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Water for the processing of medical devices

AAMI
Advancing Safety in Health Technology

Water for the processing of medical devices

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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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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Water Quality for Medical Device Processing Working Group

This standard was developed by the AAMI Water Quality for Medical Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

At the time This standard was published, the **AAMI Water Quality for Medical Device Processing Working Group** had the following members:

Cochairs: Terra Kremer
Erin A. Kyle

Members: Anas Aljabo, SteriLabs Canada Inc.
Lindsay Arencibia, Lindsay Arencibia (Individual Expert)
Kristy L. Azzolin, American Dental Association (ADA)
James Weldon Baker, NuStream Filtration Inc
Timothy Blackwell, Timothy Blackwell Person
Rachel Bradley, Rachel Bradley (Individual Expert)
Lisa Shifflett Brown, UVA Health
Deborah Lynnette Bunn, University of Maryland Medical System
Jonathan Burdach, Nanosonics Limited
Cathy Castro, Vested Medical LLC
Michael Scott Castro, Pall Medical - Port Washington
Roxanne Charles, Roxanne Charles (Individual Expert)
Nancy Chobin, Nancy Chobin (Individual Expert)
Horlando Cintron, Memorial Sloan Kettering Cancer Center - Monmouth
Jeremy Criss, Jeremy Criss (Individual Expert)
Jacqueline A. Daley, Providence St Joseph Health System
Frank Daniels, Virginia Commonwealth University Health System
Nicholas Day, University Hospitals of Cleveland
Loraine Durigan, Loraine Durigan (Individual Expert)
Afif Jhoel Escheik, Crothall Healthcare
Ernesto Rivera Esparza, Edwards Lifesciences
Michael Flanagan, Zimmer Biomet
Brian Flannigan, Phigenics LLC
Sarah Frank, Element Materials Technology (fka ALG)
Marcia Frieze, Case Medical Inc
Naomi Gamm, Abbott Laboratories
Joe Haney, AmeriWater
Douglas F. Harbrecht, Sterility Assurance LLC
Jeffrey N. Holland, Evoqua Water Technologies LLC
Timothy Hurtado, Memorial Hermann Healthcare System
David M. Jagrosse, David Jagrosse Consulting LLC
Karissa Joosten, NAMSA
Richard J. Kaestner Jr., Absolute Water Technologies
Nancy E. Kaiser, STERIS Corporation | Healthcare
Nicholas Kalanta, McLane Children's Hospital
Sajedul Islam Khan, Apollo Hospital Dhaka
Michal Koenner, Medtronic Inc Campus
Margaret Konja, SpecialtyCare
Terra Kremer, Johnson & Johnson

Kaumudi Kulkarni, Healthmark Industries Company Inc
Erin A. Kyle, Association of Perioperative Registered Nurses (AORN)
Wesley Lantz, Zimmer Biomet
William Leiva, 3M Health Care
Angela M. Lewellyn, Advantage Support Services Inc
Paul Littley, Integra LifeSciences Corporation
Anne Mattern, Anne Mattern Person
Michael Matthews, Association of Medical Device Service Organizations (AMDSO)
John L. Mazzilli, Saddleback Memorial Medical Center
Tom McElroy, IUVO BioScience
Emily Mitzel, GE Healthcare
Melissa G. Morgan, Moses H Cone Hospital - Cone Health
Derek Mortisen, Intuitive Surgical Inc
Mike Nolan, HIGHPOWER Validation Testing & Lab Services Inc
Susumu Nozawa, Siemens Healthineers
Kia Parker, The Ohio State Wexner Medical Center-University Hospital
Alpa Patel, Sotera Health LLC
Rebecca Peplau, Rebecca Peplau (Individual Expert)
Janet M. Prust, St. Croix Standards Consulting, LLC
Juan Migiel Ramos, Juan Migiel Ramos (Individual Expert)
Marc B. Rogers, Advanced Sterilization Products (ASP)
Don Rotter, Ecolab
Mandy Ryan, Stryker
Damien S. Berg, HSPA (fka IAHCSMM)
Chuck Schaefer, Charles Schaefer (Individual Expert)
Candace A. Schlicklin, Phoenix Children's Hospital
Michael J. Schoene, Bausch & Lomb Inc
Matthias Schöttler, Olympus America Inc
Richard William Schule, Cleveland Clinic
Linda Sue Schultz, Northside Hospital Surgical Services Atlanta
Cynthia Seward, Kaiser Foundation Health Plan/Hospitals
Donald Socha Esq., Getinge USA
Len Sparks, VERDA Water Quality Systems
Joan M. Spear, Joan M. Spear (Independent Expert)
Nadine Swenson, Boston Scientific Corporation
Janelle Trboyevich, Boston Scientific Corporation
Steven E. Turtil, FDA/CDRH
Melissa Walters, Melissa Walters (Individual Expert)
Dean Wellman, Midmark Corporation
Jonathan A. Wilder, Quality Processing Resource Group LLC
Ariel Wimbush, Emory Healthcare
David C. Winkler Jr., Veterans Administration (VA) Central Office
Robin Woodland, Robin Woodland (Individual Expert)
Jarl Yeager, Powder River Medical Resources
Stephanie L. Young, Stephanie Young (Individual Expert)
Roberto Zumbado, Philips

Alternates:

Jennifer Barnickel, Vested Medical LLC
Ralph J. Basile, Healthmark Industries Company Inc
Jhmeid B. Billingslea, Advantage Support Services Inc
Michael Bolcas, Integra LifeSciences Corporation
Marco Bommarito, 3M Health Care
Philip Ted Cantin, VERDA Water Quality Systems
Greg Crego, Bausch & Lomb Inc
Jeffery Daniels, Olympus America Inc

Shawn Engberg, MD Furniture & Supply
Lorraine Floyd, Johnson & Johnson
Alex Freeman, Intuitive Surgical Inc
Tara Jacobson, Abbott Laboratories
Herbert J. Kaiser, STERIS Corporation | Healthcare
Susan G. Klacik, HSPA (fka IAHCSMM)
Angela Le, ResMed Inc.
Daniel Lightfoot PhD, Nanosonics Limited
Shaun McGinley, Zimmer Biomet
Kim Miller, HIGHPOWER Validation Testing & Lab Services Inc
Ronald Moody, Veterans Administration (VA) Central Office
Shane Pinkston, Getinge USA
Michael Polozani, Case Medical Inc
Shawn Powers, IUVO BioScience
Kaleb Price, Northside Hospital Surgical Services Atlanta
Nicola Revellin, GE Healthcare
Jessica Rue, Boston Scientific Corporation
Anne Schuler, LexaMed Ltd
Richard Sparano, Medtronic Inc Campus
Aaron Troutt, Williamson Medical Center
Dustin E. Van Bree, Sotera Health LLC
Jill A. Warren, Siemens Healthineers
Mary Wen, FDA/CDRH
Erika Wilson, Phigenics LLC

NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the AAMI Sterilization Standards Committee had the following members:

Cochairs: Janet M. Prust
Patrick B. Weixel

Members: Gregory Darnall Aldrich, Fairbanks Memorial Hospital
Anas Aljabo, SteriLabs Canada Inc.
Eseosa Tony Amenaghawon, Eseosa Tony Amenaghawon (Individual Expert)
Brett Anderson, Cochlear Ltd
Jennifer R. Asleson, Quality, Microbiology & Sterilization Services LLC
Richard Bancroft, STERIS Corporation | Healthcare
Marie K. Brewer, UnityPoint Health - Surgery Center Cedar Rapids
Trabue Daley Bryans, BryKor LLC
Jonathan Burdach, Nanosonics Limited
Charles Cogdill, Medtronic Inc Campus
Emily Craven, Boston Scientific Corporation
Jacqueline A. Daley, Providence St Joseph Health System
Gordon M. Ely, LexaMed Ltd
Afif Jhoel Escheik, Crothall Healthcare
Deannard Esnard, Deannard Esnard (Individual Expert)
Nicole Felderman, CIVCO Medical Solutions
Brian J. Fortier, Aorta Medical Inc
Daniel Fowler, WuXi AppTec Inc
Magnus Graham, BSI Healthcare
Shelley Hagan, Henry Ford Health

Ashley Hammer, Washington Regional Medical Center
Joyce M. Hansen, Johnson & Johnson
Douglas F. Harbrecht, Sterility Assurance LLC
Deborah A. Havlik, DA Havlik Consulting
Crystal Heishman, U of L Hospital - University of Louisville
Ebow Holdbrook-Smith, WellSpan Health
Mollie J. Holter, MicroBio Consulting LLC
Stephanie Jean Homuth, Hennepin County Medical Center Warehouse
Clark W. Houghtling, Cosmed Group Inc
Angela G. Jensen, Rush Foundation Hospital
Nicholas Kalanta, McLane Children's Hospital
Susan G. Klacik, HSPA (fka IAHCSMM)
Erin A. Kyle, Association of Perioperative Registered Nurses (AORN)
Byron J. Lambert, Abbott Laboratories
Marissa Jones Lewis, Veterans Administration (VA) Central Office
Michael K. Loadman, Michael Loadman (Individual Expert)
Emily Lorcheim, ClorDiSys Solutions, Inc
Kelly Marcum, HCA Healthcare
John L. Mazzilli, Saddleback Memorial Medical Center
Patrick J. McCormick, Bausch & Lomb Inc
Russell Mills, Zimmer Biomet
Leslie Nichols, Mayo Clinic
Gerry A. O'Dell, Gerry O'Dell Consulting
James O'Reilly, St Joseph Health System - Trinity Health
Ken Paddock, Baxter Healthcare Corporation
Alberto Guzman Paret, Cordis US Corp
Kia Parker, The Ohio State Wexner Medical Center-University Hospital
Kimberly Patton, Performance Review Institute MedAccred
Nancy Pickens, Nancy Pickens (Individual Expert)
Karana M Pierre, Karana M Pierre (Individual Expert)
Janet M. Prust, St. Croix Standards Consulting, LLC
Joan E. Rickard, Montefiore Medical Center
Angela Salmen, Angela Salmen (Individual Expert)
Linda Sue Schultz, Northside Hospital Surgical Services Atlanta
Joan M. Spear, Joan M. Spear (Independent Expert)
Sopheak Srun, Quality Tech Services LLC
Mark Swanson, Quality and Regulatory Expert Partners (QRX)
Larry Talapa, 3M Health Care
Julie TerWee, Pfizer Parenteral Center of Excellence
James Treharn, St Peter's Health
Sara Vinson, University of Florida
Adrienne C. Watson, Adrienne Watson (Individual Expert)
Sean Weir, Sean Weir (Individual Expert)
Patrick B. Weixel, FDA/CDRH
James Sidney Wiggs, Legacy Health System
Ariel Wimbush, Emory Healthcare
Martell Winters, Sotera Health LLC
Roberto Zumbado, Philips

Alternates: Jennifer Benolken, DuPont Tyvek Medical and Pharmaceutical Protection
Damien S. Berg, HSPA (fka IAHCSMM)
Stacy Bohl, Boston Scientific Corporation
Carolyn Braithwaite-Nelson, Philips
Richard Burgess, BSI Healthcare
Densley Coke, Densley Coke (Individual Expert)
Kimbrell Darnell, Becton Dickinson & Company

Aaron David DeMent, Sotera Health LLC
April Doering, 3M Health Care
Anna M. Grayson, Grayson Associates
David Kelman, Sterile Edge
Cathy Leckwart, WuXi AppTec Inc
Paul Lorcheim, ClorDiSys Solutions, Inc
Michelle Luebke, Baxter Healthcare Corporation
Gerald E. McDonnell, Johnson & Johnson
Shaun McGinley, Zimmer Biomet
David Ford McGoldrick, Abbott Laboratories
Shane Pinkston, Getinge USA
Christine L. Render, Cosmed Group Inc
Jimmy Reyes, Alcon Laboratories Inc
Petra Richards, Kaiser Foundation Health Plan/Hospitals
Susan Rogers, Veterans Administration (VA) Central Office
Molly S. Swanson, Quality Tech Services LLC
Lisa Ward, STERIS Corporation | Healthcare

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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.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "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.

