2.1 Quality control and safety of a sterilization process are ultimately dependent upon untiring vigilance. The type of process, and the details of the operating cycle, should be selected with due regard to the nature of the product. Items for sterilization should be properly cleaned, packaged and assembled in accordance with procedures established during performance qualification. Every production cycle should be monitored and carefully documented. Products should not be released until predetermined conditions have been met. The sterilizer itself should be subject to preventative maintenance and periodic testing. In these areas vigilance will necessitate skilful personnel, fully trained in the operation of sterilizers.

2.2 For assurance on these points, responsibility rests ultimately with the user, supported by the Authorised Person, the Competent Person, the Test Person, the Maintenance Person and the Microbiologist.

Maintenance

2.3 EN 554 (steam sterilization) and EN 550 (EO sterilization) make the following requirements for the maintenance of sterilizers:

a. preventative maintenance shall be planned and performed in accordance with documented procedures;

b. the procedure for each planned task and the frequency at which it is carried out shall be specified and documented;

c. the sterilizer shall not be used to process medical devices until all maintenance tasks have been satisfactorily completed and recorded;

d. records of maintenance shall be retained as specified in 4.16 of EN ISO 9001 or in 4.15 of EN ISO 9002;

e. the maintenance scheme, maintenance procedures and maintenance records shall be reviewed periodically by persons designated by management.

2.4 The guidance in Chapter 4 puts these requirements into practice.

Safety precautions

2.5 Part 1 of this SHTM discusses the principal health and safety legislation applying to sterilization.

2.6 HSE guidance note PM73: 'Safety at autoclaves', applies to steam sterilizers and emphasises the guidance contained in this memorandum.

2.7 Any equipment issued to operators should comply with the Provision and Use of Work Equipment Regulations 1992. Guidance may be found in the HSE document 'Work equipment' (L22).

2.8 Users should note the requirements of The Manual Handling Operations Regulations 1998 with regard to loading and unloading sterilizers. Guidance may be found in the HSE document 'Manual handling' (L23). Reference should also be made to the 'Lifting Operation and Equipment Regulations 1998 (LOLER)'.

2.9 Access to sterilizer loading areas, plant rooms and equipment should be restricted to those entitled to be there.

Hazards associated with sterilization

2.10 Attention is drawn to the following hazards which may be encountered in the practice of sterilization:

a. the hazard of scalding from escaping steam;
b. the high temperatures (up to 200°C) at which sterilizers are operated;
c. the stored energy hazards associated with the operation of pressure vessels contained within steam and EO sterilizers;
d. the stored energy hazards associated with the pressurised containers in which EO gas is transported;
e. the explosive hazards associated with the sterilization of fluids in sealed glass containers;
f. the toxic properties of formaldehyde gas used in LTSF sterilizers;
g. the toxic and explosive properties of ethylene oxide gas used in EO sterilizers;
h. the infection hazard associated with pathogens that may be handled by personnel using certain laboratory sterilizers;
i. the hazard of infection to patients and staff by the inadvertent release of an unsterile load due to inadequate quality control;
j. the hazard to patients arising from residual ethylene oxide or formaldehyde present in the product;
k. the hazards associated with the handling of heavy and hot loads while loading and unloading sterilizers.

2.11 More detailed information about each process is given in Chapters 5 to 12.

Safety of pressure vessels

2.12 The majority of sterilizers discussed in this SHTM contain pressure vessels that are subject to the Pressure Systems and Transportable Gas Containers Regulations 1989. Users are reminded of the following safety measures:

a. *door interlocking safety devices* are designed to prevent:

   (i) the pressurisation of the chamber before the door is secured;

   (ii) the uncontrolled release of chamber contents while the chamber is under pressure;

b. any *escape of steam* should be reported immediately and appropriate action taken;

c. arrangements for regular *systematic inspection and maintenance* must be adhered to;

d. all operators must be adequately *trained and supervised* for their allotted tasks;

e. documented *operating procedures* must be followed at all times.

Unloading

2.13 During the cooling stage the temperature of the load may be much higher than that in the chamber. Containers of liquid could be pressurised and may explode; liquids spilled on unloading may cause scalding. Users should take note of the following safety measures:

a. *thermal door-locks* are fitted to sterilizers designed to process fluids, to prevent the door mechanism being released while the temperature of the fluid is too high;

b. a *cooling timer* may be used in addition to a thermal door-lock;

c. *adequate training* should ensure that the operator is aware of the nature of the load and any hazards associated with it;

d. operators should wear appropriate *personal protective equipment* in addition to their normal working clothes (see paragraph 2.14);

e. reaching into a hot sterilizer can be hazardous; consideration should be given to the provision of a *load transfer* system such as sliding shelves or a carriage and trolley.

Personal protective equipment

2.14 Operators and maintenance personnel should be issued with appropriate personal protective equipment (PPE) complying with the Personal Protective Equipment at Work Regulations 1992 (see Part 1 of this SHTM). The choice of PPE should follow a suitable assessment of risk for each type of sterilizer. Examples of PPE that may be required, in addition to normal working clothes, include:

a. impervious apron to protect against liquid spills;

b. heat-resistant gloves for handling hot loads;

c. protective gloves for handling potentially infected material;

d. safety shoes for use when loading and unloading sterilizers;

e. eye and face protection for use when removing glass containers from a sterilizer;

f. respiratory protective equipment and protective clothing for emergency use with EO sterilizers (see paragraphs A3.35–A3.48).

2.15 PPE should always be regarded as a “last resort” to protect against risks to health and safety; engineering controls and safe systems of work should always be considered first. Guidance on the selection of PPE may be found in ‘Personal protective equipment: guidance on regulations’ (L25) published by HSE.

Compatibility of load and process

2.16 The user should ensure that the load is suitable for the process to which it is to be exposed.

2.17 When selecting a process for a given item, the user should consider the following questions in conjunction with the advice of the manufacturer of the item:

a. *Is sterilization required?* In some cases, where the infection risk is intermediate to low, disinfection or cleaning may be sufficient. The guidance in Table 2 should be followed.

b. *Will the item be damaged by exposure to the process?* Several common items cannot withstand the moisture of steam sterilization or the high temperatures of dry-heat sterilization.

c. *Will the item fail to be sterilized by exposure to the process?* Even if an item can withstand the process it may not be sterilized if, for example, steam cannot penetrate narrow tubing.

d. *Is the process excluded by health and safety considerations?* Some medical devices should not be exposed to formaldehyde or ethylene oxide.

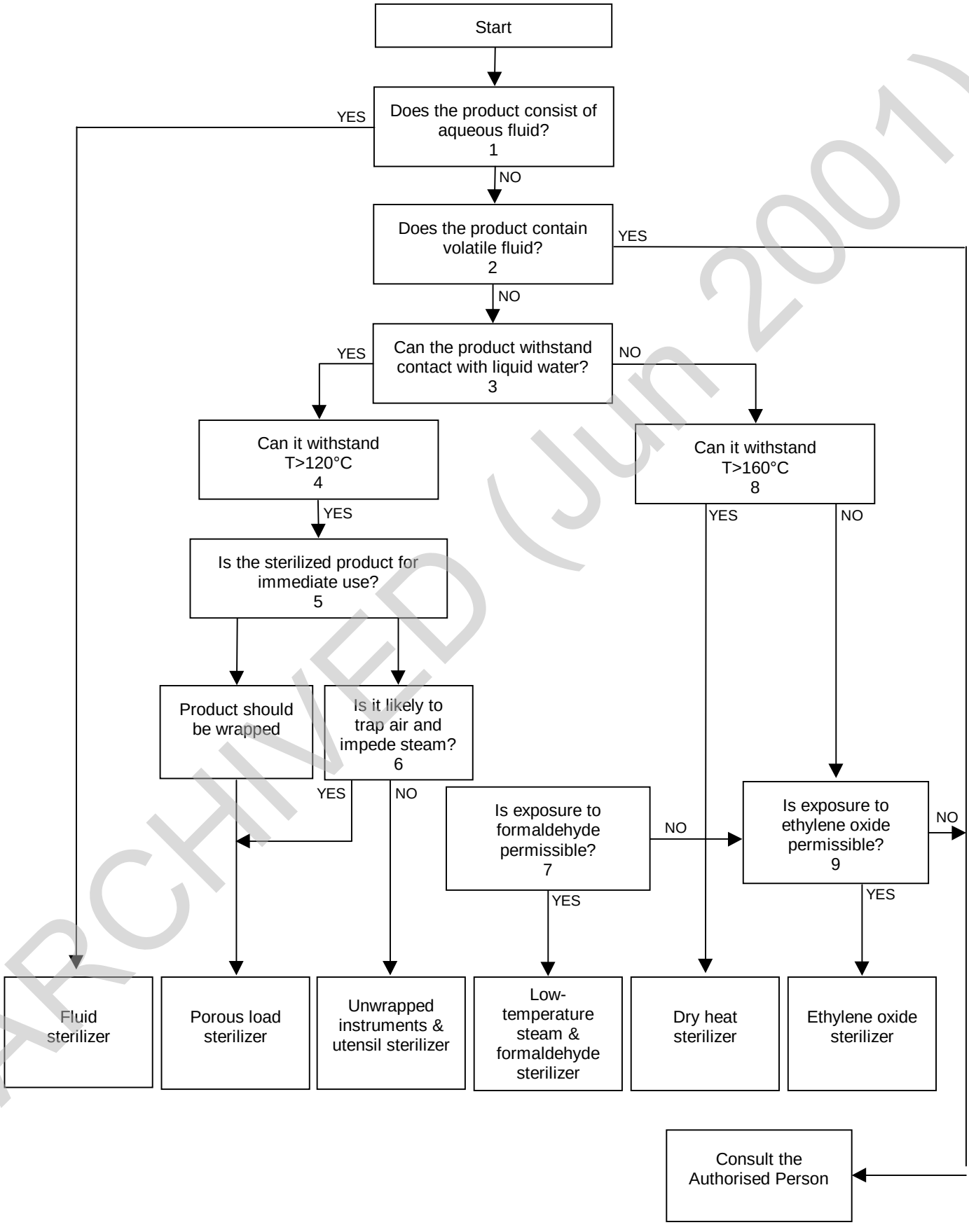
Table 2: Recommended processes for the decontamination of medical devices according to risk of infection

Infection risk	Application	Recommendation
High	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area.	Sterilization
Intermediate	Items in contact with intact skin, mucous membranes or body fluids, particularly after use on infected patients or prior to use on immuno-compromised patients.	Sterilization or disinfection. Cleaning may be acceptable in some agreed situations.
Low	Items in contact with healthy skin or mucous membranes or not in contact with patient.	Cleaning

Adapted from: *Sterilization, disinfection and cleaning of medical equipment*, MDA 1993.

2.18 The flow-chart in Figure 1 will assist users in selecting an appropriate sterilization process. The Authorised Person should be consulted in cases of doubt.

Figure 1: A guide for the selection of a sterilization process



Notes to Figure 1

Figures refer to boxes on the flow chart.

1 *Does the product consist of aqueous fluid?*

If the product is a water solution, then it must be processed in a fluid sterilizer. Bottles or other containers holding aqueous fluids must not be placed in any other kind of sterilizer.

2 *Does the product contain volatile liquid?*

None of the processes discussed in this SHTM are suitable for volatile liquids other than water.

3 *Can the product withstand contact with liquid water?*

All steam sterilizers produce condensate on any surface which is in contact with steam. Water will therefore condense inside hollow items, within unsealed containers and inside porous packaging. Porous packaging is likely to become saturated. Packaging designed for steam sterilizers will not be damaged by such exposure.

4 *Can it withstand temperatures in excess of 120ºC?*

High-temperature steam sterilizers operate at sterilization temperatures of 121ºC, 126ºC or 134ºC, with the highest temperature preferred. Most items of glass or metal will withstand such temperatures, but items with plastic components may not. Some items constructed of two or more different metals may distort at these temperatures and some medicinal products may be damaged. In exceptional cases lower temperatures may be used provided the bioburden and the required sterility assurance level are known.

5 *Is the sterilized product for immediate use?*

If the product is to be used in a controlled medical environment immediately after the chamber door has been opened, then it need not be wrapped and a sterilizer for unwrapped instruments and utensils is acceptable. Otherwise the item should be wrapped and processed in a porous load sterilizer.

6 *Is it likely to trap air and impede steam?*

Items which are for immediate use may nevertheless require a porous-load sterilizer if they are likely to trap air and impede the penetration of steam. See paragraph 7.13 for further guidance.

7 *Is exposure to formaldehyde permissible?*

Certain items should not be processed by LTSF for reasons of health and safety. See paragraph 10.29.

8 *Can it withstand temperatures in excess of 160ºC?*

Products that cannot withstand contact with liquid water may be processed in a dry-heat sterilizer if they can withstand the high temperatures and prolonged holding times.

9 *Is exposure to ethylene oxide permissible?*

Certain items should not be processed by EO for reasons of health and safety. See paragraph 11.18.

2.19 Processes using toxic gases (LTSF and EO) are a last resort and should not be used for items which could be sterilized or disinfected by another method. Many heat-sensitive items are currently processed by LTSF or EO where LTS disinfection would have been adequate and safer.

Process development

2.20 Once a basic process has been selected, users should consider whether the standard operating cycle needs to be modified to cope with specific load items. For example, delicate items may not be able to withstand the rapid pressure changes that take place in the chamber of a porous load sterilizer and the rate of change of pressure may need to be reduced.

2.21 If the cycle variables are modified from the values used during validation, revalidation (and possibly repeat validation) will be necessary (see Part 3 of this SHTM).

“Single-use” medical devices

2.22 Many medical devices are intended by their manufacturers to be used once only and then discarded. However, it is not uncommon for hospitals to clean, sterilize and reuse the more expensive of these devices (such as cardiac catheters) where it is considered safe and economical to do so.

2.23 Users considering reprocessing single-use items should note the following points:

a. the construction of many such devices, often with long and narrow lumens, makes them difficult to clean with any degree of confidence;

b. if the efficacy of cleaning procedures cannot be assured then neither can the sterilization process;

c. where devices have been sterilized by radiation, subsequent sterilization by EO can lead to structural weakening of certain plastic components;

d. the user will have no redress from the manufacturer for any subsequent failure of the device, whatever the cause.

2.24 The MDA gives the following advice on reprocessing.

An organisation that reprocesses a single-use device for reuse against the instructions of the original manufacturer, and then supplies it to other organisations, will be returning the device to the market and it is likely to be regarded as a manufacturer in its own right, with all of the obligations that entails. This is because the organisation is considered to be placing a new device on the market under its own name and must therefore meet the full obligations of the Medical Devices Directive.

If single-use devices are reprocessed for use solely within the organisation, this would not be seen as placement upon the market. Hence the requirements of the Directive, so far as they relate to manufacture, would not apply.

2.25 Further information may be found in MDA Device Bulletin 9501.

Cleaning

2.26 Cleaning and drying of reusable load items before packaging and sterilization are essential, since the efficacy of the process will be reduced if soiling protects micro-organisms from exposure to the sterilant. All items should therefore be scrupulously clean. Washer-disinfectors are suitable for preparing many such items for sterilization and guidance may be found in SHTM 2030.

2.27 Discard items and materials should not be cleaned.

Packaging

2.28 ENs 550 and 554 require the packaging specification to be part of the definition and documentation of the sterilization process. The user should therefore ensure that each load is packaged and assembled in accordance with documented procedures validated during performance qualification.

2.29 When handled in accordance with instructions the packaging should protect the product from physical damage and maintain the sterility of the product up to the point of use.

2.30 The packaging should not inhibit the efficacy of the process by, for example, hindering the removal of air or the penetration of steam, impeding the conduction of heat to the load, outgassing, altering the humidity in the chamber, or absorbing chemical sterilants.

2.31 The packaging should be able to withstand the sterilization process. It may be necessary to carry out preliminary tests on the product and its packaging in order to determine the levels and rates of change of temperature, pressure and other cycle variables which start to cause unacceptable changes in the performance qualities of the product or its packaging.

2.32 Packaging materials should be stored in the conditions recommended by the manufacturer. Packaging material that has become dehydrated, for example, may adversely affect the efficacy of an EO sterilization process.

2.33 Specifications for packaging materials may be found in EN 868. Extensive guidance on packaging is given in Part 5 of this SHTM, with a brief summary in Chapters 5 to 12 of this Part.

Performance qualification

2.34 Performance qualification (PQ) is defined as the process of obtaining and documenting evidence that the sterilizer, as commissioned, will produce acceptable goods when operated in accordance with the process specification.

2.35 A loading condition is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the top shelf of the chamber constitutes a different loading condition from an identical load placed on the bottom shelf. The specification is part of the PQ report for that loading condition. Note that the specification may require load items to be arranged in precise positions or permit them to be placed randomly in the chamber.

2.36 The extent of the PQ required will depend on the type of sterilizer and the nature of the load. All users should adopt the following procedure for every sterilizer.

a. Establish a list of the distinct loading conditions to be processed in the sterilizer. Each production load should correspond to one of the listed loading conditions.

b. 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 commissioning (see Part 3 of this SHTM).

c. Where the loading condition is a lesser challenge than the commissioning loads, the results of the commissioning tests may be used as PQ data.

d. Where the loading condition is a greater challenge than the commissioning loads, PQ tests will be required as specified in Part 3 of this SHTM.

2.37 The user is responsible for deciding which loading conditions require PQ tests. The user is recommended to seek advice as follows:

a. sterilizers to be used for medicinal products – from the Quality Controller and the Test Person;

b. LTSF and EO sterilizers – from the Microbiologist and the Test Person;

c. all other sterilizers – from the Test Person.

2.38 The flow chart in Figure 2 will assist users in determining whether PQ tests are required or whether data from the commissioning tests will be sufficient. In cases of doubt, advice should be sought from the Authorised Person.

2.39 PQ tests are normally performed as part of the initial 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. Detailed instructions for carrying out PQ tests are given in Part 3 of this SHTM.

2.40 In some cases a new load may be adequately represented by one of the existing loading conditions for which a PQ report exists. Further PQ tests will not then be necessary. Where a new load is not covered by an existing PQ report, full PQ tests as specified in Part 3 should be conducted.

2.41 When designing a new loading condition, it is important that the correct packaging is selected and specified along with the load itself. The packaging specification should not then be altered in subsequent production cycles without repeating the PQ procedure unless the loading condition with new packaging can be demonstrated to be equivalent to one covered by an existing PQ report.

Position of PQ sensors

2.42 Temperature sensors should be placed as described in Chapter 8 of Part 3 of this SHTM. In selecting which load items require sensors, the following observations should be noted:

a. small load items will heat up and cool down faster than large items;

b. load items placed near the steam inlet port will heat up faster than those placed further away.

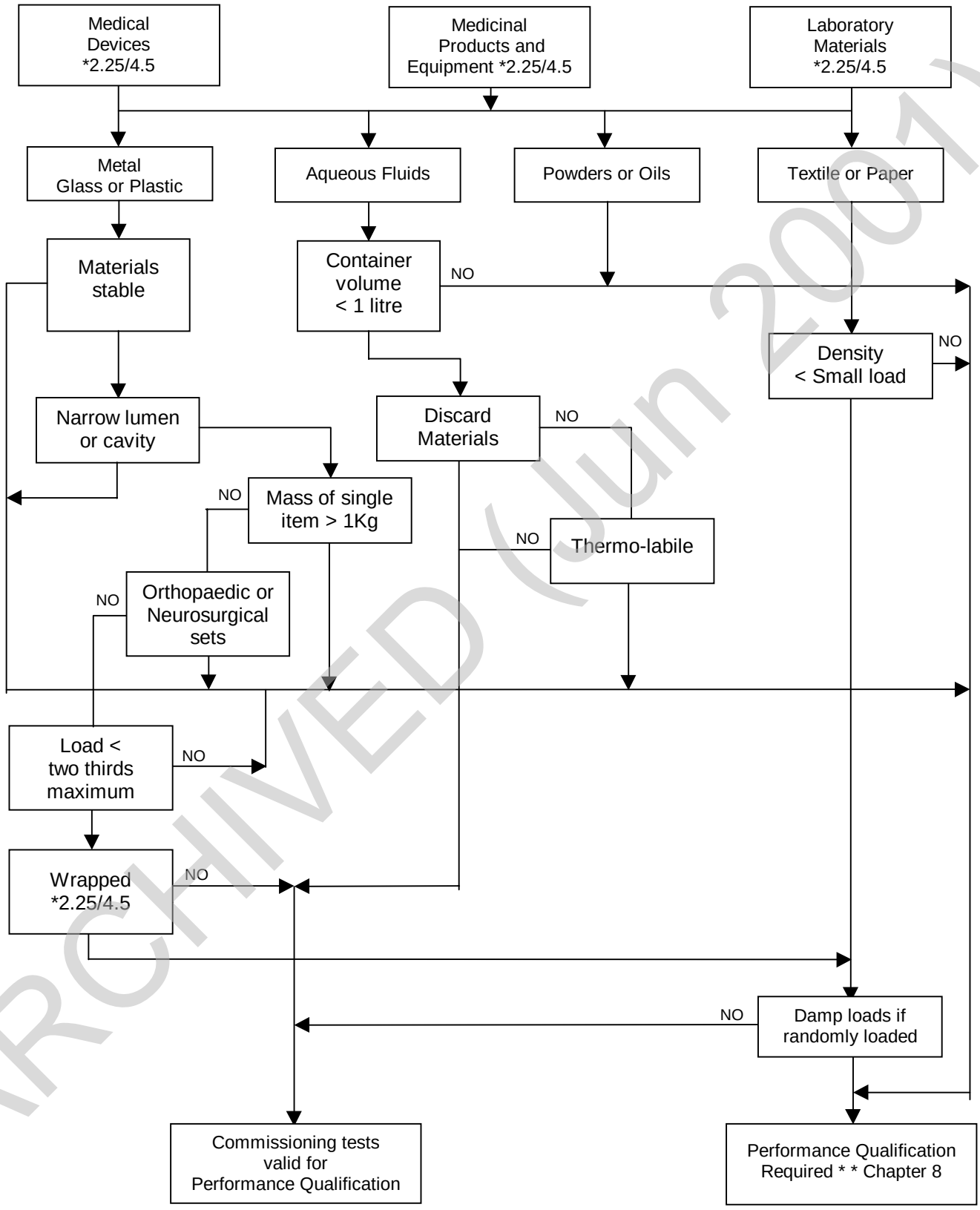
Cycle variables

2.43 For the purposes of this SHTM the following definitions have been adopted.

2.44 The **cycle variables** are the physical properties, such as time, temperature, pressure, humidity and sterilant gas concentration, that influence the efficacy of the sterilization process.

Figure 2: Performance qualification assessment guide

VALIDATION



***Refer to part 3 for clause references**

**** A PQ for a load with a greater challenge to the process may be used providing product efficacy is not**

2.45 Most operating cycles have a stage in which the load is exposed to the sterilization (or disinfection) conditions for a specified length of time. This period is known as the **holding time**.

2.46 The **sterilization conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

2.47 The holding time is preceded by a period in which the sterilization conditions are present in the chamber but not yet present throughout the load. This is known as the **equilibration time**.

2.48 Together, the equilibration time and the holding time constitute the **plateau period**. While the duration of the plateau period can always be determined from the recorded chamber temperature, the equilibration and holding times cannot be distinguished unless the temperature in the part of the load that is slowest to reach the sterilization temperature is also being recorded or measured.

2.49 Certain LTSF sterilizers may achieve sterilization by exposing the load to a series of pulses of formaldehyde rather than a continuous holding time.

2.50 For EO sterilizers the plateau period is equivalent to the **gas exposure time**. The holding time cannot be determined by thermometry alone.

2.51 For steam and dry-heat sterilizers, the sterilization conditions are specified by a **sterilization temperature band**, defined by a minimum acceptable temperature, known as the **sterilization temperature**, and a maximum allowable temperature. The higher the sterilization temperature the shorter the holding time and the more rapidly the cycle is completed. A sterilization temperature band can also be quoted for LTSF and EO sterilizers, but since these processes depend primarily upon chemical action such a band is only a partial specification of the sterilization conditions. Bands for the different types of process are listed in Table 3. See Table 9 (Chapter 12) for recommendations for laboratory sterilizers.

2.52 Whereas the bands for high-temperature steam are normally 3°C wide, the 134°C band is anomalous in that the maximum allowable temperature may be either 137°C or 138°C. In BS 3970, 138°C is cited both for porous-load sterilizers (Part 3) and transportable sterilizers for unwrapped instruments and utensils (Part 4). At the time of writing these Parts are still current and existing sterilizers are largely designed to operate with a maximum allowable temperature of 138°C.

Table 3: Recommended sterilization temperature bands

	High-temperature steam			Dry heat			LTS	LTSF	Ethylene oxide
Sterilization temperature [°C][a]	121	126	134	160	170	180	71[b]	71[c]	30-56
Maximum allowable temperature [°C]	124	1029	137[d]	170	180	190	80	80	[e]
Minimum holding time [min]	15	10	3	120	60	30	10	180[f]	[g]

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

b. Disinfection temperature.

c. This temperature is conventional but others may be used.

d. See paragraph 2.52.

e. For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.

f. For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses of formaldehyde required to achieve sterilization.

g For EO, the "gas exposure time" is determined for each sterilizer by microbiological methods during commissioning but is typically 2-7 hours depending upon sterilization temperature and gas concentration.

2.53 However, EN 285, which is to replace BS 3970: Part 3, specifies that for "large" porous-load sterilizers all bands should be 3°C wide, implying a maximum allowable temperature of 137°C. This is the temperature adopted in this SHTM. Unfortunately, the proposed EN on "small" sterilizers (essentially transportables) permits a width of 4°C for all bands where unwrapped instruments and utensils are to be processed. The existing and proposed requirements are summarised in Table 4. The recommendation of this SHTM is that a width of 3°C should be adopted for all sterilization bands.

2.54 The 143°C band listed in Table 4 has been rarely used in the NHS because any time advantage offered by the short holding time is outweighed by the longer heating and cooling times.

2.55 Settings for the automatic controller will be determined during performance qualification. Generally these will consist of a chamber temperature within the sterilization temperature band and a plateau period designed to accommodate the equilibration time and the holding time. Guidance on the setting of the cycle variables will be found in Chapters 5 to 12.

Table 4: Sterilization temperature bands for high-temperature steam specified by British and European Standards

	Maximum allowable temperature						
	Fluids	Porous loads			Unwrapped		
Sterilization temperature [°C]	BS 3970: Part2	BS 3970: Part3	EN 285 ("large")	Proposed type B* ("small")	BS 3970: Part 4	Proposed type N* ("small")	Holding time [min]
115	-	-	-		118	-	30
121	124	124	124	124	124	125	15
126	-	129	129	129	129	130	10
134	-	138	137	137	138	138	3
143	-	-	-	146	-	147	1

* Proposed European Standard under discussion by CEN

Cycle monitoring and documentation

2.56 It is vital that every production cycle is monitored and documented and that records are kept securely. Guidance on record-keeping is given in Chapter 3.

2.57 Except for the simpler processes (specified in the relevant chapter) documentation noted in the sterilizer process log for each sterilized load should include:

a. sufficient information to identify the sterilizer uniquely (by a unique reference number; by the name of the manufacturer, the model of sterilizer and the serial number; or by any sufficient combination of these);

b. a specification of the loading condition (defined either by the nature and number of load items, items of chamber furniture, and their distribution in the chamber, or by a coded reference to a detailed specification held elsewhere);

c. a specification of the operating cycle (defined either by the settings for the cycle variables or by a coded reference to a detailed specification held elsewhere);

d. a reference to the result of any routine pre-production test, such as a Bowie-Dick test;

e. the batch process record from the recorder fitted to the sterilizer marked with the reference number of the master process record used to validate it;

f. any deviations from the PQ specification in terms of loading condition and settings of cycle variables whether or not these result in an acceptable cycle;

g. the date and time of the start of the operating cycle;

h. the cycle number as indicated on the cycle counter;

i. the name or other identification of the operator;

j. any other records specified in Chapters 5 to 12.

