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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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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]

3.51
water hardness
property resulting from the presence of calcium and magnesium salts and, in special cases, salts of strontium and/or barium

Note 1 to entry: The unit of measurement of water hardness is the millimole per litre (mmol/l).

[SOURCE: ISO 2174:1990, 001, modified — Kept first sentence of definition, moved second sentence to a Note to entry, and remaining content is not included here.]

3.52
water quality criteria
set of defined parameters characterizing the quality of water to assess its suitability for specific uses

[SOURCE: ISO 6107:2021, 3.606]

4 Potable water quality

4.1 General

The physical, chemical and microbial quality of potable water can vary depending on the source of the water, treatment by the services provider, transport system to the user, and storage within the facility prior to use of the potable water by the facility. The quality from the same raw water source can vary over time and by seasonal influence. Microorganisms, pollutants, dissolved gases, chlorination or salts can appear during hot, cold or temperature shifting periods, during excessive or particularly low consumption from the source and by carry over during heavy rain or floods.

Within the facility, the quality of the potable water can be altered further by a variety of pre-treatments prior to final treatment, storage and circulation within the facility for supply to the point of use for the sterilizer or WD. Guidance on commonly used methods to treat potable water, their effect, advantages and disadvantages, are provided in Annex A and Table A.1.

4.2 Water analysis

4.2.1 It is necessary to assess the chemical, microbial and physical quality of the potable water supply in order to determine whether substances are present that can affect the effectiveness of the process or cause damage or deterioration of the equipment. The outcome of this determination establishes the extent of pre-treatment and final treatment needed to produce water meeting the water quality criteria required for its intended use in the sterilizer or WD within the facility.

NOTE 1 Where treatment and supply are well controlled and tested by the water supply authority, or other parties in the water supply network, their data on the quality of potable water can be an input into the risk assessment (see, for example, 5.1).

NOTE 2 Annex C gives examples of the presentation of water quality issues during the processing of medical devices.

4.2.2 The method of analysis employed and its analytical sensitivity depends on the specifications required by the relevant standard applicable to the process or the equipment used for a specific process.

NOTE Relevant process and equipment standards include ISO 11135, ISO 14937, the ISO 15883 series, the ISO 17665 series, ISO/TS 22421, ISO 22441, ISO 25424, EN 285, EN 1422, EN 13060 and EN 14180.

4.2.3 The quality of potable water should be tested in accordance with validated analytical methods to confirm its chemical, microbial and physical quality.

4.2.4 Confirmation of the chemical quality of treated potable water for use in sterilizers or WDs can include assessment of the determinants in 11.4.2.

4.2.5 Confirmation of the microbial quality of treated potable water for use in sterilizers or WDs can include performing a viable count of aerobic mesophilic bacteria, determination of bacterial endotoxins level or tests for absence of:

— *Pseudomonas aeruginosa*;

— (Atypical) *Mycobacterium* sp.;

— *Legionella* sp.;

— specific microorganisms of clinical significance.

NOTE These tests are of particular importance for WDs for thermolabile endoscopes. They can be of less significance for cooling systems or non-critical system designs, such as downstream of filters or for supply of steam generators. Bacterial endotoxins can present a risk to specific loads and applications, such as instruments for eye surgery.

4.2.6 Confirmation of the physical quality of treated potable water for use in sterilizers or WDs can include determination of levels of particulates or measurement of temperature.

5 Water quality requirements for different applications/processes

5.1 The required water quality criteria and the extent and type of testing of water to be carried out should be determined based on a risk assessment taking into consideration, but not limited to, the following factors:

a) equipment specifications;

b) limitations with respect to water quality;

c) product contact (see 5.3).

The outputs of the risk assessment can result in definition of requirements, such as for water temperature, water hardness, bioburden or endotoxin levels in the water.

5.2 The requirements for water quality for each stage in a WD or sterilizer are specified in the relevant standard applicable to that process or the equipment (i.e. sterilizer or WD) or the instructions for use (IFU) provided with the specific equipment or the medical device.

NOTE 1 Relevant process and equipment standards include ISO 11135, ISO 14937, the ISO 15883 series, the ISO 17665 series, ISO/TS 22421, ISO 22441, ISO 25424, EN 285, EN 1422, EN 13060 and EN 14180.

NOTE 2 Processing of some specific instruments, for example ophthalmic instruments, can necessitate special requirements for water quality, including rinsing with sterile water.

5.3 Water can be used in a sterilizer or WD:

a) in direct contact with the product being treated, alone or in combination with chemical agents;

EXAMPLE WD cleaning and rinsing stages, spray stages in moist heat sterilizers.

b) to generate steam that contacts the product;

EXAMPLE Moist heat sterilization, low temperature steam and formaldehyde (LTSF) sterilization, ethylene oxide (EO) sterilization.

NOTE The quality of the feedwater can affect the quality of the steam generated. The quality of steam supplied to the equipment can also be affected by the manner in which it is distributed from the steam generator to the equipment. The quality of steam is considered in the relevant process or equipment standard and is outside the scope of this document.

c) to heat or cool the equipment or product, either as steam or water, without directly contacting the product;

EXAMPLE Moist heat sterilization of aqueous fluids in sealed containers, heating jacketed vessels, operating heat exchangers, steam condensers in WDs.

d) to operate or control some elements of the equipment, such as vacuum pumps or valves.

EXAMPLE Vacuum pumps for moist heat sterilization of wrapped goods or porous loads, LTSF, EO sterilization.

5.4 If the WD or sterilizer requires a water supply, the requirements for water to be supplied to the WD or sterilizer should be specified. Where multiple supplies are needed, different requirements can apply to each supply. The specification for water quality should ensure that the water cannot damage the WD or sterilizer, impair the performance of the process or damage the load. See also Annex B and Annex C. A comparison of descriptors for water quality is given in Annex D.

NOTE This can include specification for the water quality criteria supplied to equipment for a water treatment system within a sterilizer or WD. Potable water can either be disinfected external to a WD, or within a WD.

6 Water in direct contact with the product being treated

6.1 Washer-disinfectors (WDs)

6.1.1 General

The WD can be designed to operate either with potable water supplied directly to the WD or with potable water supplied to the water treatment systems supplying the WD.

Water quality requirements can be different for various processing stages in the WD, depending on the intended process load. Processing stages can include flushing, cleaning, intermediate rinsing, thermal or chemical disinfecting, and final rinsing stages. The physical, chemical and microbial quality of the water supplied to the WD can affect the efficacy or efficiency of the process. The chemical, microbial and physical quality of rinse water used either at the end of the cleaning stage (if no further processing of the load is intended) or at the end of the disinfection stage to remove residual chemicals, should not impair the cleanliness, disinfection, safety or performance of items in the load. Examples of water quality for use in WDs are given in B.2.

Water treatment systems can include a softener, filter, deionizer or RO plant, as specified for the WD.

The potable water supplied to the WD or to the water treatment equipment for the WD should be fitted with a backflow protection device to prevent contamination of the distribution system.

If the water treatment system is a part of the WD, risk mitigation should be applied depending on the intended use, such as by disinfection of specified parts of the equipment during the operating cycle or providing a separate self-disinfection cycle.

