

Sterilization

**Part 4: Operational management
(New edition)
with
Part 6: Testing and validation
protocols**

Health Technical Memorandum 2010

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About this publication

Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

HTM 2010 is published in five volumes:

- Part 1 – **Management policy** – is a summary of the information required by non-technical personnel responsible for the management of sterilization services. It discusses the various types of sterilizer, for both clinical and laboratory use, and also contains guidance on legal and policy matters, and on the appointment and responsibilities of personnel. It should be read by anyone consulting this memorandum for the first time;
- Part 2 – **Design considerations** – contains information relevant to the specification and installation of new sterilizing equipment. It discusses the requirements for each type of sterilizer and outlines the specifications to be included in any contract. Practical considerations for the installation of sterilizers are discussed, including siting, heat emission, ventilation, noise and vibration, and mains services with an emphasis on steam quality;
- Part 3 – **Validation and verification** – covers all aspects of validation and periodic testing of sterilizers. It includes detailed schedules and procedures for tests and checks to be carried out for commissioning and performance qualification and for subsequent periodic testing;
- this volume includes Part 4 – **Operational management** – which covers all aspects of the routine operation and maintenance of sterilizers, stressing the need for a planned maintenance programme

along with the type of records to be kept. Advice on the safe and efficient operation of sterilizers is given, as well as procedures for reporting defects and accidents; and Part 6 – **Testing and validation protocols** – which provides step-by-step guidance on testing and validation of processes;

- Part 5 – **Good practice guide** – provides supplementary advice on a number of matters concerned with the effective usage of sterilizers.

The contents of this HTM in terms of management policy and operational policy are endorsed by:

- a. the Welsh Office for NHS Wales;
- b. Health Estates for Northern Ireland;
- c. the NHS in Scotland Estates Environment Forum.

References to legislation appearing in the main text of this guidance apply to the United Kingdom as a whole, except where marginal notes indicate variations for Scotland or Northern Ireland. Where appropriate, marginal notes are also used to amplify the text.

Executive summary

HTM 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;

b. laboratory sterilizers:

- (i) high-temperature steam sterilizers used with one or more specialised operating cycles;
- (ii) culture media preparators.

In Scotland LTSF sterilizers are considered to be disinfectors

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 HTM and that the intended operating procedures will ensure an efficacious process for the different types of load.

This HTM 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.

Scottish Health Planning Notes 13 – ‘Sterile services department’, and 15 – ‘Accommodation for pathology services’, apply in Scotland

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

Although this edition of HTM 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.

Executive summary

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 HTM 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 HTM has been aligned with existing or anticipated standards and advice is offered where no standard has yet been formulated.

The sterilizers described in this HTM 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.

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.

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 (Parts 4 and 6) substantially revises previous editions of Part 4 and includes guidance on testing and validation of sterilization processes.

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1.0 General

Introduction

1.1 This Part of HTM 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 HTM 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 Bibliography 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 HTM, 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.

In Scotland, LTSF Sterilizers are considered to be 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 HTM.

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 HTM.

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 HTM 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 HTM 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. (The directive on in-vitro diagnostic medical devices is yet to be published.) 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 HTM:

- a. EN 556 covering the requirements for a medical device to be labelled “sterile”;
- b. EN 554 covering sterilization by “moist heat” (i.e. 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 HTM:

- 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 Bibliography.

1.21 This edition of HTM 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, HTM 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 HTM 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 HTM 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 Appendix 6 contains written procedures for the procurement, validation and management of sterilizers designed to support a quality system for the production of sterile goods. 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 HTM 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 HTM.

The Pressure Systems and Transportable Gas Containers Regulations (Northern Ireland) 1991 apply in Northern Ireland

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 HTM.

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 HTM.

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 HTM. 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 HTM.

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 HTM.

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 Bibliography). At the time of writing (1996) 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	15	30	5	10

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 1994, HSE Guidance Note EH40 (1995).

1.46 The COSHH Regulations 1994 also introduce new controls on biological agents which are of relevance to Users of laboratory sterilizers.

2.0 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 HTM 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).

The Provision and Use of Work Equipment Regulations (Northern Ireland) 1993 apply in Northern Ireland

2.8 Users should note the requirements of The Manual Handling Operations Regulations 1992 with regard to loading and unloading sterilizers. Guidance may be found in the HSE document 'Manual handling' (L23).

The Manual Handling Operations Regulations (Northern Ireland) 1992 apply in Northern Ireland

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;
- j. the hazard of infection to patients and staff by the inadvertent release of an unsterile load due to inadequate quality control;
- k. the hazard to patients arising from residual ethylene oxide or formaldehyde present in the product;
- l. 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 HTM contain pressure vessels that are subject to the Pressure Systems and Transportable Gas Containers Regulations 1989. Users are reminded of the following safety measures:

The Pressure Systems and Transportable Gas Containers Regulations (Northern Ireland) 1991 apply in Northern Ireland

- 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

The Personal Protective Equipment at Work Regulations (Northern Ireland) 1993 apply in Northern Ireland

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 HTM). 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.

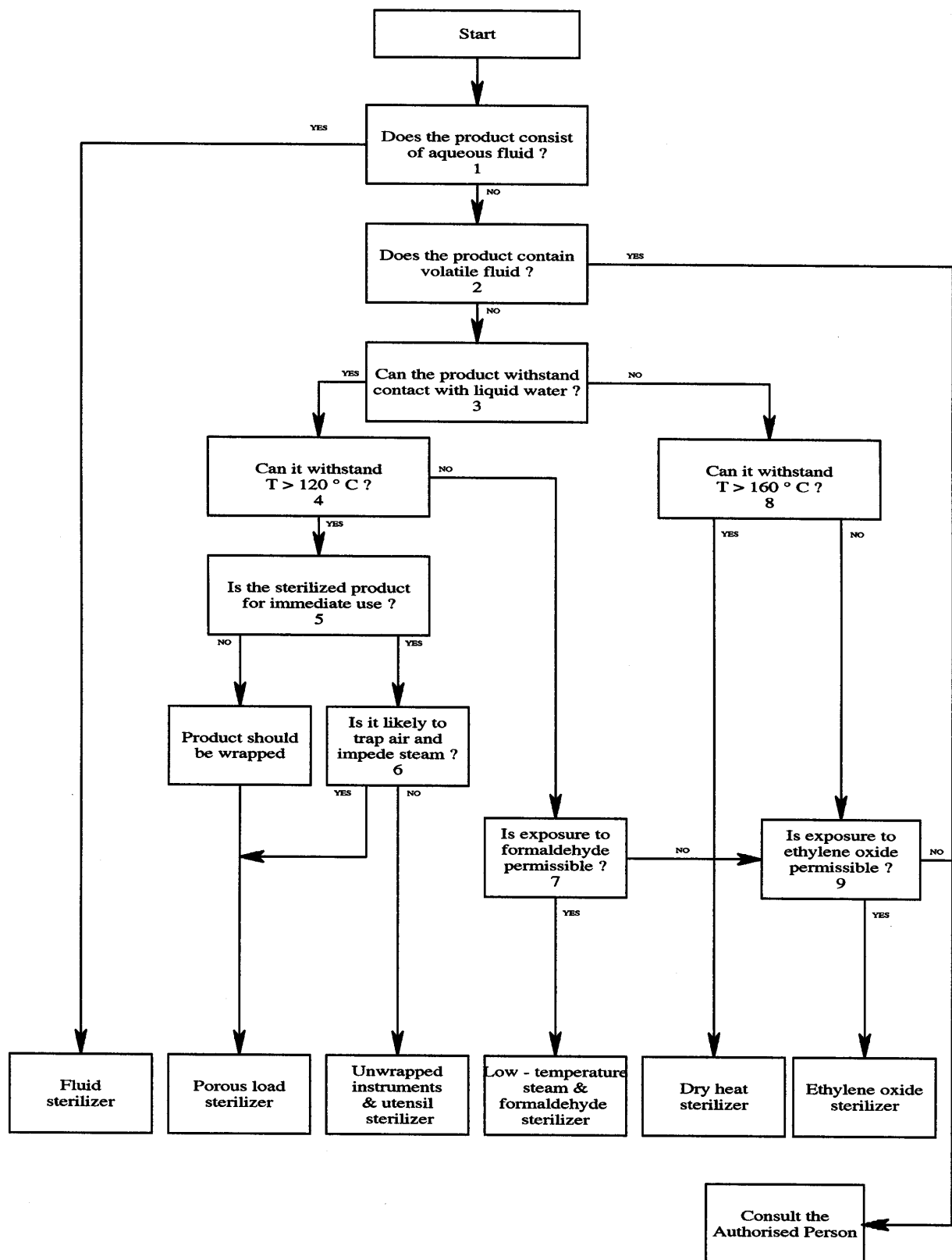
Table 2 Recommended processes for the decontamination of medical devices according to risk of infection

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 HTM 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 120°C?

High-temperature steam sterilizers operate at sterilization temperatures of 121°C, 126°C or 134°C, 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 160°C?

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 HTM).

“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 HTM 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 HTM, 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 HTM).

- 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 HTM.

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 HTM.

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 HTM. In selecting which load items require sensors, the following observations should be noted:

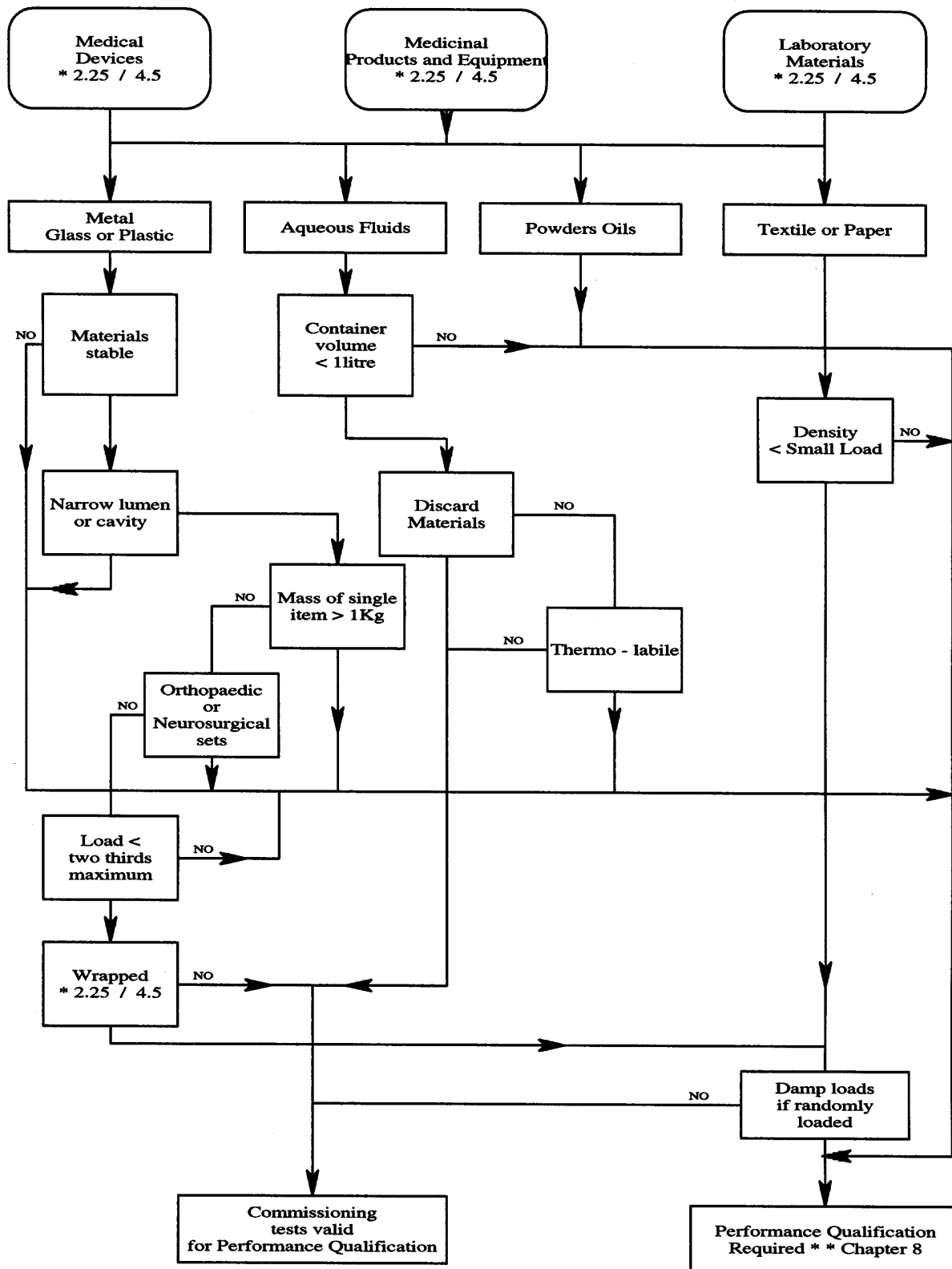
- a. small load items will heat up and cool down faster than large items;
- b. load items placed near the steam inlet port will heat up faster than those placed further away.

Cycle variables

2.43 For the purposes of this HTM 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.

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 affected

Figure 2 Performance qualification assessment guide

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.

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	129	137 (d)	170	180	190	80	80	(e)
Minimum holding time [min]	15	10	3	120	60	30	10	180 (f)	(g)

- The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.
- Disinfection temperature.
- This temperature is conventional but others may be used.
- See paragraph 2.52.
- For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.
- For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses of formaldehyde required to achieve sterilization.
- 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.

2.52 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 BS3970, 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.

2.53 However, EN 285, which is to replace BS3970: 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 HTM. 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 HTM 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

Sterilization temperature [°C]	Maximum allowable temperature						Holding time [min]
	Fluids	Porous loads			Unwrapped		
	BS3970: Part 2	BS3970: Part 3	EN 285 ("large")	Proposed type B* ("small")	BS3970: Part 4	Proposed type N* ("small")	
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;
- j. the name or other identification of the operator;
- k. 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 HTM). 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 HTM 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:

- 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”, i.e. 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.

In Scotland, the management of clinical waste and heat treatment processes, published by the Scottish Centre for Infection and Environmental Health, Aug 1994, ISBN 1 873772106, should be referred to

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 HTM.

3.0 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.

The collection, fractionation, quality control and uses of blood and blood products, World Health Organisation 1981

3.2 The following principles, based upon those issued by the World Health Organisation 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;
- j. 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 than 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 HTM 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 NHS Estates. An example of a log book for a porous load sterilizer is given in Appendix 5. The log book is regarded as part of the plant history file.

In Scotland, log books are available from Scottish Healthcare Supplies

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 HTM);
- 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;

3.0 Record-keeping

- 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.

4.0 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 HTM, 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 HTM.

Maintenance Person

4.5 As discussed in Part 1 of this HTM, 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.

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 HTM 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 EN ISO 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.

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

The Pressure Systems and Transportable Gas Containers Regulations (Northern Ireland) 1991 apply in Northern Ireland

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 HTM). 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 sterilizer 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 BS2646: 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 HTM.

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 HTM 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 HTM.

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 HTM 2031 for guidance);
- c. room ventilation and local exhaust ventilation (see HTM 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 HTM.

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.

5.0 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 four 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 HTM, 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, e.g. filters and flasks with small orifices, a thermometric performance qualification test is required (see Part 3 of this HTM).

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 HTM.

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 HTM);
- 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:

5.0 Operation of porous load sterilizers

- 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 HTM. 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 HTM. 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 HTM. Users should note that this test will not reliably detect wetness due to sporadic carry-over of water.

5.45 Part 2 of this HTM 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 HTM.

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.

6.0 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.

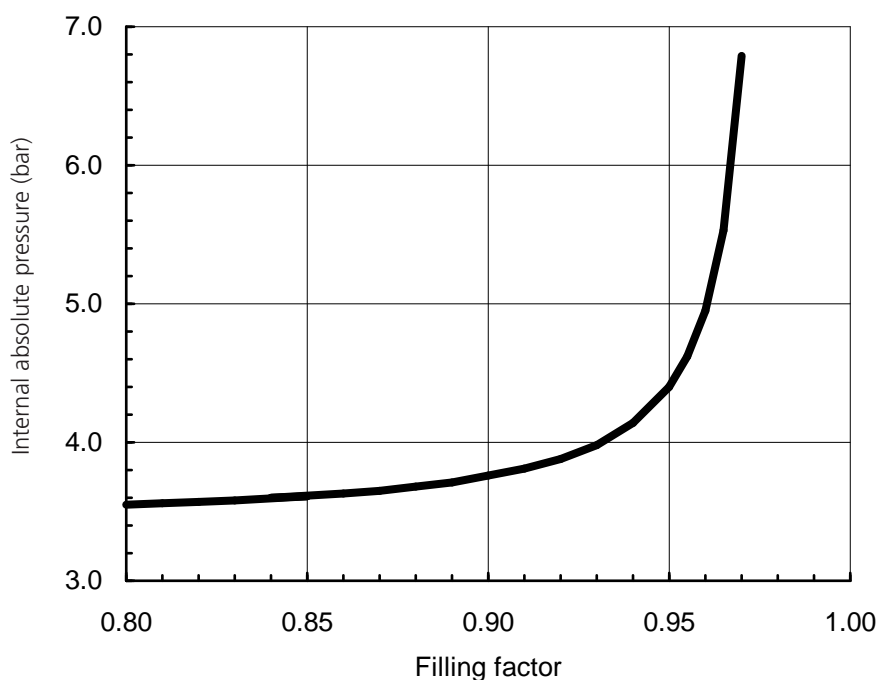
6.21 It is essential that the elastomer is held in tight contact with the neck of the bottle in order to prevent the entry of micro-organisms or other materials which might contaminate the product. It is a characteristic of such containers that when they are charged with the specified volume of the product 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.

Figure 4 Internal pressure against filling factor for aqueous fluids at 121°C



Note: Pressures are calculated assuming that the product is pure water bottled at 15°C.

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 HTM 2031. See also Part 2 of this HTM 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:

- the nominal capacity of any container exceeds 1 litre;
- the product cannot withstand the equilibration time associated with the commissioning tests (see Part 3 of this HTM);

- 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	Maximum allowable temperature	Minimum holding time
[°C]	[°C]	[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. 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;
- 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 HTM.

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.

7.0 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 BS3970 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 HTM 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 HTM 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 HTM 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 (unpacked 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. BS3970: 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 mm² 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 placed 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 HTM 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 BS3970: 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 HTM, 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 HTM), 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.

Product release

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.

8.0 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 160 °C 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 80 °C. 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.

8.0 Operation of dry-heat sterilizers

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 HTM.

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	Maximum temperature	Minimum holding time
[°C]	[°C]	[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 HTM.

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.

9.0 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 disinfectant 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 HTM specifies that new LTS disinfectors should conform to the requirements of BS3970. 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 $73 \pm 2^\circ\text{C}$.
- 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.

10.0 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.

In Scotland LTSF sterilizers are considered to be 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 HTM specifies that new LTSF sterilizers should conform to the requirements of BS3970. 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 $5.0 \pm 0.2 \text{ mbar min}^{-1}$) 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 BS3970 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 $(\text{CH}_2\text{O})_n \cdot x\text{H}_2\text{O}$, 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 1994 (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.

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 15-25°C. 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), i.e. 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.
- j. 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.

Sterilization and disinfection of heat-labile equipment, 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); e.g. "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 HTM.

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 HTM. 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 HTM 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 HTM.
- 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.

11.0 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. *Gas 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.
- j. *Air admission.* Air is admitted to the chamber until the pressure approaches atmospheric pressure.
- k. *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.

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

Product compatibility

Sterilization and disinfection of heat-labile equipment, Central Sterilising Club 1986

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.

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 HTM.

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 $\pm 5^{\circ}\text{C}$ from the nominal conditions within the area and the RH should not deviate by more than $\pm 15\%$ 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 $300 \text{ mg litre}^{-1}$ is commonly used. Concentrations greater than $1200 \text{ mg litre}^{-1}$ 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;
- j. 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 HTM. 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: 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: 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 HTM 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 HTM 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 HTM). 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.

12.0 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 pre-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	138	3
	126	130	10
	121	125	15
Make-safe of contained fluid discard (a)	134	138	3
	126	130	10
	121	125	15
Sterilization of culture media (pre-set cycle)	121	124	15
	115	118	30
Sterilization of culture media (variable cycle)	102-134		up to 60
	121 (b)	124	15
Disinfection of fabrics	134	138	3
	126	129	10
	121	124	15
Sterilization of glassware and equipment	134	138	3
	126	129	10
	121	124	15
Free steaming (variable cycle)	102-104		up to 60
	95 (b)	98	15
Culture media preparator	121	124	30
	115	118	15

a. All bands for make-safe are 4 degrees wide to conform with BS2646: Part 3.

b. Although the cycle is variable, this temperature band should be used for testing purposes.

12.8 The COSHH Regulations 1994 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 HTM). 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 HTM 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 HTM).

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 BS2646. 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 HTM.

12.24 Items for making-safe should be placed in a discard box as specified in Part 2 of this HTM. 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.

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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 BS2646. 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 BS2646. 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 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 BS2646. 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 HTM.

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 BS2646. 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 BS2646. 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 Koch 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 BS2646 is not applicable (see Part 2 of this HTM).

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 HTM. 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.

13.0 Reporting of incidents

Introduction

13.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in England is set out in MDA SN 9701 published by the Medical Devices Agency (MDA) for the NHS Management Executive and in EPL(95)16. Arrangements for Scotland, Northern Ireland and Wales are different. The rest of this chapter applies to England only.

Reporting procedures are set out in MEL(1995)74 for Scotland, PEL(93)36 for Northern Ireland and WHC(89)26 for Wales

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 HTM, the User is assumed to fill this role.

13.3 The User should be familiar with the reporting procedures established by NHS Estates and the MDA 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 HTM). If the defect involves a pressure vessel, an inspection by the Competent Person (Pressure Systems) is required.

Department of Health reporting procedures

13.8 Certain types of defects should be reported to the Department of Health. Reportable defects are those where some central action may be helpful in bringing about necessary improvements in the standards of safety, design, construction, performance reliability or economics. Examples of reportable defects include the following:

- a. accidents involving sterilizers;
- b. failures of the integrity of the pressure vessel, i.e. failures of door mechanisms, explosions and bursting or cracking of parts of the chamber, door, jacket or structural members;
- c. incipient or potential defects likely to lead to such failures;
- d. failures of the basic safety devices connected with closing or opening of the door and pressurisation of the chamber;
- e. failures of electrical safety;

- f. any constructional features which do not comply with safety codes or with accepted good practice or are hazardous in some way;
- g. any unusual circumstances which may jeopardise safety or proper functioning, e.g. if safety devices or the automatic process controls can be defeated under certain conditions;
- h. inability of a properly maintained and operated machine to meet the performance standards specified for it;
- j. unreliability, persistent malfunction, frequent failures of particular components or any other feature which generates excessive or abnormally expensive maintenance or operational requirements, having regard to the intensity of use and operating conditions;
- k. electromagnetic interference to or from other equipment and particularly to computer control systems.

13.9 Adverse incidents should be reported either to NHS Estates or to the MDA.

13.10 All adverse incidents involving **transportable (benchtop) sterilizers** should be reported to the MDA. The reporting procedure is set out in Safety Notice MDA SN 9701, 'Reporting adverse incidents relating to medical devices'. The address and telephone numbers can be found in Appendix 1.

13.11 Adverse incidents involving **permanently installed sterilizers** should be reported to NHS Estates. The reporting procedure is set out in the NHSE document, 'Reporting defects and failures relating to non-medical equipment, engineering plant, installed services, buildings and building fabrics'. The address and telephone numbers can be found in Appendix 1.

13.12 The User is recommended to display a notice on or near each sterilizer setting out the appropriate reporting procedure.

Statutory reporting procedure

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1986 apply in Northern Ireland

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;

13.0 Reporting of incidents

- 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 MDA or to NHS Estates, 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 HTM 2010 and used in Part 4. Paragraph and chapter references indicate where further information may be found in this Part. Cross references to other terms are shown in bold type.

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 (4.37, 5.39).
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 (2.58, 3.12).
biological indicator	A device, consisting of an inoculated carrier contained within a primary pack, designed to test the efficacy of an operating cycle (2.59).
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 (5.33).
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 (11.6).
chamber	The part of the sterilizer in which the load is placed.
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 a change of colour, whether specified values of one or more cycle variables have been attained (2.64).
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 (11.8d).
contained fluid discard	Discard material held in sealed glass containers or sealed plastic containers of volume greater than 50 ml (see small plastic discard) (12.30).

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 (12.51).
cycle variables	The physical properties. e.g. time, temperature, pressure, humidity and gas concentration, that influence the efficacy of the operating cycle (2.43-2.55).
degassing	<p>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 (10.55, 11.52).</p> <p>2. A pre-heating treatment of boiler feed-water to reduce the amount of non-condensable gases in the steam supply.</p>
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 (12.27).
discard box	A box designed to contain discard material for processing by a make-safe cycle (12.24).
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.
disinfectors	An apparatus designed to achieve disinfection .
dry-heat sterilizer	A clinical sterilizer designed to sterilize loads by exposure to hot dry air near atmospheric pressure (Chapter 8).
EO sterilizer	A clinical sterilizer designed to sterilize loads by exposure to ethylene oxide gas or EO gas mixtures (Chapter 11).
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 (2.47).
ethylene oxide (EO)	Sterilant gas used to sterilize items that would be damaged by exposure to heat or moisture. Chemical formula $\text{CH}_2\text{CH}_2\text{O}$ (Chapter 11).
F_0	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 (6.34).
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.
fluid sterilizer	A clinical sterilizer designed to sterilize fluids in sealed containers by exposure to high-temperature steam under pressure (Chapter 6).
flushing	In 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 (11.8h).

formaldehyde	Sterilant gas used in combination with low-temperature steam to sterilize items that would be damaged by exposure to high-temperature steam . Chemical formula HCHO. Also known as methanal (10.9).
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 (10.9).
free steaming	A process, used in laboratory sterilizers , in which the load is exposed to steam near atmospheric pressure (12.50).
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 (2.50).
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 (2.45).
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).
Koch steamer	A laboratory apparatus designed to expose a load to steam near atmospheric pressure and commonly used for melting solidified agar (12.50).
laboratory sterilizer	A sterilizer designed to sterilize, disinfect or make-safe laboratory materials and equipment (Chapter 12).
load	Collectively, all the goods, equipment and materials that are put into a sterilizer or disinfecter 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 (6.32, 8.31).
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 plant room .
loading condition	A specified combination of the nature and number of load items , the items of chamber furniture , and their distribution within the chamber (2.35).
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 (4.47c).
low-temperature steam (LTS)	Steam at a temperature below the boiling point of water at local atmospheric pressure.

LTS disinfectors	A clinical disinfectors designed to disinfect loads by exposure to low-temperature steam at sub-atmospheric pressure (Chapter 9).
LTSF sterilizer	A clinical sterilizer designed to sterilize loads by exposure to low-temperature steam and formaldehyde gas at sub-atmospheric pressure (Chapter 10).
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 (12.21, 12.30).
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 (2.71).
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 for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of 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) (1.12).
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) (1.8).
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 .
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 (10.12).

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 (2.34).
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 and which protects against one or more risks to his or her health and safety (2.14).
plant history file	A file containing validation , maintenance and other engineering records for each sterilizer (3.9).
plant room	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 (2.48).
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 (Chapter 5).
preconditioning	Treatment of a load to attain predetermined conditions, such as temperature and humidity, before the start of an operating cycle (11.31).
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 (6.9, 6.16).
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 (4.17).
priming	Of a steam generator, the delivery of steam containing water in suspension due to violent boiling or frothing (5.42).
process indicator	A chemical indicator used to distinguish between processed and unprocessed load items (2.64).
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 (12.21).
sterilant	An agent used to effect sterilization , such as steam, hot air, or a sterilizing 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 (2.46).
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 (2.51).
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 (2.51).
sterilizer	An apparatus designed to achieve sterilization .
sterilizer process log	A log, kept by the User, which contains records for each production cycle (3.10).
superheated steam	Steam whose temperature, at any given pressure, is higher than that indicated by the vaporisation curve of water (5.47).
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 (12.15).
transportable	Requiring no permanent connections or installation and capable of being moved manually without mechanical assistance. Synonymous with "bench-top".
usable chamber space	The space inside the chamber which is not restricted by chamber furniture and which is consequently available to accept the load .
validation	A documented procedure for obtaining, recording and interpreting data required to show that a sterilization process will consistently comply with predetermined specifications.

Abbreviations

BP	British Pharmacopoeia
BPR	batch process record
BS	British Standard
°C	degree Celsius
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CFCs	chlorofluorocarbons
COSHH	Control of Substances Hazardous to Health (Regulations)
EN	European Standard (Europäische Norm)
EO	ethylene oxide
EU	European Union (formerly European Community)
GGMP	EU 'Guide to good manufacturing practice for medicinal products'
HBN	Health Building Note
HCFCs	hydrochlorofluorocarbons
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HTM	Health Technical Memorandum
ISO	International Organisation for Standardisation
kg	kilogram
LTMEL	long-term maximum exposure limit
LTS	low-temperature steam
LTSF	low-temperature steam and formaldehyde
m	metre
mbar	millibar
MCA	Medicines Control Agency
MDA	Medical Devices Agency
min	minute

Abbreviations

ml	millilitre
MPR	master process record
mS	millisiemens
NHS	National Health Service
NHSE	NHS Estates
PM	planned maintenance
PPE	personal protective equipment
ppm	parts per million
PQ	performance qualification
PRQ	performance requalification
PVC	polyvinyl chloride
RH	relative humidity
SSD	sterile services department
STMEL	short-term maximum exposure limit
TSE	transmissible spongiform encephalopathy
UK	United Kingdom

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EN 866: Biological systems for testing sterilizers

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Northern Ireland

Reporting adverse incidents and reactions and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant and medicinal products (PEL(93)36)

Decontamination of equipment prior to inspection, service or repair (PEL(94)34). Management Executive Estates Services Directorate Northern Ireland, 1994.

NHS Estates publications

HBN 13 – Sterile services department, NHS Estates 1992.

HBN 13 Supplement 1 – Ethylene oxide sterilization section, NHS Estates 1994.

HBN 15 – Accommodation for pathology services, NHS Estates 1991.

HTM 10 – Sterilizers, DHSS 1980 (out of print).

HTM 83 – Firecode: Fire safety in healthcare premises: general fire precautions. NHS Estates, 1994.

HTM 2010 – Sterilization, NHS Estates 1994/5/6 (5 volumes).

HTM 2025 – Ventilation in healthcare premises, NHS Estates 1994 (4 volumes).

HTM 2030 – Washer-disinfectors (in preparation).

HTM 2031 – Clean steam for sterilization (in preparation).

Reporting defects and failures relating to non-medical equipment, engineering plant, installed services, and building fabric (EPL(95)16). NHS Estates.

Medical Devices Agency publications

Activities of healthcare establishments (in-house manufacture) in the UK (Directives Bulletin 18), Medical Devices Agency, June 1995.

Decontamination of equipment prior to inspection, service or repair (HSG(93)26), NHS Management Executive, 17 June 1993.

Information about the EC Medical Devices Directives (Directives Bulletin 8), Medical Devices Directorate, April 1993.

Reporting adverse incidents and reactions, and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant, and medicinal products (HSG(93)13), NHS Management Executive, 1993.

Reporting adverse incidents relating to medical devices (MDA SN 9701), Medical Devices Agency, 1997.

The reuse of medical devices supplied for single use only (MDA Bulletin 9501), Medical Devices Agency – [DATE UNKNOWN]

Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, Medical Devices Directorate, 1993.

Other references

Code and rules of conduct and disciplinary regulations for registered Authorised Persons (Sterilizers), Institute of Healthcare Engineering and Estate Management (First draft, undated).

Guidelines for the safe operation of ethylene oxide sterilization plant, ICI plc (undated).

Information relevant to the installation of, and ancillary equipment for, ethylene oxide sterilizers (CEN TC 102 WG6 N67+), CEN (unpublished).

Product safety data: ethylene oxide, ICI Chemicals & Polymers Ltd 1995.

The rules governing medicinal products in the European Community. Volume IV: Good manufacturing practice for medicinal products (CO-71-91-760-EN-C), Office for Official Publications of the European Communities 1992.

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

The collection, fractionation, quality control and uses of blood and blood products, World Health Organisation 1981.

Appendix 1 – Useful addresses

UK health agencies

NHS Estates, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE
Switchboard: Tel. 0113-254 7000.
Defect and failure reports: Tel: 0113-254 7052.

Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ, Tel. 0171-273 3000.

Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ. Switchboard: Tel. 0171-972 8000, Adverse Incidents Centre: Tel: 0171-972 8080, Fax: 0171-972 8109. Internet: mda_mail@mda.win-uk.net

Public Health Laboratory Service, Central Public Health Laboratory, 61 Colindale Avenue, London NW9 5HT, Tel. 0181-200 4400.

Scotland

Healthcare Engineering and Environment Unit, University of Strathclyde, Room 8.51 Graham Hills Building, 50 George Street, Glasgow G1 1QE
Tel. 0141-552 4400, extension 3446.

Incident Reporting and Investigation Centre, 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.

The Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow G20 9NB. Tel. 0141-946 7120.

Scottish Healthcare Supplies, Trinity Park House, South Trinity Road, Edinburgh EH5 3SH. Tel. 0131-552 6255.

Estates Environment Forum, c/o Healthcare Engineering and Environment Unit, University of Strathclyde, Room 8.51, Graham Hills Building, 50 George Street, Glasgow G1 1QE. Tel. 0141-548 3446.

Wales

Welsh Office, Cathays Park, Cardiff CF1 3NQ, Tel. (01222) 825111.

Northern Ireland

Estate Policy, Health Estates, Stoney Road, Dundonald, Belfast BT16 0US
Tel. (01232) 520025, fax (01232) 523900
Defect centre: (01232) 523714.

Health and safety

Health and Safety Executive, Broad Lane, Sheffield S3 7HQ. Tel. 0114-289 2345, fax 0114-289 2333. Addresses of area HSE offices may be found in the local telephone directory.

Standards organisations

British Standards Institution, Head office: 2 Park Street, London W1A 2BS, Publications: Linford Wood, Milton Keynes MK14 6LE. Tel. (01908) 221166.

European Committee for Standardisation, Rue de Stassart 36, B-1050 Brussels.

Other organisations

Central Sterilising Club, c/o A.C. Viant (Secretary), 2 Crown Court, Bradford-on-Avon BA15 1BG. Tel. (01225) 865042, fax (01225) 868416.

Institute of Healthcare Engineering and Estate Management, 2 Abingdon House, Cumberland Business Centre, Northumberland Road, Portsmouth PO5 1DS. Tel. (01705) 823186.

Institute of Sterile Services Management, (Chairman) Mrs Ishbel Ingram, Sterile Services Manager, Hope Hospital, Salford Royal Hospitals NHS Trust, Stott Lane, Salford M6 8HD. Tel. (0161) 787 5098, fax (0161) 787 5096.

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 (BSE).

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 1994, 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.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1986 apply in Northern Ireland

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	139 kPa (20°C), 349 kPa (50°C)
Density of liquid at 4°C	890 kg m ⁻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

Further guidance is contained in HTM 83 – ‘Fire safety in healthcare premises: general fire precautions’

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.

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 ($> 3 \text{ mS m}^{-1}$). 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 (e.g. 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.

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 700 ppm 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 – 30 ppm). 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 – 1000 ppm). 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 0.1 ppm, 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 BS4275, '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 1000 ppm. 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.

In Scotland, procedures should be prepared in accordance with Firecode in Scotland and the appropriate HTMs

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.

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 HTM 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 HTM.

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 HTM, 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 HTM; 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 HTM 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;
- d. 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 HTM;
- b. maintenance schedules, based on the guidelines in Part 4 of this HTM;
- 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.

Part 6 – Testing and validation protocols

Appendix 5 – Sample log book for porous load sterilizers

Sterilizer log book

This log book contains sufficient log sheets for one year and has been designed to comply with the guidance given in Health Technical Memorandum 2010 and the requirements specified in BS 3970, EN 285 and EN 554. This log book should be used with porous load sterilizers and provided with a sterilizer after successful completion of validation.

References noted on each log sheet refer to clauses in HTM 2010 Part 3.

The log book is part of the records for process control and monitoring and should be kept by the User for a period at least equivalent to the lifetime of the last product sterilized as defined by the supplier. This period must not be less than two years from the date of despatch of the product from supplier.