2.58 The batch process record obtained from the sterilizer recorder should be sufficiently detailed to confirm that the requirements for critical parts of the operating cycle are met. This is best achieved by ensuring that a continuous graph is plotted as the cycle progresses and, for a digital system, that the values of all samples are retained for later inspection.

2.59 Biological indicators are not required for monitoring of steam or dry-heat processes, though they may occasionally be necessary for performance qualification of unusual loads (see Part 3 of this SHTM). See Chapters 10 and 11 about the use of biological indicators in LTSF and EO sterilizers.

2.60 If in doubt as to which records are required, the user should consult the Authorised Person. As a rule, it should be possible to trace any sterilized goods from the point of use back through the supply chain to the specific sterilizer and cycle in which they were processed and establish the precise values of the cycle variables throughout the cycle. A bar code attached to each load item is a practical way of keeping track of sterilized goods.

2.61 Cycles abandoned for any reason should be noted in the sterilizer process log along with any remedial action taken. Operators should be encouraged to note and report any observations which suggest that the sterilizer may not be working as it should be.

2.62 Where a load has been reprocessed following the failure of an earlier cycle, records of the original cycle should be readily traceable from the reprocessing records.

2.63 Further guidance on documentation is given in Chapters 5 to 12.

Process indicators

2.64 A foolproof system to differentiate between processed and unprocessed load items should be used to prevent an unprocessed item being mistaken for one that has been sterilized. A convenient method is to use chemical indicators which change colour on exposure to the sterilization process. Such “process indicators” are available in a variety of forms including adhesive tape, labels and preprinted panels on sterilization packaging. Process indicators should conform to the specifications for Class A indicators given in EN 867: Part 2.

2.65 Users should note that process indicators demonstrate only that the load item has been exposed to an operating cycle. *They offer no assurance that the load item is sterile and can play no part in the validation and monitoring of the process.*

Product release

2.66 The user, in consultation with the Authorised Person, should establish and document procedures to ensure that loads are not released for use until the user is satisfied that the operating cycle has been reproduced within the permitted tolerances established during performance qualification.

2.67 For medicinal products, the Quality Controller will establish the procedures for product release.

2.68 The procedures should confirm the following:

a. that the load has been packaged and assembled in accordance with the PQ specification;

b. that the settings for the operating cycle are in accordance with the PQ specification;

c. that the batch process record for the cycle conforms with the relevant master process record within the permitted tolerances (see paragraph 2.71);

d. that any indicated readings required to be noted during the cycle have been noted and are in accordance with the PQ specification;

e. that the sterilized load shows no obvious anomalies, such as damaged packaging or leaking containers, that may suggest a faulty cycle. (If any degree of deterioration is acceptable this should be part of the PQ specification.)

2.69 Loads processed in LTSF or EO sterilizers should not be released until the results of the routine microbiological tests are known (see Chapters 10 and 11).

2.70 Regardless of the above procedure, whenever an operator has cause to suspect that the load may not have been properly sterilized the load must not be released. The user should be informed immediately.

Master process record

2.71 A master process record (MPR) is a record of the values and permitted tolerances of cycle variables (normally time, temperature and pressure) for a correctly functioning operating cycle against which production cycles can be checked. (The term “master temperature record” was used in earlier editions of HTM 10.) It is derived either from the batch process record (BPR) obtained during a thermometric PQ test or, if no PQ test has been deemed necessary, from the BPR obtained from a full-load thermometric test carried out during commissioning. It may be a one-to-one transparent copy of the BPR, a “template” derived from the BPR, or data stored in a computer control system and compared automatically. See Part 3 of this SHTM for further information on MPRs.

2.72 Cycle variables recorded on the MPR may include chamber temperature, chamber pressure and the temperature inside one or more load containers as a function of time.

2.73 When a BPR from a production cycle is compared with the appropriate MPR, the value of the cycle variables on the BPR should be contained within the limits shown on the MPR for the entire cycle.

Rejected loads

2.74 Failure to meet any of the product release requirements should lead to the load being placed in quarantine and the cause of the failure investigated. The investigation should be documented and the handling of the product should be in accordance with the procedures for control of non-conforming product required by EN ISO 9001 or 9002.

2.75 Documented procedures for dealing with rejected loads should be agreed between the user and the Authorised Person. There are basically three options:

NOTE: The management of clinical waste and heat treatment processes, published by the Scottish Centre for Infection and Environmental Health, Aug 1994, ISBN 1 873772106, and Scottish Hospital Technical Note 3; *Clinical waste management*, issued by the Estates Environment Forum, should be referred to.

a. the load may be reprocessed; this should only be permitted if the nature of the load and its packaging is such that they will not be unacceptably degraded by a second exposure to the sterilization process;

b. the load may be "reworked", ie. dismantled, repackaged and then reprocessed;

c. the load may be discarded; in this case, procedures should ensure that load items are permanently marked as rejected, removed from the supply chain and that there is no risk of them being mistaken for correctly processed items.

2.76 Procedures for the disposal of a discarded load should ensure that no hazard is caused either to personnel or to the environment.

Storage

2.77 After sterilization and before product release, conditions for product storage and handling should not compromise the qualities of the product.

2.78 Detailed guidance on storage and distribution of sterile goods can be found in Part 5 of this SHTM.

3. Record-keeping

Introduction

3.1 The importance of maintaining careful records cannot be stressed too highly. Complete and accurate records are an essential element in ensuring the safe and efficient functioning of sterilizers and compliance with regulatory requirements.

3.2 The following principles, based upon those issued by the World Health Organisation “The collection, fractionation, quality control and uses of blood and blood products (1981)”, for the processing of blood products, apply equally to quality control of sterilization processes. Records should:

a. be original (not a transcription), indelible, legible and dated;

b. be made concurrently with the performance of each operation and test;

c. identify the person recording the data as well as the person checking the data or authorising continuation of processing;

d. be detailed enough to allow a clear reconstruction and understanding of all relevant procedures performed;

e. allow tracing of all successive steps and identify the inter-relationships of dependent procedures, products and waste materials;

f. be maintained in an orderly fashion permitting the retrieval of data for a period consistent with dating periods (shelf life) and legal requirements;

g. indicate that processing and testing were carried out in accordance with procedures established and approved by management;

h. if necessary, allow a prompt and complete recall of any particular batch;

i. show the lot numbers of materials used for making up specified batches of products.

3.3 The requirements for record-keeping in ENs 550 and 554 are the same as ENs 46001 and 46002, namely that the supplier should retain the quality records for a period of time at least equivalent to the lifetime of the medical device defined by the supplier, but not less that two years from the date of dispatch from the supplier. The supplier should establish a record for each batch of medical devices that provides traceability and identifies the quantity manufactured and quantity released for distribution. The batch record should be verified and the load authorised for release by the user.

3.4 For medicinal products, the record-keeping principles outlined in the GGMP should be followed.

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

a. a plant history file;

b. a sterilizer process log.

3.6 Both of these are the responsibility of the user. They should be made available to any other personnel who need to use them. This will include the Authorised Person, Test Person, Maintenance Person, Microbiologist, Competent Person and operators.

3.7 In the case of sterilizers used for processing medicinal products, the form of these records should be approved by both the Production Manager and the Quality Controller.

3.8 Log books for recording data obtained from periodic tests are available from Scottish Healthcare Supplies. An example of a log book for a porous load sterilizer is given in Part 6 of this SHTM. The log book is regarded as part of the plant history file.

Plant history file

3.9 The plant history file contains engineering records of the sterilizer installation. It should be kept throughout the life of the sterilizer (see paragraph 3.3). 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, Authorised Person, Test Person, Maintenance Person, Competent Person, 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 Competent Person in respect of pressure vessels;
- data from periodic tests carried out by the Test Person or the Maintenance Person;
- 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 process log

3.10 The sterilizer process log 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, Authorised Person, Test Person, Maintenance Person, Competent Person, 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 Part 3 of this SHTM);
- data from the periodic tests carried out by the user;
- records of routine housekeeping carried out by the user (see paragraph 4.21);
- 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.

3.11 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 (this is essential for EO sterilizers);
- reference number of the master process record;
- values of cycle variables required to be observed and noted by the operator during the cycle;
- a signature confirming whether or not the cycle was satisfactory;
- any notes or observations on the cycle.

3.12 The batch process record 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 master process record;
- a signature confirming whether or not the cycle was satisfactory.

3.13 Other requirements for entries in the sterilizer process log may be found in Chapters 5 to 12.

4. Maintenance

Introduction

4.1 Sterilization is a process whose efficacy cannot be verified retrospectively by inspection or testing of the product before use. For this reason sterilization processes have to be validated, the performance of the process routinely monitored, and the equipment maintained.

4.2 Means of assuring that a sterilizer is fit for its intended purpose will include the validation and periodic testing programme specified in Part 3 of this SHTM, and also the programme of planned maintenance (PM) as described in this Chapter.

4.3 The philosophy of maintenance and testing embodies three main principles to ensure that required standards of performance and safety are attained and sustained:

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

b. all sterilizers are subjected to a planned programme of preventative maintenance irrespective of whether or not a preventative maintenance scheme is being operated on the premises generally;

c. expertise on all aspects of the maintenance of sterilizers should be available at two levels; these are represented by the Authorised Person and the Maintenance Person.

4.4 Testing of sterilizers is dealt with in Part 3 of this SHTM.

Maintenance Person

4.5 As discussed in Part 1 of this SHTM, the Maintenance Person is defined as a person designated by management to carry out maintenance duties on sterilizers.

4.6 The Maintenance Person should be a fitter or an electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of sterilizer. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others. The Maintenance Person is typically an employee of the organisation operating the sterilizer, an employee of the sterilizer manufacturer, or an employee of an independent contractor.

4.7 The principal responsibilities of the Maintenance Person are:

a. to carry out the maintenance tasks outlined in this chapter;

b. to carry out additional maintenance and repair work at the request of the user.

4.8 A Maintenance Person who has a minimum of two years experience in the maintenance of sterilizers and who has obtained a recognised qualification in the testing of sterilizers may perform the duties of the Test Person for the daily, weekly and quarterly tests described in Part 3 of this SHTM.

Planned maintenance programme

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

a. all parts of the sterilizer which are vital to correct functioning or safety should be tested at weekly intervals. This is interpreted as follows:

   (i) there is no need to test components individually in those cases where any malfunction will be revealed by the periodic tests prescribed in Part 3 of this SHTM for weekly or more frequent intervals;

   (ii) 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 which may only be required to perform their safety function when presented with an abnormal condition;

b. the maintenance programme should include, at appropriate intervals, those tasks such as lubrication and occasional dismantling of particular components (such as pumps) the need for which is indicated 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 which are working correctly should be left alone and not disturbed unnecessarily;

c. maintenance should be carried out under a quality system such as ENISO 9000. Spares fitted to sterilizers constructed under a quality system should be sourced from a similarly approved quality system.

Design of a PM programme

4.10 The PM programme supplied by the sterilizer manufacturer should be used where it is available. If no manufacturer's programme can be obtained, a programme should be drawn up in consultation with the Authorised Person and the Maintenance Person.

4.11 Although the sterilizer manufacturer may carry out certain inspection and maintenance procedures under the terms of his guarantee, these may not constitute a full PM programme. The user should therefore ensure that the complete PM programme is carried out by the Maintenance Person (who may be an employee of the manufacturer, see paragraph 4.6) during the guarantee 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 of his liability on to the management. Where maintenance is carried out under lump sum term contract (see Part 2) such failure is tantamount to breach of contract and can give the contractor cause to terminate the contract if he so wishes.

4.12 A set of procedures should be developed for each sterilizer, containing full instructions for each maintenance task.

4.13 The frequency at which any given task needs to be carried out will depend on how heavily the sterilizer is used. Where there is a two-shift system, for example, it will be necessary to adjust the programme so that work is carried out more frequently than under a single-shift system. Where sterilizers are used infrequently, however, less frequent maintenance is not always acceptable. Infrequent use requires increased maintenance of certain components because of failure of valves, seals, pumps, etc., due to sticking through lack of use. Only when a component is subject to progressive wear in use is the frequency of maintenance related to frequency of use.

4.14 It is important that maintenance is planned so that a sterilizer is out of service for as little time as possible. Maintenance should, where practicable, be scheduled to immediately precede the periodic tests as specified in Part 3 of this SHTM.

Review of the PM programme

4.15 The PM programme, procedures and records should be reviewed at least once a year by the user and the Maintenance Person in association with the Authorised Person. To do this, it is necessary to keep systematic records of all work done, so that judgement can be made in consultation with the manufacturer on what changes, if any, to the PM programme would be desirable.

4.16 The review should aim to identify:

a. any emerging defects;

b. any changes required to the maintenance scheme;

c. any changes to any maintenance procedure;

d. any additional training required by personnel concerned with maintenance;

e. whether records have been completed satisfactorily, signed and dated.

Inspection of pressure vessels

4.17 Under the Pressure Systems and Transportable Gas Containers Regulations 1989, all sterilizers containing pressure vessels are subject to a periodic inspection by a Competent Person (see Part 1 of this SHTM). The Regulations apply to all steam sterilizers, to EO sterilizers operating above 0.5 bar, to dedicated steam generators, to cartridges and cylinders used to supply sterilant or purging gas to EO sterilizers, and to the steam and compressed air services. Pressure vessels include doors and their closing systems. The Authorised Person will advise on the application of the Regulations to any particular installation.

4.18 The Competent Person has three principal duties under the Regulations:

a. advising on the scope of the written scheme of examination for each pressure vessel;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

4.19 The user should cooperate closely with the Competent Person 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.

Modifications

4.20 Occasionally, modifications to the sterilizer may be recommended by the manufacturer or by the UK Health Departments 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.

Routine housekeeping

4.21 Certain simple maintenance tasks may be carried out by the user (or by an operator under the user's supervision) and should be recorded in the sterilizer process log. Examples of such tasks include the following:

a. steam sterilizers: daily, or more often if necessary, clean the strainer fitted in the opening to the chamber discharge line;

b. all sterilizers: daily, wipe the door seal with a clean damp cloth and inspect it for damage. This can normally be done by the operator if the seal is completely exposed when the door is open;

c. all sterilizers: carry out any door safety checks required by the written scheme of examination and which are within the technical competence of the user. (Other door safety checks, normally weekly, will be carried out by the Maintenance Person.)

Maintenance of laboratory sterilizers

4.22 Laboratory sterilizers differ from clinical sterilizers in that they may have cycles expressly designed for the routine making-safe of discard material that is or may be contaminated with pathogenic micro-organisms. Sterilizers without a make-safe cycle may occasionally be used to process infected material if the designated machine is out of service. The user should ensure that a documented procedure is established for the decontamination of a sterilize before it is handed over to maintenance personnel. Such a procedure should comply with the guidelines set out in HSG(93)26, 'Decontamination of equipment prior to inspection, service or repair'.

4.23 Since the contamination status of a sterilizer cannot be established by inspection, all maintenance work should be conducted under a permit-to-work system in which a certificate, signed by the user and the Laboratory Safety Officer, is given to maintenance personnel to indicate that the sterilizer is safe. Where it is not possible to guarantee that a sterilizer is free of contamination (such as where a machine breaks down with a discard load in the chamber), this should be made clear on the permit to work and detailed procedures for safe working should be supplied. This latter option should only be resorted to in exceptional cases and is not an acceptable alternative where decontamination is practicable. A suggested format for the permit to work is given in Figure 3.

Figure 3 Suggested permit to work for laboratory sterilizers

PERMIT TO WORK

This permit relates only to the hazards caused by the possible microbiological or chemical contamination of the sterilizer. The sterilizer is not guaranteed safe against any other source of risk.

Location of sterilizer_____

Manufacturer _____ Serial no:_____

Model _____ Inv. no:_____

- I confirm that the above sterilizer has been decontaminated and cleaned as required to render it safe for maintenance or repair (or)
- It is not possible to guarantee that the sterilizer is free of contamination. Guidance on safe working practices is attached (delete as appropriate).

User: Name: _____ Signature: _____Date:_____ Time: ___

Safety Officer: Name: _____Signature: _____Date _____ Time: ___

RECEIPT (delete as appropriate)

- I accept responsibility for carrying out the work on the above sterilizer.
- I have received the guidance on safe working practices.

Name: _____ Signature: _____Date: ____ Time: ___

HAND-BACK (delete as appropriate)

- The work on the above sterilizer has been completed / suspended.
- The sterilizer may / may not be returned to service.

Name: _____ Signature: _____Date: ____ Time: ____

CANCELLATION

This permit-to-work is now cancelled.

User: Name: _____ Signature: _____Date ____ Time: ____

4.24 Maintenance of laboratory sterilizers should conform with the guidance given in BS 2646: Part 4.

Features requiring special attention

4.25 The following sections provide background information to some of the features requiring special attention in any PM programme.

Stainless steel chambers

4.26 Stainless steel, or mild steel clad with stainless steel, is used in the manufacture of many sterilizer chambers. Over a wide variation in specification, stainless steels, and to a much lesser extent stainless-clad mild steel, are susceptible to cracking from crevice corrosion and stress corrosion initiated by chemical attack. These phenomena occur when the material is subjected to a combination of heat, stress and contact with chemicals, notably chlorides or strong alkalis. The damage resulting from the combined effects occurs at levels far below those which would be of significance if acting separately. Heat and stress are present in all steam sterilizers.

4.27 Material in compression is less susceptible to crevice and stress corrosion than material in stress. Some manufacturers use “shot blasting” (also known as “shot peening”), to convert the tension stresses in the skin of the stainless steel to compression stresses.

4.28 Chemical contact may occur in sterilizers under the following circumstances:

a. in sterilizers processing certain fluids, such as saline solution, a spillage will introduce chloride salts into the chamber;

b. if there is excessive carry-over of boiler water with the steam, this is likely to include significant concentrations of both alkalis and chloride salts;

c. in small electrically heated sterilizers, where steam is generated within the chamber by an immersion heater, a build-up of alkalis and chloride salts may occur if tap water is used to generate steam; this can result in severe pitting corrosion leading to the perforation of the chamber.

4.29 Where cleaning with water is required, only water with a low chloride level, such as distilled water or good quality condensate, should be used.

4.30 Vessels which have not been shot-blasted should be lightly polished by hand. This should be done in accordance with the manufacturer’s instructions and at quarterly intervals on sterilizers used to process fluids. Polishing should only be done using iron-free materials. Household or domestic scouring and polishing compounds should not be used since they often contain chlorine or other corrosive agents which might cause, rather than prevent corrosion. After polishing, the chamber should be thoroughly flushed out with water of low chloride content.

4.31 During cleaning and polishing, precautions should be taken to prevent damage to the door seal and the entry of foreign matter into the chamber drain.

Air-tightness of the chamber

4.32 Air-tightness 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.

4.33 Leaks may also occur in the following places:

a. joints in pipework;
b. connections to gauges;
c. blanked-off connections for test gauges;
d. entry points for temperature sensors (whether in use or blanked off);
e. glands and seats of valves;
f. bellows-operated door safety interlocks;
g. cracks in chamber welds or platework.

Door-locking mechanisms

4.34 There have been a number of incidents in which sterilizer door-locking mechanisms have failed during operation.

4.35 Maintenance and inspection of door safety devices and door-locking and chamber sealing systems must be carried out in accordance with the manufacturer's written instructions. Security and settings of door safety switches and door-locking components must be checked weekly and the settings must comply with those provided by the manufacturer.

4.36 Capstan-operated, hinged door-locking mechanisms should be examined for excessive wear on the internal thread sections. Where these are hard to see, thread profile gauges should be used. If there is evidence of excessive wear, then the sterilizer should be removed from service until the capstan wheel assembly can be replaced.

Air detector

4.37 Particular care should be taken when installing, removing or adjusting any part of an air detector. It is preferable not to interfere with it except when necessary. The sensitivity of the air detector should be adjusted in accordance with the manufacturer's instructions and the setting determined during validation as detailed in Part 3 of this SHTM.

4.38 Air detectors work by measuring either temperature or pressure. Certain older temperature-operated air detectors may not fail safe if there is a leak from the detector to the outside. It is crucial that air detectors are carefully checked for air-tightness once a week. A leak too small to be detected by the vacuum leak test given in Part 3 of this SHTM could be large enough to permit the expulsion by steam of any air present in the detector and cause it to indicate falsely that all the air had been removed from the chamber.

4.39 If it has been necessary to adjust the air detector, the Test Person should carry out recommissioning tests as described in Part 3 of this SHTM.

Instruments

4.40 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.

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

4.42 The recorder 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 should be regarded with caution and interpreted from knowledge of the characteristics of the particular recording system, the load and previous records.

4.43 Recording systems which are working correctly should not be interfered with more than is absolutely necessary. Adjustments should be done strictly in accordance with the manufacturer's instructions.

4.44 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.

Ancillary equipment

4.45 Ancillary equipment used in conjunction with the sterilizer should also be subject to planned maintenance in accordance with manufacturers' instructions.

4.46 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.

4.47 Examples of ancillary equipment include:

a. all engineering services to the sterilizer, especially steam;

b. dedicated steam generators (see SHTM 2031 for guidance);

c. room ventilation and local exhaust ventilation (see SHTM 2025 and the HSE document 'The maintenance, examination and testing of local exhaust ventilation' (HS(G)54) for guidance); correct functioning is essential to the safe operation of LTSF and EO sterilizers;

d. personal protective equipment;

e. equipment used to monitor, alarm or protect against exposure to formaldehyde or ethylene oxide.

Returning a sterilizer to service

4.48 The user, with the assistance of the Authorised Person, 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 recommissioning (yearly) tests specified in Part 3 of this SHTM.

4.49 The Maintenance Person should certify that the work has been completed and that the sterilizer is safe to use.

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

5. Operation of porous load sterilizers

Introduction

5.1 This chapter gives guidance on the routine operation of clinical high-temperature steam sterilizers designed to process wrapped goods and porous loads.

5.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1.

The process

5.3 Porous load sterilizers heat load items by direct contact with high-temperature steam at a typical sterilization temperature of 134°C (see Table 5).

5.4 The operating cycle of a porous load sterilizer normally has five stages.

a. Air removal – Sufficient air is removed from the chamber and the load to permit attainment of the sterilization conditions.

b. Steam admission – Steam is admitted to the chamber until the specified sterilization temperature is attained throughout the chamber and load.

c. Holding time – The temperature throughout the chamber and load is maintained within the sterilization temperature band for the appropriate holding time.

d. Drying – Steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases.

e. Air admission – Air is admitted to the chamber until the chamber pressure approaches atmospheric pressure.

5.5 The complete cycle time for a sterilization temperature of 134°C is typically 35 minutes for a standard full load, but the drying stage may need to be extended for up to a further 20 minutes for loads of high heat capacity, such as trays of instruments, that take longer to dry.

Product compatibility

5.6 A porous load sterilizer is suitable for processing a very wide range of goods and is the method of choice in most cases.

5.7 Items to be processed in a porous load sterilizer should have been washed and dried by a validated cleaning process.

5.8 To reduce the possibility of superheating, load items consisting of textiles should be allowed to air for a period of not less than fours hours after laundering (see paragraph 5.50).

Items that should not be processed in a porous load sterilizer

5.9 The following items should not be processed in a porous load sterilizer:

a. items which would be damaged by exposure to moist heat at 121-134°C;

b. items which would be damaged by rapid pressure changes (up to 10 bar min^{-1});

c. aqueous fluids (a fluid sterilizer is required);

d. non-aqueous fluids (a dry-heat sterilizer is required);

e. items in sealed containers (air will not be extracted).

Design of the load

5.10 Items processed in porous load sterilizers will either consist entirely of porous materials (such as dressings) or else comprise wrapped goods, usually of metal (such as surgical instruments).

5.11 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam; and

b. to ensure that the condensate formed during the cycle does not result in a wet load.

5.12 With some exceptions, porous load sterilizers may be loaded randomly. It is not necessary to ensure that the loading condition is replicated in detail for each cycle.

Air removal

5.13 The presence of air in the load can impede the penetration of steam and thereby drastically reduce the effectiveness of the sterilization process. Steam will not easily displace air contained in porous materials, such as a paper bag containing an instrument. Any air remaining in the packages before the start of the holding time will occur in random locations and in different volumes. During the holding time it may unpredictably delay or prevent saturated steam from contacting the surfaces over which this air is present. Levels of air will depend on the theoretical dilution rate, the method used for air removal and the air leakage into the chamber.

5.14 Porous load sterilizers have an active air removal system in which air is replaced with steam by a series of vacuum and pressure changes. Provided it is validated according to the schedule set out in Part 3 of this SHTM, a sterilizer complying with EN 285 will be capable of removing sufficient air from packages randomly placed in the chamber and which contain porous material not exceeding the density of the standard test pack.

5.15 Where the density of porous material exceeds that of the standard test pack, or the load consists of components into which steam penetration is not instantaneous, eg. filters and flasks with small orifices, a thermometric performance qualification test is required (see Part 3 of this SHTM).

5.16 As well as air retained in the load, steam penetration may be inhibited if non-condensable gases are liberated from the load as it is heated. This may happen with certain packaging materials, inks, adhesives, labels, etc. Packaging materials should conform to one of standards listed in paragraph 5.27. As a precaution, new non-metallic boxes or trays should be processed in a non-production cycle before being used with production loads.

Handling of condensate

5.17 As in all steam sterilizers, the energy which heats the load is derived almost entirely from the latent heat given up as the steam condenses on the load items. (It is not a simple conduction of heat from hot steam to the cool load.) The more latent heat is given up, the more condensate will be formed. This condensate (hot water) is an essential and unavoidable consequence of steam sterilization.

5.18 The amount of condensate formed will depend on the latent heat required to raise the load to the sterilization temperature. This depends on the heat capacity of the load, which in turn depends on the mass and specific heat capacity of each item. Loads containing metal items have a higher heat capacity than a load of purely porous materials and therefore will produce more condensate. Essentially all of the condensate will be formed before the start of the holding time.

5.19 The process is substantially reversible, however, and by subjecting the chamber to a vacuum during the drying stage, the lowered boiling point of water associated with the reduced pressure enables the heat energy stored in the load item to re-evaporate the condensate and as a consequence the item is both cooled and dried. The re-evaporation process will not occur if the condensate becomes separated from the load items.

5.20 In order to ensure that porous loads are dry at the end of the cycle, it is therefore necessary either to drain the condensate completely clear of the load, or to retain it close to the hot load items where it can be evaporated. With wrapped loads, the latter solution is preferred. No special measures are needed for purely porous loads, but metal items are likely to produce sufficient condensate to saturate their wrapping. The condensate may then spread to other parts of the load from which it may not be evaporated. This

migration of condensate may be avoided by including absorbent padding (in addition to the wrapping) suitably positioned inside each pack.

5.21 The optimum amount and arrangement of this extra padding can only be determined by experiment. As a rule, metal items should be well spaced and separated by padding. With preset instrument trays, for example, the instruments should be spaced out across the tray. Unusually heavy items, such as orthopaedic hammers, should be placed away from other instruments and well padded. Loads containing large amounts of metal may require performance qualification tests.

5.22 Holloware, such as bowls and tubes, should be arranged in such a way that condensate will not collect inside them. It may not be practical to ensure that wrapped holloware is always processed inverted and in this case the drainage problem may be overcome by placing absorbent materials inside the holloware.

5.23 Drip deflectors between tiers of instrument trays will ensure that condensate does not drain from one tray to another.

5.24 If a mixed load of porous and wrapped metal items is to be processed, the porous items should be placed above the metal items to ensure that condensate does not drip on to them.

Packaging materials

5.25 Items to be sterilized should use packaging materials which are permeable to air and steam but have an effective maximum pore size which is small enough to exclude microbial contamination under the specified storage and transport conditions.

