TECHNICAL SPECIFICATION

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Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

Stérilisation des produits de santé — Exigences communes applicables aux stérilisateurs utilisés pour la stérilisation terminale des dispositifs médicaux dans les établissements de santé

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A sterile health care product is one that is free of viable microorganisms. International Standards that specify requirements for validation and routine control of sterilization processes require, when it is necessary to supply a sterile health care product, that adventitious microbiological contamination of that health care product prior to sterilization be minimized. Even so, health care products produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such health care products are non-sterile. The purpose of sterilization is to inactivate or remove the microbiological contaminants and thereby transform the non-sterile health care products into sterile ones.

Conformance with the requirements of International Standards for development, validation and routine control of sterilization processes ensures that the sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low probability of there being a viable microorganism present on a health care product after sterilization.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that a processed medical device is sterile and, in this regard, suitable for its intended use. Attention is also given to a number of factors including:

a) the microbiological status of incoming raw materials or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the medical device;

c) the control of the environment in which the medical device is manufactured, assembled and packaged;

d) the specified performance and maintenance of equipment;

e) the control of personnel and their hygiene;

f) the process and materials of the sterile barrier systems that are used to package the medical device;

g) the conditions under which the medical device is transported;

h) the conditions under which the medical device is stored.

The delivery of a validated and accurately controlled sterilization process is enabled by the use of sterilizing equipment that is designed, constructed, installed and qualified to deliver the sterilization process safely and reproducibly. This document defines common, general requirements that apply across a range of sterilizing equipment that can then be used:

1) as a template for future revisions of standards for sterilizing equipment for particular sterilization processes, and

2) to apply to equipment for which a particular standard does not exist.

This approach also provides opportunities not only to achieve a comprehensive and consistent set of global standards for sterilizing equipment but also to build on the work done in developing the existing standards for sterilizers at national and regional level to reach an international alignment on the requirements.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test); and

— "can" is used to express possibility and capability.

The conjunction "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The rationale for the requirements in this document has been provided in Annex A.

Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

1 Scope

This document specifies the common requirements for sterilizers used for terminal sterilization of medical devices in health care facilities. This document covers sterilizers that operate with a variety of sterilizing agents (alone or in combination) within a sealed vessel at different temperatures, above, at, or below atmospheric pressure.

This document provides high-level requirements and respective test methods that are general in nature.

This document does not provide quantitative requirements for process parameters or parameters of the sterilization cycle, or requirements for performance testing, validation or routine control of sterilizers because these depend on the respective sterilization method.

This document does not supersede or modify requirements or test methods of published standards applying to sterilizers, or future editions thereof.

This document does not apply to:

— sterilizers using radiation as the sterilizing agent;

— sterilizers for laboratory equipment;

— sterilizers used to prepare culture media;

— sterilizers used for bio-decontamination of laboratory or other waste including decontamination of pathogens in a high risk category;

— systems used for bio-decontamination of rooms and isolator systems;

— systems used for sterilization in place; or

— washer-disinfectors.

NOTE Whilst this document provides requirements for sterilizers used in health care applications, there will be elements that are applicable to industrial applications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 8573-1, *Compressed air — Part 1: Contaminants and purity classes*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 20417, *Medical devices — Information to be provided by the manufacturer*

IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

IEC 61326-1, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code, or tool.

[SOURCE: ISO 11139:2018, 3.4]

3.2
accompanying information
information accompanying or marked on a sterilizer and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the sterilizer, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the sterilizer.

Note 2 to entry: The accompanying information can consist of the label (see 3.29), marking, instructions for use, technical description, installation manual, quick reference guide, etc.

Note 3 to entry: Accompanying information is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — "Medical device or accessory" has been changed to "sterilizer", the term "processing" has been removed, Note 1 to entry has been modified to exclude a requirement and Note 4 to entry has been deleted.]

3.3
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed *cycle parameters* (3.12)

[SOURCE: ISO 11139:2018, 3.18]

3.4
bio-decontamination
removal and/or reduction of biological contaminants to an acceptable level

[SOURCE: ISO 11139:2018, 3.27]

3.5
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified *sterilization process* (3.66)

[SOURCE: ISO 11139:2018, 3.29]

3.6
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

3.7
chamber
part of equipment in which a load is processed

[SOURCE: ISO 11139:2018, 3.36]

3.8
chemical indicator
test system that reveals change in one or more pre-specified *process variables* (3.50) based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43]

3.9
cleaning
removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.10
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.11
cycle complete
message from the automatic controller that the operating cycle has ended successfully

[SOURCE: ISO 11139:2018, 3.71]

3.12
cycle parameter
value of a *cycle variable* (3.13) including its tolerance used for *control* (3.10), *monitoring* (3.39), indication, and recording of an operating cycle

[SOURCE: ISO 11139:2018, 3.72]

3.13
cycle variable
property used to *control* (3.10), monitor, indicate, or record an *operating cycle* (3.42)

[SOURCE: ISO 11139:2018, 3.74]

3.14
desorption
removal of the *sterilizing agent* (3.68) from the *chamber* (3.7) and the load at the end of the *exposure phase* (3.17)

[SOURCE: ISO 11139:2018, 3.78]

3.15
double-ended
having separate doors for loading and unloading in separate areas

[SOURCE: ISO 11139:2018, 3.92]

3.16
equipment maintenance
combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: ISO 11139:2018, 3.106]

3.17
exposure phase
cycle stage between the introduction of the sterilizing or disinfecting agent into the *chamber* (3.7) and when the agent is removed

[SOURCE: ISO 11139:2018, 3.111]

3.18
fault
situation in which one or more of the process or *cycle parameters* (3.12) is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

3.19
filter
construct of porous material through which a *fluid* (3.20) is passed to remove viable and/or non-viable particles

[SOURCE: ISO 11139:2018, 3.117]

3.20
fluid
substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma.

[SOURCE: ISO 11139:2018, 3.120]

3.21
hazard
potential source of harm

[SOURCE: ISO 11139:2018, 3.130]

3.22
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more *hazards* (3.21)

[SOURCE: ISO 11139:2018, 3.131]

3.23
health care product
medical device (3.36), including in vitro diagnostic medical device, or medicinal product, including biopharmaceutical

[SOURCE: ISO 11139:2018, 3.132]

3.24
humidity
measure of water vapour present in a gas

Note 1 to entry: Humidity is usually expressed as absolute humidity (i.e. vapour pressure density), relative humidity, or dew point.

[SOURCE: ISO 11139:2018, 3.136]

3.25
indicate
display a value, condition, or stage of process

[SOURCE: ISO 11139:2018, 3.139]

3.26
information supplied by the manufacturer
all information related to the identification and use of a sterilizer, in whatever form provided, intended to ensure the safe and effective use of the *sterilizer* (3.67)

Note 1 to entry: For the purposes of this document, shipping documents and promotional material are excluded from information supplied by the manufacturer. However, some authorities having jurisdiction can consider such supplemental information as information supplied by the manufacturer.

[SOURCE: ISO 20417:2021, 3.10, modified — "Medical device or accessory" has been changed to "sterilizer" and Notes 1, 3 and 4 to entry have been deleted.]

3.27
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.28
instructions for use
IFU
portion of the *accompanying information* (3.2) that is essential for the safe and effective intended use of a *sterilizer* (3.67) directed to the user of the sterilizer

Note 1 to entry: The instructions for use, or portions thereof, can be located on the display of a sterilizer.

[SOURCE: ISO 20417:2021, 3.11, modified — "Medical device or accessory" has been changed to "sterilizer", "package insert" has been removed, "use" has been changed to "intended use", Notes 1, 2, 4 and 5 to entry have been deleted and Note 3 to entry has been modified.]