If a separate water treatment equipment is supplying a WD, risk mitigation should be applied depending on the intended use, such as applying periodic disinfection to that equipment and associated pipework.

NOTE 1 See the ISO 15883 series for further guidance on requirements for specific WD.

NOTE 2 See EN 1717 in relation to backflow protection, if required by national regulations.

6.1.2 Water quality

The temperature of water to a WD for the pre-wash stage should prevent the occurrence of protein coagulation, which can occur at temperatures above 45 °C. This situation can ultimately lead to failure of the cleaning process, and affect the effectiveness of the thermal or chemical disinfection process.

The quality of water supplied to the WD should be tested periodically (see 11.1).

6.1.3 Final rinse water quality

Rinse water used in the final stage after cleaning and disinfection should be of suitable quality for its intended use, considering the items being processed. The rinse water should be of treated potable water quality and can be taken from a built-in water tank only if the water in the tank is kept constantly above a set minimum temperature or is automatically disinfected in the process immediately prior to the rinse.

NOTE 1 For example, in order to maintain a minimum temperature of 65 °C, the tank would have to be maintained at a higher temperature, e.g. 75 °C, so that when the supply is replenished by incoming cold water the temperature remains above 65 °C.

The minimum acceptable chemical quality of final rinse water, and additional requirements for microbial quality or bacterial endotoxins are specified, for example, in the standard for WD used to process specific endoscopes (see ISO 15883-4).

NOTE 2 It is the dose of endotoxin that ultimately impacts the patient and this includes the exposure surface of the medical device, as well as the total amount of endotoxin.

NOTE 3 Particles, ions or other substances in the water can lead to deposition on surfaces which affect the sterilization process or the biocompatibility of the medical device.

Final rinse water should not be stored for re-use in the final rinsing stage of subsequent WD cycles but can be re-used in other stages, such as the pre-wash, provided that there is no unacceptable risk associated with the re-use of this water (see also the ISO 15883 series).

6.1.4 Water quality used during operational qualification (OQ) and performance qualification (PQ) of WDs

The quality of the water used during OQ and PQ of the WD can affect the outcome of these tests and subsequent declaration of conformance of the WD to the applicable standard. When performing OQ and PQ, water quality tests should be conducted and include tests for those determinants known to influence the efficacy of the process. See 11.4 for a list of tests to consider.

The level of determinants should be within the limits required by the manufacturer of the WD.

NOTE 1 See ISO 15883-1.

NOTE 2 National guidelines and local environmental conditions can direct the need to test for levels of additional determinants.

6.2 Moist heat sterilization using water spray or immersion

The water quality for the hot water spray/hot water immersion sterilization process of the contained product, and cooling water, should be specified and not affect the material or function of the sterilizer or harm the sterilizer, the sterilization process or load.

The quality of cooling water or any final spray rinse water can affect the post-sterilization quality of the load.

7 Water to generate steam that contacts the product

7.1 Moist heat sterilization

7.1.1 Contaminants in feed water supplied to the steam generator can ultimately affect the level of contaminants present in the sterilizing agent. These contaminants in steam can result in corrosion of some materials in the load, contamination of products or damage the sterilizer itself. Steam supplied to

moist heat sterilizers should be free from contaminants which can impair the sterilization process or harm the sterilizer or load.

7.1.2 Steam generated from water of low pH or containing chlorides can lead to corrosion or pitting. Elevated silicates can lead to staining and residue build up. Water within the steam generator can contain carbonate (CO_3), bicarbonate (HCO_3), or hydroxide (OH) that accumulate to result in high or very high pH if poorly maintained. Operation of a sterilizer using untreated or poorly treated water containing calcium carbonate without performing blowdowns can cause a significant rise in alkalinity. This can cause foaming in the steam generator and deterioration to glass or other components.

7.1.3 Non-condensable gases dissolved in feed water can cause an increase in non-condensable gases in the generated steam which can result in failure of a sterilization cycle. The amount of non-condensable gases dissolved in the feedwater, and hence in the steam, can be reduced by increasing the temperature of the feedwater supplied to the steam generator.

7.1.4 Distilled or deionized water can be recommended for a stainless-steel steam generator to help prevent the build-up of minerals in the sterilizing system and to ensure the quality of the steam generated for sterilization. Appropriate materials of construction should be selected to be compatible with the corrosive nature of low conductivity water.

NOTE See ISO/TS 17665-2, ISO/TS 22421, EN 285, ANSI/AAMI ST8, ANSI/AAMI ST55 and ANSI/AAMI ST79 for further guidance.

7.1.5 The feed water supplied to the steam generator for the sterilizer should be fitted with a backflow protection device to prevent contamination of the distribution system.

NOTE See EN 1717 in relation to backflow protection.

7.1.6 Maintenance to the steam generator, such as use of descaling chemicals or changes to the water treatment, can cause the level of chemical contaminants to exceed the specified maximum.

7.1.7 The quality of feed water supplied to the steam generator should be specified and monitored, taking into account the design of the steam generator system. At a minimum, the conductivity of the feed water should be either continually monitored or monitored weekly. Measurement of feed water quality should be made prior to the addition of any additives or feed water conditioners.

NOTE 1 For quality of potable water, see Directive 98/83/EC.

NOTE 2 Table B.1 gives guidance on the level of specific contaminants for feed water supplied to a dedicated steam generator.

7.1.8 Material or additives in contact with water and steam should not compromise the required water quality attributes.

7.2 Ethylene oxide (EO) sterilization

7.2.1 For sterilization processes performed in a rigid sterilizer chamber, water is utilized to generate steam to heat and humidify the load during pre-humidification (if used), and humidification during the EO gas exposure stage. The steam is not intended to function as a sterilizing agent. The quality of water supplied for the generation of steam used in the EO chamber should not impair the sterilization process or harm the sterilizer or load.

NOTE See ISO 11135, EN 1422 and ISO/TS 22421 for further guidance.

7.2.2 Equipment components should be qualified to ensure that the equipment supplying water and steam, including filters (if used), is installed and performs reliably according to the applicable specifications and requirements.

7.2.3 Potable water supplied to the EO sterilizer should be fitted with a backflow protection device to prevent contamination of the distribution system.

NOTE See EN 1717 in relation to backflow protection.

7.2.4 Water hardness (measured as a hardness value - Σ ions of alkaline earth) can cause corrosion and scaling problems, depending on other ion concentrations and solubility factors.

NOTE 1 See Table B.1 for guidance on levels of contaminants in feed water.

NOTE 2 For quality of potable water, see Directive 98/83/EC.

7.2.5 Water filters should be checked periodically for integrity (see Table A.1).

NOTE The frequency of periodic checks for water filters is based on the considerations in risk management and filter manufacturer recommendations.

7.3 Low temperature steam and formaldehyde (LTSF) sterilization

7.3.1 Steam is admitted to an LTSF sterilizer together with a vaporized aqueous solution of formaldehyde to generate the intended sterilizing conditions.

NOTE See ISO 25424, EN 14180 and ISO/TS 22421 for further guidance.