5.26 Goods are normally double-wrapped; at least one of the layers will usually be a sheet of paper, a paper bag or a plastic pouch. The inner lining may be chosen primarily for its absorbency in order to retain condensate as described above.

5.27 Load items should be wrapped in materials complying with one of the following parts of EN 868: Packaging materials for sterilization of wrapped goods:

a. Part 1: General requirements and requirements for the validation of packaging of terminally-sterilized devices;

b. Part 2: Sterilization wrap – requirements and tests;

c. Part 3: Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels;

d. Part 4: Paper bags – requirements and tests;

e. Part 5: Heat-sealable pouches and reel material of paper and plastic film construction – requirements and tests;

f. Part 8: Reusable sterilization containers – requirements and tests.

5.28 Extensive guidance on packaging materials and methods is given in Part 5 of this SHTM.

Performance qualification

5.29 PQ tests are not normally required for the majority of loading conditions processed in a porous load sterilizer since they are less of a challenge to the cycle than the full-load and small-load tests carried out during validation.

5.30 PQ tests are required where:

a. the density of any porous load item exceeds the density of the standard test pack (see Part 3 of this SHTM);

b. the mass of any single metal item exceeds 1 kg;

c. the construction of any load item is such that sufficient air may not be removed to ensure the rapid penetration of steam;

d. any cycle variable has been modified from the setting used in validation.

5.31 Two categories of product require special consideration:

a. minimally invasive surgical instruments (such as laparoscopic biopsy forceps) which present particular problems of air removal and steam penetration;

b. barrier fabrics (such as Gore-tex) which have such low porosity to both air and steam that normal air removal stages may be inadequate.

Selection of cycle variables

5.32 The preferred sterilization temperature is 134°C. However, any of the lower sterilization temperature bands in Table 5 may be used where load items would be damaged at 134°C.

Table 5: Sterilization conditions for porous load sterilizers

Sterilization temperature [°C]	Maximum allowable temperature [°C]	Minimum holding time [min]
134	137	3
126	129	10
121	124	15

See paragraphs 2.52-2.53 for comment on maximum allowable temperatures.

Cycle monitoring and documentation

5.33 Users are reminded that a Bowie-Dick test should be carried out at the start of each day as described in Part 3 of this SHTM. Production should not begin until the test has been shown to be satisfactory. Some departments may also require a daily vacuum leak test.

5.34 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

5.35 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature (chamber temperature) recorded by a sensor in the active chamber discharge;

b. the pressure (chamber pressure) recorded by a sensor in the chamber.

5.36 It is not necessary to monitor the temperature inside the load.

5.37 In addition to the above information, any cycle aborted due to a fault sensed by the air detector should be noted along with the remedial action taken.

Product release

5.38 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged;

c. the load items are visibly dry.

Troubleshooting

Air detector fault

5.39 The air detector is designed to register a fault when the level of air and gas sampled from the chamber is high enough to affect the even and rapid penetration of steam into the load. Possible causes of an air detector fault include:

a. an inefficient air removal stage;

b. an air leak during the air removal stage;

c. non-condensable gases evolved from the packaging;

d. non-condensable gases in the steam supply;

e. a defective air detector.

5.40 When a cycle has been aborted due to an air detector fault the sterilizer should be taken out of service. If there is no obvious cause for suspicion, such as a change in the loading condition, the sterilizer should be subjected to the weekly tests as described in Part 3 of this SHTM. These will include an air detector function test.

Wet loads

5.41 Any item with wet outer packaging should be rejected since the moisture compromises the protective qualities of the wrapping.

5.42 Wet spots or patches on the packaging show that liquid water has been drawn into the chamber. There are several possible explanations, including:

a. poorly draining steam traps between the sterilizer and boiler (a sudden demand for steam can draw water out of a full trap);

b. severe pressure fluctuations in the main;

c. priming of the boiler leading to carry-over of water in the steam.

5.43 Occasionally, load items with dry outer packaging may be found to be wet inside. While the sterility of the product may be satisfactory, there remains the possibility that the load was wet throughout at some stage and therefore sterility cannot be assured. Since they are invariably discovered by the end-user at the point of need, such wet items do not promote confidence in the sterile supply service.

5.44 Packages that are damp inside are often the result of inadequate packaging and loading (see paragraphs 5.17–5.24), especially when metal objects have been processed. If the precautions outlined above have been followed, however, the cause may be a wet steam supply. This can be confirmed by the steam dryness test described in Part 3 of this SHTM. Users should note that this test will not reliably detect wetness due to sporadic carry-over of water.

5.45 Part 2 of this SHTM describes the engineering requirements for a steam supply of the correct dryness for sterilization. The sudden appearance of wet loads from a loading condition and operating cycle that have been used successfully for a long time may indicate a change in the steam service. For example, there may be a fault somewhere in the system or there may have been engineering modifications to the steam service; new or modified boilers, extensions to the steam main and new equipment installed elsewhere may all affect the dryness of the steam supplied to the sterilizer.

5.46 Another possibility is that operating practice in the boiler room may have changed. For example, it is common in hospitals to shut down all but one boiler for the summer months. When demand increases again in the autumn, the boiler may start to prime (carry over water) before the other boilers are returned to service.

Superheating

5.47 Superheating, arising from steam that is too dry, can cause a failure to sterilize. It is uncommon and can be difficult to identify. A failed process indicator is one sign; charring of wrapping materials is another.

5.48 One possible cause of superheating 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. Engineering solutions to this problem are described in Part 2 of this SHTM.

5.49 Superheat can also arise 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.

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

Spontaneous combustion

5.51 There have been reports of textile loads bursting into flame within the sterilizer chamber. Invariably this is because the load has been allowed to become excessively dry and hot. There are two circumstances in which this may occur:

a. the load is placed in a heated chamber and left for a considerable time before the cycle is started; ignition is believed to occur when the load becomes rehydrated on the introduction of steam to the chamber;

b. the load is left inside the chamber for a long time after the end of the operating cycle; ignition occurs when the door is opened and the load exposed to air. This is most likely to happen where the operating cycle has aborted due to a fault condition and the load is not removed promptly.

5.52 Users should be mindful of this risk and establish operating procedures to ensure that loads are not left in heated chambers for longer than necessary.

6. Operation of fluid sterilizers

Introduction

6.1 This chapter gives guidance on the routine operation of clinical high-temperature steam sterilizers designed to process aqueous fluids in sealed containers.

6.2 The guidance given here assumes that the sterilizer is to be used to process medicinal products in compliance with the EU Directives discussed in Chapter 1. Users should be aware, however, that products in which medicinal products are contained within a delivery system, such as certain irrigations and ophthalmic preparations, may be classified as medical devices as well as medicinal products.

The process

6.3 Fluid sterilizers heat load items by direct contact with high-temperature steam at a typical sterilization temperature of 121°C. Although steam does not penetrate to the product inside the sealed containers, sterilization is effected by the water molecules in the product itself. That is why these sterilizers cannot be used to process non-aqueous fluids.

6.4 A fluid sterilizer will normally have the following operating cycle.

a. *Heat-up*. Steam is admitted to the chamber, heating the load.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the active chamber discharge, reaches the sterilization temperature, which is typically 121°C (see Table 6).

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature. This time depends on the nature and amount of the product, and the material, size and shape of the container.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is cooled, either by spraying with sterile water (usually chamber condensate) or the circulation of cooled air, until the temperature in the hottest part of the load has fallen below 80°C.

6.5 Heat transfer to the contents is predominantly by conduction through the walls of the containers and by internal convection. A small radiant heat transfer component is also present. During the heat-up phase of the operating cycle, the outside temperature of the load containers quickly approaches that of the chamber space, with a corresponding increase in the temperature of condensate in the active chamber discharge.

Safety precautions

6.6 The main hazard with fluid sterilizers is the high pressure attained inside glass bottles at the sterilization temperature. This pressure may cause weak or damaged containers to burst during sterilization and such explosions may damage other containers in the load.

6.7 A hazard to the operator may result if bottles are removed from the sterilizer before they have cooled to a safe temperature. At a sterilization temperature of 121°C the absolute pressure inside a bottle having a nominal fill of fluid is in the region of 3.6 bar (see Figure 4). If the door were to be opened at this temperature, and the load subject to cold draughts or unintentional impact, the stresses arising in the glass would be sufficient to crack the bottle and cause an explosive breakage. Fluid sterilizers are fitted with a thermal door-lock to ensure that when glass bottles are being processed the door cannot be opened until the temperature inside all the containers has fallen below a safe maximum of 80°C. (Even at this temperature the pressure inside a bottle is approximately 1.8 bar.) Failure to observe this requirement has led to serious accidents resulting from the explosion of glass bottles.

6.8 Operators should be aware that some bottles may break before the end of the cycle and broken glass may need to be removed before the next cycle can begin.

6.9 Operating cycles for plastic containers have the following modifications:

a. pressure ballasting with air is used to prevent pressure differences arising between the inside and the outside of containers sufficient to burst or distort them;

b. the door may be opened when the temperature inside the containers falls below 90°C. This prevents “blooming” of the containers. On no account should these cycles be used with glass containers unless the thermal door lock has been reset to 80°C.

Product compatibility

6.10 Fluid sterilizers may be used to process a wide range of medicinal products in the form of aqueous solutions in sealed containers of either glass or plastic.

Items that should not be processed in a fluid sterilizer

6.11 The following items should not be processed in a fluid sterilizer:

a. fluids in unsealed bottles (the product may be modified by the evaporation of water and the entry of steam and condensate, and will not remain sterile after removal from the chamber);

b. non-aqueous fluids (they will not be sterilized);

c. contaminated fluids intended for discard (discard material should not be processed in clinical sterilizers).

Design of the load

6.12 Items processed in fluid sterilizers will normally consist of large numbers of identical containers such as bottles, bags, ampoules or vials. While the containers are usually made of glass, plastic containers may also be processed. All containers should be sealed to prevent the escape of the contents and the entry of steam or condensate.

6.13 The loading condition should be designed with the aim of permitting the free circulation of steam and coolant over the surfaces of the containers.

Bottles

6.14 Bottles in a load should preferably all be of the same size. Where mixed sizes are unavoidable, the PQ tests should ensure that the largest bottles are monitored to ensure that they attain the required sterilization conditions.

6.15 It is important that steam is allowed to pass freely around the surfaces of bottles. They should be placed in crates or on trays designed to locate each bottle so that it cannot touch its neighbours. Chamber furniture should also allow the free passage of steam and condensate.

6.16 Plastic bottles, particularly those made of polymers which undergo a reduction in tensile strength at the temperatures used for steam sterilization, are often only suitable for use in sterilizers which include air or gas ballasting to increase the pressure throughout the cycle and thus restrain the bottle from bursting.

Plastic bags

6.17 Plastic bags should not be stacked on top of each other. Steam should be allowed to circulate freely around them. Bags may be hung from racks within the chamber or placed on shallow shelves.

Vials and ampoules

6.18 Loads consisting of small containers, such as vials and ampoules, have a large surface-area-to-volume ratio and therefore will cause steam to condense rapidly during the heat-up stage. Where steam is admitted to the chamber through a single inlet, it will first condense on the ampoules nearest to the inlet and these will consequently heat up faster than those further from the inlet. This will produce a large difference in temperature across the chamber and an extended equilibration time. This is acceptable provided that the product can withstand the extended heating experienced by the ampoules near the steam inlet and the ampoules slowest to heat up are correctly identified for the thermometric PQ test.

6.19 Where the product cannot withstand this extended heating, the size of the load should be reduced so that it can be placed further from the steam inlet. A sterilizer with multiple inlets is the preferred solution.

Closure systems

6.20 Containers should have gas-tight seals to prevent evaporation of water from the contents and the entry of steam or condensate. Glass bottles for sterile fluids are commonly sealed with compound closures comprising an elastomeric disc or plug which is secured to the neck of the bottle by means of an aluminium screw cap, an aluminium crimped-on (or turned-on) cap, a cap made of plastic material or a retaining closure embodying both plastic and aluminium parts.

6.21 It is essential that the elastomer is held in tight contact with the neck of the bottle in order to prevent the entry of micro-organisms or other materials which might contaminate the product. It is a characteristic of such containers that when they are charged with the specified volume of the product there remains a substantial air space (sometimes referred to as ullage) above the liquid. The proportion of the total internal volume of a bottle filled with liquid may vary with the design of the bottle but is commonly 80-90 percent, so the ullage may be about 10-20 percent of the internal volume. Such a space is necessary for thermal expansion of the liquid during sterilization.

6.22 When a sealed bottle is sterilized, the pressure inside exceeds that in the sterilizer chamber by a substantial margin. The pressure within the bottle is due to the partial pressures of the air and steam at the sterilization temperature plus an additional factor due to the compression of the air and steam mixture in the ullage by thermal expansion of the liquid in the bottle. Thus at any single temperature the pressure within a bottle under sterilizing conditions will be determined largely by the proportion of the total internal volume filled with liquid since, as this increases, the effect of thermal expansion on the air and steam mixture also increases. Figure 4 shows the internal absolute pressure in a rigid container of water at 121°C as a function of filling factor. This diagram is equally applicable to all sizes of container.

6.23 This high internal pressure imposes a stress on the closures which may be distorted or even ruptured as a result. Distortion of closures, especially of aluminium parts, may allow the elastomeric seal to lift or loosen in the bottle neck and allow the escape of some air from the ullage. Should this occur, the bottle on cooling tends to develop a partial internal vacuum. This itself is no danger to the product but may allow the entry into the bottle of spray cooling fluid which will dilute the product and may carry in chemical or microbial contamination. An attempt is made to reduce the risk of product contamination by using retained condensate in the sterilizer (or in some cases filtered gas) as the cooling agent. But since the failure of the seal may not be apparent by visual inspection, an acceptable product requires that the closure of the bottle remains an effective seal throughout the sterilization process.

6.24 Since the above problems arise as a result of the inevitable excess pressure generated within bottles, the security of bottle closures is the responsibility of the user. Thus the user is required to ensure that the closures and containers are suitably designed to withstand the proposed sterilizing conditions. This is best achieved by ensuring that containers and closures comply with a recognised standard. Where containers are reused, the user has to institute a rigid system of inspection after washing to ensure that all bottles with signs of damage, especially of the neck area, are discarded. It is imperative that a bottle is not charged with a volume of fluid greater than the stated nominal volume of the bottle.

6.25 Users are recommended to establish a quality system to ensure that the probability of failure of a closure is low enough that the sterility of the product is not jeopardised. This will generally require the user to identify the parameters of the container and closure system which could lead to a failure and to set limits of acceptance which have been validated to demonstrate closure integrity. Production cycles may require the introduction of a dye into the chamber to identify failed closures. Electronic monitoring systems are also available. Within the NHS it may not be practicable to determine the probability of failure statistically, and in such cases sufficient assurance of sterility may be achieved by ensuring that the steam supplied to the sterilizer, and any coolant water in contact with the load, complies with the “clean steam” purity specification described in SHTM 2031. See also Part 2 of this SHTM for a discussion on the fail-safe design of heat exchangers.

Performance qualification

6.26 PQ tests are not required for loading conditions presenting less of a challenge to the cycle than the full-load and small-load tests carried out during commissioning. Decisions on which loading conditions require PQ tests should be made by the user, in consultation with the Quality Controller and Test Person.

6.27 PQ tests are required where:

a. the nominal capacity of any container exceeds 1 litre;

b. the product cannot withstand the equilibration time associated with the commissioning tests (see Part 3 of this SHTM);

c. any cycle variable has been modified from the setting used in validation.

6.28 Users should consider the economic benefits of conducting PQ tests even for stable products, since the heating and cooling times will be generally shorter than that required for the commissioning tests.

Selection of cycle variables

6.29 The sterilizer should be preset to operate in the standard sterilization temperature band shown in Table 6. Other combinations of sterilization temperature and holding time may be used provided that they have been satisfactorily demonstrated to deliver an adequate level of lethality when operated routinely within established tolerances.

Table 6: Sterilization conditions for fluid sterilizers

Sterilization temperature [°C]	Maximum allowable temperature [°C]	Minimum holding time [min]
121	124	15

6.30 The automatic controller should be preset to a plateau period, established during performance qualification, sufficient to include both the minimum holding time and the equilibration time.

Cycle monitoring and documentation

6.31 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

6.32 Where the temperature of the load is to be monitored, the load temperature probe should be inserted into a load item known to be the slowest to attain the sterilization temperature. Where two probes are provided (normally in sterilizers over 600 litres) the second probe should be inserted into the load item known to be the fastest to attain the sterilization temperature. The probe should be located along the geometric axis of the container and inserted to a depth of 85% of the container height.

6.33 A batch process record should be generated for each production cycle. he batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the active chamber discharge;

b. the pressure ("chamber pressure") recorded by a sensor in the chamber;

c. the temperature ("load temperature") recorded by the load temperature probe.

6.34 In certain applications the operating cycle may be controlled by measuring the lethality (F_0) delivered to the load as the cycle progresses. An extensive discussion on the applications of the F_0 principle may be found in Part 5 of this SHTM.

Product release

6.35 Documented procedures for release of medicinal products should be established by the Quality Controller.

6.36 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. not more than one container (or 1%, whichever is the greater) has burst or broken.

6.37 If the batch process record is unacceptable the load should be rejected. A decision on reprocessing should be based upon a validated procedure which takes account of the chemical and physical stability of the product.

6.38 The load should be examined for damaged containers. The occasional broken bottle or bag may be acceptable provided intact containers have not also been damaged.

6.39 Blooming of plastic containers is a surface effect which normally clears and does not harm the container or the contents. The user and Quality Controller should decide whether blooming is acceptable.

7. Operation of sterilizers for unwrapped instruments and utensils

Introduction

7.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to process unwrapped solid instruments and utensils by exposure to high-temperature steam.

7.2 The guidance given here assumes that the sterilizer is to be used to process medical devices However, these sterilizers do not meet the essential requirements of the EU Directives discussed in Chapter 1, which do not permit the supply of unpackaged sterile medical devices.

The process

7.3 This type of sterilizer is used to process unwrapped surgical instruments and utensils intended for immediate use in a controlled medical environment. Heating is by the direct contact of the product with saturated steam.

7.4 Air is normally removed from the sterilizer by passive displacement, either downward or upward depending on whether steam is supplied externally or generated internally. Active air removal systems of the type found in a porous load sterilizer are rare.

7.5 A few models have a drying stage in which the load is dried by passing filtered air through the chamber, but it is more usual for the load to be partially dried by evaporation after it has been removed from the machine.

7.6 A sterilizer conforming to BS 3970 will have the following operating cycle:

a. *Heating*. The water is heated and steam generated in order to vent the air from the chamber until the sterilization temperature is attained.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the active chamber discharge, reaches the sterilization temperature.

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is allowed to cool naturally in the chamber.

Water supply

7.7 In transportable sterilizers steam is generated by the heating of feedwater within the chamber. The recommendations contained in SHTM 2031 should be followed.

7.8 Users should note that the recommendation for feedwater is designed to facilitate effective sterilization and avoid damage to the machine. Where the steam quality in the chamber is required to meet the specification for pyrogen-free “clean steam” (set out in SHTM 2031), only water complying with Sterilized Water for Injections BP is acceptable.

7.9 A sufficient supply of suitable water should be kept at hand. Operating procedures should ensure that the water level in the sterilizer is checked before every cycle and the reservoir replenished at specified intervals. This is particularly critical for clean steam (see SHTM 2031).

Safety precautions

7.10 As there is no thermal door-lock on the sterilizer, the load may still be very hot (up to 100°C) when it is removed from the chamber. Operators should therefore be issued with heat-resistant gloves.

7.11 Care should be taken not to contaminate load items with the gloves when removing the load from the chamber.

Product compatibility

7.12 These sterilizers are designed to process unwrapped instruments and utensils for immediate use in a controlled medical environment, such as an operating theatre. They should not be used to process items that are wrapped or items intended to be stored or transported before use.

7.13 Because these sterilizers have no active means of extracting air from load items, they should not be used with instruments and utensils whose construction could impede the passive removal of air and the subsequent penetration of steam. In practice, this means that hollow or porous items should not be processed in this type of sterilizer. A sterilizer with an active air removal system, such as a porous load sterilizer, is required in such cases. Draft European standards in preparation at the time of writing (1996) regard an item as hollow, and therefore unsuitable, if the item possesses a cavity of depth greater than the width of its orifice, or a double-ended hole of length greater than twice its width. This is a conservative criterion, and many borderline items may be safely processed if they are placed correctly in the chamber (see 7.17). However, the risk of incomplete sterilization is a real one, and Users should carefully examine each type of item to be processed to ensure that air removal and steam penetration will be effective. Failure to observe this requirement has led to serious incidents in which patients have

become infected by unsterile surgical instruments. The Authorised Person should be consulted in cases of doubt.

Items that should not be processed

7.14 The following items should not be processed in a sterilizer for unwrapped instruments and utensils:

a. medical devices intended to be supplied in compliance with the EU Directives discussed in Chapter 1 (unpackaged devices are not acceptable);

b. medicinal products;

c. wrapped items and other items likely to trap air and impede the penetration of steam (see paragraph 7.13);

d. aqueous fluids (a fluid sterilizer is required);

e. items not for immediate use.

Design of the load

7.15 Load items should be arranged on shelves or trays that permit the free circulation of steam and draining of condensate. Items should not be allowed to rest on the bottom of the chamber.

7.16 Trays or baskets should be constructed of open mesh or with sufficient ventilation holes to ensure that they present no barrier to air removal and steam penetration. BS 3970: Part 4 specifies that any such load containers used in these sterilizers should be perforated such that the total area of the perforations is at least 10% of the surface area of the container. The perforations should be uniformly distributed and each of area 20 mm^2 or more. Draft European standards make the same requirement.

7.17 As far as possible, load items should be arranged to ease the removal of air and the penetration of steam and allow condensate to run directly to the drain, away from the individual objects. Items of the load which could retain air and condensate, such as bowls, should be places on their sides so that air will be displaced and condensate will drain out.

Selection of cycle variables

7.18 Sterilizers conforming to the standards discussed in Part 2 of this SHTM will have a single operating cycle, normally with a sterilization temperature of 134°C and a holding time of at least 3 min. If other cycles are provided (see Table 7), the highest sterilization temperature compatible with the load should be chosen.

7.19 It is recognised that users of transportable sterilizers in primary health care units, such as GP and dental practices, where close supervision of the sterilizer is not practicable may wish to operate their machines with a wider margin of safety than would be the case in a hospital SSD staffed by full-time specialist personnel. In such cases the machine's plateau period may be preset to the extended plateau period given in Table 7.

Table 7: Sterilization conditions for sterilizers for unwrapped instruments and utensils

Sterilization temperature [°C]	Maximum allowable temperature [°C][a]	Minimum holding time [min]	Extended plateau period[b] [min]
134	137	3	4
126	129	10	15
121	124	15	20
115[c]	118	30	-

a. See paragraphs 2.52-2.53 for comment on maximum allowable temperatures.

b. See paragraph 7.19.

c. Permitted by BS 3970: Part 4 but not recommended for NHS use.

7.20 Users should note that the "plateau period" here is regarded as beginning when the chamber temperature attains its preset value as signalled by the indicator light. The conventional plateau period (see paragraph 2.48), which starts when the chamber temperature attains the sterilization temperature, cannot normally be defined on these small sterilizers which have no means of detecting when that temperature has been reached.

7.21 The need for regular testing, as specified in Part 3 of this SHTM, is re-emphasised.

Cycle monitoring and documentation

7.22 Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

7.23 Where a recorder is fitted to the sterilizer (as recommended in Part 2 of this SHTM), a batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the coolest part of the chamber (normally the active chamber discharge);

b. the pressure ("chamber pressure") recorded by a sensor in the chamber.

7.24 Where a recorder is not fitted, the following records should be made:

a. once a day, note the duration of the plateau period, and the indicated chamber temperatures and pressures at the beginning, middle and end of the plateau period, for a selected production cycle;

b. where practicable, note the indicated chamber temperature and pressure at the approximate mid-point of the plateau period for each production cycle.

7.25 The load may be released for use provided that:

a. *either*, during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. *or*, during the plateau period:

(i) the values of the plateau period and the indicated chamber temperature and pressures as described in paragraph 7.24a are within the permitted tolerances established during performance qualification;

(ii) the values of the indicated chamber temperature and pressures as described in paragraph 7.24b are also within the permitted tolerances established during performance qualification.

7.26 As load items are not wrapped, they are exposed to the air at the end of the cycle and subject to rapid recontamination. They should therefore be used without delay.

8. Operation of dry-heat sterilizers

Introduction

8.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to hot, dry air. Such sterilizers are correctly known as “dry-heat sterilizers” and sometimes as “hot-air sterilizers” or “sterilizing ovens”.

8.2 The guidance given here assumes that the sterilizer is to be used to process either medicinal products or medical devices in compliance with the EU Directives discussed in Chapter 1.

The process

8.3 Dry heat sterilizers expose the load to hot, dry gas (normally hot air) at a temperature of 160ºC or greater (see Table 8). The load is heated by conduction from the hot air to the load items. The process is slow and cycle times are several hours.

8.4 A dry-heat sterilizer will typically have the following operating cycle.

a. *Heating-up*. Hot air is heated electrically and circulated through the chamber.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the part of the chamber known to be the slowest to heat up, reaches the sterilization temperature.

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is cooled by circulating cold, filtered air through the chamber or through a jacket.

Safety precautions

8.5 The main hazard associated with dry-heat sterilizers is the high temperatures at which they operate. The highest sterilization temperature permits the temperature of the load to rise to 190°C (see Table 8). In the event of a control failure, the chamber temperature may rise to 200°C before the thermal cut-out shuts off the heaters.

8.6 In normal operation, a thermal door-lock prevents the door being opened until the temperature in all parts of the load has fallen to 80ºC. Nonetheless, operators should take great care in both unloading hot load items from the chamber and reloading a chamber that remains hot from a previous cycle.

Product compatibility

8.7 Dry heat may be used to process a variety of items and materials which would either be damaged by exposure to high-temperature steam or LTSF or would not be sterilized.

8.8 Suitable items include solids, heat-stable powders, waxes, greases, ointments, non-stainless metals, hollow needles, glass syringes and items in sealed containers. Dry heat may also be used for non-aqueous fluids such as white soft paraffin, paraffin gauze dressings, eye ointment bases, oily injections, silicone lubricant and pure glycerol.

Items that should not be processed by dry heat

8.9 The following items should not be processed by dry heat:

a. items that would be damaged by exposure to hot air at 160°C, such as glycerol/water mixtures, rubber, certain plastic or electrical items;

b. aqueous fluids (a fluid sterilizer is required).

8.10 As cycle times can be several hours, items must be able to withstand not only the holding time, but also the relatively slow heating and cooling stages.

Design of the load

8.11 The loading condition should be designed with two aims in mind:

a. to permit air to circulate freely within the chamber and around each item of the load;

b. to allow heat to be transmitted to and within each item of the load.

8.12 The time required for an individual load item to attain the sterilization temperature will depend upon its size, shape and thermal conductivity, and can vary widely. Powders and oils, in particular, take a long time to heat up. Loads should therefore be designed to contain items of similar size and nature.

8.13 If a mixed load cannot be avoided, then great care must be taken during performance qualification to identify the load items that are the slowest to heat up. The duration of the plateau period should be selected to ensure that these items are exposed to the sterilization temperature for the correct time.

Load preparation and packaging

8.14 All items must be clean and dry before sterilization.

8.15 Glass or metal syringes should be assembled and hinged instruments should be closed.

8.16 Delicate instruments, such as eye instruments, should be supported to guard against physical damage.

8.17 Good thermal contact between load items and their containers is essential. In the case of a heavy instrument, heat conduction can be improved by supporting the instrument in a metal cradle within its container. Smaller items may be wrapped in heavy or light gauge metal foil or contained in aluminium cans or tubes each of which may be sealed with push-on caps, screw caps, or crimp-on foil caps. Crimp-on foil caps with a pre-printed chemical indicator are also available.