3.29
label
written, printed, or graphic information appearing on the *sterilizer* (3.67) itself

Note 1 to entry: Label includes the marking on the sterilizer.

[SOURCE: ISO 20417:2021, 3.12, modified — The term "item" has been replaced with "sterilizer", reference to packaging and provision of multiple items has been deleted, Notes 1 and 3 to entry have been deleted, and Note 2 to entry has been designated as Note 1.]

3.30
load
product, equipment, or materials to be processed together within an *operating cycle* (3.42)

[SOURCE: ISO 11139:2018, 3.155]

3.31
load configuration
distribution and orientation of a *load* (3.30)

[SOURCE: ISO 11139:2018, 3.156]

3.32
loading door
means of access through which a *load* (3.30) is passed into the chamber before processing

[SOURCE: ISO 11139:2018, 3.157]

3.33
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *sterilizer* (3.67)

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, marking is different from "direct marking" as described in systems for unique device identification (UDI) of medical devices.

[SOURCE: ISO 20417:2021, 3.16, modified — "Medical device or accessory" has been changed to "sterilizer". Note 2 to entry has been modified. Note 3 to entry has been deleted.]

3.34
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO 11139:2018, 3.164]

3.35
measuring chain
series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement)

[SOURCE: ISO 11139:2018, 3.165]

3.36
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy, or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

— items specifically intended for *cleaning* (3.9) or sterilization of medical devices;

— pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.37
microbial contamination
presence of unintended bacteria, fungi, protozoa, or viruses

[SOURCE: ISO 11139:2018, 3.171]

3.38
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: ISO 11139:2018, 3.176]

3.39
monitoring
continual checking, supervising, critically observing, or determining the status, in order to identify change from the performance level required or expected

[SOURCE: ISO 11139:2018, 3.180]

3.40
national standard
measurement standard recognized by national authority to serve in a state or economy as the basis for assigning quantity values to other measurement standards for the kind of quantity concerned

[SOURCE: ISO/IEC Guide 99:2007, 5.3]

3.41
normal operation
use of equipment in accordance with the manufacturer's instructions and with all *process parameters* (3.49) within the specified tolerances

[SOURCE: ISO 11139:2018, 3.185]

3.42
operating cycle
complete set of stages of a process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the operating cycle.

[SOURCE: ISO 11139:2018, 3.188]

3.43
operating pressure
fluid (3.20) pressure occurring during an *operating cycle* (3.42)

[SOURCE: ISO 11139:2018, 3.189]

3.44
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO 11139:2018, 3.220.3]

3.45
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

3.46
pore size rating
nominal pore size of a *filter* (3.19) as claimed and stated in the labelling

[SOURCE: ISO 11139:2018, 3.196]

3.47
pressure vessel
housing and its direct attachments up to the coupling point connecting it to other equipment, designed and built to contain fluids under pressure

Note 1 to entry: A vessel can be composed of more than one chamber.

[SOURCE: ISO 11139:2018, 3.202]

3.48
primary standard
measurement standard established using a primary reference measurement procedure, or created as an artefact, chosen by convention

[SOURCE: ISO/IEC Guide 99:2007, 5.4, modified — The examples have been deleted.]

3.49
process parameter
specified value for a *process variable* (3.50)

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: ISO 11139:2018, 3.211]

3.50
process variable
chemical or physical attribute within a *cleaning* (3.9), disinfection, packaging, or *sterilization process* (3.66), changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: ISO 11139:2018, 3.213]

3.51
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

[SOURCE: ISO 11139:2018, 3.217]

3.52
record
<data> collect, store, and make accessible

[SOURCE: ISO 11139:2018, 3.223]

3.53
recorder
equipment that *records* (3.52) and produces a permanent record of information graphically, digitally, or electronically

[SOURCE: ISO 11139:2018, 3.224]

3.54
reference load
specified load created to represent combinations of items that provide defined challenge(s) to a process

[SOURCE: ISO 11139:2018, 3.226]

3.55
response time
τ_{90}
<sensor> period required for a 90 % change in sensor output when exposed to a step change in the variable being measured

[SOURCE: ISO 11139:2018, 3.234]

3.56
safety data sheet
SDS
document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

[SOURCE: ISO 11139:2018, 3.239]

3.57
serial number
production control containing a combination of letters or numbers, selected by the manufacturer, intended for quality control and identification purposes to uniquely distinguish an individual sterilizer from other sterilizers with the same catalogue number or model number

[SOURCE: ISO 20417:2021, 3.22, modified — "Medical device" has been changed to "sterilizer".]

3.58
services
supplies from an external source needed for the function of equipment

[SOURCE: ISO 11139:2018, 3.252]

3.59
specify
stipulate in detail within an approved document

[SOURCE: ISO 11139:2018, 3.259]

3.60
stage
<operating cycle> part of an *operating cycle* (3.42) with a specified function

EXAMPLE Air removal stage, plateau period, drying stage, final air admission stage.

[SOURCE: ISO 11139:2018, 3.262]

3.61
sterilant
chemical or combination of chemicals used to generate a *sterilizing agent* (3.68)

[SOURCE: ISO 11139:2018, 3.268]

3.62
sterile
free from viable *microorganisms* (3.38)

[SOURCE: ISO 11139:2018, 3.271]

3.63
sterile barrier system
SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the *sterile* (3.62) contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

3.64
sterilization
validated process used to render product free from viable *microorganisms* (3.38)

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 11139:2018, 3.277]

3.65
sterilization cycle
predetermined sequence of stages performed in a *sterilizer* (3.67) to achieve product free of viable *microorganisms* (3.38)

[SOURCE: ISO 11139:2018, 3.279]

3.66
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

Note 1 to entry: This series of actions includes pre-treatment of product (if necessary), exposure under specified conditions to the sterilizing agent, and any necessary post treatment. The sterilization process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

[SOURCE: ISO 11139:2018, 3.284]

3.67
sterilizer
equipment designed to achieve *sterilization* (3.64)

[SOURCE: ISO 11139:2018, 3.287]

3.68
sterilizing agent
physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under specified conditions

[SOURCE: ISO 11139:2018, 3.288]

3.69
technical description
portion of the *accompanying information* (3.2) directed to the responsible organization and service personnel that is essential for preparation for the first use and safe use, maintenance or repair as well as transport or storage for the expected lifetime of a *sterilizer* (3.67)

Note 1 to entry: The technical description may be included in the instructions for use.

[SOURCE: ISO 20417:2021, 3.30, modified — "Medical device" has been changed to sterilizer, "processing" has been deleted and Note 2 to entry has been deleted.]

3.70
terminal sterilization
process whereby a product is sterilized within its *sterile barrier system* (3.63)

Note 1 to entry: Some jurisdictions can also consider a sterilization process in which a product is sterilized without a sterile barrier system as being terminally sterilized.

[SOURCE: ISO 11139:2018, 3.295, modified — Note 1 to entry has been added.]

3.71
type test
technical operation to verify conformity of an equipment type to a standard or specification, and to establish data for reference in subsequent tests

[SOURCE: ISO 11139:2018, 3.306]

3.72
unloading door
means through which a load is removed from the chamber after processing

[SOURCE: ISO 11139:2018, 3.310]

3.73
usable chamber space
specified geometry within the *chamber* (3.7) that is available to accept the load

[SOURCE: ISO 11139:2018, 3.311]

3.74
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 11139:2018, 3.313]

3.75
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 11139:2018, 3.314]

4 General

4.1 Product definition

4.1.1 When demonstrating that a sterilizer type conforms with this document, sterilizers classified as the same type shall have the same intended use with the same sterilizing agent specification. In addition, unless it has been demonstrated that there is no decrease in the performance of an operating cycle, a sterilizer type shall have:

a) the same number of loading or unloading doors;

b) all service connections into the chamber in the same orientation;

c) the same control system with all fixed sensors located in the same position and orientation;

d) the same pre-set programmes of operating cycle(s) including the same cycle parameters.