7.3.2 Potable water supplied to the sterilizer should be fitted with a backflow protection device to prevent contamination of the distribution system.

NOTE See EN 1717 in relation to backflow protection.

7.3.3 The water hardness value (Σ ions of alkaline earth) should be typically between 0,7 mmol/l and 2,0 mmol/l, as values outside this range can cause scaling and corrosion problems, depending on other ion concentrations and solubility factors.

7.3.4 Feed water intended for steam production within the sterilizer or for a dedicated steam supply should be free from contaminants that can impair the sterilization cycle or harm the sterilizer or sterilized load.

NOTE 1 See Table B.1 for guidance on feed water quality.

NOTE 2 For quality of potable water, see Directive 98/83/EC.

7.4 Vaporized hydrogen peroxide (VH202) sterilization

7.4.1 Steam can be used to humidify the load in vaporized hydrogen peroxide (VH2O2) sterilization, but it is not intended to function as a sterilizing agent. Water that can be in contact with the load should be free from contaminants which can impair the sterilization process or harm the sterilizer or load.

NOTE See ISO 22441, EN 17180[1)] and ISO/TS 22421 for further information.

7.4.2 Equipment components should be qualified to ensure that the equipment supplying steam and water, including filters (if used), is installed and performs reliably according to the applicable specifications and requirements. Potable water supplied to the VH2O2 sterilizer should be fitted with a backflow protection device to prevent contamination of the distribution system.

NOTE 1 See EN 1717 in relation to backflow protection.

1) Under preparation.

NOTE 2 See Table B.1 for guidance on levels of contaminants in feed water and condensate.

NOTE 3 For quality of potable water, see Directive 98/83/EC.

7.4.3 Water filters should be checked periodically for integrity (see Table A.1).

NOTE The frequency of periodic checks for water filters is based on the considerations in risk management and filter manufacturer recommendations.

8 Water for the equipment without direct contact to the product

8.1 Washer-disinfectors (WDs)

8.1.1 Water can be used for a steam condenser for indirect venting of the chamber of the WD or operate a specific part of the WD (e.g. a valve).

NOTE See ISO 15883-1 for further guidance.

8.1.2 If potable water is supplied to a steam condenser, it should be fitted with a backflow protection device to prevent contamination of the distribution system.

NOTE See EN 1717 in relation to backflow protection.

8.2 Sterilizers

8.2.1 General

8.2.1.1 Water can be used in sterilizers as a supply to the vacuum pump to evacuate the chamber.

NOTE See EN 285, EN 1422, EN 13060, EN 14180, ISO 22441 and EN 17180 [2)] for further guidance.

8.2.1.2 If potable water is supplied to a sterilizer, it should be fitted with a backflow protection device, to prevent contamination of the distribution system.

NOTE See EN 1717 in relation to backflow protection.

8.2.1.3 Water supplied to the vacuum system should be potable water. Water should be supplied to the vacuum system of the sterilizer at a temperature not exceeding a specified value.

NOTE Water temperatures can affect the final vacuum level attained and pressure change rates. Standards for sterilizers for moist heat can specify a maximum temperature, for example, of 20 °C for moist heat or 15 °C for EO, LTSF or VH2O2 sterilizers.

8.2.1.4 The water hardness value (Σ ions of alkaline earth) should not cause scaling and corrosion problems, depending on other ion concentrations and solubility factors. The IFU for use of the sterilizer can provide information on the appropriate quality of water to be supplied to the vacuum system.

NOTE For quality of potable water, see Directive 98/83/EC.

8.2.2 Ethylene oxide (EO) sterilizers

Water can be used in EO sterilizers for heating the jacket of the rigid sterilizer chamber and as a supply to the vacuum pump to evacuate the chamber.

2) Under preparation.

8.2.3 Vaporized hydrogen peroxide (VH202) sterilizers

Water can be used in VH2O2 sterilizers for cooling purposes.

9 Water treatment systems

9.1 General

Guidance on commonly used systems to treat potable water, their effect, advantages and disadvantages, are provided in Annex A and Table A.1.

Potable water is water that comes from surface or ground sources and receives treatment to control microorganisms, chemicals and physical attributes to a predetermined level and specified by local standards as being safe to drink. Potable water supplied to a facility can vary seasonally so it is often subjected to a pre-treatment process to maintain a consistent quality to various processes within a facility. These processes can include chlorination, fluoridation, sand filtration, addition of water softeners, coarse filtration, submicron filtration, pH adjustment, carbon filtration. While some geographical areas provide potable water of the necessary quality to be used in the processing of medical devices, potable water can require additional treatment.

The pre-treated potable water can also be subjected to a further purification process to deliver the specified water quality for the medical device processing step. Commonly used processes can include deionization (DI), softening, RO, electrodeionization (EDI), ultrafiltration and distillation.

NOTE Water treatment systems are often packaged units that are provided preassembled and are not often engineered systems. These packaged treatment systems have been designed to cope with a wide variety of feedwater quality with little input from the user. In this application the use of disposable cartridges is common and the technologies listed below can be combined, e.g. RO/EDI unit.

9.2 Considerations for water treatment

Considerations for water treatment systems can include the following:

a) the final water quality specification required at the points of use (sterilizer or WD);

b) the source water quality including any variations over time;

c) the quantity of water required by the points of use (sterilizer or WD);

d) provision of accessible sample points;

e) provision of on-line instrumentation to monitor water quality, for example conductivity, within the treatment or purification system, or at the points of use (sterilizer or WD);

f) a means of routine system disinfection including all pipework located between the water treatment system and the sterilizer or WD;

g) periodic maintenance of system including all pipework located between the water treatment system and the sterilizer or WD;

h) temperature control within the system or at the point of use (sterilizer or WD);

i) measures to minimize microbial growth, e.g. regarding the system design, materials, temperature;

j) the choice of materials of construction to be used in the treatment stage with consideration to the range of operating temperatures, corrosion resistance and compatibility with the disinfection methods to be used.

NOTE Examples of acceptable materials can include stainless steel and suitable thermoplastics.

9.3 Prefiltration

Sediment filters (also known as bed filters) can be located at or near the beginning of the water treatment system and are intended to remove relatively coarse particulate materials from incoming water. These units contain multiple layer(s), each layer retaining progressively smaller particles.

Cartridge filters can be installed at the inlet to a water system, but their usual application is as a final filtration step prior to RO. Filter cartridges consist of a filter medium with a central drainage core. The cartridge is contained within a filter housing with seals to separate the incoming and outgoing water streams.

9.4 Carbon filter

A typical carbon filtration unit utilises either bituminous based or coconut based activated carbon with a very high surface area to reduce the level of chlorine in the water and also to reduce the level of lower molecular weight organics in the water. Chlorine is removed because it can cause chemical damage by oxidation to RO membranes or EDI modules (see 9.7 and 9.8) which can be utilised in the water treatment system. Some disposable carbon filter cartridge systems use carbon in the form of a block or bound in a filter matrix.

9.5 Water softeners

A water softener contains cation exchange resin to exchange the relatively insoluble divalent and multivalent cations such as calcium and magnesium with the more soluble sodium cation. The softening process is required to prevent scaling occurring when ions present in hard feedwater are concentrated during subsequent steps such as RO or to provide soft water for washing stages, rinsing stages and disinfection in a WD.

