American National Standard

ANSI/AAMI ST108:2023

Water for the processing of medical devices

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Water for the processing of medical devices

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AAMI

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Abstract: This standard covers the selection and maintenance of effective water quality suitable for processing medical devices. It provides guidelines for selecting the water quality necessary for the processing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Keywords: carbon filters, deionization, disinfection, distillation, medical devices, pasteurization, processing, reverse osmosis, rinsing, sediment filters, steam purity, sterilization, ultrafiltration, water filtration, water quality, washing, water softening, water quality, water treatment

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Foreword

This standard was developed by the AAMI Water Quality for Medical Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to set the quality requirements for the different categories of water used in processing of medical devices and provides guidance as to when and where to use water of each category. In addition, this standard provides information on how to verify that the water continues to meet those minimum requirements. This standard also provides valuable information for the performance qualification of a water treatment/delivery system and a monitoring program to ensure water quality remains within the stated specifications.

This is the first edition of this American National Standard, which revises and replaces AAMI TIR34 [1]. The goal of this standard is to specify the minimum requirements for the water quality and steam purity necessary to effectively process medical devices intended for use on a patient.

The professionals responsible for the processing of medical devices prior to use are experiencing increasing challenges including: the increasing complexity of modern medical devices with hidden, difficult to access areas (e.g., lumens and complex mechanisms) where clinical soil can become lodged; and the emerging and reemerging incidence of "superbugs" that must be removed or inactivated for patient safety but are able to survive processing in situations where soil removal is incomplete. Any limitation on or diminishment of cleaning efficacy can lead to patient morbidity or mortality and decreased device use life. Water of the appropriate quality for the processing of medical devices prior to clinical use is an important part of the solution to these problems.

A common factor in the processing of medical devices is the use of water. While medical devices cleared by the U.S. Food and Drug Administration's (FDA) for sale into the health care market have been provided with validated processing instructions and procedures, these procedures may not be completely effective if water of specified quality is not used. Similarly, cleaning agents work better, and devices are rinsed more thoroughly if the water is of the specified quality. Each health care facility may require a specific approach to treating water for processing needs based on a variety of factors.

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- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the ANSI/AAMI ST108, *Water for the processing of medical devices* (ANSI/AAMI ST108:2023), but it does provide important information about the development and intended use of the document.

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Introduction

Water quality is an important consideration in all stages of medical device processing, as is the purity or chemical content of the steam that is generated for moist heat sterilization. The health care facility should have a multidisciplinary team in place that develops a strategy to confirm all aspects of water quality that impact the processing of medical devices within this standard. Appropriate water quality and steam purity in device processing requires collaboration between the personnel who process medical devices and the personnel who establish and maintain the water treatment system.

Water treatment and delivery systems can be configured in many ways to achieve the required water quality specifications. Water can be treated by a variety of methods that yield different levels of water quality. Gram-negative bacteria and nontuberculous mycobacteria can grow in water regardless of treatment process. The rate of growth and the microbial levels attained are a function of several factors related to the water (e.g., variety and concentration of organic contaminants, pH, temperature). Water systems that are closely monitored for quality reduce variability of processing conditions and effectiveness of cleaning and disinfection processes as well as reduce the potential of microbial proliferation. The importance of monitoring water quality to prevent problems with microbial proliferation cannot be overemphasized.

This standard defines multiple levels of water quality and steam purity suitable for medical device processing, and it describes the water treatment processes that can be utilized in order to produce water of the quality to meet each of these categories.

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Water for the processing of medical devices

1 Scope

1.1 General

This standard establishes minimum requirements for the water quality used at different stages in the processing of medical devices (e.g., reusable devices and single-use devices provided non-sterile requiring processing prior to use such as non-sterile implants and processed single-use devices) to make them ready for use on the next patient. These requirements are established to assist medical device processing professionals in the selection of the appropriate water quality needed for cleaning, rinsing, disinfection, and sterilization of medical devices.