NOTE 1 A mirror image of the original orientation does not constitute a new type.

NOTE 2 Where change within the control system does not affect the sequence of stages of the sterilization cycle, and the parameters limiting the cycle performance, or the safety attributes, such a change does not constitute a new type.

Conformance is demonstrated by inspection of the technical documentation.

4.1.2 If all other design aspects remain the same, the following variations shall not constitute a new sterilizer type:

a) height of the sterilizer chamber above the floor;

b) differences in the dimensions of the sterilizer chamber not greater than ±10 % of the dimensions with congruent sterilizer chamber shapes;

c) prolonging the duration of the exposure phase of an operating cycle;

NOTE Additional regulatory requirements can apply to prolonging the exposure phase.

d) prolonging desorption, cooling or drying after the exposure phase;

e) any change of the design or provenance of equipment, providing there is available documented evidence to show there is no decrease in the safety or performance of the sterilizer which can affect conformance with this document.

Conformance is demonstrated by inspection of the technical documentation.

4.2 Equipment development

The design and development process is a critical element in product realization of a sterilizer. To ensure the consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained. Processes of particular importance in relation to the design and development of a sterilizer include but are not limited to:

— risk management;

— control of documentation, including records;

— assignment of responsibility;

— provision of adequate resources, including competent human resources and infrastructure;

— control of product, including services, provided by external parties;

— calibration of instrumentation.

NOTE 1 ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

NOTE 2 ISO 14971 provides requirements for a risk management system for medical devices.

NOTE 3 ISO 12100 provides requirements for risk management of machinery.

4.3 Calibration

4.3.1 Instrumentation on the sterilizer and instruments used for test purposes shall be calibrated. The system(s) for calibration of instrumentation shall provide metrological traceability to a primary standard or national standard with a known level of measurement uncertainty.

NOTE National calibration standards are often mutually recognized and traceable to international standards with recognized fixed-points.

Conformance is demonstrated by inspection of the technical documentation.

4.3.2 Means shall be provided to permit connection of reference instruments for the calibration of instrumentation.

Conformance is demonstrated by inspection.

5 Equipment design and construction

5.1 Safety and security

5.1.1 The sterilizer shall conform with IEC 61010-2-040.

NOTE IEC 61010-2-040 provides safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields.

Conformance is demonstrated in accordance with IEC 61010-2-040.

5.1.2 Sterilizers shall conform with IEC 61326-1 regarding immunity to electromagnetic interference.

The immunity performance criteria selected shall ensure that sterilizer performance is met when exposed to the applicable disturbance phenomena of IEC 61326-1.

Conformance is demonstrated in accordance with IEC 61326-1.

5.1.3 Sterilizers shall incorporate means of protection from unauthorized access that could interfere with its performance or create a hazardous situation. If the sterilizer provides a connection to an IT environment or network, means shall be provided to prevent access or interaction:

a) between that environment or network and the sterilizer that interferes with the sterilizer performance or creates a hazardous situation;

b) between the sterilizer and that environment or network protocol(s) that interferes with the specified performance of the environment or network.

NOTE See IEC 80001-1, ISO/IEC 27001, ISO/IEC 27002, UL 2900-1 and ISO/IEC 21823-1. IEC 80001-1 defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security. ISO/IEC 27001 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system and ISO/IEC 27002 gives guidelines for organizational information security standards and information security management practices. UL 2900-1 applies to network-connectable products that need to be evaluated and tested for vulnerabilities, software weaknesses and malware. ISO/IEC 21823-1 provides an overview of interoperability as it applies to Internet of Things systems and a framework for interoperability for such systems.

Conformance is demonstrated by inspection of the technical documentation.

5.2 Chamber

5.2.1 Dimensions

5.2.1.1 The internal dimensions of the chamber shall be specified by reference to the principle dimensions at specified positions, measured in millimetres.

a) For cylindrical horizontal or cylindrical vertical chambers:

   1) diameter;

   2) depth.

b) For rectangular parallelepiped chambers:

   1) width;

   2) height;

   3) depth.

c) For other configurations the chamber shall be specified in analogy to a) or b).

Conformance is demonstrated by inspection of the technical documentation.

5.2.1.2 The usable chamber space shall be specified. The following dimensions shall be specified in millimetres.

a) For cylindrical horizontal or cylindrical vertical usable chamber space:

   1) diameter;

   2) depth.

b) For rectangular parallelepiped usable chamber space:

   1) width;

   2) height;

   3) depth.

c) for other configurations the chamber shall be specified in analogy to a) or b).

Conformance is demonstrated by inspection of the technical documentation.

5.2.2 Doors

The chamber shall be provided with one or two doors.

Conformance is demonstrated by inspection.

5.2.3 Chamber integrity

If a leak into or from the chamber or connected relevant pipework can create a hazardous situation, or affect the intended function or performance of the equipment or the process, means shall be provided to conduct a leak test(s) capable of detecting that leak.

Conformance is demonstrated by inspection of the technical documentation.

5.2.4 Pressure vessels

If the chamber is a pressure vessel, documentation shall be provided demonstrating conformity with the regulations, codes or standards applicable to pressure equipment in the jurisdiction of intended use.

Conformance is demonstrated by inspection of the technical documentation.

5.2.5 Uniformity of conditions

The conditions within the usable chamber space shall be maintained within the tolerances specified for the sterilization cycle.

Conformance is demonstrated by comparing parameters or specified outcomes to results of measurements of process variables as far as practicable at one or more representative position(s) throughout the usable chamber space with the chamber unloaded. If measurement of a variable is not practicable, appropriate biological indicators or chemical indicators shall be used to supplement the measurements that can be made.

5.2.6 Ancillary equipment and components

5.2.6.1 Means shall be provided to insert and remove the load from the chamber and maintain the load in its intended position within the usable chamber space.

Conformance is demonstrated by inspection of the technical documentation.

5.2.6.2 If a filter is fitted to the sterilizer to prevent microbial contamination during admission of air into the chamber in an operating cycle, it shall be:

a) microbially-retentive, as specified by the filter manufacturer;

b) suitable for the application;

c) readily accessible for replacement;

d) equipped with means to prevent unintended fluid flow from the chamber into the filter.

Conformance is demonstrated by inspection of the technical documentation.

5.3 Materials

The sterilizer and ancillary equipment shall be made of materials which, in normal use, will not react with the sterilizing agent or carrier fluids in a manner and to an extent that could lead to deterioration that could:

a) affect the operation of the sterilization cycle;

b) have a detrimental effect on the materials;

c) release a substance known to be toxic in such quantity that would create a health or environmental hazard; or

d) create a hazardous situation.

Conformity is checked by inspection, and by examination of data accumulated by the manufacturer of the sterilizer or supplier of materials during failure-mode analysis and during tests, to demonstrate that the materials used and specified are compatible with the sterilizing agent or carrier fluids.

5.4 Interlocks

5.4.1 Sterilizers shall be equipped with an interlock so that, under conditions of normal operation, the pressure in the chamber cannot be increased or decreased and sterilizing agent cannot enter or escape from the chamber when the door is unlocked or unsealed.

Conformance is demonstrated by inspection of the technical documentation.

5.4.2 The interlock system shall allow the closed loading door to be re-opened and closed before an operating cycle is initiated.

Conformance is demonstrated by inspection.

5.4.3 It shall not be possible to open a sterilizer door(s) during an operating cycle.

Conformance is demonstrated by inspection of the technical documentation.

5.4.4 Indication of cycle complete shall be cancelled when a door is opened.

Conformance is demonstrated by inspection.