8.18 The packaging does not need to be porous since the heat transfer normally takes place by conduction. However, in sealed packaging the contents of the pack when heated can exert a considerable pressure which may be sufficient to rupture the packaging material or seals. Vented packaging systems that allow pressure equilibration may be suitable for use in sterilizers which operate with a chamber atmosphere which has been filtered through a bacteria-retentive filter. This is particularly important during the cooling stage.

8.19 For items such as laboratory glassware, foil may be used to close the open end of the product to prevent contamination when the load is removed from the sterilizer.

8.20 Kraft paper bags or a simple layer of wrapping material can be used to pack individual items. Plastic bags of the sort sold for roasting meat in domestic ovens may also be suitable.

8.21 An extensive discussion on packaging materials and methods may be found in Part 5 of this SHTM.

Arrangement of load items

8.22 Random loading is not acceptable.

8.23 Load items should be placed in the chamber in such a way that air can circulate freely around them. This requires a space of at least 10 mm between adjacent items. They should therefore not be stacked and should not be allowed to touch each other.

8.24 Shelves and trays should be either perforated or made of wire mesh.

8.25 Because of the importance of air circulation, even minor variations in the loading pattern may seriously affect heat distribution and prevent complete sterilization of the load. Purpose-made shelving or spacers should be used to ensure accurate and repeatable positioning of load items.

Performance qualification

8.26 Because of the need for careful design of the load, performance qualification is required for each loading condition to be processed. The full-load test used during commissioning is not an acceptable substitute. The number of different loading conditions should be rationalised by careful design to minimise the number of PQ tests required.

8.27 Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Test Person.

Selection of cycle variables

8.28 The cycle variables should be selected to expose the load to one of the three combinations of sterilization temperature and holding time given in Table 8. The highest sterilization temperature compatible with the load should be chosen.

Table 8: Sterilization conditions for dry-heat sterilizers

Sterilization temperature [°C]	Maximum temperature [°C]	Maximum holding time [min]
160	170	120
170	180	60
180	190	30

8.29 A few heat-sensitive products may require lower temperatures and consequently prolonged holding times. The advice of the Authorised Person should be sought in such cases.

Cycle monitoring and documentation

8.30 The integrity of the air filter should be checked daily or, in the case of medicinal products, during each cycle. This will normally be done by measuring the differential pressure across the filter during the cooling stage and ensuring that the measured value is within the limits specified by the manufacturer. Note that this check is not the same as the air filter integrity test described in Part 3 of this SHTM.

8.31 Where the temperature of the load is to be monitored, the load temperature probe should be inserted into a load item known to be the slowest to attain the sterilization temperature. Where two probes are provided (normally in sterilizers over 600 litres) the second probe should be inserted into the load item known to be the fastest to attain the sterilization temperature. Sensors sealed into load containers should be located along the geometric axis and inserted to an approximate depth of 50% of the container height.

8.32 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

8.33 The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the coolest part of the chamber;

b. for medicinal products, the temperature ("load temperature") recorded by load temperature probes placed:

(i) in the load item known to be the slowest to reach the sterilization temperature;

(ii) for larger sterilizers, also in the load item known to be the fastest to reach the sterilization temperature.

Product release

8.34 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged.

9. Operation of LTS disinfectors

Introduction

9.1 This chapter gives guidance on the routine operation of clinical disinfectors designed to disinfect load items by exposure to low-temperature steam (LTS). See Chapter 10 for guidance on the operation of low-temperature steam and formaldehyde (LTSF) sterilizers.

9.2 The guidance given here assumes that the disinfector is to be used to process medical devices. However, the LTS process does not meet the sterilization requirements of the EU Directives discussed in Chapter 1. LTS should not be used for processing medicinal products.

9.3 LTS disinfectors are occasionally used to decontaminate soiled surgical components to make them safe to handle before they are washed and sterilized (see also paragraph 9.8). In such cases the machine used for initial decontamination should be reserved for that purpose and not be used also for the terminal disinfection of medical devices.

The process

9.4 Disinfection is achieved by direct contact with low-temperature saturated steam at sub-atmospheric pressure at a nominal temperature of 73°C (and not exceeding 80°C) for a minimum holding time of 10 minutes.

9.5 The LTS process kills most vegetative micro-organisms and some heat-sensitive viruses. It disinfects but does not sterilize.

9.6 LTS is free of toxic residues that may occur with chemical disinfection.

9.7 Part 2 of this SHTM specifies that new LTS disinfectors should conform to the requirements of BS 3970. Such a machine will have the following operating cycle.

a. *Preheating*. The walls of the chamber are heated to the preset operating temperature between 71°C and 78°C. This reduces condensation on the walls of the chamber (the door is not normally heated).

b. *Air removal*. Sufficient air is withdrawn from the chamber to permit the attainment of the disinfection conditions. This normally requires an absolute pressure of less than 50 mbar.

c. *Air ingress monitoring*. The chamber is automatically subject to a vacuum leak test before the cycle proceeds any further. If the leak rate is higher than a preset value (normally 5.0 ± 0.2 mbar min^{-1}) the cycle is aborted.

d. *Steam admission*. Steam is admitted to the chamber until the temperature attained throughout the load is 73 ± 2°C.

e. *Disinfection*. The temperature throughout the chamber and load is maintained at or above the disinfection temperature (71°C) for a holding time of not less than 10 min.

f. *Drying*. Steam is extracted from the chamber and the chamber pressure is reduced sufficiently to permit the evaporation of condensate from the load, either by prolonged evacuation of the chamber or by the injection and subsequent extraction of heated air or other gases within the chamber.

g. *Air admission*. Air is admitted to the chamber through a filter until the chamber pressure is within 100 mbar of atmospheric pressure.

Safety precautions

9.8 Where LTS disinfectors are used to decontaminate soiled items before cleaning, operators should be aware that the steam may not have penetrated below the surface of the soil and that decontamination may therefore not be complete. Care is required in the subsequent handling of the item before it is cleaned.

Product compatibility

9.9 LTS disinfection is suitable for a wide range of heat-sensitive items capable of withstanding a moist process.

9.10 The process is particularly suitable for the disinfection of respiratory and anaesthetic equipment, external pacemakers and for rigid endoscopes not requiring a sterilization process.

Items which should not be processed by LTS

9.11 The following items should not be processed by LTS:

a. items requiring sterilization;

b. items which may be damaged by the conditions of heat, moisture and pressure during the cycle;

c. items in sealed containers (the steam will not reach them);

d. oily or greasy items (oil or grease will impede the penetration of steam);

e. items likely to be contaminated with bacterial spores or other agents of similar resistance to the disinfection process.

Design of the load

9.12 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam; and

b. to ensure that the condensate formed during the cycle does not result in a wet load.

Air removal

9.13 The presence of air in the load can impede the penetration of steam and thereby drastically reduce the effectiveness of the disinfection process.

9.14 The principles of ensuring effective air removal for LTS disinfectors are the same as those for porous load sterilizers (see paragraphs 5.13-5.16).

Handling of condensate

9.15 The principles of ensuring that condensate does not result in wet loads are the same as those for porous load sterilizers (see paragraphs 5.17-5.24).

Packaging materials

9.16 Packaging materials for LTS sterilizers should meet the same requirements as those for porous load sterilizers (see paragraphs 5.25-5.28). Any process indicators in the form of printed panels designed for high-temperature steam processes will not, however, reliably respond to the LTS process. Until specific LTS indicators are available, plain bags should be used.

Selection of cycle variables

9.17 The LTS operating cycle is preset by the manufacturer and usually no adjustment is possible.

Cycle monitoring and documentation

9.18 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

9.19 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the active chamber discharge;

b. the pressure (“chamber pressure”) recorded by a sensor in the chamber.

Product release

9.20 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged;

c. the load items are visibly dry.

10. Operation of LTSF sterilizers

Introduction

10.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to low-temperature steam and formaldehyde (LTSF). See Chapter 9 for guidance on the operation of low-temperature steam (LTS) disinfectors.

NOTE: Despite their name, LTSF sterilizers are disinfectors.

10.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1. Due to its toxicity, LTSF should not be used for sterilization of medicinal products.

10.3 LTSF sterilizers are occasionally used to decontaminate soiled surgical components to make them safe to handle before they are washed and sterilized. In such cases the sterilizer used for initial decontamination should be reserved for that purpose and not be used also for the terminal sterilization of medical devices.

10.4 The user should seek advice from the Authorised Person, the Microbiologist or the manufacturer if in any doubt about the operation of LTSF sterilizers.

The process

10.5 Sterilization is achieved by direct contact with a mixture of low-temperature saturated steam and formaldehyde gas at sub-atmospheric pressure at a typical operating temperature of 73°C and not exceeding 80°C.

10.6 LTSF has a broad-spectrum action against vegetative bacteria, bacterial spores, fungi and most viruses.

10.7 Many operating cycles are in use, in which there are variations in the pattern of injection of steam and formaldehyde injection, the depth of vacuum, length of holding stages and the amount of formaldehyde employed. Part 2 of this SHTM specifies that new LTSF sterilizers should conform to the requirements of BS 3970. Such a sterilizer will have the following operating cycle.

a. *Preheating*. The walls of the chamber are heated to the preset operating temperature (typically 73°C, but the standard does not specify this). This reduces condensation on the walls of the chamber (the door is not normally heated).

b. *Air removal*. Sufficient air is withdrawn from the chamber to permit the attainment of the sterilization conditions. This normally requires an absolute pressure of less than 50 mbar.

c. *Air ingress monitoring*. The chamber is automatically subjected to a vacuum leak test before the cycle proceeds any further. If the leak rate is higher than a preset value (normally 5.0 ± 0.2 mbar min^{-1}) the cycle is aborted.

d. Sterilization.

   (i) Phase 1. The required steam and formaldehyde conditions within the chamber and load are attained.

   (ii) Phase 2. The temperature, humidity and formaldehyde concentration are maintained within specified limits for the holding time.

e. *Gas removal*. Formaldehyde and steam are removed from the chamber and load.

f. *Drying*. Steam is extracted from the chamber and the chamber pressure is reduced sufficiently to permit the evaporation of condensate from the load, either by prolonged evacuation of the chamber or by the injection and subsequent extraction of heated air or other gases within the chamber.

g. Air admission. Air is admitted to the chamber through a filter until the chamber pressure is within 100 mbar of atmospheric pressure.

10.8 Since the sterilization process is ultimately dependent on chemical action, a routine microbiological test is required for each production load to confirm that sterilization conditions have been attained (see paragraph 10.48).

Formaldehyde solution

10.9 Formaldehyde (CH_2O), also known as methanal, is a colourless, toxic gas with a strong, characteristic odour. It is normally produced within the sterilizer by the evaporation of Formaldehyde Solution BP, also known as formalin, containing 34-38% w/w formaldehyde stabilised with methanol.

10.10 Analytical reagent grade formaldehyde solution, also specified in the British Pharmacopoeia, is unstabilised and is not suitable for use in sterilizers.

10.11 BS 3970 permits other “primary materials” to be used for the generation of formaldehyde, though formalin is by far the most common. If other materials are used, the user should ensure that adequate information on safety and usage is supplied by the manufacturer of the product.

Polymerisation

10.12 When formalin is allowed to stand or evaporate, white flocculent masses of paraformaldehyde are precipitated. Paraformaldehyde is a mixture of polymethylene glycols (of the general form $(CH_2O)_n$, xH_2O, where n is 6-50) formed by the reaction of formaldehyde with water. It is readily converted back to formaldehyde gas by heating.

10.13 Paraformaldehyde may be formed in LTSF sterilizers where the formaldehyde gas is allowed to condense on a cold, wet surface. As the reaction removes formaldehyde from the chamber atmosphere it can lead to a failure of the sterilization process. Paraformaldehyde deposits may also block pipework in the heat exchanger and so reduce the efficiency of vaporisation of the formalin. Polymerisation is controlled mainly by careful handling of condensate (see paragraphs 10.32–10.37). Heated doors, provided on some models, are also helpful.

10.14 Experience has shown that on larger LTSF machines an occasional flushing cycle, in which the formalin supply is replaced with water and a cycle run with an empty chamber, is beneficial in reducing polymerisation problems. Flushing cycles may conveniently be run overnight.

Safety precautions

10.15 Where LTSF sterilizers are used to decontaminate soiled items before cleaning, operators should be aware that the sterilant may not have penetrated below the surface of the soil and that decontamination may therefore not be complete. Care is required in the subsequent handling of the item before it is cleaned.

10.16 Formalin is a toxic liquid which requires careful handling and secure storage.

Effects on health

10.17 Formaldehyde gas has a pungent odour which is very irritating to the eyes and respiratory tract, with a threshold of detection by smell at around 0.8 ppm, though the threshold for irritation may be lower. The threshold for eye irritation may be as low as 0.01 ppm; 4 ppm usually causes the eyes to water. Mild effects on the throat may occur at 0.5 ppm; 10 ppm causes severe irritation to the eyes, nose and throat. Formaldehyde is assigned a maximum exposure limit of 2 ppm (both short-term and long-term limits) under the COSHH Regulations 1999 (see Schedule 1). The presence of formaldehyde in the air can therefore be sensed by personnel at levels below the maximum exposure limit; in this respect, LTSF sterilization is safer than EO sterilization.

NOTE: Refer also to EH40 ‘Occupational Exposure Limits’ Table 1.

10.18 Workers regularly exposed to formaldehyde may become acclimatised to the effects at low concentrations. There is no evidence to suggest that exposure to formaldehyde leads to chronic impairment of lung function. There have been only a few case reports of occupational asthma associated with formaldehyde exposure, despite its widespread use in industry. However, skin contact has been shown to cause allergic contact dermatitis.

10.19 Although there is no epidemiological evidence that formaldehyde is associated with cancer in humans, HSE advises that it should be regarded as a potential carcinogen.

10.20 Formalin liquid can cause irreparable damage if splashed in the eyes. Eye-washing facilities should be provided. Hazard labels should be displayed prominently in all areas in which formalin is handled and used.

Replenishing the formalin supply

10.21 In normal operation of LTSF sterilizers, the greatest risk of exposure occurs when the formalin supply in the sterilizer is replenished. A written procedure for the filling and the connection of formalin tanks should be devised, based on a risk assessment complying with the COSHH Regulations. Care should be taken that the exposure limits given in Schedule 1 are not exceeded. All staff whose duties include replenishing the formalin supply should receive instruction.

10.22 Formalin should be stored in a closed container in a locked cabinet at a temperature of 15-25ºC. Vessels required for handling the formalin, such as jugs and funnels, should also be kept in the cabinet.

10.23 On certain older sterilizers replenishment of the formalin supply is a matter of removing the empty tank from the sterilizer and installing a full one in its place. On newer sterilizers, formalin is decanted into the tank from a storage container.

10.24 The decanting operation should be done in a well-ventilated room where an accidental spillage will not endanger staff or patients. A safety cabinet or fume cupboard is desirable. The following precautions should be observed when decanting is necessary.

a. Dress in appropriate personal protective equipment (PPE), ie. apron, facemask and gloves (see paragraphs 2.14-2.15).

b. Remove the formalin tank from the sterilizer and take it to a bench or worktop near a sink or hand-basin where plenty of running water is available.

c. Take the formalin bottle from the storage cupboard.

   (i) Check the expiry date. If the date has passed, the solution should not be used.

(ii) Examine the solution to ensure that polymerisation and separation have not taken place. The solution should be clear, with no sign of white particles or sediment. If there are any signs of polymerisation, the solution is not suitable for sterilization and should not be used.

d. Check the quantity of formalin to be decanted into the tank.

e. Decant the solution slowly into the tank. Do not lift the storage bottle above chest height.

f. When the decanting is complete, wash any jugs or funnels used in the process with ample clean, cold water.

g. Return the tank to the sterilizer and install it in accordance with the manufacturer's instructions.

h. Return the formalin storage bottle and filling vessels to the cabinet and lock the door.

i. Remove the PPE, discard or clean as appropriate, and return it to its storage location.

Product compatibility

10.25 LTSF is a suitable process for a wide variety of items which are unsuitable for sterilization by high-temperature steam or dry heat. This includes many materials and items of equipment with integral plastic parts which could be damaged by heat. Complex items, such as certain electromedical equipment, may be sterilized by this process.

10.26 For example, LTSF can be used for sterilizing ophthalmic and cardiology items such as retinal and cataract detachment probes, cardiac catheters and pacing electrodes. It is also useful for elastic bougies, artificial joints, foetal scalp electrodes, amniotic membrane perforators and similar heat-labile items.

10.27 The reversible adsorption of formaldehyde by some materials must be considered. The high surface area of fabrics can adsorb large quantities of formaldehyde (effectively absorption) and these may remain for long periods unsuitable for patient use.

10.28 Because of the hazards associated with LTSF, it should not be used to sterilize items which could be processed by other means. A survey by the Central Sterilising Club showed that many items processed in hospital LTSF sterilizers carry only an intermediate infection risk (see Table 2 in Chapter 2) and LTS disinfection would have been more appropriate. Examples include face masks, ventilator tubing, nebulisers, airways, mattresses, sheepskins, breast milk expressors and toys.

NOTE: Sterilization and disinfection of heat-labile equipment, by Central Sterilising Club 1986.

Items which should not be processed by LTSF

10.29 The following items should not be processed by LTSF:

a. items which may be damaged by the conditions of temperature, pressure, moisture and chemical environment prevailing during the cycle;

b. items in sealed containers (the sterilant will not reach them);

c. oily or greasy items (oil or grease will impede the penetration of the sterilant);

d. items contaminated with body fluids (hardened, fixed protein deposits will be produced); eg. “dirty returns” from operating theatres, clinics, etc.;

e. electrical or other items requiring a dry process, e.g. fully assembled air drills, dental hand pieces and infant ventilators;

f. certain flexible fibre-optic endoscopes (differential expansion will crack the sealants and let moisture penetrate the optics);

g. items which may absorb and retain unacceptable quantities of formaldehyde.

Design of the load

10.30 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam and formaldehyde; and

b. to ensure that the condensate formed during the cycle is quickly drained clear of the load.

Air removal

10.31 The presence of air in the load can impede the penetration of steam and formaldehyde and thereby drastically reduce the effectiveness of the sterilization process. The principles of ensuring effective air removal for LTSF sterilizers are the same as those for porous load sterilizers (see paragraphs 5.13-5.16).

Handling of condensate

10.32 As in all steam sterilizers, water condenses during the heating stages of the LTSF cycle. This problem is particularly acute when sterilizing metal items.

10.33 In contrast to porous load sterilizers (see paragraphs 5.17-5.24), where it is preferable to retain condensate close to the load items to permit re-evaporation, condensate formed in LTSF sterilizers should be drained clear of the load as quickly as possible. This is for two reasons:

a. excessive moisture may impede the penetration of formaldehyde gas into the load (especially where items have narrow lumens);

b. condensate allowed to remain on the load will promote the formation of paraformaldehyde (see paragraph 10.13).

10.34 Chamber furniture should therefore be made from materials of high thermal conductivity (such as aluminium) to reduce heat-up time and so avoid cool surfaces. Open mesh supports should be used to allow drainage as well as gas penetration.

10.35 Packs should be arranged in a manner which will permit the free drainage of condensate.

10.36 To retain heat and reduce condensate formation, the door should remain closed whenever the machine is not in use.

10.37 LTSF sterilizers should always be preheated prior to use. This may be either from a previous LTSF cycle, or from an LTS cycle used specifically for preheating.

Packaging materials

10.38 The basic considerations for packaging are similar to those for porous load sterilizers (see paragraphs 5.25-5.28), except for the following:

a. the extent to which packaging materials will retain both moisture and formaldehyde residuals may affect the efficacy of the process;

b. materials which are slow to attain the sterilization temperature may promote polymerisation;

c. materials of high heat capacity promote the formation of excessive amounts of condensate.

10.39 It is therefore recommended that packaging should be kept to a minimum.

10.40 Packaging may consist of paper, used as plain or creped wraps, or in the form of bags or, in combination with plastic film, as pouches. Light cardboard boxes, or corrugated polypropylene boxes, adequately vented and overwrapped with paper or other material as a bacterial barrier, are also suitable. When particularly delicate instruments are to be processed, the use of open-cell foam for support and protection is acceptable.

10.41 To assist in the detection of paraformaldehyde deposits, packaging materials should preferably be of dark colour (such as green) rather than white.

10.42 If packaging designed for porous-load sterilizers is used, Users should note that any process indicators in the form of printed panels will not reliably respond to the LTSF process. If specific LTSF indicators are not available (they should conform to EN 867: Part 2) plain bags should be used.

10.43 Extensive guidance on packaging may be found in Part 5 of this SHTM.

Performance qualification

10.44 Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Microbiologist and Test Person.

Selection of cycle variables

10.45 The concentration of formaldehyde in the chamber during the holding time will have been determined during performance qualification and is typically around 15 g m^{-3} for an operating temperature of 73°C. This is equivalent to the evaporation of 40 ml of formalin per cubic metre of the chamber volume (this is the volume of the pressure vessel, not the usable chamber space).

10.46 Other cycle variables are preset by the manufacturer.

Cycle monitoring and documentation

10.47 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

10.48 A routine microbiological test should be carried out with every production load as described in Part 3 of this SHTM. Note that the full result of the test will not be known until the biological indicator has been cultured for 7 days.

10.49 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the active chamber discharge;

b. the pressure ("chamber pressure") recorded by a sensor in the chamber.

10.50 The operator should note the indicated amount of formalin consumed during the cycle and check that the gas removal stage has been completed satisfactorily before opening the door.

Product release and storage

10.51 The load may be released for degassing provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the correct amount of formalin has been taken from the tank;

c. the chemical indicator used in the routine microbiological test shows a uniform colour change;

d. there is no visual evidence of polymerisation (see paragraph 10.59);

e. the packaging is undamaged;

f. the load items are visibly dry.

10.52 The load may subsequently be released as sterile provided that the microbial culture results of the routine microbiological test described in Part 3 of this SHTM are satisfactory.

10.53 It is common practice in some units to release loads on the strength of the batch process record and not wait until the result of the microbiological test is known. The rationale for this is that the BPR confirms that the load has been exposed to a high-grade LTS disinfection process and is therefore safe for use. A subsequent failure of the microbiological test would lead to the sterilizer being withdrawn from service for investigation but would not normally lead to the recall of the released goods.

10.54 While such practices have been justified on the grounds of economy, they would not be acceptable under the EU Directives on medical devices. If the microbiological test shows a failure, the machine is, by definition, not working to the specifications established during validation and the process is therefore not adequately controlled (see paragraph 10.58).

10.55 A degassing time for each load will have been established during performance qualification. This will typically be no more than one hour. An active degassing system is not necessary. Goods processed in an LTSF sterilizer should be stored in such a way that air from the ventilation system cannot carry traces of formaldehyde over goods from other types of sterilizer.

Troubleshooting

Cycle fault

10.56 The automatic controller may indicate a fault for a number of reasons, including:

a. a vacuum leak greater than a preset value (normally 5.0 ± 0.2 mbar min^{-1});

b. failure to attain the sterilization temperature;

c. insufficient formalin for a complete cycle.

10.57 Should a fault develop, the risk of exposure to formaldehyde is much greater than in normal operation. The Maintenance Person should be notified immediately. The batch process record should be carefully compared with the master process record to establish the precise point the cycle has reached. If it is suspected that formaldehyde has not been withdrawn from the chamber, the door of the sterilizer should not be opened until the loading area has been evacuated. Both the room ventilation and local exhaust ventilation should be operating. Provided the chamber has reached atmospheric pressure, the door can then be cranked partially open by an

operator wearing a respirator. The chamber and load should be left overnight with the ventilation systems running during which time the formaldehyde will safely disperse.

Failure of the routine microbiological test

10.58 Failure of the microbiological test shows that the prescribed sterilization conditions have not been attained. If the batch process record shows that the physical cycle variables were satisfactory, then suspicion should fall on the formaldehyde component of the process.

a. The concentration of formaldehyde in the chamber was too low. There are several reasons why this might be.

   (i) Insufficient formalin was consumed. This would normally lead to a fault indication and would have been revealed by inspection of the formalin level indicator.

   (ii) Some of the formaldehyde was polymerised (see paragraph 10.59);

   (iii) Some of the formaldehyde was dissolved in condensate. Check that there are no places in the load or chamber where standing water could collect (this could happen if chamber furniture or loading trolleys become dented).

   (iv) Some of the formaldehyde was absorbed into the load. This is improbable if performance qualification tests have been conducted and previous loads have been processed satisfactorily.

b. The loading condition is too great a challenge to the penetration of formaldehyde. Again, this is unlikely if performance qualification has been satisfactory.

Polymerisation of formaldehyde

10.59 The scientific background to formaldehyde polymerisation is discussed in paragraph 10.12. Evidence that polymerisation has occurred during a cycle is normally in the form of patchy white deposits of paraformaldehyde in the chamber and on the load items. There are three main causes to be considered.

a. Too much water was present in the chamber. Principles for avoiding wetness are discussed in paragraphs 10.32–10.37. If the loading condition has been processed many times before without difficulty, then the problem may lie in the steam supply which should be tested for dryness as described in Part 3 of this SHTM.

b. Too much formalin was used in the cycle. This is unlikely if the formalin indicator is working correctly and has been read correctly.

c. Failure (or partial failure) of the heat exchanger. If white streaks are visible in and around the steam entry port, it is likely that liquid formalin has entered the chamber. This implies that the temperature in the heat exchanger was too low for complete vaporisation.

11. Operation of ethylene oxide sterilizers

Introduction

11.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to ethylene oxide gas (EO).

11.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1. Due to its toxicity, EO should not be used for sterilization of medicinal products.

11.3 Sterilization by EO should be regarded as a last resort, only to be used when other forms of sterilization are not possible. The wide variety of items processed in hospital SSDs will increase the difficulty in validating the process to achieve consistently low levels of residual EO. Items sterilized by EO may therefore contain higher levels of residuals than are desirable.

The process

11.4 EO is a highly penetrative, non-corrosive agent which has a broad-spectrum action against viruses, vegetative bacteria, bacterial spores, fungi, and other living cells under optimal conditions of concentration, relative humidity, temperature and exposure time. It may be used at temperatures and pressures which minimise damage to sensitive equipment. Typical operating temperatures are in the range 20-60°C.

11.5 Two types of EO sterilizer are employed in the NHS.

11.6 In low-pressure sterilizers, of chamber volumes around 150 litres, the sterilant is pure EO at sub-atmospheric pressure. The gas is supplied from a single-use, disposable cartridge contained within the chamber. The cartridge limits the amount of EO in use at any one time and so reduces the toxic and explosive hazards. The chamber is designed to contain the effects of an explosion of the contents of a single cartridge. Compared with high-pressure sterilizers (see paragraph 11.7), low-pressure machines are relatively cheap to install and to run, requiring no piped EO service and no gas disposal plant. The low pressure in the chamber allows pressure-sensitive equipment to be processed safely.

11.7 In high-pressure sterilizers, of chamber volume up to 500 litres, the sterilant is EO diluted with another gas, supplied from cylinders. The mixtures are chosen to expose the load to an EO concentration of around 500-1000 mg litre^{-1} while keeping the potential hazards to a minimum Two gas systems are in common use:

a. EO with chlorofluorocarbons (CFCs) or hydrochlorofluorocarbons (HCFCs) at pressures up to 2 bar: CFCs have traditionally been used as a diluent gas but are no longer acceptable for environmental reasons; HCFCs require even more critical control of humidity than other systems and are themselves due to be phased out;

b. EO with carbon dioxide at pressures up to 6 bar.