9.6 Deionization (DI) or demineralization

Deionization (DI) can produce a large volume of water on demand. DI resins need to be periodically regenerated or replaced. In some cases, DI tanks are provided by a vendor and replaced by that vendor when the resistivity/conductivity reaches a certain level. Resistivity/conductivity monitors should be used with DI tanks to continuously monitor water quality. DI removes both positively and negatively charged ions very effectively. Conductivity of water decreases in proportion to the removal of ions, so low conductivity indicates that there has been efficient removal of ions.

NOTE Conductivity is a measure of the capability of water to pass electrical flow and is directly related to the concentration of ions in the water. It decreases as ions are removed from water. Resistivity is a measurement of water's opposition to the flow of a current over distance. It decreases as the ionic concentration in water increases. Conductivity is the reciprocal of resistivity.

DI does not effectively remove noncharged or weakly charged species, such as some organic compounds and silica, nor does it remove microorganisms or endotoxins. Poor maintenance of the DI system can lead to microbial overgrowth that results in increased levels of microorganisms and endotoxin in the water. Additional treatment steps can be needed for specific applications after DI to ensure the microbial quality of the treated water (e.g. filtration treatments that remove pyrogens, submicron filters that remove microorganisms, ultrafilters).

9.7 Reverse osmosis (RO)

RO removes most ionic species from the water. The initial resistivity can be not as high as that achieved by DI, but it is sufficient for most medical device processing needs. RO also removes microorganisms, endotoxins, organic compounds, and colloids effectively. A two-pass RO system, in which the first RO system feeds the second RO system, produces water of very high quality. Another approach widely used is a first pass RO followed by DI. RO does produce purified water relatively slowly, so a storage tank can be needed. The capital costs are considerably higher than for DI, but the system does not require the frequent resin exchange or regeneration that is characteristic of the DI process.

9.8 Electrodeionization (EDI)

EDI is used to remove ions, silica and organics from the feedwater and is often used as a polisher after RO to reduce conductivity. The operating principle is based on using ion selective membranes to control the migration of ions within an electric field between cation and anion electrodes. In a typical unit, a cation selective membrane only allows cations to pass and an anion selective membrane only allows anions to pass. By arranging these in an alternating array, a series of alternating process stream and waste compartments are created. Under the influence of an applied electric field, ions migrate out of the process stream compartments and are transferred to the waste stream. Within the units, the applied electric current splits water into hydrogen and hydroxide ions which automatically regenerate the ion exchange resins.

9.9 Ultrafiltration

Ultrafiltration is similar to RO except that there is usually no rejection of ionic material. An ultrafiltration membrane operates by size exclusion at the molecular level and is capable of removing organics, microorganisms and endotoxins. They can be situated in the early stages of the treatment system to remove organics or in the final stages often post RO to act as a polisher.

9.10 Distillation

Distillation relies on the vaporization and condensation of water to remove dissolved and suspended substances. Distillation effectively removes microorganisms, endotoxins, organic compounds and colloids. Various styles of distillation system are available. This method of water treatment generally requires more energy to operate than RO or DI. Distilled water is produced relatively slowly, so a storage tank is needed. Capital costs are considerably higher than for DI, but a distillation system does not require the frequent resin exchange or regeneration that is characteristic of the DI process. Care should be taken to prevent scaling or coating with colloidal material. Normally, dechlorinated soft water or deionized water is used to feed a distillation system to keep the amount of scaling to a minimum.

10 Water distribution and storage

10.1 General

10.1.1 The intended use of the water and local conditions should be considered in planning for a water distribution system and, if necessary, a water storage system. For example, requirements for the microbial quality of water used to generate steam or to supply final rinse water after thermal disinfection in a WD can differ from the requirements for final rinse water after chemical disinfection in a WD for thermolabile endoscopes. Considerations of local conditions can include water quality from the local municipal waterworks and its maintenance, supply pressure and temperature. Depending on the extent of the water distribution, the storage system, the local conditions and the intended use, the water quality can be inadequate.

10.1.2 Following either initial treatment(s) or terminal treatment(s), the water used within a facility can be distributed, circulated within a closed loop, or held within a storage tank prior to supply to the sterilizer or WD.

10.1.3 A well designed storage and distribution system is key to the success of the water system. The optimal design of any water system should achieve four main criteria which are as follows:

a) maintain the quality of water within acceptable limits;

b) deliver water to points of use at the specified flow rate, temperature and pressure;

c) have sufficient capacity to meet the requirements of the points of use during routine operations;

d) be compatible with in-use disinfection method(s).

10.2 Storage vessels

The purpose of the storage vessel is to store and maintain the final treated quality of water before distribution to the points of use. Depending on the intended use and specifications of the points of use, considerations can include the following.

a) The vessel should be fitted with a vent filter. The vent filter should be replaceable and prevent intrusion of particles that can carry microbial contamination. The filtration class should be at least ISO 35 H, in accordance with ISO 29463-1 or equivalent (EN 1822 H13).

b) The tank should be constructed from suitable materials which do not significantly reduce the water quality and, if applicable, are compatible with the in-use disinfection method(s).

c) Measures should be taken to ensure flow into and out of the tank allows for adequate circulation of water within the tank.

10.3 Distribution pipework

The design of the distribution pipework should consider the following:

a) The distribution piping system should be designed to ensure continuous flow. Where one-way systems are utilised a risk assessment should be performed with adequate justification for use.

b) The distribution pipework should be designed to ensure turbulent flow.

c) The pipework and fittings, including valves, should have smooth surface finishes.

d) The piping should be constructed from suitable materials which do not significantly reduce the water quality and are compatible with the in-use disinfection methods. Acceptable materials of construction include stainless steel and suitable thermoplastics.

e) The distribution pipework should be designed to minimise or eliminate dead legs.

NOTE Dead legs can create stagnant water.

10.4 Storage and distribution system disinfection

The storage and distribution system should be designed to facilitate disinfection to maintain the microbial quality of the water.

The system can be disinfected using heat and this can be achieved through either maintaining continuous hot recirculation above a minimum temperature, for example 70 °C, or through intermittent hot water disinfection at a suitable frequency. Other methods of disinfection include use of ozone or periodic chemical exposure. With chemical disinfection it is important to ensure that the final rinse step has removed the disinfecting agent to an acceptable level. The choice of disinfection method can influence the choice materials of construction and associated instrumentation to control and monitor the disinfection process and this should be considered during the design phase.

10.5 Distribution pumps

A distribution pump and its associated elements (e.g. valves) can be a key component of the storage and distribution system. The distribution pump should be constructed from suitable materials which do not introduce contamination into the system.

10.6 Inline ultraviolet (UV) lamps

For microbial control, UV lamps which emit light at 254 nm have been demonstrated to have good germicidal effectiveness. The UV lamp needs to be designed for the defined application and flow rates.

UV irradiators should be equipped with an online monitor of radiant energy output that alerts the user when the lamp should be replaced.