5.4.5 In addition to 5.4.1 to 5.4.4, for double-ended sterilizers:

a) at the successful completion of a sterilization cycle, the loading door shall remain locked until the unloading door has been opened, closed and locked again;

b) for test purposes, a test load may be removed through the loading door using a special key, code or tool;

c) for test purposes, a key, code or tool may be required to open either the loading or the unloading door;

d) if a fault is indicated, both doors shall remain locked, and opening of a door shall be allowed only after the end of a suitable recovery procedure (see 5.7.4 and 6.4.2.4) or a service action by use of a key, code or tool;

e) for maintenance purposes, it shall be possible for both doors to be open at the same time using a special key, code or tool (see also 5.7.5).

Conformance is demonstrated by inspection of the technical documentation.

5.5 Test connections

5.5.1 The sterilizer shall be equipped with at least one test connection.

The number and types of test connections and how test equipment can be introduced into the sterilizer chamber shall be specified. Test connection(s) shall be designed in such a way that all areas of the chamber can be reached in a suitable manner with suitable measurement techniques.

NOTE 1 Keeping the number of test connections to a minimum reduces the risk of leakage. One test connection can be used for multiple measurements by use of adaptors.

NOTE 2 Failure to provide test connections can complicate the performance of validation.

NOTE 3 A standard for a sterilizer using a particular sterilizing agent can specify the test connection for that particular sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.5.2 Test connections shall be at points of easy access, but not in pipes for media transport (e.g. steam, sterilizing agent, air).

Conformance is demonstrated by inspection of the technical documentation.

5.5.3 The test connection shall provide access into the sterilizer chamber providing it causes no adverse effect on the measurement of the conditions in the sterilizer chamber.

Conformance is demonstrated by inspection of the technical documentation.

5.5.4 The test connections shall be sealed and provided with means to prevent physical or chemical damage.

Conformance is demonstrated by inspection of the technical documentation.

5.5.5 If a test connection can be opened and closed without the use of a tool, means shall be provided to prevent opening if conditions inside the equipment could cause a hazardous situation.

NOTE Means can include interlocks, fitting an interlocked cover over the test connection or providing a protective barrier to avoid creation of a hazardous situation.

Conformance is demonstrated by inspection.

5.6 Vibration

Vibrations from sterilizers shall be reduced by design, selection of components and devices limiting vibrations, particularly at source. If vibrations can cause a loss of stability of the sterilizer, means shall be provided for suitable fixation.

NOTE Vibration from other sources applicable to the intended use of the sterilizer can also be considered.

Conformance is demonstrated by inspection of the technical documentation.

5.7 User interfaces

5.7.1 The control used to start the automatic operating cycle shall be located at the loading side of the sterilizer or in a remote operating facility.

If used, a remote operating facility shall provide at least an equal level of monitoring and safety as operation from the loading side of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.7.2 If a fault is indicated, or on completion of an operating cycle for test or equipment maintenance purposes, it shall not be possible to open a door until appropriate action is taken (see 6.4.2).

5.7.3 Double-ended sterilizers shall be provided with the indicating devices specified in 6.6 at both ends of the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

5.7.4 Means shall be provided for the user to terminate the sterilization cycle without causing a hazardous situation. If a fault results in aborting or terminating an operating cycle in progress, the visual

indication of the fault shall continue until the user completes a specified action to clear the indication of the fault. If an operating cycle is interrupted, opening of the sterilizer door shall require the use of an access device.

Conformance is demonstrated by inspection of the technical documentation.

5.7.5 Means shall be provided to permit operation of the sterilizer for equipment maintenance, test purposes and in cases of emergency, without causing a hazardous situation. The activation of any service mode shall be clearly indicated in order to avoid safety features being inactivated during normal operations.

Conformance is demonstrated by inspection.

5.7.6 Indicating, measuring and recording instruments shall be identified as to their function. Instruments and indicating devices shall be located where they can be viewed readily by the user under normal operation of the sterilizer. Instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 ± 15) lx. If an instrument on the sterilizer is adjustable, adjustment shall require the use of a special key, code or tool.

Conformance is demonstrated by inspection.

5.7.7 When fitted, acoustic signals not associated with a hazardous situation shall be time-limited to 30 s or it shall be possible to interrupt them.

Conformance is demonstrated by inspection.

6 Indicating, monitoring, controlling and recording

6.1 General

The cycle parameters for controlling, monitoring, recording and indicating the operating cycle(s) shall be established and incorporated into pre-set programme(s) of the sterilizer.

NOTE A pre-set programme can have a range of cycle parameters selectable by the end user.

Conformance is demonstrated by inspection of the technical documentation.

6.2 Automatic control

6.2.1 The sterilizer shall operate with pre-set programmes permanently stored in the automatic controller. Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording of process parameters such that an ineffective process appears effective. This may be achieved either by the use of independent systems for control and recording, or by a cross-check between control and recording that identifies any discrepancies and indicates a fault.

Examples of the interrelationship between control and recording are illustrated in Annex B.

Conformance is demonstrated by inspection of the technical documentation.

6.2.2 The automatic controller shall not cause a hazardous situation, if:

a) the values of cycle parameters are outside the specified limits;

b) a power failure occurs;

c) a failure of another utility occurs.

Conformance is demonstrated by inspection of the technical documentation.

6.2.3 Software for monitoring and control shall be verified and validated. The methods used in the verification and validation processes shall be selected based on the intended purpose of the software. The methods shall be justified and specified.

NOTE See, for example, the IEC 61508 series, IEC 62304 and IEC 62061. The IEC 61508 series applies to safety-related systems when one or more of such systems incorporate electrical or electronic or programmable electronic devices. IEC 62304 defines the life cycle requirements for medical device software. IEC 62061 specifies and makes recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems for machines.

Conformance is demonstrated by inspection of the technical documentation.

6.2.4 The automatic controller shall be protected against short circuit in components or equipment, which are directly or indirectly connected to the controller.

NOTE See IEC 60204–1 or IEC 60335. Verification can be achieved by assessing conformance with IEC 60204–1 or IEC 60335-1. IEC 60204–1 applies to non-portable electrical, electronic and programmable electronic equipment and systems to machines. IEC 60335-1 deals with the safety of electrical appliances for household and similar purposes including appliances not intended for normal household use but which nevertheless might be a source of danger to the public, such as appliances intended to be used by laymen in shops.

Conformance is demonstrated by inspection of the technical documentation.

6.2.5 When a sensor is used for a control function, it shall have a broken sensor protection that fails to safety.

NOTE Failure to safety can be electronic or mechanical.

Conformance is demonstrated by inspection of the technical documentation.

6.2.6 The automatic controller shall be located such that the maximum values of temperature, humidity and any limiting ambient pressure values specified for the automatic controller are not exceeded.

Conformance is demonstrated by inspection of the technical documentation.

6.2.7 Means shall be provided so that if a failure of the automatic controller occurs, the door can be opened without causing a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

6.3 Control and monitoring system

6.3.1 The control and monitoring system shall have separate measuring chains for the measurement of control data and independent data for the monitoring system. Independent measurement systems with separate measurement chains for controlling and recording shall be applied to defined cycle variables and process variables. Separate analogue to digital converters shall be used for the control data and independent data.

NOTE 1 Measurement systems providing a higher level of redundancy can be used.

NOTE 2 Risk analysis identifies which cycle variables or process variables require redundant supervision.

Conformance is demonstrated by inspection of the technical documentation.

6.3.2 The control and monitoring system shall have segregated software modules that process the control data and the independent data independently of each other.

Conformance is demonstrated by inspection of the technical documentation.

6.3.3 The control data shall be provided to the control function from the data processing system and the control measurement chain.