11.8 The operating cycle of an EO sterilizer constructed to EN 1422 will have the following stages, though the order may be varied slightly.

a. *Chamber preheating*. With the load in place, the chamber is heated to a preset working temperature.

b. *Air removal*. Sufficient air is removed from the chamber and load to permit the subsequent attainment of the sterilization conditions and to ensure that the admission of EO will not result in a flammable or explosive mixture.

c. *Automatic leak test*. A vacuum leak test is carried out to ensure that air does not leak into the chamber. For sterilizers operating at pressures higher than 1.05 bar, a pressure leak test is also carried out to ensure that EO does not leak out of the chamber.

d. *Conditioning*. The load is heated and humidified to a preset sterilization temperature and humidity (at least 40% RH). The length of this stage will depend on the extent of any preconditioning.

e. *Gas injection*. Gas is admitted to the chamber until the operating pressure has been attained.

f. Ga*s exposure*. The temperature and gas pressure (or concentration) are maintained within limits throughout the chamber and load for a preset holding time.

g. *Gas removal*. Gas is removed from the chamber to reduce the concentration below the flammable limit when air is admitted at the end of the stage. Some gas will still be left in the load.

h. *Flushing*. Sufficient gas is removed from the load so that there is no longer a safety hazard to the operator when the sterilizer is unloaded. The flushing agent is normally filtered air or an inert gas.

i. *Air admission*. Air is admitted to the chamber until the pressure approaches atmospheric pressure.

j. *End of cycle*. If the door remains unopened for more than 15 min after the end of the air admission stage, the gas removal and/or flushing stages are automatically repeated to prevent an accumulation of gas in the chamber.

11.9 Typical process times, including degassing after the cycle is complete, can range from 12 to 24 hours depending on the sterilization temperature, gas concentration and the nature of the load.

11.10 Since the sterilization process is ultimately dependent on chemical action, a routine microbiological test is required for each production load to confirm that sterilization conditions have been attained (see paragraph 11.43).

Safety precautions

11.11 EO presents hazards not found in conventional sterilizers. The gas is toxic, flammable and explosive. Extensive guidance on safety precautions to be followed in handling EO can be found in Appendix 3. See also 'Ethylene oxide sterilization section' (HBN 13 Supplement 1) published by NHS Estates.

NOTE: Management Executive Letter MEL(1995)48 modifies HBN 13 Supplement 1 for use in Scotland.

Product compatibility

11.12 EO sterilizers can be used to process heat-sensitive materials which cannot withstand low-temperature steam. They should not be used to process products which can be sterilized by alternative methods; that is by high-temperature steam, dry heat or LTSF.

11.13 A survey by the Central Sterilising Club showed that many items processed in hospital EO sterilizers carry only an intermediate infection risk (see Table 2 in Chapter 2) and LTS disinfection would have been safer and more appropriate. Examples include face masks, ventilator tubing, airways, breast milk expressors, plastic vaginal speculae, amniotic membrane perforators and eye patches. None of these items requires EO sterilization and some may be designated by the manufacturer as single-use only.

NOTE: Sterilization and disinfection of heat-labile equipment, by Central Sterilising Club 1986.

11.14 It is common practice to use EO to resterilize items such as cardiac catheters that are intended by the manufacturer to be used only once. While this may be justified on economic grounds, attention is drawn in paragraphs 2.22-2.25 to the difficulties in validating cleaning procedures for such items and the possible legal implications of reusing them. Users also should bear in mind that some medical devices designed for single-use may have been originally sterilized by radiation. In certain circumstances these may be weakened by subsequent exposure to EO and should therefore not be resterilized.

11.15 Low-pressure EO is suitable for items such as certain flexible endoscopes and electronic equipment which would be damaged by exposure to an LTSF process.

11.16 Certain types of EO sterilizer, notably those employing EO diluted with carbon dioxide, operate at pressures up to 6 bar. Users should ensure that load items would not be damaged by exposure to such pressures.

11.17 Care should be taken that materials submitted for sterilization do not undergo undesirable reactions with EO. If doubt exists about this, it is advisable to contact the supplier of the gas.

Items that should not be processed by ethylene oxide

11.18 The following items should not be processed by EO:

a. items that could be sterilized by another process;

b. items which may be damaged by the conditions of temperature, pressure and chemical environment prevailing during the cycle;

c. medicinal products;

d. ventilatory and respiratory equipment;

e. soiled items;

f. plastic items previously sterilized by radiation;

g. items which may absorb and retain unacceptable quantities of EO residuals.

Design of the load

11.19 Packaging materials and methods should be selected which are compatible with the EO sterilization process and which maintain sterility and the quality of the contained product. Packaging should be designed to allow removal of air and penetration of both steam and EO.

11.20 Because a wide variety of EO processes are in use, packaging suitable for one EO sterilizer may not be suitable for another. For example, package seals may be weakened and possibly fail in a cycle with relatively high humidity and several large and rapid changes in pressure, where seals of the same type would have been satisfactory for a cycle employing less extreme conditions.

11.21 The extent to which packaging absorbs or adsorbs EO and its permeability to EO may have a major influence on the efficacy of the cycle and the subsequent aeration process. Cartons (shelf packs, transit cartons) may be convenient but they may increase the humidification time, the gas exposure time and subsequent level of EO residuals.

11.22 Because of the need to control humidity, the extent to which packaging absorbs moisture may have a major influence on the efficacy of the process and must be considered before a satisfactory humidification stage can be demonstrated.

11.23 Process control is also a concern since packaging material that has become dehydrated may absorb excessive moisture during the conditioning phase; if

this possibility were not recognised during validation the achieved cycle lethality may be adversely affected.

11.24 In practice, many of the packaging materials routinely used for steam sterilization in hospitals are equally suitable for EO. However, Users should be aware that because of the lower temperatures employed in the EO process a wider range of materials is available.

11.25 Paper bags or plastic/paper pouches are usually found to be the most convenient for small items. Polythene bags with gas exchange ports of Tyvek are also suitable.

11.26 Large procedure trays containing endoscopes or other heat-sensitive equipment may be wrapped in sheets of plain or crepe paper, or textiles. Moulded foam inserts may be used to provide mechanical protection.

11.27 Biological indicators should be placed in the load before preconditioning (see 11.43).

Performance qualification

11.28 PQ tests are required for loading conditions representing every production load. Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Microbiologist and Test Person.

11.29 Because of the wide variety of items processed by EO, it is not always practicable to conduct PQ tests for every possible loading condition. Users are advised to categorise load items by the degree to which they can absorb and retain moisture and EO, and then ensure that loads are made up of items in the same category. For example, rubber absorbs EO readily, while electronic devices do not.

11.30 The amount of microbial contamination (the bioburden) after cleaning may need to be determined as part of the performance qualification process, though this is not normally required in hospitals where a wide range of items are to be sterilized and gas exposure times are calculated to be more than sufficient to deal with the maximum anticipated bioburden. Where such determinations are required they should comply with EN 1174.

Preconditioning

11.31 If EO sterilization is to be effective, it is essential that the humidity within any part of the load should not be less than 30% RH, and that there should be no free water within the chamber.

11.32 To ensure that these extremes of humidity are not exceeded when sterilizing different types and sizes of load which have been stored in unknown ambient temperatures and humidity, it may be necessary to subject the load to a preconditioning treatment in a known environment. Preconditioning may be done within the sterilizer chamber before the start of the operating cycle, or in a purpose-built room or cabinet. Specifications for preconditioning rooms or cabinets can be found in Part 2 of this SHTM.

11.33 Preconditioning may not be necessary where workloads are small. In such cases the conditioning stage of the operating cycle may be satisfactory (see paragraph 11.8d). However, Users should note that the humidity instruments attached to the sterilizer may not be as reliable as those provided for a purpose-built preconditioning room or cabinet. For this reason, preconditioning is always recommended.

11.34 Within limits, the humidity within the chamber can be determined from the mass of steam injected, the pressure change within the chamber, the moisture absorbent characteristics of the load and the temperature and humidity of the load before it is placed in the sterilizer chamber. However, whenever preconditioning is to be done in the sterilizer chamber, the humidity should be by direct measurement (but see paragraph 11.46a) and within limits its value should be known for each cycle.

11.35 All packaged product within the preconditioning area should be identified. For each batch processed, the levels of the physical values achieved during preconditioning should be recorded. These should include the following.

a. the ambient temperature of the packaged product entering the preconditioning room;
b. the time when the packaged product enters the preconditioning room;
c. the time when the packaged product leaves the preconditioning room;
d. the temperature record for the period the packaged product is in the preconditioning room;
e. the humidity (RH) record for the period the packaged product is in the preconditioning room.

11.36 The temperature and humidity within the preconditioning area should be set to the same values that will prevail during the gas exposure time. The temperature within the load at the end of the preconditioning period should not deviate by more than ± 5°C from the nominal conditions within the area and the RH should not deviate by more than ± 15% RH from the nominal conditions in the area. The time taken to achieve these conditions during validation should be noted and used as the minimum specified for routine operations.

11.37 The preconditioning area should be subject to performance qualification. PQ should be performed with the preconditioning area in both fully loaded and typical partly loaded states and carried out with the loading patterns and pallet spacings specified in documented procedures.

11.38 The reference position for monitoring temperature and RH during preconditioning should be that at which it is most difficult to achieve the desired conditions. Data for this routine monitoring should be reviewed before the load is released for sterilization.

11.39 The ambient temperature of items entering the preconditioning area should be at or above the minimum temperature specified during validation. It is not generally necessary to routinely determine the temperature of load items before preconditioning where the conditions of storage are known.

Selection of cycle variables

11.40 The EO concentration prevailing during the gas exposure stage will have been established during performance qualification. A concentration of at least 300 mg litre^{-1} is commonly used. Concentrations greater than 1200 mg litre^{-1} do not result in a substantial increase in the effectiveness of the sterilization process.

11.41 Apart from adjustment of flushing times, other cycle variables are preset and cannot be modified by the user.

Cycle monitoring and documentation

11.42 Each cycle should be noted in the sterilizer process log (see paragraph 3.11). The following information should be recorded for each load processed:

a. for preconditioning (if used), the temperature and humidity monitored and recorded from a position which can be related to that at which it is most difficult to achieve the specified conditions;

b. time of commencement and removal of load from preconditioning (if used) of each load;

c. time of commencement of the operating cycle;

d. chamber temperature and pressure during the operating cycle measured from a representative position within the chamber;

e. evidence that the gaseous sterilant has been admitted to the chamber;

f. a measure of the quantity of EO used or the concentration of EO in the chamber;

g. duration of the gas exposure time;

h. time, temperature, pressure changes (if any) and/or the operation of the air supply (if used) during aeration;

i. the results of the routine microbiological test.

11.43 A routine microbiological test should be carried out with every production load as described in Part 3 of this SHTM. Note that the full result of the test will not be known until the biological indicators have been cultured for 7 days.

11.44 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the coolest part of the chamber;

b. the pressure ("chamber pressure") recorded by a sensor in the chamber.

Chamber humidity

11.45 A load which has been preconditioned may lose moisture during the air removal stage of the operating cycle and steam may be injected during the conditioning stage (before gas injection) to maintain the moisture content at the specified level.

11.46 The humidity within the chamber should be monitored in one of two ways:

a. by direct measurement of RH. Many RH sensors are poisoned by absorption of EO and provision should be made either to isolate the sensor from the chamber atmosphere before EO is admitted, or to remove the sensor for degassing after the sterilization cycle is complete. Note that the RH as perceived by a sensor at a low pressure may be different from that measured at a higher pressure;

b. by monitoring the rise in temperature and pressure as steam is admitted; care should be taken to ensure that the measured values truly relate to RH and are reproducible. Details of the calculation are given in Part 3 of this SHTM: Appendix 2.

EO concentration

11.47 The pressure rise at gas injection provides the primary, though indirect, measure of the EO concentration in the chamber. The measuring equipment should have sufficient sensitivity to allow recordings of small quantities of gas which may be admitted throughout both the gas injection and gas exposure stages. Details of the calculation are given in Part 3 of this SHTM: Appendix 2.

11.48 Since the EO concentration is critical to the efficacy of the cycle, a second, independent system is required to confirm that the pressure rise is due to EO. Either of the following may be used:

a. monitoring the change in mass of the gas supply cylinder or cartridge;

b. metering the volume of gas delivered to the chamber.

11.49 Where a sterilizer is supplied from a disposable cartridge, it can be assumed that the entire contents of the cartridge are released into the chamber. However, it should not be assumed that the mass of the contents corresponds precisely to the manufacturer's stated value. As a matter of routine, the cartridge should be weighed immediately before it is placed in the sterilizer and after it has been removed to establish the mass of gas consumed, and the results noted in the sterilizer process log.

Product release

11.50 The load may be released for degassing (see paragraph 11.52) provided that:

a. the preconditioning records are satisfactory;

b. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

c. the correct amount of EO has been injected into the chamber;

d. the chemical indicators used in the routine microbiological test show a uniform colour change;

e. the packaging is undamaged;

f. load items are visibly dry.

11.51 The load may subsequently be released as sterile provided that the microbial culture results of the routine microbiological test described in Part 3 of this SHTM are satisfactory and approved by the Microbiologist.

Degassing

11.52 Most, if not all, materials retain varying amounts of EO following sterilization. The residual EO in items for medical use should be reduced to a safe level, both for personnel handling the items and for the patient. Other compounds may also be present as reaction products of EO, such as ethylene chlorohydrin, and the concentration of these may also need to be reduced. Reference in this SHTM to reduction of residual EO should be read as applying equally to any other toxic reaction products which may be present.

11.53 Certain materials, such as polyvinyl chloride, silicone and rubber, are particularly absorbent and require longer degassing times. If not removed, residual EO will give rise to burning sensations and other irritant or toxic effects when the sterilized item is implanted or in contact with body tissue.

11.54 Permitted levels of EO residuals, and methods for their determination, are given in EN 30993: Part 7.

11.55 Reduction of residual EO occurs naturally as gas diffuses from the product into the surrounding air down the concentration gradient. Under normal ambient conditions this process may be very slow and significant amounts of EO may be present in the environment. For these reasons degassing by storage under ambient conditions is not recommended; mechanical degassing should be used.

11.56 The time required for degassing depends on a number of factors:

a. the composition, form and mass of the items in the load;

b. the concentration of residual EO when the load is removed from the sterilizer (this will in part depend on the EO concentration and gas exposure time, but more importantly on the extent and nature of the flushing stage in the sterilizer);

c. the temperature at which degassing takes place;

d. the concentration of residual EO which is acceptable for the intended use of the product.

11.57 The time required under the prevailing conditions should be determined for each type of product as part of performance qualification. Where this is impracticable, such as where a sterilizer is used for low numbers of a great variety of items, the degassing process should be determined for the item which has the longest degassing time. This is likely to be the largest and most complex item made from polyvinyl chloride.

11.58 A validated and monitored degassing procedure should be followed. Degassing can be performed within the sterilizer or in a separate chamber or area (see Part 2 of this SHTM). The temperature profile and air flow rate during degassing should be monitored and recorded.

Troubleshooting

Failure of the routine microbiological test

11.59 Failure of the microbiological test shows that the prescribed sterilization conditions have not been attained. If the test itself appears to have been carried out correctly (the biological indicators should be checked to make sure the correct type has been used) and the batch process record is satisfactory, then the following possibilities should be considered.

a. The concentration of EO in the chamber was too low. There are several reasons why this might be.

(i) Insufficient EO was admitted. This would normally lead to a fault indication and would be revealed by inspection of the chamber pressure record and the secondary method (mass or volume, see paragraph 11.48).

(ii) Some of the EO was polymerised. Green streaks on the chamber walls near the inlet port suggest that liquid EO entered the chamber. The preheater should be checked.

(iii) Some of the EO was absorbed into the load. This is improbable if performance qualification tests have been conducted and previous loads have been processed satisfactorily.

b. The humidity in the chamber was either too high or too low. Humidity is critical to the operation of EO sterilizers and even small deviations from the ideal level can have large effects on the efficacy of the cycle. Incorrect humidity is the single most common cause of failure. If the preconditioning records are satisfactory, suspicion should fall on the sterilizer humidifying system.

c. The loading condition is too great a challenge to the penetration of EO. This is unlikely if performance qualification has been satisfactory.

12. Operation of laboratory sterilizers

Introduction

12.1 This chapter gives guidance on the routine operation of high-temperature steam sterilizers ("laboratory sterilizers") designed to process materials and equipment for use in clinical laboratories.

12.2 These sterilizers are not suitable for processing either medical devices or medicinal products and are therefore not subject to the EU Directives discussed in Chapter 1.

Sterilization conditions

12.3 European Standards for medical devices and medicinal products require that for a product to be labelled "sterile", no more than one micro-organism should survive in 10^6 load items (see EN 556). There is no universally accepted probability of survival for laboratory purposes. In laboratory practice for make-safe loads, the high initial concentration of micro-organisms is considered to be balanced by a higher acceptable probability of survival than in items intended to be used on patients. This has allowed the standard sterilization conditions adopted for medicinal products and medical devices (see paragraphs 2.43-2.55) to be used for laboratory make-safe loads.

12.4 The same standards are also used for sterilizing culture media, fabrics and equipment and glassware; for these loads (but not for make-safe loads) times and temperatures may be reduced if necessary to minimise deterioration of the product. Account should also be taken of the contributory effect of high temperatures during the heat-up and cooling stages on the degradation of culture media constituents.

12.5 Examples of recommended sterilization conditions are shown in Table 9.

12.6 The effect of the initial cell population (bioburden) on the number of survivors after heating reinforces the need to reduce numbers by cleaning equipment and glassware before sterilization. In microbiology laboratories it is possible, with good laboratory practice and by using dehydrated culture media from reputable manufacturers, to ensure that there are minimal numbers of contaminating micro-organisms in media prepared for sterilization. However, in discard boxes to be subjected to a make-safe process, the numbers of micro-organisms present are inevitably several orders of magnitude greater and no re-treatment is possible to reduce the concentration of what may be very heat-resistant spores.

Safety precautions

12.7 Users should ensure that operational procedures are in accord with the safety guidelines set out in the HSC document 'Safe working and the prevention of infection in clinical laboratories' and the accompanying 'Model rules for staff and visitors'.

Table 9: Recommended sterilization conditions for laboratory sterilizers

Name of operating cycle	Sterilization temperature [°C]	Maximum temperature [°C]	Minimum holding time [min]
Make-safe of small plastic discard (a)	134 126 121	138 130 125	3 10 15
Make safe of contained fluid discard (a)	134 126 121	138 130 125	3 10 15
Sterilization of culture media (pre-set cycle)	121 115	124 118	15 30
Sterilization of culture media (variable cycle)	102-134 121 (b)	 124	Up to 60 15
Disinfection of fabrics	134 126 121	138 129 124	3 10 15
Sterilization of glassware and equipment	134 126 121	138 129 124	3 10 15
Free steaming (variable cycle)	102-104 95 (b)	 98	Up to 60 15
Culture media preparator	121 115	124 118	30 15

a. All bands for make-safe are 4 degrees wide to conform with BS 2646: Part 3.

b. Although the cycle is variable, this temperature band should be used for testing purposes.

12.8 The COSHH Regulations 1999 introduce new controls on biological agents which are of relevance to users of laboratory sterilizers.

Hazards

12.9 Due to the wide variety of loads processed in laboratory sterilizers, the range of potential hazards is wider than for a typical clinical sterilizer (see paragraph 2.10). Additional hazards may include:

a. spillage of biohazardous material;

b. spillage of hot material;

c. spillage of corrosive substances;

d. vapour from volatile chemicals.

12.10 Access to the loading area should be limited to personnel aware of the hazards from potentially infective material. The loading position should not be obstructed.

12.11 All materials awaiting sterilization should be placed so they cannot be overturned, spilled or damaged.

12.12 Loading and unloading procedures should be designed to avoid health hazards and also injuries to personnel by the elimination of awkward lifting positions and excessively heavy load containers (see paragraph 2.8). Heavy loads should not be lifted into or out of vertically mounted chambers by personnel of unsuitable build or strength. Consideration should be given to the provision of mechanical assistance.

Operating procedures

12.13 A written standard operating procedure based on the manufacturer's instructions and local conditions of use should be adopted and should include the following:

a. a statement specifying the safe operating limits of the sterilizer including the maximum pressures and temperatures for safe operation;

b. a statement that operators should be instructed to note and report any defects or unusual or out-of-range conditions to their supervisor;

c. training requirements for the operators of the sterilizer and a statement that those unfamiliar with the equipment are forbidden to operate it unless supervised, or until they are considered competent in its use;

d. maintenance requirements: the scope of user maintenance should be defined and restricted to cleaning, functional checks and any user safety checks recommended in the instruction manual.

12.14 Operating instructions should always be readily accessible and users should ensure that they are followed.

12.15 Certain laboratory sterilizers are provided with a switch to override the thermal door-lock during the cooling stage of the cycle (see Part 2 of this SHTM). The switch is protected by a key, code or tool which is not available to the operator. The responsibility for the operation of the thermal door-lock override should be assigned to the user or other senior member of the laboratory staff. The override should only be used if all the implications of such action are documented and understood.

Operating cycles

12.16 Operating cycles recommended in this SHTM are as follows:

a. make-safe of small plastic discard;

b. make-safe of contained fluid discard;

c. sterilization of culture media (preset or variable cycle);

d. disinfection of fabrics;

e. sterilization of glassware and equipment;

f. free steaming.

12.17 The specialised sterilizer known as a culture media preparator is also discussed.

12.18 Sterilizer loads should be carefully segregated to ensure that the appropriate cycle is selected for each type of load. Particular care should be taken to ensure that culture media, discard, glass containers with caps fitted, and contained fluid are processed in sterilizers fitted with a thermal door-lock, demonstrated to be effective on these cycles (see Part 2 of this SHTM).

12.19 Materials processed in laboratory sterilizers can be either “clean” or “dirty”. Clean work is material which will be used within the laboratory, such as culture media, tubing and filters. Dirty work is discard material which is to be made safe. In larger laboratories, separate sterilizers are often designated for clean and dirty work.

12.20 The discovery of non-sporing infective agents with an increased resistance to chemical and heat treatment (“slow viruses”, “prions”, “TSE agents”) has led to the need for increased temperatures and holding times for treatment of material from a suspected case of infection by these agents. None of the standard cycles described here is effective in inactivating such agents. Advice can be found in Appendix 2.

Make-safe of small plastic discard

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

12.22 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. Glass containers and larger plastic containers should be processed with the make-safe cycle for contained fluid discard (see paragraph 12.30). Items of unknown content should likewise be treated as contained fluid discard.

12.23 Items made from polystyrene, such as plastic Petri dishes, start to soften at around 70°C. Any air remaining in the chamber at that point may become trapped as bubbles within the melting plastic and prevent complete sterilization. The hardened plastic mass removed at the end of the cycle may then contain pockets of viable micro-organisms that may cause a health hazard if the plastic is subsequently broken. Users should therefore ensure that the air-removal stage of the cycle is substantially complete before the load temperature attains 70°C. That is why plastic Petri dishes are specified for the small-load and full-load thermometric tests described in Part 3 of this SHTM.

12.24 Items for making-safe should be placed in a discard box as specified in Part 2 of this SHTM. It is important that the box is of the type used for performance qualification, otherwise the specified sterilization conditions may not be achieved.

12.25 Discard should be stored in the box at the work station for later sterilization. Once in the box, items should not be handled until after they have been made safe. They should not be transferred from one box to another. The box and contents should be sterilized together.

12.26 Discard should be enclosed when the box is moved. Loose-fitting lids are satisfactory for transport within a laboratory. Alternatively, the discard material may be placed in a discard bag (see paragraph 12.27) inside an open box, providing the neck of the bag is closed before the box is moved. Whenever discard material is transported outside the laboratory suite a sealed and locked lid should be fitted. The lid should be opened or removed before the cycle begins and sterilized along with the box.

12.27 Discard bags, if used, should always be contained in a discard box and opened widely before sterilization to permit the removal of air and the penetration of steam. The open mouth of the bag should not be folded back over the rim of the box, since this would impede the removal of air from the space between the bag and the box. Bags with identification markings for discard material are available which are designed to melt at 134°C to assist air removal.

12.28 Discard boxes awaiting sterilization should not be stored in the loading area.

12.29 Load temperature probes should not be inserted into discard loads. Any probes provided in the chamber should be stowed in a safe, fixed position, usually on a bracket provided for this purpose.

Make-safe of contained fluid discard

12.30 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646. 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.

12.31 While essentially the same as the culture media cycle (paragraph 12.35), higher sterilization temperatures are preferable. Lower sterilization temperatures should only be used if plastic containers are to be processed.

12.32 Fluid containers should be placed in discard boxes to prevent contamination of the chamber if a bottle breaks during the cycle (see paragraph 6.7 about pressure inside bottles).

12.33 A risk assessment should be made before corrosive chemicals or materials and chemicals (including disinfectants) likely to produce harmful vapour are processed. Such materials should be enclosed in a sealed, unbreakable container, preferably of metal.

12.34 Load temperature probes should not be inserted into discard loads. Any probes provided in the chamber should be stowed in a safe, fixed position, usually on a bracket provided for this purpose.

Sterilization of culture media (preset or variable cycle)

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

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

12.37 A variable cycle, in which combinations of sterilization temperature and holding time can be set by the operator, is necessary for some heat-labile products. It is normally provided in addition to the preset culture media cycle.

12.38 The culture media cycle is also suitable for disinfecting unwrapped equipment, such as tubing sets, where a glassware and equipment cycle is not available (see paragraph 12.48).

12.39 Culture media are particularly sensitive to heat, the degree of deterioration being related to the time the medium is maintained above the sterilization temperature. The heating and cooling stages also contribute significantly to this deterioration, so heating and cooling times should be as short as possible. Large volumes of fluids will heat up and cool down slowly, therefore volumes of fluid should be kept small; a maximum container volume of 500 ml is recommended.

12.40 Agar-based media take longer to heat up than water-based media; this differential is greater the larger the volume. When media are to be sterilized in volumes of over 100 ml, agar-based and water-based products should be processed separately.

12.41 Loads should be designed to process containers of similar size. For example:

a. up to 100 ml;

b. 101 ml to 1000 ml;

c. 1001 ml to 3 litre.

12.42 Containers should be loosely capped unless they are specifically designed to be sealed. However, sealing bottles can increase the likelihood of an explosion during sterilization (see paragraph 6.6 about pressure inside bottles) and extends the cooling time.

12.43 A fault may result in contaminated or over-heated culture media. After a fault, a careful assessment should be made before the batch is reprocessed or discarded.

Disinfection of fabrics

12.44 This cycle is a variant of the “glassware and equipment” cycle specified in BS 2646. It is designed to disinfect (but not sterilize) fabric materials such as towels, clothing, wrapped animal bedding, and other porous materials.

12.45 If the fabrics are required to be sterile and dry at the end of the cycle, a machine complying with the performance requirements for a clinical porous load sterilizer should be specified. This will require validation and periodic testing in accordance with the schedule for porous load sterilizers in Part 3 of this SHTM.

12.46 The cycle differs from the glassware and equipment cycle (see paragraph 12.48) in that more pressure pulses will be required to remove air from the load.

12.47 The fabrics cycle is also suitable for sterilizing empty glassware without caps and for disinfecting wrapped tubing and wrapped filters (but see paragraph 12.49).

Sterilization of glassware and equipment

12.48 This cycle corresponds to the “glassware and equipment” cycle specified in BS 2646. It is designed to sterilize clean, empty glassware (without caps) and equipment such as tubing and filters. Loads must not contain any fluids.

12.49 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

12.50 This cycle is not specified in BS 2646. 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.

Culture media preparator

12.51 Many of the problems which relate to sterilizing culture media can be solved by the use of small sterilizers in which the media constituents are placed directly into the chamber thus avoiding the use of glass containers and their attendant hazards. Since these small machines have a unique function, their design is specialised in comparison with other laboratory sterilizers and BS 2646 is not applicable (see Part 2 of this SHTM).