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.

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);

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]

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,

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

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

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]

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]

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

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)

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

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]

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

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.

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.

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);

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

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]

Table 2—Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg $CaCO_3$/L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

* Steam parameters are for monitoring as steam condensate

**See 6.3 a) for specifics. For local steam generation, the condensate pH should be 5.0 to 7.5. For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2

*** When Utility Water is used after chemical high-level disinfection as a final rinse, the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL

**** If hardness is greater than 150 mg/L a water softener is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness

6.3 Rationale for Table 2 water quality parameters and other considerations:

a) **pH**: Water having extremes in pH can cause damage of device surfaces. In addition, an extreme pH can interfere with the efficacy of cleaning agents and disinfectants (see E.2.18). Utility water is expected to have a pH in the range of 6.5 to 9.5. The pH of the water will be dependent on the disinfection chemistry (e.g., chlorine, monochloramine) and water treatment strategy of the local municipality. Potable water is typically in the higher portion of this range. For Critical Water the specification is based upon typical values for the water produced. For boiler-treated steam that travels through an extensive distribution network that can be oxidized (e.g., black iron), acidic pH can result in corrosion of the piping and transfer of rust to the sterilizer load, therefore pH should be controlled to maintain a pH of 7.5 to 9.2. For steam produced by a dedicated generator the pH can be in the range of 5.0 to 7.5 (see EN 285).

b) **Alkalinity**: Total alkalinity is the measure of dissolved solids which are alkaline in nature such as bicarbonate, carbonate, and hydroxide. High alkalinity levels increase the tendency of hard water salts to form scale. High alkalinity in the final rinse water increases potential for concentration of alkaline dissolved solids onto the device during drying. This dried alkaline residue can then be reactivated under the high temperature and humidity conditions of a steam sterilizer causing devices to become stained or corroded. The performance of

cleaning agents that are not buffered may be impacted by excess alkalinity. Different types of alkalinity may buffer differently and impact scale type or cleaning agents in different ways.

c) **Bacteria**: Critical Water should have very low levels of bacteria. Although water treatment equipment may produce water that is essentially free from microorganisms, the water distribution system may allow for introduction of low levels of bacteria, requiring routine monitoring. Levels higher than the bacterial levels in Table 2 may increase the bioburden on the load and can increase the risk of patient infections and pyrogenic reaction due to increased endotoxin levels generated by certain types of bacteria.

d) **Endotoxin**: The limit specified by United States Pharmacopeia (USP) for transfusion and infusion assemblies and similar medical devices (USP <161>) is 20 EU remaining on its surface. Critical Water can be derived by a process that would be expected to remove endotoxin. While treatment can reduce endotoxin, some endotoxin might be detected because of passage of the water through tubing that is not endotoxin-free. If the final rinse of a medical device is done with Critical Water containing less than 10 EU/mL, the amount of endotoxin left on the device would be expected to be only a fraction of that amount so the device would have far less than the allowed limit of 20 EU remaining on its surface. Because Utility Water is not produced by a process that removes endotoxin and it is not used for the final rinse of critical devices that contact the patient's bloodstream, endotoxin testing of such water is unnecessary unless it is used as the rinse water after high-level disinfection of medical devices because this rinsing is after the antimicrobial process.

NOTE Adverse effects have been demonstrated when 1 to 4 ng/kg of purified endotoxin (1 ng/kg equals 2 EU/kg) are injected [86]. However, the threshold amount of endotoxin in rinse water that would lead to sufficient residuals on a reprocessed medical device to cause an adverse patient reaction is not clearly defined in the literature. There are no published data or guidelines for endotoxin levels in water used to reprocess medical devices. The 10 EU/mL value described here was adopted by AAMI WG95 committee consensus on the grounds that it was thought unlikely to result in sufficient residual endotoxin on a device to cause an adverse patient reaction.

e) **Total organic carbon (TOC)**: Residual TOC should be minimized due to the unknown nature of the TOC and its potential effect on patient tissue and mucosa. The TOC value for Critical Water is based on the expected efficacy of carbon filtration, RO, or distillation in removing organic material and has been defined as less than 1.0 mg/L (ppm). Utility Water would be expected to have total organic carbon levels that are not significantly different than tap or untreated water. Water with high levels of TOC can impact efficacy of UV lamps at controlling microbial growth in water storage systems.

NOTE No studies have been published that establish how much organic material is needed to interfere with disinfection and sterilization processes.

f) **Color and turbidity**: EPA drinking water standards require water to be colorless and clear and contain no sediment. Color and residues are indicative of contaminants and increase the potential to leave contaminants on medical devices during processing. Contaminants left behind on medical devices during certain parts of the processing steps can both stain and/or interfere with subsequent processes. The same criteria for color have been applied to both categories.

6.3.1 Ionic characteristics

a) **Conductivity**: this is a measure of the total amount of electrically charged impurities (ions) that are present in the water sample. It is measured in terms of electrical current over a distance with units of µS/cm. It is a broad measurement of the impurities in the sample and is used as a proxy for Total Dissolved Solids. It gives an indication of the general purity of the sample. High conductivity indicates the presence of large amounts of charged ions, some of which can result in corrosion or staining of instruments.

b) **Chloride**: When chloride ions are present in sufficient concentrations they can result in corrosion of stainless steel or soft metals.

c) **Nitrate**: residual nitrates can be very reactive with other compounds. Residual amounts of nitrates on medical device surfaces may affect subsequent processes.

d) **Phosphate**: phosphates can enter water as run off from agricultural uses and can contribute to scale formation, leave residues on instrumentation, and interact with cleaning chemicals

e) **Sulfate**: sulfates can form scale with positively charged ions. Routinely monitored water treatment systems with increasing levels of sulfate can be indicative of resin bed issues.

f) **Silicate**: silicates can form hard to remove residues, especially if allowed to remain on instruments during subsequent steps of processing involving heat.

g) **Iron**: iron ions can deposit on stainless steel surfaces and cause corrosion. It can also result in rust/corrosion that can manifest in a variety of colors (e.g., brown, black, etc.).

h) **Copper**: copper ions can deposit on surfaces of items being processed and cause green staining and/or corrosion.

i) **Manganese**: manganese ions can deposit on surfaces of items being processed and cause black staining and/or corrosion.

j) **Aluminum**: aluminum ions can deposit on surfaces of items being processed and cause staining and/or corrosion.

k) **Zinc**: zinc ions can deposit on surfaces of items being processed and cause staining and/or corrosion.

NOTE Metal ions (e.g., iron, copper, zinc, etc.) can also contribute to hardness values and deposit on metal surfaces resulting in galvanic corrosion.

l) **Water hardness**: Water hardness is a critical parameter to control as it affects residues on devices. Tap water is generally considered “hard” if it has calcium and magnesium levels higher than 150 ppm; therefore, this level is given as the upper limit for Utility Water. Avoiding excess hardness prolongs the life of washer-disinfectors; reduces the risk of hard-water deposits on medical devices during processing and helps ensure the efficacy of cleaning agents. If hardness is greater than 150 mg/L(ppm), water softening is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness or metal ions in solution. For Critical Water, the treatment process would be expected to remove contaminants and produce water that has calcium and magnesium levels of less than 1 ppm. Using Critical Water for the final rinse of critical medical devices reduces the likelihood of hardwater deposits.

7 Water quality selection and requirements

7.1 Categories of medical devices

Medical devices can be placed into one of three categories depending on the potential risk for infection associated with their intended use [82]. The Centers for Disease Control and Prevention (CDC) has described the level of disinfection or sterilization needed after decontamination and before patient use for the three Spaulding categories [43]:

a) Critical devices are instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or into other normally sterile areas of the body, and products with sterile fluid pathways. Examples of critical devices include surgical instruments, needles, cardiac catheters, implants, gastrointestinal sphincterotomes, biopsy forceps, rigid endoscopes used for minimally invasive surgery, inner surface components of extracorporeal blood-flow devices such as heart-lung machines, blood oxygenators, and the blood compartments of hemodialyzers. Critical devices present a high degree of risk of transmission of infection if contaminated and, therefore, should be sterile at the time of use.

   Some critical devices (intravascular, intrathecal, and intraocular devices) pose a risk of producing pyrogenic reactions in patients if endotoxin (or any other substances that cause pyrogenic reactions, such as bacterial cell wall constituents) remain on the device at sufficient levels after processing. To reduce the risk of pyrogenic reactions, the final rinse should be with Critical Water treated so as to prevent recontaminating the device.

b) Semi-critical devices are instruments or objects that contact intact mucosal membranes or non-intact skin of the patient during use but do not usually penetrate the blood barrier or other normally sterile areas of the body. Examples include noninvasive, flexible endoscopes, endotracheal and aspirator tubes, laryngoscopes,

respiratory therapy equipment, and vaginal specula. Semi-critical devices should be sterilized, if possible. However, if sterilization is not feasible, the device should be subjected, at a minimum, to a high-level disinfection process. In most cases, meticulous physical cleaning followed by high-level disinfection provides a reasonable degree of assurance that the device is free of pathogenic microorganisms. The final rinse should be with Critical Water as to not to recontaminate the device.

NOTE Within the dental setting, instruments, devices, and equipment are categorized as semi-critical. These can be heat-resistant or heat-sensitive. The CDC recommends that all semi-critical heat-resistant instruments, devices and equipment, and all hand pieces and attachments that attach to and detach from the dental unit, should be heat sterilized [42].

c) Non-critical devices are instruments or objects that usually contact only the intact skin of the patient. These items, which include bedpans, reusable anesthesia masks, blood pressure cuffs, most neurologic and cardiac diagnostic electrodes, and certain surfaces of radiological imaging (e.g., x-ray machines), are less likely to transmit infections directly to patients. Consequently, depending on the particular item and degree of contamination, cleaning with a cleaning agent and warm water may be adequate; some items may require some level of disinfection before reuse. Non-critical devices are frequently processed through washer–disinfectors that provide cleaning and thermal disinfection, making the device safe to handle. Because non-critical devices do not usually pose a risk of pyrogenic reactions or infections in patients, the use of Utility Water is usually acceptable for all processing stages.

