TECHNICAL SPECIFICATION

ISO/TS 17665-2

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Sterilization of health care products — Moist heat —

Part 2: Guidance on the application of ISO 17665-1

Stérilisation des produits de santé — Chaleur humide —

Partie 2: Directives relatives à l'application de l'ISO 17665-1

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 17665-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 17665 consists of the following parts, under the general title *Sterilization of health care products — Moist heat*:

— *Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Guidance on the application of ISO 17665-1* [Technical Specification]

Introduction

The guidance given in this Technical Specification is not intended as a checklist for assessing compliance with ISO 17665-1. This guidance is intended to assist in obtaining a uniform understanding and implementation of ISO 17665-1 by providing explanations and acceptable methods for achieving compliance with specified requirements. It highlights important aspects and provides examples. Methods other than those given in this guidance may be used. However, the use of alternative methods has to be demonstrated to be effective in achieving compliance with ISO 17665-1.

The main body of this document is applicable to all settings where moist heat sterilization is carried out. The annexes to this guidance document also specify detailed means of implementing the requirements of ISO 17665-1 and represent current best practices.

The numbering of the clauses in the main body of this Technical Specification corresponds to that in ISO 17665-1.

Medical devices reprocessed in health care facilities include a wide variety of product with varying levels of bioburden. Appropriate and thorough cleaning and, where necessary for safe handling, decontamination processes are essential prior to presenting product for sterilization. Mixed product loads are common in healthcare facilities with throughput volumes dictated by historical and predicted demand for sterile product.

Health care facilities do not normally specify sterilization processes for any individual medical device. Also, it is impractical for health care facilities to determine bioburden on a medical device. It is important that specified instruments be disassembled before decontamination and thoroughly inspected after completion of the sterilization process. Reassembly and assessment of functionality are also needed. Therefore, the medical device manufacturer's instructions (see ISO 17664[23]) should be followed for all aspects of cleaning, disinfection, packaging and sterilization. Many devices can be fully immersed and can be washed and disinfected in automated equipment (see ISO 15883[19-22]). For devices that cannot be fully immersed and that cannot tolerate thermal decontamination, alternative methods of disinfection should be used to ensure safe handling. Such procedures and policies should be in place to ensure that medical devices undergo appropriate reprocessing. Particular attention needs to be paid to the drying and storage of sterile medical devices. Requirements for packaging of medical devices are covered in ISO 11607-1[8] and ISO 11607-2[9].

If multiple sterilization cycles can lead to degradation and limit the useful life of a medical device, the manufacturer will specify the number of reprocessing cycles that can normally be tolerated.

When selecting a medical device, priority should be given to properties such as ease of cleaning and disassembly.

Additional guidance specific to health care is offered in Annex D of this Technical Specification.

Sterilization of health care products — Moist heat —

Part 2: Guidance on the application of ISO 17665-1

1 Scope

This Technical Specification provides general guidance on the development, validation and routine control of moist heat sterilization processes and is intended to explain the requirements set forth in ISO 17665-1. The guidance given in this Technical Specification is provided to promote good practice related to moist heat sterilization processes and to assist those developing and validating a moist heat sterilization process according to ISO 17665-1.

NOTE 1 The structure of the main body of this ISO Technical Specification (Clauses 1 to 12) corresponds to the structure of ISO 17665-1, so that the guidance given under a particular clause or subclause of this part of ISO 17665 applies to the requirements given in the corresponding clause or subclause of ISO 17665-1. For example, guidance for subclause 5.2 of ISO 17665-1:2006 is given in 5.2. This guidance is provided in addition to the guidance given in ISO 17665-1:2006, Annex A. See also Annexe E.

NOTE 2 Special considerations specific to sterilization processes performed in health care facilities are given in Annex D.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

NOTE The normative references in ISO 17665-1 refer to published standards, the content of which should be used to assist in demonstrating compliance to the clause in which they are cited. Some are required mainly for moist heat sterilization in industry or for manufacturers of moist heat sterilizers and could go beyond typical practice for those performing sterilization in health care facilities.