12.52 The manufacturer's recommendations on operation should be followed.

Performance qualification

12.53 Some loads processed in clinical laboratories may not be represented by the reference loads used in the commissioning tests described in Part 3 of this SHTM. In these cases, thermometric PQ tests should be undertaken to establish master process records for these loads.

Product release

12.54 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. not more than one container (or 1%, whichever is the greater) has burst or broken.

12.55 The load should be examined for damaged containers. The occasional broken bottle or bag may be acceptable provided intact containers have not also been damaged.

12.56 Discard for disposal outside the laboratory must be safe to handle.

12.57 Other materials processed in the sterilizer will be used in the laboratory. "Fit for use" should be defined by the user.

12.58 Blooming of plastic containers is a surface effect that does not harm the container or the contents. The user should decide whether blooming is acceptable.

Troubleshooting

Faults on make-safe cycles

12.59 A written procedure based on a risk assessment should be established for dealing with a fault on a make-safe cycle, taking into account the nature of the load. The usual practice is to decontaminate the sterilizer by flushing the chamber with steam. Where this is not possible, the user should proceed on the advice of the Laboratory Safety Officer. The guidelines given in HSG(93)26, 'Decontamination of equipment prior to inspection, service or repair', should be followed.

12.60 When considering the appropriate course of action, users should note the following:

a. the Laboratory Safety Officer should be notified before any attempt is made to open the sterilizer;

b. chamber condensate should be considered to be contaminated with viable micro-organisms;

c. disinfection of the chamber and/or pipework should not involve prolonged contact with disinfectants corrosive to metal;

d. a contaminated sterilizer should never be removed from the laboratory for repair.

13. Reporting of incidents

Introduction

13.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in Scotland are set out in MEL(1995)74.

13.2 Management should designate, for each sterilizer, a responsible person to act as liaison officer for the reporting of incidents. For the purposes of this SHTM, the user is assumed to fill this role.

13.3 The user should be familiar with the reporting procedures and with statutory reporting requirements. Training may be required.

13.4 Operators and others concerned with the operation of sterilizers should know what action to take in the event of an incident or failure.

13.5 The user should ensure that a sufficient supply of the correct reporting forms is available at all times.

13.6 The Authorised Person should advise, for each type of sterilizer, which types of defects are to be considered as serious. The list should include all defects which may result in failure to sterilize or danger to personnel or damage to the product.

13.7 If a serious defect occurs, the sterilizer should be withdrawn from service and should not be used until any necessary repairs have been made and a repeat validation has been carried out (see Part 3 of this SHTM). If the defect involves a pressure vessel, an inspection by the Competent Person (Pressure Systems) is required.

Department of Health reporting procedures Annex A

General guidance

Purpose of the reporting system

1 An adverse incident is an event which adversely affects, or has the potential to effect, the health and safety of patients, users or other persons. Local incidents may often have implications for other healthcare services. IT IS ESENTIAL, THEREFORE, THAT ALL ADVERSE INCIDENTS AND DEFECTIVE EQUIPMENT ARE REPORTED PROMPTLY. Serious deficiencies in the technical performance of equipment should also be reported, as should any observation which gives cause for concern regarding safety, even when an actual incident has not occurred. The central collation of adverse incident reports is essential for the identification of trends which may result in the issue of warnings to users of potentially hazardous equipment or unsafe procedures. The term “equipment” is taken to include any items, device, supplies, service, product, system, or plant as detailed in Annexes B and C.

Health and safety executive

2 Under their statutory powers, the Health and Safety Executive (HSE) or Local Authority Inspectors may:

- identify inadequacies in a product’s design;
- issue instructions for use, or manner of use;
- make observations and recommendations.

If any action by the HSE or Local Authority on NHS premises might have implications for other users and/or patients, staff, visitors or contractors, it should be reported to ***Scottish Healthcare Supplies (SHS)***.

Reporting

3 Reports should be submitted in accordance with:

Annex B: reports relating to all *medical equipment*: including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products;

Annex C: Reports relating to *estates equipment*: engineering plant, installed services including piped medical gas and medical scavenging systems, buildings and building fabrics, vehicles.

All adverse incidents etc. relating to products in Annexes B and C should be reported to Scottish Healthcare Supplies in full at the following address:

Incident reporting and investigation centre (IRIC)
Scottish Healthcare supplies
Trinity Park House
South Trinity Road
EDINBURGH
EH5 3SH

Daytime help and report line 0131 551 8333
Emergency 0131 552 6380
Fax 0131 552 6535

Procedures to be followed and information to be supplied

4 The initial report of an incident should contain as much essential detail as available. However, it should never be delayed on this account and serious cases should be reported by the fastest means possible. **All oral reports should be supported in writing**, preferably using the standard Adverse Incident Report Form (Annex D). Copies of this form are available form Scottish Healthcare Supplies (SHS).

5 All material evidence should be labelled and kept secure, under the charge of a responsible officer. This includes the equipment and, where appropriate, packaging or other means of batch identification. The equipment should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eye witness reports. In serious cases, this record should be witnessed, and the witness should also make a personal written record.

6 Defective items should not be allowed to be repaired or returned to the supplier or discarded before an investigation has been carried out. In addition, items should not be cleaned (but see paras. 11-12 below). The manufacturer or supplier of a defective product should be informed promptly, and may be allowed to inspect the product if accompanied by an officer from the Health Board, NHS Trust or other NHS body, or SHS, with knowledge of the product so as to prevent tampering or false claims. The HSE may also wish to inspect the equipment. In the case of a large batch of consumable items may be possible to pass samples to the manufacturer if this will aid the investigation. However, the manufacturer must not be allowed to exchange, interfere with or remove any part of the product if this would prejudice the investigations of SHS or other official bodies.

7 Where clinical need requires equipment to be kept in use, and the defective part(s) are clearly identifiable and removable, they may be removed, secured and labelled for later inspection, and the equipment repaired for re-use.

8 Where a manufacturer wishes to investigate a defective, or possible defective, CE marked medical device, this should be reported to SHS who will seek guidance from the medical Devices Agency (the UK Competent Authority). It should be noted that from June 1998 *all* medical devices must be CE marked before they can be placed on the market, in accordance with the medical Device Regulations. Active implantable medical devices however, *must* be CE marked as from 1 January 1995.

9 As far as "estates and associated equipment" incidents are concerned as set out in Annex C, the SHS will oversee any necessary investigations (using private contractors as necessary) and liase with the NHS in Scotland Estates and Environment Forum whose Healthcare Engineering and Environment Unit will provide the professional lead.

Notification system

10 Where the results of investigations have implications for other users a Hazard Notice, Safety Action Notice or other safety warning may be issued. A sample *Hazard Notice* is given in Annex F and a sample *Safety Action Notice* is given in Annex G. General Managers and Chief Executives are responsible for ensuring adequate distribution systems for these publications are in place.

Handling of contaminated products

11 Requirements for the forwarding of contaminated products for investigation are detailed in:

- SHHD letter DGM (1987) 66 dated 6 November 1987 (updated guidance to be issued soon).
- Safety Action Bulletin No 63 SAB (90) 61 issued September 1990.
- Hazard Notification HAZ 1991/007 issued 11 March 1991.

All products, devices and sample which have been or could have been in contact with blood, other bodily fluids of pathological samples must be accompanied by a Contamination Status Certificate when being passed to SHES or the supplier/manufacturer for examination. The Contamination Status Certificate should be presented external to the packaging which contains the potentially contaminated item in order that the certificate may be examined before opening the packaging. The requirement also applies to unused disposable items except where packaging seals are unbroken. A sample of a suitable Contamination Status Certificate is reproduced as Annex E and may be copied or adapted for local use.

12 Advice should be sought from the SHS Incident Reporting and Investigation Centre prior to the sending or transporting of contaminated products for examination by SHS or the supplier/manufacturer. Where possible, products should be decontaminated before being handled. This should be carried out

using a method recommended by the manufacturer to avoid destroying vital evidence. It is illegal to send contaminated products through the post.

Other action/responsibilities

13 This reporting system does not replace the duty of local staff to take other action as required legally, by local procedures or in line with other national requirements eg:

- Preventing further use of equipment which may be defective;
- Reporting to particular local NHS officers (eg. Radiation Protection Advisers);
- Reporting notifiable incidents to the Health and Safety Executive under the Reporting of Injuries, Disease and Dangerous Occurrence Regulations 1985, and the Ionising Radiations Regulations 1985;
- Reporting to the Procurator Fiscal in the case of a fatal accident;
- Informing the manufacturer of a serious adverse incident involving CE marked equipment to assist him in fulfilling his obligations under certain EC directives adopted as UK regulations.

Food

14 Problems with food, other than special dietary products, should be reported to:

- Scottish Executive Health Department
- Scottish Executive Rural Affairs Department
- Scottish Healthcare Supplies, Contracts Branch for Food which is on central contract to the NHS.

Drugs

15 Guidance on reporting problems involving medicinal products (drugs alerts) is contained in NHS Circular 1991 (GEN) 25 issued September 1991 and Circular 1993 (GEN) 16 issued on 14 December 1993.

Notes

16 Official notifications to the HSE which are copied to SHS under the terms of this circular should be clearly stated as such. Notification to SHS does not count as, or substitute for any other report.

17 If a patient dies unexpectedly, the clinician in charge of the case should report the death immediately to the Procurator Fiscal. Pending instructions from the Procurator Fiscal or his officer, any implicated product must not be interfered with in any way unless this is necessary for safety or to prevent the loss of samples or material evidence. Although the manufacturer of suspect equipment should be informed immediately, neither he nor his agent

should be allowed to inspect the equipment or remove any part of it without the Procurator Fiscal's prior agreement. SHS may be required to impound implicated equipment on behalf of the Procurator Fiscal.

18 As a result of regulations implementing EC directives, manufacturers of CE marked devices will be required by law to report to the UK Competent Authority (Medical Devices Agency) any serious incident (ie. death or injury) involving their products. The first directive applies to Active Implantable Medical Devices (for example, implantable cardiac pacemakers), and the UK regulations came into force on 1 January 1993. The second directive covers a much wider range of Medical Devices and the UK regulations came into force for a transitional period commencing on 1 January 1995 and became mandatory in June 1998. An EC directive on In-vitro Diagnostic Devices is under preparation and is not expected to be in force before 1997.

Annex B

Reports relating to all medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products

Reportable cases

1 Adverse incidents involving medical equipment may arise due to short comings in the equipment itself, user practice, service, maintenance, modification or adjustments, management procedures, instructions for use or environmental conditions.

2 A report should be sent if equipment is involved in one of the following:

- death;
- injury;
- deterioration in health;
- unreliable test results leading to inappropriate treatment or medication;
- where there is a potential for any of the above to occur.

NOTE: Single incident, when added to other information or reports, might indicate a national or international problem.

Product categories

- **Imaging and Radiotherapy Equipment**: X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluoroscopy, film processors.
- **Electromedical Equipment**: infusion pumps, fluid warmer, automatic, tourniquets, physiological monitoring and measurements, and equipment used in: dialysis, cardiology, physiotherapy, opthamology, audiology, speech therapy, electrotherapy, endoscopy , obstetrics.
- **Life Support Equipment**: anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.
- **Operating Department Equipment**: microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.
- **Powered Surgical Equipment**: Diathermy, drills, saws, lasers.
- **General Ward Equipment**: mobile examination lamps, powered and non-powered beds, ripple mattresses, pressure garments,

thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists and lifting apparatus.

- **Dental and Chiropody Equipment**: instruments, chairs, curing lights, drills, water/air/suction.
- **Laboratory Equipment**: analysers, centrifuges, media preparators, safety cabinets, warming cabinets, incubators, refrigerators, test equipment.
- **Cleaning and Sterilisation Equipment**: autoclaves, sterilisers (steam, gas, chemical, dry heat), stills, disinfectors, instrument and equipment washers.
- **Aids for the Disabled**: wheelchairs, walking aids.
- **Implants**: heart valves, pacemakers, defibrillators, infusion pumps, orthopaedic prostheses.
- **Post Mortem Equipment**.
- **Single Use Devices**: syringes, needles, administration sets, catheters, dressings, sutures, etc.
- **Orthotic and Prosthetic Appliances**.
- **Certain Dietary Products**: enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.
- **Electrical Interference Problems**: involving any of the above.
- **Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

Annex C

Reports relating to estates systems and equipment: engineering and plant, installed services including piped medical gas and medical gas scavenging systems, buildings and building fabrics, vehicles

Reportable cases

1 Adverse incidents in estates equipment may arise due to shortcomings in the equipment itself, user practice, service, maintenance, modifications or adjustments, management procedures, instructions for use or environmental conditions.

2 A report should be sent if equipment is involved in one of the following:

- death;
- injury;
- deterioration in health;
- damage;
- where there is a potential for any of the above to occur.

NOTE: Single incident, when added to other information or reports, might indicate a national or international problem.

Product categories

- **Buildings and Grounds**: components, services and plant used in maintenance and construction.
- **Engineering Plant and Services of all Types**: lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air-conditioning, water, drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).
- **Fire Protection Installations and Equipment**.
- **Transport**: vehicles and equipment.
- **Equipment**: in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.
- **Piped Medical Gas and Vacuum Installations**: oxygen, medical air etc, vacuum insulated evaporators and anaesthetic scavenging systems.
- **Fixed Luminaries**: including operating and examination lamps.

- **Communications Equipment**: telephones (including radio telephones), nurse call, paging, alarms, building management systems, radio and television, IT structures cabling/data, VHF/UHF communication equipment.
- **Lighting Protection and Anti-Static Precautions**.
- **Incinerators and Waste Disposal Systems**.
- **Fuel Supply and Storage Systems**.
- **Fume Cupboards and Microbiological Safety Cabinets**: (installation aspects only), ductwork and interaction with ventilation systems.
- **Electrical Interference Problems**: involving any of the above.
- **Legionella Protection Equipment and Systems**.
- **Building Environmental Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

Urgent reports

are required in the respect of:

- An explosion or sudden fracture of a pressure vessel, pressurised system or steam/high pressure hot water main.
- A major electrical explosion eg. of power transformers or high voltage switchgear.
- A runaway and crash of a passenger lift.
- Piped medical gas system malfunction.
- Fire alarm system failure.

Annex D
Standard Adverse Incident Report Form

Annex E
Sample Contamination Certificate

Annex F
Sample Hazard Notice

Annex G
Sample Safety Action Notice

SCOTTISH HEALTHCARE SUPPLIES **Annex D**

By arrangement with the NHS in Scotland, Management Executive ad Estates Environment Forum

ADVERSE INCIDENT REPORT FORM – ADV/REP/1

1. TO: Incident Reporting & Investigation Centre (IRIC)

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH EH5 3SH

Daytime help & report line: *0131 5518333*
Emergency: *0131 552 6380*
Fax: *0131 552 6535*

2. FROM:

Hospital/Health unit/NHS Trust:……..
Name:…… Fax:……
Title:…….. Tel No.:……..
Dept:…… Extension:……

3. EQUIPMENT / DEVICE

Description:……
Model:…… Serial/Lot No:……..
Manufacturer:…….. Date of Manufacture:……..
Supplier:…….. marked:……YES/NO*……..
Supplier's Address:……
…… Telephone No:……

4. ADVERSE INCIDENT, PROBLEM OR CONCERN (continue on separate sheet if necessary)

Hospital/Unit:…….. Injury: None/Patient/Staff/Other*……..
Dept/Ward:…… Injury details and treatment required……..
Observed by:…….. ……
Date(s):…… ……..
Nature of problem:……
……
Possible Cause:……
……
Consequence:……
…

5. ACTION TAKEN

Device/Lot Quarantined:…….YES/NO*……Location:……
Additional

6. CONTAMINATED EQUIPMENT/DEVICES

Defective equipment / devices should not be modified or accessories removed before inspection has taken place. All devices with possible contact with blood or other body fluids, or pathological samples, and all disposable devices, whether used or unused, should be accompanied by a Contamination Status Certificate.

CONTAMINATED DEVICES SHOULD NOT BE SENT BY MAIL..

7. DECLARATION

Accompanying this form:
*Detailed report
*Used / unused device (s)
*Contamination Status Certificate

Signature: Date:

…….. ……

Annex D

ADVERSE INCIDENT REPORTING

PRODUCT CATEGORIES

Reports relating to all medical equipment including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products.

- Imaging and Radiotherapy equipment; *X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluroscopy, film processors.*
- Electromedical equipment; *infusion pumps, fluid warmers, automatic tourniquets, physiological monitoring and measurement, dialysis, cardiology, physiotherapy, ophthalmology, audiology, speech and language therapy, electrotherapy, endoscopy, obstetrics.*
- Life support equipment; *anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.*
- Operating Department equipment; *microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.*
- Powered surgical equipment; *diathermy, drills, saws, lasers.*
- General ward equipment; *mobile extension lamps, powered and non-powered beds, ripple mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists/lifting apparatus.*
- Dental and Chiropody equipment; *instruments, chairs, curing lights, drills, water/air suction.*
- Laboratory equipment; *analysers, centrifuges, media preparators, safety cabinets, incubators, warming cabinet, refrigerators, test equipment.*
- Cleaning and sterilisation equipment; *autoclaves, sterilisers (steam, gas, chemical, dry heat) stills, disinfectors, instrument and equipment washers.*
- Aids for the disabled; *wheelchairs, walking aids.*
- Implants; *pacemakers, defibrillators, infusion pumps, orthopaedic prostheses, heart valves.*
- Post Mortem equipment;
- Single Use Devices; *syringes, needles, administration sets, catheters, dressings, sutures, etc.*

- Orthotic and Prosthetic Appliances;
- Certain Dietary products; *enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.*
- Electrical interference problems; *involving any of the above.*
- Aspects of Control of Substances Hazardous to Health (COSHH*); involving any of the above.*

Reports relating to estates systems and equipment:- engineering systems and plant, installed services including piped medical gas and medical gas scavenging systems, building and building fabrics, vehicles

- Buildings and Grounds; *components, services and plant used in maintenance and construction.*
- Engineering Plant and Services of all types; *lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air conditioning, water drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).*
- Fire Protection installations and equipment;
- Transport; *vehicles and equipment.*
- Equipment; *in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.*
- Piped medical Gas and Vacuum installations; *oxygen, medical air etc., vacuum insulated evaporators, anaesthetic gas scavenging systems.*
- Fixed Luminaires; *including operating and examination lamps.*
- Communication equipment*; telephones,(including radio telephones) nurse call, paging, alarms, building management systems, radio and television, IT structured cabling/data, VHF/UHF communication equipment.*
- Lightning Protection and Anti-static precautions;
- Incinerators and waste disposal systems;
- Fuel Supply and Storage systems;
- Fume Cupboards and Microbiological Safety Cabinets (installation aspects only) ; *ductwork and interaction with ventilation systems;*
- Legionella Protection Equipment and Systems;
- Electrical interference problems; Involving any of the above.
- Substances Hazardous to Health (COSHH); Involving any of the above.

13.12 The user is recommended to display a notice on or near each sterilizer setting out the appropriate reporting procedure.

Statutory reporting procedure

13.13 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 place responsibilities on employers to report certain incidents and dangerous occurrences to the local office of the Health and Safety Executive (HSE). The action to be taken following any incident with a sterilizer will need to be detailed in hospital procedures to ensure compliance with this legal requirement.

13.14 The user must notify HSE immediately, normally by telephone, if any of the following should occur:

a. any fatal injuries to employees or other people in an accident connected with the operation of the sterilizer;

b. any major injuries to employees or other people in an accident connected with the operation of the sterilizer;

c. any of the dangerous occurrences listed in the Regulations.

13.15 The user must send a written report to HSE within seven days of any incident including:

a. any of the notifiable incidents listed above;

b. any other injury to an employee which results in their absence from work or being unable to do their normal work for more than three days;

c. any of the cases of ill health listed in the Regulations.

13.16 A record must be kept of any injury, occurrence or case of disease requiring a report. This should include the date, time and place, personal details of those involved and a brief description of the nature of the event.

13.17 Examples of dangerous occurrences applicable to sterilizers include:

a. the explosion, collapse or bursting of any closed vessel;

b. electrical short circuit or overload causing fire or explosion;

c. any explosion or fire resulting in the suspension of normal work for more than 24 hours;

d. an uncontrolled or accidental release or escape of any pathogens or substance from any apparatus or equipment;

e. any incident where breathing apparatus malfunctions in such a way as to deprive the wearer of oxygen.

13.18 Examples of reportable diseases applicable to sterilizers include:

a. poisoning by ethylene oxide;

b. any illness caused by a pathogen.

13.19 Full details may be found in ‘A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985’, HS(R)23, published by HSE.

13.20 Incidents and dangerous occurrences which are reported to HSE should also be reported either to the Scottish Healthcare Supplies, as appropriate, by telephone during the first working day after the incident and then followed by a written report.

Glossary

The following list of definitions has been adopted in SHTM 2010 and used in Part 2. Certain pressure terms have been modified to comply with the requirements of EN 764. Paragraph references indicate where further information may be found in Part 2. Cross references to other terms are shown in bold type. References in parentheses at the end of definitions are to this part of SHTM 2010.

absolute pressure	pressure for which the zero value is associated with absolute vacuum.
aeration	a part of the **sterilization process** during which **sterilant gas** and/or its reaction products desorb from the **load** until predetermined levels are reached. See **degassing** and **flushing**.
air detector	a device used to determine that sufficient air or other **non-condensable gases** have been removed from the **chamber**.
allowable pressure	of a pressure vessel, a limit to the **operating pressure** specified for safety reasons. See **design pressure**.
automatic controller	a device that, in response to predetermined **cycle variables**, operates the **sterilizer** sequentially through the required stages of the **operating cycle**.
batch process record (BPR)	a permanent record of one or more **cycle variables recorded** during a complete **operating cycle** by instruments fitted permanently to the **sterilizer**.
Biological indicator	a device, consisting of an inoculated carrier contained within a primary pack, designed to test the efficacy of an **operating cycle**.
Bowie-Dick test	a test, used mainly with porous load sterilizers, to show whether or not steam penetration into a **standard test pack** is even and rapid.
cartridge	in **EO sterilizers**, a portable, single-use, simple vessel containing **sterilant** gas under pressure from which the gas is delivered by puncturing the cartridge.
chamber	the part of the **sterilizer** in which the **load** is placed.

chamber exhaust ventilation (CEV)	a ventilation system designed to extract gas from the **chamber** of an **EO sterilizer** supplied from a **cartridge**.
chamber furniture	shelves, pallets, loading trolleys and other fixed or movable parts that support the **load** within the **chamber**.
chamber temperature	the lowest temperature prevailing in the **chamber**.
chemical indicator	a device designed to show, usually by change of colour, whether specified values of one or more **cycle variables** have been attained.
clinical sterilizer	a **sterilizer** designed to process **medical devices** or **medicinal products** to be used in the clinical care of patients.
commissioning	the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the equipment specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.
conditioning	in **EO sterilizers**, the treatment of a **load** within the **operating cycle**, but prior to **sterilization**, to attain a predetermined temperature and humidity throughout the load.
contained fluid discard	discard material held in sealed glass containers or sealed plastic containers of volume greater than 50 ml (see **small plastic discard**).
cooling stage	the period of the **operating cycle**, after the **holding time** has been completed, during which the **load** remains in the **chamber** while the load cools to a safe temperature.
culture media preparator	a specialised **laboratory sterilizer** designed for the **sterilization** and dispensing of culture media.
cycle complete	recognition by the **automatic controller** that the preset values for the **cycle variables**, necessary for a successful **operating cycle**, have been attained and that the sterilized **load** is ready for removal from the **chamber**.
cycle variables	the physical properties, for example time, temperature, pressure, humidity and gas concentration, that influence the efficacy of the **operating cycle**.

dedicated steam supply	a supply of steam produced by a generator for the exclusive use of a **sterilizer** or group of sterilizers.
degassing	1. in **LTSF** and **EO sterilizers**, an **aeration** procedure in which **sterilant** gas and its reaction products are desorbed from the **load** by defined treatment outside the **sterilizer** after completion of the **operating cycle**. 2. a pre-heating treatment of boiler feed-water to reduce the amount of **non-condensable gases** in the steam supply.
design pressure	of a pressure vessel, the pressure chosen for the design calculations. See **operating pressure**, **allowable pressure**.
discard	laboratory material which is, or may be, infected by micro-organisms and is to be made safe before disposal.
discard bag	a bag, usually of plastic, designed to receive solid **discard** material before being placed in a **discard box** for processing by a **make-safe** cycle.
discard box	a box designed to contain discard material for processing by a make-safe cycle.
disinfection	a process used to reduce the number of viable micro-organisms in a **load** but which may not necessarily inactivate some viruses and bacterial spores.
disinfector	an apparatus designed to achieve **disinfection**.
double-ended sterilizer	a **sterilizer** in which there is a door at each end of the **chamber**.
dry-heat sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to hot dry air near atmospheric pressure.
dryness value	a dimensionless quantity, approximating to the dryness fraction, derived to determine whether steam is of the correct dryness for **sterilization** purposes. A dryness value of 1.0 represents dry **saturated steam**.
EO sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **ethylene oxide** gas or EO gas mixtures.

equilibration time	the period which elapses between the attainment of the **sterilization temperature** in the **chamber** and the attainment of the sterilization temperature in all parts of the **load**.
ethylene oxide (EO)	**sterilant** gas used to sterilise items that would be damaged by exposure to heat or moisture. Chemical formula CH_2CH_2O.
F_O	a quantity, measured in minutes, used to determine the efficacy of an **operating cycle** and equivalent to a continuous period at a temperature of 121°C.
fail-safe	an attribute of **sterilizer** design whereby failure of any component or its associated services does not create a safety hazard.
fault	the recognition by the **automatic controller** that the preset **cycle variables** for the **operating cycle** have not been attained and that **sterilization** or **disinfection** has been jeopardised.
flash sterilizer	a device designed to achieve **sterilization** by exposing the **load** to a very high temperature steam for a few seconds.
fluid sterilizer	a **clinical sterilizer** designed to sterilise fluids in sealed containers by exposure to **high-temperature steam** under pressure.
flushing	in **LTSF** and **EO sterilizers,** an **aeration** procedure by which remaining **sterilant** gas is removed from the **load** within the **chamber** by the passage of air or other inert gas.
formaldehyde	**sterilant** gas used in combination with **low-temperature steam** to sterilise items that would be damaged by exposure to **high-temperature steam.** Chemical formula HCHO. Also known as methanal.
formalin	formaldehyde Solution BP. A 38% aqueous solution of **formaldehyde** stabilised with 10% w/v ethanol, commonly used as the primary material for generating formaldehyde gas.
free steaming	a process, used in **laboratory sterilizers,** in which the **load** is exposed to steam near atmospheric pressure.

free-standing	of a **sterilizer,** installed in a room which is not separated into a **plantroom** and a **loading area**.
full load	a specified **load,** used in thermometric tests, to represent the maximum size and mass of load which the **sterilizer** is designed to process.
gas exposure time	in **EO sterilizers,** the time for which the **chamber** is maintained at the specified temperature, gas concentration, pressure and humidity.
gauge pressure	pressure equal to the difference between the **absolute pressure** and local atmospheric pressure.
high-temperature steam	steam at a temperature above the boiling point of water at local atmospheric pressure.
holding time	the period during which the temperature in all parts of the **chamber, load** and any coolant fluid is held within the **sterilization temperature band.** It follows immediately after the **equilibration time**.
hot-air sterilizer	see **dry-heat sterilizer**.
indicated	an indicated value is that shown by a dial or other visual display fitted permanently to the **sterilizer** (see **recorded** and **measured)**.
installation checks	a series of checks performed by the contractor to establish that the **sterilizer** has been provided and installed correctly, is safe to operate, does not interfere with nearby equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for **sterilization**.
installation tests	a series of tests performed by the contractor after the **installation checks** to demonstrate that the **sterilizer** is working satisfactorily.
integral steam supply	a supply of steam produced in a sterilizer **chamber** or in a generator directly connected to it. The pressure in the sterilizer chamber is equal to that in the generator.
Köch steamer	a laboratory apparatus designed to expose a **load** to steam near atmospheric pressure and commonly used for melting solidified agar.