1.2 Inclusions

This standard covers the quality of the water delivered to the point-of-use and used in medical device processing (cleaning, rinsing, disinfection and sterilization). It defines water types based on the qualities possessed and where it will be used. Included in this document are:

a) Responsibility for the water management program;

b) Importance of water quality;

c) Adverse effects of water impurities on medical device processing;

d) Categories and requirements of water quality for medical device processing;

e) Selection of water of the appropriate quality;

f) Purity requirements of water used to generate steam;

g) Effective water treatment and qualification;

h) Considerations for ongoing maintenance, monitoring and quality improvement of the water treatment system;

i) Troubleshooting water quality issues.

This standard also provides definitions of terms and a bibliography.

1.3 Exclusions

This standard does not cover:

a) Water requirements for hemodialysis applications;

b) Water requirements for laboratory use;

c) Steam quality requirements (i.e., physical qualities of steam such as: moisture content, noncondensable gas content and Superheat). See ANSI/AAMI ST79 [8];

d) Water treatment performed within the medical device processing equipment (e.g., washers, washer/disinfectors, or automated endoscope reprocessors (AERs);

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e) Water quality of municipal water supply; and

f) Testing of water post use.

2 Normative references

There are no normative references used in the development of this document.

3 Terms and definitions

For the purpose of this standard, the following terms and definitions apply.

3.1
A_0
measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K

[SOURCE: ISO 11139:2018]

3.2
absolute rated filter
absolute filter rating meaning 99.9 % of the particles larger than a specified micron rating will be trapped on or within the filter

3.3
action level
value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018]

3.4
alert level
value from monitoring providing early warning of deviation from specified conditions

[SOURCE: ISO 11139:2018]

3.5
anion
negatively charged atom or molecule

3.7
automated endoscope reprocessor (AER)
machine intended to disinfect or sterilize loads containing endoscopes

Note to entry: Some AERs have provisions for processing accessories.

3.8
bacterial endotoxin test
BET
assay for measuring bacterial endotoxin by combining a liquid test sample extract with *Tachypleus* or *Limulus* amebocyte lysate (TAL/LAL) reagent and measuring the resulting proportional reaction via visual, turbidimetric, or chromogenic techniques [7]

3.9
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO 11139:2018]

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Note to entry: When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (CFUs) per unit of measure.

3.10
biofilm
a community of microorganisms; biofilms can consist of single or multiple types of microorganisms, either as actively multiplying, dormant, or generally associated with the biofilm structure; they can include “wet” (associated with water) or “dry” biofilms and are typically developed on or associated with surfaces or interfaces (e.g., water lines or storage systems); they are microbially derived communities characterized by cells that are irreversibly associated with a substratum, interface, or each other; they are often embedded in a matrix of extracellular polymeric substances (EPSs) that they produce; and exhibit mixed phenotypes with respect to growth rate, gene transcription, and resistance mechanisms)

Note to entry 1: The biofilm may consist of single or multiple bacterial species, fungal species, or both.

Note to entry 2: Some microscopic organisms have the ability, when growing in water or water solutions or in vivo (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as extracellular polymeric substance (EPS)) and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

3.11
cation
positively charged atom or molecule

3.12
chemical sterilization
validated process that uses a chemical agent and is designed to render a product free of viable microorganisms

3.13
chloramines
compounds formed by the reaction of aqueous chlorine with ammonia or an amine compound

3.14
chlorides
an ionic compound of chlorine with a metallic element or group, especially a salt of the anion Cl^-; for example, sodium chloride NaCl or calcium chloride $CaCl_2$

3.15
chlorine, free
concentration of residual chlorine in water that is present as dissolved gas (Cl_2), hypochlorous acid (HClO), and/or hypochlorite ion (ClO)

Note to entry: The three forms of free chlorine exist together in equilibrium; their relative proportions are determined by the pH and temperature of the water.

3.16
clean (pure) steam
steam generated using “a pure steam generator (PSG)" when fed with water for injection (WFI). It is pyrogen-free, dry, saturated steam that shall meet the requirements of WFI when condensed

Note to entry: Clean steam is defined by PDA in Technical Reports 1:2007 and 48:2010 and in USP 31.

3.17
cleaning
removal of contaminants to the extent necessary for further processing or for the intended use

[SOURCE: ISO 11139:2018]

Note to entry: In health care facilities, cleaning consists of the removal, usually with cleaning agent (e.g., a physical or chemical entity, or combination of entities, having activity to render an item clean) and water, of adherent soil (e.g., blood, protein substances,

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and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical (automated) process that prepares the items for safe handling or further decontamination.

