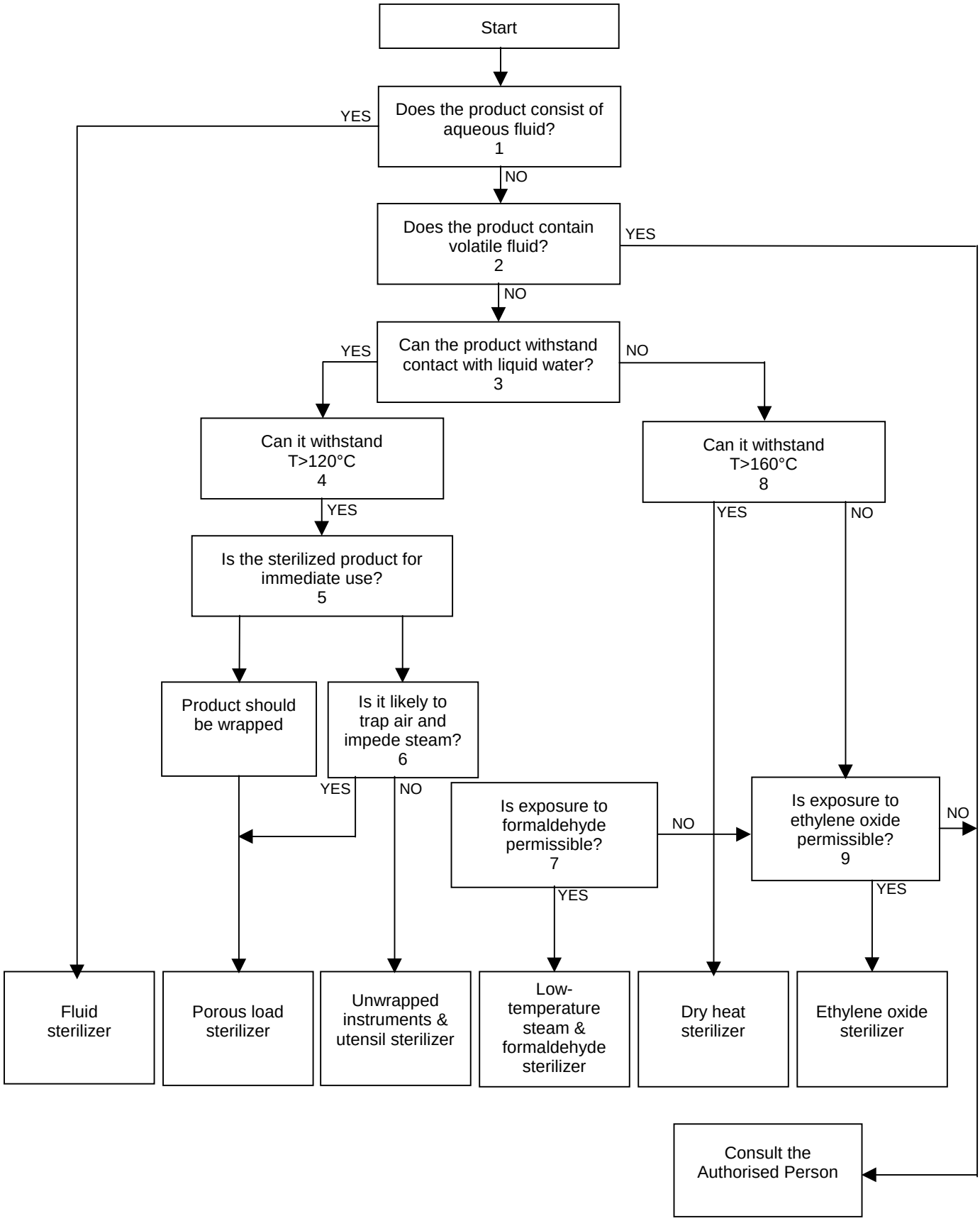
Figure 1: A guide for the selection of a sterilization process



e. a defective air detector.