11 Monitoring, maintenance and control

11.1 General

11.1.1 Depending on the intended use of the water, the water quality should be monitored. Variations in water quality can occur throughout the year, so monitoring across different seasons should be considered.

11.1.2 The treatment of water by local municipal waterworks is intended to deliver water safe for drinking (i.e. potable water) to the local geographical area. Correct sampling technique during the monitoring is important to ensure accurate measurements of the specified analytes is achieved. The treatment processes to deliver potable water can, however, deliver water that is not acceptable for use in the processing of medical devices. For example:

a) The level of carbonate in water can greatly affect disinfection/sterilization processes that utilize moist heat (e.g. steam).

b) Potable water can have a pH requirement specified by local regulation. In these cases, carbon dioxide can be introduced to the water to react with the bicarbonate (HCO_3) present to facilitate a change in pH.

c) If the carbon dioxide does not react fully, it can be present in a non-condensable gas form in water delivered to a steam generator leading to poor steam penetration during the moist heat sterilization process.

The routine monitoring by municipal waterworks typically does not include the requirement to monitor the gas concentration in the water, so additional monitoring can be needed near point of use to ensure the specified water quality is delivered to the medical devices during processing.

11.1.3 Monitoring of water quality can be either periodic or continual. Attributes such as chemical quality, dissolved solids, temperature, supply pressure, microbial quality can be considered. Where water quality is monitored periodically, the interval between monitoring should be specified in formal procedures based on the risk associated with the use of the water. Other factors to consider in establishing the interval of monitoring can include, but are not limited to:

a) regulatory requirements, local policies and guidelines;

b) requirements or guidance in relevant standards for associated equipment;

c) frequency of monitoring performed by parties in the supply of water to the facility;

d) ability of the system to produce water of the required quality reproducibly.

11.2 Water sampling technique

11.2.1 Sampling consistency

To provide confidence in water quality monitoring results, consistent procedures should be adopted and a sampling location plan followed.

11.2.2 Sampling containers

The appropriate sampling container should be used to collect the water sample. The sampling container should be of the appropriate size to collect the water sample. The sample should be labelled with sample

or equipment identification, contents, purpose and date. The container should be of the required quality not to affect the test sample either by introducing contamination or adsorbing impurities. For example, glass bottles should not be used for samples for analysis of heavy metals. In general, for physical and chemical analysis, a clean unused plastic container (e.g. high-density polyethylene) with a tight-fitting lid can be used to collect water samples. Samples intended to assess microbial quality of water should be aseptically sampled into a sterile, endotoxin-free container that is not made of polypropylene. If necessary, sample container should contain neutralizing agent to neutralize any chemical residues that can be present.

11.2.3 Flushing

Sample points should be flushed commensurate with the size of the water system and distribution loop. Biofilms can develop throughout the water system, including infrequently used valves or downstream connectors between the distribution loop and equipment. Flushing these areas with a high flow velocity across these surfaces can shear off fragile tops of biofilms possibly growing in these areas. A standardized flush before sampling can limit the microbial contamination from the sampling points.

11.2.4 Sampling technique

Valves used for sampling should be of the appropriate design to not contaminate the sample. For example, sampling locations should not provide a stagnant water environment when not in use and be accessible to the distribution loop disinfection process. Prior to sampling water for microbial quality and endotoxins, the sampling surfaces (e.g. valves, hoses) should be disinfected both externally and internally to reduce microbial contamination. Aseptic technique should be used in the water collection. If taking multiple samples for testing, care should be taken so the sampling process and disinfectant selected do not affect the results (e.g. microbial contamination from isopropyl alcohol used to disinfect a sampling port can result in false readings with some test methods).

11.3 Sterilizers — Water sampling and tests

Water samples should be taken from the supply line as close as practicable to the steam generator or sterilizer. If water is stored prior to use, samples should also be taken as close as possible to the discharge point from the storage vessel.

Tests for chemical quality of supply water should include tests for those determinants known to influence the efficacy of the process. This can include, but is not limited to, tests to determine:

a) conductivity;

b) pH;

c) total water hardness (salts of Ca^{2+}, Mg^{2+}, Sr^{2+} expressed as mmol $CaCO_3$/l);

d) total residue on evaporation;

e) inorganic phosphate [P_i] and inorganic silicate [SiO_2], determined as the molybdate reactive species;

f) chloride [Cl^-].

See also Annex B.

11.4 Washer-disinfector (WD) — Water sampling and tests

11.4.1 Supply and final rinse water

Water samples should be taken from the supply line as close as practicable to the WD. When the final rinse water is stored in a tank within the WD, heated in a calorifier in the WD or otherwise treated within the WD, samples can also be taken from the discharge point into the WD.

11.4.2 Chemical quality

Tests for chemical quality of supply water should include tests for those determinants known to influence the efficacy of the process, such as determinants affecting the effectiveness of enzymatic cleaners and other cleaning detergents, known to cause spotting, staining and/or corrosion of stainless-steel medical devices, or causing scale build-up. This can include, but is not limited to, tests to determine:

a) conductivity;

b) pH;

c) oxidizable substances [determined by the European Pharmacopoeia (EP) method or as redox potential determined by the United States Pharmacopoeia (USP) method];

d) total water hardness (salts of Ca^{2+}, Mg^{2+}, Sr^{2+} expressed as mmol $CaCO_3$/l);

e) total residue on evaporation;

f) inorganic phosphate [P_i] and inorganic silicate [SiO_2], determined as the molybdate reactive species;

g) chloride [Cl^-].

For further information, see Annex B.

For WD used for disinfection of human waste containers, determination is limited to water hardness, expressed as millimole per litre (mmol/l) of $CaCO_3$, when the water is from a potable supply (see ISO 15883-3).

11.4.3 Microbial quality

11.4.3.1 Water treatment systems

For WD type testing, the efficacy of the water treatment system should be challenged to demonstrate its ability to provide the final rinse water quality required for the specific type of WD. For thermochemical disinfection processes such as applied in an endoscope WD, it is required that an inoculum of *Escherichia coli K12* (1 x 10^6 CFU/ml) be added upstream of the water treatment system (see ISO 15883-4 and ISO 15883-7). After passing through the water treatment system, a sample of the final rinse water (not less than 200 ml) is collected and two 100 ml aliquots analysed by filtration using a 0,2 µm membrane filter. The water treatment system is shown to be effective, and therefore acceptable for use as WD final rinse water, when less than 10 CFU, and no *Escherichia coli K12*, are recovered from each of the two 100 ml samples.

Should a failure occur in the water treatment system during type testing or routine use of the WD, then it is necessary to disinfect all liquid transport systems within the WD and test the efficacy of that self-disinfection process of the liquid transport systems within the WD. The final rinse water should be sampled and tested after disinfection. Test methods involving challenge with an inoculum of *Pseudomonas aeruginosa* are described in ISO 15883-4:2018, Annex D and ISO 15883-7:2016, Annex B. The resultant microbial count should be less than 10 CFU/100 ml and absence of *Pseudomonas aeruginosa* in 100 ml.

11.4.3.2 Final rinse water

Tests should be performed on final rinse water after disinfection of the WD load, when stipulated by the relevant part(s) of the ISO 15883 series for chemical disinfection of thermolabile equipment (see Table B.2, ISO 15883-4 and ISO 15883-7).