ISO 17665-1 specifies a number of methods and procedures that can be used to monitor sterilization processes. The equipment required will normally be commercially available. A number of the normative references cited describe the specification and test methods used by commercial suppliers to qualify their products. The user of such products should ensure that purchased products comply with these standards, but will not normally need to refer to the standards.

ISO 17665-1 specifies the use of packaging complying with ISO 11607-1 and ISO 11607-2. Healthcare facilities should purchase packaging complying with these International Standards.

One method of process validation specified in ISO 17665-1 is based on the determination of bioburden. The ISO 11737[6],[7] series specifies a number of microbiological methods used during this process. Health care facilities would not normally utilize this approach for process validation.

3 Terms and definitions

For the purposes of this Technical Specification, the terms and definitions given in ISO 17665-1 and the following apply.

3.1
tests for sterility
technical operation defined in pharmacopoeia performed on product following exposure to a sterilization process

4 Quality management system elements

The guidance offered in Annex A of ISO 17665-1:2006 applies.

NOTE For additional considerations specific to health care facilities, see Clause D.2.

5 Sterilizing agent characterization

5.1 Sterilizing agent

5.1.1 Moist heat is water at elevated temperatures. Moist heat may be provided as saturated steam or can be generated in situ by applying thermal energy to water already present in the product. Moisture acts as the medium for transferring thermal energy to microorganisms.

5.1.2 Contaminants suspended in the sterilizing agent can be both toxic and corrosive and may generate a barrier between the microorganism and the sterilizing agent. They originate from water, that is heated or evaporated into steam or from contact between materials and the sterilizing agent during generation and transport to the sterilizer (see Clause 6, Clause 7 and Annex A). If the level of contaminants in the sterilizing agent can be affected by the quality of the feed water to the steam generation system, the feed water quality should be specified.

5.2 Microbicidal effectiveness

The microbicidal activity of moist heat is based on the temperature and the duration of contact between water molecules and microorganisms.

For the purpose of moist heat sterilization there are a number of acceptable time and temperature combinations recognised by some pharmacopoeias. These combinations include but are not limited to those listed in Table 1. All combinations listed are based on the concept of overkill with a safety factor that has been established for saturated steam or water in contact with the microorganism. Superheated steam behaves more like a dry gas and has a low microbicidal effectiveness compared with saturated steam. Superheated steam can result from pressure reduction and/or thermodynamic compression of saturated steam. It can also occur from the rehydration of parts of the sterilization load, particularly those parts containing natural fibres. Superheated steam conditions can be minimized by engineering of the steam supply system, for example by:

a) having a series of pressure reduction stages from the supply pipe to the sterilizer chamber and ensuring the pressure reduction ratio for each stage does not exceed 2:1;

b) ensuring steam velocity does not exceed 25 m/s;

c) ensuring materials made from natural fibres are pre-conditioned to a humidity greater than 40 % RH prior to sterilization.

Table 1 — Examples of minimum temperatures and times established for adequate levels of microbial lethality in sterilization processes

Temperature °C	Time min
121	15
126	10
134	3

5.3 Material effects

Material effects are generally limited to deformation and fracture caused by the temperatures and pressures of the sterilizing agent.

5.4 Environmental considerations

Principles of an environmental management system can be applied to a moist heat sterilization process. ISO 14001[11] provides a specification for an environmental management system. ISO 14040[12] provides guidance on designing a life cycle assessment study. The presence of noxious substances in the exhausts from the sterilizer should be considered. Further guidance on this clause is given in E.3 of ISO 14937:—[15].

6 Process and equipment characterization

NOTE The purpose of this activity is to characterize the entire sterilization process and the equipment necessary to deliver the sterilization process safely and reproducibly.

6.1 Process

6.1.1 General

A sterilization process should be specified for each product family and/or load configuration presented for sterilization.

Process parameters should apply to the equipment used. They should be optimised to ensure that for defined product families specified exposure conditions will be routinely obtained throughout the sterilizer chamber, and the maximum temperatures and rates of change of process variable (e.g. temperature and pressure) will not cause damage or degradation to the product.