7.2 Stages of medical device processing in which water quality is a consideration

This section provides recommendations for the quality of water that should be used in various stages of medical device processing, whether manual or mechanical.

The water used to process a medical device should be of sufficient quality to provide a level of assurance that the device is not damaged and that the patient will not be injured by contact with the device.

The general flow of medical device processing and the stages at which water quality is a consideration are shown in Figure 1. The water quality used in the cleaning stage should be compatible with the cleaning agent selected. Water is used for a number of rinsing stages (rinsing after point-of-use treatment, rinsing after cleaning, final rinsing), and the water quality suitable for these different stages may vary. Water that is part of the disinfection or sterilization process should be of a quality that will not interfere with the process or otherwise detrimentally affect the device being processed.

The general medical device processing methods are indicated in Figure 1 and include heat sterilization (e.g., steam, dry heat); low-temperature gas sterilization (e.g., ethylene oxide, vaporized hydrogen peroxide); high-level chemical disinfection (e.g., glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid); thermal disinfection pasteurization; and liquid chemical sterilization (e.g., glutaraldehyde, hydrogen peroxide, peracetic acid). Guidance on the water quality required for compatibility with each of these methods will be addressed later in this standard.

NOTE For low-temperature sterilization, this refers to the steam used for humidification in ethylene oxide sterilization since vapor hydrogen peroxide sterilization does not use water in its process.

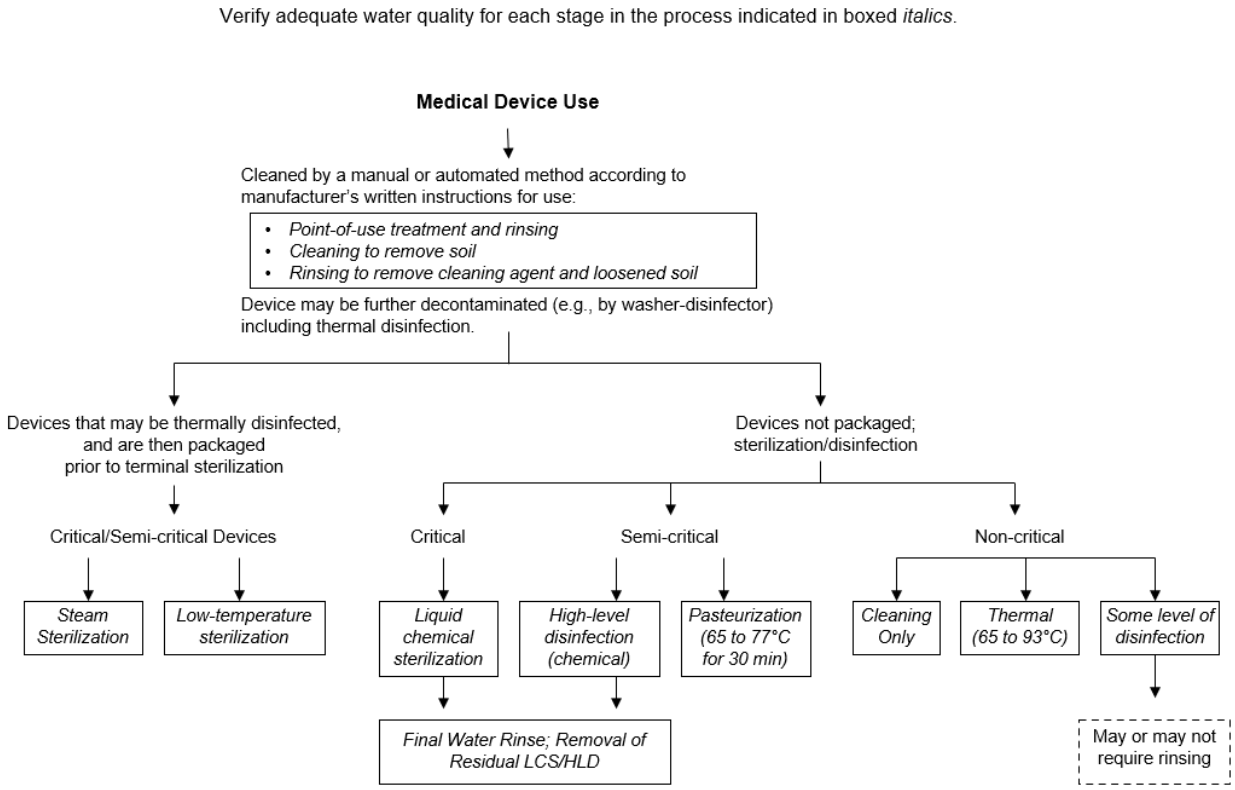


Figure 1—Stages of medical device processing in which water quality is a consideration

7.3 Cleaning

7.3.1 Manual cleaning

7.3.1.1 Point-of-use treatment

Utility Water is suitable for use for point-of-use treatment of a device immediately after patient use. The temperature of the water used for this purpose should not exceed 45 °C (113 °F) to prevent coagulation of blood and fixation of proteins on the device. (See [8] for detailed guidelines on cleaning.)

7.3.1.2 Cleaning

Utility Water should be used for the cleaning stage. Tap water may be used for the cleaning stage if it meets the requirements for Utility Water in Table 2 and/or if its characteristics are compatible with the cleaning agents used for medical device processing (as per the manufacturer's written instructions for use (IFU)). It is important that the incoming tap water be analyzed to determine its characteristics and allow the user, in consultation with the cleaning agent manufacturer, to verify that a compatible cleaning agent is used. Tap water can require further treatment to meet the requirements for Utility Water for the cleaning stage if it contains excessive dissolved minerals or other undesirable characteristics (see Table 2), to provide a level of assurance of compatibility with the cleaning agent recommended for medical device processing or materials of construction of the instruments. The need for water treatment in this stage varies from location to location—and possibly from season to season—and the water treatment system manufacturer should be consulted to validate that the treatment process will be adequate for the specific characteristics of the incoming tap water.

7.3.1.3 Rinsing

Utility Water is suitable for rinsing to remove soil loosened by the cleaning process and for removing cleaning agent residues. If the quality of the tap water does not meet the requirements for Utility Water, it is necessary to use water treatment processes to produce water that meets these requirements and provide a level of assurance that devices are not damaged, and that the ensuing disinfection or sterilization process will be effective.

7.3.1.4 Final Rinsing

Critical Water should be used for the final rinse during cleaning for devices that will contact the bloodstream or other sterile areas of the body. The final stage in rinsing requires water that does not have excessive levels of organics (e.g., endotoxin, other microbial constituents, or other unknown organic carbon sources) and inorganics.

7.3.2 Mechanical cleaning by medical washers and medical washer–disinfectors

7.3.2.1 General considerations

Mechanical washers, washer–decontaminators, and washer–disinfectors are used to decontaminate surgical instruments and medical devices that are intended for reuse.

Water is used directly in the mechanical cleaning, rinsing, and thermal disinfection of medical devices before further handling and preparation for terminal sterilization. The types, quality, and number of water sources depend on the size and type of medical washer or medical washer–disinfector. To achieve the cleaning and decontamination results validated by the manufacturer, water of the appropriate quality shall be used in all stages of the cleaning, decontamination, and disinfection process.

Medical washers and medical washer–disinfectors are often equipped with at least one control valve for hot water and one for cold water. A separate control valve for the final rinse (typically Critical Water) water is standard on some models and an option on others.

Automated control is provided in medical washers and medical washer–disinfectors that have processing cycles consisting of a series of treatment stages. The parameters of each stage within a given cycle can vary depending on the medical devices to be processed. All stages require water, and Utility Water is the minimum acceptable quality. (Drying as a stage is not addressed in this standard.) At each treatment stage, the water quality should be compatible with the:

- materials of construction of the medical washer or medical washer–disinfector;
- items being processed;
- cleaning agents used;
- disinfectants used (if any); and
- process requirements at each stage.

7.3.2.2 Water quality factors for medical washers and medical washer–disinfectors

The key water quality factors to consider for each cycle stage are as follows:

a) **Water hardness:** Most medical washers and washer–disinfectors can be operated with water having a hardness value of up to 400 ppm as $CaCO_3$ but will likely be more effective and efficient when the water has a hardness value of less than or equal to 150 ppm as $CaCO_3$. Some medical washers and medical washer–disinfectors are fitted with internal water softening systems.

b) **pH level:** For all stages of the process, including the thermal rinse, pH levels shall meet the requirements of Table 2 for the type of water used. Water that is either too acidic or too alkaline can cause pitting and staining of instruments and shorten their useful lives. The pH level during the cleaning agent stages can depend upon

the specific type of cleaning agent chemistry used. The cleaning agent manufacturer's written IFU should be followed.

c) **Water temperature:** The temperature at which water is has a major influence on the effectiveness of the process. The user should always consult the cleaning agent manufacturer's written IFU because these instructions vary from product to product, even when products are supplied by the same manufacturer.

d) **Ionic contaminants** (e.g., chloride, heavy metals): Water used in the mechanical cleaning and disinfection of medical devices should have metal ion concentration as shown in Table 2.

e) **Microbial level**: The purpose of the decontamination process is to remove soil and reduce the microbial contamination to an acceptable level for the further processing or intended use of the medical device. The water used at each stage of the medical washer or medical washer–disinfector cycle should not increase the bioburden of the items in the load. The acceptable extent and nature of the microbial contamination in the water supplied to the equipment depends on the stage in the process cycle at which it is used and on the intended use of the decontaminated load at the end of the process.

f) **Bacterial endotoxin**: Bacterial endotoxin can be present in Utility Water because this category of water has had no treatment that would remove bacteria or endotoxin. If the incoming water to the washer–disinfector is of this quality, medical devices processed through the cleaning and rinsing process could have residual endotoxin. For this reason, Critical Water should be used for a final rinse.

7.3.2.3 Water quality considerations during cycle stages in a medical washer or medical washer–disinfector

The following sections describe specific water quality requirements for typical cycle stages in a medical washer or medical washer–disinfector. Water supplied to the washer-disinfector meeting the recommendations of the washer manufacturer's written IFU should be used in all stages.

7.3.2.3.1 Initial Rinse

The initial stage of a washer/disinfector cycle is a pre-cleaning stage. Utility Water at or below a temperature of 25 °C (77 °F) is typically used during this stage. Residual blood on the instruments can be coagulated and made more difficult to remove if water exceeding 45 °C (113 °F) is used.

7.3.2.3.2 Wash stage

Utility Water is typically used during the cleaning agent stage(s). Cleaning agent effectiveness is heavily influenced by water temperature. Cleaning agent additives often are formulated to compensate for variations in the hardness level of tap water. The cleaning agent manufacturer's written IFU should be followed closely to ensure correct concentration.