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

Wet loads

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

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

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

b. severe pressure fluctuations in the main;

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

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

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

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

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

Superheating

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

5.48 One possible cause of superheating is an excessive reduction in pressure through a throttling device, such as a pressure reducing system or a partially closed main steam valve. In this case superheating arises from adiabatic expansion. Engineering solutions to this problem are described in Part 2 of this SHTM.

5.49 Superheat can also arise if the steam is admitted into the chamber with excessive velocity. This problem is usually detected and overcome during commissioning, by fitting a throttling device in or over the steam inlet port with some modifications to the baffle plate assembly.

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

Spontaneous combustion

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

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

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

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

6. Operation of fluid sterilizers

Introduction

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

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

The process

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

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

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

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

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

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

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

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

Safety precautions

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

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

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

6.9 Operating cycles for plastic containers have the following modifications:

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

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

Product compatibility

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

Items that should not be processed in a fluid sterilizer

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

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

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

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

Design of the load

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

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

Bottles

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

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

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

Plastic bags

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

Vials and ampoules

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

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

Closure systems

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

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

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

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

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

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

Performance qualification

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

6.27 PQ tests are required where:

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

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

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

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

Selection of cycle variables

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

Table 6: Sterilization conditions for fluid sterilizers

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

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

Cycle monitoring and documentation

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

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

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

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

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

c. the temperature (“load temperature”) recorded by the load temperature probe.

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

Product release

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

6.36 The load may be released for use provided that:

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

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

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

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

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

7. Operation of sterilizers for unwrapped instruments and utensils

Introduction

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

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

The process

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

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

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

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

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

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

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

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

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

Water supply

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

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

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

Safety precautions

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

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

Product compatibility

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

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

surgical instruments. The Authorised Person should be consulted in cases of doubt.

Items that should not be processed

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

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

b. medicinal products;

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

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

e. items not for immediate use.

Design of the load

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

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

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

Selection of cycle variables

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

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

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

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

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

b. See paragraph 7.19.

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

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

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

Cycle monitoring and documentation

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

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

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

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

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

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

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

7.25 The load may be released for use provided that:

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

b. *or*, during the plateau period:

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

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

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

8. Operation of dry-heat sterilizers

Introduction

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

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

The process

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

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

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

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

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

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

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

Safety precautions

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

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

Product compatibility

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

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

Items that should not be processed by dry heat

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

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

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

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

Design of the load

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

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

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

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

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

Load preparation and packaging

8.14 All items must be clean and dry before sterilization.

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

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

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

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

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

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

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

Arrangement of load items

8.22 Random loading is not acceptable.

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

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

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

Performance qualification

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

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

Selection of cycle variables

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

Table 8: Sterilization conditions for dry-heat sterilizers

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

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

Cycle monitoring and documentation

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

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

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

8.33 The batch process record will contain the following:

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

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

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

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

Product release

8.34 The load may be released for use provided that:

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

b. the packaging is undamaged.

9. Operation of LTS disinfectors

Introduction

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

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

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

The process

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

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

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

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

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

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

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

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

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

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

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

Safety precautions

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

Product compatibility

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

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

Items which should not be processed by LTS

9.11 The following items should not be processed by LTS:

a. items requiring sterilization;

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

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

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

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

Design of the load

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

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

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

Air removal

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

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

Handling of condensate

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

Packaging materials

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

Selection of cycle variables

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

Cycle monitoring and documentation

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

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

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

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

Product release

9.20 The load may be released for use provided that:

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

b. the packaging is undamaged;

c. the load items are visibly dry.

10. Operation of LTSF sterilizers

Introduction

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

NOTE: Despite their name, LTSF sterilizers are disinfectors.

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

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

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

The process

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

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

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

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

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

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

d. Sterilization.

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

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

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

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

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

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

Formaldehyde solution

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

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

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

Polymerisation

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

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

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

Safety precautions

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

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

Effects on health

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

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

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

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

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

Replenishing the formalin supply

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

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

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

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

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

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

c. Take the formalin bottle from the storage cupboard.