3.18
cleaning agent
physical or chemical entity, or combination of entities, having activity to render an item clean

[SOURCE: ISO 11139:2018]

3.19
conductivity
the indirect measurement of ion concentration in water; conductivity measures the ion facilitated electron flow in water

Note to entry: Conductivity is measured by a conductivity meter and has units of microsiemens/cm (µS/cm). A microsiemen is defined as conductance such that the current through the device will increase by one milliamp (mA) for every increase of one volt potential difference across the device.

3.20
critical devices
as defined by Spaulding's classification, medical devices that are introduced into or have contact with the bloodstream or normally sterile areas of the body; examples include, but are not limited to, implants and surgical instruments

3.21
critical water
water meeting the quality requirements in Table 2.

Note to entry: This document provides requirements and recommendations for the appropriate use of water of this quality.

3.22
cross-flow filtration
process in which particulates (e.g., microbiological species, insoluble particulates) are removed from liquids or gases by passage through a porous material, with the filtered particles flowing in one direction and the filtrate flowing in the opposite direction

3.23
***D* value**
time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated dose conditions

3.24
dead-leg
with respect to water distribution systems, piping that is more than 3-5 times as long as its internal diameter and that does not have constant water flow

3.25
decontamination
removal of contaminants to a specified level.

Note to entry: A decontamination process can include a cleaning (physical removal) and/or an antimicrobial (e.g., disinfection) process, depending on the defined level previously specified as being appropriate for a defined purpose, and is often a combination of these processes [BI&T 2021]

3.26
deionization
DI
water treatment process that uses ion-exchange resins to produce high purity water

3.27
depth filter
filter that consists of mats of fibers and generally has a broad pore-size distribution and high particle-holding capacity

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Note to entry: Depth filters are often used as prefilters to remove large particles and to extend the service life of subsequent filters.

3.28
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018]

3.29
distillation
water treatment process that uses vaporization and subsequent condensation to purify water

Note to entry: For purposes of this standard, distilled water is considered to be water generated from a properly maintained still on-site, not bottled water labeled as distilled.

3.30
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]

3.31
endotoxin unit
EU
standard unit of measure for endotoxin activity initially established relative to the activity contained in 0.2 nanograms of the U.S. Reference Standard Endotoxin Lot EC-2 [29], [7]

Note 1 to entry: FDA's reference endotoxin EC-6, USP Lot G [29], and the World Health Organization's primary international endotoxin standard (IS) are sublots of the same endotoxin preparation, making the EU and IU (International Unit) equal [76].

Note 2 to entry: unit of measure for endotoxin is EU/mL

3.32
EPA
U.S. Environmental Protection Agency

3.33
FDA
U.S. Food and Drug Administration

3.34
feedwater
water being fed to water treatment equipment or steam generator (e.g., potable water delivered to deionizer)

3.35
green sand
manganese-containing ion exchange resin used to remove soluble iron and manganese from water

Note to entry: The manganic ion form in the ion exchange resin oxidizes ferrous and manganous ions in water to their insoluble ferric and manganic forms. The resulting manganous ion in the ion exchange resin can be regenerated to the manganic ion form with potassium permanganate.

3.36
hardness, water
concentration of calcium and magnesium ions in water, expressed as parts per million (ppm) or milligrams per liter (mg/L) of calcium carbonate ($CaCO_3$) equivalents

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Note to entry: Soft water is 0 to 60 ppm $CaCO_3$, moderately hard water is 60 to 120 ppm, hard water is 120 to 180 ppm, and very hard water is greater than 180 ppm.

3.37
heterotrophic plate count
HPC
procedure that estimates the number of viable bacteria that use organic molecules as their principal energy source. It can be used to determine the efficiency of a water treatment process and the quality of the water produced

Note to entry: Three different methods, using three different types of media, can be used to perform a heterotrophic plate count: spread plate, pour plate, and membrane filtration.

3.38
high-level disinfectant
HLD
agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC sporicidal activity test as a sterilant.

