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

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

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Foreword

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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).

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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 the following URL: www.iso.org/iso/foreword.html.

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

This first edition of ISO 11139 cancels and replaces ISO/TS 11139:2006, which has been technically revised.

The main changes compared with the previous edition are as follows:

— all the terms and definitions have been reviewed based on existing documents in the field and future needs, and have been revised accordingly for consistency of use;

NOTE This vocabulary is now the source document for these terms.

— additional terms and definitions have been added.

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

This document provides the fundamental vocabulary for sterilization of health care products and associated equipment. It provides the foundation for other standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products used in ensuring effective application of these processes. This document is intended to help the user to understand the vocabulary of cleaning, disinfecting, sterilizing, and aseptically processing health care products, in order to be able to implement the related standards effectively.

This document contains the terms and definitions that apply to all standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products developed by ISO/TC 198 and other European standards in the same field of application.

The terms and definitions are arranged in alphabetical order in English.

ISO/TC 198 has produced a white paper describing the principles used to develop this compilation of terms and definitions and proposals on its use in the development of new and revised standards for disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products. This white paper is available through the International Organization for Standardization.

The Bibliography includes the standards referenced in Annex A. If a term has been dropped in a current revision, reference has not been made.

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

1 Scope

This document defines terms in the field of the sterilization of health care products including related equipment and processes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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
A_0
measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K

3.2
absolute pressure
pressure for which the zero value is associated with absolute vacuum

3.3
absorbed dose
<radiation> quantity of ionizing radiation energy imparted per unit mass of a specified material

3.4
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.

3.5
action level
value from monitoring that necessitates immediate intervention

3.6
active ingredient
chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose

3.7
aeration
part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

3.8
air break
physical separation in water supply pipes to prevent back flow from equipment

3.9
air detector
device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate

3.10
airlock
enclosure with interlocked doors designed to maintain pressure control between adjacent areas

3.11
alert level
value from monitoring providing early warning of deviation from specified conditions

3.12
analyte
chemical substance that is the subject of chemical analysis

3.13
aseptic presentation
transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

3.14
aseptic processing
handling of sterile product, containers, and/or devices in a controlled environment in which the air supply, materials, equipment, and personnel are regulated to maintain sterility

3.15
aseptic processing area
APA
facilities for aseptic processing, consisting of several zones

3.16
aseptic technique
conditions and procedures used to minimize the risk of the introduction of microbial contamination

3.17
assurance of sterility
qualitative concept comprising all activities that provide confidence that product is sterile

3.18
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

3.19
bacterial challenge test
<aseptic processing> technical operation performed to evaluate the capability of a filter to retain microorganisms from a liquid bacterial suspension under specified conditions

3.20
bacteriostasis/fungistasis test
technical operation performed to detect the presence of substances that inhibit microbial multiplication

3.21
batch
defined quantity of a product intended or purported to be uniform in character and quality produced during a specified cycle of manufacture

3.22
bedpan washer-disinfector
washer-disinfector for human waste containers that additionally empties and flushes

3.23
bioburden
population of viable microorganisms on or in a product and/or sterile barrier system

3.24
bioburden correction factor
numerical value applied to a viable count to compensate for incomplete removal of microorganisms from a product and/or failure to culture microorganisms

3.25
bioburden estimate
value established by applying a correction factor to a bioburden count

3.26
bioburden spike
individual bioburden value that is significantly greater than other bioburden values in a set

3.27
bio-decontamination
removal and/or reduction of biological contaminants to an acceptable level

3.28
biological contaminant
cell or biological entity other than the intended components present in product

EXAMPLE Viruses, bacteria, fungi, protozoa, multicellular parasites, contaminating eukaryotic cells, aberrant proteins known as prions, endotoxins, or active DNA/RNA.

Note 1 to entry: This can include extrinsic and/or intrinsic contaminants.