Conformance is demonstrated by inspection of the technical documentation.

6.3.4 The independent data shall be provided as a one-way flow to data retention.

NOTE This does not exclude the transfer of informative data between the control function and failure detection, and data retention, via a combined system for data transfer.

Conformance is demonstrated by inspection of the technical documentation.

6.3.5 The control and monitoring system shall include means for failure detection. This shall receive both processed control data and independent data, and shall indicate a failure if the control data and independent data differ from specified conditions.

Conformance is demonstrated by inspection of the technical documentation.

6.3.6 The independent data and the control data shall be stored in a data retention module, along with notification of failures. These data shall be transferred to a recorder, that may be integrated into the control and monitoring system, built into the sterilizer, or as an external device(s).

NOTE The external device can be a specific local device, or a remote data storage device.

Conformance is demonstrated by inspection of the technical documentation.

6.3.7 A printer may be provided as an option.

6.4 Failure

6.4.1 General

6.4.1.1 Failure of items critical to process or safety, including the operating equipment and services, should be detected by the monitoring system of the equipment.

NOTE 1 A failure can require different types of indications depending upon its potential effects and urgency, such as audible/visual alarms, warnings, error indications, messages, displays, as well as subsequent automated responses of equipment or correction by the operator.

NOTE 2 The consequences of a failure can depend on the current operation mode of the equipment. Different levels for alarms and indications depending on the related criticality can be provided.

EXAMPLE A failure of the sterilant supply during the conditioning phase of an operating cycle results in an alarm and an abort of the operating cycle. On the other hand, the same failure during the desorption/drying phase does not necessarily affect the successful completion of the operating cycle, but only causes a warning message and prevents the start of a next operating cycle.

6.4.1.2 Such failure of items critical to process or safety detected by the monitoring system of the equipment shall be indicated and explained in the instructions for use regarding the activation conditions, the intended or potential consequences and the required correction.

Conformance is demonstrated by inspection of the technical documentation and the instructions for use.

6.4.2 Fault

6.4.2.1 If a failure addressed by 6.4.1.1 causes one or more of the process or cycle parameters to be outside its/their specified tolerances during an operating cycle, or if an operating cycle is interrupted by the operator, a fault shall be indicated and shall cause an audible or visual alarm.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.2 If a fault is indicated, the current operating cycle stage shall be stopped and identified by the record.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.3 Any visualization of a fault indication shall be distinguishable from the indication of a satisfactory operating cycle.

Conformance is demonstrated by inspection.

6.4.2.4 After a fault has been indicated, the automatic controller shall permit automatic progress to a sterilant or sterilizing agent removal stage if sterilant or sterilizing agent has been admitted to the chamber, followed by operating stages for recovery of the system which, when completed, allows the loading door to be opened without creating a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.5 After completion of the recovery operating stages "cycle complete" shall not be indicated, access to the sterilizer load shall require the use of a key, code or tool, and the load shall be considered non-sterile (see also 5.7.4).

NOTE Additional guidance regarding faults and safety can be found in IEC 61010-2-040.

Conformance is demonstrated by inspection.

6.4.3 Power failure

In the event of a power failure which causes a fault, 6.4.2 above shall apply after restoration of the power.

Conformance is demonstrated in accordance with 6.4.2.

6.4.4 Other failures

6.4.4.1 If a failure of the operating equipment, the current operating cycle, or any service does not create a fault, its indication shall be distinguishable from a fault indication.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4.2 If a failure can create a fault at a later stage of an operating cycle, or after initiation of another operating cycle, a respective warning shall be displayed.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4.3 If a failure can create a hazardous situation, the controller, in combination with other safety systems, shall automatically initiate action to prevent a hazardous situation. The failure shall be indicated by an audible and visible alarm. The alarm indication shall allow the operator to identify the failure and shall provide a directive by text or by reference to an instruction manual for correction. The failure indication shall be recorded in order to allow retrospective identification and analysis.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4.4 Any other failure may be displayed as a message as appropriate.

6.5 Instrumentation

6.5.1 The sterilizer shall be provided with instruments to measure and control the cycle variables.

Conformance is demonstrated by inspection of the technical documentation.

6.5.2 Instruments shall cover the scale range applicable to the operating cycle(s). Instruments shall have specified accuracy or maximal permissible errors sufficient for the automatic control to respond to deviations from the tolerances of the cycle parameters.

The data sampling rate and the response time of sensors and measuring chains shall be appropriate to represent the sterilization process. The following instrumentation characteristics shall permit control of the sterilization process within the specified cycle or process parameters:

a) data sampling rate;

b) control system response time;

c) hysteresis;

d) maximal permissible errors;

e) error caused by changes in ambient conditions.

Conformance is demonstrated by inspection of the specifications of the instrumentation and control system with the specified cycle or process parameters and the rate at which these parameters change during an operating cycle.

6.5.3 The applicable process variables and cycle variables shall be identified to determine the instrumentation necessary for a particular sterilization process. Potential variables for consideration include, but are not limited to:

a) time;

b) temperature;

c) pressure;

d) humidity;

e) sterilizing agent or sterilant concentration;

f) amount of sterilant or sterilizing agent.

Conformance is demonstrated by inspection of the technical documentation.

6.5.4 If dates and times are presented, the format in which the date is presented shall be specified.

NOTE The format in which the date or time is presented can be configurable to customer requirements.

Conformance is demonstrated by inspection of the technical documentation.

6.5.5 The units of measurement for each indicated parameter shall be specified.

NOTE The unit of measurement can be configurable to customer requirements. Regulatory requirements can apply to the units of measurement indicated.

Conformance is demonstrated by inspection of the technical documentation.

6.6 Indicating devices

6.6.1 The sterilizer shall be fitted with means for indication of the cycle parameter(s).

The data sampling rate and the response time of sensors and measuring chains for indicating devices shall be appropriate to represent the sterilization process. The following indication device characteristics shall permit indication of the sterilization process within the specified cycle or process parameters:

a) data sampling rate;

b) measuring chain response time;

c) hysteresis;

d) maximal permissible errors;

e) error caused by changes in ambient conditions.

Conformance is demonstrated by inspection of the technical documentation.

6.6.2 The sterilizer shall be fitted with status indicators displaying:

a) status of the services necessary to operate the operating cycle safely;

b) sterilizer door(s) locked;

c) operating cycle selected, if applicable;

d) operating cycle in progress;

e) operating cycle stage;

f) operating cycle complete;

g) fault;

h) when the sterilizer door can be opened.

Conformance is demonstrated by inspection of the technical documentation.

6.6.3 For operating cycles for test or equipment maintenance purposes, the cycle complete indication shall be different from that of a sterilization cycle.

Conformance is demonstrated by inspection.

6.6.4 A counter shall be provided to indicate the cumulative number of all operating cycles started, including operating cycles in which a fault occurred. The cycle counter shall display a minimum of four digits and shall be protected against tampering or being reset inadvertently.

Conformance is demonstrated by inspection of the technical documentation.

6.6.5 After a fault has been indicated, cycle complete shall not be indicated.

Conformance is demonstrated by inspection of the technical documentation.

6.7 Recorders

6.7.1 Sterilizers shall be fitted with means to collect and retain the cycle parameters and values of the process variables (as specified in 6.1 and 6.7.3) for recording.

Conformance is demonstrated by inspection of the technical documentation.

6.7.2 The recorders shall cover the scale range applicable to the operating cycle(s). Recorders shall have specified accuracy or maximal permissible errors sufficient to identify deviations from the tolerances of the specified cycle parameters and process parameters. The following recorder characteristics shall permit evaluation of the sterilization process against these specified parameters:

a) data sampling rate;

b) measuring chain response time;

c) hysteresis;

d) maximal permissible errors;

e) error caused by changes in ambient conditions.