laboratory sterilizer	a **sterilizer** designed to sterilise, disinfect or **make-safe** laboratory materials and equipment.
load	collectively, all the goods, equipment and materials that are put into a **sterilizer** or **disinfector** at any one time for the purpose of processing it by an **operating cycle**.
load item	one of several discrete containers, packs or other units that together constitute a **load**.
load-temperature probe	a movable temperature sensor fitted within the **sterilizer chamber** and designed to record the temperature inside selected **load items**.
loading area	the room or area in front of the **sterilizer** in which the operator works and from which the sterilizer is loaded and unloaded. It is commonly separated by a fascia panel from the **plantroom**.
loading condition	a specified combination of the nature and number of **load items,** the items of **chamber furniture,** and their distribution within the **chamber**.
loading factor	the average fraction of the **usable chamber space** occupied by a load during normal operation.
local exhaust ventilation (LEV)	a ventilation system designed to extract small amounts **EO** or **formaldehyde** vapour released during normal operation of a **sterilizer** and its ancillary equipment.
low-temperature steam (LTS)	steam at a temperature below the boiling point of water at local atmospheric pressure.
LTS disinfector	a clinical **disinfector** designed to disinfect **loads** by exposure to **low-temperature steam** at sub-atmospheric pressure.
LTSF sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **low-temperature steam** and **formaldehyde** gas at sub-atmospheric pressure.
mains steam supply	the supply of steam produced for distribution to a range of steam-consuming equipment by an independent common boiler.

make-safe	a process, used in **laboratory sterilizers,** to reduce the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination.
master process record (MPR)	a **batch process record** obtained from a thermometric **commissioning** or **performance qualification** test and annotated to show the permitted tolerances for **cycle variables** during subsequent testing and routine production.
measured	a measured value is that shown on a test instrument, such as a thermometric recorder or a test pressure gauge, attached to the **sterilizer** for test purposes (see **indicated** and **recorded**).
medical device	any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC.)
medicinal product	any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product. (Source: EU Council Directive 65/65/EEC.)
module	a standard unit of **chamber** size being a rectangular box measuring 300 x 300 x 600 mm of volume 54 litres.
non-condensable gases (NCGs)	gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the **operating cycle**.

noted	a noted value is that written down by the operator, usually as the result of observing an **indicated, recorded** or **measured** value.
operating cycle	the set of stages of the **sterilization** or **disinfection** process carried out in sequence and regulated by the **automatic controller.** It is synonymous with the terms "sterilization cycle" for **sterilizers** and "disinfection cycle" for **disinfectors**.
operating pressure	the pressure in the **chamber** during the **plateau period** of an **operating cycle**. See **allowable pressure**, **design pressure**.
override	a system by which the progress of the **operating cycle** can be interrupted or modified as necessary.
paraformaldehyde	a mixture of polymethylene glycols formed by the reaction of **formaldehyde** with water.
performance class	an integer, from 1 to 20, related to the total cycle time for a **sterilizer** with a **full load**.
performance qualification (PQ)	the process of obtaining and documenting evidence that the equipment, as commissioned, will produce acceptable product when operated in accordance with the process specification.
performance requalification (PRQ)	the process of confirming that the evidence obtained during **performance qualification** remains valid.
periodic tests	a series of tests carried out at daily, weekly, quarterly and yearly intervals.
personal protective equipment (PPE)	equipment, including clothing, which is intended to be worn or held by a person at work, which protects against one or more risks to his or her health and safety.
plant history file	a file containing **validation**, maintenance and other engineering records for each **sterilizer**.
plantroom	the room or area to the rear of the **sterilizer** in which services are connected and which provides access for maintenance. It is commonly separated by a fascia panel from the **loading area**.
plateau period	the **equilibration time** plus the **holding time**.

porous-load sterilizer	a **clinical sterilizer** designed to process, by exposure to **high-temperature steam** under pressure, porous items such as towels, gowns and dressings, and also **medical devices** that are wrapped in porous materials such as paper or fabrics.
preconditioning	treatment of a **load** to attain predetermined conditions, such as temperature and humidity, before the start of an **operating cycle**.
pressure ballasting	a technique used in **fluid sterilizers** by which the pressure in the **chamber** is maintained at or near to the pressure inside the **load** containers during all or part of the **operating cycle**.
pressure vessel	a collective term describing the sterilizer **chamber,** jacket (if fitted), door(s) and components that are in permanent open connection with the chamber.
priming	of a steam generator, the delivery of steam containing water in suspension due to violent boiling or frothing.
process indicator	a **chemical indicator** used to distinguish between processed and unprocessed load items.
pyrogen	a bacterial toxin that causes a rise in body temperature and which is not destroyed by steam **sterilization**.
recommissioning	a procedure to confirm that operational data established during **commissioning** remain valid.
recorded	a recorded value is that shown on the output of a recording instrument fitted permanently to the **sterilizer** (see **indicated** and measured).
revalidation	a procedure to confirm an established **validation,** consisting of **recommissioning** followed by **performance requalification**.
safety hazard	a potentially detrimental effect on persons or the surroundings arising directly from either the **sterilizer** or its **load**.
saturated steam	steam whose temperature, at any given pressure, corresponds to that of the vaporisation curve of water.

small load	a specified **load,** used in thermometric tests, to represent the minimum size and mass of load which the **sterilizer** is designed to process.
small plastic discard	**discard** material comprising or held in plastic containers not exceeding 50 ml in volume.
sterilant	an agent used to effect **sterilization,** such as steam, hot air or a sterilising gas.
sterile	condition of a **load item** that is free from viable micro-organisms. See EN 556 for the requirements for a **medical device** to be labelled “sterile”.
sterilization	a process undertaken to render a **load sterile**.
sterilization conditions	the ranges of the **cycle variables** which may prevail throughout the **chamber** and **load** during the **holding time**.
sterilization process	the complete set of procedures required for **sterilization** of a **load,** including the **operating cycle** and any treatment of the load before or after the operating cycle.
sterilization temperature	minimum acceptable temperature of the **sterilization temperature band**.
sterilization temperature band	the range of temperatures which may prevail throughout the **load** during the **holding time.** These temperatures are expressed as a minimum acceptable (the **sterilization temperature)** and a maximum allowable and are stated to the nearest degree Celsius.
sterilizer	an apparatus designed to achieve **sterilization**.
sterilizer process log	a log, kept by the User, which contains records for each production cycle.
superheated steam	steam whose temperature, at any given pressure, is higher than that indicated by the vaporisation curve of water.
thermal door lock	an interlock fitted to certain **sterilizers** to prevent the door from being opened until the temperature in the **chamber** and **load** falls below a preset value.

transportable	requiring no permanent connections or installation and capable of being moved manually without mechanical assistance. Synonymous with “bench-top”.
type tests	a series of tests conducted by the manufacturer to establish the working data for a **sterilizer** type.
usable chamber space	the space inside the **chamber** which is not restricted by **chamber furniture** and which is consequently available to accept the **load**.
utilisation factor	the fraction of the open hours for which a sterilizer is available to process loads.
validation	a documented procedure for obtaining, recording and interpreting data required to show that a **sterilization process** will consistently comply with predetermined specifications.
works tests	a series of tests to establish the efficacy of each **sterilizer** at the manufacturer’s works.

Abbreviations

BP	British Pharmacopoeia
BPR	batch process record
BS	British Standard
°C	degree Celsius
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CEV	chamber exhaust ventilation
CFCs	Chlorofluorocarbons
COSHH	Control of Substances Hazardous to Health (Regulations)
dBA	decibel, A-weighted
EMC	electromagnetic compatibility
EN	European Standard (Europäische Norm)
EO	ethylene oxide
EU	European Union (formerly European Community)
GGMP	EU, *Guide to good manufacturing practice for medicinal products*
h	hour
HBN	Health Building Note
HCFCs	Hydrochlorofluorocarbons
HDN	Hospital Design Note
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HTM	Health Technical Memorandum
ISO	International Organisation for Standardisation
Kg	Kilogram
kW	kilowatt
l	litre
LEV	local exhaust ventilation
LTMEL	long-term maximum exposure limit
LTS	low-temperature steam
LTSF	low-temperature steam and formaldehyde
µm	micrometre (micron, 10^{-6} m)
m	metre
mbar	millibar (10^{-3} bar)
MCA	Medicines Control Agency
MDA	Medical Devices Agency
mg	milligram (10^{-3} g)
min	minute
ml	millilitre (10^{-3} l)
mm	millimetre (10^{-3} m)
mmol	millimole (10^{-3} mole)
MPR	master process record
mS	millisiemens
NCG	non-condensable gas
PES	programmable electronic system
PM	Planned maintenance

ppm	parts per million
PPE	Personal protective equipment
PQ	performance qualification
PRQ	performance requalification
PVC	Polyvinyl chloride
RH	relative humidity
s	second
SSD	sterile services department
STMEL	short-term maximum exposure limit
TSE	transmissable spongiform enceptalopathy
UK	United Kingdom

References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	***Title***	***Publisher***	***Date***	***Notes***
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1968	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Health and Medicines Act	HMSO	1988	
	Registered Establishments (Scotland) Act	HMSO	1987	
	Water (Scotland) Act	HMSO	1980	
SI 3146	Active Implantable Medical Devices Regulations	HMSO	1992	
SI 2179 & 187	Building Standards (Scotland) Regulations	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations	HMSO	1988	
SI 2372	Electromagnetic Compatibility Regulations	HMSO	1992	
SI 3080	Electromagnetic Compatibility (Amendment) Regulations	HMSO	1994	
SI 2451	Gas Safety (installation and use) Regulations	HMSO	1994	
SI 917	Health & Safety (First Aid regulations)	HMSO	1981	

Publication ID	Title	Publisher	Date	Notes
SI 682	Health & Safety Information for Employees Regulations	HMSO	1989	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Signs and Signals) Regulations	HMSO	1996	
SI 2792	Health and Safety (Display Screen Equipment) Regulation (as amended)	HMSO	1992	
SI 2307	Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)	HMSO	1998	
SI 2051	Management of Health and Safety at Work Regulations	HMSO	1992	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2169	Pressure Systems and Transportable Gas Containers Regulations	HMSO	1992	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1985	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulation	HMSO	1992	
British Standards				
BS 2646	**Autoclaves for sterilization in laboratories** **Part 1:** Specification for design, construction, safety and performance **Part 2:** Guide to planning and installation **Part 3:** Guide to safe use and operation **Part 4:** Guide to maintenance **Part 5:** Methods of testing for function and performance	BSI Standards	1993 1990 1993 1991 1993	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 5304	**British standard code of practice for safety of machinery**	BSI Standards	1988	
BS EN 866	**Biological systems for testing sterilizers and sterilization processes**	BSI Standards		
	Part 1: General requirements		1997	
	Part 2: Particular systems for use in ethylene oxide sterilizers		1998	
	Part 3: Particular systems for use in moist heat sterilizers		1997	
BS EN 30993	**Biological evaluation of medical devices**	BSI Standards		
	Part 3: Tests for genotoxicity, carcinotoxicity, and reproductive toxicity		1994	
	Part 4: Selection of tests for interaction with blood		1994	
	Part 5: Tests for cytotoxicity, in vitro methods		1994	
	Part 6: Tests for local effects after implantation		1995	
BS EN 837-1	**Bourdon tube pressure gauges: dimensions, metrology, requirements and testing**	BSI Standards	1998	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard**	BSI Standards		
	Part 1: Residential, commercial and light industry		1992	
	Part 2: Industrial environment		1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard**	BSI Standards		
	Part 1: Residential, commercial and light industry		1998	
	Part 2: Industrial environment		1995	
BS 5295	**Environmental cleanliness in enclosed spaces**			
	Part 1: Specification for clean rooms and clean air devices		1989	
BS EN 45003	**Calibration and testing laboratory accreditation systems, general requirements for operation and recognition**	BSI Standards	1995	
BS EN 45011	**General requirements for bodies operating product certification systems**	BSI Standards	1998	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 45012	**General requirements for bodies operating assessment and certification/registration of quality system**	BSI Standards	1998	
BS EN 45014	**General criteria for supplier's declaration of conformity**	BSI Standards	1993	
BS EN 980	**Graphical symbols for the use in the labelling of medical devices**	BSI Standards	1997	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 60751	**Industrial platinum resistance thermometer sensors**		1996	
BS 3928	**Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors)**	BSI Standards	1969	
BS EN 867	**Non-biological systems for use in sterilizers** **Part 1:** General requirements **Part 2:** Process indicators **Part 3:** Specification for Class B indicators for use in the Bowie and Dick test	BSI Standards	1997	
BS EN 868	**Packaging materials and systems for medical devices which are to be sterilized. General requirements**	BSI Standards	1997	
BS 2648	**Performance required for electrically heated laboratory drying ovens (PD2517,6/56)**	BSI Standards	1955	
BS EN 764	**Pressure equipment. Terminology and symbols: pressure, temperature, volume**	BSI Standards	1995	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing**	BSI Standards	1994	
BS EN ISO 9002	**Quality systems. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	
BS EN 134	**Respiratory protective devices. Nomenclature of components. Names of components in three CEN languages and diagrams for respiratory protective equipment**	BSI Standards	1998	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 7671	**Requirements for electrical installations. IEE wiring regulations**	BSI Standards	1992	16th edition
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**		1992	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use**			
	-1: General requirements		1993	
	-2-041: Particular requirements for autoclaves and sterilizers using steam for the treatment of medical materials and for laboratory processes		1997	
	-2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes		1997	
	-2-043: Particular requirements for autoclaves and sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes		1998	
BS 6001	**Sampling procedures for inspection by attributes**	BSI Standards	1991	
BS 5815	**Sheets, sheeting, pillowslips, towels, napkins and continental quilts secondary covers**	BSI Standards	1989	
	Parts 1: Specification for sheeting etc		1988	
	Part 2: specification for towels etc.		1991	
	Part 3: Specification for counterpanes etc.			
BS EN 45020	**Standardization and related activities**	BSI Standards	1998	
BS 6257	**Specification for paper bags for steam sterilization for medical use**		1989	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**		1984	
BS EN 60804	**Specification for integrating averaging sound level meters**		1994	
BS 7720	**Specification for non-biological sterilization indicators equivalent to the Bowie and Dick Test**		1995	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 593	**Specification for laboratory thermometers**		1989	
BS 1781	**Specification for linen and linen union textiles**		1981	
BS 2775	**Specification for rubber stoppers and tubing for general laboratory use**		1987	
BS 5164	**Specification for indirect acting electrical indicating and recording instruments and their accessories**		1975	
BS 3970	**Sterilizing and disinfecting equipment for medicinal products** **Part 1:** Specification for general requirements **Part 2:** Specification for steam sterilizers for aqueous fluids in sealed rigid containers **Part 3:** Specification for steam sterilizers for wrapped goods and porous loads **Part 4:** Specification for transportable steam sterilizers for unwrapped instruments and utensils **Part 5:** Specification for low temperature steam disinfectors **Part 6:** Specification for sterilizers using low temperature steam with formaldehyde	BSI Standards	1990 1991 1990 1990 1993	
BS EN 1174	**Sterilization of medical devices. Estimation of population of micro-organisms on product**	BSI Standards	1996	
BS EN 552	**Sterilization of medical devices. Validation and routine control of sterilization by irradiation**	BSI Standards	1994	
BS EN 285	**Sterilization, steam sterilizers, large sterilizers**	BSI Standards	1997	
BS EN 550	**Sterilization of medical devices. Validation and routine control of sterilization by ethylene oxide**	BSI Standards	1994	
BS EN 554	**Sterilization of medical devices. Validation and routine control of sterilization by moist heat**	BSI Standards	1994	
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized medical devices to be labelled 'STERILE'**	BSI Standards	1995	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 1422	**Sterilizers for medical purposes – ethylene oxide sterilizers – specification**	BSI Standards	1998	
BS EN 46001	**Specification for the application of EN ISO9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for the application of EN ISO9002 to the manufacture of medical devices**	BSI Standards	1994	
BS EN 60584-1	**Thermocouples reference table**	BSI Standards	1996	
BS EN 60581-2	**Thermocouples. Manufacturing tolerances**	BSI Standards	1996	
BS EN 25667-1	**Water quality. Guidance on design of sampling programmes**	BSI Standards	1994	
BS EN 25667-2	**Water sampling . Guidance on sampling techniques**	BSI Standards	1993	
BS 6068	**Water quality** **Sect.1.2** Glossary **Sect 6.5** Guidance on sampling of drinking water and water used for food processing **Sect. 6.7** Guidance on sampling of water and steam in boiler plants.	BSI Standards	1997 1991 1994	
European Union Directives				
65/65/EEC	Approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	Official Journal of the European Communities (OJEC), no 22, 9/2/65, p 369		
75/107/EEC	Approximation of the laws of member states relating to bottles used as measuring containers.	Official Journal of the European Communities (OJEC), L42, 15/2/75		
90/385/EEC	Approximation of the laws of the Member States relating to active implantable medical devices.	Official Journal of the European Communities (OJEC), L189 20/7/90, p 17		
91/356/EEC	Laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	Official Journal of the European Communities (OJEC). L193 17/7/91, p 30		

Publication ID	*Title*	*Publisher*	*Notes*
80/778/EEC	Quality of water intended for human consumption	Official Journal of the European Communities, 1980	
93/42/EEC	Medical Devices Directorate	Official Journal of the European Communities (OJEC), L169 12/7/93, p 1	
Scottish Health Technical Guidance			
SHTM 2023	Access and accommodation for engineering services	EEF 1999	CD-ROM
SHTM 2045	Acoustics	EEF 1999	CD-ROM
SHPN 15	Accommodation for pathology services	HMSO 1994	
SHTM 2031	Clean steam for sterilizers	EEF 1999	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	EEF 1999	CD-ROM
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF 1999	CD-ROM
SHTM 2007	Electrical services supply and distribution	EEF 1999	CD-ROM
SHTM 2011	Emergency electrical services	EEF 1999	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	EEF 1999	CD-ROM
SHTN 4	General Purposes Estates and Facilities Model Safety Permit-to-Work system	EEF 1998	
SHPN 1	Health service building in Scotland	HMSO 1991	
SHPN 2	Hospital briefing and operational policy	HMSO 1993	
SHTM 2027	Hot and cold water supply, storage and mains services	EEF 1999	CD-ROM
SHTM 2022	Medical gas pipeline systems	EEF 1999	CD-ROM
	NHS in Scotland – Scotconcode	EEF 1999	Version 3
SHGN	Pressure Systems and Transportable Gas Containers Regulations 1989	EEF 1999	CD-ROM
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO 1993	
SHGN	'Safe' hot water and surface temperatures	EEF 1999	CD-ROM
SHPN 13	Sterile services department	HMSO 1994	
SHTM 2025	Ventilation in healthcare premises	EEF 1999	CD-ROM
SHTM 2030	Washer-disinfectors	EEF 1999	CD-ROM

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
NHS in Scotland Firecode				
HTM 82	Alarm and detection systems	EEF	1998	CD-ROM
Fire Practice Note 6	Arson prevention and control in NHS healthcare premises	EEF	1998	CD-ROM
Fire Practice Note 5	Commercial enterprises on hospital premises	EEF	1998	CD-ROM
Fire Practice Note 3	Escape bed lifts	EEF	1998	CD-ROM
HTM 81	Fire precautions in new hospitals	EEF	1998	CD-ROM
HTM 85	Fire precautions in existing hospitals	EEF	1998	CD-ROM
Fire Practice Note 7	Fire precautions in patient hotels	EEF	1998	CD-ROM
HTM 86	Fire risk assessment in hospitals	EEF	1998	CD-ROM
HTM 83	Fire safety in healthcare premises: general fire precautions	EEF	1998	CD-ROM
HTM 84	Fire safety in NHS residential care properties	EEF	1998	CD-ROM
Fire Practice Note 4	Hospital main kitchens	EEF	1998	CD-ROM
Fire Practice Note 10	Laboratories on hospital premises	EEF	1998	CD-ROM
HTM 87	Textiles and furniture	EEF	1998	CD-ROM
UK Health Technical Guidance				
HTM 2014	Abatement of Electrical Interference	HMSO	1993	
HBN 29	Accommodation for pharmaceutical services	HMSO	1988	
HTM 67	Building components: laboratory fitting out system	HMSO	1993	
CONCODE	Contracts and commissions for the NHS estate – contract procedures	HMSO	1994	
MES	Model Engineering Specifications	NHS Estates	1997	As required
MES C14	Sterilizers	NHS Estates	1993	
HBN 13	Supplement 1 - Ethylene oxide sterilization section	HMSO	1994	
MES C02	Thermal insulation	NHS Estates	1993	
Health and Safety Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	

Publication ID	Title	Publisher	Date	Notes
HN(76)126	Hospital design note 4 (noise control): amendments to appendices II, IV and VII	DHSS	1976	
STB3A/85/12	Performance and safety specification for media sterilizers. Media devices directorate	DHSS	1985	
	Emmerson, A. M. *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to the Department of Health Medical Devices Directorate.* Medical devices directorate	Department of Health	1993	
	Biological tests for graded milk. Memo 139/Foods.	Ministry of Health	1937	
	Scottish Infection Manual Guidance on the core standards for the control of infection in hospitals, healthcare premises and at the community interface	Scottish Office	1998	
HS(R) 30	*A guide to the pressure systems and transportable gas container regulations*	HSE	1989	
	Programmable electronic systems in safety related applications: General technical guidelines	HSE	1987	
	Programmable electronic systems in safety related applications: an introductory guide	HSE	1987	
L 5	General COSHH ACOP (Control of substances hazardous to health) Carcinogens ACOP (Control of carcinogenic substances) and Biological agents ACOP (Control of biological agents) Control of Substances Hazardous to Health Regulations1999 Approved Code of Practice	HSE	1999	
L 22	Safe use of work equipment: Approved code of practice and guidance	HSE	1998	
L 23	Manual handling operations: guidance on regulations	HSE	1998	
L 24	Workplace health, safety and welfare: Approved code of practice and guidance	HSE	1992	
L25	Personal protective equipment at work at work: guidance on regulations		1992	
L113	Safe use of lifting equipment: Approved code of practice and guidance	HSE	1998	
COP 37	Safety of pressure systems.: Approved code of practice	HSE	1990	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
COP 38	Safety of transportable gas containers: Approved code of practice	HSE	1990	
Miscellaneous References				
	Atomic absorption spectrophotometry 1979 version	HMSO	1979	(out of print)
	Cadmium in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Colour and turbidity of waters 1981	HMSO	1981	(out of print)
	Determination of anions and cations, transition metals, and other complex ions and organic acids and bases in water by chromatography 1990	HMSO	1990	
	Lead in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Lead and cadmium in fresh waters by atomic absorption spectrophotometry (second edition) a general introduction to electrothermal atomization atomic absorption spectrophotometry 1986	HMSO	1986	(out of print)
	Measurements of electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters.	HMSO		(out of print)
	Mercury in waters, effluents, soils and sediments etc, additional methods	HMSO	1985	(out of print)
	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

Appendix 1 – Useful Addresses

Medicines Control Agency,
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ.
Tel. 0171 273 3000.

Medical Devices Agency,
14 Russell Square,
London WC1 B 5EP.
Tel. 0171 972 2000.

Scottish Executive Health Department,
St Andrew's House,
Edinburgh EH1 3DG.
Tel. 0131 556 8400.

NHS in Scotland, Healthcare Engineering and Environment Unit,
Room 8.51,
Graham Hills Building,
50 George Street,
Glasgow, G1 1QE.
Tel. 0141 548 3446

Public Health Laboratory Service,
Central Public Health Laboratory,
61 Colindale Avenue,
London NW9 5HT.
Tel. 0181-200 4400.

Health and safety

Health and Safety Executive,
375 West George Street,
Glasgow, G2 4LW.
Tel. 0141 275 3000

Belford House
59 Belford Road,
Edinburgh, EH4 3UE.
Tel. 0131 247 2000

Health and Safety Executive Information Line
Tel. 0541 545 500

Standards organisations

British Standards Institution
Head office: 2 Park Street,
London W1A 2BS .

Publications:
Linford Wood,
Milton Keynes MK14 6LE.
Tel. 01908 221 166.

European Committee for Standardization,
Rue de Stassart 36, B-1050 Brussels

Other organisations

Association of Consulting Engineers,
Alliance House, 12 Caxton Street,
London SW1 H 0QL.
Tel. 0171 222 6557.

Institute of Healthcare Engineering and Estate Management ,
2 Abingdon House, Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1 DS.
Tel. 01705 823186.

Institution of Electrical Engineers,
Publication Sales Department, PO Box 26,
Hitchin,
Hertsfordshire SG5 1SA.
Tel. 01438 742792.

Institution of Mechanical Engineers, Publication Sales Department,
PO Box 24, Northgate Avenue,
Bury St Edmunds,
Suffolk IP32 6BW.
Tel. 01284 763277.

Appendix 2 – Sterilization of items contaminated with TSE agents

Introduction

A2.1 The following information is extracted from the HSE document 'Precautions for work with human and animal Transmissible Spongiform Encephalopathies', compiled by the Advisory Committee on Dangerous Pathogens and issued to the NHS under Department of Health circular PL(94)CO/5.

A2.2 The term transmissible spongiform encephalopathy (TSE) describes a rare and fatal degenerative condition of the central nervous system occurring in man and in certain animal species. The three TSEs that are recognised in man are:

a. Creutzfeld-Jakob disease (CJD);

b. Gerstmann-Straussler-Scheinker syndrome (GSS);

c. kuru.

A2.3 The two chief TSEs in animals include:

a. scrapie (in sheep);

b. bovine spongiform encephalopathy (BS E).

A2.4 Similar diseases include transmissible mink encephalopathy (TME), chronic wasting disease (CWD) in Rocky Mountain elk and captive mule deer, and TSEs in small numbers of exotic ungulates and cats.

A2.5 Although these diseases appear to be caused by transmissible agents, the nature of these agents remains uncertain.

A2.6 Animal TSEs are classified as Hazard Group 1. Human TSEs are now classified as Hazard Group 3 (formerly Hazard Group 2) as required by the COSHH Regulations 1999, although full Containment Level 3 precautions are not always required.

Sterilization

A2.7 All agents of TSE exhibit an unusual resistance to conventional decontamination methods used in clinical and laboratory practice. They are not significantly affected by a number of standard chemical agents such as formalin and ethylene oxide, and infectivity persists after autoclaving at conventional times and temperatures (such as 121°C for 15 min). In addition, only extremely high doses of ionising and UV irradiation have been successful in reducing infectivity.

A2.8 The Advisory Committee on Dangerous Pathogens recommends porous load sterilization as the method of choice in most situations. Two processes are recommended:

a. a single cycle at 134-138°C for a minimum holding time of 18 min;

or

b. six cycles at 134-138°C for a minimum holding time of 3 min.

A2.9 The latter represents the standard operating cycle for a porous load sterilizer (run six times) and may be used if the single, longer cycle is not available.

A2.10 Although no practical problems appear to have arisen with this time and temperature combination, recent preliminary studies of a scrapie agent under rigorous experimental conditions have shown some residual infectivity. This may be due to the use of relatively high-titred and more thermostable strains. Further work is planned to confirm the appropriate lower temperature limit.

A2.11 Users should consult Annex 2 of the HSE document for specialised advice on:

a. the effectiveness of other sterilization processes;
b. treatment of work surfaces and non-heat-stable equipment;
c. decontamination and disposal of liquids;
d. decontamination of microbiological safety cabinets;
e. fixation for histology;
f. disposal of tissue.