A copy of each log sheet should be kept with the validation report and the second copy may be kept by others.

The User must ensure that prescribed tests and maintenance are carried out by suitably qualified persons and that all relevant log sheets are completed and signed. Data from the relevant test carried out during validation must be written into the spaces provided on each log sheet. Batch process records, together with data obtained from any relevant thermometric test, must also be attached to each log sheet.

The units for temperature, pressure and time are degrees centigrade (°C), kPascals (kPa) (absolute), and minutes and seconds respectively. When instruments are calibrated in different units, for example bar for pressure, the type of unit should be stated on the log sheet.

The yearly record is valid as performance requalification for load items randomly located in the chamber and presenting less of a challenge to the process than the challenge from the load use in the small load and full load tests. Load items falling into this category should be listed in the record for performance qualification. All other loading conditions should be subjected to performance qualification and performance requalification.

The provision of technical services and the management of sterilization should be available from qualified persons. A list of designated officers and their responsibilities are detailed in HTM 2010 Part 1. The User is ultimately responsible for declaring a sterilizer as “fit for use”. Advice on the services available from an authorised person is also given in Part 6.

Contents

1. [Information details page 134](#)
 - 1.1 Schedule of validation tests
 - 1.2 Schedule of periodic tests
2. [Validation tests page 138](#)
 - 2.1 Installation record sheet
 - 2.2 Commissioning record
 - 2.3 Performance qualification record
3. [Periodic tests page 145](#)
 - 3.1 User daily record
 - 3.2 Weekly record
 - 3.3 Quarterly record
 - 3.4 Yearly record
 - 3.5 Performance requalification record
4. [Sterilizer record page 155](#)
 - 4.1 Sterilizer modification and repair record

Section 1 – Information details

POROUS LOAD STERILIZER LOG BOOK INFORMATION SHEET

MANAGEMENT *	Cost Code No.
SERVICE PROVIDER (eg HOSPITAL.)	Cost Code No.
LOCATION	Cost Code No.
USER	Cost Code No.
DEPARTMENT	Cost Code No.
INSURANCE COMPANY	Telephone No.....

SPECIALIST SERVICES

AUTHORISED PERSON.....	Telephone No.....
TEST PERSON.....	Telephone No.....
MAINTENANCE PERSON.....	Telephone No.....
COMPETENT PERSON.....	Telephone No.....
MICROBIOLOGIST	Telephone No.....

STERILIZER DETAILS

PLANT REFERENCE	
MANUFACTURER.....	Serial No.....
DATE OF MANUFACTURE.....	
MODEL & PROCESS TYPE.....	Cubic Capacity.....
WORKING PRESSURE.....Chamber.....Bar	Jacket.....Bar Hydrostatic Test Date.....
COMMISSIONING DATE.....	VALIDATION FILE REFERENCE.....

PRESSURE SYSTEMS AND TRANSPORTABLE GAS CONTAINERS REGULATIONS (1989)

INSPECTION TEST DATE AND CERTIFICATE NUMBER	
1st SITE TEST.....	4th SITE TEST.....
2nd SITE TEST.....	5th SITE TEST.....
3rd SITE TEST.....	6th SITE TEST.....

***** *KEY PERSONNEL ARE DEFINED IN HTM 2010 PART 1*

Schedule of validation tests

Log book report(s) validation tests

		HTM 2010 Ref. Part 3
Contractor	Installation tests	
1.	Vacuum leak test	11.2
2.	Verification of calibration of sterilizer instruments	12.2
3.	Automatic control test	12.1
Test Person	Commissioning tests	
1.	Steam non-condensable gas test	9.4
2.	Steam superheat test	9.20
3.	Steam dryness test	9.30
4.	Vacuum leak test	11.2
5.	Vacuum leak test (temperature and pressure sensors connected)	11.2
6.	Automatic control test	12.1
7.	Verification of calibration of sterilizer instruments*	12.2
8.	Chamber wall temperature test	13.3
9.	Air detector performance test for a small load	11.45
10.	Air detector performance test for a full load	11.53
11.	Thermometric test for a full load	13.15
12.	{Load dryness test}*	13.25
13.	Thermometric test for a small load	13.7
14.	{Load dryness test}*	13.25
15.	Thermometric test for a small load (to check consistency with test 13)	13.7
	Performance qualification tests (see below)	
16.	Vacuum leak test (sensors removed)	11.2
17.	Air detector function test	11.60
18.	Bowie-Dick test for steam penetration	13.3
19.	{Sound pressure test}	10.1
Test Person	Performance qualification tests	
1.	Thermometric tests for performance qualification as required by the User	8.13
2.	Hospital load dryness check	13.25

* May be done at the same time as the preceding test.

Schedule of periodic tests

Log book report(s) periodic tests for porous load

		HTM 2010 Ref. Part 3
User/Operator	Daily test	
	1. Warm Up Cycle 2. Bowie-Dick test for steam penetration	13.39
Test Person	Weekly tests	
	1. Weekly safety checks 2. Vacuum leak test 3. Air detector function test 4. Automatic control test 5. Bowie-Dick test for steam penetration*	5.7 11.2 11.60 12.1 13.39
Test Person	Quarterly tests	
	1. Weekly safety checks 2. Vacuum leak test 3. Vacuum leak test (temperature and pressure sensor connected) 4. Automatic control test 5. Verification of calibration of sterilizer instruments* 6. Thermometric test for a small load* 7. Vacuum leak test (sensors removed) 8. Air detector function test 9. Bowie-Dick test for steam penetration	5.7 11.2 11.2 12.1 12.2 13.7 11.2 11.60 13.39
Test Person	Yearly and revalidation tests	
	1. Yearly safety checks 2. Steam, non-condensable gas test** 3. Steam superheat test** 4. Steam dryness test** 5. Vacuum leak test 6. Vacuum leak test (temperature and pressure sensors connected) 7. Automatic control test 8. Verification of calibration of sterilizer instruments* 9. Air detector performance test for a small load 10. Air detector performance test for a full load 11. Thermometric test for a small load 12. Tests for performance requalification as required by the user 13. Vacuum leak test (sensors removed) 14. Air detector function test 15. Bowie-Dick test for steam penetration	5.8 9.4 9.20 9.30 11.2 11.2 12.1 12.2 11.45 11.53 13.7 8.64 11.2 11.60 13.39
Test Person	Performance requalification test	
	1. Performance Requalification	8.64

* May be done at the same time as the preceding test

** Subject to agreement between the User and Authorised person these tests may be omitted providing there is no evidence of a steam quality problem.

Section 2 – Validation test records

POROUS LOAD STERILIZERS									
INSTALLATION RECORD						Date.....completed			
Client.....			Department.....			Date of tests.....			
Sterilizer manufacturer.....			Serial number.....			Plant reference number.....			
Type test file reference.....			Date.....						
Task		Schedule reference		Result			Initial		
Preliminary checks completed (3.14)									
Electrical checks (3.15)									
Functional checks (3.16)									
Installation checks(3.6)				Results					
				Steam	Water	Compressed air	Drainage	Ventilation	Electrical
Pressure									
Pressure drop all services operating									
Flow rates are adequate									
Drains effectively remove effluent when all sterilizers are operating									
Task		Cycle No		Start time		Results			
Vacuum leak test (11.2)					leakage per/ min		Pass / Fail	
Automatic control test (12.1)								Pass / Fail	
Automatic control test (12.1)				Insert data from each automatic control test					
Air removal		Negative pulsing				Positive pulsing			
Cycle		Pulses		Pulses		Pulses		Pulses	
start time	Duration	Number	Pressure		Duration	Number	Pressure		
			Minimum	Maximum			Minimum	Maximum	
Works tests			kPa	kPa			kPa	kPa	
Installation			kPa	kPa			kPa	kPa	
Sterilizing		Holding time							
Duration		Recorder				Indicators			
		Temperature		Pressure		Temperature		Pressure	
		Minimum	Maximum	Minimum	Maximum	Maximum		Maximum	
Works tests		°C	°C	kPa	kPa	°C		kPa	
Installation		°C	°C	kPa	kPa	°C		kPa	
Drying and Vacuum break		Drying				Vacuum break			
Cycle		Duration		Pressure		Temperature		Duration	
finish time									
Works tests				kPa		°C			
Installation				kPa		°C			
Verification of calibration sterilizer instruments (12.2)									
		Measured		Recorder Error		Indicator Error			
Chamber temperature		°C		°C		°C			
Chamber pressure		kPa		kPa		kPa			
Jacket pressure		kPa		kPa		kPa			
Holding timer setting		SetMins.....Secs		Error.....					
Contractor									
The sterilizer and its installation have been checked for safety and for compliance with the specification (schedule reference.....) and they have been found to be satisfactory									
Contractor signature print name.....date.....									

Note :- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

POROUS LOAD STERILIZERS										Sheet 1 of 3
COMMISSIONING RECORD										Week No.....
Plant reference number.....					Validation file reference.....					
Date of tests.....					Sterilizer serial number.....					
Task	Schedule reference	Result				Initial				
Preliminary checks completed (3.14)										
Electrical checks (3.15)										
Functional checks (3.16)										
Installation checks(3.6)										
Installation checks		Results(3.6)								
		Steam	Water	Compressed air	Drainage	Ventilation				
Pressure										
Pressure drop all services operating										
Flow rates are adequate										
Drains effectively remove effluent when all sterilizers are operating										
Steam tests	Schedule reference	Result				Initial				
NCG (9.4)										
Superheat (9.20)										
Dryness (9.30)										
	Cycle number									
Vacuum leak test * (11.2)	Leakage per minute								
Vacuum leak test * (11.2) (with sensors)	Leakage per minute								
Automatic control test (12.1)										
Air detector test (small load)* (11.45)	Leakage per minute								
Air detector test (full load) (11.53)	Leakage per minute								
Small load test (13.7)										
Load dryness test(13.25)		% gain in mass								
Full load test (13.15)										
Load dryness test (13.25)		% gain in mass								
Sound power test (10.1)										
Vacuum leak test * (11.2) (with sensors removed)	Leakage per minute								
Air detector function test * (11.60)		Setting :.... °C / Leakage per minute								
Bowie & Dick test * (13.39)		Type of test pack.....								
Automatic control test (12.1)		Insert data from each automatic control test								
Air removal		Negative pulsing				Positive pulsing				
	Cycle		Pulses					Pulses		
	start time	Duration	Number	Pressure		Duration	Number	Pressure		
				Minimum	Maximum			Minimum	Maximum	
Commissioning				kPa	kPa			kPa	kPa	
Works				kPa	kPa			kPa	kPa	
Sterilizing		Holding time								
	Duration	Recorder				Indicators				
		Temperature		Pressure		Temperature		Pressure		
		Minimum	Maximum	Minimum	Maximum	Maximum	Maximum			
Commissioning			°C	°C	kPa	kPa		°C	kPa	
Works			°C	°C	kPa	kPa		°C	kPa	
Drying and Vacuum break	Cycle	Drying				Vacuum break				
	finish time	Duration	Pressure		Temperature		Duration			
Validation			kPa		°C					
Quarterly			kPa		°C					

Ref NHSE 96/1/C

Note :- *The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature*

POROUS LOAD STERILIZERS						Sheet 2 of 3
COMMISSIONING RECORD						Week No.....
Plant reference			Serial number			
Calibration						
Test instruments			File reference.....			
			Calibration date due.....			
Verification of the calibration of the sterilizer instruments						
	Measured	Recorder error		Indicator error		
		Works	Commissioning	Works	Commissioning	
Jacket pressure	kPa	kPa	kPa	kPa	kPa	
Chamber pressure	kPa	kPa	kPa	kPa	kPa	
Chamber temperature °C	°C	°C	°C	°C	°C	
Time min, sec						
Small load test						
Insert data from each small load test						
Readings to be noted when:-						
a. drain/vent temperature attains the sterilizing temperature						
b. the centre of the standard test pack attains the sterilizing temperature						
c. when the vent/drain temperature falls below the sterilizing temperature						
Small load test	a		b		c	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						
Full load test						
	a		b		c	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						

Ref NHSE 96/1/C2

POROUS LOAD STERILIZERS												Sheet 1 of 2	
PERFORMANCE QUALIFICATION RECORD (PQ)												Week No.....	
Plant reference number.....						Validation file reference.....							
Date of tests.....						Sterilizer serial number.....							
Performance qualification reference.....						Loading condition reference.....							
Task	Schedule reference					Result		Valid until		Initial			
Commissioning													
Yearly test													
Performance qualification													
microbiological *													
thermometric													
* Performance qualification using microbiological methods if a sterilizing environment cannot be demonstrated by thermometric tests. Data from the microbiological test are attached to this log sheet													
Test instruments													
File reference.....Calibration certificate number.....Calibration due.....													
Error at the sterilizing temperature :-													
Sensor number	1	2	3	4	5	6	7	8	9	10	11	12	
before PQ test													
after PQ test													
Data from the tests have been compared with the requirements for sterilization detailed in specification reference.....for loading condition reference It is confirmed that compliance with the requirements are obtained using operating cycle reference.....													
Test Person signatureprint name.....date.....													
Audited by:-													
Authorised Person signatureprint name.....date.....													
I have compared this data with the requirements given in the specification and I am satisfied that this loading condition can be processed in sterilizer serial number.....													
User signature.....Print name.....date.....													

NHSE9617.DOC

POROUS LOAD STERILIZERS										Sheet 2 of 2	
PERFORMANCE QUALIFICATION RECORD (PQ)										Week No.	
Plant reference number.....					Validation file reference.....						
Date of tests.....					Sterilizer serial number.....						
Performance qualification reference.....					Loading condition reference.....						
Summary of thermometric tests											
					Test 1	Test 2	Test 3				
Cycle number											
Air removal	Negative pulsing	duration									
		number									
		pressure minimum									
		pressure maximum									
	Positive pulsing	duration									
		number									
		pressure minimum									
		pressure maximum									
Sterilizing temperature (ST) (Set)											
Holding time (Set)											
		Location of each sensor	Test and sensor number								
			1	2		3					
Sterilizing	Time when ST is attained	drain / vent									
		fastest load item									
		slowest load item									
	Time when temperature falls below ST	drain / vent									
		fastest load item									
		slowest load item									
	Holding time	drain / vent									
		fastest load item									
		slowest load item									
		temperature maximum									
		pressure maximum									
		pressure minimum									
		actual ST									
Sensors located in the positions shown on the attached sheet reference No.....											
					Test 1	Test 2	Test 3				
Drying and Vacuum break	drying	duration									
		pressure minimum									
		pressure maximum									
	Vacuum break	duration									
Duration of the cycle											
Comments											
.....											
.....											
.....											
This is a summary of the data obtained during performance qualification for loading condition reference.....											
sterilizer serial number.....											
Test Person signature.....print name.....date.....											

Section 3 – Periodic test records

[illegible]

Notes:-

The plateau period is deemed to start when the chamber temperature attains the pre-set temperature

POROUS LOAD STERILIZERS									
WEEKLY RECORD								Week No.....	
Plant reference number.....					Validation file reference.....				
Date of tests.....					Sterilizer serial number.....				
Task			Schedule reference		Result			Initial	
Weekly maintenance									
Weekly safety checks * (5.7)									
Housekeeping									
Daily record check									
Weekly tests			Cycle No						
Vacuum leak test * (11.2)				Leakage per mins				
Air detector function test * (11.60)					Setting :..... °C / Leakage per mins				
Bowie & Dick test * (13.39)					Type of test pack.....				
Automatic control test (12.1)					Insert data from each automatic control test				
Air removal				Negative pulsing			Positive pulsing		
Cycle				Pulses			Pulses		
start time		Duration		Number		Pressure		Duration	
				Minimum		Maximum			
Validation						kPa		kPa	
Weekly						kPa		kPa	
Sterilizing		Holding time							
		Duration		Recorder				Indicators	
				Temperature		Pressure		Temperature	
				Minimum		Maximum		Maximum	
Validation				°C		°C		kPa	
Weekly				°C		°C		kPa	
Drying and Vacuum break		Cycle		Drying				Vacuum break	
		finish time		Duration		Pressure		Temperature	
						kPa		°C	
Validation						kPa		°C	
Weekly						kPa		°C	
<p>All maintenance and weekly safety checks have been completed in accordance with the schedules and relevant maintenance procedures and the sterilizer is satisfactory</p> <p>Maintenance person signature.....print name.....date.....</p>									
<p>Data from the tests have been compared with data in the validation file for the equivalent tests carried out during validation and it is confirmed as being comparable within the limits specified</p> <p>Test Person signature.....print name.....date.....</p>									
<p>I have reviewed the records with the Test Person and Maintenance Person and declare the sterilizer is fit for use</p> <p>User signature.....print name.....date.....</p>									

Note :- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

POROUS LOAD STERILIZERS										Sheet 1 of 2	
QUARTERLY RECORD										Week No.....	
Plant reference number.....					Validation file reference.....						
Date of tests.....					Sterilizer serial number.....						
Task		Schedule reference		Result			Initial				
Maintenance											
Weekly safety checks * (5.7)											
Housekeeping											
Daily record check											
Weekly record check											
		Cycle No									
Vacuum leak test * (11.2)			Leakage per minute							
Vacuum leak test * (11.2) (with sensors)			Leakage per minute							
Automatic control test (12.1)											
Vacuum leak test * (11.2) (with sensors removed)			Leakage per minute							
Air detector function test * (11.60)				Setting :.... °C / Leakage per minute							
Bowie & Dick test * (13.39)				Type of test pack.....							
Automatic control test (12.1)					Insert data from each automatic control test						
Air removal		Negative pulsing				Positive pulsing					
		Cycle		Pulses		Pulses		Pulses			
		start time	Duration	Number	Pressure	Duration	Number	Pressure	Pressure		
		Minimum		Maximum		Minimum		Maximum			
Validation				kPa		kPa					
Quarterly				kPa		kPa					
Sterilizing		Holding time									
		Duration		Recorder				Indicators			
		Temperature		Pressure		Temperature		Pressure			
		Minimum		Maximum		Maximum		Maximum			
Validation				°C		°C		kPa			
Quarterly				°C		°C		kPa			
Drying and Vacuum break		Cycle		Drying				Vacuum break			
		finish time	Duration	Pressure		Temperature		Duration			
Validation				kPa		°C					
Quarterly				kPa		°C					
Calibration											
Test instruments					File reference.....						
					Calibration date due.....						
Verification of the calibration of the sterilizer instruments											
		Measured		Recorder error		Indicator error					
				quarterly		validation		quarterly			
Jacket pressure		kPa		kPa		kPa		kPa			
Chamber pressure		kPa		kPa		kPa		kPa			
Chamber temperature °C		°C		°C		°C		°C			
Time Min, Sec.											

Note :- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

POROUS LOAD STERILIZERS				Sheet 2 of 2		
QUARTERLY RECORD				Week No.....		
Plant reference			Serial number			
Small load test Insert data from each small load test Readings to be noted when:- <ul style="list-style-type: none"> a. drain/vent temperature attains the sterilizing temperature b. the centre of the standard test pack attains the sterilizing temperature c. when the vent/drain temperature falls below the sterilizing temperature 						
Small load test	a		b		c	
	Validation	Quarterly	Validation	Quarterly	Validation	Quarterly
Temperature above the STP*	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
		Validation	Quarterly	*S.T.P = standard test pack <input type="checkbox"/> acceptance criteria for dryness to be based on touch		
Total cycle time						
Holding time						
Dryness of STP <input type="checkbox"/>						
Cycle start time						
Cycle finish time						
Comments <div style="border: 1px dotted black; height: 150px; margin-top: 5px;"></div>						
All maintenance and weekly safety checks have been completed in accordance with the schedules and relevant maintenance procedures and the sterilizer is satisfactory Maintenance person signature.....print name.....date.....						
Data from the tests have been compared with data in the validation file (reference.....) for the equivalent tests carried out during validation and it is confirmed as being comparable within the limits specified Test Person signature.....print name.....date.....						
I have compared the results from these tests with the data in the validation file (reference.....) and that I have also reviewed these and the batch records with the Test Person and Maintenance Person and I am satisfied that the sterilizer is fit for use User signature.....print name.....date.....						

POROUS LOAD STERILIZERS										Sheet 1 of 3
YEARLY RECORD										Week No.....
Plant reference number.....					Validation file reference.....					
Date of tests.....					Sterilizer serial number.....					
Task	Schedule reference	Result	Initial							
Maintenance										
Yearly safety checks * (5.8)										
Housekeeping										
Daily record check										
Weekly record check										
Quarterly record check										
		Cycle No								
Vacuum leak test * (11.2)			Leakage per minute						
Vacuum leak test * (11.2) (with sensors)			Leakage per minute						
Automatic control test (12.1)										
Air detector test (small load)* (11.45)			Leakage per minute						
Air detector test (full load) (11.53)			Leakage per minute						
Small load test (13.7)										
Full load test (13.15)										
Vacuum leak test * (11.2) (with sensors removed)			Leakage per minute						
Air detector function test * (11.60)				Setting :.... °C / Leakage per minute						
Bowie & Dick test * (13.39)				Type of test pack.....						
Automatic control test (12.1)				Insert data from each automatic control test						
Air removal		Negative pulsing				Positive pulsing				
	Cycle		Pulses					Pulses		
	start time	Duration	Number	Pressure		Duration	Number	Pressure		
				Minimum	Maximum			Minimum	Maximum	
Validation				kPa	kPa			kPa	kPa	
Quarterly				kPa	kPa			kPa	kPa	
Sterilizing	Holding time									
	Duration	Recorder				Indicators				
		Temperature		Pressure		Temperature		Pressure		
		Minimum	Maximum	Minimum	Maximum	Maximum		Maximum		
Validation		°C	°C	kPa	kPa	°C	kPa			
Quarterly		°C	°C	kPa	kPa	°C	kPa			
Drying and Vacuum break	Cycle	Drying				Vacuum break				
	finish time	Duration	Pressure		Temperature		Duration			
Validation			kPa		°C					
Quarterly			kPa		°C					

NHSE 96/1/4

Note :- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

POROUS LOAD STERILIZERS						Sheet 2 of 3
YEARLY RECORD						Week No.....
Plant reference			Serial number			
Calibration						
Test instruments			File reference.....			
			Calibration date due.....			
Verification of the calibration of the sterilizer instruments						
	Measured	Recorder error		Indicator error		
		Yearly	Validation	Yearly	Validation	
Jacket pressure	kPa	kPa	kPa	kPa	kPa	
Chamber pressure	kPa	kPa	kPa	kPa	kPa	
Chamber temperature °C	°C	°C	°C	°C	°C	
Time Minutes Seconds						
Small load test						
Insert data from each small load test						
Readings to be noted when:-						
a. drain/vent temperature attains the sterilizing temperature						
b. the centre of the standard test pack attains the sterilizing temperature						
c. when the vent/drain temperature falls below the sterilizing temperature						
Small load test	a		b		c	
	Validation	Yearly	Validation	Yearly	Validation	Yearly
Temperature above the STP*	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Validation	Yearly	*S.T.P = standard test pack <input type="checkbox"/> acceptance criteria for dryness to be based on touch			
Total cycle time						
Holding time						
Dryness of STP <input type="checkbox"/>						
Cycle start time						
Cycle finish time						
Full load test						
	a		b		c	
	Validation	Yearly	Validation	Yearly	Validation	Yearly
Temperature above the STP*	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Validation	Yearly	*S.T.P = standard test pack <input type="checkbox"/> acceptance criteria for dryness to be based on touch			
Total cycle time						
Holding time						
Dryness of STP <input type="checkbox"/>						
Cycle start time						
Cycle finish time						

[illegible]

POROUS LOAD STERILIZERS												Sheet 1 of 2			
PERFORMANCE REQUALIFICATION RECORD (PRQ)												Week No.....			
Plant reference number.....						Validation file reference.....									
Date of tests.....						Sterilizer serial number.....									
Performance qualification reference.....						Loading condition reference.....									
Task	Schedule reference	Result	Valid until					Initial							
Commissioning															
Yearly test valid															
Performance qualification															
* microbiological															
thermometric															
Performance requalification															
* microbiological															
thermometric															
* is required if biological tests were carried out during validation															
Test instruments															
File reference.....												Calibration certificate number		Calibration due.....	
Error at the sterilizing temperature :-															
Sensor number	1	2	3	4	5	6	7	8	9	10	11	12			
before PRQ test															
after PRQ test															
<p>Data from the tests have been compared with the data in the validation file performance qualification referenceand it is confirmed as being comparable within the limits specified.</p> <p>Test Person signatureprint name.....date.....</p> <p>Audited by:-</p> <p>Authorised Person signatureprint name.....date.....</p> <p>I have compared the results from these tests with the data in the validation file for performance qualification reference and I have also reviewed data in the batch records with the Test Person, Maintenance Person and Authorised Person. I am satisfied that this loading condition can be processed in sterilizer. serial number.....</p> <p>User signature.....Print name.....date.....</p>															

NHSE 96/1/6

POROUS LOAD STERILIZERS				Sheet 2 of 2			
PERFORMANCE REQUALIFICATION RECORD (PRQ)				Week No.....			
Plant reference number.....				Validation file reference.....			
Date of tests.....				Sterilizer serial number.....			
Performance qualification reference.....				Loading condition reference.....			
Summary of thermometric tests							
				Test 1	Test 2	Test 3	Validation
Cycle number							
Air removal	Negative pulsing	duration					
		number					
		pressure minimum					
		pressure maximum					
	Positive pulsing	duration					
		number					
		pressure minimum					
		pressure maximum					
Sterilizing temperature (ST) (Set)							
Holding time (Set)							
		Location of each sensor	Test and sensor number				
			1	2	3	Validation	
Sterilizing	Time when ST is attained	drain / vent					
		fastest load item					
		slowest load item					
	Time when temperature falls below ST	drain / vent					
		fastest load item					
		slowest load item					
	Holding time	drain / vent					
		fastest load item					
		slowest load item					
		temperature maximum					
		pressure maximum					
		pressure minimum					
		actual ST					
Sensors are located in the positions shown on the attached sheet reference No.....							
				Test 1	Test 2	Test 3	Validation
Drying and Vacuum break	drying	duration					
		pressure minimum					
		pressure maximum					
	Vacuum break	duration					
Duration of the cycle							
Comments							
This is a summary of the data obtained during performance qualification and performance requalification for loading condition reference.....sterilized in sterilizer serial number..... Test Person signature.....print name.....date.....							

Section 4 – Schedule of repairs and maintenance

[illegible]

Appendix 6 – Procedures for the procurement, validation, revalidation and operational management of sterilization

CONTENTS

Procurement and Validation *page 159*

- Procurement
- Loading Analysis
- Sterilization Process
- Type of Sterilizer
- Specification Analysis
- Procurement
- Documentation
- Installation Checks and Tests
- Documentation Validation Report
- Documentation Handover
- Operational Management

Operational Procedures – Porous Load *page 170*

- Validation
- Commissioning Tests
- Performance Qualification Tests
- Revalidation
- Performance Requalification Tests
- Maintenance and Periodic Testing
 - Weekly
 - Quarterly
- Revalidation (Yearly Tests)
- Recommissioning
- Maintenance Schedules P.P.M.
 - Daily Housekeeping
 - Weekly Maintenance
- Maintenance Schedules P.P.M.
 - Quarterly
 - Yearly

Operational Procedures – Fluids *page 179*

- Validation
- Commissioning Tests
- Performance Qualification Tests
- Revalidation
- Performance Requalification Tests
- Maintenance and Periodic Testing
 - Weekly
 - Quarterly
- Revalidation
- Yearly Recommissioning
- Maintenance Schedules P.P.M.
 - Daily Housekeeping
 - Weekly Maintenance
 - Quarterly Maintenance
 - Yearly Maintenance

Operational Procedures – Unwrapped Instruments and Utensils *page 188*

- Validation
- Commissioning Tests
- Performance Qualification Tests
- Revalidation
- Performance Requalification Tests
- Maintenance & Periodic Testing
 - Weekly
 - Quarterly
- Revalidation
- Yearly Tests and Recommissioning
- Maintenance Schedules P.P.M.
 - Daily Housekeeping
 - Weekly Maintenance
 - Quarterly
 - Yearly

Operational Procedures – Dry Heat *page 197*

- Validation
- Commissioning Tests
- Performance Qualification Tests
- Revalidation
- Performance Requalification Tests
- Maintenance and Periodic Testing
 - Weekly
 - Quarterly
- Revalidation
- Yearly Tests and Recommissioning
- Maintenance Schedules P.P.M.
 - Daily Housekeeping
 - Weekly Maintenance
- Maintenance Schedules P.P.M.
 - Quarterly
 - Yearly

Operational Procedures -Low Temperature Steam Disinfectors, Low Temperature Steam and Formaldehyde *page 206*

- Validation
- Commissioning Tests
- Performance Qualification Tests
- Revalidation
- Performance Requalification Tests
- Maintenance and Periodic Testing
 - Weekly
 - Quarterly
- Revalidation
- Yearly Tests and Recommissioning
- Maintenance Schedule P.P.M.
 - Daily Housekeeping

Weekly Maintenance

Maintenance Schedule P.P.M.

Quarterly

Yearly

Operational Procedures – Ethylene Oxide *page 215*

Validation

Commissioning Tests

Performance Qualification Tests

Revalidation

Performance Requalification Tests

Maintenance and Periodic Testing

Weekly

Quarterly

Revalidation

Recommissioning Tests

Maintenance Schedule P.P.M.

Daily Housekeeping

Weekly Maintenance

Maintenance Schedule P.P.M.

Quarterly

Yearly

Operational Procedures – Laboratory *page 224*

Validation

Commissioning Tests

Performance Qualification Tests

Revalidation

Performance Requalification Tests

Maintenance and Periodic Testing

Weekly

Quarterly

Revalidation

Recommissioning

Maintenance Schedule

Daily Housekeeping

Weekly Maintenance

Maintenance Schedule

Quarterly

Yearly

Operational Procedures Culture Media Preparators *page 233*

Validation

Commissioning Tests

Revalidation

Recommissioning Tests

Maintenance Schedule P.P.M.

Daily Housekeeping

Weekly Maintenance

Maintenance Schedule P.P.M.