Conformance is demonstrated by inspection of the specifications of the recorder with the specified cycle or process parameters and the rate at which these parameters change during an operating cycle.

6.7.3 The applicable process variables shall be identified to determine the variables to be recorded for a particular sterilization process. Potential variables for consideration include, but are not limited to:

a) time;

b) temperature;

c) pressure;

d) humidity;

e) sterilizing agent or sterilant concentration;

f) amount of sterilant or sterilizing agent.

Conformance is demonstrated by inspection of the technical documentation.

6.7.4 If dates and times are presented, the format in which the date is presented shall be specified.

NOTE The format in which the date or time is presented can be configurable to customer requirements.

Conformance is demonstrated by inspection of the technical documentation.

6.7.5 The units of measurement for each indicated parameter shall be specified.

NOTE The unit of measurement can be configurable to customer requirements. Regulatory requirements can apply to the units of measurement indicated.

Conformance is demonstrated by inspection of the technical documentation.

6.7.6 The data recorded shall be identified on the record.

Conformance is demonstrated by inspection.

7 Services and local environment

7.1 General

7.1.1 The requirements that are not part of the sterilizer but are needed for the sterilizer to perform as intended shall be specified, including but not limited to:

a) the necessary services;

b) the surrounding environmental conditions;

c) the supporting infrastructure.

Conformance is demonstrated by inspection of the technical documentation.

7.1.2 The sterilizer shall be provided with means to isolate each service. Isolation of a service shall not create a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

7.1.3 Means shall be provided to prevent the ingress of particulates from the services or environment that could affect the performance of the sterilizer or products being sterilized.

NOTE Strainers or filters of a relevant pore size rating can be used.

Conformance is demonstrated by inspection of the technical documentation.

7.2 Sterilizing agent and sterilant

The requirements for the sterilizing agent and sterilant, including its composition, means of generation, handling and storage conditions, if applicable, shall be specified.

Conformance is demonstrated by inspection of the technical documentation.

7.3 Electrical supply

The requirements for the electrical supply system shall be specified, including its configuration, voltage, minimum and maximum values, and connected power. The sterilizer shall be designed to operate when the mains supply voltage is maintained within ±10 % of the nominal supply voltage.

NOTE Examples of configuration include single phases or three-phase supply or rated frequency.

Conformance is demonstrated by inspection of the technical documentation.

7.4 Water

7.4.1 If the sterilizer requires a water supply, the requirements for water to be supplied to the sterilizer shall be specified for each specific use within the sterilizer (e.g. feedwater, service liquid, cooling water, process water). The specification for the water shall ensure that any contaminants are not present in a concentration that could damage the sterilizer, impair the sterilization process or damage the sterilization load.

Conformance is demonstrated by inspection of the technical documentation.

7.4.2 If a water reservoir is fitted, the reservoir shall:

a) be fitted with a valve or other device to allow draining of the reservoir and associated pipework;

b) either be large enough to contain sufficient water for the running of a sterilization cycle or the number of consecutive operating cycles specified to be performed with the test load having the maximum water consumption, or be provided with means to refill automatically;

c) be vented and its design shall facilitate cleaning, inspection and filling;

d) be provided with means to indicate if the water in the reservoir is not sufficient for the current sterilization cycle, if no automatic refill is provided;

e) be designed to prevent back siphoning.

The sterilizer shall not be capable of starting an operating cycle if there is insufficient water in the reservoir.

Conformance is demonstrated by inspection of the technical documentation.

7.5 Steam

If the sterilizer requires an external steam supply, the requirements for steam to be supplied to the sterilizer shall be specified for each specific use within the sterilizer (e.g. steam for sterilization, contacting the product, as a heating medium).

If boiler additives are permitted to be used during steam generation, permitted additives and their maximum permitted concentration(s) shall be specified to limit potential contamination of steam.

NOTE The specification of boiler additives can take into account possible compatibility considerations for the materials used in the sterilizer construction, the possible adverse effect on the sterile barrier system and the toxicity of residual levels which can be deposited on the surface of the product.

Conformance is demonstrated by inspection of the technical documentation.

7.6 Vacuum

If the sterilizer requires an external vacuum system to operate as intended, the requirements for the external vacuum system shall be specified.

Conformance is demonstrated by inspection of the technical documentation.

7.7 Drains

If the sterilizer requires connection to an external drainage system, the requirements for the drainage system shall be specified. The maximum temperature of fluid released from the sterilizer to an external drainage system shall be specified.

NOTE Drainage systems can, for example, be specified as being permanently resistant to 80 °C and resistant to 100 °C for a short period.

Means shall be provided to prevent fluid released from the sterilizer to a drain creating a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

7.8 Lighting

The user interfaces of the sterilizer shall be designed to allow operation with a minimum external illumination of 200 lx.

Conformance is demonstrated by inspection of the technical documentation.

7.9 Compressed air

If the sterilizer requires a compressed air supply, the requirements for compressed air to be supplied to the sterilizer shall be specified for each specific use within the sterilizer (e.g. pneumatic operation of valves, door operation).

NOTE For compressed air contacting the load, see 7.10.

When compressed air is used to operate the sterilizer the air quality shall conform with ISO 8573-1 classification regarding particles, dew point and oil contamination. The required classification shall be specified.

The permissible pressure range for the compressed air supply shall be specified.

Conformance is demonstrated by inspection of the technical documentation.

7.10 Air and inert gases

If the sterilizer requires air or inert gases to be admitted to the chamber, the requirements for the air or inert gas shall be specified in the technical description (see 11.6). Such air and inert gases admitted to the chamber during the sterilization cycle shall be supplied or treated to ensure that it is free from oil and filtered (see also 5.2.6.2).

Conformance is demonstrated by inspection of the technical documentation.

7.11 Ventilation

The environmental conditions necessary for the correct operation of the sterilizer shall be specified (e.g. temperature, humidity, ventilation air flow, number of room air changes per hour).

NOTE 1 This can require the provision of a ventilation system designed and constructed to remove the heat transmitted from the sterilizer and from the sterilizer load when unloading.

NOTE 2 Additional ventilation can be required to prevent exposure to a hazardous situation as a result of release of the sterilizing agent or carrier gases from the sterilizer or sterilization load when the sterilizer is unloaded.

Conformance is demonstrated by inspection of the technical documentation.

8 Emissions

8.1 Electromagnetic emissions

Sterilizers shall conform with IEC 61326-1 regarding electromagnetic emissions.

Sterilizers operating in areas intended for medical electrical equipment or in the vicinity of other sensitive equipment shall be regarded as Class B equipment as specified in IEC 61326-1.

Conformance is demonstrated in accordance with IEC 61326-1.

8.2 Noise

8.2.1 Noise emission from the sterilizer, with the exception of any audible alarm (see 6.4), shall be reduced by design and selection of components with low noise emission levels, particularly at source.

Conformance is demonstrated by inspection of the technical documentation.

8.2.2 The A-weighted sound power and emission sound pressure levels shall be determined in accordance with ISO 3746. The noise emission tests shall be performed in normal use condition with empty sterilizer chamber.

The A-weighted emission sound pressure level shall be determined at the operator's position and shall be indicated in the technical description.

NOTE There can be regulatory requirements for the maximum level of noise emitted by equipment in the workplace and the information to be provided in the technical description. If an A-weighted emission sound pressure level does not exceed 70 dB(A), some jurisdictions can allow only this fact to be indicated in the technical description.

Conformance is demonstrated by inspection of the technical documentation.

8.2.3 If changes to or modification of tested equipment have previously been identified as not contributing to more than 3 dB (A) to the total sound power level, further testing and change of the specification may be omitted.

Conformance is demonstrated by inspection of the technical documentation.