7.3.2.3.3 Post-wash rinse stage

Utility Water, unless otherwise indicated by the medical device or cleaning agent manufacturer's written IFU, is suitable for rinsing and removing soil loosened by the cleaning process and for rinsing and removing cleaning agent residues. If the quality of the tap water could cause corrosion, tarnishing, or salt deposits, it is necessary to use various water treatment processes (e.g., softening, deionization) to produce water that meets the requirements for Utility Water and to verify devices are not damaged, and that the ensuing disinfection or sterilization process will be effective.

7.3.2.3.4 Disinfection stage

Chemical disinfectants should always be used according to the disinfectant manufacturer's written IFU for time, temperature, and any other conditions specified. If dilution of LCSs or HLDs is necessary, Utility or Critical Water may be used, provided that the manufacturer of the liquid chemical disinfectant has validated its use with the water type stated in the manufacturer's written IFU.

Thermal disinfection is delivered by heated water. Most washer–disinfectors provide thermal disinfection. Critical Water should be used in the final rinse step of the washer-disinfector cycle. It should also be used in the thermal disinfection

stage, if it is not in the final rinse. The washer–disinfector manufacturer's written IFU should be consulted for the target temperature for thermal disinfection. Recommended minimum temperature/time combinations are:

- 80 °C (176 °F) for 10:00 minutes
- 85 °C (185 °F) for 3:10 minutes
- 90 °C (194 °F) for 1:00 minutes

These have been shown to provide a margin of safety for technicians handling the processed instruments [63].

7.3.2.3.5 Final rinse stage

Critical Water should be used in the final rinse step of the washer disinfector cycle. The device manufacturer's written IFU should be consulted before rinsing the device. Cycle cost and the availability of Critical Water should be assessed in equipment that uses multiple rinses in the same stage.

The water used for the final rinse is very dependent on the category of the medical device. For critical and semi-critical devices, Critical Water is necessary because of concerns about specific water contaminants (e.g., endotoxin). However, specific device manufacturer's written IFU may specify a higher water quality immediately before use (i.e., sterile distilled, sterile) than those specified in this document so the device manufacturer's written IFU should always be followed.

The maximum temperature of the rinse water should be compatible with the items being processed. Many medical devices are temperature-sensitive and can be damaged if the rinse temperature is too high.

7.3.2.3.6 Automated cleaning by ultrasonic cleaners

Ultrasonic cleaners are used to facilitate the cleaning of jointed and serrated stainless steel instruments and other medical devices as recommended in the device manufacturer's written IFU. Ultrasonic cleaning may be used in conjunction with manual cleaning and with medical washers or washer–disinfectors. It is recommended to use Utility Water unless otherwise indicated by the ultrasonic or medical device manufacturer's written IFU.

The key water quality factors to consider for ultrasonic cleaning are:

a) water hardness;

b) water temperature;

c) ionic contaminants (e.g., chloride, heavy metals);

d) microbial level; and

e) bacterial endotoxin.

f) Physical appearance (color, clarity, and absence of particulates/sediment)

NOTE Water quality can be impacted over the period of use and water changes should be performed ([8] Clause M.2.2.7)

The level of monitoring required for each factor varies with the type of equipment.

If the ultrasonic cleaner does not provide a final rinse, the device manufacturer's written IFU for manually rinsing the device should be followed.

7.4 Disinfection

7.4.1 General considerations

Water quality is a factor in thermal disinfection processes. If the quality of the water used for the final rinse that is heated for thermal disinfection is inappropriate, residues can deposit onto the medical devices and lead to staining or corrosion.

The quality of water can affect the efficacy of LCSs or HLDs that are diluted to achieve the correct use-dilution. The post-disinfection rinse applies only to liquid chemical processes that have a final rinse aimed at removing any residual LCSs or HLDs. For devices processed with LCSs or HLDs, it is important that the final rinse not re-contaminate the device. Therefore, selecting the quality of water for the final rinse should take into account not only the removal of inorganic residuals but also the need to avoid re-contamination of the device with microorganisms or organic residuals (e.g., endotoxin or other microbial constituents).

7.4.2 Medical devices that are liquid chemical high-level disinfected

High-level disinfected medical devices are usually semi-critical, and the water quality recommendations in this section focus on the processing of semi-critical devices. The quality of water that should be used to process devices that will not be packaged, but will be high-level disinfected (e.g., by liquid chemicals such as glutaraldehyde, hydrogen peroxide, peracetic acid, or ortho-phthalaldehyde), is shown in Table 3. The number and type of post-disinfection rinses should be defined by the disinfectant manufacturer to ensure that residuals are reduced to a safe level before use.

Table 3—Water quality for processing of devices requiring high-level disinfection

Stage in process	Function	Water quality
1. Point-of-use treatment of patient-used medical device.	Begin removing the clinical soil and prevent drying of soil and the formation of biofilm on the device or inside lumens.	Utility Water is acceptable, at a temperature not exceeding 45 °C (113 °F).
2. Cleaning with cleaning agent (usually enzymatic cleaning agent).	Remove patient organic and inorganic material (soil) that is not removed by simple point-of-use treatment (Stage 1).	Utility Water is acceptable to dilute cleaning agent.
3. Post-wash rinse.	Remove cleaning agent residues and any loosened soil.	Utility Water is acceptable. Enough water should be used to thoroughly rinse/flush the device according to the device manufacturer's written IFU.
4. Dilution of liquid chemical high-level disinfectant (if applicable) and liquid chemical exposure.	High-level disinfection.	Utility or Critical Water may be used, provided that the manufacturer of the liquid chemical sterilants has validated its use for this purpose.
5. Final rinse after high-level disinfection.	Remove residual HLD and reduce likelihood of hard-water deposits on device.	For AERs, the incoming water may be Utility or Critical Water according to the AER manufacturer's written IFU. For manual processes, Critical Water should be used.

7.4.3 Medical devices that receive pasteurization or thermal disinfection

Respiratory equipment is usually classified as a semi-critical device. One method that is accepted for processing this type of medical device is pasteurization. Non-critical medical devices that are compatible with high-temperature water may be processed using thermal disinfection in washer–disinfectors, provided that adequate temperature conditions are achieved.

Utility Water should be used to process devices that will not be packaged but will be thermally disinfected or pasteurized. Examples are the processing of non-critical devices such as bedpans (thermal disinfection) or semi-critical devices such as respiratory tubing (pasteurization). The use of Utility Water for non-critical applications is acceptable unless the microbial levels might present infection hazards for use or if there is a concern for hard water deposits, Critical Water may be used as the final rinse.

For washer–disinfectors, the rinse water may be heated to an adequate temperature (as specified in the manufacturer's written IFU) to achieve thermal disinfection. For pasteurization, devices should be completely immersed, and all channels and lumens perfused with water.

7.5 Sterilization

7.5.1 Sterilization processes requiring steam generation

The quality of water that should be used to process devices that will be packaged and then sterilized is listed in Clause 7.3. Steam used for sterilization should be free from contaminants in concentrations that could impair the sterilization process, damage the sterilizer, or damage the devices to be sterilized. Requirements are listed in Table 2.

7.5.2 Liquid chemical sterilant

Prepare liquid chemical sterilants for use according to the water quality specifications in the liquid chemical sterilant manufacturer’s written IFU.

8 Water treatment systems installation and operation qualification

8.1 Introduction

Tap water is often of insufficient quality to be used for specific processing activities and therefore generally needs some form of water treatment to meet the criteria of Utility Water, Critical Water, or water to generate Steam (see Table 2). Water treatment is the removal of contaminants from water, and it can be achieved by several different processes. Each water treatment process has specific applications and the process selected should be chosen depending on the specific requirements for the water. For each process, there are also specific maintenance issues that should be addressed to ensure a consistent supply of water of appropriate quality. This section describes general issues associated with water treatment.

8.2 General issues associated with water treatment

The equipment used for water treatment is described in detail in Annex E. The range of water treatment options is wide, and users may find it confusing to determine when one water treatment method is preferred over another. Certain issues need to be considered when making choices about the type of water treatment to use.

When a new water treatment system is needed, the health care facility normally works with a water treatment specialist familiar with the quality of tap water in the area to design the system, They can recommend the water treatment devices needed to produce the water quality needed by the facility and suggest other equipment to address the individual situation at the facility. The choice of water treatment equipment should be based on the quality of the incoming water, the quantity of water that will be used, the rate of usage, and the quality of the water desired. The initial step in decision-making is to analyze a sample of the incoming water to determine contaminant and their concentration.

To produce Critical Water, it is particularly important that the water treatment system is designed to remove microorganisms from the feedwater source. Some water treatment technologies such as carbon filtration and deionization inherently offer no microbial removal capabilities; therefore, it is important that the treatment technologies be configured in the proper sequential order to verify microbiological control. For example, if deionization tanks are used in the system, technologies such as ultraviolet disinfection and/or submicron filtration should be installed downstream to control any microbiological contamination (see Annex F).

NOTE To facilitate clarity and communication as it pertains to the site's specific water treatment system design and configuration, a diagram (e.g., Process Flow Diagram (PFD), Process and Instrumentation Diagram (P&ID)) should be posted in the same room as the water treatment system.

8.3 Design of water treatment systems

8.3.1 General considerations

Production of the desired quality of water may require separate systems, each designed to produce a particular water quality, or they may be combined into a single water treatment system.

8.3.2 General description of Water Treatment System Configurations

See Annex F for further information on examples of common water treatment equipment and system configurations.

These systems should allow for routine equipment maintenance and monitoring of water quality, as well as maintenance of water quality when the water is transported from the treatment system to the point-of-use.

Any state and/or local regulations pertaining to the waste, excessive consumption, misuse, or contamination of the water supply (e.g., preventing overflows and air gaps, water softener brine restrictions) must be observed.

8.3.2.1 Water Treatment Systems designed to produce Utility Water

These systems are designed to remove contaminants from the potable water supply within the health care facility and produce water meeting the Utility Water specifications.

Typical configuration;

- Pretreatment equipment;
    - Removes larger particulate material and suspended solids;
    - Decreases hardness;
    - Removes organics and/or chlorine (as required).
    - Reduces dissolved solids

8.3.2.2 Water Treatment Systems designed to produce Critical Water

These systems can be fed by a separate Utility Water system, which has already pretreated the water, or they contain their own pretreatment equipment. In either case, Critical Water systems are designed to further treat the feedwater by removing dissolved solids and submicron contaminants. They are also designed to store, distribute, and further treat the water with a particular emphasis on the removal of microorganisms and endotoxin. Critical Water systems are designed to produce water meeting the Critical Water specifications as provided in Table 2. Water produced by a Critical Water system is typically used for final rinse prior to sterilization of a critical device, after high-level disinfection, or as feedwater for steam generating equipment as part of the processing of medical devices.

Typical configuration;

- Pretreatment equipment (if applicable);
    - Removes larger particulate material and suspended solids;
    - Decreases hardness;
    - Removes organics and/or chlorine (as required).
- Primary treatment equipment;

- Removes dissolved solids and submicron contaminants;
- Reduces the levels of microorganisms (Reverse Osmosis (RO));

— Storage, distribution, and final treatment equipment;

- Stores, distributes, and further treats (“polishes”) the water prior to its use;
- Further reduces and controls the levels of microorganisms and endotoxin.