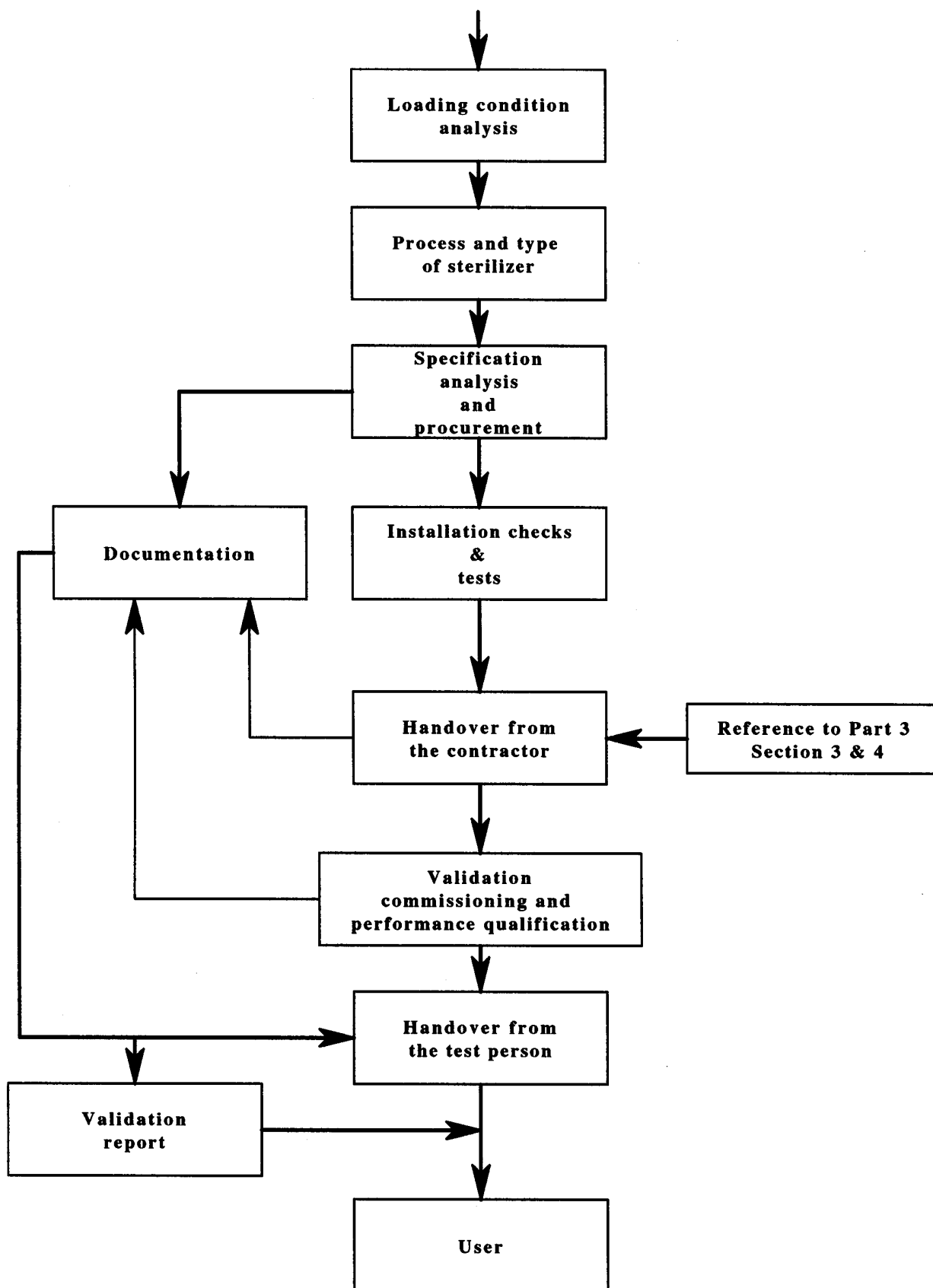
Yearly

Corrective Action *page 238*

Pressure Vessels Failures

Process Cycle Failures

Operational procedures – Procurement and validation

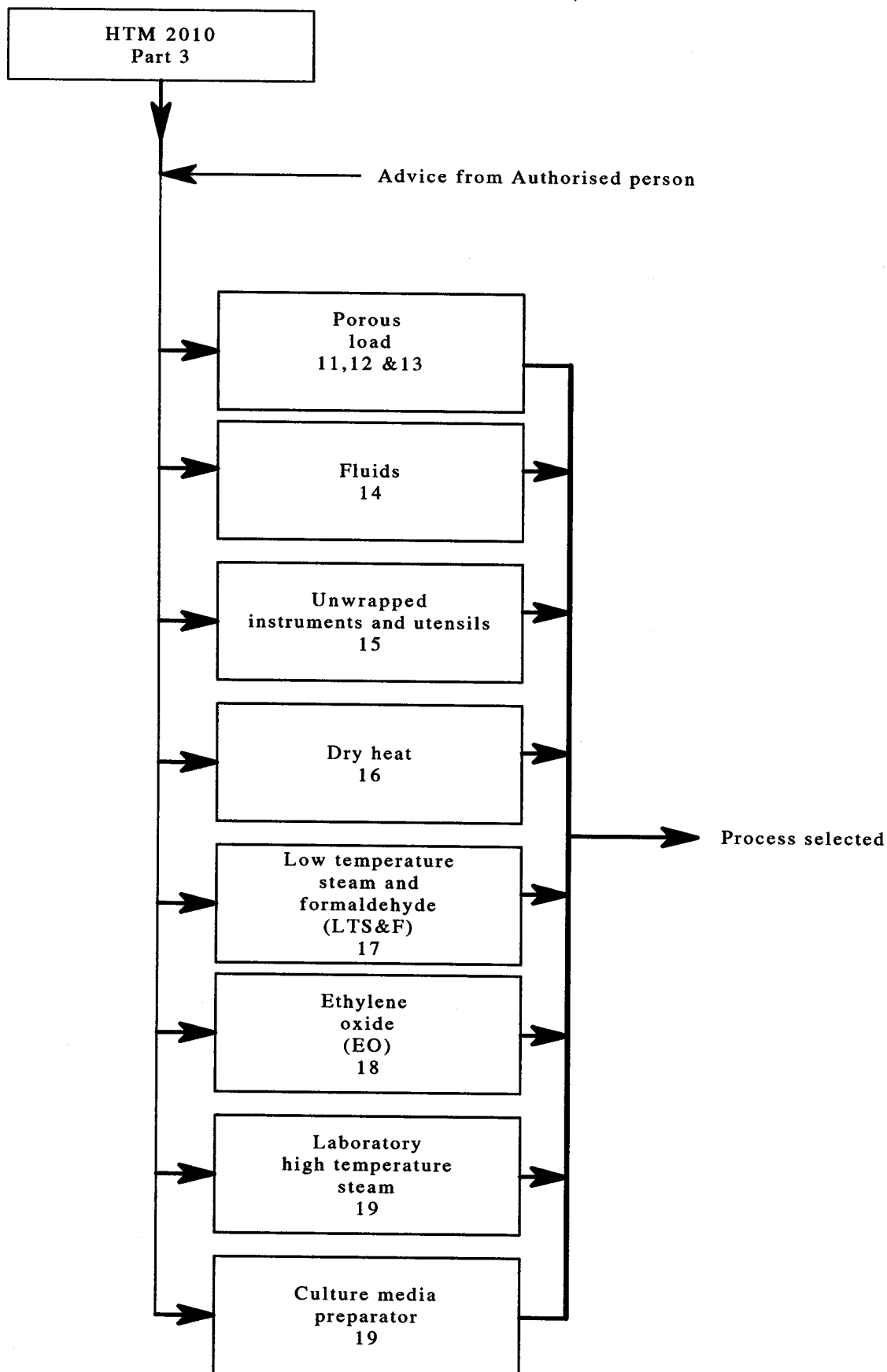


Refer to HTM2010 part 3 for clause references

LOADING CONDITION ANALYSIS

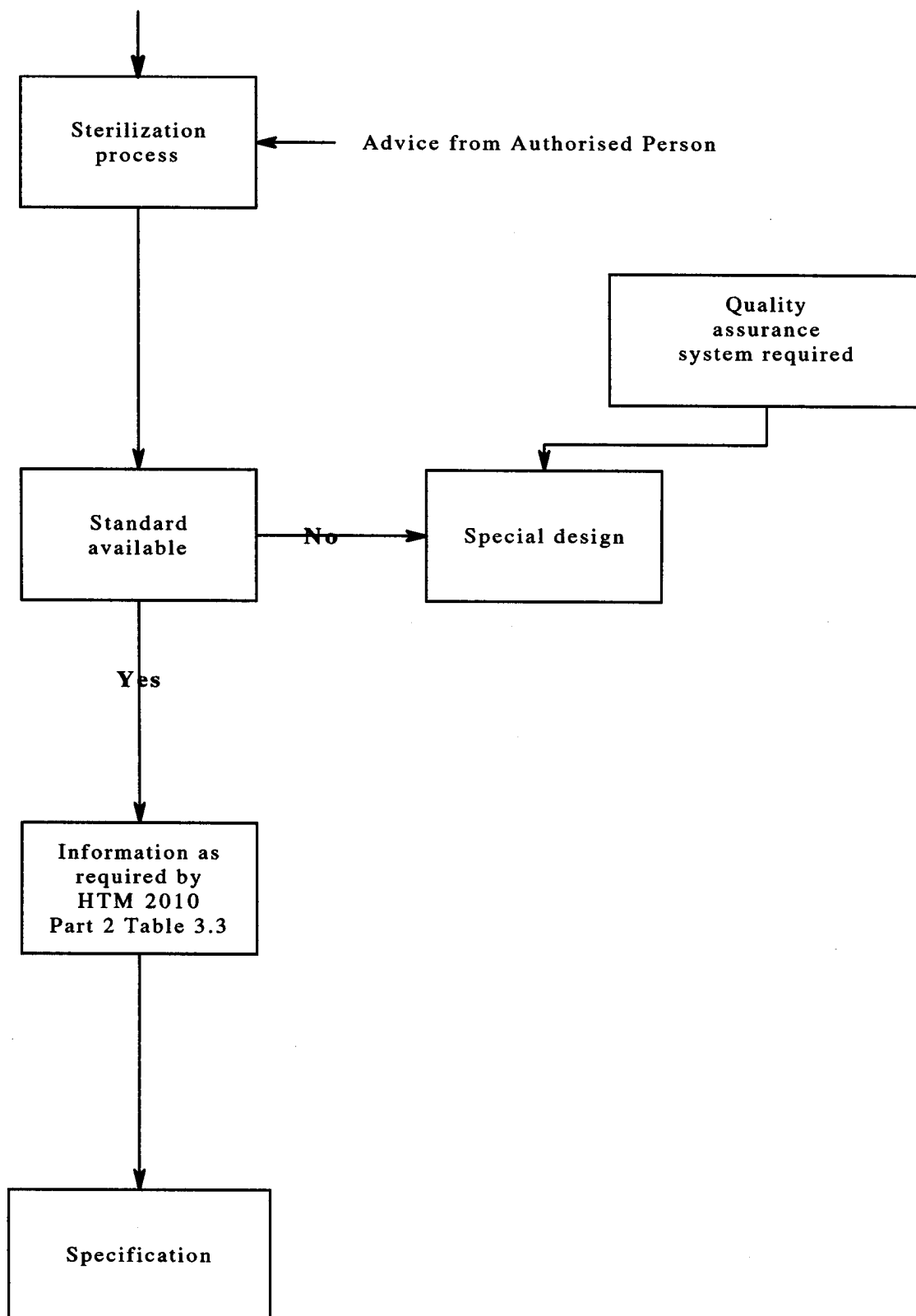
- 1. Identify the load items to be sterilized**
- 2. Estimate the largest sterilizer load in sterilizer modules**
(See HTM 2010 3.24 part 2)
- 3. Identify whether each load item can withstand moist heat**
- 4. Identify the maximum temperature, vacuum, pressure and maximum rate of change of pressure each load item can withstand**
- 5. Identify the type and size of load container to be used and type of chamber furniture**
- 6. Identify whether sterilization is achieved by contact of the sterilant on all surfaces to be sterilized or by thermal transfer through a container**
- 7. Specify the type of process**

STERILIZATION PROCESS

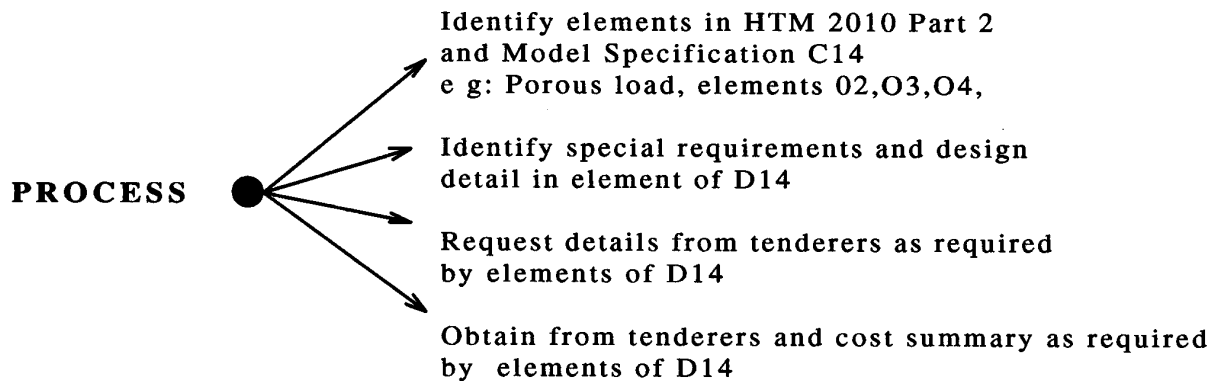


Refer to HTM 2010 part 3 for clause references

TYPE OF STERILIZER



SPECIFICATION ANALYSIS

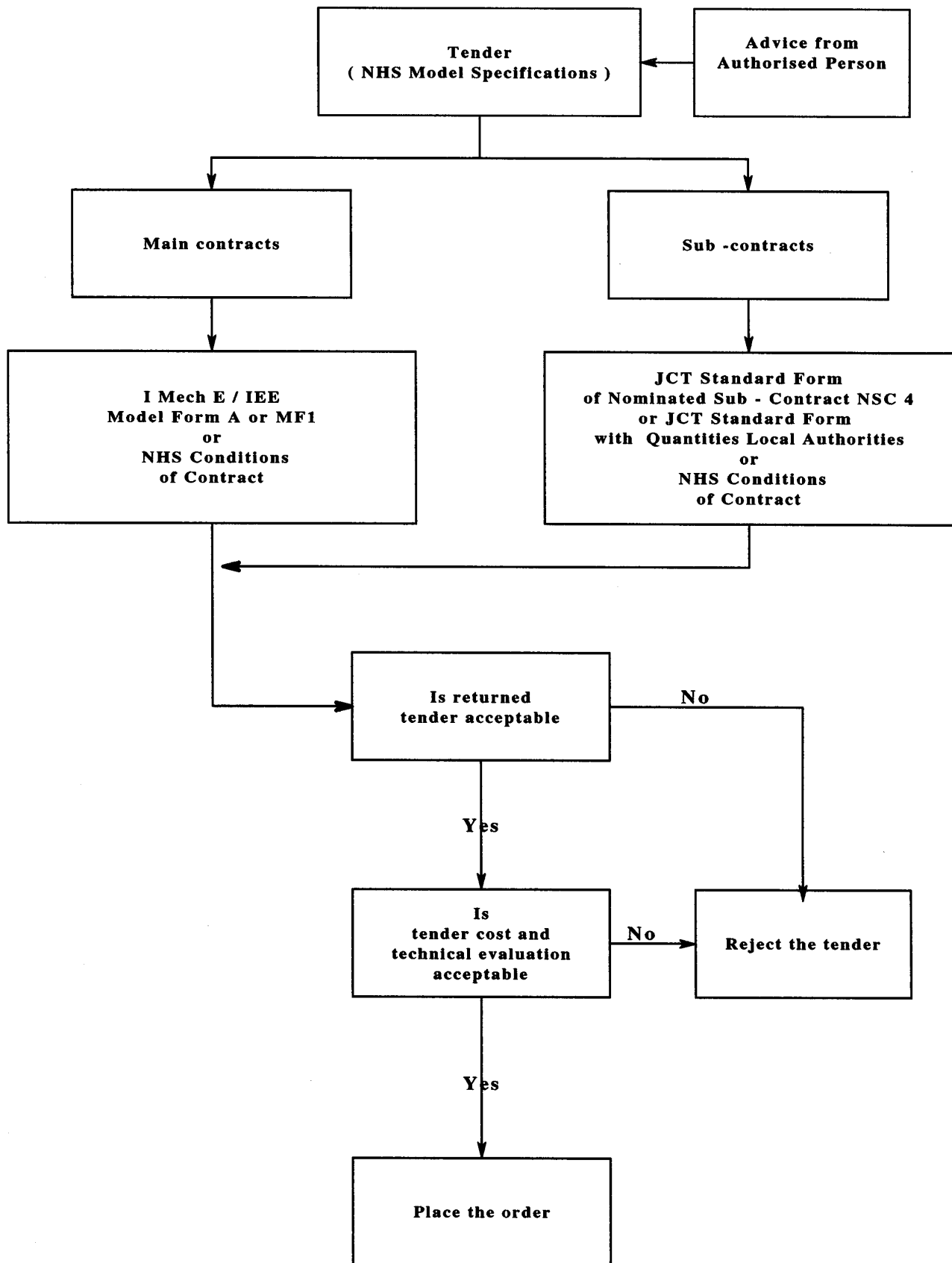


Particular attention should be given to section D14 of the specification which addresses the following components of the sterilizer and installation

- | | |
|---|---|
| 1. Process and performance class | 11. Whether a factory inspection will be required |
| 2. Type of door(s) | 12. Number of units required |
| 3. Usable chamber space
(number of sterilizer modules) | 13. Chamber furniture and type |
| 4. Fascia or enclosure | 14. Drainage and other discharges |
| 5. Floor loading | 15. Training |
| 6. Dimension including portorage | 16. Documentation & certificates of compliance |
| 7. Materials of construction | 17. Contract conditions including defects liability |
| 8. Additional instrumentation | 18. Installation |
| 9. Delivery packaging | 19. Installation checks and tests |
| 10. Services
(steam complying with HTM 2010
Part 3 paragraphs 9.4,9.20,9.30.) | 20. Manuals and Maintenance procedures |
| | 21. Fault and effect analysis |
| | 22. Operator and user instructions |

PROCUREMENT

Tender for sterilizer



DOCUMENTATION

Delivery



To include



Certificate of compliance for each pressure system.



Declaration that the sterilizer complies with the specification and performance requirements for a sterilizer previously type tested. Required only if compliance with a type-tested range is claimed.



Declaration that the sterilizer complies with the specification together with data from validation tests listed in HTM2010 Part 3 Section 4. Required only if a type-tested range is not claimed.



Works tests records.



Installation drawings.



Pipework, electrical and mechanical drawings.



Fault and effect analysis.



Maintenance manual, including spare parts lists and details of all safety systems and settings.

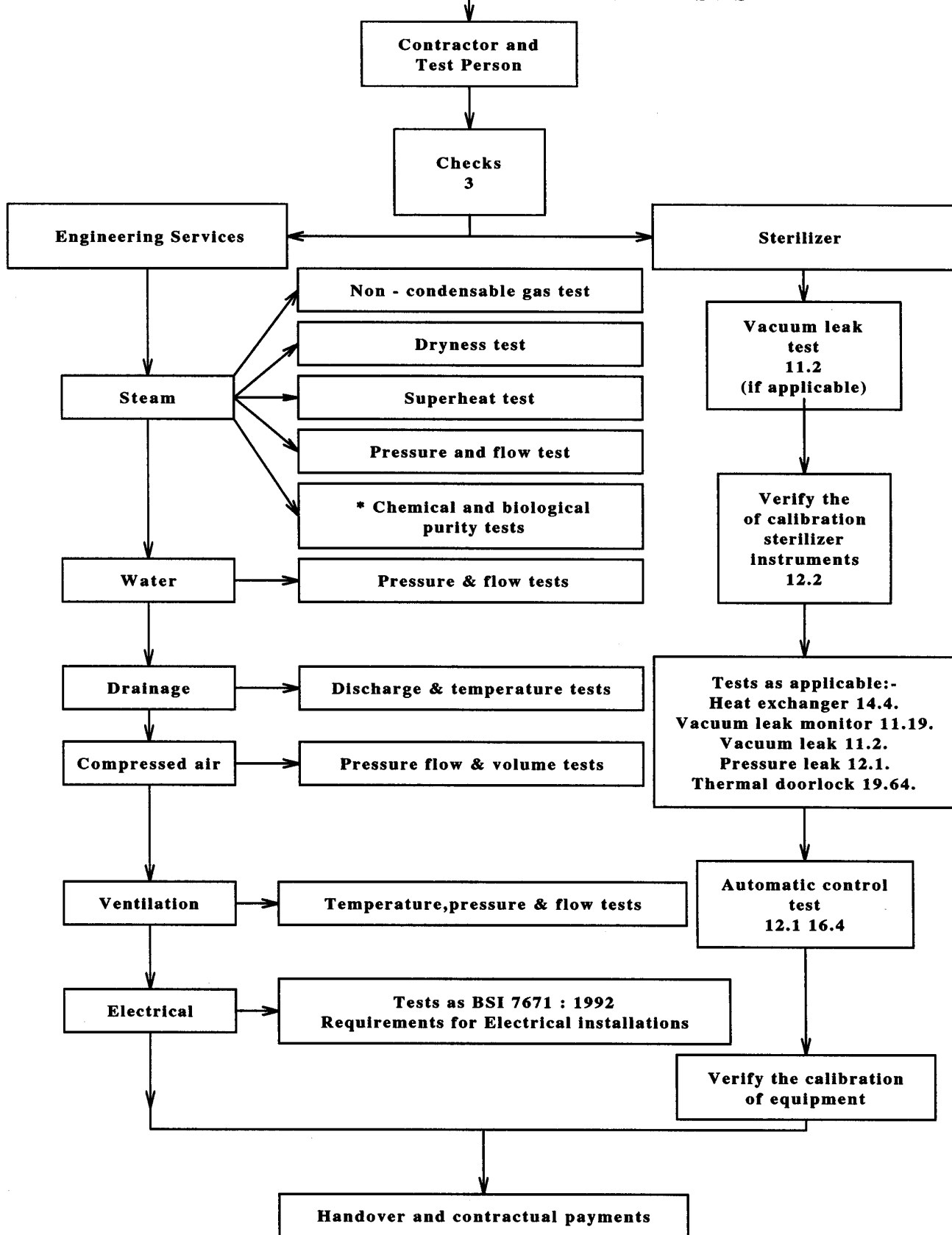


Operators manual.



Users instructions.

INSTALLATION CHECKS AND TESTS



Refer to HTM 2010 part 3 for clause references

Tests to be carried out each on type of sterilizer where relevant

* See HTM 2031

DOCUMENTATION

Validation report



To include



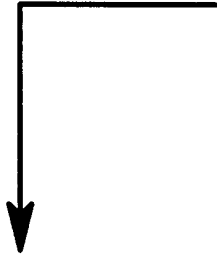
- Copy of the test instrument calibration record, together with data to verify the calibration of all instrumentation.
- Results and report for the installation checks.
- Results and report for the commissioning tests.
- Results and report for the tests listed in HTM 2010 Part 3 Section 4.
(*Tests listed in the relevant table for the type of process*)
- Specification for the sterilizer and the services.
- Process cycle(s) together with the manufacturer's parameters.
- Documentation to show compliance with the specification.
- Process cycle together with the parameters after validation.
- Pressure vessel test certificate(s).
- Loading condition(s) for which the validation report is valid.
- Maintenance procedures, including User procedures, and the frequency (PPM) they are required to be carried out.
- Copy of the Summary Sheet(s) (HTM 2010 Part 3 Appendix 3).
- Copy of the operator instructions.

DOCUMENTATION

Handover

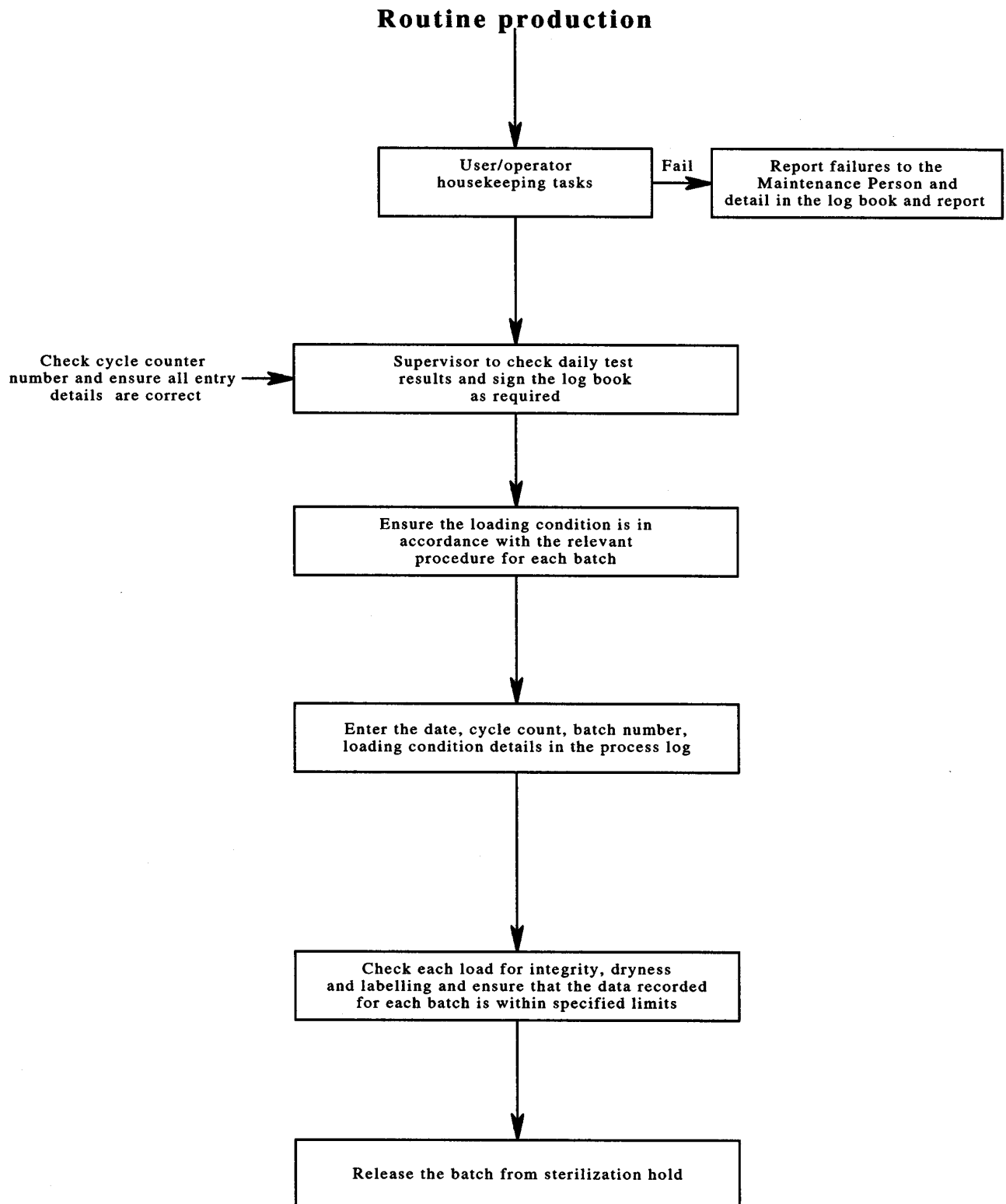


To include



- **Copy of the summary sheets**
- **Copy of the operator's instructions**
- **Analogue recording of each cycle (if requested).
May be generated from the validation data**
- **User maintenance tasks including safety checks**

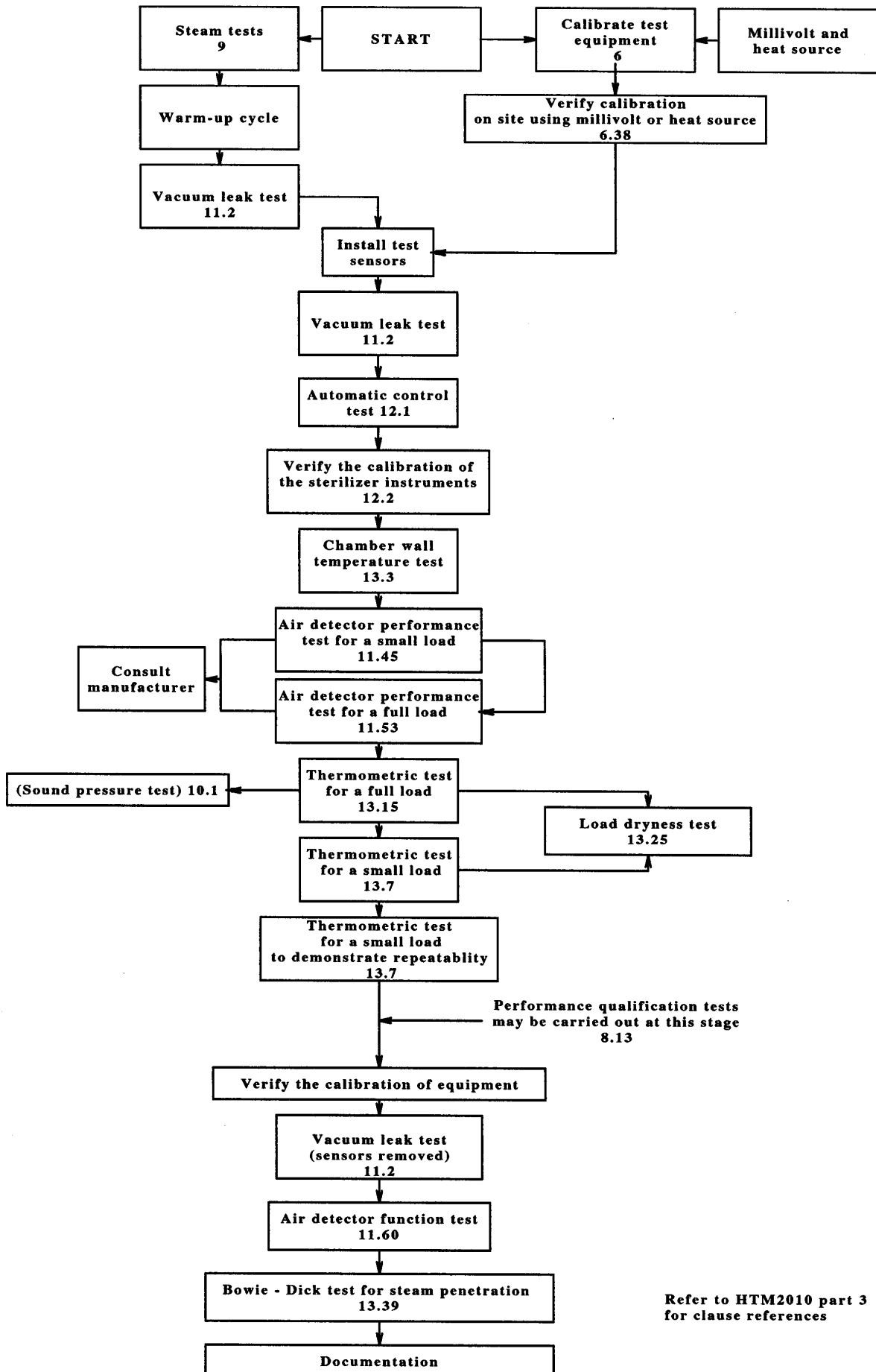
OPERATIONAL MANAGEMENT



Operational procedures – Porous load

VALIDATION

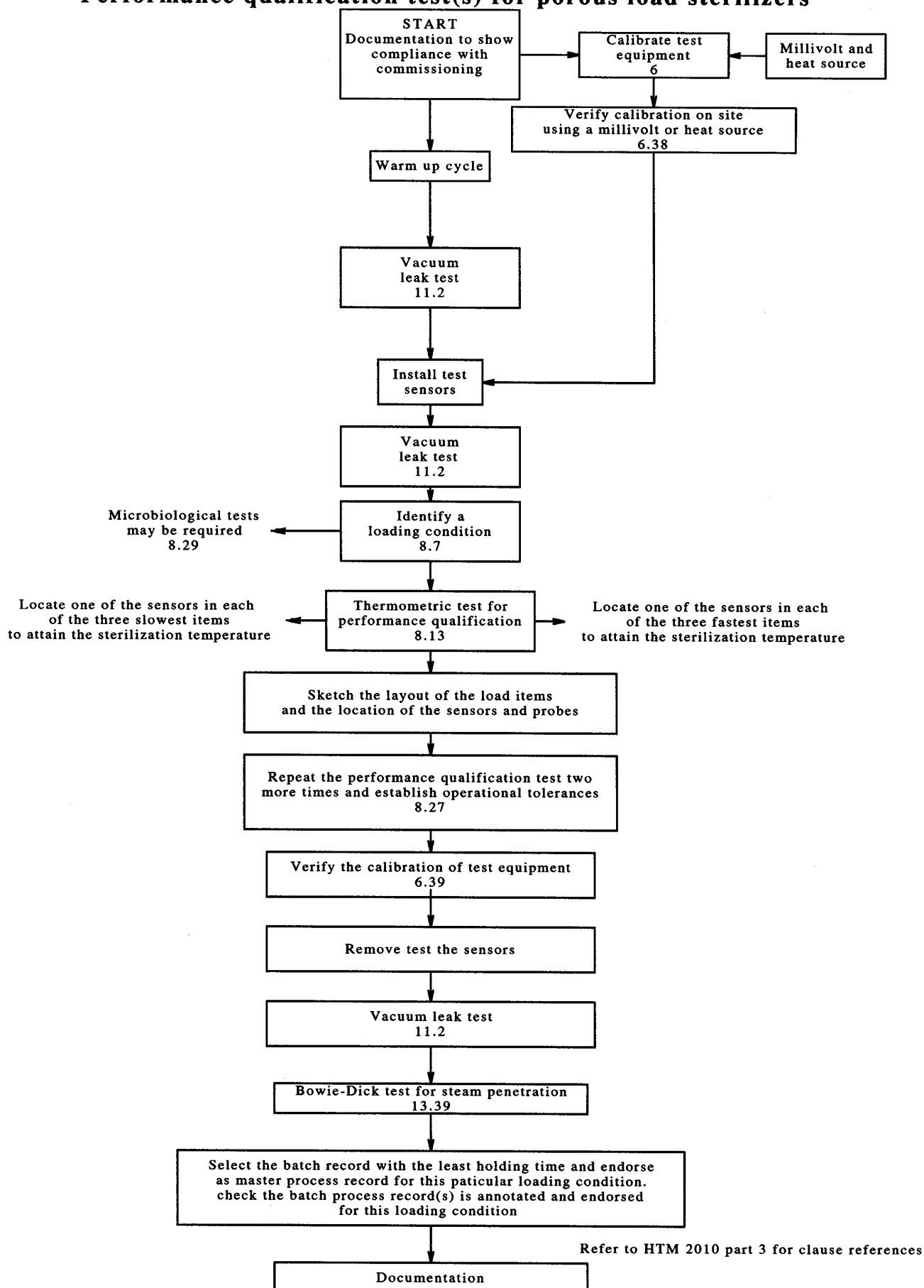
Commissioning tests for porous load sterilizers



Refer to HTM2010 part 3
for clause references

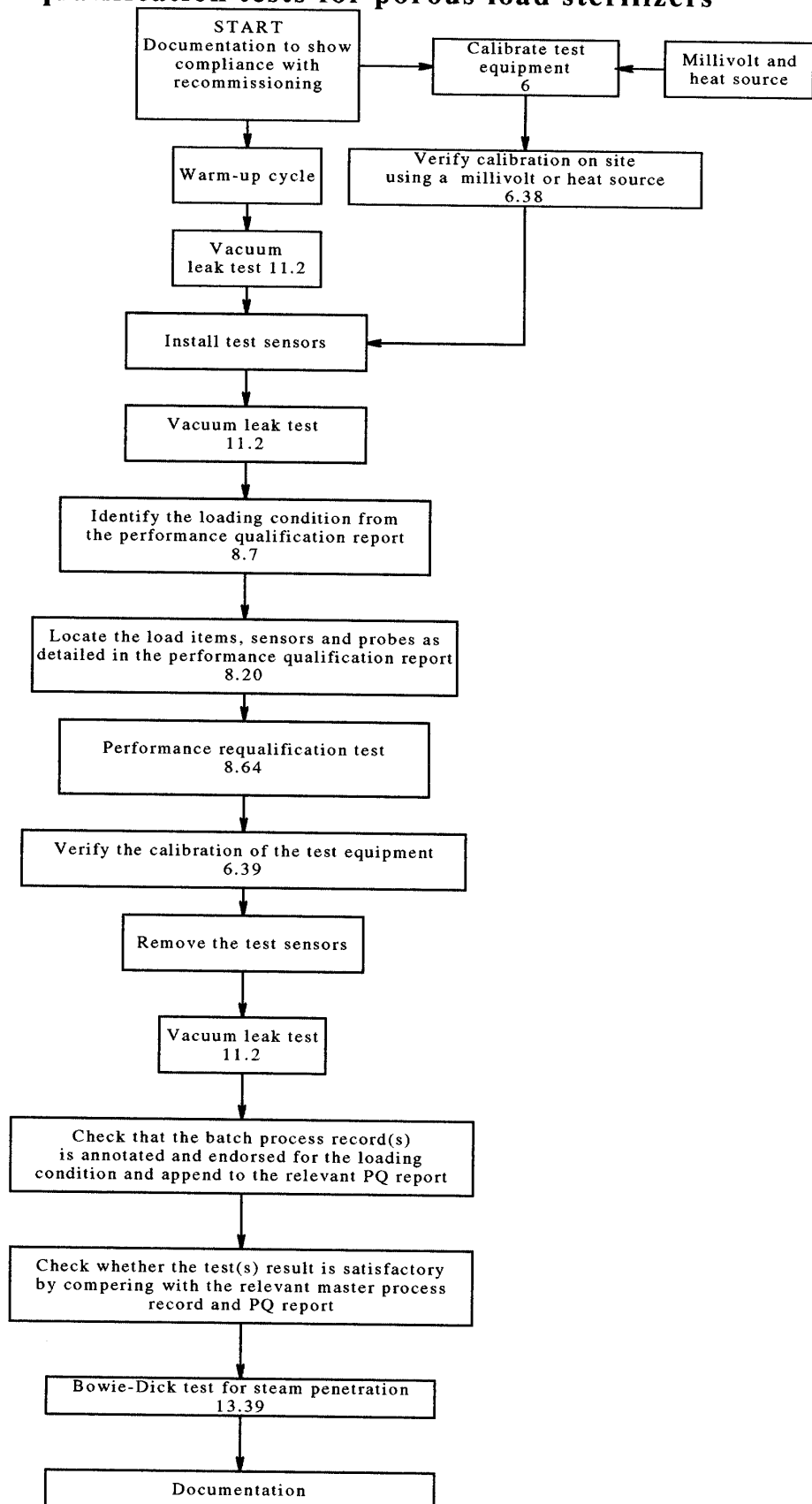
VALIDATION

Performance qualification test(s) for porous load sterilizers



REVALIDATION

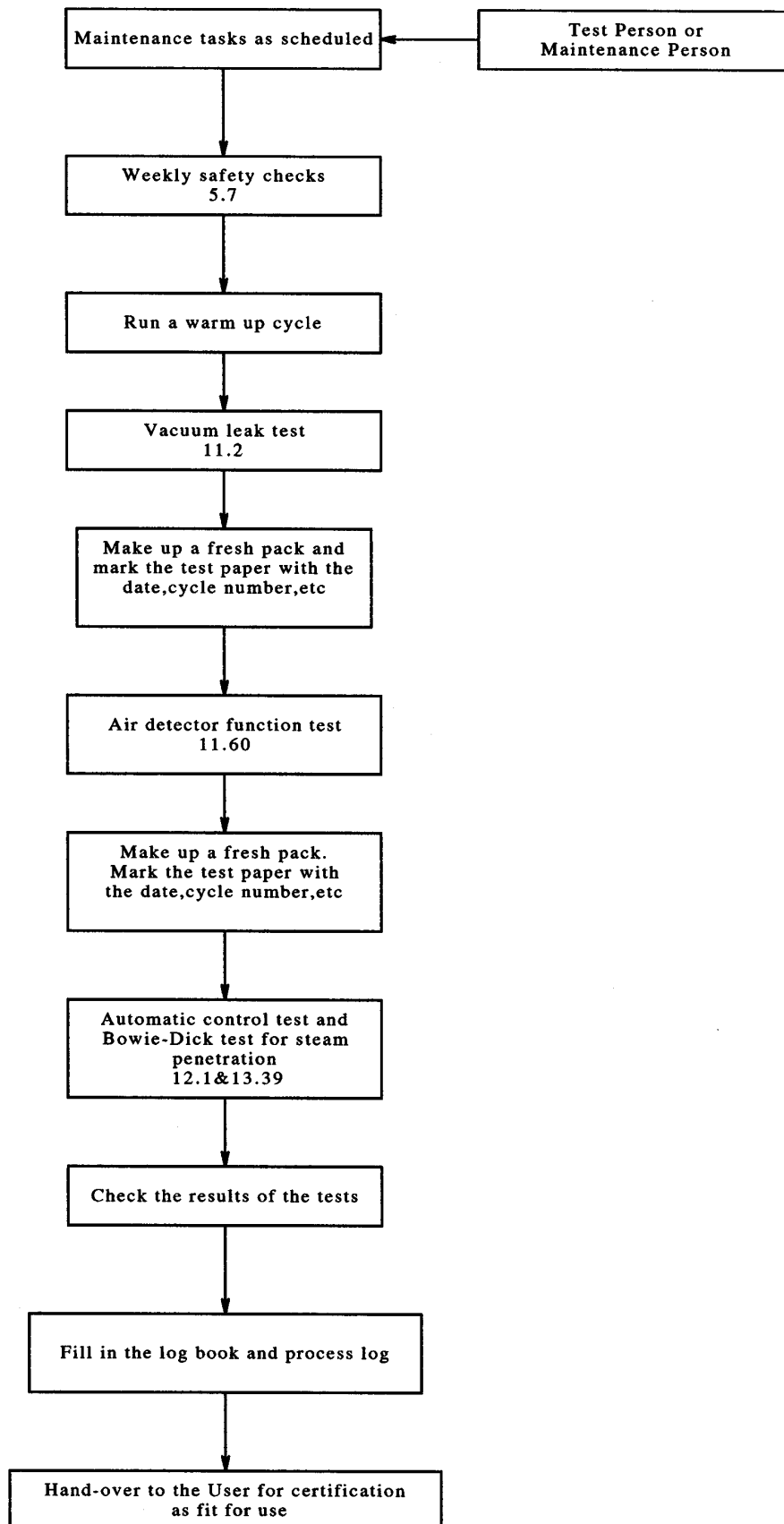
Performance requalification tests for porous load sterilizers



Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING

(Porous load weekly)

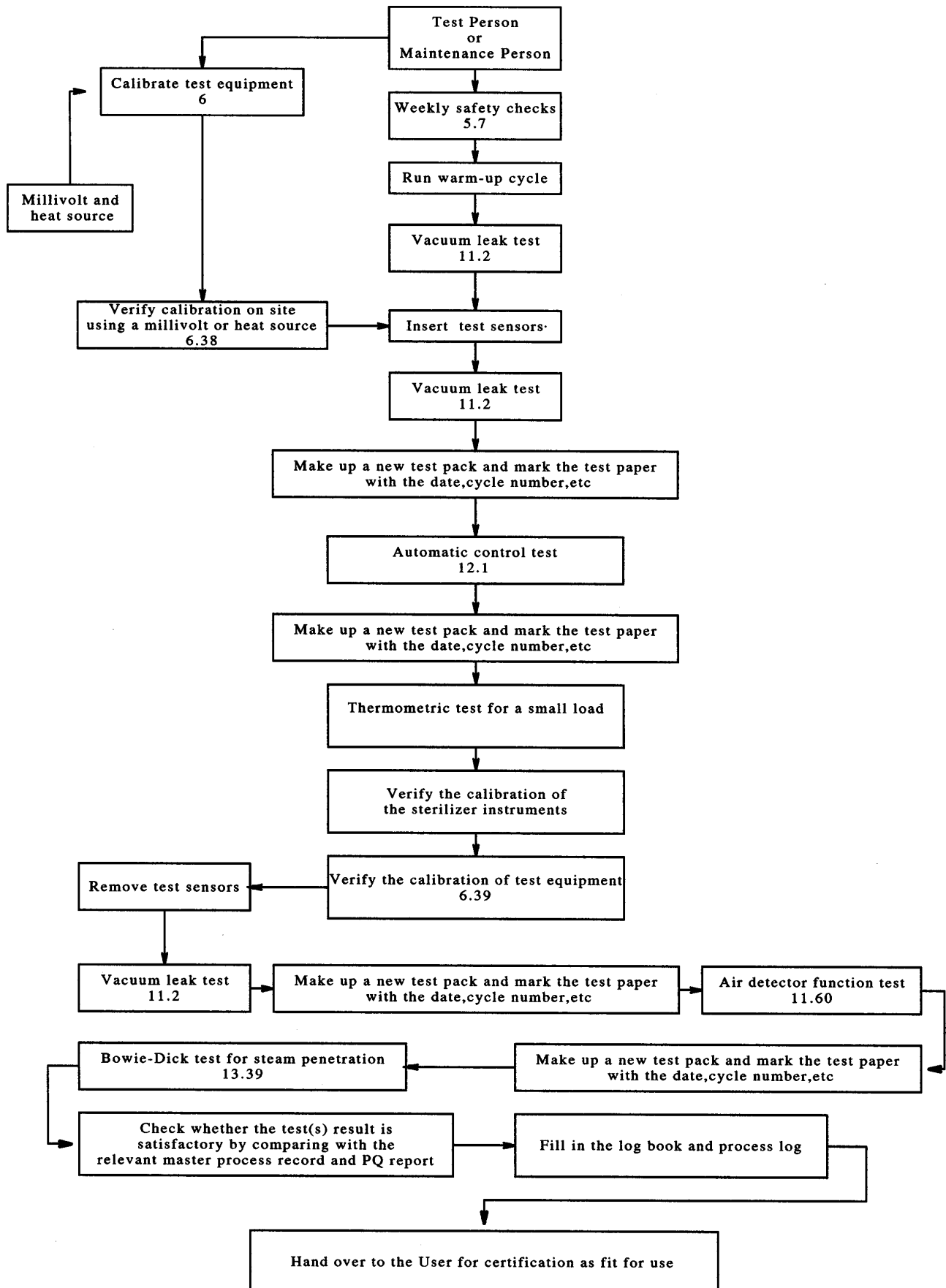


Refer to HTM 2010 part 3 for clause references

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MAINTENANCE AND PERIODIC TESTING

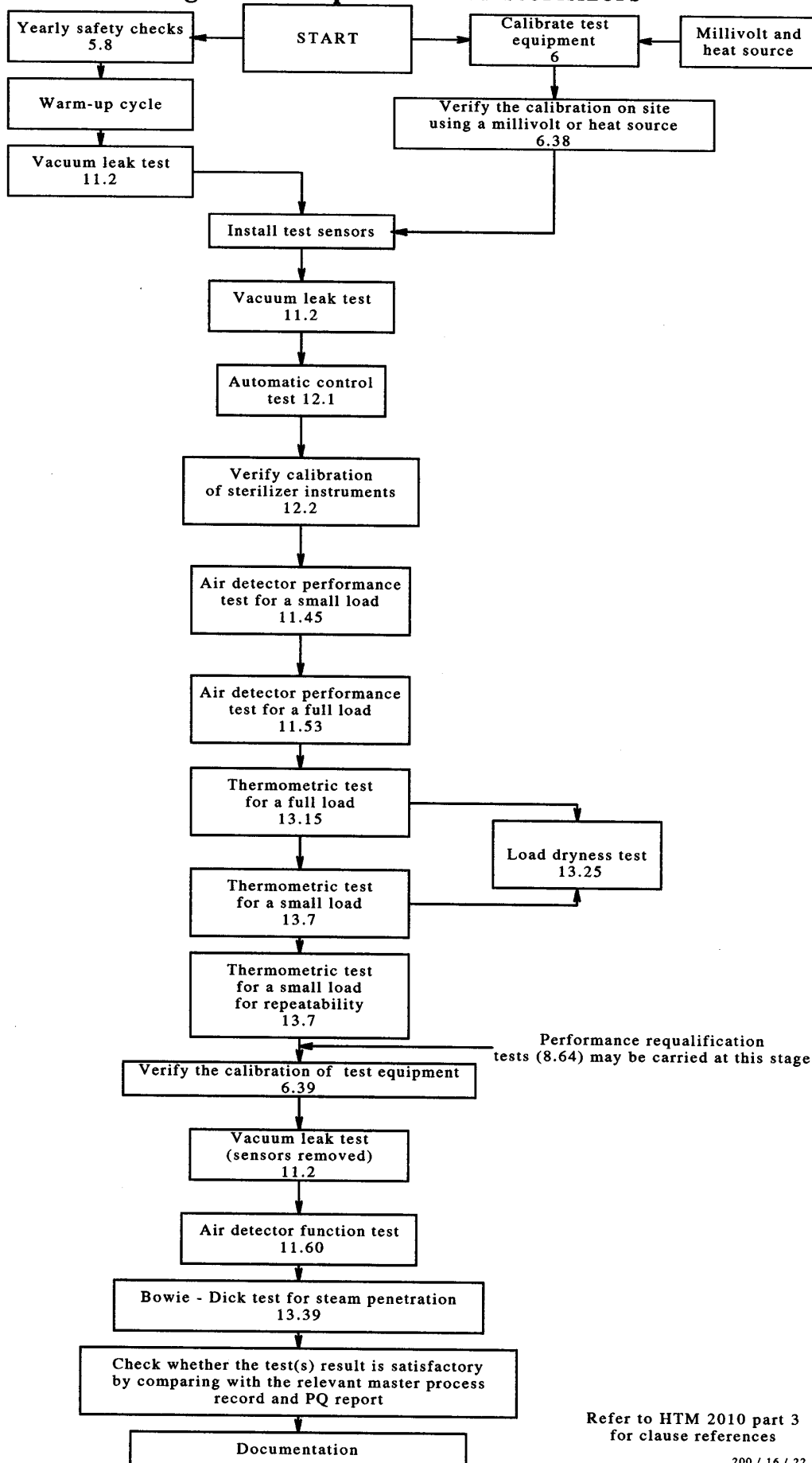
(Porous load-quarterly)



Refer to HTM 2010 part 3 for clause references
200 / 16 / 21

REVALIDATION (Yearly tests)

Recommissioning tests for porous load sterilizers



Refer to HTM 2010 part 3
for clause references

PLANNED PREVENTATIVE MAINTENANCE
Porous load sterilizer

The User or Maintenance Person should tick each task when it has been completed

PL	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY		D	W		
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Check the log book and production records. Complete as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Check chart recorder or data logger. Fit new chart, replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Check chamber and clean as detailed for the type of material chamber is constructed from	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Check chamber discharge strainer. Remove and clean as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Check door systems required by the scheme of inspection. Clean the door seal and its contact surface	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Check gauges and digital indicator(s). If faulty report and repair or change as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Checks the door safety interlocks and control systems as required by the scheme of inspection	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Examine all pipe work connections and components for leaks. Repair as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Examine door seal(s). Replace if damaged	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Lubricate the door closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	Carry out weekly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED INSPECT RECORDS WITH THE USER	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Daily tests Satisfactory ✓ Not satisfactory X Weekly tests Satisfactory ✓ Not satisfactory X	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Complete the log book	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at the frequency indicated by ☐ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE

Porous load sterilizer

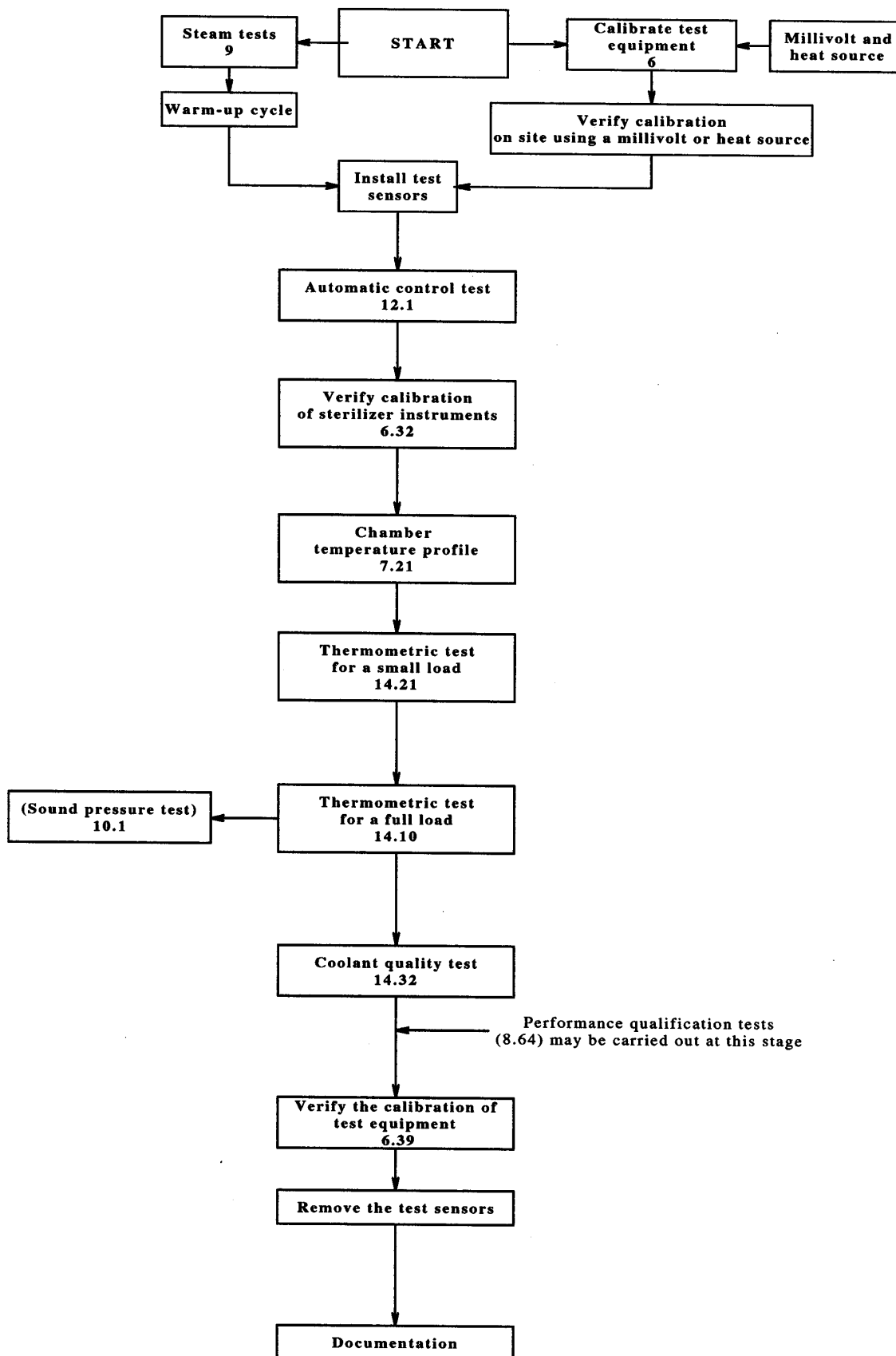
The Maintenance Person should tick each task when it has been completed

PL	MAINTENANCE SCHEDULES				
	<i>Q = QUARTERLY</i> <i>Y = YEARLY INTERVALS</i>	1st Q	2nd Q	3rd Q	4th Y
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Examine the condenser or the vent discharge as appropriate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Examine and check electrical connections	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacture's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3				<input type="checkbox"/> ●
18.	Refit all covers, and note the cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete the log book and summary sheets	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to user.	●	●	●	●

Tasks to be undertaken at frequency indicated by ● and as appropriate by the:-
Maintenance Person, Manufacturer, Service contractor

Operational procedures – Fluids

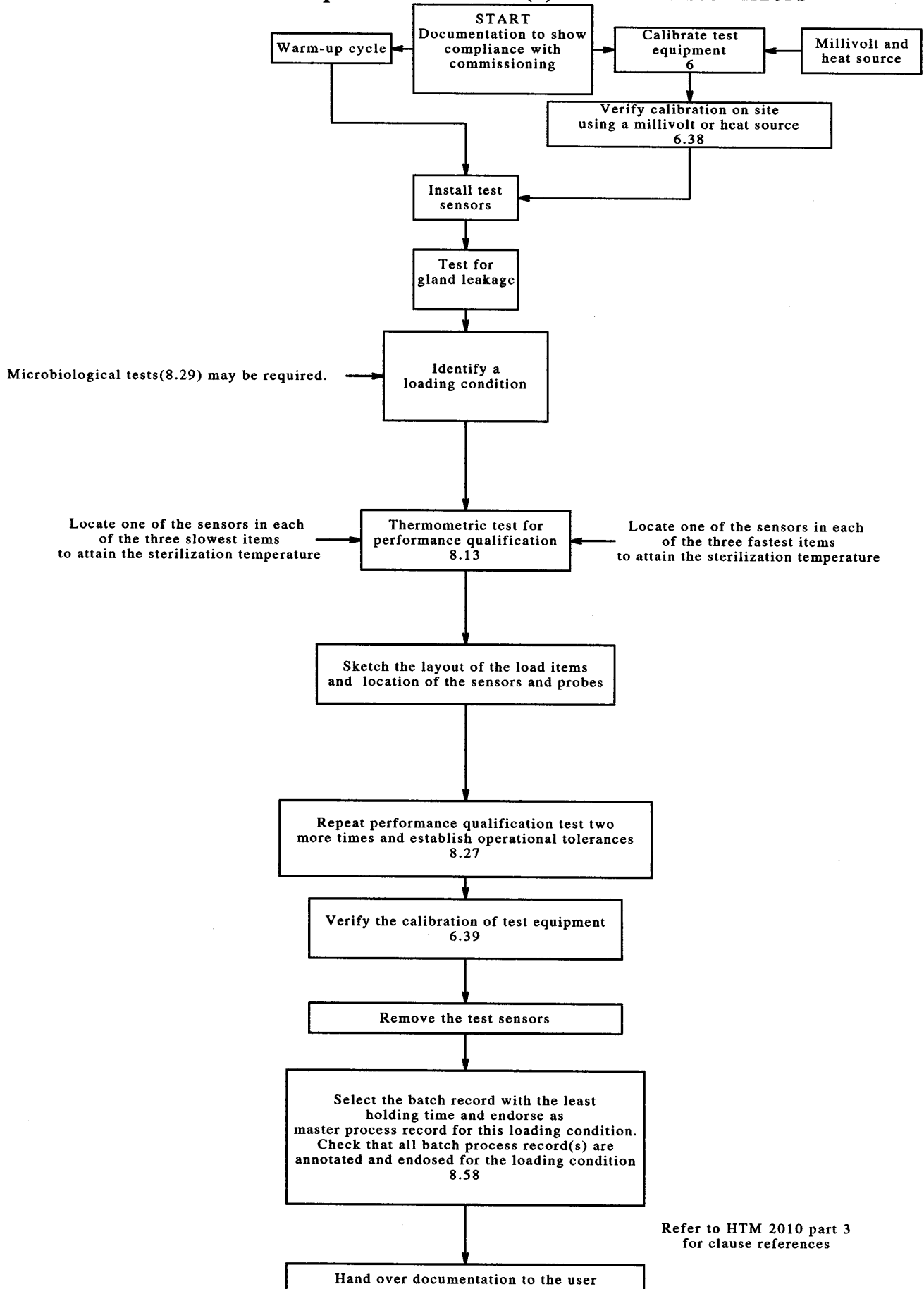
VALIDATION Commissioning tests for fluids sterilizers



Refer to HTM 2010 Part 3 for
clause references

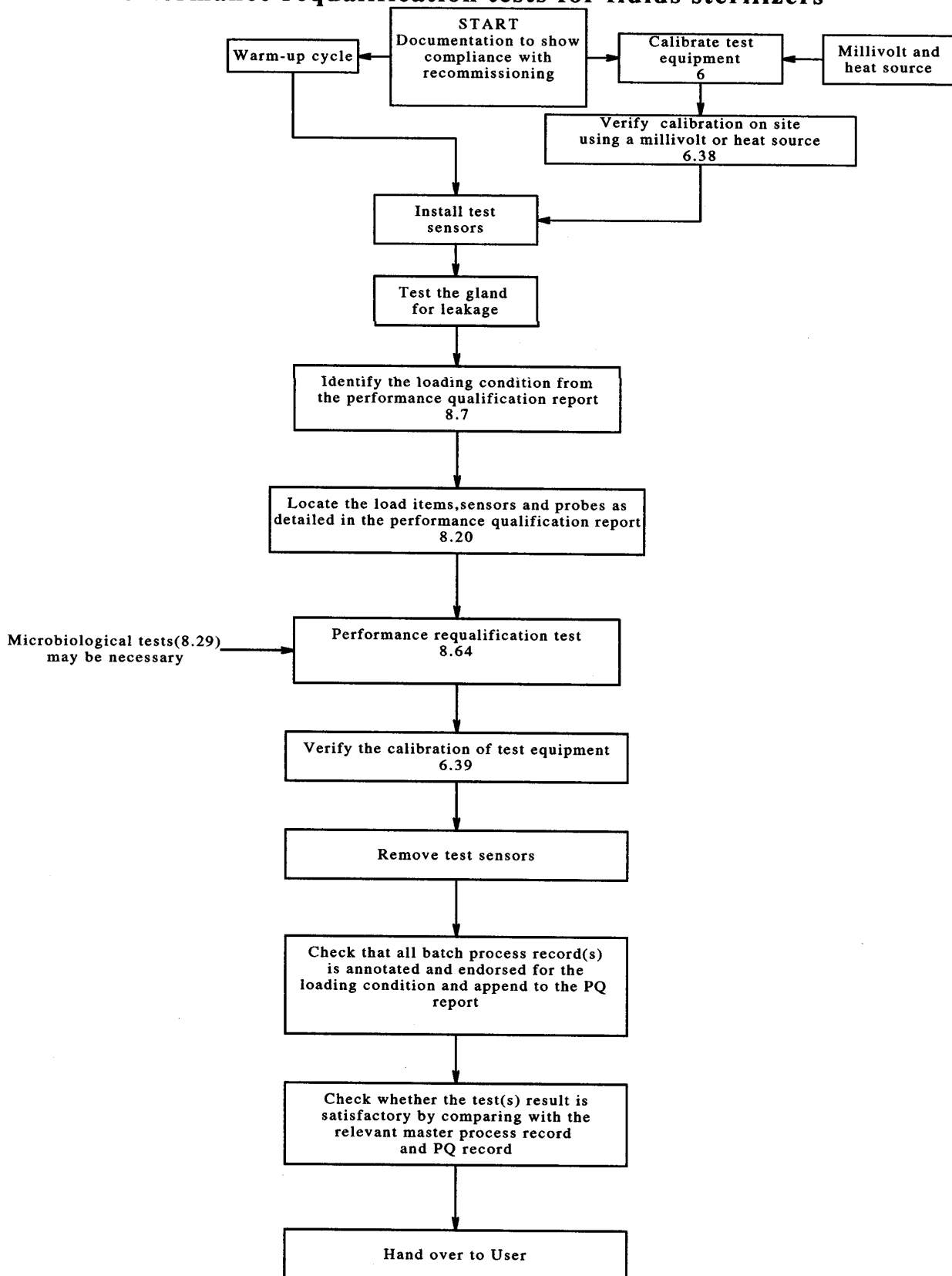
VALIDATION

Performance qualification test(s) for fluids sterilizers



REVALIDATION

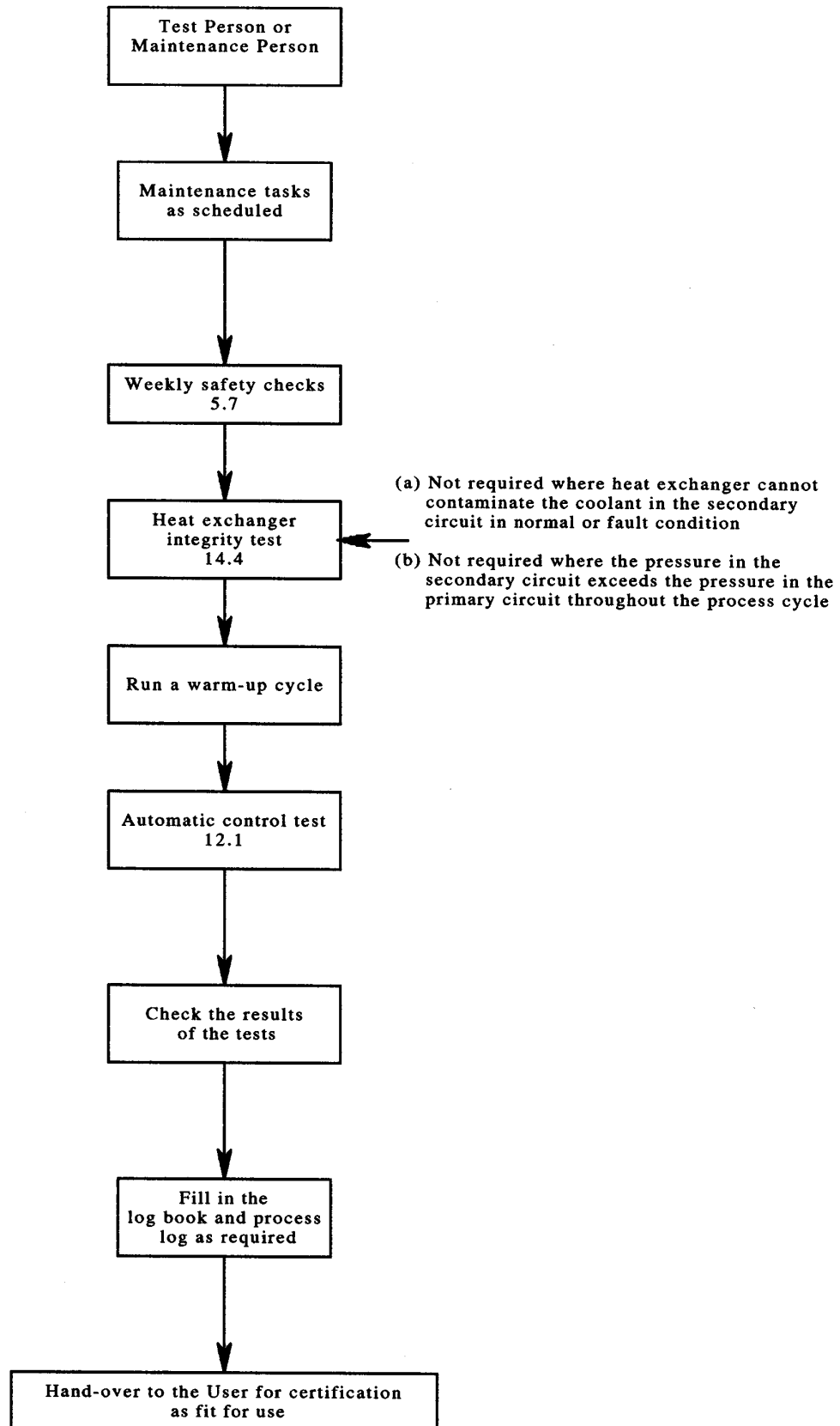
Performance requalification tests for fluids sterilizers



Refer to HTM2010 part 3 for clause references

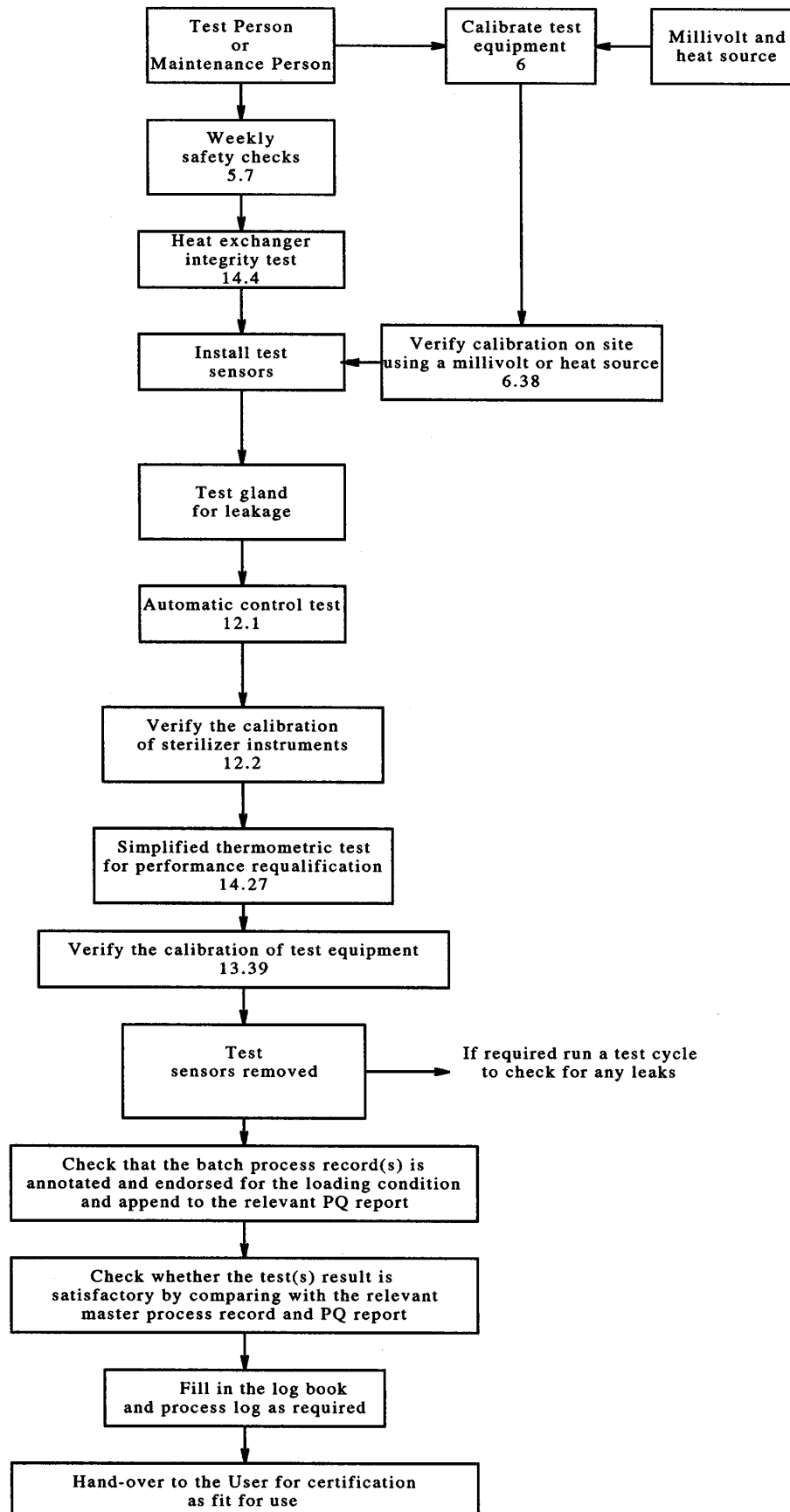
MAINTENANCE AND PERIODIC TESTING

(Fluids-Weekly)



Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING (Fluids-quarterly)

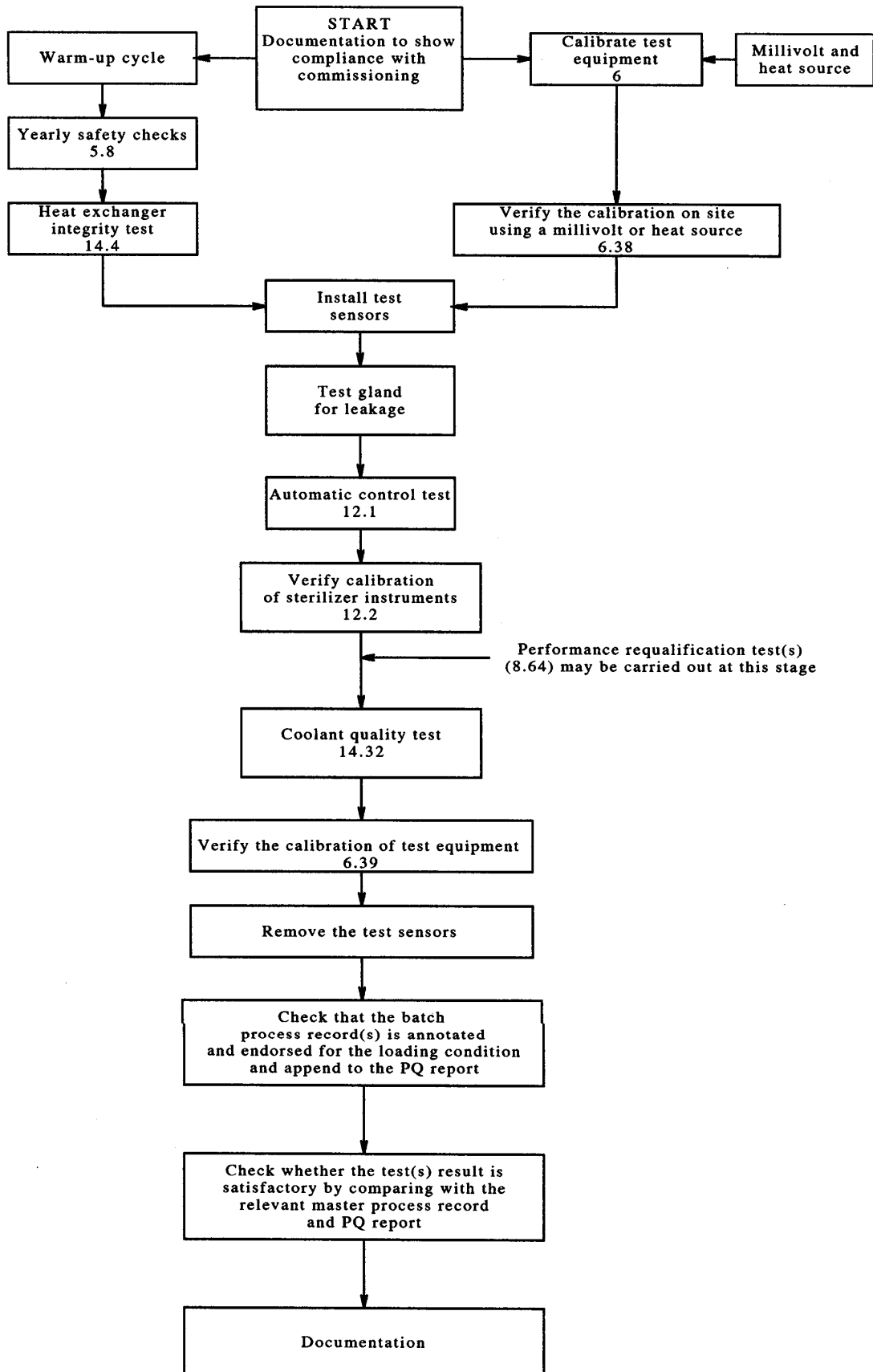


Refer to HTM 2010 part 3 for clause references

200 / 16 / 30

REVALIDATION (Yearly tests)

Recommissioning tests for fluids sterilizers



Refer to HTM 2010 part 3 for clause references

200 / 16 / 31

PLANNED PREVENTATIVE MAINTENANCE
Fluids sterilizer

The User or Maintenance Person should tick each task when it has been completed

FL	MAINTENANCE SCHEDULES				
<i>D = DAILY W = WEEKLY</i>		D	W		
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		✓✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Check log book and production records complete as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Check chart recorder or data logger fit new chart;replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Check chamber and clean as detailed for the type of material the chamber is constructed from	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Check chamber discharge strainer remove and clean as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Check the door system as required by the scheme of inspection .Clean the door seal and its contact surface	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Complete heat exchanger integrity tests as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Check gauges and digital indicator(s). If faulty repair or change as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Checks as required by the scheme of inspection the door safety interlocks and control systems	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Examine all pipe work connections and components for leaks and repair as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Examine the door seal(s) replace if damaged	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Lubricate the door closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	Carry out weekly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and manufactures instructions	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED INSPECT RECORDS WITH USER AND QUALITY CONTROL	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Weekly tests Satisfactory ✓ Not satisfactory ✗	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Complete log book. Check batch process record(s) for test compliance with master process record(s).	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19.	Report on completion and notify the user of any defect or safety hazard.Complete service records.Hand over to User	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

User Quality Controller and Maintenance Person , Manufacturer , Service contractor

Tasks to be undertaken at frequency indicated by ☐ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE**Fluids sterilizer**

The Maintenance Person should tick each task on completion of a service inspection or maintenance

FL	<i>Q = QUARTERLY</i> <i>Y = YEARLY INTERVALS</i>	1st Q	2nd Q	3rd Q	4th Y
MAINTENANCE SCHEDULES					
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Check the heat exchanger(s). Service filters and vents Test as required or replace.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Check electrical connections for security	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacture's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufactures instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the temperature sensor(s) and recorder and recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3				<input type="checkbox"/> ●
18.	Refit all covers, note cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete log book and summary sheets. Check batch process records for test compliance with master process record	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Report on completion and notify the user of any defect or safety hazard. Complete service records. Hand over to user.	●	●	●	●