3.39
high-level disinfection
complete elimination of all microorganisms in or on an instrument, except for large numbers of bacterial spores [43]

Note to entry: For a process that can be used for both chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

3.40
hydrophobic
does not readily absorb water; insoluble in water

3.41
inorganic solutes
compounds (e.g., salts) that do not contain organic carbon and that are dissolved in a liquid

3.42
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018]

3.43
intermediate-level disinfectant
agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores [42]

3.44
***Limulus* amebocyte lysate**
LAL
reagent extracted from amebocytes taken from hemolymph of the horseshoe crab, *Limulus polyphemus*, which reacts with endotoxin, to form a gelatinous clot and is used to estimate endotoxin levels in bacterial endotoxin test methods [7]

3.45
lipopolysaccharide
LPS
gram-negative bacterial cell wall component typically composed of lipid A, a core polysaccharide, and an O-side chain; *see also* endotoxin [7]

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3.46
liquid chemical sterilant
LCS
solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim; see definition 3.67

3.47
low-level disinfection
process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores

3.48
microfilter
filter designed to remove particles in the range of 0.1 to 3 microns (µm) in diameter

3.49
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: ISO 11139:2018]

3.50
non-critical devices
as defined by Spaulding's classification, medical devices that contact only intact patient skin; examples include, bedpans, reusable anesthesia masks, and blood pressure cuffs

3.51
non-pyrogenic
does not induce a fever; term used to describe an item or product that contains endotoxin levels less than or equal to specified limits [7]

Note to entry: Nonpyrogenic can also be used to describe and label health care products that contain endotoxin levels less than specified limits and do not elict a pyrogenic reaction. Other products (e.g., pyrgogen-free water) can have alternate labeling requirements.

3.52
non-pyrogenic water
water containing endotoxin at less than a specified endotoxin limit demonstrated to produce a pyrogenic response

3.53
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]

3.54
pasteurization
disinfection process that uses hot water at temperatures of 65 °C to 77 °C (150 °F to 170 °F) for a contact time of at least 30 minutes

3.55
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

[SOURCE: ISO 11139:2018]

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3.56
pH level
number denoting alkalinity or acidity

Note to entry: The pH scale is logarithmic and runs from 0 to 14; the neutral point is 7. Numbers below 7.0 indicate acidity, and those above 7.0 indicate alkalinity.

3.57
plant or house steam
steam produced in health care settings using water from the municipal supply that can either be treated or untreated to meet the specifications for feedwater for the boiler

3.58
point-of-use treatment (of clinically used medical devices)
point-of-use treatment refers collectively to the activities that the user of a medical device performs at the point of use (e.g., where the procedure was performed) to prepare it for processing; point-of-use treatment occurs immediately after patient use and can include rinsing, flushing, wiping (to prevent biofilm formation and drying of soil), disconnecting accessories, preparing handoff communication, and preparing the instrument/device for transport to the decontamination facility and placing it in an appropriately labeled container

3.59
point-of-water use
POU
closest point in the distribution loop where the water is exposed to a medical device during processing

3.60
point-of-water use system
POU system
water treatment system in which purification (usually filtration) takes place just before a single water supply outlet

Note to entry: Examples of a POU system are a filter in the line leading to the faucet (such as a filter under a kitchen sink) and a filter attached to the faucet (such as a screw-on tap filter).

3.61
potable water
water that has been treated and delivered in a manner so that it meets EPA guidelines intended for direct or indirect human consumption [21]

3.62
process
to prepare a device, instrument, or piece of equipment for reuse by any or a combination of the following processes; point-of-use treatment, cleaning, disinfection, sterilization, and rinsing at appropriate stages

3.63
process steam
steam produced in a health care facility for sterilization using a stainless steel boiler fed with Critical Water

3.64
product water
water that has been treated to achieve a predetermined quality at the output of the treatment system or process

3.65
pure steam generator
a pure (or clean) steam generator converts incoming water for injection (WFI) feedwater into clean steam using plant steam as the heating medium. The plant steam does not contact the clean steam. The steam generator is constructed so as to not add any impurities to the steam produced

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3.66
pyrogen
any substance that induces a fever

[SOURCE: AAMI ST72:2019]

Note to entry: Pyrogens can be classified into two groups: microbial (e.g., bacteria, fungi, viruses) and nonmicrobial (e.g., drugs, device materials, steroids, plasma fractions).