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

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

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

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

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

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

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

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

Product compatibility

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

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

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

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

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

Items which should not be processed by LTSF

10.29 The following items should not be processed by LTSF:

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

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

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

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

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

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

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

Design of the load

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

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

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

Air removal

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

Handling of condensate

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

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

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

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

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

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

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

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

Packaging materials

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

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

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

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

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

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

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

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

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

Performance qualification

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

Selection of cycle variables

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

10.46 Other cycle variables are preset by the manufacturer.

Cycle monitoring and documentation

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

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

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

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

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

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

Product release and storage

10.51 The load may be released for degassing provided that:

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

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

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

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

e. the packaging is undamaged;

f. the load items are visibly dry.

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

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

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

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

Troubleshooting

Cycle fault

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

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

b. failure to attain the sterilization temperature;

c. insufficient formalin for a complete cycle.

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

Failure of the routine microbiological test

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

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

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

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

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

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

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

Polymerisation of formaldehyde

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

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

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

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

11. Operation of ethylene oxide sterilizers

Introduction

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

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

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

The process

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

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

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

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

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

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

11.8 The operating cycle of an EO sterilizer constructed to BS 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.

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

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

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

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

Safety precautions

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

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

Product compatibility

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

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

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

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

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

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

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

Items that should not be processed by ethylene oxide

11.18 The following items should not be processed by EO:

a. items that could be sterilized by another process;
b. items which may be damaged by the conditions of temperature, pressure and chemical environment prevailing during the cycle;
c. medicinal products;
d. ventilatory and respiratory equipment;
e. soiled items;
f. plastic items previously sterilized by radiation;
g. items which may absorb and retain unacceptable quantities of EO residuals.

Design of the load

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

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

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

11.22 Because of the need to control humidity, the extent to which packaging absorbs moisture may have a major influence on the efficacy of the process

and must be considered before a satisfactory humidification stage can be demonstrated.

11.23 Process control is also a concern since packaging material that has become dehydrated may absorb excessive moisture during the conditioning phase; if this possibility were not recognised during validation the achieved cycle lethality may be adversely affected.

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

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

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

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

Performance qualification

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

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

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

Preconditioning

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

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

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

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

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

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

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

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

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

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

Selection of cycle variables

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

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

Cycle monitoring and documentation

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

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

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

c. time of commencement of the operating cycle;

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

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

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

g. duration of the gas exposure time;

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

i. the results of the routine microbiological test.

11.43 A routine microbiological test should be carried out with every production load as described in Part 3 of this SHTM. Note that the full result of the test

will not be known until the biological indicators have been cultured for 7 days.

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

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

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

Chamber humidity

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

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

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

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

EO concentration

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

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

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

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

11.49 Where a sterilizer is supplied from a disposable cartridge, it can be assumed that the entire contents of the cartridge are released into the chamber. However, it should not be assumed that the mass of the contents corresponds precisely to the manufacturer's stated value. As a matter of

routine, the cartridge should be weighed immediately before it is placed in the sterilizer and after it has been removed to establish the mass of gas consumed, and the results noted in the sterilizer process log.

Product release

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

a. the preconditioning records are satisfactory;

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

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

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

e. the packaging is undamaged;

f. load items are visibly dry.

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

Degassing

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

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

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

11.55 Reduction of residual EO occurs naturally as gas diffuses from the product into the surrounding air down the concentration gradient. Under normal ambient conditions this process may be very slow and significant amounts of EO may be present in the environment. For these reasons degassing by

storage under ambient conditions is not recommended; mechanical degassing should be used.

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

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

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

c. the temperature at which degassing takes place;

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

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

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

Troubleshooting

Failure of the routine microbiological test

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

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

   (i) Insufficient EO was admitted. This would normally lead to a fault indication and would be revealed by inspection of the chamber pressure record and the secondary method (mass or volume, see paragraph 11.48).

   (ii) Some of the EO was polymerised. Green streaks on the chamber walls near the inlet port suggest that liquid EO entered the chamber. The preheater should be checked.

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

b. The humidity in the chamber was either too high or too low. Humidity is critical to the operation of EO sterilizers and even small deviations from the ideal level can have large effects on the efficacy of the cycle. Incorrect humidity is the single most common cause of failure. If the preconditioning records are satisfactory, suspicion should fall on the sterilizer humidifying system.

c. The loading condition is too great a challenge to the penetration of EO. This is unlikely if performance qualification has been satisfactory.