Instructions or requirements pertaining to incoming water (e.g., maximum pressure, minimum pressure, maximum flow rate) should be obtained from the water treatment equipment manufacturer.

The water treatment system may be installed at a location remote from the delivery points or directly adjacent to the point-of-use. The design of the water distribution system is critical to maintaining the quality of the water or steam at the point-of-use.

8.3.3 Pipework

The pipework used to supply various grades of water or steam should be chemically and process compatible with the fluid carried. Stainless steel piping should be used for steam produced from Critical Water. House steam can be delivered to the point of steam use using black iron piping.

Copper, stainless steel, polyvinylidene fluoride (PVDF), polypropylene, and other plastics are typically used for water distribution. The pipework should be free draining and should not contain dead-legs or other areas where water or steam condensate could become stagnant. On a Critical Water loop, water should be circulated at a velocity of 3 to 5 feet per second (FPS) to reduce potential biofilm, bacterial growth and endotoxin. Provision should be made for the routine disinfection of water distribution lines and associated disinfection equipment.

NOTE A dead-leg is defined as a length of the piping network between the circulation loop and at the water point-of-use exceeding 3-5 times the piping internal diameter.

8.3.4 Treatment system configuration

To minimize the length and complexity of the distribution system, the water treatment system should be located, if possible, in a secure area immediately adjacent to the areas in which the water is to be used. Access to the treatment system should be restricted to those individuals responsible for monitoring and maintaining the system.

The layout of the water treatment system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance. An area for processing samples and performing on-site tests is also recommended. Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to be audible and/or visual both in the water treatment area and in the area where the water is used or monitored.

Schematic diagrams, commonly referred to as PFDs, should be prepared to identify components, valves, sample ports, and flow direction. Additionally, piping should be labeled to indicate the contents of the pipe and the direction of flow.

NOTE Labels such as “Critical Water” and “Utility Water” and color-coded “arrow tape” provide convenient means of identifying pipe content and flow direction.

Users should verify that all major water system components are labeled in a manner that not only identifies the component but also describes what its function is, how its performance is verified, and what actions should be taken in the event that performance is not within an acceptable range.

8.3.4.1 Water distribution and storage

The function of the water storage and distribution system is to distribute water from the purification system to its points of use, including individual rinse stations and device processing systems. A water storage and distribution system typically contain a large volume of water exposed to a large surface area of piping and storage tank walls. The

purification process removes all bacteriostatic agents from the water. This combination of circumstances predisposes the distribution system to bacterial proliferation and biofilm formation. Therefore, a water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection of the entire distribution system (see Annex H).

8.4 Installation and operation qualification requirements

The installation and operation qualification requirements are specific to the treatment methods selected. Water treatment system manufacturers provide the qualification parameters.

8.4.1 Validation plan

A validation plan for a water system typically includes the following steps:

1) Establish the acceptance criteria for quality characteristics of the water and operating parameters of the water treatment system.

2) Define or map the water treatment system that is capable of producing the desired quality characteristics from the available water source.

3) Select the equipment.

4) Select the control systems.

5) Select the monitoring techniques.

6) Conduct the installation qualification (IQ):

    a) Complete instrument qualifications.

    b) Develop protocols for inspections to verify the configuration of the water treatment system.

    c) Define the acceptance criteria, and document that the installation meets those criteria.

7) Conduct the operational qualification (OQ):

    a) Perform protocols that verify that the water treatment equipment and system alerts and controls are functional.

    b) Develop protocols for verification of the system’s quality characteristics.

    c) Establish alert and action levels for the quality characteristics and operating parameters.

8) Conduct the performance qualification (PQ):

    a) Verify the alert and action levels for the quality characteristics.

    b) Complete the documentation.

    c) Establish a validation maintenance program that includes a change-control mechanism.

9) Define a schedule for periodic review of system performance and requalification.

9 Water treatment systems performance qualification—evaluation of water quality

9.1 General considerations

Determining the dependability of a water treatment system requires a period of monitoring and observation. After the installation and qualification of a water treatment system, a typical validation program involves intensive daily sampling and testing at post water treatment system test points and at the point-of-water-use for a defined period of time against the criteria listed in Table 2 and then testing at a reduced frequency for at least one calendar year to identify seasonal changes. Construction, water supply interruption and repair of any water treatment system components should be kept in mind when assessing potential reasons to reassess frequency.

9.2 Quality characteristics

During validation, it is imperative to know the characteristics of the water system. Water monitoring is validated based on the acceptance criteria defined in the water quality requirements (see Table 2). The routine testing performed after the validation depends on the defined quality characteristics of the water (see Table 4).

9.3 Sampling

During performance qualification, the entire water treatment system should be assessed. The current state of the water system (i.e., water treatment system and distribution loop) should be understood prior to selecting the sampling locations. The number of sample sites for daily sampling may be reduced, provided that all sample sites are examined at some point during the performance qualification. If all sample sites are examined, routine monitoring can be reduced on the basis of the results of the performance qualification. The following sampling locations should be evaluated during the performance qualification:

- The incoming water;
- Following each treatment step; and
- At the point-of-water-use including:
    - Utility Water at the delivery point to the washers or decontamination sinks, or nearby on contiguous plumbing;
    - Critical Water at point-of-use or as close to the point at which the water will be representative of water that will contact the device;
    - Steam sampling of the steam condensate collected at the delivery point for the sterilizer/steam filter.

NOTE The performance qualification of a new water system should require a plan that includes enough data points to validate the consistent delivery of the specified water quality. Routine monitoring should be completed thereafter to address the changes in source water in the lakes, ponds, etc. and to address seasonal changes as well as the effects of construction or building operations. Samples should be taken per performance qualification requirements to ensure that the distribution system/loop does not contaminate the water.

10 Water treatment systems routine monitoring

10.1 Introduction

Monitoring water quality is primarily the responsibility of the facility's engineering / water maintenance personnel and is addressed in detail in Annex G. However, it is necessary that device processing personnel understand the implications of the results of water quality monitoring. Processing personnel should be aware that the quality of water can vary significantly even within the same facility. Table 1 outlines various water quality monitoring duties they need to perform in their department to ensure that they are receiving the proper type and quality of water. This section provides a brief overview of water characteristics that should be monitored and by whom.

10.2 Goals of water quality monitoring

As discussed in the introduction to this standard, ongoing monitoring is performed to verify that the water quality is maintained and does not deteriorate over time. If water quality is not monitored, the water treatment system could become heavily contaminated with metals, microorganisms or other contaminants and could contribute to corrosion, staining, and increased microbial levels after processing. The results of water quality monitoring should be reviewed on a facility-wide basis, and necessary remedial action should be taken if the parameters being monitored are outside of acceptable limits. Water maintenance personnel should communicate with device processing personnel and patient care personnel to ensure that they are aware that patient risk may be elevated during times when the water quality is not adequate.

10.3 Monitoring of water characteristics

10.3.1 General considerations

Table 4 in Clause 6 defines the characteristics of three specific categories of water. Table 5 and Table 6 provide an overview of the characteristics that should be monitored and at what frequency. Table 5 and Table 6 are summaries and not exhaustive. Annex G describes in detail the water monitoring that should be undertaken for the entire water treatment process within a facility.

Although the bulk of water quality monitoring is performed by water maintenance personnel, it is important that the test results be made available to device processing personnel and patient care personnel so that, in conjunction with infection prevention and control personnel, decisions can be made regarding medical device processing if the water quality is found to be unacceptable. For example, if endotoxin or bacterial levels are beyond acceptable limits (Table 2), the water produced is not qualified as Critical Water should not be used for the final rinse of critical devices. Alternative sources of water that meet the water characteristic specifications in Table 2 should be used instead, until the problem is rectified. If the incoming tap water is not colorless and clear, it may be necessary to use other water sources for device processing until the problem is rectified.

10.3.2 Water temperature

Maintaining the prescribed water temperature is an essential part of the processing of medical devices including decontamination, cleaning, and sterilization. The recommended temperature varies, depending on the stage of the cleaning process, the method of cleaning, and the type of cleaning agent (e.g., cleaning agent, enzyme cleaner). For each cleaning solution, there is an optimal range of temperatures to maximize cleaning effectiveness. The cleaning agent manufacturer’s written IFU for water temperature should be followed.

For the water used as part of vacuum systems on steam sterilization equipment, water should be kept at temperatures <60 ºF.

10.4 Routine water quality sampling

Routine monitoring should be performed to verify that the specified water quality is delivered to the points of use. Sampling sites are selected to be representative of water coming in contact with the device and should be selected based on risk established in the performance qualification. Routine monitoring can be reduced on the basis of the results of the performance qualification, risk assessment and system control. Water quality should be evaluated on a periodic basis or after interruptions and restoration or supply, boil-water situations, repairs or disinfection of the distribution system.

NOTE Additional information for routine monitoring of water treatment systems can be found in Annex G.

Table 4—Water quality monitoring requirements

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Conductivity	µS/cm	<500	<10	<10
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Total Hardness	mg $CaCO_3$/L	<150	<1	<1
Bacteria	CFU/mL	<500	<10	N/A
Endotoxin	EU/mL	N/A	<10	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment

*NOTE 1 Sampled as Steam condensate

**NOTE 2 The pH range for steam is wider than for Critical Water as some steam may not be generated locally but from a centralized/facility system. The need to add chemicals to the boiler and the steam to travel distances over black iron piping may result in higher pH requirements. A pH <7.5 in these systems should be avoided.

There are performance qualification specifications for water quality defined in Table 2. For ongoing monitoring of the quality, a reduced set of specifications with greater frequency (Table 4), allows for setting of a baseline of expected quality parameters. The values expressed in Table 4 (i.e., action levels) are not to be exceeded, however trending baseline data and setting an alert level can give early indication of the water quality trend. The baseline data can be used for indicating variations that may impact the water quality and setting of appropriate alert levels.

The alert levels can be identified using a method determined by the facility's multidisciplinary team or can be calculated using the example provided in Clause G.1.2.

An alert should be triggered if a sample results in data outside of the range defined by the upper control limit (UCL) and the lower control limit (LCL).

When data is outside the upper or lower alert levels, it is an excursion, a deviation from a regular pattern, path, or level of operation. Any excursions outside of those typically seen values (within action levels) can be identified as warning of potential issues. The monitoring program is an opportunity to address potential problematic issues prior to failing of specifications and can help anticipate repair or replacement of water treatment equipment or processes.

An excursion (e.g., data point outside alert level) should prompt investigation in order to find the assignable causes and associated risks and then mitigate, where possible. These causes may indicate a change in conditions (e.g., seasonal, construction, repair).

11 Continuous quality improvement

11.1 Introduction

This section identifies performance measures and process monitors that can be used for continuous quality improvement (CQI) programs. CQI programs are recognized as an effective means of improving the performance of any process. For water quality, a CQI program encompasses the entire process of decontamination through sterilization. The quality of the water is important in each stage and needs to be monitored at various times in the process.