The sterilization process specification should include all the process parameters that define the exposure profile throughout the operating cycle. It should also include the ones used to verify reproducibility. The portion of the operating cycle over which lethality is established should be identified, and the upper and lower limits of each process parameter that can affect both this lethality and the performance of the medical device should be defined.

Provision should be made to record data for judging the effectiveness and suitability of a routine sterilization process. The accuracy of measurement should be related to the tolerances of the process parameters.

If it is proposed to use an existing sterilization process to treat a new medical device, the existing sterilization process should be detailed and contain information and data sufficient to enable process definition (see Clause 8) to be carried out for the proposed new medical device(s) or loading configuration. The challenge identified for the new medical device or loading condition should be less than or equal to the challenge from the existing sterilization load(s). For some product families, assurance that defined exposure conditions will be reproduced might only be possible if the size of the sterilization load and the load configuration have been clearly defined.

If biological indicators and chemical indicators are to be used, they should not replace routine monitoring, measurement of process variables and any periodic tests.

Compatibility of a new medical device to the least favourable sterilization process conditions should be assessed. Such assessment should include process parameter tolerances, uncertainties of measurement associated with process parameters and the quality of the services (see Annex A).

Any restrictions on the size and mass of the sterilization load and its configuration should be identified and included in the operating instructions.

The relationship between the temperature measured at the reference measuring point and the temperature measured in the sterilization load should be known for each product family.

The performance of a medical device can be affected by contaminants on its surface. The contaminants and maximum acceptable concentration(s) contained in each fluid coming into contact with the medical device should be specified and included in the sterilization process specification. Some of the contaminants and their maximum levels which need to be considered are identified in Annex A.

6.1.2 Saturated steam processes

Steam may be generated in, or admitted to a sterilizer chamber from an external source. Air in the sterilizer chamber will be gradually removed by gravity displacement, active flow or by forced evacuation. The presence of saturated steam will be obtained at the measurement location, e.g. the chamber discharge, when the measured temperature is coincident with the temperature of saturated steam calculated from the pressure (see Annex C). Both temperature and pressure are process variables, and the point of temperature measurement is defined as the reference measuring point.

If variations in process parameters and/or the amount of non-condensable gas remaining in the sterilizer chamber at the end of air removal can result in an ineffective process, the sterilizer manufacturer or designated person (see A.4.2 in ISO 17665-1:2006) should provide adequate information to the user and should include:

— the upper and lower limits for each process parameter, and the method used for air removal;

— sources of non-condensable gas;

— test methods, test frequency and acceptance criteria for sterilization process evaluation.

The removal of air from the sterilizer chamber by either active flow or by gravity displacement is only predictable for simple solid medical devices. Air removal is unpredictable for medical devices such as instruments containing lumens, heavy solid masses and instruments and textiles contained within their primary packaging. For such medical devices, an operating cycle that employs forced or dynamic air removal should be used. An example is one that employs a number of vacuum and/or steam pulses to serially dilute the air from the sterilizer chamber and medical device(s). During each pulse, steam will move into and out of the medical device and the condensing steam will re-evaporate and cause a dynamic ‘scouring’ of the residual air contained in packages, crevices and lumens. The number of pulses, the upper and lower pressures associated with each pulse, the rate of change of pressure and temperature, and the interval of time between each change, are process variables and will play a part in effecting air removal. When assigning the suitability of a product family to a sterilization process, the combination of these pressures and temperature changes, the rates of change, and the duration of each change should be considered.

Whenever the measured temperature exceeds the theoretical temperature calculated from measured pressure as described in Annex C, superheated steam may be present. The presence of superheated steam may be detrimental to the medical device and or its packaging and may compromise the sterilization process.

Effective air removal from lumens, porous loads and other complex designs incorporating enclosed spaces is difficult. The physical conditions required for effective air removal are influenced by length, width and shape of lumen, wall thickness, material of the product, mass, density, the packaging system and other items in the same packaging system. A sterilization process that removes air from the sterilizer chamber to a low level

may fail to remove sufficient air from a lumen to permit steam penetration. Dalton's law states that the total pressure in an enclosed space is equal to the sum of the partial pressures of the individual gases present. In theory the temperature in a sterilizer chamber containing a mixture of steam and residual air will be lower than the calculated temperature derived from the pressure in accordance with steam table values (see Annex C). However there is evidence to show that an amount of residual air sufficient to cause a process failure in a sterilization load may only depress steam temperature by as little as 0,01 °C. As a consequence the differences between the temperature measured at the temperature measurement point and the temperature calculated from the sterilizer chamber pressure using steam table values (see Annex C) may not be adequate to detect the small volumes of air which could concentrate in lumens or enclosed spaces and prevent steam penetration. Under such circumstances adequate air removal and steam penetration should be predicted from data obtained from a steam penetration test and/or a process monitoring device.