3.67
pyrogenic
induces a fever; term used to describe an item or product that contains endotoxin levels above specified limits

[SOURCE: AAMI ST72:2019]

3.68
residue
remains after a process, preparation, separation, or purification

3.69
resistivity
ability of water to resist the flow of electricity; a measure of the resistance of water and the inverse of conductivity

Note to entry: Resistivity is measured by a resistance monitor and described in megaohms-cm (MΩ-cm).

3.70
reverse osmosis
RO
membrane separation process for purifying water that is based on molecular sieving and ionic rejection and that is effective in removing ions as well as dissolved organic contaminants with molecular weights above 100 daltons

3.71
rinsing
process of flushing the exterior or interior of a medical device with a liquid such as water to remove organic and inorganic material at various stages in medical device processing

3.72
sediment
material that settles at the bottom of a liquid

3.73
semi-critical devices
as defined by Spaulding's classification, medical devices that contact intact mucous membranes or non-intact skin but do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body; examples include, but are not limited to, gastrointestinal endoscopes and respiratory therapy equipment

3.74
single-use medical device
medical device labelled or intended to be used on one individual during a single procedure

Note to entry: A single-use medical device is not intended to be further processed and used again.

[SOURCE: ISO 11139:2018]

3.75
softening
technique that removes water hardness (multivalent positive ions e.g., calcium, magnesium, and iron)

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3.76
steam
vaporized water that is used in specific applications for medical device processing and is produced by a centralized boiler, generator, or heat exchanger at point-of-use; when tested as a condensate meets specified criteria

3.77
steam purity
the chemical characteristics of steam relative to the contaminants in the steam condensate shown in Table 2

3.78
sterilant or sterilizing agent
physical or chemical entity, or combination of entities, that has sufficient microbicidal activity to achieve sterility under defined conditions

3.79
sterile
free from viable microorganisms

3.80
sterile processing department/area
an area that processes and controls medical supplies, devices, and equipment, sterile and non-sterile, for some or all patient care areas of the facility

[SOURCE: ISO 11139:2018]

Note to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven. See sterilization.

3.81
sterilization
validated process used to render a product free from viable microorganisms

[SOURCE: ISO 11139:2018]

Note to entry: In a sterilization process, the nature of microbiological 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.

3.82
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

Note to entry: This series of actions includes pretreatment of product (if necessary), exposure under defined conditions to the sterilizing agent, and any necessary post-treatment. The sterilizing process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

3.83
storage tank
tank in which water is stored for future use, typically at the user's facility

3.84
submicron filter
mechanical filtration process that has the capacity to retain particles or organisms that are less than 1 micron (µm) in their smallest cross-sectional dimension

3.85
tap water
water that is obtained from the tap, faucet, or fixture

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Note to entry: Tap water refers to the location from which the water is obtained. This water may not meet the requirements for Utility Water.

3.86
thermal disinfection
disinfection process that uses hot water at adequate temperatures (higher than 60 °C) to kill residual microorganisms

Note to entry: The efficacy of microbial kill depends on the temperature and exposure time. For a more detailed discussion, see Annex E.

3.87
total dissolved solids
TDS
a measure of the dissolved combined content of all inorganic and organic substances present in a liquid in molecular, ionized, or micro-granular (colloidal sol) suspended form

Note to entry: TDS concentrations are often reported in parts per million (ppm)

Note to entry: TDS measurements are commonly used to assess the performance of water treatment systems. TDS values are often expressed in terms of $CaCO_3$ or NaCl equivalents (ppm).

3.88
total organic carbon
TOC
measure of both natural (residuals from natural plant and animal decomposition) and synthetic organic substances

3.89
ultrafilter
membrane filter with a pore size in the range 0.001 to 0.05 µm

Note to entry: The performance of an ultrafilter is usually rated in terms of a nominal molecular weight cut-off (MWCO), which is defined as the smallest molecular weight species for which the filter membrane has more than 90 % rejection. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal. Ultrafilters are not commonly used to remove particulates.