The discharge surface of any sampling ports should be swabbed with 0,2 µm filtered 70 % iso-propanol prior to collection of not less than 200 ml water into a sterile container. Samples should be tested within 4 h of collection or stored at 2 °C to 5 °C and tested within 48 h of collection.

The microbial quality of final rinse water is determined by conducting filtration through a 0,2 µm filter on a sample of not less than 100 ml. The filter is placed on R2A-medium, or other suitable low nutrient medium and incubated at 28 °C to 32 °C for a minimum of five days to determine the aerobic mesophilic viable count (see ISO 15883-1 for R2A medium). Use of the same agar medium for testing incoming water and final rinse water can assist with the comparison of results.

NOTE 1 Other methods, including rapid methods, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used.

At the point of use, the final rinse water in WD intended to process thermolabile endoscopes should ensure fewer than 10 CFU/ 100 ml sample of final rinse water, and the water be free of *Pseudomonas aeruginosa* in 100 ml, and (atypical*) Mycobacterium* sp. in 100 ml (see Table B.2, and ISO 15883-4:2018, Annex E).

NOTE 2 A neutralization method can be required prior to testing in order to eliminate antimicrobial activity from residual detergents or disinfectants.

NOTE 3 Specific microbiological media and incubation conditions can be required for the detection of certain types of microorganisms, such as *Pseudomonas aeruginosa* and (atypical) *Mycobacterium* sp. (see ISO 15883-4:2018, Annex E).

11.4.4 Bacterial endotoxins

The level of bacterial endotoxins in the final rinse water can be determined by performing the limulus amoebocyte lysate (LAL) test with a sensitivity of 0,25 EU/ml, or better, if specified in a part of the ISO 15883 series. The bacterial endotoxin test method given in the European Pharmacopeia (EP) or United States Pharmacopeia (USP) meet these criteria.

NOTE Alternative assays to the LAL test can be considered, for example, rapid cartridge tests or recombinant Factor C (rFC) assays.

12 Investigation of out-of-specification results

12.1 General

Water treatment includes a collection of water purification devices and associated piping, pumps, valves, and gauges that together produce water of a specified quality and deliver it to the point of use. The monitoring of these processes provide evidence that the water system remains in a state of control. When water samples exceed a pre-specified contaminant level, an investigation of the out-of-specification result can provide root cause with corrective and preventative actions designed to re-establish the state of control.

12.2 Elements of out-of-specification investigation

12.2.1 Interpretation of results

During an out-of-specification investigation, the test results can indicate what part of the water system is contributing to the contamination. Understanding which part of the water system a specific test challenges, can increase the effectiveness of an out-of-specification investigation (e.g. water hardness measures the performance of the water softening equipment).

Sampling locations can be used to identify where the contamination is entering the system. For example, if water sample results for microbial quality exceed the specification at the point of use, but not directly

after the water treatment system, then the contamination is likely generating from the piping, sampling points, or equipment connections.

NOTE Identification of the bacteria isolated in a sample can be useful to identify the source of microbial contamination.

12.2.2 Investigation

An out-of-specification investigation should be conducted to investigate all possible root causes for the unexpected result. Beginning the investigation at the result and concluding at the water treatment system is recommended when conducting an investigation. Any investigation should answer the following questions:

a) Was the correct water sample collected and analysed?

b) Is the test result reliable (e.g. any deviations with the test system)?

c) Was the sampling procedure performed as required (e.g. performed using aseptic technique)?

d) Does the distribution loop provide opportunities for microbial growth to occur (e.g. dead legs, static valves, appropriate flow rate)?

e) Is the water treatment system performing as expected and current for preventative maintenance?

13 Maintaining water quality

13.1 Sterilizers

The quality of water supplied to a steam generator can influence the quality of steam generated, depending on the specific design, temperature and operational aspects. Treatment of water supplying the boiler by the addition of chemicals, sometimes referred to as boiler additives, such as anti-foaming agents and corrosion inhibitors, can result in contamination of the steam. These contaminants can:

— Alter the properties of saturated steam that can affect its use as a sterilizing agent; such contaminants include non-condensable gases that can be exacerbated by the use of dealkalization treatments or base-exchange water softening.

— Be toxic; the addition of toxic filming amines, used to protect condensate return lines, can result in contamination of loads.

— Be pyrogenic; bacterial growth that can occur in water softening, deionisation or RO processes, while not surviving the steam generating process, the pyrogens they produce can be delivered to the sterilizer.

— Be corrosive; presence of chlorides, phosphates and silicates in feed water can cause corrosion and damage to polymers and steels, including stainless steel.

Steam, generated in carbon steel equipment for general facility use or for heating purposes, can be unsuitable for use in a sterilizer where the steam contacts the load. Some steam generators and sterilizers are constructed from materials that are resistant to the aggressive effects of ‘clean steam’ and are intended to operate without boiler additives (see for example EN 285 or EN 13060).

Steam quality for sterilizers can be maintained, and the presence of potential contaminants in the steam minimized, by treatment of feed water for the steam generator with processes that do not add chemicals to the feed water or by:

a) using additives and conditioners approved for use in food and health care applications in steam sterilizers;

b) monitoring additives to the feed water.

Contaminants in the feed water can differ from those in the steam. For adequate risk mitigation, contaminants in steam can be determined. Suggested maximum values of contaminants in condensate from steam supply to the sterilizer chamber can be considered (see for example EN 285 and EN 13060).

NOTE It is not considered appropriate to add additives to the steam generator and feed water conditioners, or amines to the steam lines or distribution system.

13.2 Washer-disinfectors (WDs)

Water quality should be monitored either periodically or continually for each cycle.

The water quality criteria can include consideration of chemical composition, water hardness, temperature, supply pressure and microbial contamination.

The physical and chemical quality of final rinse water should be controlled to the level suitable for its intended use. This can be achieved, for example, by having:

— the water treatment system serviced on a routine basis;

— an alarm or indication system for the water treatment if conductivity goes above specified limit.

The microbial quality of final rinse water should be controlled to the level suitable for its intended use. This can be achieved, for example, by:

a) maintaining a dedicated reservoir at a temperature above a set minimum for the time demonstrated to achieve disinfection of the final rinse water;

b) disinfecting immediately prior to use;

c) thermal disinfection during the final rinse in the WD;

d) filtering to remove suspended particles of a size greater than 0,2 µm;

e) using sterile water, held in a closed container, with a connection to the WD designed and constructed to provide aseptic transfer.

Preventative maintenance of pipework conveying treated final rinse water should be at a predetermined frequency.

14 Cleaning and disinfection of water treatment systems

14.1 General

Cleaning and disinfection of water treatment systems depends on the specific process, the materials of construction of the system, the extent and type of contamination identified, the intended use of the treated water and on any instructions relevant to the installed treatment system. Equipment manufacturers for water treatment systems can provide methods and procedures for periodic cleaning and disinfection. Particular procedures can also be required for major cleaning and disinfection processes or removal of biofilm, if this becomes necessary.