A steam penetration test is designed for a specified product family(ies) and is used to check that the amount of non-condensable gas remaining in the sterilizer chamber at the commencement of the plateau period will not obstruct the presence of saturated steam on the surfaces of the medical device for the duration of the holding time. The efficiency of the air removal system, air leakage into the sterilizer chamber and non-condensable gas carried by the steam contribute to this amount. Air leakage into the sterilizer chamber and non condensable gases carried by the steam can be checked by tests (see for example, Annex A and EN 285[25]). The total presence of non-condensable gas is monitored by the steam penetration test.

A steam penetration test may be based upon temperature measurement, biological indicators or chemical indicators, as applicable. The test system should provide a challenge representative of the product family(ies) it represents. A number of steam penetration and air removal test devices are available. Performance requirements for chemical indicators can be found in ISO 11140-3[55], ISO 11140-4[56], ISO 11140-5[57], ISO 11140-6 [1)] and EN 285[25]. Guidance on the selection and use of chemical indicators is given in ISO 15882[18]. Requirements for biological indicators are found in ISO 11138-3[4]. Guidance on the selection and use of biological indicators is found in ISO 14161[13].

A reference load can consist of a single medical device type, medical devices from different product families or medical devices assigned to different product families but assembled into a single package. For any reference product or medical device, difficulty in air removal and the challenge to the sterilization process should not be less than that for any medical device in the product family(ies) assigned to the sterilization process (see also Annex A and Annex B).

If it is proposed to use a process challenge device (e.g. an air detector or other monitoring device) to represent a product family(ies), then the validity of the device when exposed to the sterilization process should be established by the process challenge device manufacturer, sterilizer manufacturer or designated person (see A.4.2 of ISO 17665-1:2006).

6.1.3 Contained product processes

A product may be heated in a water immersion cycle, a water spray cycle, a cycle with an air and steam mixture, a cycle with steam and gravity displacement, or a cycle with forced air removal. Air and steam mixtures are often used to prevent distortion or fracture of the sterilized container caused by the internal pressure generated from heating both the water-based solution and air in any sealed container.

The energy required to heat up a sterilization load to the defined sterilization temperature depends on the product family, the size of a sterilization load and its initial temperature. Heat transfer will depend on the heating medium, its contact with the product container, the material of the container and container support system, and the temperature difference at the heat transfer site. The type of product family and the load configuration will have a major influence on temperature differences between containers. These differences may be minimized by increasing the flow and distribution of the heating medium by forced circulation. Mass flow and homogeneity of the heat transfer medium throughout the sterilizer chamber can be verified by process variables such as fan speed, circulation pressure and flow. Temperature of the heat transfer medium at the outlet should be identified as a process variable. If steam is used, the temperature of the steam environment should also be handled as a process variable. Consideration may need to be given to ensure the

1) ISO 11140-6 is under development and is based on EN 867-5[27].

heat transfer medium is pyrogen free and free of chemical impurities that may cause spotting on packaging. In addition, the heat transfer medium may need to be sterile during cooling and the period of the operating cycle for which lethality is claimed.

The temperature distribution within the product container will depend on the shape of the container, viscosity of the product, conduction through the container wall and product, and convection within the product. Large product containers will need longer times to heat up and cool down, which could restrict the size of container that can be used for products sensitive to prolonged exposure.

During the sterilization process, the locations of the product containers exhibiting the highest and lowest temperatures during the heating phase and the highest and lowest temperatures during the cooling phase in the sterilization load should be identified. The temperatures measured in these locations should be treated as process variables; however, if either location cannot be reproduced, a statistical approach may need to be used to ensure the specified lethality is consistently attained while maintaining product integrity.

