International Standard

ISO 11139

First edition
2018-08

AMENDMENT 1
2024-01

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definitions

Stérilisation des produits de santé — Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes

AMENDEMENT 1: Termes et définitions modifiés et supplémentaires

Reference number
ISO 11139:2018/Amd.1:2024(en)

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Published in Switzerland

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definitions

3.111 exposure phase

Replace the term and the text of the definition with the following:

3.111
exposure stage
cycle stage between the introduction of the sterilizing agent or disinfecting agent into the chamber and when its microbicidal effect has become negligible

Note 1 to entry: The exposure stage comprises that part of the process for which microbial lethality is claimed.

3.113.2 F_{BIO} value

Replace the text of the definition with the following:

3.113.2
F_{BIO} value
expression of the resistance of a biological indicator calculated as the product of the logarithm to base 10 of the initial population of microorganisms and the *D* value

Add the following new entry 3.113.4 $F_{BIOLOGICAL}$ value:

3.113.4
$F_{BIOLOGICAL}$ value
expression of the delivered lethality of a process, measured in terms of actual kill of microorganisms on or in a biological indicator (BI) challenge system

Note 1 to entry: $F_{BIOLOGICAL}$ can be calculated by multiplying the D_{121} value by the difference between the log to the base ten of the starting population and the log to the base ten of the enumerated population after processing.

3.133 holding time

Replace the text of the definition with the following:

3.133
holding time
period during which process or cycle parameters are maintained within their specified tolerances for defined cycle stages

Add the following new entry 3.133.1 holding time:

3.133.1
holding time
<moist heat sterilization> period for which the temperatures at the reference measurement point, and at all points within the load, are continuously within the sterilization temperature band

3.151 labelling

Replace the text of the definition with the following:

3.151
labelling
label, instructions for use and any other information related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8]

3.166 medical device

Added "in or on the human body" in the paragraph after the list, as follows:

3.166
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 which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, 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 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.

3.214 processing

Add new entry number and definition as follows:

3.214.1
processing
<biologics and tissue-based product> activity performed in the preparation, manipulation, preservation for storage and packaging of a biological or tissue-based product

Renumber 3.214 processing <preparation of medical devices> as:

3.214.2
processing

3.254 simulated product

Replace the text of the definition with the following:

3.254
simulated product
item intended to represent specified characteristics of a product or product family used to demonstrate a defined performance of a process related to these characteristics

3.293.1 temperature band

Replace the text of the definition with the following:

3.293.1
temperature band
<operating> range of temperatures expressed as the minimum and maximum temperatures in the usable chamber space during a holding time

Note 1 to entry: An operating cycle can comprise more than one holding time.

3.296 terminally sterilized

Replace the text of the definition with the following:

3.296
terminally sterilized
exposed to a successful sterilization process in its sterile barrier system

After 3.327

Add the following new term entries:

3.328
acceptance range
<irradiation> range within which the statistic under consideration lies with a specified probability when the process is in a state of control

3.329
accompanying information
information accompanying, or marked on, a medical device or accessory and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the medical device or accessory, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the medical device or accessory.

Note 2 to entry: The accompanying information can consist of the label, 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).

Note 4 to entry: The label can include the information on the packaging of the medical device.

Note 5 to entry: E(electronic)-documentation can include any or all types of information supplied by the manufacturer partially or entirely.

Note 6 to entry: Marketing information is also known as promotional material.

[SOURCE: ISO 20417:2021, 3.2, modified — The term "processing" has been removed from the definition, Note 1 to entry has been modified to exclude a requirement, Note 4 to entry has been deleted, and Notes 5 to 7 have been renumbered Notes 4 to 6 to entry.]

3.330
biologic
product that is synthesized from living organisms, or their products, and used as a diagnostic, preventive or therapeutic agent

3.331
companion tissue
tissue from the same donor(s) that is not intended to be used for transplantation

3.332
contained product sterilization
<moist heat sterilization> validated process where indirect contact of a heating medium on the external surfaces of contained product is used to create moist heat internally to achieve the specified requirements for sterility within the contained product

3.333
critical medical device
<washer-disinfector> item processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical medical devices usually require sterilization before use.

Note 2 to entry: National regulations can use alternative wording for this term.

