TECHNICAL SPECIFICATION

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Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

Recommandations relatives à la qualité de l'eau destinée aux stérilisateurs, à la stérilisation et aux laveurs désinfecteurs de produits de santé

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 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

The quality of water supplied to sterilizers and washer-disinfectors (WDs) used for processing medical devices is an important aspect of the effective functioning of that equipment and the ultimate safety and functioning of medical devices and other health care related equipment being processed.

Potable water can vary in its specific quality aspects within countries, between countries around the world and over time due to the supply source, means of transport or distribution, and storage. Although potable water is considered fit for consumption, it is not necessarily of sufficient quality for processing medical devices as its microbial and chemical quality can vary considerably. For this reason, it can be necessary for potable water to be subjected to some form(s) of treatment prior to use in sterilizers and WDs used for processing medical devices and other health care related products.

The quality of water is influenced by a number of variables that can be characterized as physical, chemical and microbiological attributes.

Water treatment systems can be configured in many ways. The primary goal of all water treatment systems is achieving the water quality specifications suitable for the products and each step of processing. Water can be treated by a variety of methods that yield different levels of water quality. Commonly used water treatments can include, for example, softening, deionization (DI), filtration, reverse osmosis (RO), ozonization, distillation and sterilization.

Country-specific guidance documents can recommend the quality of water to be used when processing medical devices or other health care products in sterilizers and WDs.

This document provides guidance on the quality of water for sterilizers, sterilization and WDs used to process health care products; specific water quality attributes are taken from the relevant sterilizer, sterilization or WD standards. The scope of this document specifically excludes making changes to the water quality attributes that are recommended in the source documents, but where discrepancies exist between different applications for water, for example between different sterilization modalities, these differences can be addressed in future revisions to those source documents.

Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

1 Scope

1.1 Inclusions

This document provides guidance on the quality of water for sterilizers, sterilization and washer-disinfectors (WDs) used to process health care products.

This document covers the quality of water used directly for cleaning, thermal and chemical disinfection, rinsing and sterilization, as feedwater for the generation of steam, as a service to a sterilizer or WD, or as a cooling agent.

This document provides specific guidance on:

— water quality for different applications;

— water treatment systems;

— water distribution and storage;

— monitoring and control of water quality;

— investigating out of specification results.

NOTE Guidance given in this document can also be applied to specifications for the quality of water required for manual cleaning or disinfection of medical devices (see the ISO 17664 series).

1.2 Exclusions

This document does not supersede or modify requirements or test methods of published standards applying to:

— development, validation or routine control and monitoring of a sterilization process;

— sterilizers;

— WDs.

This document does not specify requirements for water treatment systems (see, for example, standards for particular sterilizers or WDs).

This document does not specify the water quality for manufacturing pharmaceuticals, cell-based health care products or medical devices.

This document does not provide guidance on the attributes of steam quality (see, for example, EN 285).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
analyte
chemical substance that is the subject of chemical analysis

[SOURCE: ISO 11139:2018, 3.12]

3.2
aseptic technique
conditions and procedures used to minimize the risk of the introduction of *microbial contamination* (3.25)

[SOURCE: ISO 11139:2018, 3.16]

3.3
biofilm
growth of surface attached *microorganisms* (3.26) within their extracellular polymeric substances, which results in surface slime

[SOURCE: ISO 20670:2018, 3.8, modified — Removed "biofilm" from the definition.]

3.4
calorifier
closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated *fluid* (3.21) through a heat exchanger

[SOURCE: ISO 11139:2018, 3.32]

3.5
chemical disinfection
disinfection (3.14) achieved by the action of one or more chemicals

[SOURCE: ISO 11139:2018, 3.42]

3.6
cleaning
removal of *contaminants* (3.8) to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.7
clean-in-place
CIP
cleaning (3.6) of internal surfaces of parts of equipment or an entire process system, without or with minimal disassembly

[SOURCE: ISO 11139:2018, 3.48]

3.8
contaminant
physical, chemical, biological or radiological substance or matter in water

Note 1 to entry: The presence of contaminants does not necessarily indicate that the water poses a health risk.

[SOURCE: ISO 20670:2018, 3.15]

3.9
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.10
dead leg
area of entrapment in vessel or piping that is not easily accessed

[SOURCE: ISO 11139:2018, 3.76]

3.11
deionization
DI
partial or nearly complete removal of ionic species, particularly by the use of ion-exchange resins

[SOURCE: ISO 6107:2021, 3.158]

3.12
demineralization
reduction of the content of ionic species and dissolved inorganic substances in water by a physical, chemical or biological process

[SOURCE: ISO 6107:2021, 3.159]

3.13
disinfectant
chemical or combination of chemicals used for *disinfection* (3.14)

[SOURCE: ISO 11139:2018, 3.82]

3.14
disinfection
process to inactivate viable *microorganisms* (3.26) to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.15
distillation
process of evaporation followed by condensation used, for example, to prepare water of high purity

[SOURCE: ISO 6107:2021, 3.188]

3.16
electrodeionization
EDI
method for removing ions by combination of mixed bed *ion exchange* (3.22) and *electrodialysis* (3.17) in an electrodialyser, where the fresh water chamber is filled with mixed bed ion exchange resin, and the ion exchange resin can be electrochemically regenerated by polarization during the electrodialysis process

Note 1 to entry: Generally, it is a polishing process for production of ultrapure reclaimed water and used after *reverse osmosis (RO)* (3.35).