6.2 Equipment

NOTE For additional considerations specific to health care facilities, see D.3.2.

6.2.1 Regional and national standards for sterilizing equipment have been published (e.g. EN 285), which recommend materials that can be used in the construction of a sterilizer. Materials used by a manufacturer for the construction of a sterilizer can be based on the sterilization process delivered by the sterilizer and the product family(ies) that will be sterilized. The materials chosen should minimize corrosion and any contaminant that can be released during routine operation. Steam, heat transfer, fluids or air used to pressurize the sterilizer chamber can carry corrosive and toxic agents. These should be identified and maximum permissible levels specified (see Annex A). Protection of materials by filming amines such as hydrazine should not be used as an alternative to the correct choice of material and the control of corrosive contaminants.

It is preferable that sterilization records be established independent from the automatic controller and indicating instruments. A system that combines recording, control and indication may lead to an ineffective sterilization process being interpreted as effective. Independent recorders are characterized by separate measurement, data processing and printing of values. Interchange of informative data between the recorder and the controller for other purposes is not excluded.

An air detector may be fitted to a sterilizer that uses vacuum and steam pulsing to remove air during the air removal stage of a saturated steam sterilization process. It is used to predict whether non-condensable gas remaining in the sterilizer chamber at the commencement of the plateau period could accumulate in parts of the sterilization load (e.g. lumens) and cause a failure of the sterilization process in these parts. The setting of the air detector is based on the defined process parameters and the product family(ies) that the sterilization process is designed to process**.** Non-condensable gas identified by an air detector may also contain gas released when a product or its packaging is heated. Air detector tests are specified in Annex A and EN 285.

6.2.2 The specification for the equipment should include sufficient information to perform a process definition for a new product or loading configuration. (See Clause 8).

6.2.3 A sterilization process delivered in accordance with its specification is dependant upon the quality of the services provided. During maximum demand, pressure measured at the connection to the sterilizer for each fluid, gas or steam service should not fall below the minimum specified by the sterilizer manufacturer. For example, the efficiency of a water ring vacuum pump and a heat exchanger deteriorates with falling water pressure and rising water temperature. Microbial contamination can occur if air entering the sterilizer chamber contains particles greater than 0,2 µm. If services are provided by another party, recommendations from the sterilizer manufacturer should be followed and conformity confirmed.

Local regulations for environmental considerations could govern the discharge of high temperature effluent from the sterilizer chamber into the public sewer system, the leakage of the materials used to generate the sterilizing agent, the particulates released from the product and/or packaging during sterilization, and the volume of water used during the process.

Safety is part of equipment design and operation. Reference should be made to IEC 61010-2-040[24] and national regulations.

6.2.4 Systems such as containers, shelving, racks and carriers designed to support and/or contain the medical device should not unduly restrict uniform steam distribution, circulation of heat transfer fluid, removal of residual air, drainage of condensate or drainage of water. The system should also prevent damage to the medical device and/or its packaging and retain the integrity of the sterilization load.

6.2.5 No guidance offered.

6.2.6 Software design should be structured. Guidance is given in Good Automated Manufacturing Practice, Guide For Validation Of Automated Systems In Pharmaceutical Manufacturing (GAMP 4)[39].

7 Product definition

NOTE For additional considerations specific to health care facilities, see Clause D.4.

7.1 During product design, consideration should be given to the procedures for disassembly (if appropriate), cleaning, disinfection, inspection and sterilization.

Guidance and methods for the cleaning and disinfection of medical devices prior to sterilization are addressed in the ISO 15883 series of standards[19-22]. Information to be provided by a medical device manufacturer for the reprocessing of a medical device is given in ISO 17664[25].

7.2 The major function of a package is to ensure that the medical device remains sterile until opened for use. Packaging should withstand the stresses that occur during a sterilization process, remain secure, and should not have a negative effect on the quality of the medical device (for example, by generating particles). Packaging for a medical device sterilized by saturated steam should meet the requirements of ISO 11607[8],[9]. For non-permeable packaging (e.g. vials, ampoules, flexible pouches), the material and design should permit heat transfer to the product and, if a closure is fitted, it should remain secure and sealed.