3.334
donor identification
unique identifier assigned to all transplantable tissue and companion tissue that originates from the same donor

3.335
end product testing
testing carried out on product samples that have completed the entire manufacturing process

3.336
endotoxin limit
maximum allowable level of endotoxin specified for a product

3.337
endotoxin unit
EU
international unit
IU
standard unit of measure for endotoxin activity initially established relative to the activity contained in 0,2 ng of the U.S. Reference Standard Endotoxin Lot EC-2 [United States Pharmacopeia (USP) standard reference material]

Note 1 to entry: Currently, the U.S. Reference Standard Endotoxin EC-6, USP Lot G, and the World Health Organization's primary international endotoxin standard (IS) are sub-lots of the same endotoxin preparation, making the EU and IU equal.

3.338
endpoint
point where an assay or reaction is indicated to have reached a specified level

3.338.1
endpoint
<bacterial endotoxin> the most dilute concentration of a test or control solution for which a positive reaction for bacterial endotoxin is observed

3.338.2
endpoint
<chemical indicator> point of the observed change defined by the manufacturer, occurring after the indicator has been exposed to specified stated values

3.338.3
endpoint
<geometric mean> antilog of the average of the logarithmic values with respect to the endpoints from replicate dilution series converted back to a base 10 number used to establish the central tendency or typical value from a test solution

3.339
health care facility
HCF
dedicated setting where health care professionals deliver services for patient care

EXAMPLE Hospitals, free-standing ambulatory surgical centres, nursing homes, extended care facilities, medical, dental and physician offices or clinics and other specialised treatment facilities.

3.340
implantable health care product
product inserted internally to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure

Note 1 to entry: An implantable health care product can be permanent or temporary.

3.341
information supplied by the manufacturer
all information related to the identification and use of a medical device or accessory, in whatever form provided, intended to ensure the safe and effective use of the medical device or accessory

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 — Notes 1, 3 and 4 to entry have been deleted, and Note 2 to entry has become Note 1 to entry.]

3.342
instructions for use
IFU
portion of the accompanying information that is essential for the safe and effective intended use of a medical device or accessory directed to the user of the medical device

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

[SOURCE: ISO 20417:2021, 3.11, modified — '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 become Note 1 to entry.]

3.343
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

Note 2 to entry: The term "intended use" is used in some jurisdictions while "intended purpose" is used in others.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — "intended purpose" added to term and Note 2 to entry has been added.]

3.344
interference
<bacterial endotoxin test> (BET) interfering factor observed in the performance of the test that exceeds the acceptable threshold for a given BET technique (e.g. positive product control that indicates a detected endotoxin level less than 50 % or greater than 200 % or ±2 lambda)

3.345
interfering factors
<bacterial endotoxin test> non-endotoxin related factor, usually attributable to a characteristic of the test sample, that causes inhibition or enhancement

3.346
intraocular
located or occurring within or administered through the eye

3.347
intralymphatic
located in or occurring within or administered through a lymph vessel

3.348
intrathecal
located in or occurring within or administered through the space under the arachnoid membrane of the brain or spinal cord

3.349
intravascular
located in or occurring within or administered through the heart or blood vessel(s)

3.350
label
<medical device, accessory> written, printed, or graphic information appearing on the item itself

Note 1 to entry: Label includes the marking on the medical device or accessory.

[SOURCE: ISO 20417:2021, 3.12, modified — Reference to packaging and provision of multiple items has been deleted, Notes 1, 3 and 4 to entry have been deleted, and Note 2 to entry has become Note 1 to entry.]

3.351
lambda
λ
<endotoxin testing> labelled sensitivity of an LAL gel-clot reagent expressed in EU/mL or, for chromogenic or turbidimetric tests, the lowest point (endotoxin concentration) on the referenced standard curve

3.352
lipopolysaccharide
Gram-negative bacterial cell wall component composed of lipid A, a core polysaccharide, and an O-side chain

3.353
marking
information, in text or graphical format, durably affixed, printed, etched, or equivalent, to a medical device or accessory

Note 1 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 — Note 2 to entry has been modified and renumbered as Note 1 to entry. Notes 1 and 3 to entry have been deleted.]

3.354
maximum valid dilution
MVD
<endotoxin testing> maximum amount a sample can be diluted, or the total extraction volume used relative to the sensitivity of a bacterial endotoxins test (BET) in which the specified endotoxin limit can be detected

3.355
method suitability test
test to determine whether a particular sample contains interfering factors that diminish its accuracy by introducing enhancement or inhibition into the test system

3.356
national standard
<metrology> measurement standard recognized by a 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, modified — The term "national measurement standard" has been deleted and the domain <metrology> has been added.]