Ports, piping and materials supporting clean-in-place (CIP) without dead legs in the assembled water treatment system and procedures for cleaning with suitable cleaning agents followed by sufficient rinsing to remove residuals can be recommended. Removal of biological contamination particularly applies to the parts of the plant operating at lower temperatures and not likely to prevent the growth or formation of biofilm.

14.2 Access to the water treatment system

Systems should be designed to be user friendly with clear guidance on system control. The system should be allotted adequate space for installation that will allow access to all components for

maintenance and allow adequate space around the equipment for access. Space should be allowed in between components and the ends of the system to allow for replacement of expendable items and repairs. Systems should meet all local building requirements.

RO systems should be set up to permit cleaning and disinfection, and for ongoing maintenance according to the IFU.

Sample ports should be placed at the distribution loop outlet after the final treatment step as well as right before re-entry into the storage tank. Where feasible, an accessible sample port should be placed after critical processes for water treatment.

14.3 Cleaning and disinfection methods

The specific process applied for cleaning or disinfection is dependent on the materials of construction and the design of the water treatment system.

Processes to be applied can include the following:

a) Cleaning by flushing suitable for some parts of a system, for example, in combination with thermal, chemical treatments and/or pulsed pressure.

b) Thermal disinfection suitable for systems constructed from materials that can withstand elevated temperature.

NOTE The temperature of the system can be elevated to a specified temperature for a specified time. Account is taken of the time to attain temperature and the cooling time.

c) Chemical disinfection selected depending on the material of construction of the system. In order for disinfection to be effective, the specified concentration of the chemical agent is attained and maintained for a specified period. Following application of a chemical agent, rinsing and flushing of the system can be required. Examples of chemical agents that can be used in particular systems include alcohols, chlorine, chlorine dioxide, sodium hydroxide, potassium hydroxide, hydrogen peroxide, citric acid, nitric acid, phosphoric acid and peracetic acid.

Annex A
(informative)

Water quality treatment methods and processes

Table A.1 outlines processes for water treatment, their intended effect, advantages and disadvantages when used in treatment systems intended for supply of water for use in sterilizers and WDs.

Table A.1 — Water treatment systems, intended effect, advantages and disadvantages

Water treatment system	Effect	Advantages	Disadvantages
Pre-filtration	Reduces the particulates concentration in the water (depends on the filter porosity).	Protects later treatment processes from particulates that can affect their performance (e.g. flow reduction or fouling) and lead to increased preventative maintenance.	As the cartridge accumulates particulate material, resistance to flow through the filter increases, which is indicated by an increase in ΔP. Depending on the design and porosity of the prefilter, can lead to the accumulation of bacteria upstream of the filter.
Carbon filter	Removes free chlorine, chloramine and total organic carbon before RO or DI.	Protects RO membrane and DI from degradation by chlorine.	Supports bacterial growth.
Water softeners	Reduces the water hardness. Calcium and magnesium ions in the water are replaced by sodium ions.	Protects later processes from scaling.	These units allow bacterial growth and can result in a significant increase in the microbial content of the water. Sodium salts can leave white deposits on the load items.
Deionization (DI) or demineralization	DI or demineralization systems can remove virtually all the dissolved ionic material by ion-exchange.	Rate of production. Efficiency of ion removal. High resistivity.	Deionized water can become contaminated with microorganisms and the resin column can be colonized. The maintenance of these systems in line with the manufacturer's requirements is essential to safeguard output quality. DI can be used in combination with carbon adsorption and ultrafiltration.
Distillation	Removes dissolved inorganic compounds, bacteria, bacterial endotoxins, viruses, and cysts.	Simple operation.	Very expensive to produce due to the high energy usage. Periodic descaling and removal of precipitated solids required to maintain equipment efficiency.
NOTE References used for Table A.1 include References [44] and [66].			

Table A.1 *(continued)*

Water treatment system	Effect	Advantages	Disadvantages
Reverse osmosis (RO)	RO treatment plants remove almost all dissolved inorganic contaminants, high proportion of organic material, bacterial endotoxins and microorganisms by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient.	Reliability. Minimizes inorganic deposits on the load.	According to the quality of the potable supply water a carbon filter and/or a softening system can be required ahead of the RO membrane to remove traces of chlorine or reduce water hardness.
Electrodeionization (EDI)	EDI is a continuous process of removing ionized species from water without chemicals. The method combines ion exchange resins and ion-selective membranes with direct current. EDI is typically used to polish RO permeate and is an alternative to conventional mixed bed DI.	Enable use of low-pressure RO in combination. Eliminates need to store and handle chemicals for resin regeneration in mixed beds. Electricity is the only consumable.	Requires purification pre-treatment. Requires certain feedwater chemistry to keep it from scaling/fouling. Membrane replacement costs can be high. Variabilities in feed composition can affect performance. Ionic species formed from carbon dioxide passing from RO will raise conductivity in the EDI produced water.
Filtration	Physical removal of particulates. Depending on pore size rating of the filter, capable of removal of microbial contaminants (e.g. via 0,22 µm membrane filter) or smaller particles or endotoxin (e.g. via filters of pore size rating between 2 nm and 100 nm).	Can achieve bacterial and endotoxin removal, dependent on pore size rating of the filter.	Verification of pressure drop across the filter. A filter integrity test can be required to ensure system works effectively. Periodic disinfection can be required to prevent bioburden build-up in associated pipework. When changing the filter, care needed to prevent recontamination of the clean side of the associated pipework.
Disinfectant addition (see 14.3 c)	Used to reduce bacterial population.	Can be an effective method at disinfecting a distribution loop and minimizing the risk of biofilm formation.	Confirmation required to show that residual chemical concentration in the water is not toxic to the patient and has no negative impact on the load, especially in relation to corrosion.
NOTE References used for Table A.1 include References [44] and [66].			

Annex B
(informative)

Water quality for use in sterilizers and washer-disinfectors (WDs)

B.1 Water supplied to sterilizers

B.1.1 As described in 5.3, if the sterilizer requires a water supply, the requirements for water to be supplied should be specified for each specific use. The specification for the water should ensure that any contaminants are not present in a concentration that can damage the sterilizer, impair the performance of the process or damage the product.

B.1.2 In addition, the quality of the feed water supplied to a steam generator can affect the quality of the steam generated. If a dedicated steam generator is used, the sterilizer should be designed to operate with steam produced from water without contaminants in a concentration that can impair the sterilization process or harm or contaminate the sterilizer or load. Depending on the design of the steam generator system, holding time, temperature, operational aspects and the resulting steam quality, different levels of contaminants in feed water can be tolerable. The use of water for steam generation with contaminants at levels exceeding those recommended can greatly shorten the working life of a sterilizer. The quality of steam supplied to the sterilizer can also be affected by the manner in which it is distributed from the steam generator to the equipment.

B.1.3 The levels of contaminants in water supplied to a sterilizer can be specified by the manufacturer or be provided by international, regional or national standards or guidelines. Examples of recommended limits on contaminants are illustrated in Table B.1. The values in Table B.1 have been taken from European standards for sterilizers for particular processes, EN 285, EN 13060 and EN 14180.