11.2 Quality process

Procedures for determining water quality should be based on a documented quality process that measures objective performance criteria (e.g., pH, hardness, purity, temperature) that have a direct effect on the outcome. This quality process should be developed in conjunction with personnel from other areas (e.g., facility engineering, the sterile

processing department, infection prevention and control) and integrated into the overall quality process in the health care facility. Variables in the system may be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, the health care facility policies and procedures for the handling of unfavorable or unplanned events, and the type of process variable.

An investigation should be conducted for any problem relating to any aspect of water quality. Problems and updates should be reported to those involved with medical device processing.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to individuals, groups, or teams as needed.

Table 5 and Table 6 describe the water quality monitoring that shall be performed as part of a quality improvement process within their area. Continuous quality improvement involves conducting risk analyses (see Clause 5).

Table 5—Frequency for water quality monitoring at water generation system

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*	
			Utility Water	Critical Water
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly	Monthly
Conductivity	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly	Daily
Total Alkalinity	Colorimetric dipsticks Alkalinity test kit**	After the last treatment step, storage tanks (if used)	Quarterly	Monthly
Total Hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	After the last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly
Endotoxin	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly

*NOTE 1 The recommendations for frequency of testing in this table are the recommended minimum frequency. If problems or issues arise with the water quality, it may be necessary to increase the frequency until they are resolved.

**NOTE 2 When using these tests, the user should carefully follow the manufacturer's written IFU for accurate results. When measuring Critical Water levels, the water sample must be filled to the brim for these test kits, sealed and, if the sample is hot, allowed to cool to room temperature before testing. Testing within 15 minutes of sample collection prevents carbon dioxide absorption that can result in an inaccurate pH.

Table 6—Frequency for water quality monitoring at point-of-water-use

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*		
			Utility Water	Critical Water	Steam
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Conductivity	Conductivity meter** or Colorimetric dipsticks	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total Alkalinity	Colorimetric dipsticks or Alkalinity test kit**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit** ,or Handheld meter**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Bacteria	Heterotrophic plate count (see Annex H)	Each location of point-of-use in department	Quarterly	Monthly	N/A
Endotoxin	LAL test (see Annex H)	Each location of point-of-use in department	N/A	Monthly	N/A
Visual Inspection	Visual Inspection of inside of equipment - Look for residue, staining, scaling, and discoloration (Annex I)	Spray Arms/Inside Chamber Walls/Inside Interior of Machine	Daily	Daily	Daily

*NOTE 1 The recommendations for frequency of testing in this table are the recommended minimum frequency. If problems or issues arise with the water quality, it may be necessary to increase the frequency until they are resolved.

**NOTE 2 Test type needed to measure Critical Water and Steam levels. Steam condensate must be filled to the brim, sealed, and allowed to cool before testing to prevent carbon dioxide absorption.

The minimum frequency of testing aligns with established water monitoring programs performed during medical device manufacturing. Device processing is an extension of the medical device supply chain, so a continuation of the water quality requirements is necessary for continued patient safety. The testing frequency described in Table 5 and Table 6 are recommended minimum frequencies to demonstrate the water system remains in a state of control. The risk assessment performed by the multidisciplinary team may identify sampling points that will require an increase in testing frequency (e.g., less frequently used point-of-use, portion of circulation loop containing a dead-leg).

The risk assessment also determines the collection points for water quality monitoring at the point of generation and at the point of water use. When the water treatment is near (within a few feet) of the point of use, a lower number of sampling points is likely versus when the distribution loop is lengthy. Table 5 describes water monitoring at the point of generation and Table 6 describes water monitoring at the point of use.

The test frequency recommended in the tables provides verification testing that water quality delivered to the points of use remain in a state of control over time. To facilitate ease of testing for the user and maintenance of the microbiological quality of the system, the testing is grouped (e.g., pH, total hardness and alkalinity can be tested using a single test, so the frequency is the same).

Because the treatments for producing Critical Water can result in increased microbial levels, biofilm development and endotoxin, if not maintained properly, the testing should be more frequent (monthly). In addition, as compared to Utility Water, Critical Water production system changes may affect the chemical attributes of water (e.g., pH, conductivity, total alkalinity, and total hardness). Contamination of the water system that will change the microbiological quality of the water can be event related and changes in the microbiological quality of the water will be more readily apparent than changes of physical attributes.

Although bioburden and endotoxin levels can be related, endotoxin values can be higher than bacteria levels depending on the shedding rate of biofilms within the system. Therefore, both tests should be performed with the same frequency.

12 Water treatment systems maintenance

12.1 General considerations

Proper maintenance of a well designed water treatment system should follow the original equipment manufacturers (OEM) recommendations. Improper maintenance can lead to equipment performance issues, water system component failure, and/or improper water quality levels that do not meet the guidelines of this standard. Bacterial growth, increased endotoxin levels, and poor final water quality are indicative of a poorly maintained water treatment and delivery system.

Loop systems and tanks (see Annex G.4) should be disinfected monthly as a best practice.

A regular system maintenance schedule should be followed to meet OEM recommendations including expendable components based on site specific water conditions, at a minimum, and indicators should be defined for each piece of equipment in the water treatment system.

It is recommended that a daily checklist be used to monitor basic system parameters, such as loop final water quality and critical OEM directed readings, which may include levels of expendable items that need to be monitored.

Testing of at least the loop out and the loop return should be done no less frequently than monthly to verify bacterial levels and endotoxin levels.

12.2 Serviceability of system

Systems shall be designed with clear guidance on system controls that are easy to follow and reduce errors. The system should be allotted adequate room for installation that will allow access to all components for maintenance and allow adequate access around the equipment. 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 codes.

Reverse osmosis systems should be set up to permit disinfection and allow for low and high pH chemical cleanings for ongoing maintenance.

Systems should be on a fully recirculating loop to allow for full and effective disinfection of the system piping and have a fully drainable tank for complete and faster disinfection. Existing direct feed systems should be updated to recirculating systems, when possible, to allow for effective disinfection. Until such time that the loop is installed, the direct feed may be required to be monitored and disinfected more frequently to reduce the risk of bacterial growth and/or endotoxin accumulation. All newly designed and installed systems shall be on a fully recirculating loop.

Sample ports shall be placed at the loop out after final filtration as well as right before re-entry into the storage tank. Where feasible, an accessible sample port should be placed before individual points of use (e.g., immediately before the inlet to the washer-disinfector).

13 Special considerations

13.1 Post construction or extended shutdown

Typically performed by facilities engineering personnel:

- Reverse osmosis system/ultra filtration should be flushed. Flushing should be run every 24-hours for a minimum of 30-minutes or follow OEM recommendations.
- Pretreatment apparatus or filters should be scheduled to backwash or regenerate every 48-hours maximum.
- Pretreatment filter(s) should be changed out prior to putting into service.
- Water treatment equipment should be disinfected prior to putting into service.
- Flush Critical Water systems, by running water for two system volumes post disinfection. Contact the processing equipment manufacturer for guidance regarding how to flush stagnant water from equipment.
- Remove aerators and flush hot and cold sink water for a minimum of 5-minutes or until visibly clear and free of particles/debris.
- Total bacteria and endotoxin tests should be performed prior to putting into service.
- After construction, or an extended period of disuse, Critical Water systems should be flushed to remove stagnant water prior to sampling. Bacterial testing and endotoxin testing should be performed on the loop.
- Upon receipt of total bacteria and endotoxin tests with acceptable results, the unit may be placed into service.

13.2 Extended boil water alerts and steps to take after alerts are lifted

- Once the boil water alert has been lifted, flush all equipment (e.g., water treatment equipment/loop) with a disinfectant that is compatible with piping materials and equipment and restart. Also, flush feedwater source (prior to treatment equipment).
    - After disinfectant application is complete, flush for at least five minutes and until residual disinfectant is detected at feedwater source prior to treatment.
    - If chlorine cannot be detected at point-of-use after flushing, supplemental disinfection may need to be considered (drinking water regulations will apply, by performing supplement disinfection).
- Drain, disinfect, flush, and refill water storage tank.
- Change pretreatment filters, backwash carbon tanks, regenerate softener, clean and disinfect RO membranes, disinfect distribution loop.
- If steam sterilizers are used in processing, check the steam system.
    - Check water quality used for steam generation.
    - Check with manufacturer for written instructions for bringing the system back online following a contamination event.

- If using deionization tanks these should be replaced with new deionization tanks prior to going back into service.

- The loop final filter should be replaced with a new absolute rated final filter.

13.3 Interruptions in service

If an interruption of service is from the utility feedwater source or a building system, shut down and restart.

- Apply disinfectant and flush for at least five minutes and until residual disinfectant is detected at feedwater source prior to treatment. Disconnect the feed to the unit and flush the feed source directly to the drain.

- If disinfectant cannot be detected at point-of-use after flushing one may need to consider supplemental disinfection (drinking water regulations will apply, by performing supplemental disinfection the health care facility would now be considered a small public water system).

If the system cannot be disconnected from the feed source and directed to drain:

- Change pretreatment filters, backwash carbon tanks, regenerate softener, clean and disinfect RO membranes, and disinfect distribution loop.

- If steam sterilizers are used in processing, check the steam system.

    - Check water quality used for steam generation.

    - Check with manufacturer for instructions for bringing system back online following a contamination event.

- If using deionization tanks these should be replaced with new deionization tanks prior to going back into service.

- The loop final filter should be replaced with a new Absolute Rated Final Filter.

13.4 System repair, modification and/or routine maintenance on a Critical Water production, storage, and distribution system

A Critical Water system is or should be designed to deliver water meeting all specified parameters to the points of use. See Clause 8.3 for details of Critical Water system design and Table 2 for the specified parameters.

Routine maintenance, repair, or system expansion can require that the Critical Water system be opened to the atmosphere, which exposes the piping and water in the system to ambient airborne microbiological flora. In the interests of patient safety, these should be assumed to be pathogenic. Thus, any time piping is replaced, or system modification is completed on a Critical Water system, the system piping and storage should be disinfected.

Disinfection should be performed after installation, expansion, major repairs, non-compliant bacterial levels, or other changes to the system (e.g., nearby building construction or water supply interruptions). In addition, disinfection should ideally be completed for prophylactic purposes, even if no non-compliant bacterial or endotoxin results have been observed (See Annex G).

Specific instances in normal maintenance in which system disinfection is required include:

13.4.1 Pretreatment equipment

Examples: cartridge particulate filtration, multimedia filtration, softener, carbon filter, sodium bisulfite injection system, and anti-scalant injection system

This equipment typically does not require regular disinfection. However, if testing indicates non-compliant bacterial levels at the sample port immediately downstream of the pretreatment equipment, the equipment should be disinfected

according to material compatibility. If testing still indicates non-compliant bacterial levels, the filtration media should be replaced. Non-compliant levels are defined here as a bioburden level of too numerous to count.

13.4.2 Primary treatment equipment

EXAMPLE: reverse osmosis (RO), deionization (DI), and electrodeionization (EDI)

13.4.2.1 Reverse Osmosis (RO) unit

RO units should be cleaned, using high and low pH cleaning chemicals, when permeate (product water) indicates membrane fouling and degradation of performance. This will be dependent upon the quality of the feedwater to the RO unit, as well as the volume of water filtered by the RO. Therefore, frequency should be determined by the specific use profile of the sterile processing department and when data indicates cleaning is required. At a minimum, this should be performed at least annually.