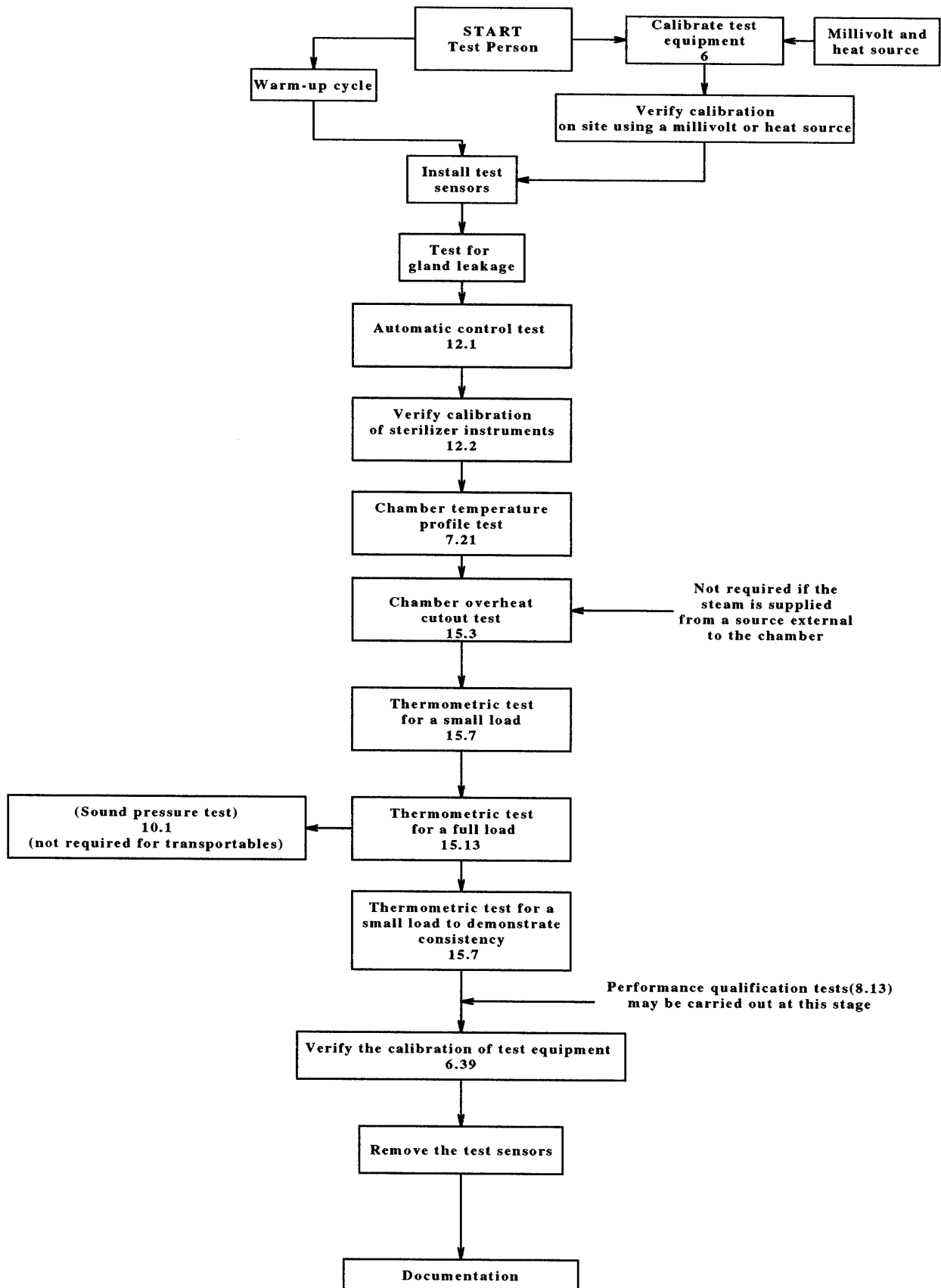
Maintenance Person sterilizers, Manufacturer, Service contractor

Tasks to be by the undertaken at frequency indicated by ● and as appropriate

Operational procedures – Unwrapped instruments and utensils

VALIDATION

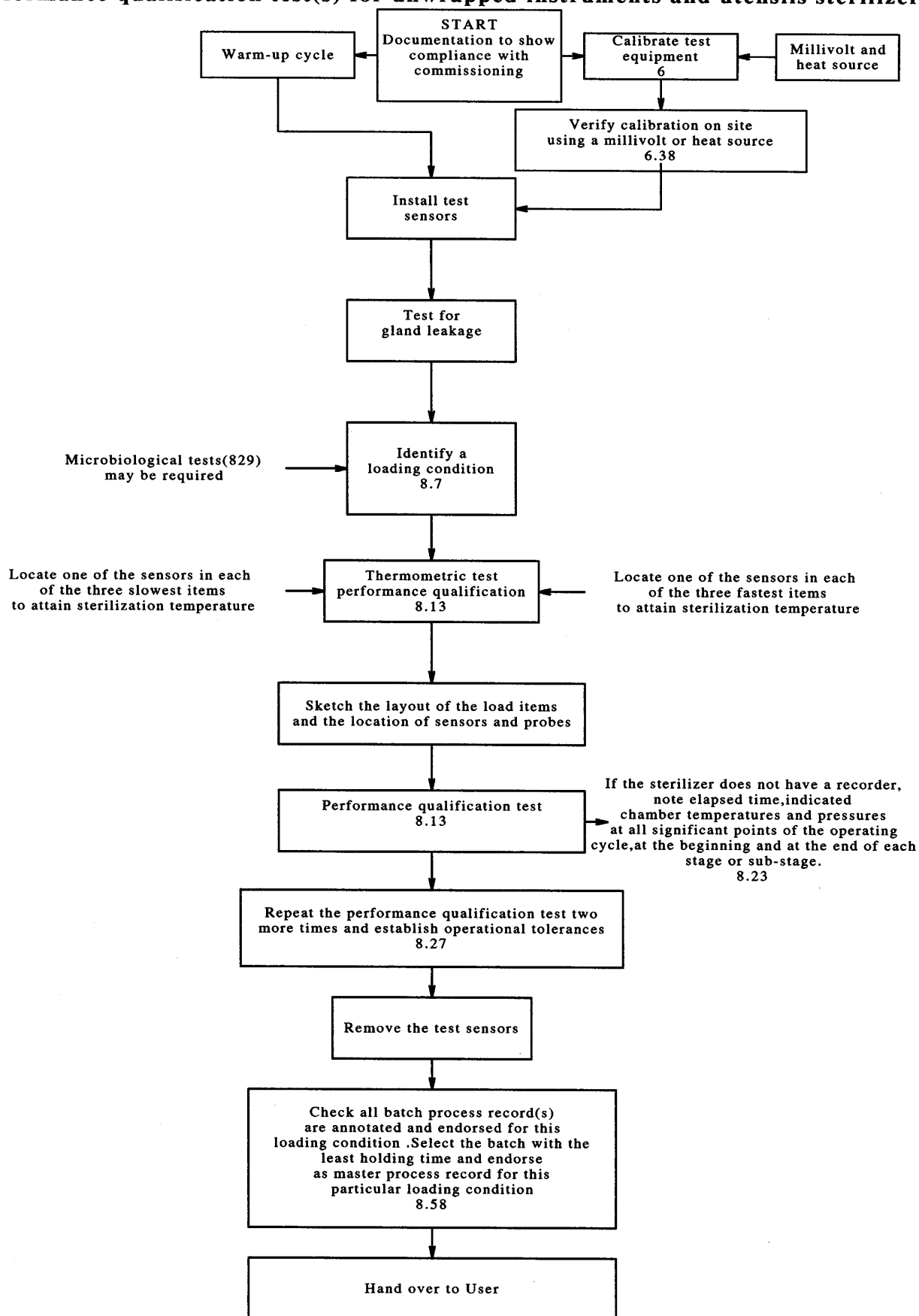
Commissioning tests for unwrapped instruments and utensils sterilizers



Refer to HTM 2010 part 3 for clause references

VALIDATION

Performance qualification test(s) for unwrapped instruments and utensils sterilizers

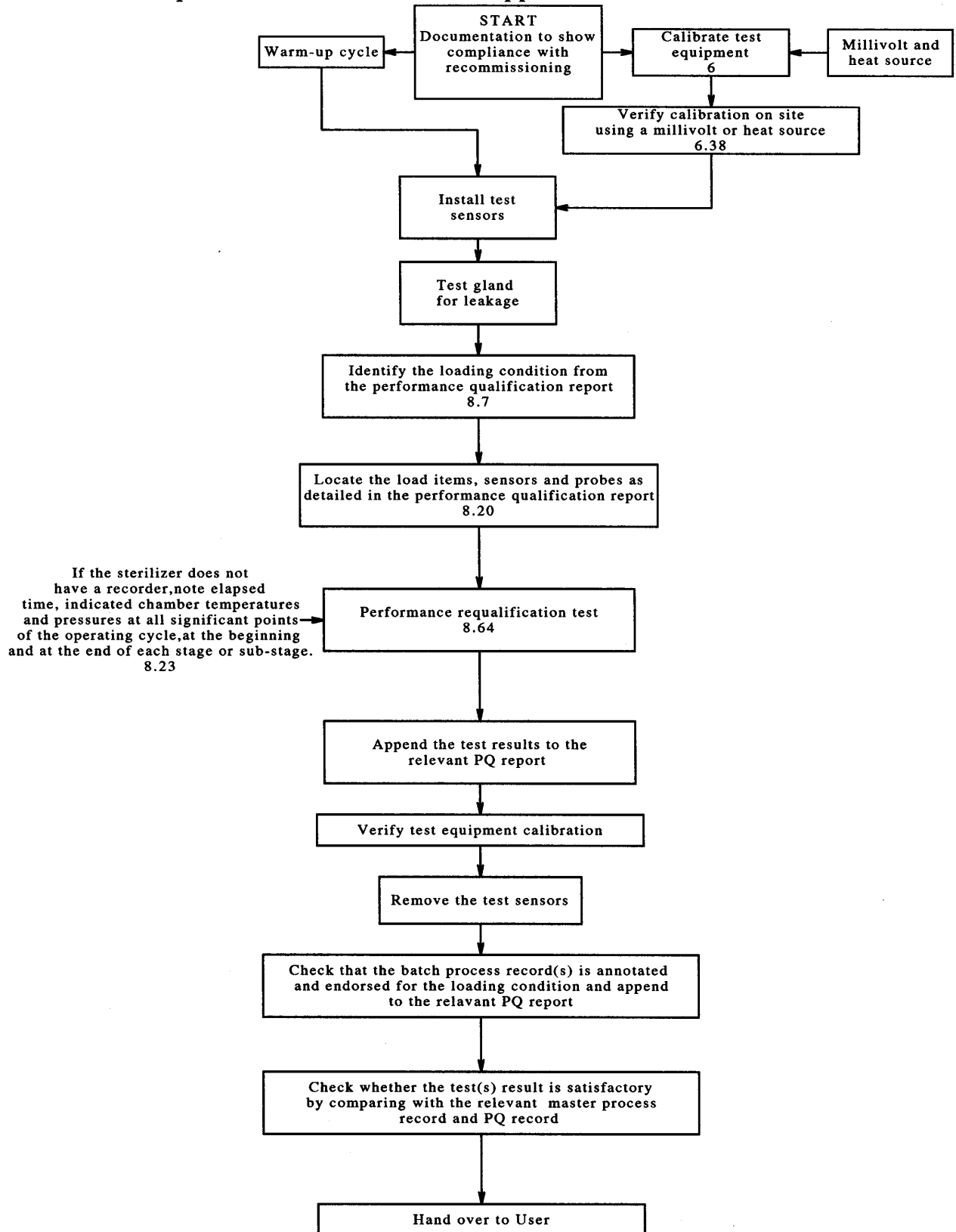


Refer to HTM 2010 part 3 for clause references

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REVALIDATION

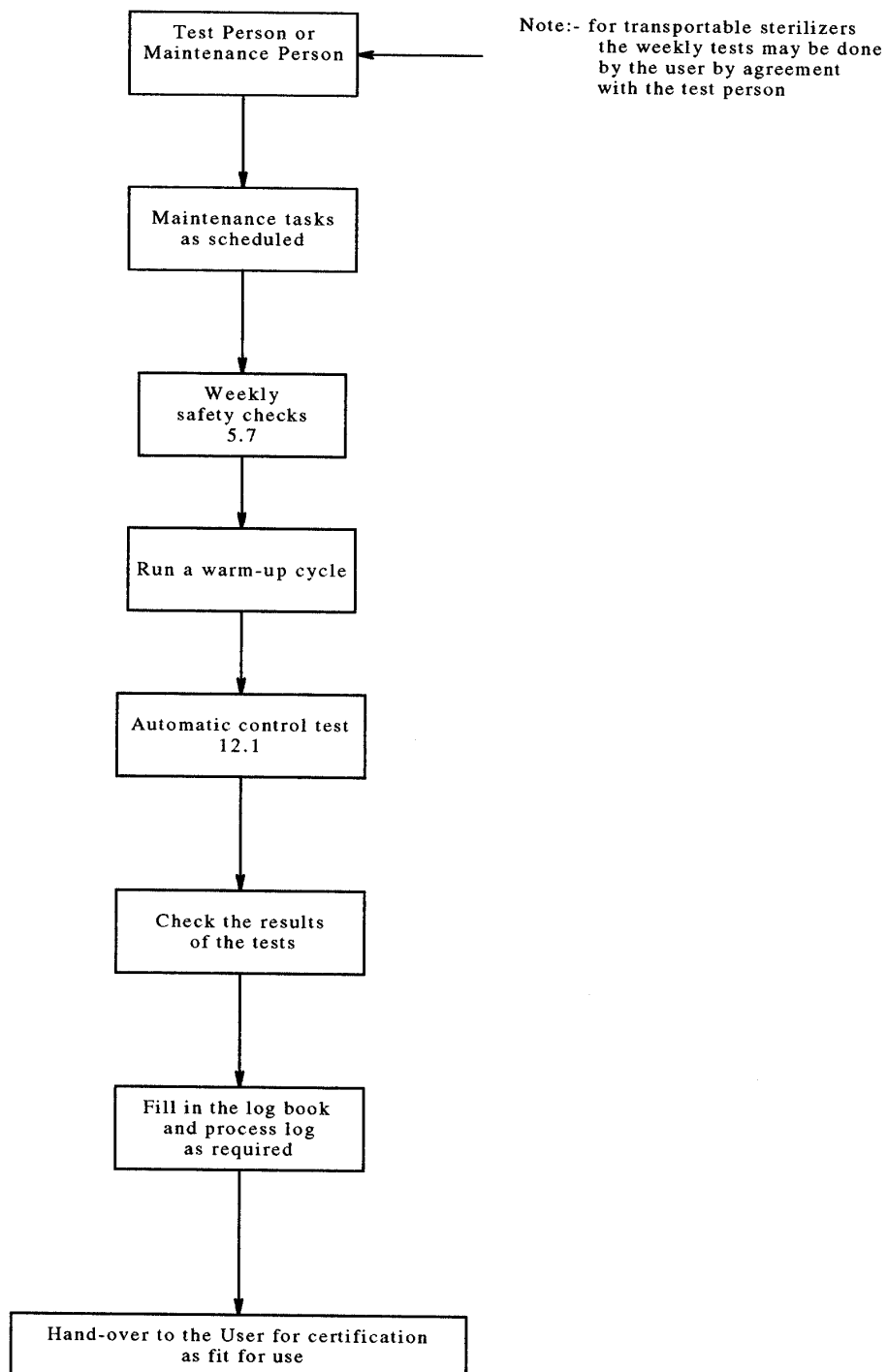
Performance requalification tests for unwrapped instruments and utensils sterilizers



Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING

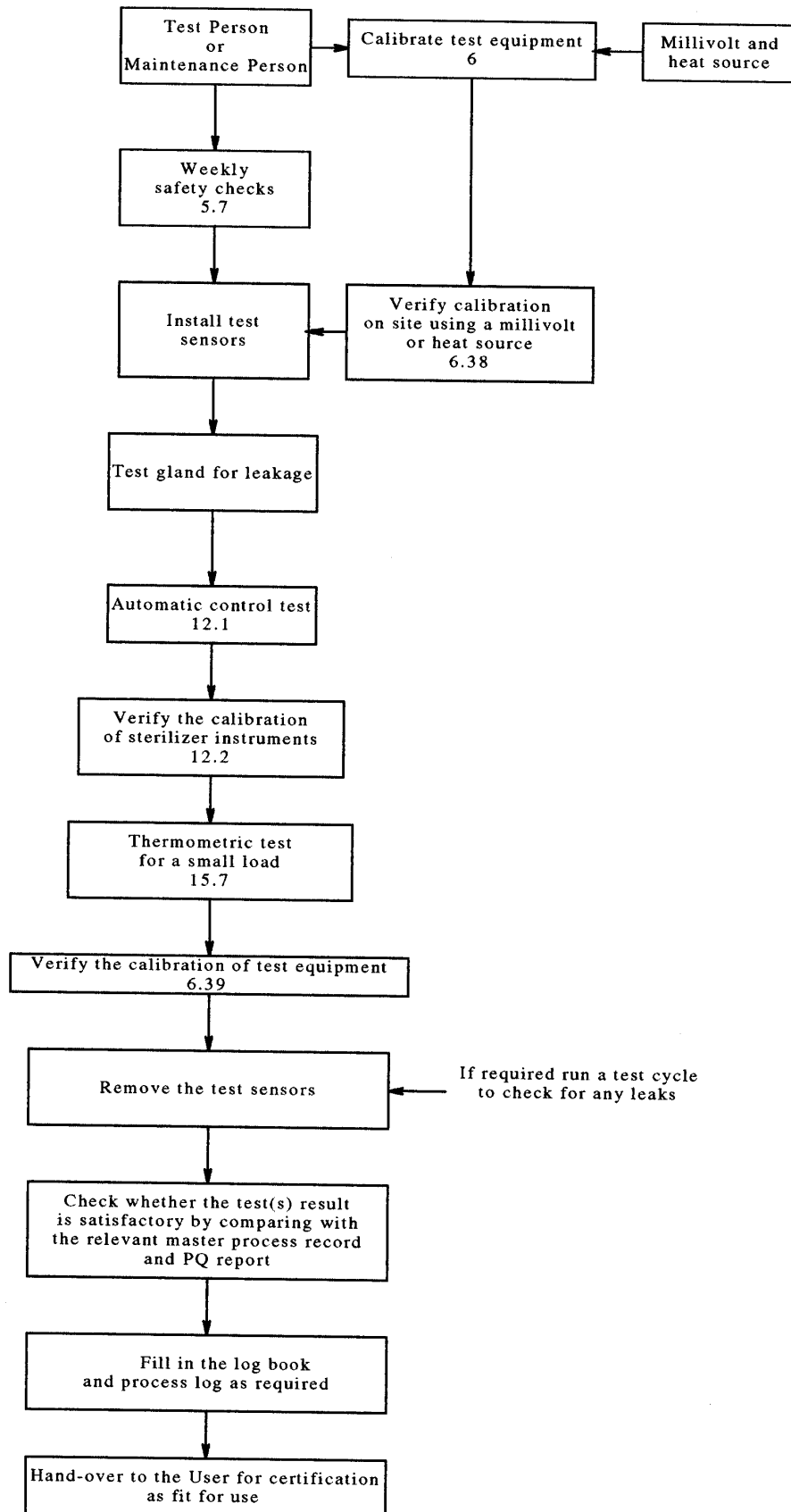
(Unwrapped instruments and utensils-weekly)



Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING

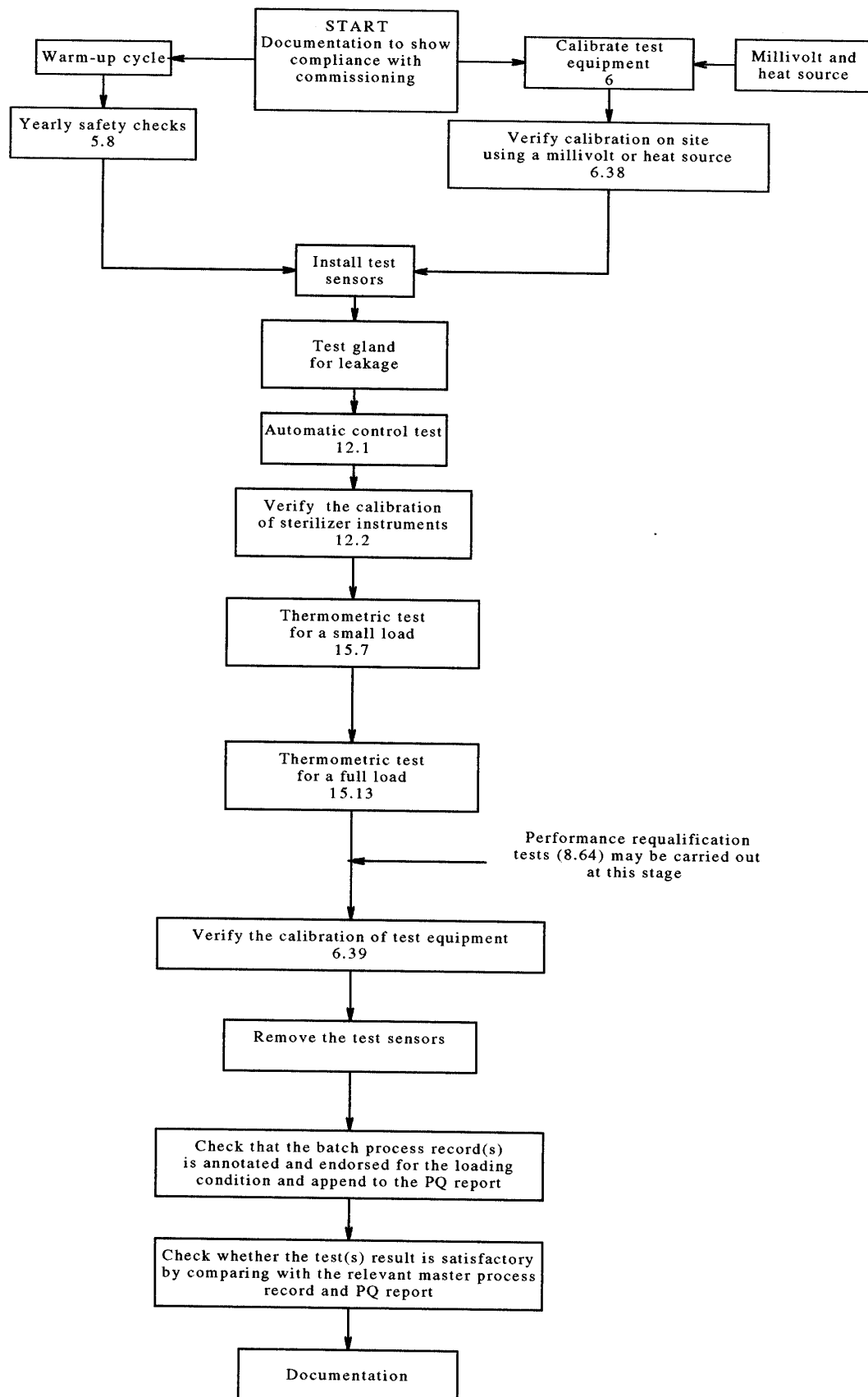
(Unwrapped instruments and utensils-quarterly)



Refer to HTM 2010 part 3 for clause references

REVALIDATION (Yearly tests)

Recommissioning tests for unwrapped instruments and utensils sterilizers



Refer to HTM 2010 part 3 for clause references

PLANNED PREVENTATIVE MAINTENANCE

Unwrapped instrument and utensils sterilizer

The User or Maintenance Person should tick each task when it has been completed

T		MAINTENANCE SCHEDULES			
D = DAILY W = WEEKLY		D	W		
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct instrument readings		✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Check the log book and process records. Complete as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Check the chart recorder or data logger. Fit new chart replenish ink or fit new ink cartridge as required (If fitted)	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Check the chamber and clean as detailed for the type of material the chamber is constructed from	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Check the water reservoir and the condenser return system. Clean and change distilled water in reservoir or top up as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Check the door system as required by the scheme of inspection. Clean door seal and its contact surface. Report any damage to the Maintenance Person	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Check the gauges and digital indicator(s). If faulty repair or change as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Check the door safety interlocks and control systems lubricate the door closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Examine all pipe work connections and components for leaks. Repair as required	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Examine door seal(s). Replace if damaged	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Carry out weekly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and manufacture's instructions	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT THE RECORDS THE WITH USER	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	Daily tests Satisfactory ✓ Not satisfactory ✗ Weekly tests Satisfactory ✓ Not satisfactory ✗	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Complete the log book.	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	SMTWThFSa □□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at the frequency indicated by ■ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE

Unwrapped instrument and utensil sterilizer

The Maintenance Person should tick each task when it has been completed

T	MAINTENANCE SCHEDULES				
Q = QUARTERLY Y = YEARLY INTERVALS		1st Q	2nd Q	3rd Q	4th Y
Service the following items within the contract and at the frequency indicated and check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains or plug	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check the gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Examine the condenser in the reservoir/ and discharge from chamber vent	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Examine electrical connections for security.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings .	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
18.	Refit all covers, note cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactor ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactor ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactor ✓ Not satisfactory ✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete log book and summary sheets	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete service the records. Hand over to the user.	●	●	●	●

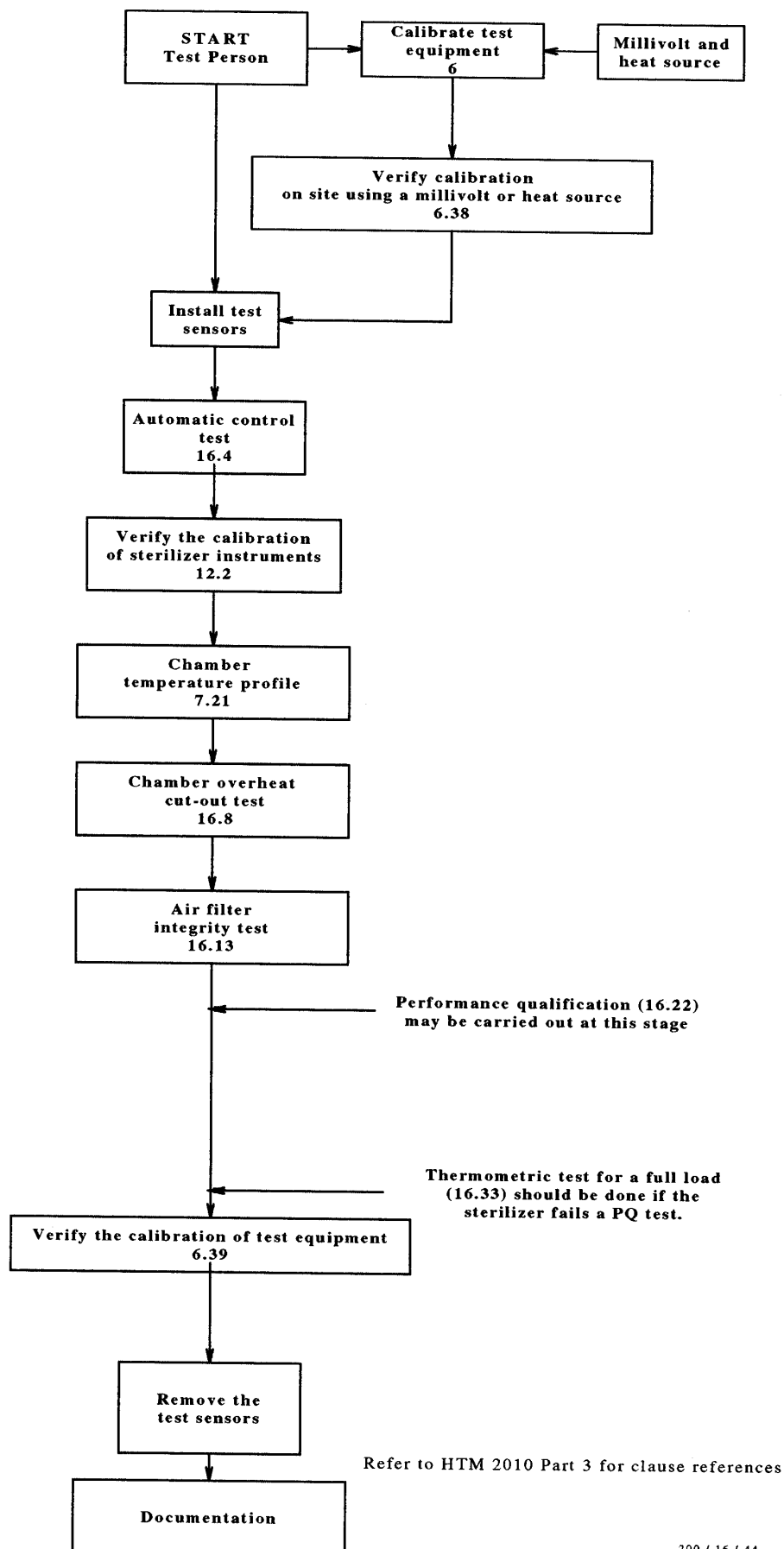
Tasks to be undertaken at frequency indicated by ● and as appropriate by the Maintenance Person sterilizers , Manufacturer , Service contractor

200/16/42

Operational procedures – Dry heat

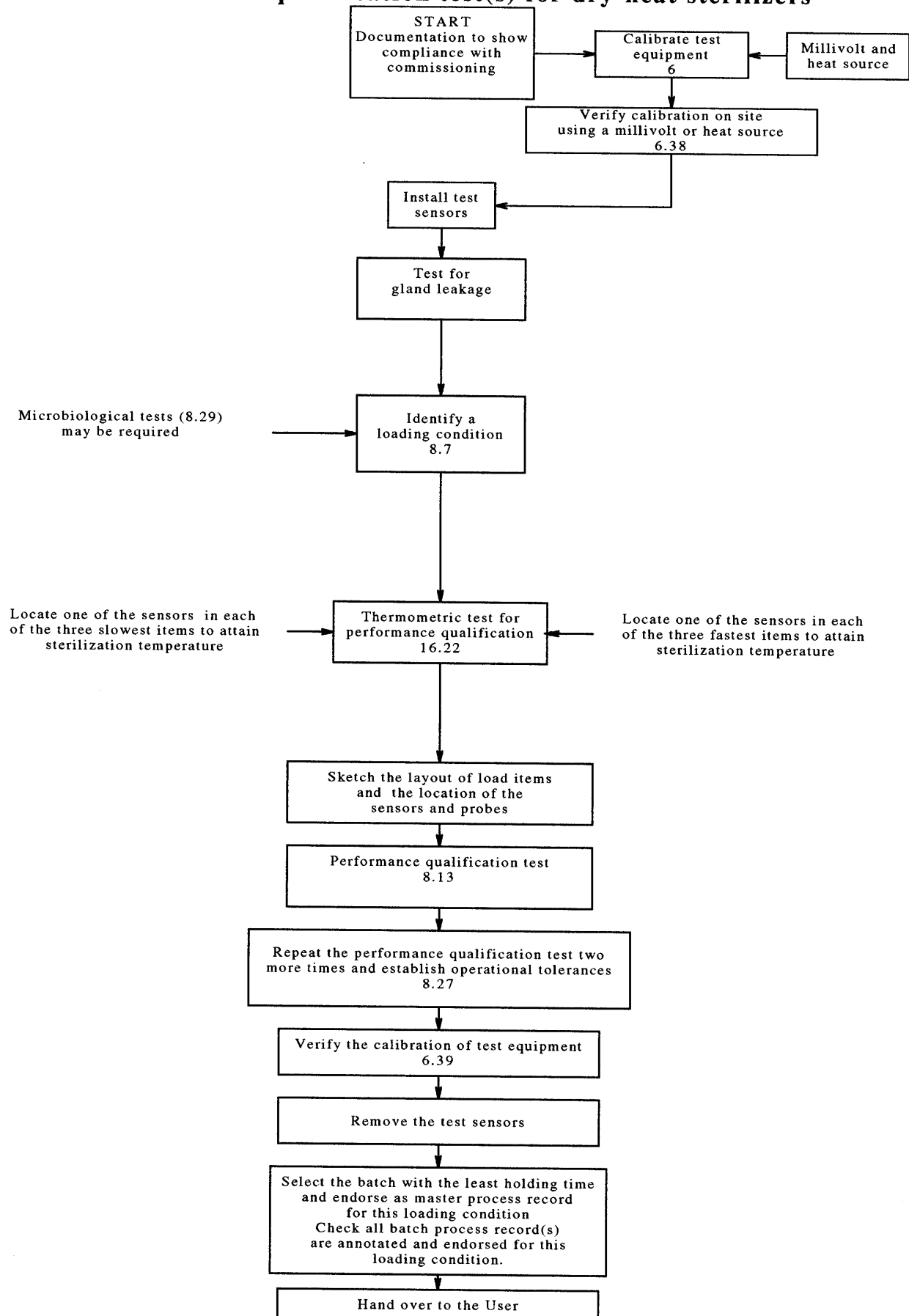
VALIDATION

Commissioning tests for dry-heat sterilizers



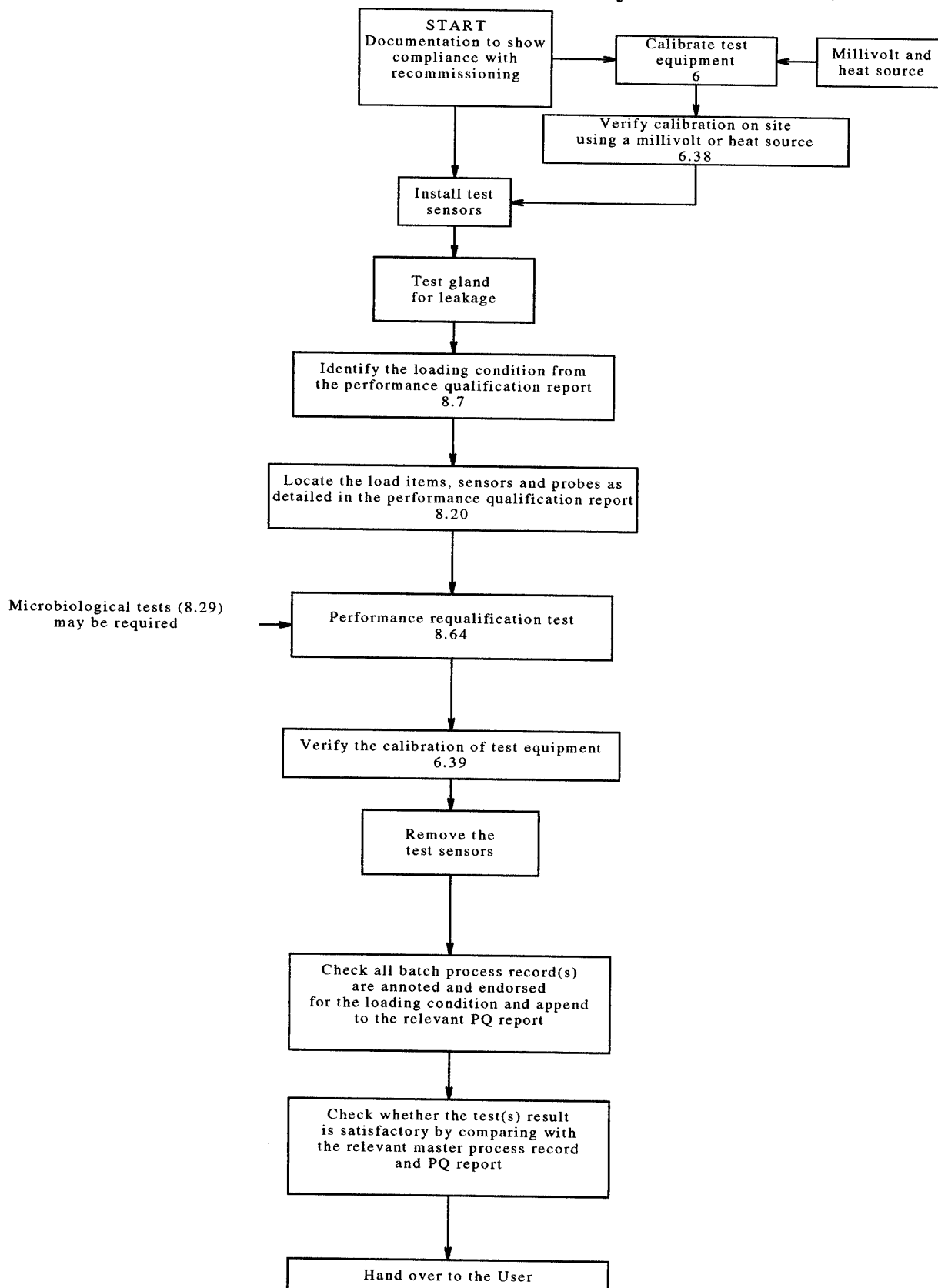
VALIDATION

Performance qualification test(s) for dry-heat sterilizers



REVALIDATION

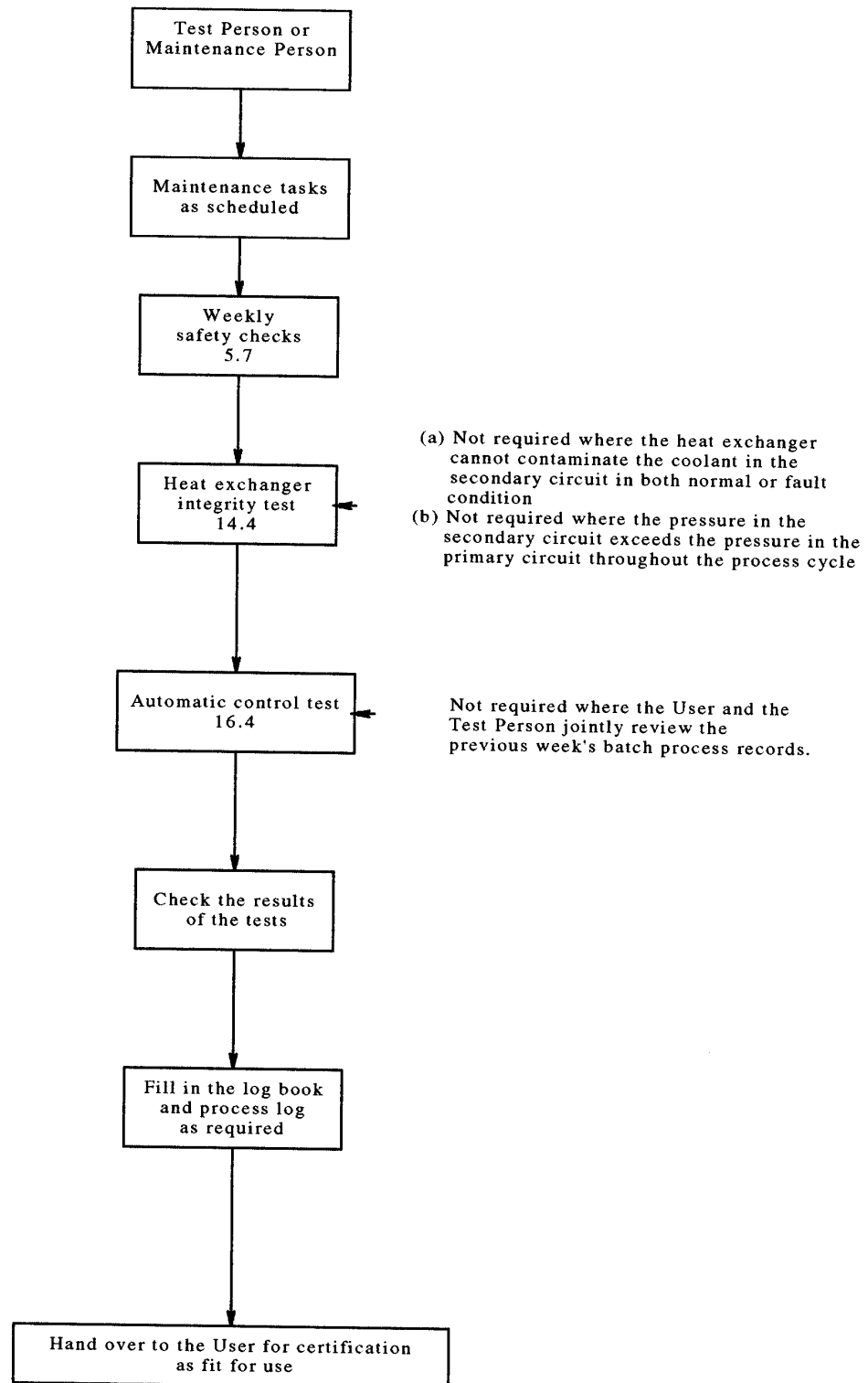
Performance requalification tests for dry-heat sterilizers



Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING

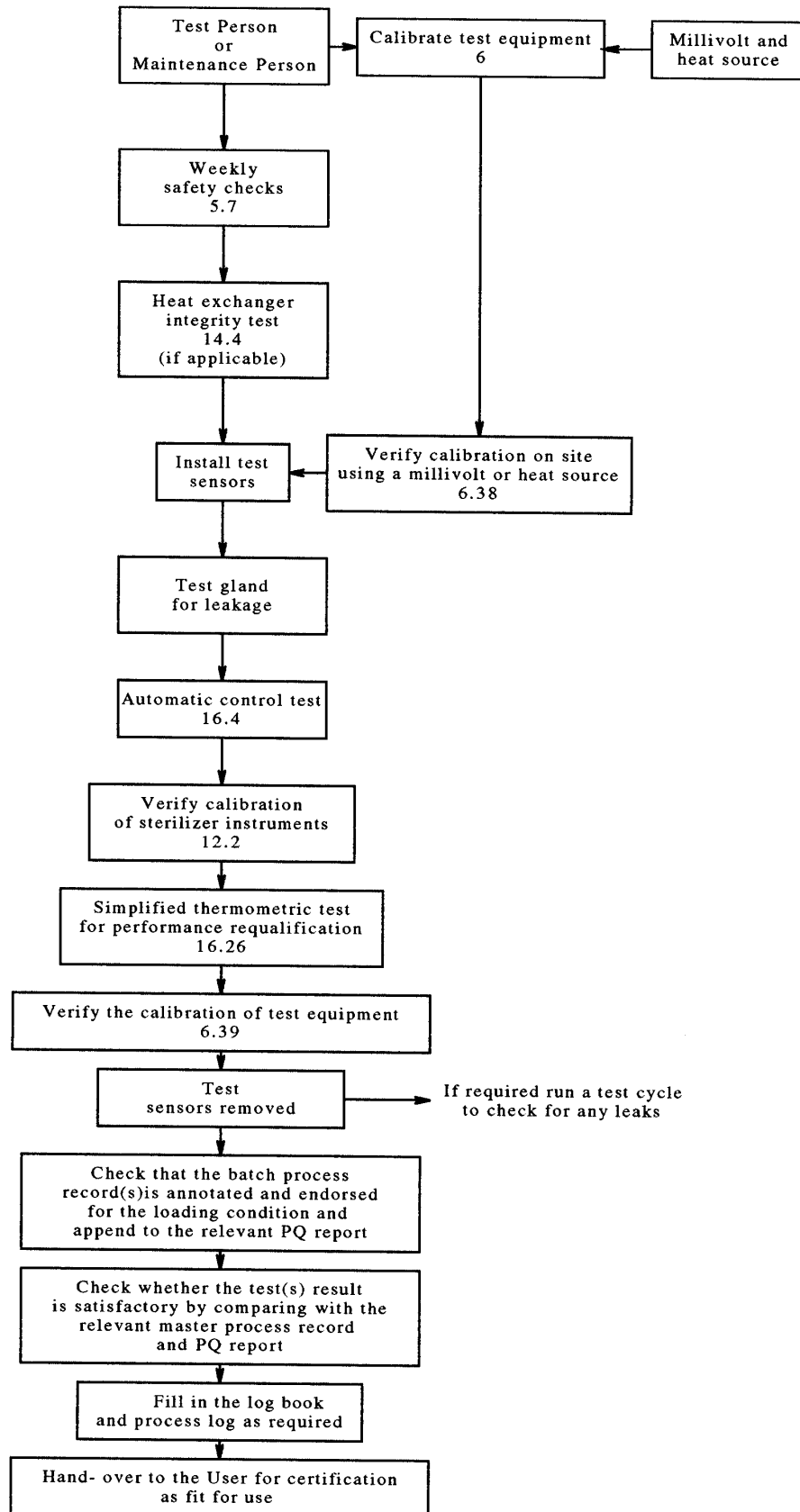
(Dry-heat weekly)



Refer to HTM2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING

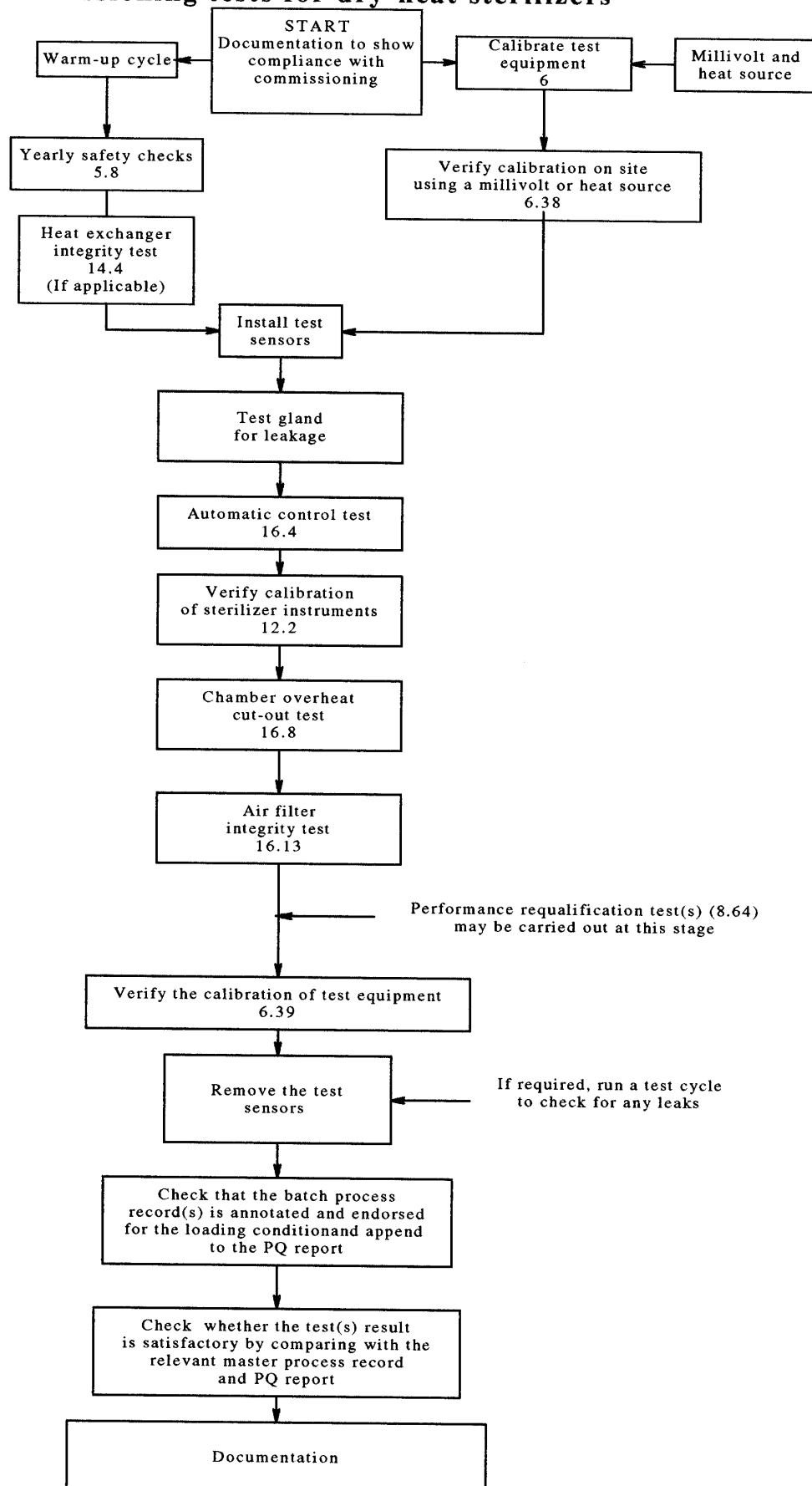
(Dry-heat quarterly)



Refer to HTM 2010 part 3 for clause references

REVALIDATION (Yearly tests)

Recommissioning tests for dry-heat sterilizers



Refer to HTM 2010 part 3 for clause references
200 / 16 / 49

PLANNED PREVENTATIVE MAINTENANCE

Dry-heat sterilizer

The User or Maintenance Person should tick each task when it has been completed

DH	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY		D	W		
Service the following items within the contract at the frequency indicated and check for safe operation and correct readings		✓✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Check the log book and production records. Complete as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Check the chart recorder or data logger. Fit new chart;replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Check the cabinet interior and clean as detailed for the type of material the cabinet is constructed from	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Check that the cabinet temperature probe(s) is not damaged . Report any damage to the Maintenance Person	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Check the door seal and wipe its contact surface. Report any damage to Maintenance Person	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Carry out heat exchanger integrity tests (if applicable)	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Check gauges and digital indicator(s). If faulty repair or change as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Check the door safety interlocks and control systems. Examine the door hinges and closure mechanism and lubricate	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Check the cooling and cabinet filters for any leakage or damage	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Examine the door seal(s) replace if damaged	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Carry out weekly maintenance tasks and checks in accordance with the manufacturer's instructions	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED: INSPECT THE RECORDS WITH USER AND QUALITY CONTROL	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	Weekly tests Satisfactory ✓Not satisfactory ✗	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Complete log book. Check batch process record(s) for compliance with master process record(s).	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Notify the user of any defect or safety hazard. Complete service records. Hand over to theUser	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

User Quality Controller and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency the indicated by ☐ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE

Dry-heat sterilizer

The Maintenance Person should tick each task on completion of a service inspection or maintenance

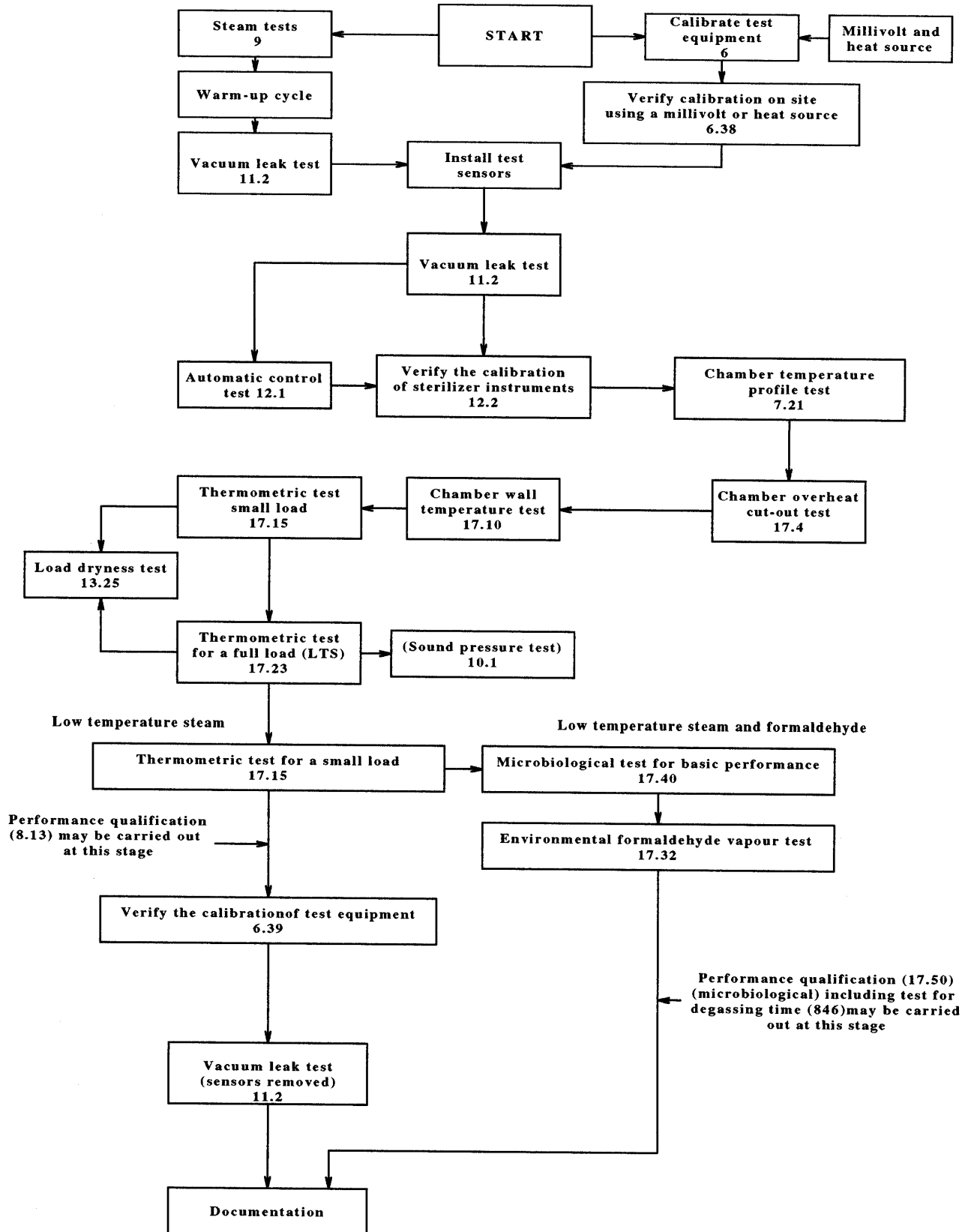
DH	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q = QUARTERLY Y = YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check the gauges and digital indicator(s) and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks and control systems	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Air filter integrity test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Overheat cut out test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
11.	Check the heat exchanger(s) cabinet filters and vents. Test for integrity as required or replace.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Check electrical connections for security	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the manufacturer's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check the cabinet in-accordance with the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the chamber temperature probes and temperature sensors and recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
18.	Refit all covers and note the cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete the log book and summary sheets. Check the batch process records for compliance with the master process record	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	●	●	●	●

Tasks to be undertaken at frequency indicated by ● and as appropriate by the Maintenance Person, Manufacturer, Service contractor

**Operational procedures – Low temperature steam disinfectors,
Low temperature steam and formaldehyde sterilizers**

VALIDATION

Commissioning tests for low temperature steam disinfectors low temperature steam and formaldehyde sterilizers

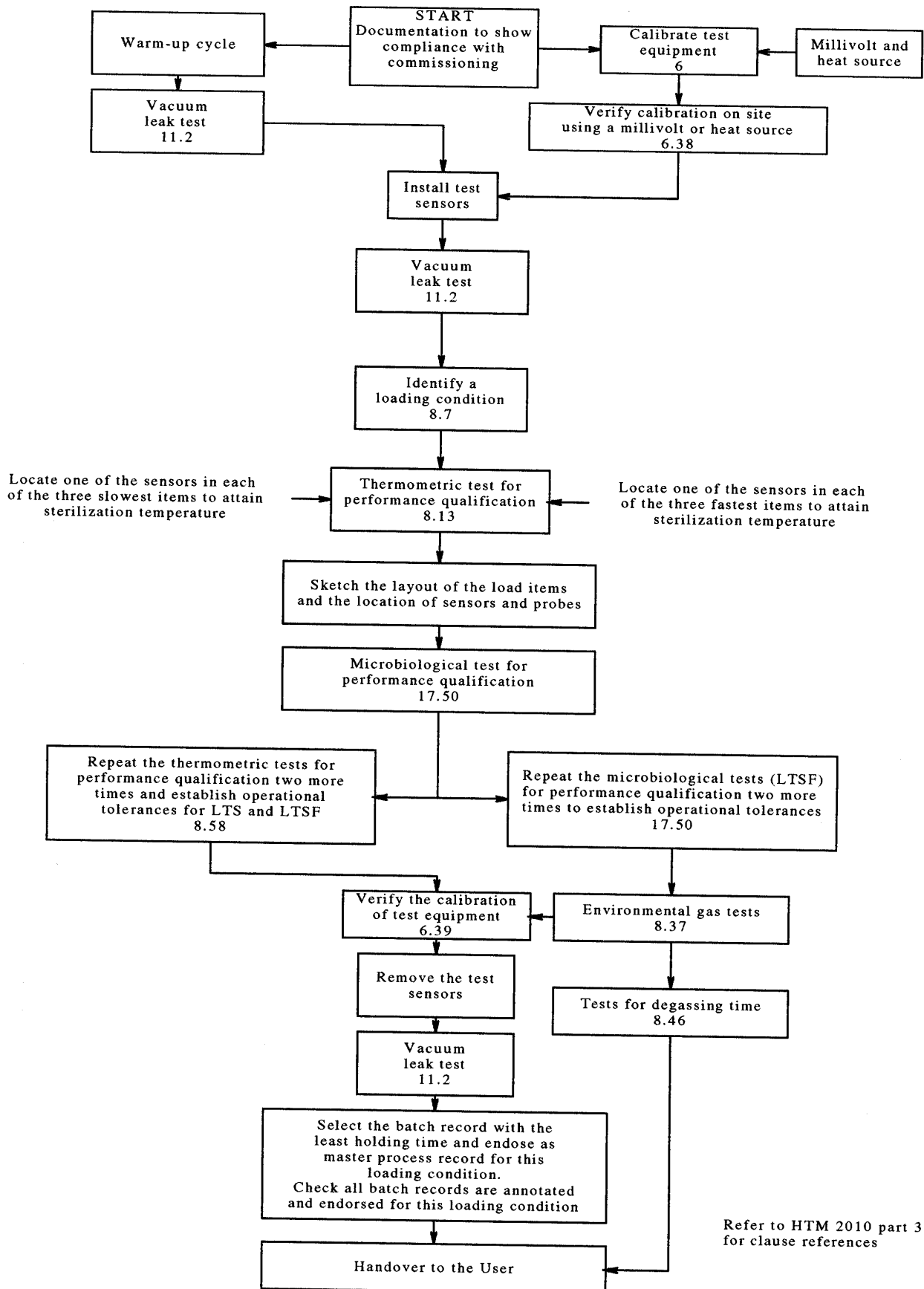


Refer to HTM 2010 Part 3 for clause references

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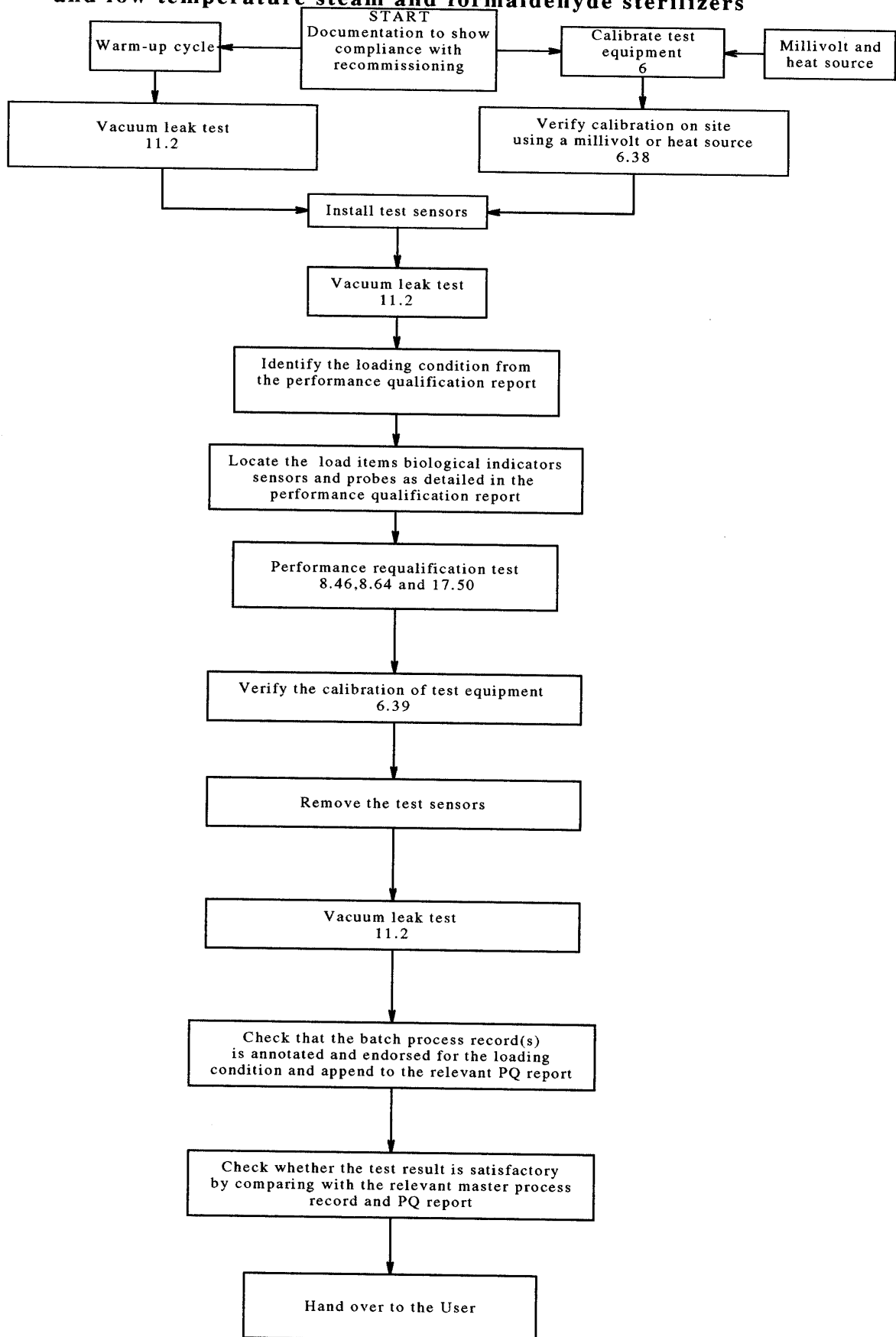
VALIDATION

Performance qualification test(s) for low temperature steam disinfectors and low temperature steam and formaldehyde sterilizers



REVALIDATION

Performance requalification for tests low temperature steam disinfectors and low temperature steam and formaldehyde sterilizers

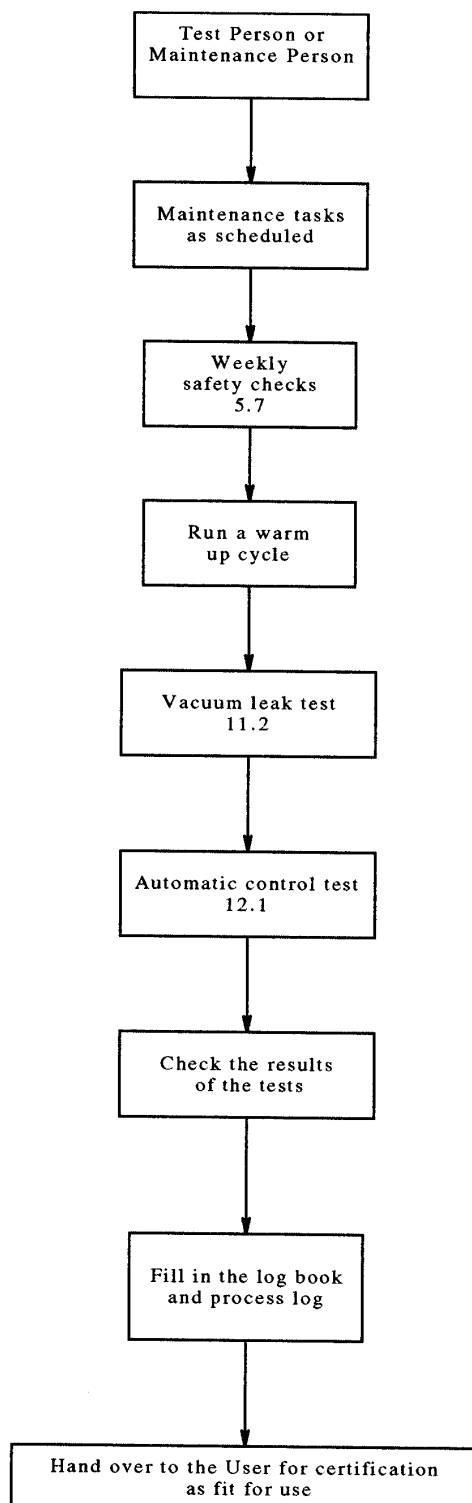


Refer to HTM 2010 part 3 for clause references

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MAINTENANCE AND PERIODIC TESTING

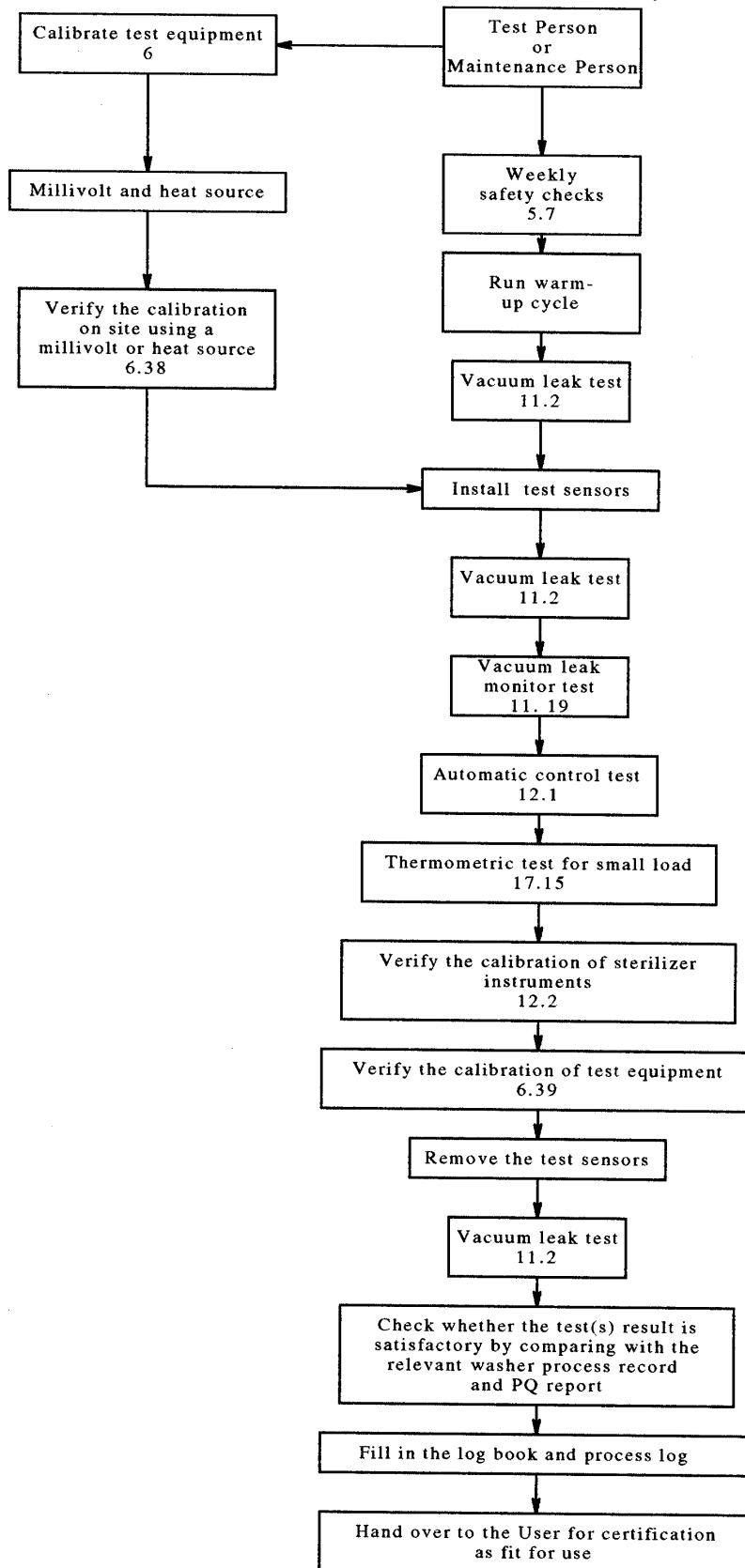
Low temperature steam disinfectors and low temperature steam formaldehyde sterilizer weekly



Refer to HTM 2010 part 3 for clause references

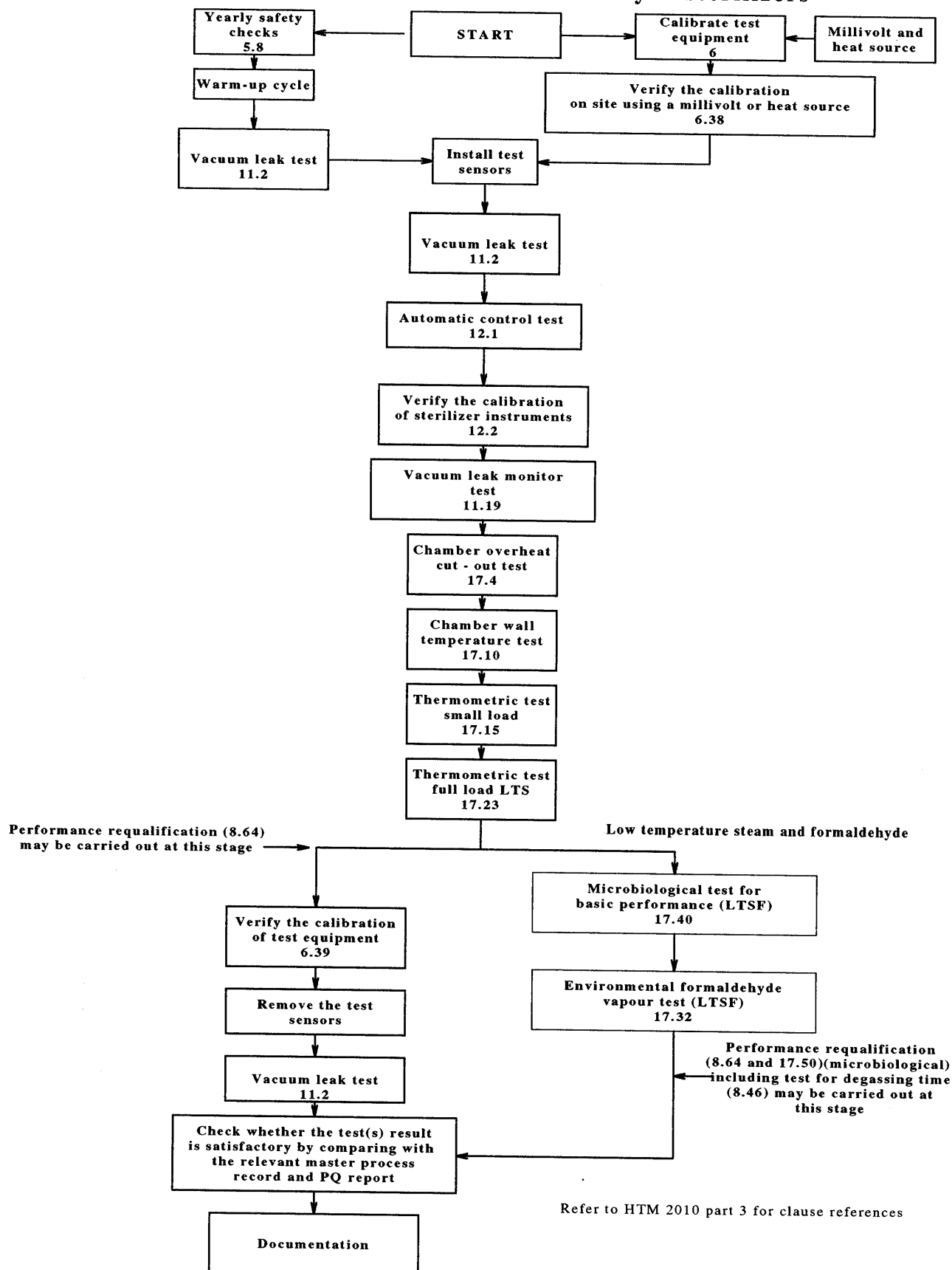
MAINTENANCE AND PERIODIC TESTING

Low temperature steam disinfectors and low temperature steam and formaldehyde sterilizer quarterly



Refer to HTM 2010 part 3 for clause references

REVALIDATION (yearly tests)
Recommissioning tests for low temperature steam disinfectors
low temperature steam and formaldehyde sterilizers



PLANNED PREVENTATIVE MAINTENANCE

Low temperature steam and formaldehyde sterilizer

The User or Maintenance Person should tick each task when it has been complete

LTS.F	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY					
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		D ✓✓✓✓✓✓✓	W ✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□□	□	■	■
2.	Check the log book and production records together with the routine microbiological test for LTSF. Complete as required	SMTWThFSa □□□□□□□	□	■	■
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□□	□	■	■
4.	Check the chamber and clean as detailed for the type of material chamber is constructed from	SMTWThFSa □□□□□□□	□	■	■
5.	Check the chamber discharge strainer. Remove and clean as required	SMTWThFSa □□□□□□□	□	■	■
6.	Check the door system as required by the scheme of inspection. Clean the door seal and its contact surface	SMTWThFSa □□□□□□□	□	■	■
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4	SMTWThFSa □□□□□□□	□	■	■
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□□	□	■	■
9.	Check gauges and digital indicator(s). If faulty repair or change as required	SMTWThFSa □□□□□□□	□	■	■
10.	Check the door safety interlocks and control systems as required by the scheme of inspection. Lubricate the closure mechanism as required	SMTWThFSa □□□□□□□	□	■	■
11.	Examine all pipe work connections and components for leaks. Repair as required	SMTWThFSa □□□□□□□	□	■	■
12.	Examine door seal(s). Replace if damaged	SMTWThFSa □□□□□□□	□	■	■
13.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□□	□	■	■
14.	Carry out weekly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	SMTWThFSa □□□□□□□	□	■	■
15.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH USER	SMTWThFSa □□□□□□□	□	■	■
16.	Daily tests Satisfactory ✓ Not satisfactory X Weekly tests Satisfactory ✓ Not satisfactory X	SMTWThFSa □□□□□□□	□	■	■
17.	Complete the log book.	SMTWThFSa □□□□□□□	□	■	■
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	SMTWThFSa □□□□□□□	□	■	■

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by ■ U = User M = Maintenance person

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PLANNED PREVENTATIVE MAINTENANCE
Low temperature steam and formaldehyde sterilizer

The Maintenance Person should tick each task when it has been completed.