3.90
utility water
water meeting the quality requirements in Table 2

NOTE: This document provides requirements and recommendations for the appropriate use of water of this quality.

3.91
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 11139:2018]

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.

3.92
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 11139:2018]

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Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “verified” is used to designate the corresponding status.

3.93
water for injection
WFI
water meeting drinking water standards [38], purified by distillation or a purification process that is equivalent or superior to distillation in the removal of chemicals and microorganisms and rendered sterile by filtration or thermal inactivation

3.94
water management program
a multistep process to identify hazardous conditions and take steps to minimize the growth and transmission of waterborne pathogens in building water systems; the program requires continuous review and documentation of the plan’s implementation, operation, and mitigation strategies as appropriate

Note: see ASHRAE188 for example program

3.95
water purity
indication of the extent to which impurities (e.g., dissolved organic and inorganic solids, ionic and liquid chemical solutes, and microbial contaminants) have been removed from the water

3.96
water quality
descriptor of the levels of various impurities present in water (see Table 2)

3.97
water treatment system
collection of water purification devices and associated piping, pumps, valves, and gauges that together produce treated water of a specified quality and deliver it to the point-of-water-use

3.98
z value
change in exposure temperature of a thermal sterilization or disinfection process, which corresponds to a tenfold change in *D* value

4 Roles and responsibilities

4.1 Introduction

This section identifies the multidisciplinary team responsible for water quality and the water management program and specifies the roles each plays in maintaining an acceptable level of water quality. The individuals or group assigned to the multidisciplinary team shall have demonstrated competency to perform their assigned function as well as the resources to address any issues or changes to the program.

4.2 Considerations

The multidisciplinary team responsible for the water management program may be comprised of individuals both internal and external to the health care facility and should define the water quality needed for processing medical devices.

4.3 Multidisciplinary team roles

Senior organizational leadership should select the individual(s) responsible for leading the multidisciplinary team for water management. This team is responsible for compliance with the local code, infection prevention and control accreditation standards. The team members in these disciplines may be employed by the facility or be contracted and

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should have knowledge of water systems and associated processes in use. The membership of the multidisciplinary team should include representatives with demonstrated expertise of the following disciplines, but is not limited to:

a) Senior organizational leadership with authority to make command decisions about water restrictions or other response measures (executive sponsorship);

b) Facilities engineering staff;

c) Infection prevention and control (IP) program staff;

d) Medical device processing personnel with knowledge of water use within the device processing areas (e.g., sterile processing);

e) Clinical engineering staff with the ability to address risk management and procurement of equipment for water management;

f) Surgical suite/procedure room personnel: and

g) Water treatment specialist.

The multidisciplinary team is responsible for developing, implementing, and documenting all applicable requirements of the Water Management Program.

4.3.1 Executive sponsorship

Executive sponsors with the authority to allocate resources.

4.3.2 Facilities engineering personnel

Facilities engineering personnel are responsible for the water system installation, qualification, validation for the appropriate water quality for device processing and water system maintenance. All of these disciplines may not exist on staff but may be represented by an outside vendor/contractor.

4.3.3 Infection prevention and control personnel

Infection prevention personnel participate on the multidisciplinary team to develop or assist with the development of policies, procedures, and protocols for the required water quality for device and instrument processing as part of a quality assurance program to meet regulatory, standards, guidelines and accreditation requirements. Infection prevention and control personnel:

— review the water management program and verify that the testing meets regulatory requirements, standards and guideline requirements that impact water quality;

— perform ongoing surveillance monitoring of patients who were potentially exposed to waterborne pathogens carried by instrument/devices (e.g., implants, endoscope, bronchoscopes, etc.) that may have been processed by water of unacceptable quality;

— in collaboration with the multidisciplinary team, review water monitoring test results and make recommendations on the development of corrective action plans;

— facilitate/perform risk assessment in collaboration with the multidisciplinary team related to water quality impacting the Medical Device Processing Department and the processing of instruments and devices by high-level disinfection;

— bring concerns/issues/reports from the multidisciplinary team to the Infection Prevention and Control Committee for discussion and recommendations;

— when appropriate, escalate issues/concerns to facility leadership.