RO units should also be disinfected using a compatible disinfection method at least annually or if testing indicates non-compliant bacterial levels at the sample port immediately downstream of the RO unit.

13.4.2.2 Deionization (DI) exchange tanks

DI exchange tanks are typically not compatible with the disinfection methods. Therefore, the DI exchange tanks should be exchanged with replacement tanks when testing indicates non-compliant bacterial levels at the sample port immediately downstream of the DI tanks and there is not a bacteriostatic filter downstream of the DI tanks.

13.4.2.3 Electrodeionization (EDI) unit

EDI units should be disinfected when testing indicates non-compliant bacterial levels at the sample port immediately downstream of the EDI unit.

13.4.3 Storage tanks and distribution equipment and piping

Examples: storage tanks, distribution pump(s), UV disinfector, bacteriostatic filtration, and distribution loop piping

High purity water storage, distribution equipment and piping should be disinfected using a compatible disinfection method if testing indicates non-compliant bacterial levels at the sample port immediately downstream of the final treatment technology, typically the bacteriostatic filters, at the inlet of the distribution loop, typically the bacteriostatic filters and on the sample port returning. If bacteriostatic filters are not compatible with disinfection methods (see Annex G), the filters must be replaced with new filters. Bacteriostatic filters should be replaced if the pressure difference (delta pressure, or ΔP) across the filter is 10 PSI or greater, or downstream testing indicates biological breakthrough and/or loop biofouling. Localized disinfection is required for areas that can be bypassed for normal maintenance. For example, the bacteriostatic filter if there is a bypass permitting its replacement without exposing the entire water system to ambient atmospheric conditions. Bypasses should be designed to ensure that stagnant water within them does not allow for bacterial growth or biofilm formation. If the bacteriostatic filter at the inlet of the distribution loop cannot be isolated during replacement, the distribution loop should be disinfected after the filters are replaced.

Storage tanks, distribution equipment, and distribution loop piping should be disinfected after the replacement of in-line probes and sensors. Storage tanks, distribution equipment, and distribution loop piping should be disinfected after service and/or replacement of recirculation pumps and associated piping. Storage tanks, distribution equipment, and distribution loop piping should be disinfected after a shutdown of a maximum duration determined by the multidisciplinary water management team, or when post-shutdown testing, if performed, indicates non-compliant bacterial levels.

Annex A
(informative)

Guidance on the application of the normative requirements

A.1 Introduction

Medical device processing should have water quality that is monitored and maintained to prolong the useful life and effective functioning of medical instrumentation and minimize the risk of adverse patient outcomes (e.g., surgical site infections) arising from contaminated medical devices. This section of the standard is intended to help users understand the major considerations associated with the quality of water used in medical device processing in health care facilities and water quality characteristics.

Water quality terminology can be confusing and should be understood to allow users to select the appropriate water quality at the point-of-use. The terminology used is an indication of the water treatment process utilized with associated quality requirements. This document uses terminology based on the quality of water rather than by its source.

Potable water may sometimes be referred to as tap water. However, tap water describes the location of the water source (e.g., fixture) rather than the water quality specification. Depending on the quality of the potable water at the facility in which the water is used, additional treatment(s) may be necessary to produce a higher quality water. Tap water is, therefore, a generalized term for water from the tap and should not infer a quality specification.

Potable water is water that has been treated by a municipal water treatment facility and delivered in a manner so that it meets the Environmental Protection Agency's (EPA) guidelines for direct or indirect human consumption. Differences in geographical location can impact the water quality for potable water. For example, regions with large mineral deposits may be considered "hard water" and need additional treatment before use in equipment.

Additionally, the required water quality for an intended use may exceed the capabilities of the treatment steps used to produce Critical Water. For example, "sterile water" has a lower specification level for bacteria and is produced, packaged and sterilized to preserve microbial quality throughout its packaged shelf life. Therefore, if the manufacturer's instructions for use specifically require "sterile water" for use during processing, only water labeled as such should be used.

Table A.1—Water descriptions

Terminology	Description/Definition	Typical Use Examples
Potable Water	Water that has been treated and delivered in a manner as to meet EPA guidelines intended for direct or indirect human consumption (see 3.56).	Water used for drinking fountain or hand washing station.
Utility Water	Water that may come from the tap but may need some form of treatment to achieve these specifications (criteria defined in Table 2) (see 3.86).	Water used for flushing, washing, and rinsing as part of the processing of medical devices.
Critical Water	Water that is usually extensively treated (Criteria defined in Table 2) (see 3.20).	Water used for final rinse prior to sterilization of a critical device, or after high-level disinfection, as part of the processing of medical devices.
Non-potable Water	Water that does not meet the EPA drinking guidelines.	Reclaimed water used for facility utilities.
Feedwater	Water as it is being fed to water treatment equipment or steam generator (see 3.33).	Water sourced to equipment (e.g., boiler) and is representative of the

Terminology	Description/Definition	Typical Use Examples
		water quality defined by the equipment manufacturer or applicable standard.
Make-Up Water	Water sent to water treatment equipment or processing equipment.	Water treated and supplied to equipment (e.g., washer disinfector) and representative of the water quality defined by the equipment manufacturer or applicable standard.
Softened Water	Water that has undergone a reduction of magnesium and calcium content.	Water often used as make-up water or feedwater.
Demineralized Water	Water that has most of the mineral content removed (e.g., copper, iron, calcium, etc.).	Often used as make-up water or feedwater.
Filtered Water	Potable water that had undergone additional filtration treatment.	Tap water filtered by equipment (e.g., AERs).
Deionized (DI) Water	Process that is applied to a type of water to achieve a defined water quality.	See Annex E.2.11
Revese Osmosis (RO) Water	Process that is applied to a type of water to achieve a defined water quality.	See Annex E.2.10
Reverse Osmosis / Deionized (RO/DI) Water	Combined treatment process of DI and RO to achieve a defined water quality.	See Annex E.2.10 and Annex E.2.11
Distilled Water	Water that has been produced using boiling followed by condensation.	See Annex E.2.15
Sterile Water	Critical Water that has undergone a sterilization process to inactivate all microorganisms.	Water used for the rinsing of ophthalmic devices.

A.2 General considerations

Table A.2—Water quality for processing devices

Stage in process	Function	Water quality
1. Point-of-use treatment	Begin removal and prevent drying of clinical soil on the device or inside lumens.	Utility Water is acceptable unless on the sterile field (then sterile water is required), at a temperature not exceeding 45 °C (113 °F).
2. Cleaning with cleaning agent	Remove patient organic and inorganic material (soil) not removed by simple POU treatment (Stage 1).	Utility Water is acceptable to dilute cleaning agent if it meets the cleaning agent manufacturer's written IFU.
3. Ultrasonic Cleaners	Remove residual soil from hinges and serrations.	Utility Water is acceptable to dilute cleaning agent if it meets the cleaning agent manufacturer's written IFU.

Stage in process	Function	Water quality
4. Post-wash rinse	Remove cleaning agent residues and any loosened soil.	Utility Water is acceptable. The water may need to be treated to achieve thorough rinsing. For each rinse, a sufficient volume of water should be used.
5. Final Rinse	Remove cleaning agent residues and any remaining soil.	For the final rinse of a critical device (and some semi-critical devices) Critical Water should be used. For each rinse, a sufficient volume of water should be used.
6. Subsequent to point-of-use treatment, cleaning, and rinsing, **one** of two methods of heat treatment is used		
5a. Thermal disinfection (e.g., final rinse in washer-disinfector)	Kill microorganisms.	Critical Water should be used, unless otherwise directed by the Washer-Disinfector manufacturer's written IFU.
5b. Pasteurization	Kill microorganisms.	Critical Water used in the pasteurizer may need to be changed daily or after each load to reduce buildup and carryover of debris. The device manufacturer's written IFU should be followed.
NOTE Verify that the quality of the water is compatible with cleaning agent manufacturer's written IFU. If the water hardness exceeds the requirements of Utility Water (see Table 2 and notes), it should be treated to meet those requirements. If after such treatment, the levels of these or other ions remain above the levels specified, DI or RO treatment should be considered.		

A.3 Water characteristics

A number of water characteristics contribute to unacceptable organic and inorganic levels: bacterial endotoxin, TOC, pH, water hardness, and ionic contaminants. For example, toxic anterior segment syndrome (TASS) is an inflammatory reaction in the eye that can lead to permanent loss of vision after cataract surgery as a result of adverse reaction to organic or inorganic matter introduced into the anterior chamber of the eye [69]. (See also [56], [61], [66], [91], and Annex M of [8].) Manufacturers of ophthalmic surgical instruments recommend that devices used for cataract surgery be thoroughly rinsed with sterile distilled water (i.e., water equivalent to the Critical Water described in Table 2 that has been sterilized) before sterilization.

Individually or in combination, these characteristics can cause changes in the appearance or color of water (e.g., the water can appear cloudy). If the water used in processing does not look clear and colorless, there is likely to be a problem that should be corrected. See Clause 6 for the characteristics of water of various quality categories.

It should be noted that the use of Critical Water as a final rinse removes residual organic and inorganic contaminants and alleviates many of the issues that can be caused by their continued presence as processing proceeds.

a) pH

The pH of water used in device processing can directly affect the medical device by causing pitting or corrosion. The pH can also indirectly affect the device by interfering with the effectiveness of the cleaning agents (especially enzymatic cleaning agents), disinfectants, or sterilants used in processing (i.e., the water pH is not compatible with the cleaning agent, disinfectant, or sterilant). The pH can be tested on site using test strips or an inexpensive meter. If the test strip shows a result out of specification, the water can be tested using a precision pH meter or sent to a lab for pH testing.

b) Total alkalinity

Water alkalinity is often described as the amount of buffering capacity a water source has against pH changes. Technically, it is the combined levels of carbonate, bicarbonate, and hydroxide ions in water. High alkalinity water produces significant carbon dioxide when used as boiler feedwater which then requires additional steam treatment to avoid corrosion of steam lines when the carbon dioxide recondenses as carbonic acid.

c) Water hardness

Hard water is caused by the presence of dissolved salts (typically calcium and magnesium) that deposit as hard mineral layers (limescale) when the water is heated or evaporated. Water hardness is often reported as the concentration of calcium and magnesium as mg/L of calcium carbonate (ppm $CaCO_3$) in the water. Very hard water can decrease the effectiveness of most cleaning agents and disinfectants (e.g., components of hard water bind with cleaning agent surfactants, preventing them from dispersing soils). Very hard water can also adversely affect the performance of medical washers and medical washer–disinfectors by fouling electrical heating elements and heat-exchange components, reducing heat-transfer efficiency, increasing water-heating costs, and depositing limescale within pipes and around spray nozzles. Hard water deposits create encrustations on medical devices that can prevent microorganisms and organic material from being properly removed during cleaning, resulting in potential adverse effects on patients. In addition, hard water can be incompatible with the components of HLDs and LCSs that are diluted to in-use concentration or diluted in the course of reuse.

d) Microbial level in water (e.g., bacteria)

The water used at each stage of processing should not increase the microbial population on the device being processed. Water entering the facility from the public utility is usually disinfected using chlorine or ozone to prevent microbial replication. Even in disinfected water, however, the level of microorganisms depends on the effectiveness of the municipal treatment process and on the state of the distribution system. For example, cleaning of the city distribution system often leads to “brown water” as a result of dislodging biofilm within the system. The microbial levels in tap water at such times can be considerably higher than when cleaning is not being performed. In addition, disinfected water can contain other inorganic components that will damage medical devices during processing, thereby necessitating on-site water treatment (Annex E) to remove these components. Maintenance of water treatment processes, distribution piping/network and addition of chemical compounds (i.e., chlorine) to distribution systems after the treatment, should all be evaluated for impact on equipment and devices in addition to microbial load.