B.1.4 The European standard for EO sterilizers (EN 1422) and the draft European standard for a vaporized hydrogen peroxide sterilizer (EN 17180[3]) do not contain a specification for water supplied to the equipment. For this reason, recommendations for water for EO and VH202 sterilizers have not been included in Table B.1.

a) EN 1422 recommends that, if boiler additives are used during steam generation, consideration should be given to potential contamination of steam used for humidification and notes that potable water is considered the minimum requirement for the generation of steam. Water used for purposes other than generating steam is required to be of a quality suitable for its intended use.

b) EN 17180[4] notes that a water hardness value between 0,7 mmol/l and 2,0 mmol/l is generally accepted. Water hardness values outside these limits can cause scaling and corrosion problems.

3) Under preparation.

4) Under preparation.

Table B.1 — Examples of recommendations for contaminants in water used for sterilization

Determinant	Water for moist heat sterilization	Water for LTSF sterilization
Residue on evaporation	≤ 10 mg/l	≤ 10 mg/l
Silicate	≤ 1 mg/l	≤ 1 mg/l
Iron	≤ 0,2 mg/l	≤ 0,2 mg/l
Cadmium[a]	≤ 0,005 mg/l	≤ 0,005 mg/l
Lead[a]	≤ 0,05 mg/l	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead[b]	≤ 0,1 mg/l	≤ 0,1 mg/l
Chloride[c]	≤ 0,5 mg/l for large steam sterilizers ≤ 2 mg/l for small steam sterilizers	≤ 0,5 mg/l
Phosphate	≤ 0,5 mg/l	≤ 0,5 mg/l
Conductivity (at 20 °C)	≤ 5 µS/cm for large steam sterilizers ≤ 15 µS/cm for small steam sterilizers	≤ 5 µS/cm
pH (20 °C) value	5 to 7,5	5 to 7,5
Appearance	Colourless, clean, without sediment	Colourless clean without sediment
Water hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l	≤ 0,02 mmol/l

NOTE The use of feed water with contaminants at levels exceeding those given above can greatly shorten the working life of a sterilizer and can invalidate the manufacturer's warranty or guarantee.

[a] The limiting values meet the requirements for potable water.

[b] European Pharmacopoeia (EP), Monograph 8, Purified Water, Test method V.3.2.8.

[c] Maximal chloride concentration in feed water influences corrosion in combination with high temperatures.

B.2 Water for use in washer-disinfectors (WDs)

B.2.1 As described in 5.4, if the WD requires a water supply, the requirements for water to be supplied should be specified for each specific use. The specification for the water should ensure that any contaminants are not present in a concentration that could damage the WD, impair the performance of the process or damage the product.

B.2.2 The levels of contaminants in water supplied to a WD can be specified by the manufacturer or be provided by international, regional or national standards or guidelines, such as:

a) ISO 15883-1, ISO 15883-3, ISO 15883-4 and ISO 15883-7;

b) AS/NZS 4187:2014+A2:2019[5];

c) Health Technical Memorandum 01-01 [65] and Health Technical Memorandum 01-06 [66];

d) DGKH, DGSV and AKI Guideline [60];

e) AAMI/CDV-1 ST108[6] [44].

Examples of recommended limits on contaminants taken from these references are illustrated in Table B.2.

5) AS/NZS 4187:2014+A2:2019 is under revision with a new designation as AS 5369:202X, *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*.

6) Under preparation.

Table B.2 — Examples of recommendations for quality of final rinse water used in a washer-disinfector (WD)

Criterion	AS/NZS 4187:2014 +A2:2019	ISO 15883-4: 2018	AAMI ST 108	HTM 01-01/ HTM 01-06	DGKH, DGSV and AKI Guideline	
					Softened water	Demineralized water
pH	5,5 to 8,0	[a]	5,0 to 7,5	5,5 to 8,0	5 to 8	5 to 7,5
Conductivity at 20 °C	≤ 30 µS/cm	[a]	< 10 µS/cm	≤ 30 µS/cm	Not specified	≤15 µS/cm
Total hardness	≤ 10 mg /l $CaCO_3$	[a]	<1 mg /l $CaCO_3$	< 50 mg/l $CaCO_3$[b)]	< 0,5 mmol CaO_3/l (< 3°dH)	≤ 0,02 mmol/l
Residue on evaporation	Not specified	Not specified	Not specified	<40 mg/l	< 500 mg/l	≤ 10 mg/l
Chloride	≤ 10 mg/l	[a]	<1 mg/l	< 10 mg/l	< 100 mg/l or < 50 mg/l[b)]	≤ 0,5 mg/l
Iron	≤ 0,2 mg/l	[a]	<0,1 mg/l	< 2 mg/l	Not specified	≤ 0,2 mg/l
Phosphates (molybdate reactive)	≤ 0,2 mg/ l	[a]	<1 mg/l	≤ 0,2 mg/ l	Not specified	≤ 0,5 mg/l
Silicates (molybdate reactive)	≤ 1,0 mg/l	[a]	<1 mg/l	≤ 0,2 mg/ l	Not specified	≤ 1 mg/l
Total viable count	≤ 100 CFU/ 100 ml	≤ 10 CFU/100 ml	<10 CFU/ml	≤100 CFU/100 ml (HTM 01-01) ≤10 CFU/100 ml (HTM 01-06)"	Not specified	Not specified
Bacterial endotoxin	≤0,25 EU/ml ≤ 30 EU/ml for thermolabile endoscope WD	[a]	<10 EU/ml	≤ 0,25 EU/ml (HTM 01-01) ≤ 30 EU/ml (HTM 01-06)	Not specified	Not specified
Pseudomonas aeruginosa	Not detected/ 100 ml	Not detected /100 ml	Not specified	Not detected/ 100 ml (HTM 01-06)	Not specified	Not specified
(Atypical) *Mycobacterium* sp.	Not detected/ 100 ml	Not detected /100 ml	Not specified	Not detected/ 100 ml (HTM 01-06)	Not specified	Not specified

NOTE AS/NZS 4187:2014+A2:2019 is under revision with a new designation as AS 5369:202X, *Reprocessing of reusable medical devices and other devices in health and non-health related facilities.*

[a] In accordance with WD IFU.

[b] Acidic process chemicals should not be used with water with a chloride content of greater than 100 mg/l, since this can result in pitting on chrome-steel instruments. In this case, an upper limit of < 50 mg/l chloride is recommended.

B.3 Methods of analysis

Conformity with the water quality criteria should be tested in accordance with acknowledged analytical or microbiological methods. Examples of methods that can be used for establishing values for determinants or criteria in Table B.1 and Table B.2 are given in Table B.3. These methods are provided only as examples and other test methods can be applied.

Table B.3 — Examples of methods of analysis

Determinant/criterion	Example test method(s)	Example reference(s)
Residue on evaporation	Total dissolved solids (TDS) determined as evaporative residue	ASTM D4902-99(2020) Ph. Eur. Monograph 0008 *Purified Water* DIN 38409-1
Silicates (molybdate reactive)	Colorimetric / Spectrophotometric	ASTM D859-16
Cadmium	Atomic absorption spectrometry (AAS)	ISO 5961