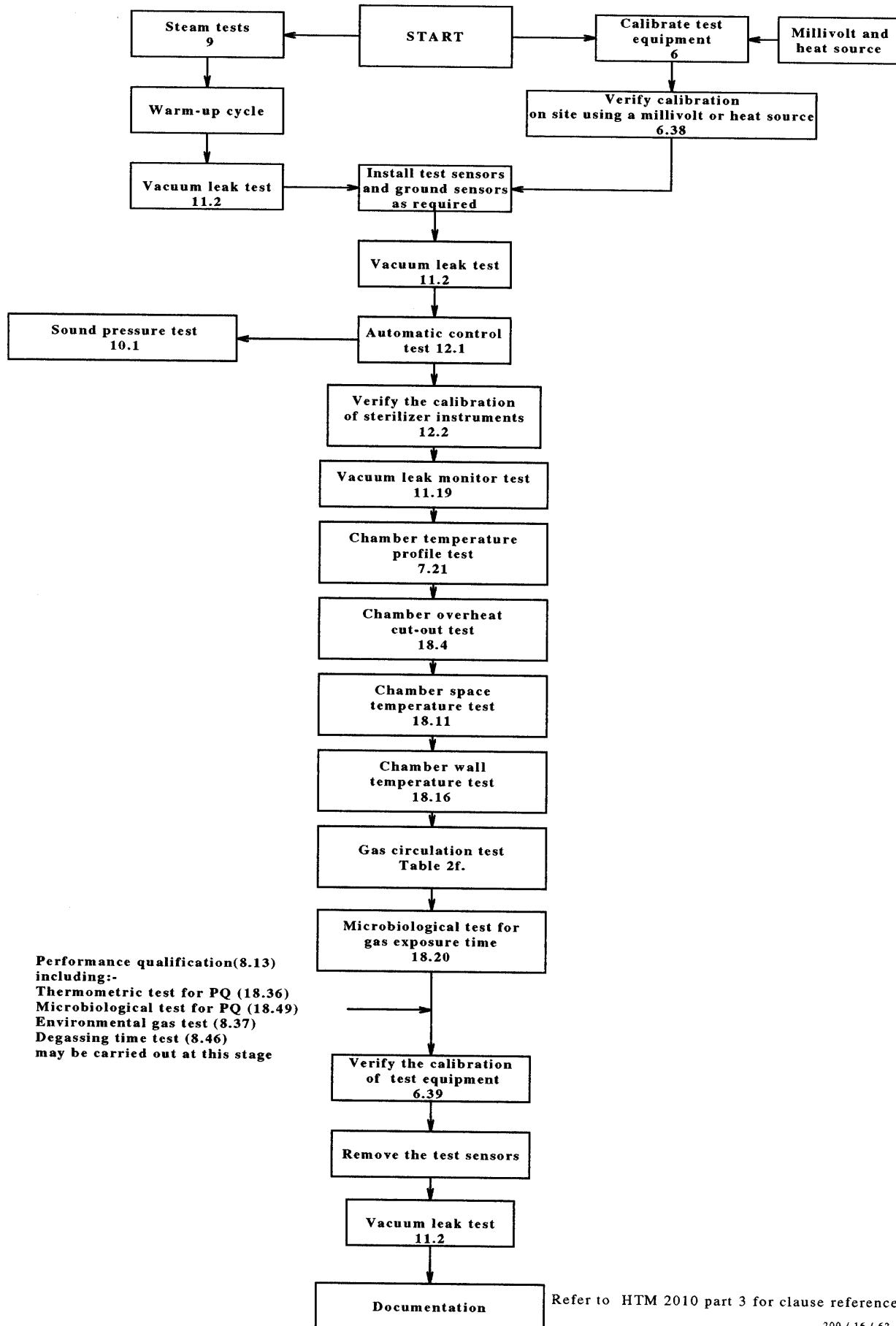
LTS.F	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q = QUARTERLY Y = YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace indicator faulty lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks and control systems as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check and formalin container vent	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Examine the condenser	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Check electrical connections for security	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the temperature sensor(s) and recorder recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
18.	Refit all covers and note the cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete log book and summary sheets	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	●	●	●	●

Tasks to be undertaken at frequency indicated by ● and as appropriate by the User, Microbiologist, Maintenance Person, Manufacturer, Service contractor

Operational procedures – Ethylene oxide sterilizers

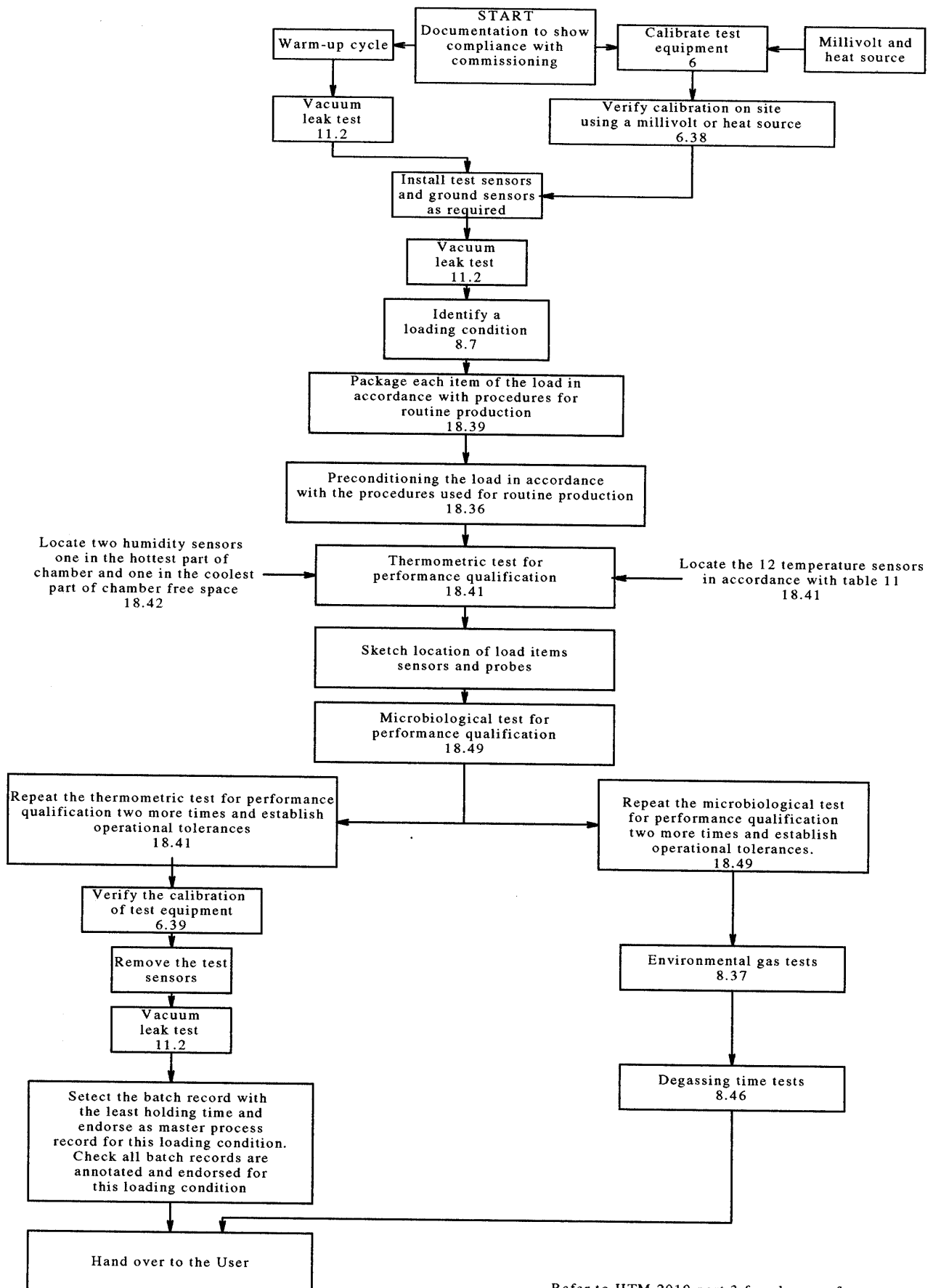
VALIDATION

Commissioning tests for ethylene oxide sterilizers



VALIDATION

Performance qualification test(s) for ethylene oxide sterilizers

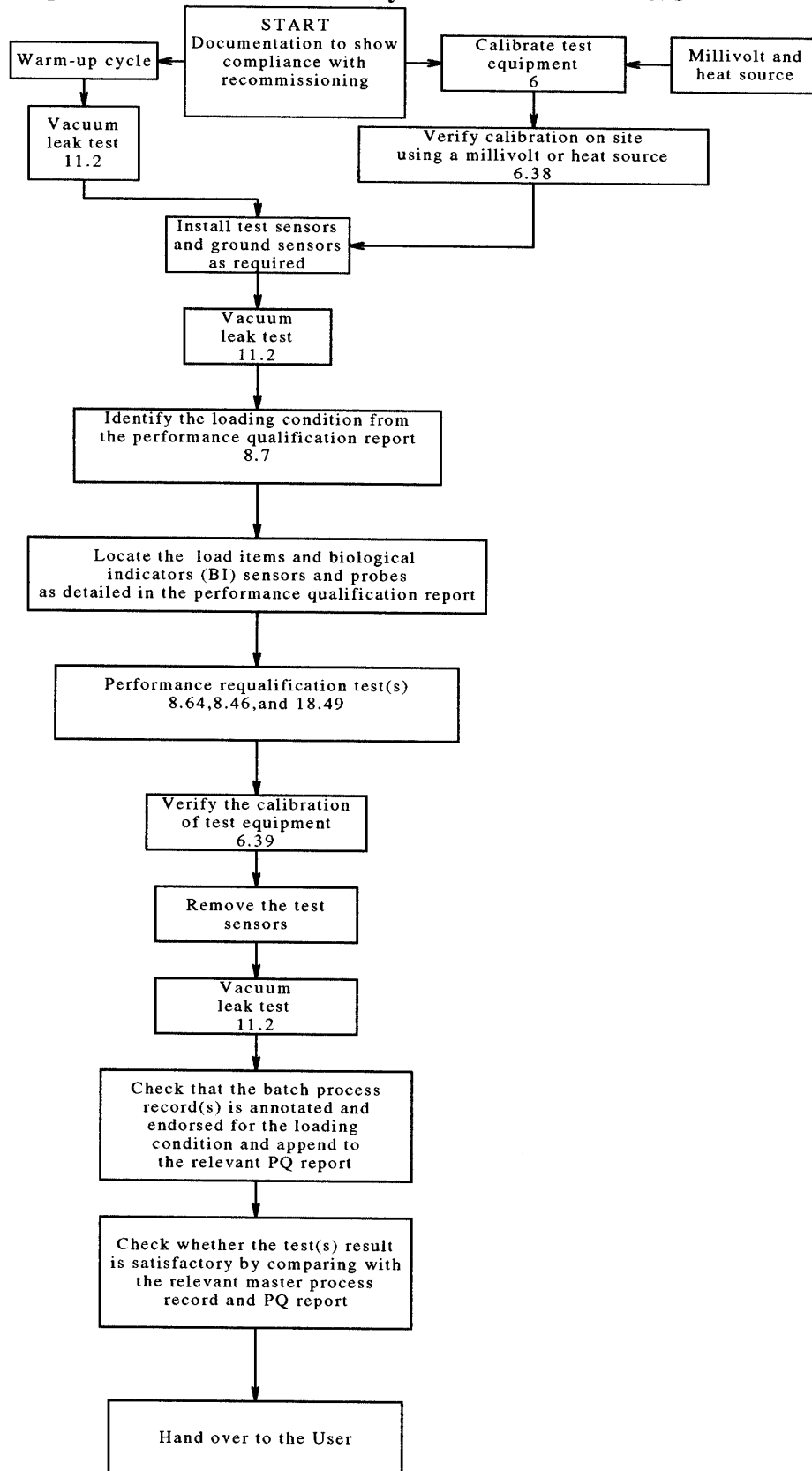


Refer to HTM 2010 part 3 for clause references

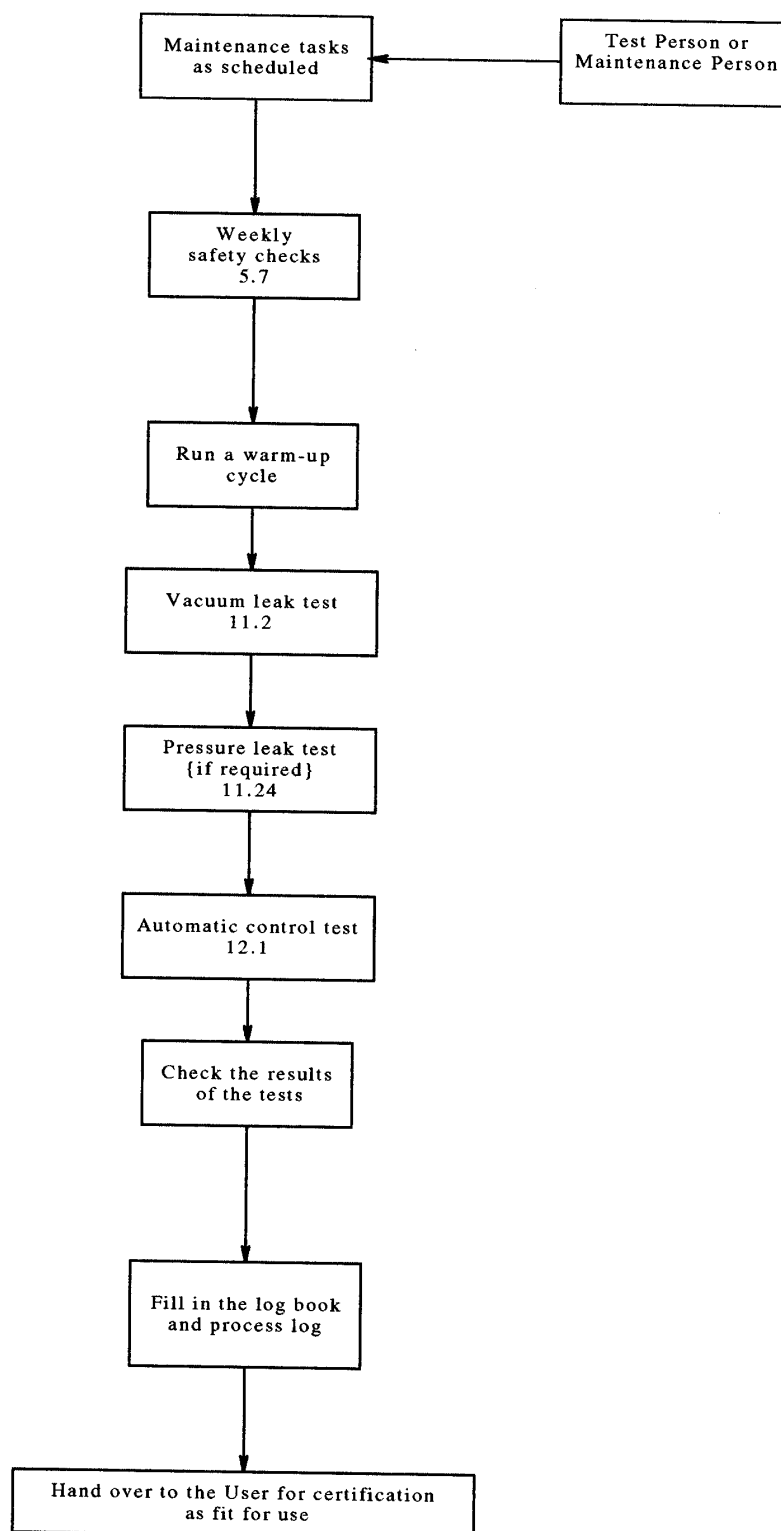
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REVALIDATION

Performance requalification tests for ethylene oxide sterilizers



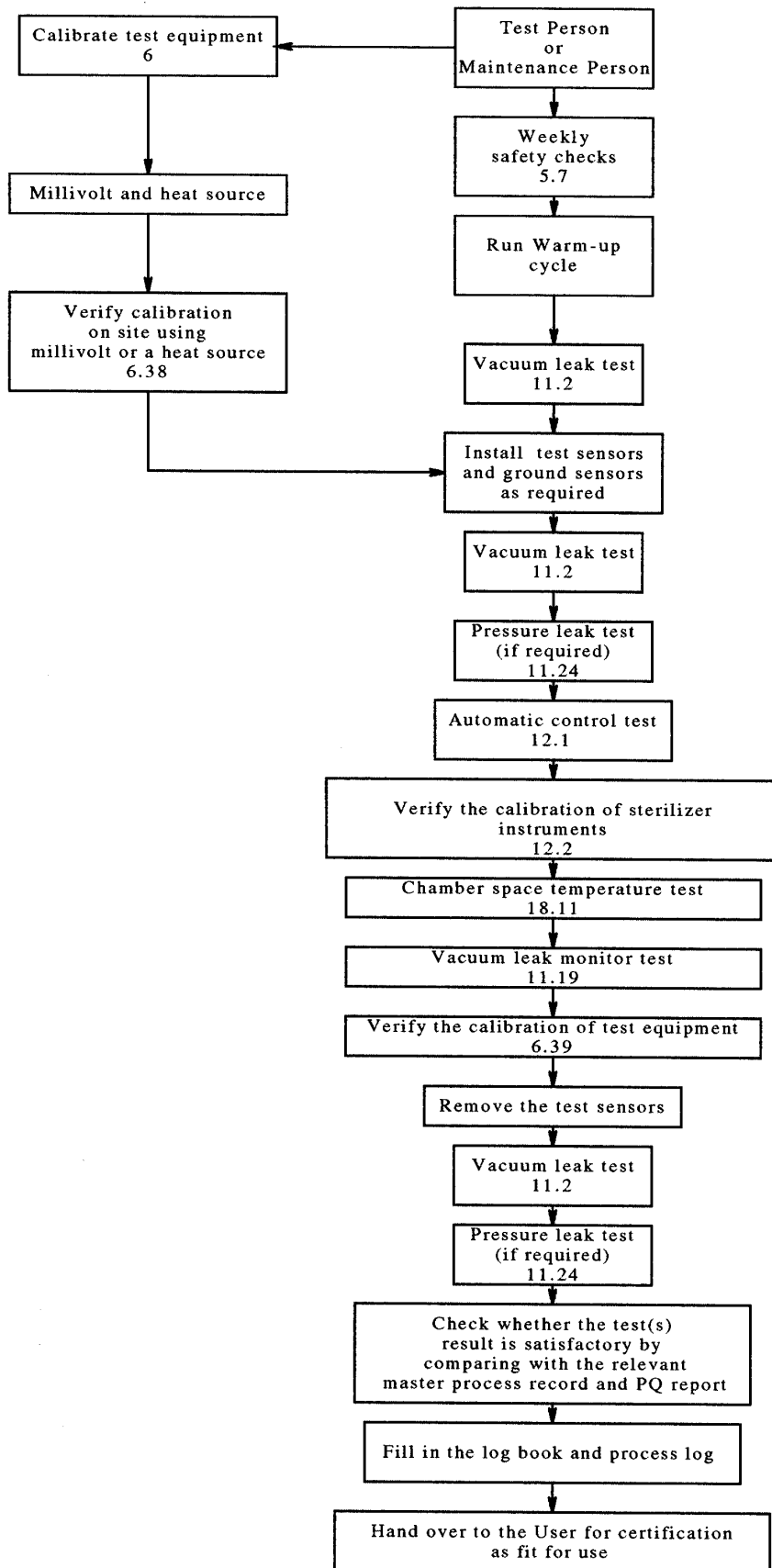
Refer to HTM 2010 part 3 for clause references

MAINTENANCE AND PERIODIC TESTING**(Ethylene oxide weekly)**

Refer to HTM 2010 part 3 for clause references

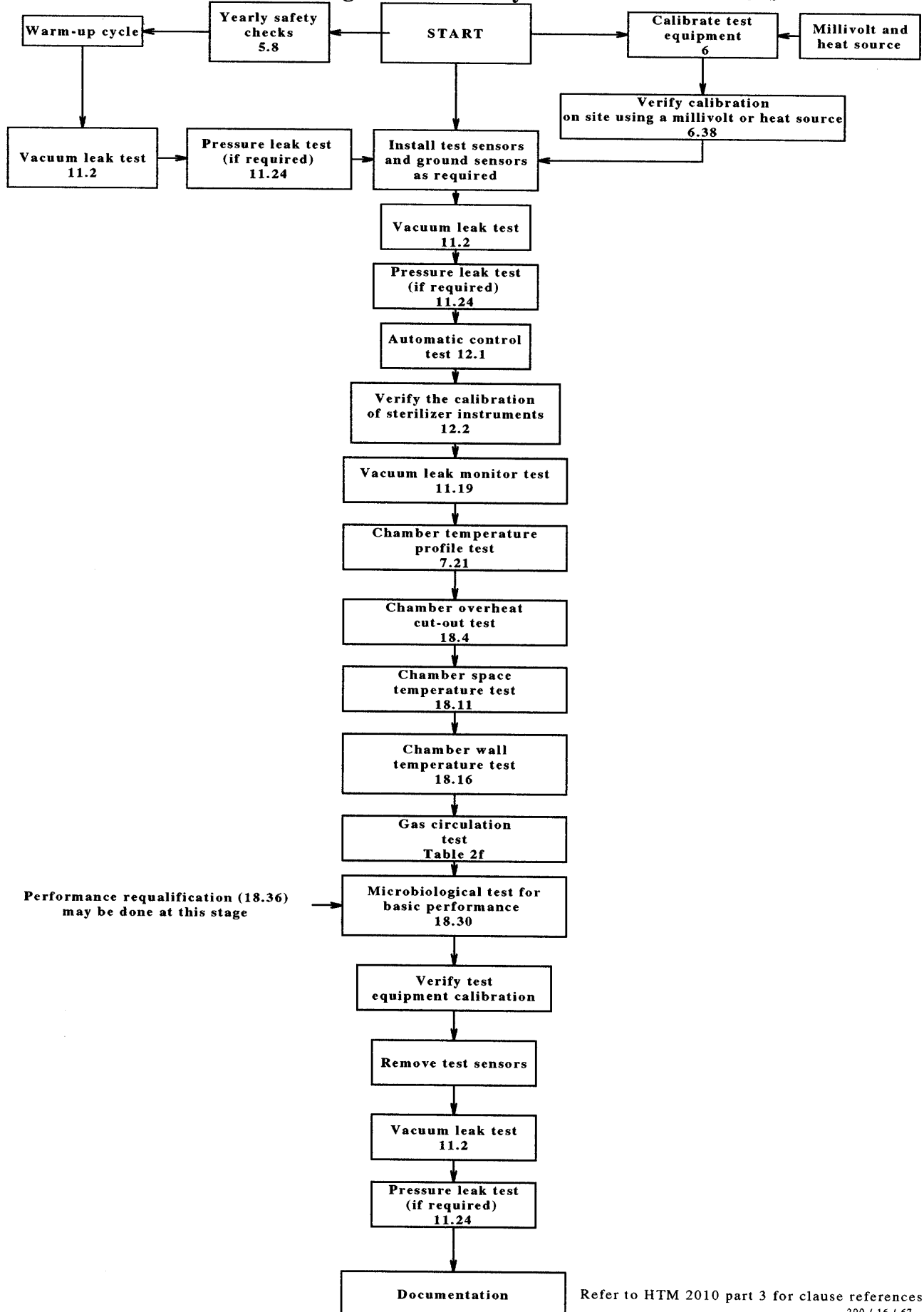
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MAINTENANCE AND PERIODIC TESTING (Ethylene oxide quarterly)



Refer to HTM 2010 part 3 for clause references

REVALIDATION (Yearly tests) Recommissioning tests for ethylene oxide sterilizers



PLANNED PREVENTATIVE MAINTENANCE

Ethylene oxide sterilizer

The User or Maintenance Person should tick each task when it has been completed

EO	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY					
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□	□	■	■
2.	Check the log book and production records together with the routine microbiological test for each production cycle. Complete as required	SMTWThFSa □□□□□□	□	■	■
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□	□	■	■
4.	Check the chamber and clean as detailed for the type of material chamber is constructed from	SMTWThFSa □□□□□□	□	■	■
5.	Check the chamber discharge strainer. Remove and clean as required	SMTWThFSa □□□□□□	□	■	■
6.	Check the door system as required by the scheme of inspection. Clean the door seal and its contact surface. Report any damage to the Maintenance Person	SMTWThFSa □□□□□□	□	■	■
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4f	SMTWThFSa □□□□□□	□	■	■
8.	Check the ethylene oxide cylinder(s) and monitoring equipment. Change as required. Report defects to the Maintenance Person	SMTWThFSa □□□□□□	□	■	■
9.	Check gauges, digital indicator(s) and indicator lamps. If faulty repair or change as required	SMTWThFSa □□□□□□	□	■	■
10.	Checks the door safety interlocks and control systems lubricate the door closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□	□	■	■
11.	Examine all pipe work connections and components for leaks. Repair as required	SMTWThFSa □□□□□□	□	■	■
12.	Examine the door seal(s). Replace if damaged	SMTWThFSa □□□□□□	□	■	■
13.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□	□	■	■
14.	Carry out weekly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	SMTWThFSa □□□□□□	□	■	■
15.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH THE USER	SMTWThFSa □□□□□□	□	■	■
16.	Daily tests Satisfactory ✓ Not satisfactory ✗ Weekly tests Satisfactory ✓ Not satisfactory ✗	SMTWThFSa □□□□□□	□	■	■
17.	Complete the log book.	SMTWThFSa □□□□□□	□	■	■
18.	Report on completion and notify the user of any defect or safety hazard. Complete service records. Hand over to User	SMTWThFSa □□□□□□	□	■	■

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at the frequency indicated by ■ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE

Ethylene oxide sterilizer

The Maintenance Person should tick each task when it has been completed

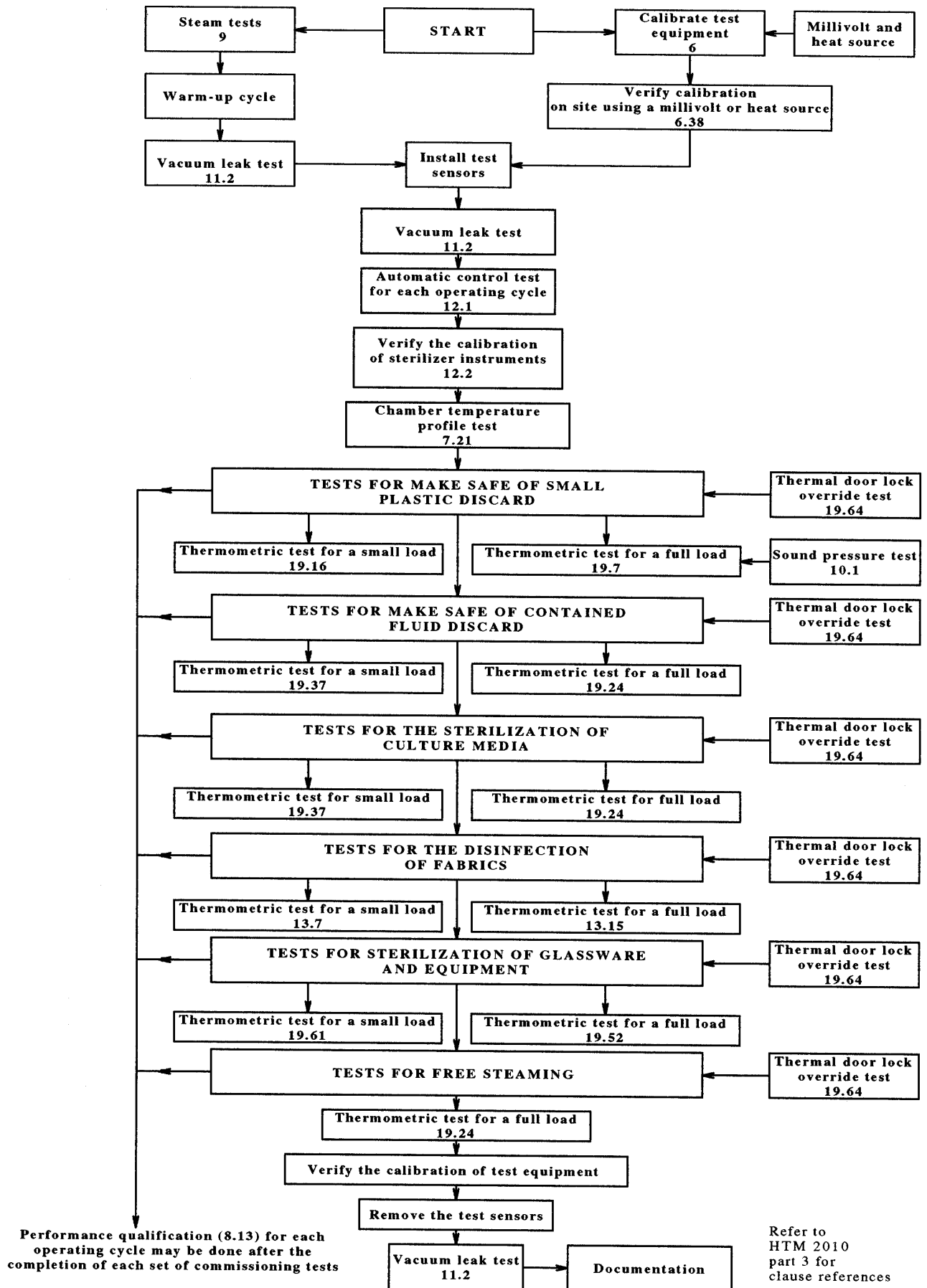
EO	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q = QUARTERLY Y = YEARLY INTERVALS					
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check the gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Checks the door safety interlocks and control systems as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check.	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Examine the heat exchanger and the discharge vent from the chamber	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Check electrical connections for security	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the temperature sensor(s), humidity sensor(s), and the pressure sensor(s) and recorder recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
18.	Refit all covers, and note the cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete the log book and summary sheets	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the user.	●	●	●	●

Tasks to be undertaken at frequency indicated by ● and as appropriate by
User, Microbiologist, Maintenance Person, Manufacturer, Service contractor