Note 2 to entry: A biological entity is a functional assembly of biological molecules or structures, and could be an enzyme complex, a membranous structure, ribosomes, etc., or a combination thereof, that is kept assembled to maintain its biological functionality.

3.29
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified sterilization process

3.30
block
<endoscope> group of channels comprising part of an endoscope with specified lengths, diameters, and interconnections

3.31
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/IEC Guide 99:2007, 2.39, modified — The notes to entry have been deleted.]

3.32
calorifier
closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated fluid through a heat exchanger

3.33
carrier
<biological indicator> supporting material on or in which test microorganisms are deposited

3.34
cell-based
containing or consisting of prokaryotic or eukaryotic cells or cell derived biological entities

Note 1 to entry: A biological entity is a functional assembly of biological molecules or structures, and could be an enzyme complex, a membranous structure, ribosomes, etc., or a combination thereof that is kept assembled to maintain its biological functionality.

3.35
cell-processing area
CPA
area for processing cell-based materials consisting of different zones for processing and, where applicable, for containment

3.36
chamber
part of equipment in which a load is processed

3.37
chamber pre-heating
process that raises the temperature of internal chamber surfaces prior to the commencement of an operating cycle

3.38
chamber reference temperature
temperature at a specified point within the chamber

3.39
change control
assessment and determination of the appropriateness of a proposed alteration to product, process, or equipment

3.40
channel separator
<endoscope> device used to keep apart interconnected fluid pathways

EXAMPLE A device inserted in a trumpet valve cylinder where multiple channels meet in order to separate the air and water pathways in the air/water valve assembly.

3.41
chemical compatibility
<filter> capability of process fluids and filter materials to be used together, under the specified process conditions, without adverse effects on either the fluids or filter materials

3.42
chemical disinfection
disinfection achieved by the action of one or more chemicals

3.43
chemical indicator
test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

3.43.1
chemical indicator system
combination of a chemical indicator and a specific test load

3.44
chemical indicator endpoint
completion of a specified change after a chemical indicator has been exposed to specified conditions

3.45
clean
visually free of soil and below specified levels of analytes

3.46
cleaning
removal of contaminants to the extent necessary for further processing or for intended use

3.47
cleaning agent
physical or chemical entity, or combination of entities, having activity to render an item clean

3.48
clean-in-place
CIP
cleaning of internal surfaces of parts of equipment or an entire process system, without or with minimal, disassembly

3.49
clinical use
use of a health care product during a procedure on a patient

3.50
closed system
<aseptic processing> means to prevent egress of hazardous agents and ingress of extrinsic contamination

3.51
closure
<packaging> means used to complete a sterile barrier system where no seal is formed

3.52
closure integrity
<packaging> characteristics of a closure to minimize the risk of ingress of microorganisms

3.53
colony forming unit
CFU
visible aggregation of microorganisms arising from a single cell or multiple cells

3.54
combination product
entity presented as a single health care product that physically, chemically, or otherwise brings together or mixes items regulated under separate legislation

Note 1 to entry: The entity could be a combination of medical device and medicinal product or biopharmaceutical product.

3.55
combined standard measurement uncertainty
standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

[SOURCE: ISO/IEC Guide 99:2007, 2.31, modified — The admitted term and the Note 1 to entry have been deleted.]

3.56
come-down period
<resistometer> time elapsed from the termination of the exposure period to an established null reaction point

3.57
come-up period
<resistometer> time elapsed from the introduction of the sterilizing agent to the attainment of the specified conditions

3.58
conditioning
treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

3.59
containment
combination of buildings, engineering functions, equipment, and work practices that allow safe handling of hazardous biological or chemical substances, and prevent accidental release of these substances to the external environment

3.60
containment area
designated location consisting of a cell processing area and an associated degowning room

3.61
containment facility
combination of manufacturing rooms including the containment area and associated rooms within a physical containment barrier

Note 1 to entry: This can include airlocks, access and support rooms, laboratories, and interconnecting corridors.