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4.3.4 Medical device processing personnel

Medical device processing personnel are responsible for the cleaning, disinfection, inspection and sterilization of medical devices. They should receive education, training, and competency verification on the importance of water quality, the patient risks associated with improper water system characteristics, and the water quality monitoring that should be performed in processing areas. Medical device processing personnel are responsible for monitoring processing equipment and medical devices being processed for any damage and discoloration that may be indicative of water quality issues. They should be given the time and resources to complete these activities.

Medical device processing can occur in different areas throughout a health care facility. The typical area that processes the majority of medical devices is the Sterile Processing department. A large part of a Sterile Processing's workload is cleaning and sterilizing devices, while additional responsibilities include high, intermediate, and low-level disinfection of other devices. A Surgery department may perform sterilization processes. An Endoscopy department performs high-level disinfection on their endoscopes. Physician and dental clinics perform sterilization processes. Other areas of a health care facility may perform device processing that is specific to their area such as a cardiac lab high-level disinfecting TEE probes.

4.3.5 Clinical engineering personnel

Clinical Engineers are involved with risk management, equipment procurement and assessment, cybersecurity, incident investigation, project management, capital planning, construction and patient safety/quality initiatives. Their involvement in water quality assurance is spread over these areas of expertise and responsibility. Their roles are different from a Biomedical Equipment Technician (BMET).

NOTE Clinical Engineers (employed or contracted) are primarily hospital based but, in some cases, can also be employed in industry or in a regulatory setting.

4.3.6 Surgical suite/procedure areas personnel

Personnel in the operating room and other procedural areas visually inspect instruments and devices for any indications of water quality issues (e.g., corrosion, discoloration, etc.) prior to use (e.g., placement in the sterile field).

4.3.7 Water Treatment Specialist

Water Treatment Specialists are involved with the selection, integration, qualification, and validation of water treatment equipment.

4.4 Multidisciplinary team responsibilities

The multidisciplinary team is responsible for the actions in Table 1.

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Table 1—Multidisciplinary team responsibilities

Primary responsibility	Action
Facilities engineering personnel, multidisciplinary water management consultant or other external contracted personnel	General assessment of water quality. Per manufacturer guidelines routinely sample water and determine if values are within specified ranges per management plan
Facilities engineering personnel in conjunction with medical device processing personnel, multidisciplinary team, water management consultant or other external contracted personnel	Implementation of water treatment processes; determine appropriate method/equipment required for the facility's water supply
Medical device processing personnel in conjunction with clinical engineering personnel, external contracted personnel, or consultant	Assurance of proper water quality for the various stages in medical device processing using water quality monitoring
All members of the multidisciplinary team	Manages the water management program

5 Risk analysis

5.1 Introduction

Water impurities can have adverse effects on medical device processing. The requirements in this standard are intended to mitigate the risks associated with water identified to be of improper quality. It is important that personnel responsible for processing medical devices or for using them in patient procedures understand the importance of water quality and how water quality failures contribute to adverse patient events and outcomes. They should be aware of the indicators that suggest that there could be problems with the water quality. As part of the water management program, monitoring water quality is a prospective process meant to confirm that control strategies are functioning as expected. Monitoring is performed in order to detect when control strategies might require review or remedial action. Some of the potential effects are listed below. This is a representative but not exhaustive list:

Adverse effects to the medical device:

- Corrosion, pitting, scaling;
- Biofilm build up;
- Increased microbial load or endotoxin content;

Adverse effects to the process:

- Decreased effectiveness of cleaning agents;
- Degradation of the water system or processing equipment (biofouling or scaling);

Adverse effects to the patient (indirect):

- Infection (e.g., water-borne pathogens);
- Toxicity (e.g., toxicity of residual chemicals, exposure);
- Pyrogenic reactions (e.g., fever);

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Adverse effects to personnel:

— Environmental Health & Safety (e.g., chemical handling, exposure and disposal, injury by high-pressure water, electrical hazards).

On 1/1/2022, the Joint Commission implemented a new water management standard (EC.02.05.02, EPs 1 through 4) that complimented the CMS requirement from 2017 (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO17-30-HospitalCAH-NH-REVISED-.pdf) which requires health care facilities to have a water management program with an individual or team responsible for the oversight and implementation of the program and provides requirements for water quality production including a risk assessment. Other accrediting agencies have similar requirements.