8.2.4 The sound power level for any additional devices supplied for use with the sterilizer shall be indicated in the technical description provided with the device(s).

Conformance is demonstrated by inspection of the technical documentation.

8.3 Exhaust emissions

8.3.1 The removal of sterilizing agent and carrier fluid from the sterilizer chamber and load in the operating cycle shall ensure that:

a) the maximum stipulated concentration of sterilizing agent or carrier fluid in/on processed items will not be exceeded when the load is removed from the sterilizer;

b) the maximum stipulated concentration of sterilizing agent or carrier fluid released into the immediate work environment, in which personnel are working without protective equipment, will not be exceeded when the load is removed from the sterilizer.

Conformance is demonstrated by inspection of the technical documentation.

8.3.2 All exhaust emissions from the sterilizers shall be controlled and, if necessary, discharged via a suitable emission control system.

Conformance is demonstrated by inspection of the technical documentation.

8.4 Heat emission

8.4.1 Pipework at a temperature greater than 60 °C shall be thermally insulated to reduce heat transmission to the environment except where this will interfere with the function of the sterilizer.

Conformance is demonstrated by inspection.

8.4.2 The maximum heat in Joules transmitted by the sterilizer to the surrounding air during an hour of continuous operation with the sterilization cycle giving the highest emission of heat, shall be specified based on an ambient temperature of (23 ± 3) °C.

Opening the sterilizer and removal of the load after end of an operating cycle shall be included in the one-hour period.

Conformance is demonstrated by inspection of the technical documentation.

9 Test instrumentation

9.1 Test instrumentation shall provide means to record the values of cycle variables and process variables (see also 6.7.3).

Conformance is demonstrated by inspection of the specifications of the test instrumentation.

9.2 Test instrumentation shall cover the scale range applicable to the operating cycle(s).

Test instrumentation shall have specified accuracy or maximal permissible errors sufficient to identify deviations from the tolerances of the specified cycle and process parameters. The following test instrumentation characteristics shall permit evaluation of the sterilization process against these specified parameters:

a) data sampling rate;

b) measuring chain response time;

c) hysteresis;

d) maximal permissible errors;

e) error caused by changes in ambient conditions.

Test instrumentation shall have a specified accuracy not less than, or maximal permissible errors not greater than, the instrumentation fitted to the sterilizer.

Conformance is demonstrated by inspection of the specifications of the test instrumentation with the specified cycle or process parameters and the rate at which these parameters change during an operating cycle.

9.3 The applicable cycle and process variables shall be identified to determine the variables to be recorded for a particular sterilization process. Potential variables to consider include, but are not limited to:

a) time;

b) temperature;

c) pressure;

d) humidity;

e) sterilizing agent or sterilant concentration;

f) amount of sterilant or sterilizing agent.

Conformance is demonstrated by inspection of the specifications of the test instrumentation

9.4 If dates and times are presented, the format in which the date is presented shall be specified.

NOTE The format in which the date or time is presented can be configurable to customer requirements.

Conformance is demonstrated by inspection of the technical documentation.

9.5 The units of measurement for each indicated parameter shall be specified.

NOTE The unit of measurement can be configurable to customer requirements. Regulatory requirements can apply to the units of measurement indicated.

Conformance is demonstrated by inspection of the technical documentation.

9.6 The data recorded shall be identified on the record.

Conformance is demonstrated by inspection.

10 Performance and assessment

10.1 General

10.1.1 Tests in this document are type tests to be carried out on samples of equipment or parts whose design and construction are representative of production units. Their purpose is to check that the design and construction ensure conformity with this document. The sequence of tests is optional unless otherwise specified. Different or additional inspections or tests may be undertaken during the production of individual sterilizers.

NOTE General requirements for installation qualification, operational qualification and performance qualification are specified in ISO 14937. Requirements for installation qualification, operational qualification and performance qualification of particular processes for sterilization are given in ISO 11135, ISO 11137, ISO 17665-1, ISO 20857, ISO 25424 and ISO 22441.

10.1.2 The equipment shall at least meet the requirements of this document. It is permissible to exceed the requirements. If a conformity value is specified as a lower limit, then the equipment may demonstrate a larger value. If a conformity value is specified as an upper limit, the equipment may demonstrate a lower value.

10.1.3 Tests on subassemblies that meet the requirements of the relevant standards specified in this document, and used in accordance with them, need not be repeated during type tests of the whole equipment.

10.1.4 Conformity with the requirements of this document is checked by carrying out all applicable tests, except that a test may be omitted if examination of the equipment and design documentation demonstrates conclusively that the equipment would pass the test.

10.1.5 If test loads or process challenge devices are necessary in type testing to demonstrate claimed performances of a cycle for specific types of load configurations as stated by the intended use, these test loads shall be specified [see also 11.5 e), f) and j)].

10.1.6 Where conformity statements in this document require inspection, this may include examination of the:

a) equipment by measurement;

b) markings on the equipment;

c) information supplied with the equipment;

d) data sheets of the materials or components from which the equipment is manufactured.

In each case, the inspection will demonstrate that the equipment meets the applicable requirements, will indicate that changes to the sterilizer are needed, or will indicate that further testing is required.

10.2 Chamber integrity

If a leak into or from the chamber or connected relevant pipework can cause a hazardous situation or affect the intended function or performance of the equipment or the process, the chamber integrity test shall be performed using the means provided in 5.2.3 to demonstrate that leakage into and from the chamber does not exceed specified values. The specified values shall be selected to allow attainment

of the specified process parameters and avoid re-contamination of the sterilizer load at the end of the sterilization process.

10.3 Attainment of conditions

The sterilizer shall achieve the applicable cycle parameters specified for each stage of the sterilization process throughout the usable chamber space within the specified tolerances.

Conformance is demonstrated by measuring the applicable cycle or process parameters at one or more representative position(s) throughout the usable chamber space with the chamber empty and with the usable chamber space loaded with reference loads(s). The rationale for the number and location of measuring positions shall be documented.

NOTE Specific test load configurations can provide a high challenge for air removal and sterilizing agent penetration into the test load.

10.4 Microbiological performance

The sterilization cycle shall be capable of achieving a probability of survival of a single microorganism of not greater than 1×10^{-6}.

Conformance is demonstrated in accordance with ISO 14937:2009, Annex D, with the usable chamber space loaded with reference load(s).

10.5 Pressure change

The maximum rate of pressure change occurring in the sterilizer chamber during each operating cycle shall be specified.

NOTE 1 This maximum rate can have implications for integrity of product including, but not limited to, its sterile barrier system.

The rate of pressure change shall be expressed as the pressure gradient calculated as a rolling average using a rate of measurement of 1 s and time interval for calculations of the rolling average of 3 s.

The method for calculation of the pressure gradient shall be specified and shall be applied to all time intervals within the operating cycle.

The maximum calculated rolling average from at least three replicated operating cycles shall be expressed as maximum rate of pressure change.

NOTE 2 These determinations can be performed in parallel with other type tests.

Conformance is demonstrated by inspection of the technical documentation.

11 Information supplied by the manufacturer

11.1 General

Information to be supplied shall conform with ISO 20417 together with the requirements in 11.2 to 11.6.

NOTE Further requirements on information to be supplied, including the content of labels, markings or use of symbols, can be contained in regulatory requirements or other applicable standards.

Conformance is demonstrated in accordance with ISO 20417 and by inspection of the information to be supplied.