Appendix 3 – Safety of EO sterilization

Introduction

A3.1 Ethylene oxide presents hazards not found in conventional sterilizers. The vapour is extremely flammable and irritates both the eyes and the respiratory system. Poisoning by ethylene oxide is a reportable disease listed in Schedule 2 of 'The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985'.

A3.2 Much of the guidance in this appendix is drawn, with permission, from 'Guidelines for the safe operation of ethylene oxide sterilization plant' published by ICI plc but no longer available.

A3.3 The advice is primarily aimed at users of large sterilizers supplied from cylinders. Many of the precautions described here will not be necessary for users of small sterilizers supplied from disposable cartridges. However, all users of EO sterilizers are strongly advised to make a risk assessment of the worst case accident that could occur. The amount of EO that could be involved is of prime consideration; the small amount contained in a cartridge is unlikely, for example, to lead to spillages of liquid.

A3.4 Personnel exposure to ethylene oxide should not exceed the maximum exposure limits given in Table 1.

A3.5 Persons employed on plant handling EO should be adequately trained and provided with detailed operating instructions.

A3.6 A selection of physical and chemical properties of EO is listed in Table A1.

Table A1: Selected properties of ethylene oxide

Relative molecular mass	44.05
Form	Liquefied gas
Colour	Colourless
Odour	Ethereal
Odour threshold	450-700 ppm
Boiling point	10.5 C
Flash point (open cup)	-17.8 C
Flammable limits in air (v/v)	3-100%
Auto ignition temperature	429 C
Vapour pressure	139kPa (20 C), 349 kPa (50 C)
Density of liquid at 4°C	890 kgm^{-3}
Solubility	Miscible in water
Vapour density (air=1)	1.5

Sources: 'Product safety data', ICI Chemicals & Polymers Ltd, 1995; 'Information relevant to the installation of, and ancillary equipment for, ethylene oxide sterilizers', CEN TC 102 WG6 N67+, CEN (unpublished).

Fire and explosion hazards

A3.7 EO is highly flammable and forms explosive mixtures with air at all concentrations above 3% (v/v). There is no upper explosive limit as normally expected for hydrocarbons; exothermic reaction replaces combustion at higher concentrations up to 100%. The auto-ignition temperature in air at atmospheric pressure is 429°C, and the decomposition temperature in the absence of air is 560°C.

NOTE: Further Guidance is contained in NHS in Scotland Firecode.

A3.8 Because of its flammability and low boiling point, EO is akin to liquefied petroleum gas (LPG). An essential difference is that it is fully miscible with water. At concentrations in water below 1% w/w the vapours are not flammable at air ambient temperature, so a leakage of liquid EO can be rendered non-flammable by diluting it 100-fold with water. In the open air appreciably less dilution (24-fold) can extinguish burning EO.

A3.9 Fire risks in general and electrical classifications are covered by conforming to typical codes related to the storage of LPG or liquefied natural gas (LNG) products and to the selection of electrical installations for use in flammable atmospheres. Additional precautions are called for because of the thermal instability of EO.

A3.10 Accumulation of electrostatic charge does not take place in EO because of its high electrical conductivity (>3mS m^{-1}). There is thus no reason to limit flow velocities in pipework.

A3.11 The aim should be to handle EO in closed equipment and to deal promptly with any leaks or spillages whenever these occur.

A3.12 For detecting leaks, gas detectors with automatic alarms located at strategic points (eg. near the sterilizer door) are recommended.

A3.13 The prime defence against escaped EO is the use of water in very large quantities to dilute the EO and render it non-flammable. Insufficient amounts of water, on the other hand, may promote the vaporisation of EO from large spillages.

Polymerisation

A3.14 Liquid EO is very susceptible to polymerisation initiated at ambient temperature by acids, bases or catalysts, such as anhydrous chlorides of iron, aluminium, tin and metal oxides. Iron rust is a moderate initiator for this reaction and therefore it should be substantially removed from any equipment containing EO. Purely thermal initiation starts at around 100°C and once started, iron is a promoter. The polymerisation is highly exothermic and if the temperature is not controlled the polymerisation is self-accelerating, leading to vaporisation of unreacted EO and possibly to explosive decomposition of the vapour.

A3.15 Slow polymerisation can occur, producing solid polymer, which is thermally stable. Solid polymer is soluble in the monomer. The polymer may also contain considerable amounts of dissolved monomer which during dispersal, may be released into the atmosphere. Further guidance is contained in NHS in Scotland Firecode.

Toxicity hazards

Vapour toxicity

A3.16 EO boils at 10.5°C and vaporises at normal atmospheric temperature and pressure so that exposure of personnel to vapour, rather than liquid contact, is the more likely hazard. High concentrations of the gas in contact with the skin may produce serious burns if not removed immediately. It has been reported that concentrations of 2000 ppm retained in rubber gloves have caused skin irritation.

A3.17 Exposure to EO vapour causes irritation of the eyes and respiratory system accompanied by headache. The vapour has anaesthetic properties. Signs and symptoms may include nausea, vomiting, coughing, irritation to the nose, loss of smell and, progressively, dizziness, stupor and coma. These effects are noticeable at concentrations greater than 50 ppm. Acute symptoms are normally delayed except in the case of serious exposure.

Fluid build-up in the lungs (pulmonary oedema) may occur up to 48 hours after exposure and could prove fatal. The effects of low concentrations of EO are not thought to be cumulative, though the evidence is equivocal and the subject of continuing research.

A3.18 The sweetish smell of pure EO is not apparent until the concentration reaches several hundred ppm (figures between 400 and 700ppm have been quoted), far above the level at which harm is caused. Personnel concerned with the operation of EO sterilizers cannot rely on smell to protect themselves against exposure. It is essential that EO environmental tests are carried out at least once a year and that there is an effective system for personal monitoring.

A3.19 Adverse reproductive effects (reduced fertility and embryotoxicity) have been reported in rats exposed to high concentrations for prolonged periods. Epidemiological studies on human reproductive effects have so far been inconclusive although spontaneous abortions and an excess of foetal deaths have been reported among women exposed to EO. The exposure levels are not known.

A3.20 EO is mutagenic in a wide variety of in vitro and in vivo biological test systems. It has been shown to cause cancer in animals and HSE advises that it should be regarded as a potential human carcinogen.

Effects of liquid EO on skin and eyes

A3.21 Liquid EO can persist under open conditions, particularly at low temperatures. Serious freeze burns can result from contact from liquid splashes or spray. Solutions of EO in water cause more rapid burning than the dry material. Delayed inflammation of the skin may also result.

A3.22 The eyes are particularly susceptible to serious permanent damage from splashes, even of dilute solutions. The onset of effects may be delayed for several hours.

Workplace monitoring and recording

A3.23 Atmospheric concentrations of EO should be monitored in the appropriate working area and any abnormalities should be reported, investigated and corrected.

A3.24 While background atmospheric monitoring of the sterilization and quarantine areas is recommended, regular personal monitoring of operators working in these areas is regarded as essential in assessing exposure.

A3.25 All assessment of operator exposure should be based on personal monitoring unless this can be obtained from workplace air sampling by showing the necessary correlation. Monitoring should be based on an 8-hour exposure unless it has been shown that exposure occurs only at specific times; in such cases the shift exposure may be calculated from measurements made at these times. Additionally, spot measurements

should be made at times of peak exposures with a view to reducing these levels.

A3.26 Plant monitoring may be useful for the early detection of leaks but considerable thought should be given to the siting of sample points and the frequency of sampling.

A3.27 Records should be established of the names and job classification of operators who work in areas where exposure to EO may occur. All personal monitoring results should be recorded. Records should be kept of all cases of acute exposure to EO. All of these records should be kept for at least 30 years.

A3.28 Users setting up monitoring systems are strongly recommended to obtain advice both from gas manufacturers or suppliers and also from properly qualified occupational health consultants.

Personal sampling

A3.29 Personal sampling should be undertaken to evaluate the level of exposure of individuals. It is the only technique recognised by HSE as producing results for judging compliance with the established exposure limits.

A3.30 A number of methods based on collection of atmospheric EO on a solid adsorbent, such as charcoal, are available. There are principally two types;

a. active sampling using a small pump;

b. passive diffusion.

A3.31 Both systems require the subsequent desorption and estimation of EO.

Environmental monitoring

A3.32 Systems which are currently in use for environmental monitoring are based on several analytical techniques including infrared spectroscopy, flame ionisation, photoionisation, mass spectrometry and gas chromatography. It should be borne in mind that each suffers from limitations dependent upon interference from other compounds which may be present concurrently with EO. The system to be established should be considered in relation to the particular installation for which it is intended.

A3.33 Newer and simpler techniques are continuously being developed and the current state-of-the-art should be considered before commitment to any particular system is made.

A3.34 The principal systems available are as follows:

a. Colour-changes indicator system (1-30ppm). This system is for spot monitoring and cannot give accurate time-weighted average reading of exposure. The MEL for EO is at the low end of the detection range, hence accuracy is poor. The system does not pinpoint the source of emissions.

b. Direct-reading infrared analysers (0.2-1000ppm). This equipment can be portable for single-point monitoring. More elaborate static units are available for continuous cycle and multipoint monitoring. These systems can give accurate time-weighted average figures for specific points and extremely good historical perspective, but give no indication of concentrations in the air breathed by personnel.

c. Gas chromatography. As with infrared there are both portable and static units providing a sensitivity of 0.1ppm, depending upon sample size and analytical system. All gas chromatography applications for time-weighted average readings require charcoal tubes for adsorption and desorption.

Personal protective equipment

A3.35 Personal protective equipment (PPE) guarding against the effects of EO should not need to be used as a matter of routine, since the sterilizer design, ventilation systems and operating procedures should preclude the presence of harmful concentrations of EO.

A3.36 Where work in contact with EO is unavoidable, the following items of PPE should be available:

a. for exposure to EO vapour – respiratory protective equipment and eye protection;

b. for exposure to EO liquid – air breathing hood, protective suit, gloves and rubber boots.

A3.37 There should be training programmes to ensure that the relevant people are able to use PPE correctly and quickly. Training should be carried out by a suitably qualified instructor.

A3.38 Suitable arrangements should be made for periodic maintenance of the equipment.

A3.39 Records should be kept of both training and maintenance.

Respiratory protective equipment

A3.40 Where atmospheric concentrations of EO are, or could reasonably be expected to be, above the Maximum Exposure Limit (see Table 1), suitable respiratory protective equipment should be worn. This may be self-contained breathing apparatus, compressed air line breathing apparatus or

a suitable canister respirator, the type of equipment being selected according to the levels of EO which may be present.

A3.41 The equipment should comply with all relevant British or European Standards. In selecting suitable equipment, reference should be made to BS 4275, 'Recommendations for the selection, use and maintenance of respiratory protective equipment'.

A3.42 The system chosen should be adequate for the protection of the wearer under all foreseeable circumstances. Factors to be taken into consideration are:

a. the highest possible exposure level;

b. the longest possible excursion time;

c. the nominal protection factor of the equipment; this will indicate the efficiency of the equipment (the best nominal protection factor is conferred by positive-pressure breathing apparatus);

d. the goodness of fit of face masks.

Breathing apparatus

A3.43 Full, positive-pressure breathing apparatus provides a totally enclosed respiratory environment for the wearer. Because of the design, there is a 30-min usage limit.

A3.44 Two sets of breathing apparatus for rescue work should be kept outside the EO working area.

Chest-mounted canister respirator

A3.45 Canister respirators should only be used when the atmospheric concentrations of EO are known to be within the levels for which the canister is designed and the duration of use should be within the life of the canister. These devices rely on a good seal between the respirator and the face of the wearer; if this seal is lessened by facial hair, spectacles, etc., a very much lower degree of protection will be achieved.

A3.46 The canister filters the air to a full face mask. It should not be used in atmospheres where the exposure level is likely to be in excess of 0.2% by volume. There is a specified time limit for usage. HSE recommends that canisters be discarded after each use unless tests against EO can show that desorption does not occur on re-use. Canisters should be degassed before disposal.

Cartridge respirator

A3.47 The cartridge fits directly into an ori-nasal mask. It should not be used in atmospheres where the EO level is likely to exceed 1000ppm. The useful life of the cartridge is 30 min for exposure to maximum concentration. It is essential to adhere closely to the manufacturer's or supplier's instructions. Cartridges should be degassed before disposal.

Protective clothing

A3.48 In emergency situations when handling liquid EO and when atmospheric concentrations are high, full protective clothing should be worn. This should provide complete protection to the skin and eyes. Particular note should be taken of the construction of the clothing, such as the sealing of seams, and of the ability of the material to limit the permeation of EO on to the skin. If any clothing becomes contaminated with liquid EO it should be destroyed.

Emergency procedures

A3.49 Comprehensive written procedures should be prepared covering shut-down, evacuation and rescue. This should involve an assessment of the worst possible consequences of an incident. The procedures thus described should be tested and audited at regular intervals.

A3.50 A fire certificate issued by the Home Office may be required. Guidance from the local fire brigade should be sought. Emergency procedures should be agreed with the fire officers and displayed in a permanent form in a prominent position. Further information is available in NHS in Scotland Firecode.

A3.51 Liaison with the local accident and emergency department is recommended, particularly to ensure that the specific hazards associated with exposure to EO are known and that the remedial treatment is available.

A3.52 First aid procedures relevant to the nature of the sterilization operation should be drawn up and agreed. Sterilizer operators and first-aiders on the site should be trained in these procedures.

Leaking cylinder

A3.53 If the cylinder is in an enclosed area, evacuate the area. Wear suitable protection. Check that the cylinder valve is closed. Move the cylinder to a fume room or open space downwind and away from persons and buildings. Post warning notices and seal off the area. The suppliers should be contacted in the event of difficulty.

Fire fighting advice

A3.54 In the event of a leakage of gas becoming ignited, the fire brigade should be called immediately. The fire should be extinguished only by closing the valve. No attempt should be made to put out the flame in any other way but, provided it is safe to do so, the cylinder should be cooled by copious spraying with water. The person directing the spray should take up a position where he or she will be protected should a cylinder explode. If flame from the burning leak impinges on cylinders, the building should be evacuated immediately and no fire-fighting attempted.

A3.55 Cylinders which have not become heated should be moved to a safe place in the open as quickly as possible, making sure any valves are turned off

first. If this is not possible, such cylinders should be kept cool by spraying with water from a safe position.

A3.56 On arrival at the premises, the fire brigade should be informed of the position of all cylinders, even those that are not directly threatened by the fire.

Spillage

A3.57 In any area where the spillage of liquid EO can occur a piped water supply should be provided. Escaped EO should be diluted with copious quantities of water sufficient to dilute the EO to less than 4%. At this concentration the vapours are not flammable. Restricted amounts of water may only serve to increase the vaporisation of EO.

A3.58 In the event of spillage, the area should be evacuated immediately. Re-entry should only be by personnel wearing full protective clothing - i.e. procedures should be prepared in accordance with Firecode in Scotland and the appropriate HTMs: rubber boots, non-absorbent overalls, gloves and breathing apparatus. The supply source should be isolated, if possible. Spillages should be cleared by drenching with sufficient water to dilute the EO at least 100-fold and never by mopping up. It should be remembered that EO is heavier than air so higher concentrations will tend to accumulate at ground level.

A3.59 EO is a persistent contaminant, and particular attention should be paid to the cleansing of contaminated clothing and equipment. Where decontamination is not possible (such as on leather items), the article should be destroyed.

First aid advice

A3.60 In the event of an accident personnel should take steps to protect themselves and isolate any sources of escaping EO. If someone is exposed to EO, medical attention should be sought immediately.

A3.61 In all cases of severe or suspected exposure to EO the person should be immediately removed from the contaminated area to a well ventilated area by trained personnel wearing the necessary protective equipment. The following action should be taken.

A3.62 If the skin has been affected:

a. remove all contaminated clothing;

b. if liquid EO is on the skin, allow it to evaporate;

c. wash skin copiously with water for 15 minutes. Exposed skin should be treated with high-pressure water such as a hose or strong shower – gentle washing is not sufficient.

A3.63 If EO has been inhaled:

a. lay the casualty flat and keep him warm and still;

b. if breathing has stopped, given artificial respiration with a Brooks airway; do not attempt mouth-to-mouth or mouth-to-nose resuscitation. If oxygen is available it should be administered by a suitably qualified person.

A3.64 If the eyes have been affected, flush copiously with water for 15 minutes.

A3.65 If EO has been swallowed, activated charcoal may be used to adsorb unreacted EO. It should be administered as an aqueous slurry of 240 ml of water to 30 g charcoal. The usual dose is 30-100 g in adults. EO is irritating and usually serves as its own cathartic.

A3.66 The possibility of delayed effects following exposure should not be overlooked.

Control and handling of cylinders

A3.67 The gas should be supplied to an agreed specification guaranteed by the supplier. The specification should include:

a. details of the composition and pressure of the gas or gas mixture;

b. a technical description of the construction and fittings of the cylinders;

c. individual cylinder identification to allow the rotation of stock.

A3.68 A procedure should be defined for the acceptance of deliveries of gas cylinders from the supplier. The procedure should include the following details:

a. confirmation of the identity of the gas by reference to the manufacturer's product identification; a copy of the code and procedure should be prominently displayed in the goods received and in the gas storage areas;

b. the leak testing of each cylinder using a suitable leak detection device or soapy water. Leak tests should be carried out:

(i) on the joint between the cylinder neck and the discharge valve;

(ii) around the valve control handle stem;

(iii) around and inside the valve discharge orifice.

A3.69 Any cylinders found to be leaking or otherwise not conforming to the specification should not be accepted and will remain the responsibility of the supplier, who should be informed immediately.

A3.70 The manufacturer's recommendation regarding the maintenance of residual pressure or weight in nominally empty cylinders for return should be followed.

A3.71 Cylinders should be stored in a cool, well-ventilated, secure area (see Part 5 of this SHTM for guidance). EO should be stored away from fire risk and sources of heat. A suitable cylinder handling trolley should be provided.

Information and training

A3.72 All personnel employed in the operation of EO sterilizers, including maintenance personnel and operators, should receive adequate, documented training. Personnel should not commence their duties until this training has been completed and detailed operating instructions have been provided. Maintenance personnel should be trained and certified by the manufacturer of the sterilizer.

A3.73 As a minimum, training should include:

a. operational policies;
b. safety provisions;
c. connection and disconnection of gas cylinders;
d. first aid;
e. emergency procedures;
f. use of respiratory equipment;
g. duties to be performed;
h. actions in the event of a fire.

A3.74 On completion of training, employees should be assessed to ensure that the training programme has been understood. No person should be permitted to work with EO until he or she has attained an adequate level of proficiency.

A3.75 All personnel coming into contact with EO should be informed of the hazards and provided with a hazard data sheet.

Maintenance

A3.76 Maintenance should only be performed by suitably trained and qualified personnel. Before working on equipment known to contain EO, the equipment should be drained, isolated, washed out with water and demonstrated to be clear of flammable vapour (by gas analysis, for example).

A3.77 Systems which have carried EO but which are thought to be free of any residue should nevertheless be thoroughly purged with nitrogen before work commences.

A3.78 Planned, regular maintenance of all elements of the gas supply system is essential to safe operation.

A3.79 A list of spares vital for safe operation should be compiled and a stock maintained.

A3.80 Before any work is carried out on equipment known to contain EO, or that has carried EO, or is thought to be free of EO, the local exhaust ventilation should be known to be effective. If work is to be carried out on the supply line from the manifold (cylinder supply) or pipe systems that have carried EO, they should first be purged with a non-flammable gas such as nitrogen before work commences.

A3.81 A procedure should be defined for the maintenance of lines and fittings which have contained EO and for subsequent pressure and vacuum testing. The following details should be included:

a. compulsory wearing of face shields, respiratory protection (where appropriate) and gloves;

b. disconnection and isolation of the source of EO;

c. the source of purging gas, together with any entrained material, shall be vented to a safe location (provision should be made for the handling and disposal of polymerised EO which may contain EO monomer);

d. on completion of the maintenance schedule, pressure testing at an appropriate pressure, with leak testing as required;

e. vacuum testing as appropriate;

f. checking that all valves and other control settings are correct before putting the sterilizer back into service.

A3.82 Where potentially flammable EO mixtures are present, sources of ignition should be prohibited. For example:

a. smoking and the use of naked flames should be strictly prohibited and matches or other means of ignition should not be carried into the work area;

b. tools made from spark-producing metals should also be prohibited; only tools and equipment which do not induce sparks should be issued;

c. garments containing synthetic fibres likely to induce static discharge should not be worn; conductive footwear should be used.

Appendix 4 – Guidance to management on the appointment of an Authorised Person (Sterilizers)

Introduction

A4.1 The Authorised Person (Sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilisers and sterilization and to review and witness documentation on validation. The shorter term “Authorised Person” is used in this SHTM.

A4.2 The specific requirements for the services of an Authorised Person should be based upon the core responsibilities outlined in Part 1 of this SHTM, namely:

a. to provide general and impartial advice on all matters concerned with sterilization;

b. to advise on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests prepared by the Test Person;

d. to advise on programmes of periodic tests and periodic maintenance;

e. to advise on operational procedures for routine production.

A4.3 The Institute of Healthcare Engineering and Estate Management (formerly the Institute of Hospital Engineering) is the registration authority for Authorised Persons. The address is given in Appendix 1.

A4.4 In appointing an Authorised Person, management should ensure that there is no conflict of interest that would compromise his or her impartiality in carrying out the assigned duties. Candidates should be required to declare any such interest at an early stage. Management should carefully assess whether such declared interests are likely to affect the ability of the candidate to carry out the duties defined above or any proposed extension to them. A candidate employed by a sterilizer manufacturer, for example, may be able to discharge all the core duties satisfactorily but be considered unsuitable to offer advice on procurement of new equipment. See also paragraph A4.7.

A4.5 Management should ensure that the selected candidate has the appropriate qualifications and experience for the sterilizers for which he or she will be responsible. Not all Authorised Persons will be qualified to advise on all types of sterilization process. It may be necessary to appoint one or more Authorised Persons specialised in different processes; namely steam, dry heat, LTSF or EO. In such cases, there should be a clear definition of each appointee’s sphere of responsibility.

A4.6 In normal circumstances an Authorised Person should have exclusive responsibility for each machine in his or her charge. It is not good practice for more than one Authorised Person to be contracted to share continuing responsibility for a particular machine. This does not prevent Users seeking a second opinion where the need arises, though such action should be the exception rather than the norm.

Contractual arrangements

A4.7 Authorised Persons are required to comply with the 'Code and rules of conduct and disciplinary regulations for registered Authorised Persons (Sterilizers)' issued by the Institute of Healthcare Engineering and Estate Management. Management should ensure that no part of the contract, nor any subsequent instructions, conflict with the code and rules of conduct.

A4.8 A term of contract is suitable for the procurement of the services of an Authorised Person. The minimum term should be one year, although a five-year term has the advantage of greater continuity, enabling the appointee to become familiar with each of the sterilizers for which he or she is responsible. Casual appointments on a one-off basis are unlikely to foster the mutual confidence necessary for a consistent quality of service.

A4.9 The contract should specify the core responsibilities outlined above and further explained below (see paragraph A4.13). Provision should be made for extensions to the contract to include, for example, the duties associated with the validation of a new sterilizer or the introduction of a new product.

A4.10 Management may also require the Authorised Person to undertake additional duties outside the range of the core responsibilities. To enable this assistance to be given when needed, the contract should include the terms of payment for such additional work. Examples of additional services are given in paragraph A4.24.

A4.11 Formal lines of accountability should be made clear in the contract. The Authorised Person should normally report in the first instance to the user, who bears the day-to-day responsibility for the operation of the sterilizer.

A4.12 On appointment, the Authorised Person should be notified in writing of the names, addresses and telephone numbers of key personnel defined in Part 1 of this SHTM; namely, the Executive Manager of the contracting organisation, the user, the Competent Person, the Test Person, the Maintenance Person and the Microbiologist; and for medicinal products, the Production Manager and Quality Controller. The Authorised Person should be notified promptly in writing of any changes to this information.

Core responsibilities

A4.13 The following are the core responsibilities that should be written into the contract.

General advice

A4.14 The Authorised Person is required to provide general and impartial advice on all matters concerned with sterilization. This will usually be provided in response to enquiries by telephone, post, fax or electronic mail, as appropriate. In some cases site visits may be required.

Validation programmes

A4.15 The Authorised Person is required to advise on programmes of validation for the processes for which he or she is qualified. These programmes should be based on the guidance given in Part 3 of this SHTM and any other regulatory requirements that may be specified.

Auditing of validation and yearly tests

A4.16 The Authorised Person is required to audit reports on validation, revalidation and yearly tests prepared by the Test Person.

A4.17 The Authorised Person should be given reasonable notice of the date of commencement any validation, revalidation or yearly tests which he or she is required to audit.

A4.18 Whether audits require a visit to the sterilizer is a matter of professional judgement dependent on the type of sterilizer, its operational history, the experience of the Test Person and the complexity of the performance qualification procedures. As a rule, site visits are recommended. However, since an Authorised Person cannot effectively audit a machine that he or she has not seen, site visits are essential on at least the following occasions:

a. for each sterilizer, before or during the first audit following appointment;

b. during the initial validation of a newly installed sterilizer.

A4.19 In order to perform this work effectively, the Authorised Person should have access to the sterilizer itself, the plant history file, the sterilizer process log and any other documentation bearing on the functioning of the sterilizer. He or she should also have reasonable access to the user, Test Person and other key personnel, and sterilizer operators. During site visits the Authorised Person should be provided with a quiet room in which to examine documentation.

A4.20 Within an agreed period following completion of the tests as notified in paragraph A4.17, the Authorised Person should provide a report of the audit. The report should include the following information:

a. names of the user, Executive Manager and the Authorised Person;

b. details of the Test Person who carried out the work, including:

   (i) name;

   (ii) relevant qualifications;

   (iii) name of employer;

c. information for each sterilizer tested including:

   (i) identification of the sterilizer (including manufacturer, model and serial number and any inventory number);

   (ii) type of process;

   (iii) dates of manufacture, installation and validation;

   (iv) date of the audit;

   (v) a list of the tests carried out (validation, revalidation or yearly, as appropriate) and a statement as to whether each was satisfactory;

   (vi) a summary of the evidence that the test equipment used in the tests was properly calibrated;

   (vii) detailed comments on the outcome of the audit, especially if there is any evidence of deterioration in performance, with recommendations;

   (viii) a signed and dated recommendation as to whether the sterilizer should be considered fit for use.

A4.21 Where the Authorised Person has reason to recommend that the sterilizer is not fit for use, this information should be conveyed to the user before leaving the site, both in writing and (if possible) verbally, in advance of the full report.

Test and maintenance programmes

A4.22 The Authorised Person is required to advise on programmes of periodic tests and periodic maintenance. Advice should cover the following:

a. programmes of daily, weekly, quarterly and yearly tests, based on the schedules in Part 3 of this SHTM;

b. maintenance schedules, based on the guidelines in Part 4 of this SHTM;

c. implementation of written schemes of examination for pressure vessels issued by the Competent Person (Pressure Vessels).

Operational procedures

A4.23 The Authorised Person is required to advise on operational procedures for routine production. Examples where advice may be needed include:

a. load design;
b. packaging;
c. product compatibility;
d. product release;
e. documentation;
f. safety;
g. training requirements;
h. compliance with legislation and standards.

Additional services

A4.24 Examples of services which would not be included in the core responsibilities may include:

a. advice on the planning, operation and quality control of whole departments;
b. delivery of training;
c. auditing of periodic tests at more frequent intervals (quarterly or weekly);
d. technical consultancy for tendering, equipment and services;
e. preparing procurement specifications for sterilizers and washer disinfectors;
f. risk assessments for health and safety purposes.