Water quality issues can contribute to adverse patient events and outcomes. This Standard assists in increasing the awareness of health care personnel of the gross indicators that suggest that there may be problems with water quality [62]. Monitoring water quality is a process meant to confirm that control strategies are working properly.

In the preparation of water for use in medical device processing, six general characteristics need to be considered:

— Physical appearance of the water (color, clarity and absence of particulates/sediment);

— The microbial level in water;

— Inorganic and organic contaminants of water;

— The pH of the water; and

— Conductivity of the water.

— Water temperature

The municipal water supply should deliver water to a health care facility with a microbial level <500 CFU/mL to be considered potable per the EPA. Water used for medical device processing should continue to deliver water of this microbial quality level to the point-of-use. Lower microbial acceptance levels should be considered for microorganisms of concern for patient safety (e.g., *Legionella*).

A risk analysis for water quality should be completed prior to water system installation. The resulting evaluation plan should be reviewed periodically as determined by the health care facility to assess the continued performance of the water system.

5.2 Effects of adverse water quality on medical device processing

5.2.1 General considerations

The primary objective of medical device processing is to prepare a device for use on a patient. Adverse patient events and outcomes to which inadequate water quality can contribute include:

a) device malfunction during a patient procedure (e.g., corrosion of a surgical instrument could result in breakage of the device inside the patient when stress is applied to the device; mechanical movement of the device could be obstructed by residual debris or corrosion inside the mechanism; degradation of optical and metal surfaces negatively impacting function);

b) toxic effects and tissue irritation results from residuals on a device or implant that was processed using water of inappropriate quality;

c) risk of patient infection resulting from the use of contaminated devices (e.g., surgical site infections);

d) pyrogenic reactions due to the presence of endotoxin; and

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e) ineffective cleaning/disinfection due to water contaminants interfering with device processing chemicals.

6 Categories of water quality for medical device processing

6.1 Introduction

The water quality needed for the various stages of medical device processing is determined by the type of medical device and by the disinfection or sterilization process used. For example, the processing of stainless steel surgical instruments that are steam sterilizable has different water quality requirements than the processing of flexible endoscopes, which require high-level disinfection or low-temperature sterilization.

6.2 Three categories of water quality

Table 2 describes three categories of water quality in terms of the characteristics that are important for medical device processing and the level of treatment that may be needed:

a) **Utility Water**: water as it comes from the tap that can require further treatment at the facility to achieve water quality measurement values outlined in Table 2. This water is mainly used for flushing, washing, and intermediate rinsing (e.g., rinsing between cleaning and disinfection).

NOTE The decision regarding the need to treat incoming tap water to provide adequate water quality for medical device processing should be undertaken in every facility that processes medical devices.

b) **Critical Water:** water that meets the water quality measurement values detailed in Table 2; to achieve these values, the water generally requires extensive treatment by a multi-step process that can include a pretreatment, does include primary treatment (e.g., RO and/or DI), storage, distribution, and can include final treatment to provide a level of assurance that microorganisms and inorganic and organic material are removed from the water. See section 8.3.2.2 for recommended treatment methods. This water is mainly used for the final rinse after high-level disinfection, for the final rinse for critical devices prior to sterilization and feedwater for process steam production.

NOTE Using Critical Water for all stages of medical device processing can be unnecessary, costly, and can cause damage to water system or processing equipment (see Annex D).

c) **Steam:** vaporized water that is produced by a centralized boiler or a generator/heat exchanger near the sterilizer. When the steam is tested as a condensate, it should meet the specified criteria as defined in Table 2.

NOTE See i Annex D for additional information.

Utility Water is predominantly used for medical device processing with the exception of final rinse, where Critical Water is recommended. At the point of production, Utility Water and Critical Water should meet the requirements as specified in Table 2. Tap water can require treatment to meet these requirements. The bacteria level for Critical Water in Table 2 (< 10 CFU/mL [< 10,000 CFU/L]) is consistent with the Clinical & Laboratory Standards Institute (CLSI) guidelines. [46]

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