3.357
non-critical device
<washer-disinfector> item processed in a washer-disinfector, whose surface(s) are intended to contact intact skin of a body but do not penetrate it, or device not intended for direct patient contact

EXAMPLE Blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, containers for transit.

Note 1 to entry: National regulations can use alternative wording for the definition of this term when applied to medical devices.

3.358
penetration type test device
PTTD
device for use in type tests to ascertain a minimum sterilizing agent penetration performance during a sterilization cycle

3.359
primary standard
<metrology> 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 term "primary measurement standard" and Examples have been deleted, and the domain <metrology> has been added.]

3.360
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: An activity can include an equipment function.

Note 2 to entry: Whether the "intended result" of a *process* is called output, product or service depends on the context of the reference.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 2, 3, 4, 5 and 6 were deleted, a new Note 1 to entry has been added, and the original Note 1 to entry was renumbered as Note 2 to entry.]

3.361
process load
<irradiation> volume of material with a specified product loading configuration irradiated as a single entity

Note 1 to entry: The process load consists of one or more irradiation containers.

[SOURCE: ISO/ASTM 52303:2015, 3.1.10, modified — The domain <irradiation> has been added.]

3.362
process target dose
D_{target}
<irradiation> dose, at a specified monitoring location, which the irradiation process parameters are set to deliver

3.363
process variability
<irradiation> measure of factors that results in a random distribution of data around the average that provides information on how well the process can perform when all special cause variation is removed

3.364
product realization
processes consistent with the quality system requirements that are needed to develop, manufacture and deliver the finished product

3.365
Reference Standard Endotoxin
RSE
<endotoxin> USP Endotoxin Reference Standard that has a defined potency of 10 000 USP EUs per vial

3.366
repeat test
<endotoxin> analysis of additional product samples from a previously tested batch or another batch

Note 1 to entry: This definition can be used in other environments where the term repeat test is used.

3.367
retest
<endotoxin> reanalysis of previously tested product samples or product sample preparation

Note 1 to entry: This definition can be used in other environments where the term retest is used.

3.368
saturated steam sterilization
validated process which involves the direct contact of saturated steam as the sterilizing agent on product surfaces to achieve the specified requirements for sterility

3.369
semi-critical medical device
<washer-disinfector> item processed in a washer-disinfector, that, during use, contacts mucous membranes or non-intact skin of a body

EXAMPLE Some probes, some respiratory therapy equipment.

Note 1 to entry: National regulations can use alternative wording for this term.

3.370
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 medical device from other medical devices with the same catalogue number or model number

[SOURCE: ISO 20417:2021, 3.22]

3.371
simulated use
use that mimics the intended use of a medical device

3.372
statistical process control
SPC
set of techniques for improving the quality of process output by reducing variability through the use of one or more control charts and a corrective action strategy used to bring the process back into a state of statistical control

[SOURCE: ASTM E2587-16:2021]

3.373
targeting buffer
<irradiation> standard factor or factors used to determine process target doses which has been demonstrated to have more conservative calculated values of UF_{lower} and UF_{upper} during historical routine processing

3.374
technical description
portion of the accompanying information 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 medical device

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

[SOURCE: ISO 20417:2021, 3.30, modified — "processing" and Note 2 to entry have been deleted.]

3.375
tissue-based product
product consisting of the organization of cells, cells and extra-cellular constituents, or extra-cellular constituents

Note 1 to entry: This can include tissues from tissue banks or material of animal origin.

3.376
worst-case
set of conditions, as compared with ideal conditions, justified to pose the highest probability of process or product failure

Note 1 to entry: The set of conditions do not necessarily induce product or process failure.

Note 2 to entry: The set of conditions should be specified within the limitations of the intended use.

Note 3 to entry: The set of conditions should encompass upper and lower processing limits and circumstances.

Add a new Clause 4

4 Abbreviated terms

BET	bacterial endotoxins test
D_{target}	process target dose
EU	endotoxin unit
HCF	health care facility
IFU	instructions for use
IU	international unit
LAL	*Limulus* amoebocyte lysate
MTD	maximum valid dilution
PTTD	penetration type test device
RSE	Reference Standard Endotoxin
SPC	statistical process control
TAL	*Tachypleus* amoebocyte lysate
USP	United States Pharmacopeia