11.2 Information to be made available prior to purchase

The following information shall be made available to prospective purchasers:

a) details of the sterilizing agent and any sterilant, including composition, and storage requirements;

b) safety data sheet for any hazardous substance specified for use;

c) external dimensions of the sterilizer and the floor loading;

d) dimensions of the usable chamber space;

e) instructions for handling during transport and storage such as conditions for stability, orientation, temperature humidity and pressure;

f) details of quality, quantity and capacity of services required for supply, drainage and ventilation;

g) if applicable, the maximum temperature of fluid released from the sterilizer to an external drainage system;

h) details of consumables and accessories dedicated to the sterilizer;

i) total heat in Joules transmitted to the surrounding air when the sterilizer is operated continuously for one hour in an ambient temperature of (23 ± 2) °C in still air;

j) requirements for ambient lighting and lighting of equipment maintenance area(s);

k) instructions on protective measures to be taken by users, including, if applicable, any personal protective equipment to be provided;

l) cleaning instructions for the chamber and the exterior including the type of agents to be used;

m) any restrictions for installation or operation, including any relevant regulatory classification.

11.3 Marking

11.3.1 Marking(s) that is(are) clearly visible shall be permanently affixed to the equipment frame or body and shall bear the following information:

a) unique device identification;

b) electricity supply rated voltage, current type, rated frequency, maximum current or power;

c) if applicable, maximum operating pressure and hydrostatic test pressure;

d) if applicable, regulatory registration identification or mark signifying regulatory approval;

e) warning symbols.

NOTE Regulatory requirements or specific standards can require additional marking(s).

11.3.2 Indicating and operating devices shall be identified as to their function.

11.4 Label

11.4.1 Instructions for disposal of the packaging of the sterilizer shall be clearly indicated on the outside of the package.

11.4.2 Each sterilizer shall be labelled with, as applicable:

a) safety precautions to be taken for operating the door;

b) safety precautions to be taken to prevent burns from high temperature;

c) applications of the sterilizer;

d) warnings and precautions.

11.5 Instructions for use

The instructions for use for each sterilizer shall include:

a) name and full address of the manufacturer;

b) common name, the manufacturer's type and model designation;

c) clear description of the intended use of the sterilizer;

d) general description of the sterilizer;

e) description of the available sterilization cycle(s), their intended application range and restrictions for use, if applicable;

f) description of the types of sterilization load(s), load configuration and appropriate loading volume;

g) specified process parameters and cycle parameters for the sterilization process;

h) details of any additional operating cycles provided by the automatic controller;

i) name and address of the holder of the regulatory approval;

j) applications of the sterilizer;

k) warnings and precautions, including a comprehensive list of residual risks;

l) storage requirements for the sterilant or sterilizing agent, if applicable;

m) instructions for the safe and effective operation of the sterilizer, including:

   1) safety precautions to be taken during routine use;

   2) safety precautions to be taken for operating the door(s);

   3) safety precautions to be taken to prevent burns from high-temperature, if applicable;

   4) considerations for loading (load size, type of materials, load configuration);

   5) available sterilization cycles and recommended settings;

   6) means by which sterilization cycles can be changed;

   7) means by which a failure to satisfy process parameters can be detected and the recommended actions;

   8) means by which an error in the monitoring, recording, or controlling of the process parameters can be detected and the recommended actions;

   9) instructions for inspection and routine equipment maintenance, including a schedule for implementing inspection and routine equipment maintenance procedures;

   10) cleaning procedures with a caution that these procedures should be carried out by trained personnel.

11.6 Technical description

The technical description for the sterilizer shall include:

a) name and address of manufacturer;

b) the common name, the manufacturer's type and model designation;

c) serial number;

d) year of manufacture;

e) unique device identification;

f) electricity supply rated voltage, current type, rated frequency, maximum current or power;

g) if applicable, maximum operating pressure and hydrostatic test pressure;

h) if applicable, regulatory registration identification or mark signifying regulatory approval;

i) requirements for external services;

j) instructions for the installation and installation qualification of the sterilizer, complete and comprehensive enough to ensure the safe and effective operation of the equipment, including such information as the required building system services and the type of materials to be used for installation, including:

   1) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment, and the specified requirements for the installation area;

   2) details of the services required for supply, drainage and ventilation;

   3) drain connection, if applicable, not to cause back pressure or obstruction to flow;

   4) the maximum temperature of fluid released from the sterilizer to an external drainage system;

   5) clearance required to allow opening of the door(s) and loading and unloading operation of the sterilizer;

   6) if applicable, provisions necessary to ensure the mechanical stability of the device during installation, operation, equipment maintenance and service.

k) instructions for inspection and routine equipment maintenance;

l) equipment maintenance interval or timetable and description of routine equipment maintenance procedures;

m) schedule for implementing inspection by the authority having jurisdiction and explanation for routine self-inspection;

n) specific directions concerning the equipment maintenance of critical components, such as filters, recorders, steam separators or traps, valves, and safety valves;

o) list of spare parts replaceable by the user;

p) list of special tools necessary for equipment maintenance;

q) if applicable, description of the recommended procedure for draining and decontaminating the water supply reservoir;

r) sound pressure levels;

s) name and telephone number or other contact information of an authorized service agent or representative;

t) dimensions of the usable chamber space;

u) details of the sterilizing agent and any sterilant, including composition, safety data sheet and storage requirements;

v) external dimensions of the sterilizer and the floor loading;

w) instructions for handling during transport and storage such as conditions for stability, orientation, temperature humidity and pressure;

x) details of consumables and accessories dedicated to the sterilizer;

y) the total heat in Joules transmitted by the sterilizer to the surrounding air during an hour of continuous operation with the sterilization cycle giving the highest emission of heat, based on an ambient temperature of (23 ± 3) °C;

z) requirements for ambient lighting and lighting of equipment maintenance area(s);

aa) instructions on protective measures to be taken by users, including, if applicable, any personal protective equipment to be provided;

bb) cleaning instructions for the chamber and the exterior including the type of agents to be used;

cc) any restrictions for installation or operation;

dd) statement that materials used in the sterilizer which can come in contact with the sterilizing agent or carrier fluids do not react to an extent that material deterioration could affect the operation of the sterilization cycle, have a detrimental effect on the materials of the sterilizer or chamber accessories, or create a hazardous situation;

ee) maximum rate of pressure change in an operating cycle.

Annex A
(informative)

Rationale for requirements

A.1 Introduction

ISO/TC 198 Working Group 11, General criteria for sterilization processes and sterilizing equipment, developed this rationale to document its reasoning for establishing the various requirements contained in this document. Those who make future revisions can use this annex, along with experience gained in the use of this document, to make this document more useful to manufacturers, regulatory bodies and health care providers and to develop standards describing particular requirements for sterilizers using a specific sterilizing agent.

A.2 Normative references

This clause is a mandatory clause in the structure of documents outlined in the ISO Directives, Part 2. It identifies other documents that are indispensable for the application of this document.

A.3 Definitions

This document incorporates applicable definitions from ISO 11139 in order to maintain consistency in the use of terms across all standards for sterilization, sterilizing equipment and associated ancillary items and materials. In accordance with the resolution of ISO/TC 198, Sterilization of health care products, the applicable definitions from ISO 11139 have been reproduced in this document for the convenience of users.

Additional definitions from other sources, such as ISO 20417 on information to be provided by the manufacturer of medical devices, have been incorporated when such definitions are used in this document.

A.4 General

The purpose of this clause is to establish the link between this document and the requirements for a system of risk management, control of documents, including records, and calibration of instrumentation required by this document.

A.5 Equipment design and construction

A.5.1 Safety and security

The purpose of this subclause is to describe the link between this document and IEC 61010-2-040, set out the relationship with applicable parts of IEC 61010 and establish requirements for cybersecurity.

A.5.2 Chamber

The purpose of this subclause is to set out of the requirements for the chamber or vessel such that it can be used safely and deliver the required process reproducibly. The requirements include its construction, requirements when the process operates above or below atmospheric pressure, description of dimensions, means of access, chamber integrity, uniformity of conditions.