Note 2 to entry: A containment facility uses a series of barriers (primary, secondary, and tertiary) to minimize the escape of hazardous agents to facility workers, the general population, and the environment, e.g. isolators (if necessary, negative pressure type); biological safety cabinets (Class I, II or III); negative air pressure cleanroom; personnel protective clothing; appropriate work practices; appropriate disposal of hazardous waste; restriction of access to the facility.

3.62
continuous process machine
equipment that moves one work unit at a time between each step of the process with the product generally remaining in motion

Note 1 to entry: This is contrasted with batch process equipment, which would expose the entire batch to each step of the process, one step at a time.

3.63
control
regulation of variables within specified limits

3.64
correction
action to eliminate a detected nonconformity

Note 1 to entry: A correction can be made in advance of, in conjunction with, or after a corrective action.

[SOURCE: ISO 9000:2015, 3.12.3, modified — The Note 2 to entry has been deleted.]

3.65
corrective action
action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified – Note 3 to entry has been deleted]

3.66
coverage factor
number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

Note 1 to entry: A coverage factor is usually symbolized *k*.

[SOURCE: ISO/IEC Guide 99:2007, 2.38]

3.67
critical processing zone
location within the aseptic processing area in which product and critical surfaces are exposed to the environment

3.68
critical surface
surface that might come into direct contact with a product, including its containers or closures, posing a risk of contamination

3.69
culture collection number
unique identification of a test organism allocated by a recognized culture collection

3.70
culture condition
combination of growth media and manner of incubation used to promote germination, growth, and/or multiplication of microorganisms

Note 1 to entry: The manner of incubation can include the temperature, time, and any other conditions specified for incubation.

3.71
cycle complete
message from the automatic controller that the operating cycle has ended successfully

3.72
cycle parameter
value of a cycle variable including its tolerance used for control, monitoring, indication, and recording of an operating cycle

3.73
cycle time
<irradiation> period of time an irradiation container spends in each dwell position in a gamma process, used as a control parameter for dose

3.74
cycle variable
property used to control, monitor, indicate, or record an operating cycle

3.75
***D* value**
D_{10} value
time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganisms

3.76
dead leg
area of entrapment in vessel or piping that is not easily accessed

3.77
depyrogenation
process used to remove or deactivate pyrogenic substances to a specified level

Note 1 to entry: Pyrogenic substances include bacterial endotoxins.

3.78
desorption
removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

3.79
development
act of elaborating a specification

3.80
dew point
temperature at which the saturation water vapour pressure is equal to the partial pressure of the water vapour in the atmosphere

3.81
direct support zone
protective area directly surrounding a critical processing zone

3.82
disinfectant
chemical or combination of chemicals used for disinfection

3.83
disinfecting agent
physical or chemical agent used for disinfection

3.84
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

3.85
disinfection temperature
minimum temperature on which the evaluation of the disinfection efficacy is based

3.86
disinfection time
period for which the process variable(s) is/are maintained at or above that/those specified

Note 1 to entry: Examples of process variables include temperature of the load, disinfectant concentration in the chamber.

3.87
dose mapping
<radiation> measurement of dose distribution and variability in material irradiated under specified conditions

3.88
dose uniformity ratio
<radiation> ratio of the maximum to the minimum absorbed dose within the irradiation container

3.89
dosimeter
device having a reproducible, measurable response to radiation that can be used to measure the absorbed dose in a given system

3.90
dosimetry
measurement of absorbed dose by the use of dosimeters

3.91
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards, and procedures for their use

3.92
double-ended
having separate doors for loading and unloading in separate areas

3.93
drying stage
part of an operating cycle that is dedicated to removing moisture from the load

3.94
endoscope connector
device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector

3.95
endoscope leak test
set of actions to identify a loss of integrity

3.96
endoscope port
part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel

3.97
endoscope product family
group of endoscopes with comparable design, including the number, construction, and purpose of the different endoscope channels