[SOURCE: ISO 23044:2020, 3.1.2]

3.17
electrodialysis
process used for the *deionization* (3.11) of water in which ions are removed, under the influence of an electric field, from one body of water and transferred to another across an ion-exchange membrane

[SOURCE: ISO 23044:2020, 3.1.3]

3.18
endotoxin
lipopolysaccharide component of the cell wall of Gram-negative bacteria that is heat stable and elicits a variety of inflammatory responses in animals and humans

[SOURCE: ISO 11139:2018, 3.101]

3.19
filter
construct of porous material through which a *fluid* (3.21) is passed to remove viable and/or non-viable particles

[SOURCE: ISO 11139:2018, 3.117]

3.20
filtration
<water> physical separation of solid particles from water, by passing the water through a physical porous barrier to trap and separate suspended solids from the water

Note 1 to entry: Examples of barrier include media bed, surface or depth *filter* (3.19), screen, or membrane.

[SOURCE: ISO 20670:2018, 3.27]

3.21
fluid
substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma.

[SOURCE: ISO 11139:2018, 3.120]

3.22
ion exchange
process by which certain anions or cations in water are replaced by other ions by passage through a bed of ion-exchange material

[SOURCE: ISO 23044:2020, 3.1.5]

3.23
load
product (3.34), equipment, or materials to be processed together within an operating cycle

[SOURCE: ISO 11139:2018, 3.155]

3.24
manual cleaning
removal of *contaminants* (3.8) from an item to the extent necessary for further processing or for intended use without the use of an automated process

[SOURCE: ISO 11139:2018, 3.159]

3.25
microbial contamination
presence of unintended bacteria, fungi, protozoa, or viruses

[SOURCE: ISO 11139:2018, 3.171]

3.26
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: ISO 11139:2018, 3.176]

3.27
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]

3.28
non-condensable gas
air and/or other gas which will not liquefy under the conditions of a *saturated steam* (3.37) process

[SOURCE: ISO 11139:2018, 3.183]

3.29
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]

3.30
ozonization
ozonation
addition of ozone to water for the purpose of, for example, *disinfection* (3.14) or oxidation of organic matter

[SOURCE: ISO 6107:2021, 3.382, modified — Removed "or wastewater" at the beginning of the definition and in the list of examples, "or the removal of unpleasant taste and odour".]

3.31
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a *product* (3.34) which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

3.32
pore size rating
nominal pore size of a *filter* (3.19) as claimed and stated in the labelling

[SOURCE: ISO 11139:2018, 3.196]

3.33
potable water
water that meets applicable drinking water standards and is safe for drinking, *washing* (3.50), and food preparation

Note 1 to entry: Further treatment of potable water can be necessary to achieve the quality necessary for the subsequent process depending upon the intended use.

[SOURCE: ISO 20670:2018, 3.53, modified — Note 1 to entry added.]

3.34
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]

3.35
reverse osmosis
RO
flow of water through a membrane from a more concentrated to a less concentrated solution, as a result of applying pressure to the more concentrated solution in excess of the normal osmotic pressure

[SOURCE: ISO 23044:2020, 3.1.13, modified — "with a filtration accuracy of 0,000 1-0,001 µm" removed from the definition and Note 1 to entry, explaining this addition to the definition, removed.]

3.36
rinsing
removing process residues through displacement by, and dilution with, water

[SOURCE: ISO 11139:2018, 3.237]

3.37
saturated steam
water vapour in a state of equilibrium between its liquid and gas phases

[SOURCE: ISO 11139:2018, 3.241]

3.38
self-disinfection cycle
operating cycle intended to disinfect all liquid transport systems' piping, chamber(s), tanks, and other components which come into contact with the water and/or solutions used for *cleaning* (3.6), disinfecting, and *rinsing* (3.36) the *load* (3.23)

Note 1 to entry: The self-disinfection cycle is used without a load in a *washer-disinfector* (3.49).

[SOURCE: ISO 11139:2018, 3.249]

3.39
services
supplies from an external source needed for the function of equipment

[SOURCE: ISO 11139:2018, 3.252]

3.40
softener
pressurized container of softening resin for replacement of hardness ions, calcium, magnesium, barium and strontium, with the sodium ion

[SOURCE: ISO 22519:2019, 3.1.7]

3.41
soil
natural or artificial contamination on a device or surface following its use or simulated use

[SOURCE: ISO 11139:2018, 3.257]

3.42
sterile, adj.
free from viable *microorganisms* (3.26)

[SOURCE: ISO 11139:2018, 3.271]

3.43
sterilization
validated process used to render *product* (3.34) free from viable *microorganisms* (3.26)

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]

3.44
sterilizer
equipment designed to achieve *sterilization* (3.43)

[SOURCE: ISO 11139:2018, 3.287]

3.45
thermolabile
readily damaged by heat

[SOURCE: ISO 11139:2018, 3.302]

3.46
treatment process
unit process designed to transform the water quality by physical, biological and/or chemical means

[SOURCE: ISO 20670:2018, 3.75]

3.47
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]

3.48
viable count
value established from enumeration of recoverable colony-forming units

[SOURCE: ISO 11139:2018, 3.316]

3.49
washer-disinfector
WD
equipment designed to clean and disinfect *product* (3.34)

[SOURCE: ISO 11139:2018, 3.319]

3.50
washing
removal of *contaminants* (3.8) from surfaces by means of an aqueous *fluid* (3.21)

[SOURCE: ISO 11139:2018, 3.321]