Operational procedures – Laboratory sterilizers

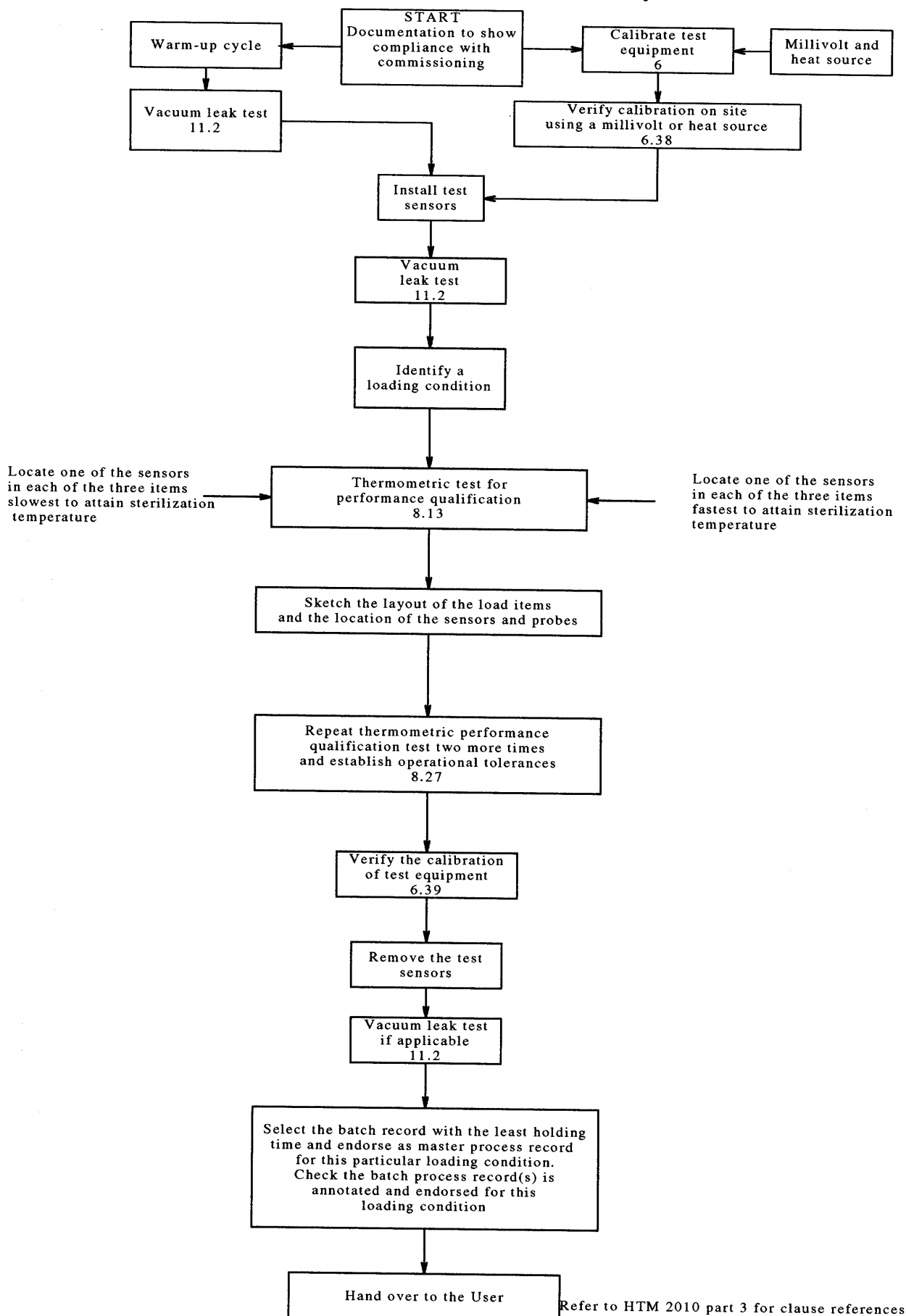
VALIDATION

Commissioning tests for laboratory sterilizers



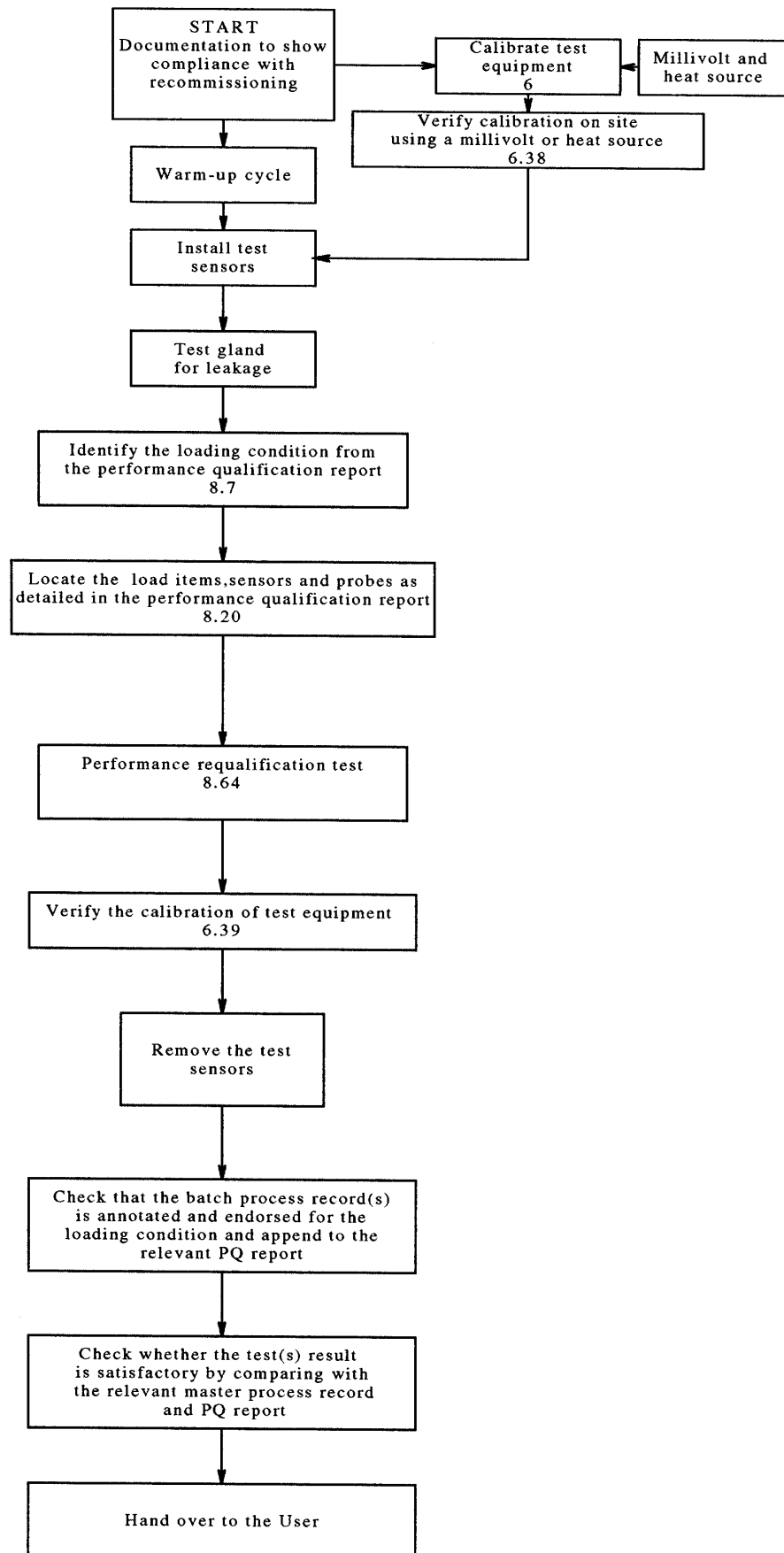
VALIDATION

Performance qualification test(s) for laboratory sterilizers



REVALIDATION

Performance requalification tests for laboratory sterilizers

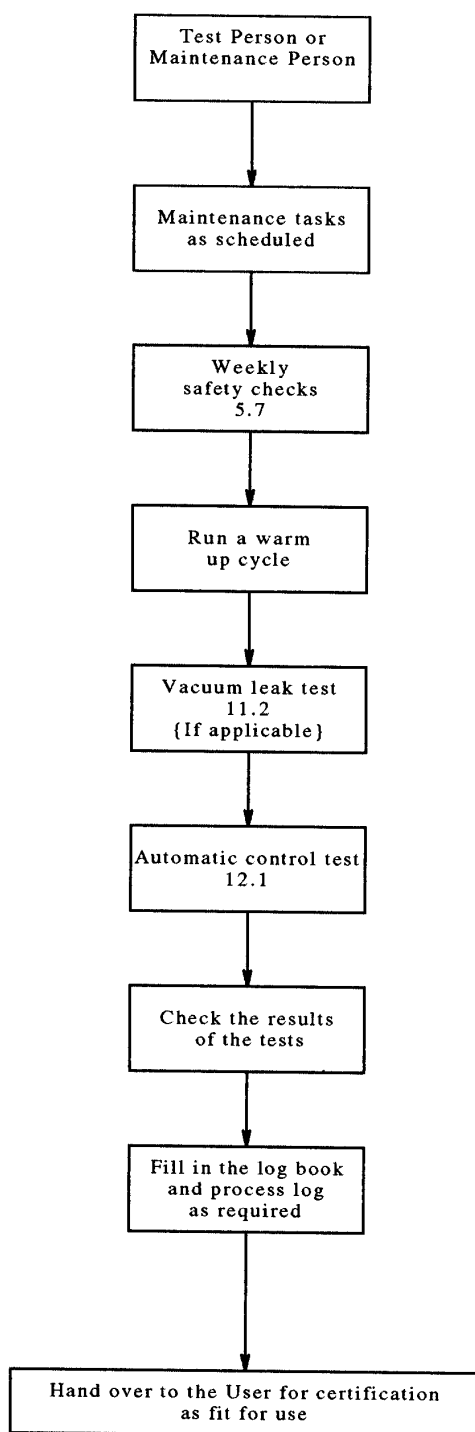


Refer to HTM 2010 part 3 for clause references

200 / 16 / 73

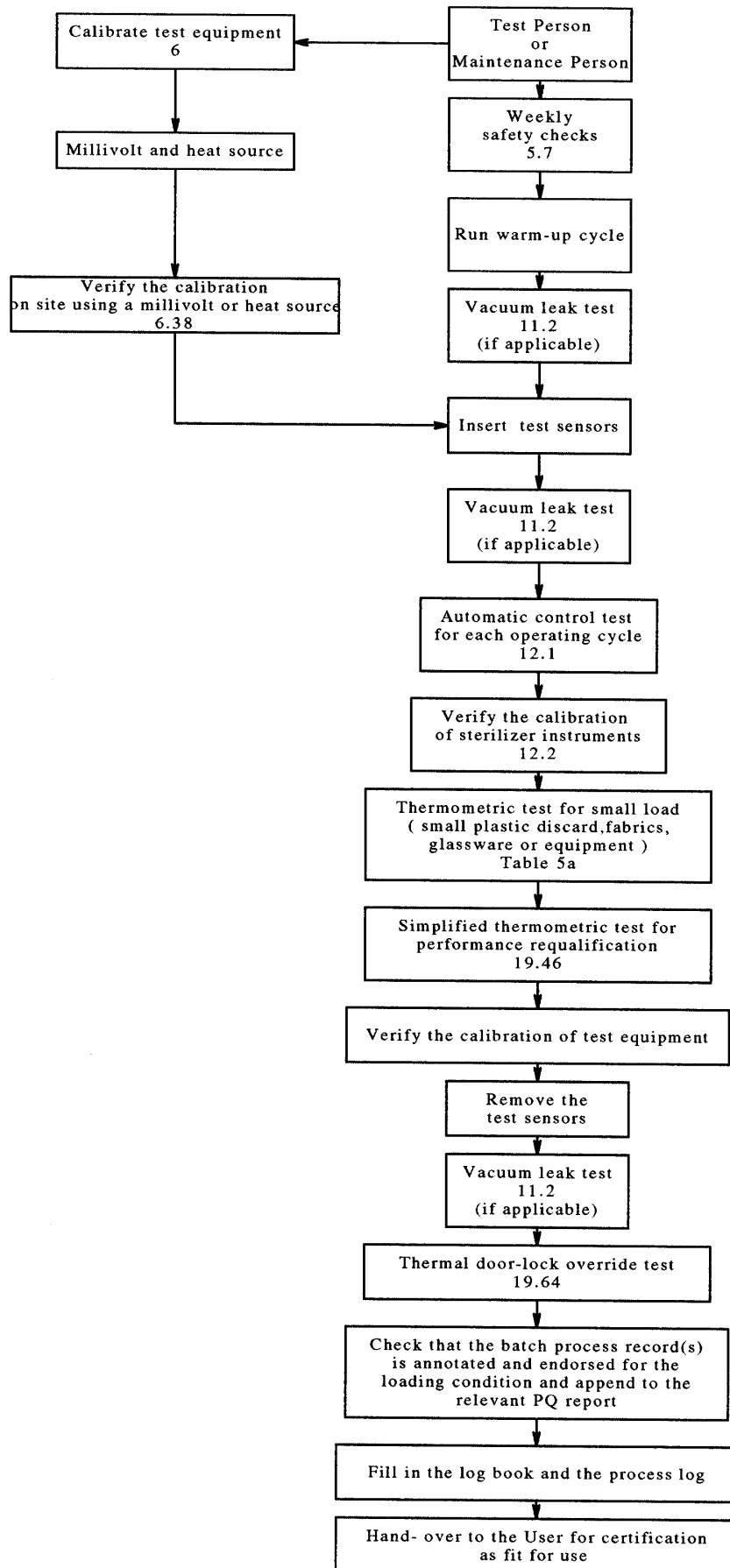
MAINTENANCE AND PERIODIC TESTING

(Laboratory sterilizers weekly)



Refer to HTM 2010 part 3 for clause references

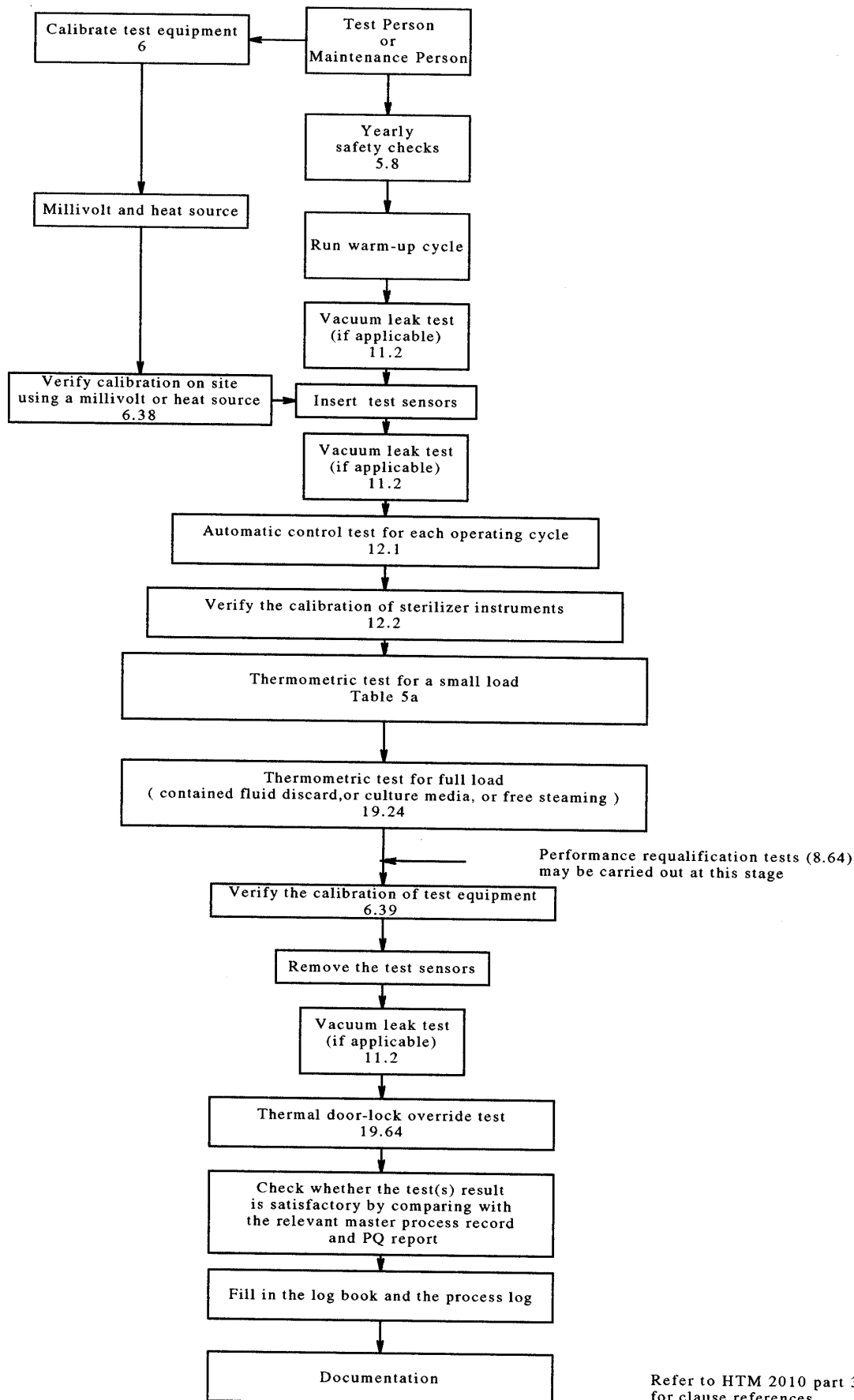
MAINTENANCE AND PERIODIC TESTING (Laboratory sterilizers quarterly)



Refer to HTM 2010
part 3 for clause references

200 / 16 / 75

REVALIDATION (Yearly tests) (Recommissioning tests for laboratory sterilizers)



Refer to HTM 2010 part 3
for clause references

PLANNED PREVENTATIVE MAINTENANCE

Laboratory sterilizer

The User or Maintenance Person should tick task when it has been completed

LAB		MAINTENANCE SCHEDULES			
D = DAILY W = WEEKLY		D	W		
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		✓✓✓✓✓✓✓	✓	U	M
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2.	Check the log book and production records. Complete as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4.	Check the chamber and clean as detailed for the type of material the chamber is constructed from	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5.	Check the chamber discharge strainer. Remove and clean as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6.	Check the door system as required by the scheme of inspection Clean the door seal and its contact surface	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7.	First production cycle each day observe and note readings in the log book of holding time and gauge readings as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8.	Replace faulty indicator lamps	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.	Check gauges and digital indicator(s). If faulty report and repair or change as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.	Check the door safety interlocks and control systems lubricate the door closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11.	Examine all pipe work connections and components for leaks. Repair as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12.	Examine door seal(s). Replace if damaged	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
14.	Carry out weekly maintenance tasks and check vessel in accordance with the scheme of inspection and manufacturer's instructions	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED INSPECT THE RECORDS WITH THE USER AND QUALITY CONTROLLER	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
16.	Weekly tests Satisfactory ✓ Not satisfactory ✗	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.	Complete the log book. Check the batch process record(s) for compliance with the master process record(s).	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to User	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

User, Microbiologist, Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by ☒ U = User M = Maintenance person

PLANNED PREVENTATIVE MAINTENANCE

Laboratory sterilizer

The Maintenance Person should tick each task when it has been completed

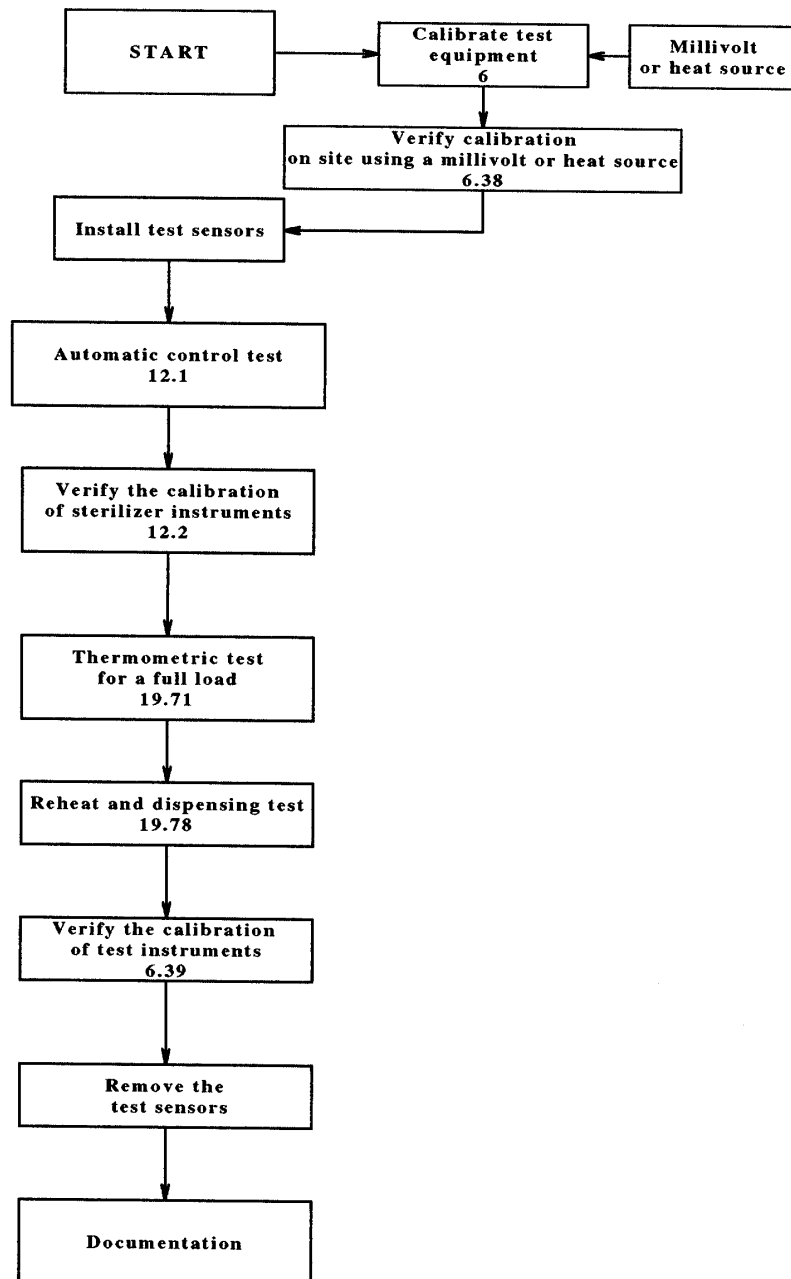
EO	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
<i>Q = QUARTERLY</i> <i>Y = YEARLY INTERVALS</i>					
Service the following items within the contract and at frequency indicated. Check for safe operation		✓	✓	✓	✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
3.	Check gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
4.	Examine the door seal(s) and replace if damaged	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
5.	Examine the door closure mechanism and lubricate	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
6.	Check the door safety interlocks and control systems as required by the scheme of inspection	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks. Repair as required	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
8.	Weekly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
9.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
10.	Safety valve check	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
11.	Check heat exchanger(s) services filters and vents. Test as required or replace	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
12.	Check electrical connections for security	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
13.	Examine timers and check their settings	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/>
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
16.	Check the temperature sensor(s) and recorder and recalibrate if necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
17.	Carry out yearly tests in accordance with HTM 2010 Part 3				<input type="checkbox"/> ●
18.	Refit all covers and note the cycle count number	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
19.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S) AS REQUIRED	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
20.	Weekly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
21.	Quarterly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
22.	Yearly Satisfactory ✓ Not satisfactory ✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> ●
23.	Complete the log book and summary sheets. Check the batch process records for compliance with the master process record	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●	<input type="checkbox"/> ●
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the user.	●	●	●	●

Tasks to be undertaken at frequency indicated by ● and as appropriate by the User, Maintenance Person, Manufacturer, Service contractor

Operational procedures – Cultural media preparator

VALIDATION

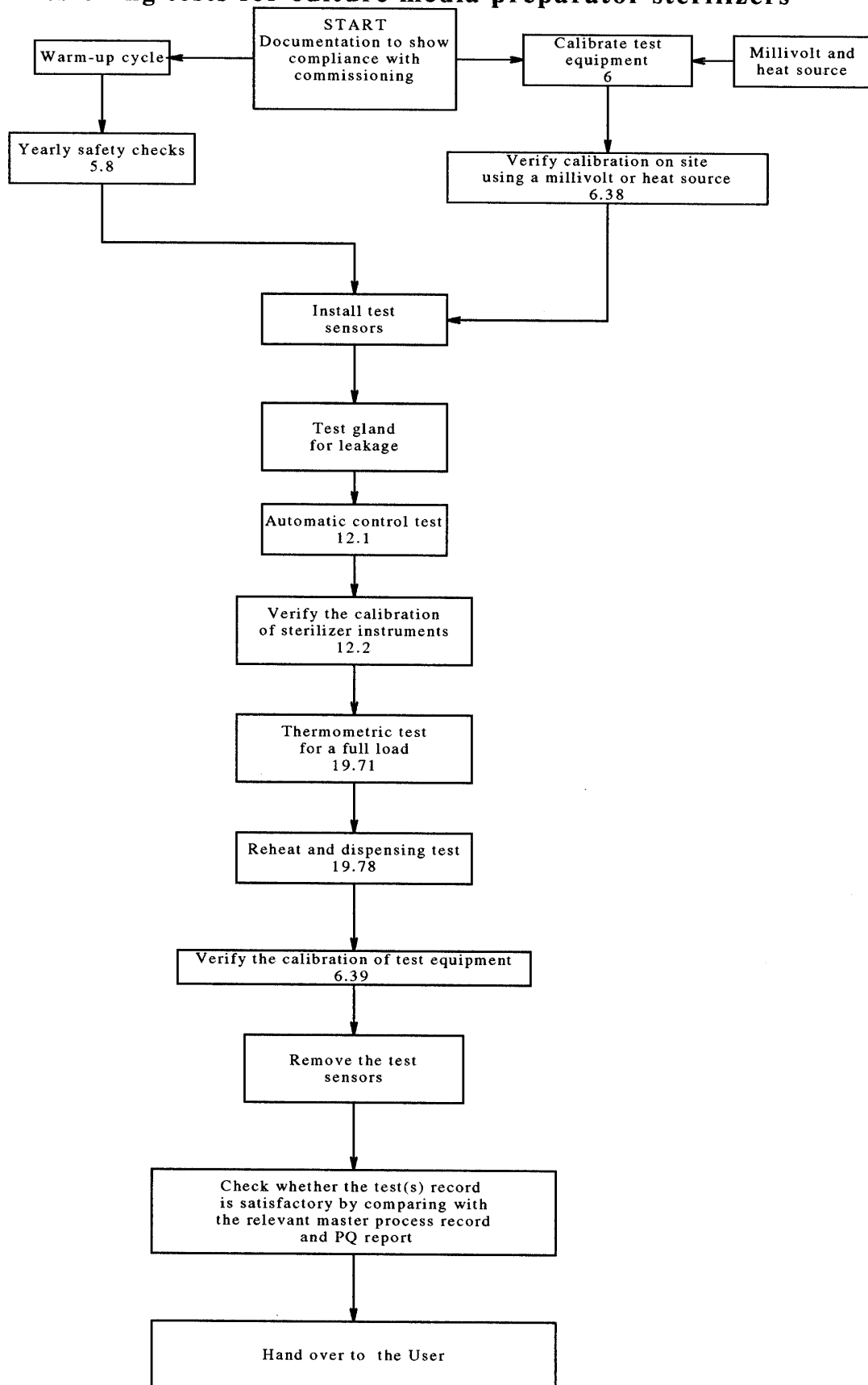
Commissioning tests for culture media preparator sterilizers



Refer to HTM 2010 part 3 for clause references

REVALIDATION (Yearly tests)

Recommissioning tests for culture media preparator sterilizers



Refer to HTM 2010 part 3 for clause references

PLANNED PREVENTATIVE MAINTENANCE**Culture media preparator sterilizer**

The User should tick each task when it has been completed

CMP		MAINTENANCE SCHEDULES			
D = DAILY W = WEEKLY		D	W	D	W
Service the following items within the contract and at the frequency indicated. Check for safe operation and correct readings		✓✓✓✓✓✓✓	✓	U	U
1.	Check all sterilizer services are turned on and correct readings are indicated on controls and gauges	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2.	Check the log book and production records. Complete as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4.	Check the chamber and clean as detailed for the type of material the chamber is constructed from	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
5.	Check the chamber discharge port. Remove and clean as required	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6.	Check the lid seal and wipe and clean its contact surface. Report any damage to Maintenance Person Sterilizers	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7.	Indicator lamps report if faulty to the Maintenance Person	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
8.	Check gauges and digital indicator(s). If faulty report to the Maintenance Person	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
9.	Check the lid and door safety interlocks and control systems lubricate the lid closure mechanism as required by the scheme of inspection	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
10.	Examine all pipe work connections and components for leaks and additive ports for sealing. Report to Maintenance Person if faulty	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
11.	Examine door seal(s) replace if damaged	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
12.	Weekly safety checks as per HTM 2010 Part 3	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
13.	Carry out weekly maintenance tasks and check vessel in accordance with the scheme of inspection and manufacturer's instructions	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
14.	Weekly tests Satisfactory ✓ Not satisfactory X	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>
15.	Complete the processing log book. Check the batch process record(s) for compliance with master process record(s)	SMTWThFSa □□□□□□□	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
16.	Notify the User and Maintenance Person of any defect or safety hazard. Complete the records Hand over to the User	SMTWThFSa □□□□□□□	<input type="checkbox"/>		<input checked="" type="checkbox"/>

User, Quality ControllerTasks to be undertaken at frequency indicated by ☒ U = User

PLANNED PREVENTATIVE MAINTENANCE**Culture media preparator sterilizer**

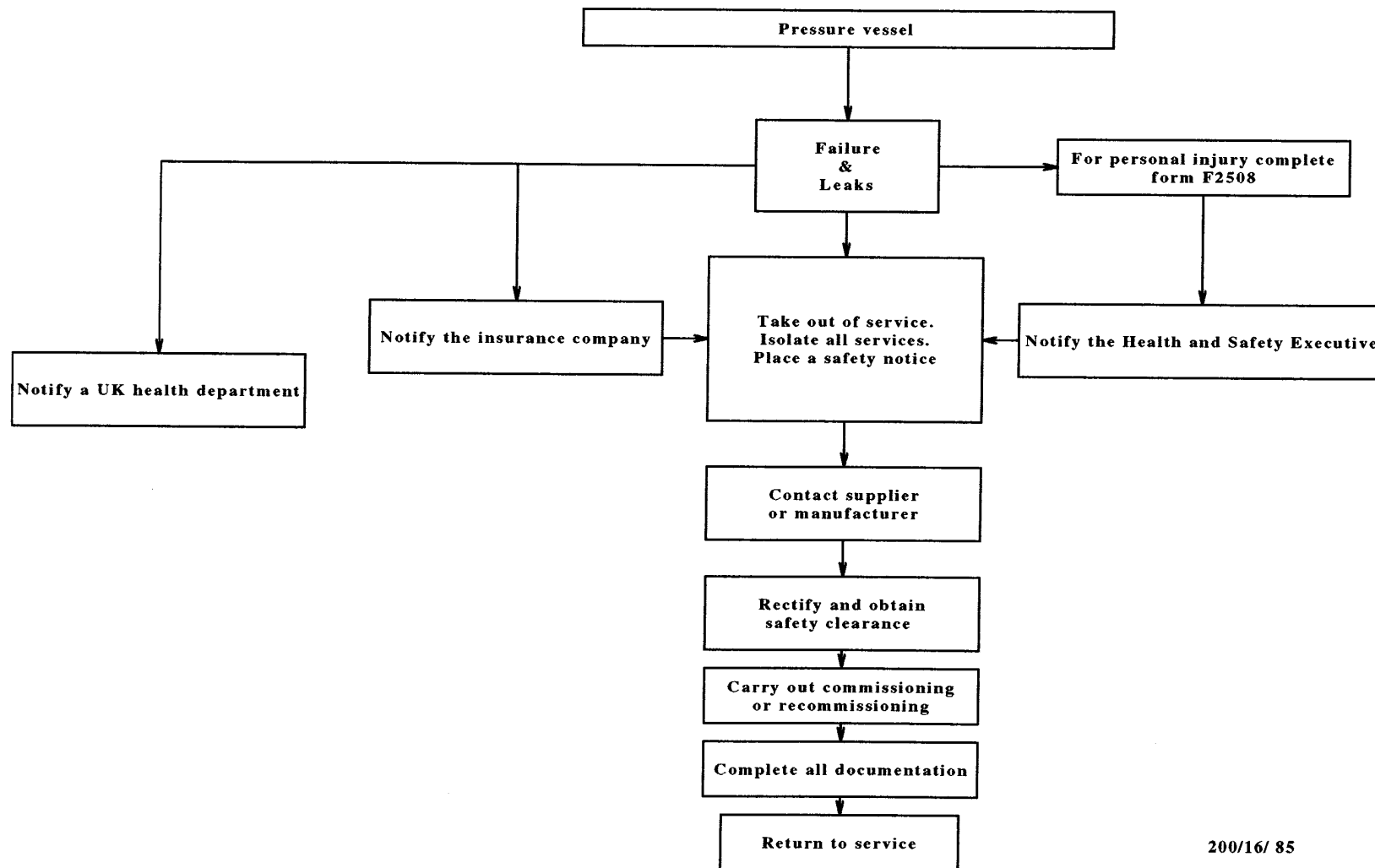
The Maintenance Person should tick each task when it has been completed

CMP	MAINTENANCE SCHEDULES	Y
<i>Y = YEARLY INTERVALS</i>		
Service the following items within the contract and at the frequency indicated. Check for safe operation		✓
1.	Check fuses and connections on the electrical mains	<input type="checkbox"/> ●
2.	Replace faulty indicator lamps	<input type="checkbox"/> ●
3.	Check gauges and their calibration. Recalibrate as required	<input type="checkbox"/> ●
4.	Examine the lid seal(s) and replace if damaged	<input type="checkbox"/> ●
5.	Examine safety lids and door closure mechanism and lubricate	<input type="checkbox"/> ●
6.	Check the door safety interlocks and control systems as required by the scheme of inspection	<input type="checkbox"/> ●
7.	Examine all pipe work connections and components for leaks and additive ports seal. Repair as required	<input type="checkbox"/> ●
8.	Yearly safety checks as HTM 2010 Part 3	<input type="checkbox"/> ●
9.	Safety valve check	<input type="checkbox"/> ●
10.	Check heat exchanger(s) service filters, and vents Test as required or replace	<input type="checkbox"/> ●
11.	Check electrical connections for security	<input type="checkbox"/> ●
12.	Examine timers and check their settings	<input type="checkbox"/> ●
13.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions	<input type="checkbox"/> ●
14.	Check the temperature sensor(s) and recorder and recalibrate if necessary	<input type="checkbox"/> ●
15.	Carry out yearly tests in accordance with HTM 2010 Part 3	<input type="checkbox"/> ●
16.	Refit all covers and note the cycle count number	<input type="checkbox"/> ●
17.	CARRY OUT PERIODIC AND AUTOMATIC CONTROL TEST(S)	<input type="checkbox"/> ●
18.	Yearly Satisfactory ✓ Not satisfactory X	<input type="checkbox"/> ●
19.	Complete the process log book. Check the batch process records for compliance with master process record	<input type="checkbox"/> ●
20.	Notify the user of any defect or safety hazard. Complete service the records. Hand over to the user	●

Tasks to be undertaken at the frequency indicated by ● and as appropriate by the Maintenance Person, Manufacturer, Service contractor

Corrective action – Sterilizers

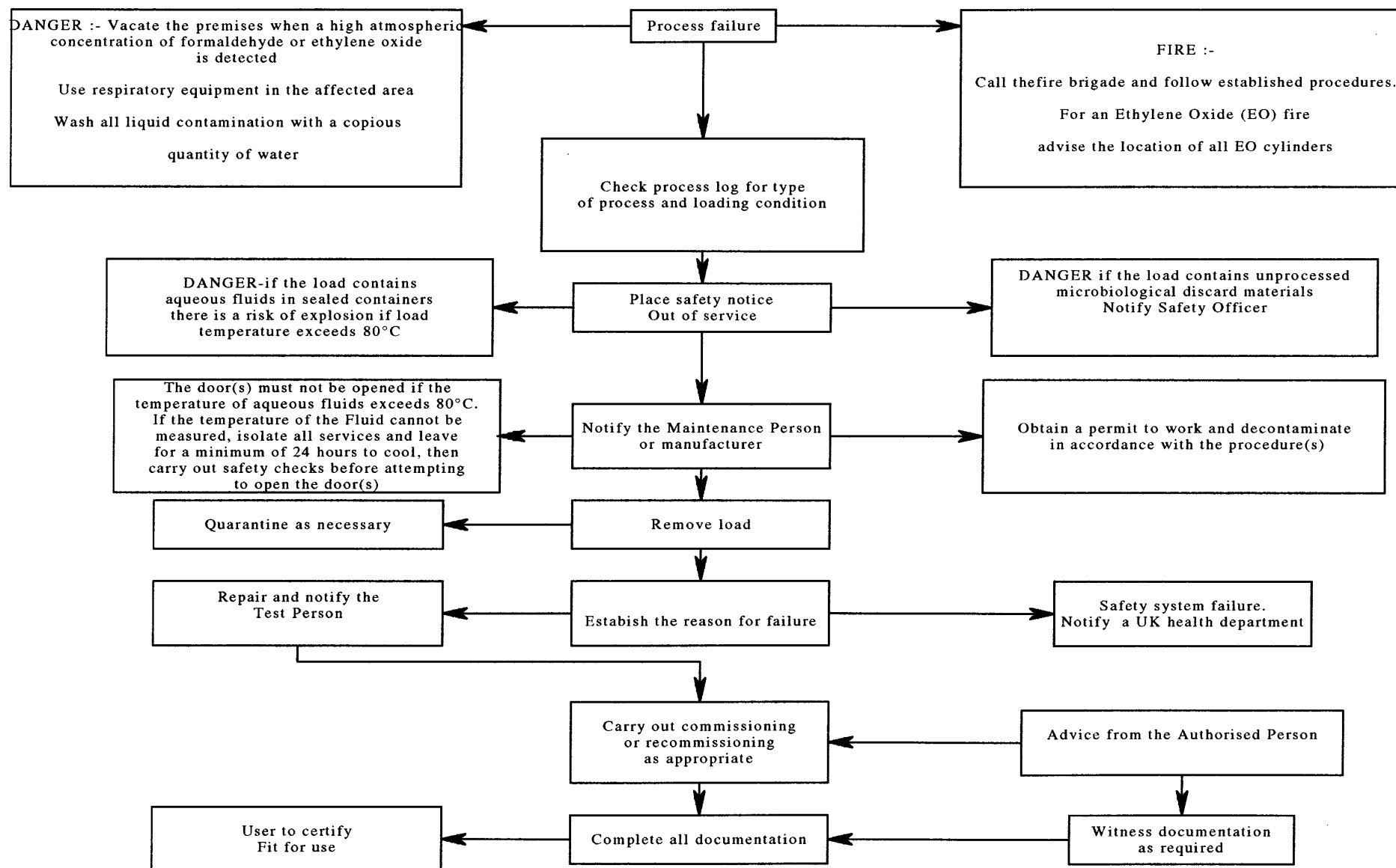
Sterilization
Corrective action after the failure of a pressure vessel



200/16/ 85

Sterilization

Corrective action after a process failure



About NHS Estates

NHS Estates is an Executive Agency of the Department of Health and is involved with all aspects of health estate management, development and maintenance. The Agency has a dynamic fund of knowledge which it has acquired during over 30 years of working in the field. Using this knowledge NHS Estates has developed products which are unique in range and depth. These are described below. NHS Estates also makes its experience available to the field through its consultancy services.

Enquiries about NHS Estates should be addressed to:
NHS Estates, Publications Unit, Department of Health,
1 Trevelyan Square, Boar Lane, Leeds LS1 6AE.
Telephone 0113 254 7000.
<http://www.nhsestates.gov.uk>

Some NHS Estates products

Activity DataBase – a computerised briefing and design system for use in health buildings, applicable to both new build and refurbishment schemes. *NHS Estates*

Design Guides – complementary to Health Building Notes, Design Guides provide advice for planners and designers about subjects not appropriate to the Health Building Notes series. *SO*

Estatecode – user manual for managing a health estate. Includes a recommended methodology for property appraisal and provides a basis for integration of the estate into corporate business planning. *SO*

Concode – outlines proven methods of selecting contracts and commissioning consultants. Reflects official policy on contract procedures. *SO*

Works Information Management System – a computerised information system for estate management tasks, enabling tangible assets to be put into the context of servicing requirements. *NHS Estates*

Health Building Notes – advice for project teams procuring new buildings and adapting or extending existing buildings. *SO*

Health Guidance Notes – an occasional series of publications which respond to changes in Department of Health policy or reflect changing NHS operational management. Each deals with a specific topic and is complementary to a related HTM. *SO*

Health Technical Memoranda – guidance on the design, installation and running of specialised building service systems, and on specialised building components. *SO*

Health Facilities Notes – debate current and topical issues of concern across all areas of healthcare provision. *SO*

Encode – shows how to plan and implement a policy of energy efficiency in a building. *SO*

Firecode – for policy, technical guidance and specialist aspects of fire precautions. *SO*

Capital Investment Manual Database – software support for managing the capital programme. Compatible with Capital Investment Manual. *NHS Estates*

Model Engineering Specifications – comprehensive advice used in briefing consultants, contractors and suppliers of healthcare engineering services to meet Departmental policy and best practice guidance. *NHS Estates*

Quarterly Briefing – gives a regular overview on the construction industry and an outlook on how this may affect building projects in the health sector, in particular the impact on business prices. Also provides information on new and revised cost allowances for health buildings. Published four times a year; available on subscription direct from NHS Estates. *NHS Estates*

Items noted “SO” can be purchased from The Stationery Office Bookshops in London (post orders to PO Box 276, SW8 5DT), Edinburgh, Belfast, Manchester, Birmingham and Bristol or through good booksellers.

NHS Estates consultancy service

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