ISO 11139:2018/PRF Amd .1:2023(E)

ISO/TC 198/WG5

Secretariat: ANSI

Date: 2023-09-1811-03

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

AMENDMENT 1 : Amended and additional terms and definitions

AMENDEMENT 1: Termes et définitions modifiés et supplémentaires

FDIS stage

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Published in Switzerland

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Field Code Changed

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***~~
***$F_{BIOLOGICAL}$* 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

Replace Added "in or on the text of human body" in the definition with paragraph after the following 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.

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

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

~~*3.230 repeatability*~~

~~Delete.~~

~~*3.231 reproducibility*~~

~~Delete.~~

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