Secondary packaging should protect the product during customary handling and distribution. If secondary packaging is exposed to the sterilization process it should retain its ability to protect the product and should not be adversely affected by the sterilization process.

If, at the end of a sterilization process, controlled conditions are required for the equilibration of a medical device and its packaging to atmospheric conditions, the method by which this is to be achieved (e.g. in an environmentally controlled chamber or room) should be defined.

7.3 No guidance offered.

7.4 A medical device that is to be sterilized can be characterized by its shape, mass, materials of construction, moving parts and packaging. A contained product will be characterized by formulation, volume and viscosity. Its container can be characterized by size, material and closure.

A study should be carried out to assign a product to a product family. The extent of this study can be reduced by first reviewing the process parameters already established for an existing sterilization process, by employing a validated cleaning process (if applicable), and by comparing the new product to those products already assigned to the sterilization process.

7.5 No guidance offered.

7.6 Exposure of a medical device to the sterilizing agent should not cause the design parameters for each material used in the construction of the medical device to exceed its maximum or minimum permissible values. As temperature rises, materials weaken and are more susceptible to physical stresses or mechanical forces. Differential expansion through low heat-conductive materials, or the expansion and contraction of dissimilar materials in contact with each other, can cause an increase in material and joint stresses.

7.7 No guidance offered.

7.8 The heat sensitivity of a liquid product can dictate the maximum fill volume, material and size of the container that can be used. The stability and sterility of the liquid should be assessed from temperature mapping studies carried out in the proposed container when the liquid is exposed to at least the upper limits of the proposed sterilization process profile.

Medical devices that are to be reprocessed can suffer accumulative changes such as surface cracking caused by differential expansion through a thick material, brittleness or delamination. Crevices and lumens can retain organic, chemical and biological contaminants that could cause material reactions or be unpredictably removed during use. Many materials that are subject to repeated moist heat sterilization have a long history of safe use, are known to be suitable and have longevity (e.g. stainless steel). Other materials however, might have limited lifespans and require further study. Reference should be made to ISO 10993-1[1], ISO 10993-17[2], ISO 17664[23] and ISO 14971[17].

7.9 An evaluation should establish that, after processing, a medical device will perform as intended and will be safe for use. The evaluation should consider mechanical, chemical, electrical, toxicological, physical, biological and morphological properties. Intended additives, process contaminants, process residues, leachable substances and degradation products should be considered for their relevance to the safety of the device and its packaging. Corrosion on some materials can occur if steam is generated from water of low pH or if the water contains a contaminant such as chlorides and silicates. For example, rubber can become oxidised in the presence of residual air at elevated steam temperatures. Dehydrated cellulosic materials can rehydrate during steam sterilization causing exothermic superheat in the material and in the vicinity of the material.

7.10 No guidance offered.

8 Process definition

NOTE For additional considerations specific to health care facilities, see Clause D.5.

8.1 The purpose of this activity is to deliver the required sterility assurance level to every part of the sterilizer load by ensuring that contaminating microorganisms are maintained in contact with moisture at a specified temperature for a specified time.

Effectiveness and reproducibility of a sterilization process can be defined by conditions that can be controlled and confirmed by physical measurement. If a condition changes and this can affect the sterility assurance level, this condition can be identified as a process variable and the value at which the change occurs, a process parameter.

Process variables should be defined and process parameters, including their tolerances, specified. The process parameters should characterize the conditions that will justify the prediction that the sterilizing agent will generate the required sterility assurance level in all parts of the product without causing any part to exceed its design limit.

For some medical devices the measurement of physical conditions (such as temperature) is not possible inside sterile barrier systems. For such medical devices the reproducible attainment of the defined sterility assurance level should be verified at a reference measurement point(s), for example, the drain for the measurement of sterilization temperature. In the case of a saturated steam process, evidence that establishes reproducibility of the sterilization process may be generated from the:

a) temperature and pressure at least at the turning points of pressure;

b) number of steam pulses;

c) pressure and/or temperature change rates;

d) exposure time;