Due to these considerations, it is necessary to (1) assess the microbial level of water used for device processing in the facility to ensure that it is acceptable; (2) monitor bacterial levels in tap water, softened water, and deionized water when systems are installed, modified, or repaired, or if problems are identified (see Annex I); and (3) monitor microbial levels in Critical Water at intervals that should conform to the recommendations of Table 2 and Table 4. Rapidly addressing unacceptable microbial levels in the water distribution system is critical to minimize biofilm. Bacteria can grow in water storage tanks, thereby negating the microbial removal aspect of the treatment process and resulting in water with unacceptable levels of microorganisms. Storage and distribution systems should be carefully controlled to maintain low microbial counts and endotoxin levels by fully recirculating the water, use of a disinfection process (e.g., thermal disinfection, ultraviolet light, ozone), and by using submicron absolute rated final filters (See Annex E). Softeners should be maintained to prevent inadequate softening or over-addition of exchange ions (e.g., chloride ions), which could lead to device damage). The World Health Organization has reviewed the heterotrophic plate count (HPC) and developed an expert consensus [34]. In the United States, the acceptable HPC level in tap water has been set at less than 500 CFU/mL. This standard is currently not enforced. The acceptable level of organisms in dialysis is less than 100 CFU/mL and dental water lines is less than 500 CFU/mL. As shown in Table 2, the recommended level of detectable organisms in water produced used for medical device processing varies depending on the treatment process. A routine procedure should be developed to monitor the microbial levels in the water produced.

The risk of adverse patient events associated with the number of microorganisms in the water depends on the type of device and its intended use. The risk is low for devices that will contact only intact tissue. The risk is higher for devices that contact the patient's non-intact skin, bloodstream, or other sterile body areas.

Microbial levels are measured as the number of colony-forming units (CFUs) per mL of water. Guidelines have been established for monitoring the microbial content of tap water [34], [70], [80]. If tap water is subjected to a water treatment process and then distributed to other sites, it is important that a process be established to reduce bacterial overgrowth of the water distribution and storage system. This process requires proper equipment, proper maintenance, and regular testing to ensure that water quality is not detrimentally affected by distribution and storage. When water is generated at the point-of-use, there is still a need to ensure that the quality of the water generated meets the expected specification. For example, 0.22 µm filtration should adequately remove all bacteria from water; however, if the filters are not maintained and changed on a regular basis, their functionality might be inadequate, and the water produced might not be bacteria-free. Bacterial control in water treatment systems is discussed in detail in Annex G.

e) Endotoxin

Bacterial endotoxin are organic compounds that are derived from the cell walls of bacteria, most commonly Gram negative bacteria (e.g., *E. coli*, *Pseudomonas aeruginosa*) and that, when introduced into the human body, can cause a feverlike (pyrogenic) reaction and other adverse effects. Unlike microorganisms, endotoxin are not reliably destroyed by disinfection or most sterilization processes. Residual endotoxin are a concern for medical devices that will contact the patient's bloodstream, cerebrospinal fluid, or the anterior chamber of the eye [58] [66] [64]. Therefore, if the incoming water used for cleaning and rinsing has high levels of endotoxin, residual endotoxin may remain on reprocessed devices. The exact threshold of endotoxin on a medical device that will result in an adverse patient reaction is difficult to specify because of several variables, including, but not limited to the source of the endotoxin (e.g., *Salmonella species*, *E. coli*, or some other Gram-negative bacteria); the amount of endotoxin that comes off the device during patient contact; the weight of the patient; and the body site that the device enters (e.g., the eye versus the gastrointestinal tract). Suffredini, et al. [86] demonstrated that intravenous injection of 1 to 4 nanograms/kilogram (ng/kg) of purified endotoxin into humans could elicit a dose-response effect on temperature and total leukocytes. Therefore, for a 50 kg human, a medical device would have to harbor at least 50 ng of endotoxin (100 EUs) to elicit an adverse patient reaction. Consequently, final rinse water containing 100 EU/mL (only a fraction of which would remain on a device after rinsing) is unlikely to stimulate an adverse patient reaction. However, if water control strategies are faulty and the system is not prospectively monitored, it is possible that rinse water could have high enough endotoxin concentrations that residuals on a medical device might result in an adverse patient reaction, depending on the body site with which the device has contact.

NOTE Bacterial endotoxin are the most common cause of pyrogenic reactions, but other organic or chemical residues can also cause such reactions.

f) Total organic carbon (TOC)

The presence of organic carbon is an indication that the water contains material derived from living sources or organic pollutants (e.g., microorganisms, plants, animals, pesticides). Water that is contaminated or overgrown with microorganisms will have a high TOC level. If water with a high TOC level is used in device processing, water residuals can discolor the device and interfere with the effectiveness of cleaning agents, disinfectants, or sterilants. Also, high organic carbon levels provide nutrition to microorganisms and can contribute to microbial overgrowth in the water.

g) Water temperature

Water temperature is an important consideration to the microbial level and the organic and inorganic components of water; it can have a significant impact on the effectiveness of processing. The temperature of the water affects the efficacy of point-of-use treatment, cleaning, rinsing, liquid chemical disinfection, and liquid chemical sterilization and steam sterilization. The temperature of water can also have an effect on contaminants in water (e.g., scale is more likely to form and precipitate in hotter water).

In general, the appropriate temperature depends on the stage of processing, as well as the medical device, cleaning agent, and cleaning equipment manufacturers' written IFU.

A.3.1 Ionic characteristics

a) Conductivity

Conductivity and resistivity measurements are electrical measurements of the ionic concentration (i.e., charged molecules such as metal ions and chlorides) in water. These measurements are mathematical inverses of one another (e.g., greater than 0.1 MΩcm resistivity is equal to less than 10 µSiemens/cm conductivity). Conductivity was selected as the measurement as it is expressed as an upper limit. Ionic contaminants in water used in medical device processing can have a negative impact on medical devices. The process that produces Critical Water removes the majority of ionic contaminants. Reduction of ionic contaminants will minimize the risk of damage (e.g., discoloration, visible deposits, or corrosion). Similarly, Utility Water should have acceptable levels of ionic contaminants to minimize the potential of staining or corrosion of medical devices during processing. Ionic contaminants are generally present at greater levels in Utility Water than Critical Water. Chloride-induced corrosion increases with the chloride ion concentration and temperature. Therefore, it is especially important that the chloride ion concentration in steam is minimized to prevent device corrosion (e.g., steam condensate should have less than 1.0 mg/mL chloride ions). Monitoring conductivity can ensure the ionic contaminant concentrations are not above the levels expected for the quality of water. Total dissolved solids may be calculated from conductivity and, therefore, is not included as a specification in this standard.

A.3.1.1 Corrosive agents

a) Chloride

Chloride corrodes stainless steel by disrupting the passive external layer and allowing the iron in the stainless steel to become susceptible to oxidation. It can also affect other metals in a similar manner or by creating chloride compounds on the surface that can be washed away in water. Chloride levels must be kept low to avoid corrosion.

b) Nitrate

Nitrate in the presence of carbon dioxide in water facilitates corrosion of carbon steel in acidic environments (pH less than 7), nitrates have had less effect on stainless steel, but still can result in corrosion if the concentration is high enough.

c) Iron

Iron deposits on the surface of instruments will inevitably lead to rust formation. In the case of stainless steel, iron deposits can lead to the formation of a corrosion site that will grow until the instrument is serviced and repassivated.

Metal ions that deposit on instruments will tend to cause corrosion. Often, this is galvanic corrosion, caused by the difference in electrochemistry of the ion and the instruments. In some cases, like iron and manganese, the ions will slip into imperfections in the stainless steel and disrupt its passive layer, resulting in stress corrosion. In general, these ions should not be left on the surface of the instruments and are best removed by a Critical Water final rinse.

d) Copper

Copper oxidation discolors instruments leading to an assumption of incomplete processing. In the worst cases, corrosion will take place if the copper deposits in a micropore or crack in the surface of the instrument where it can interact with the surrounding material.

e) Manganese

Manganese oxidizes like iron, but the resulting discoloration will be black, not brown like rust. The corrosion site of manganese forms in the same way as copper or iron, which will require the instrument to be serviced and repassivated.

f) Zinc

Zinc is predisposed to deposit on iron and its alloys (e.g., stainless steel). The galvanic interaction of the zinc and the iron in stainless steel can result in electrochemical corrosion.

A.3.1.2 Scaling agents

a) Phosphates

Phosphates can form insoluble scale on instruments that is difficult to remove, and its removal may cause damage to the surface of the instrument.

b) Sulfate

Like phosphates, sulfates can combine with positive ions to create insoluble scale on instruments that if difficult to remove and its removal may cause damage to the surface of the instrument.

c) Silicates

Silicates can form insoluble scale on instruments. Silicates can be difficult to remove, and removal may cause damage to the surface of the instrument. Silicate should be removed prior to processes requiring subsequent heating (e.g., steam sterilization).

d) Hardness

Hard water can cause scaling that should be removed before sterilization.

Annex B
(informative)

Risk analysis

A formal framework exists for risk analysis, which involves looking at a process from a clean sheet of paper, includes a so-called Fault Tree Analysis, and looking at specific failures of the process, a Failure Mode and Effects analysis. The risk analysis model is presented in more detail in ANSI/AAMI/ISO 14971:2019, *"Medical Devices - Application of Risk Management to Medical Devices"* and in ANSI/AAMI ST90: 2017, "*Processing of health care products-Quality management systems for processing in health care facilities*." Rather than perform a formal risk analysis as defined in those documents, examples are provided here specific to water for the processing of medical devices in health care institutions to inform those analyses, to be performed by each health care institution based on its unique situation and operating conditions. Examples of risks associated with water quality are presented in the tables below, categorized by the application and the water quality category.

B.1 Patient safety

Proper cleaning, to remove cleaning agent or clinical soil, and sterilization is essential for patient safety in procedures using processed instruments. Use of water of the improper quality at the incorrect step in the process may hinder effective cleaning, leave residues or bacterial/endotoxin contamination, or cause staining/damage to the instruments. If any of these are observed, patient safety could be compromised. For this reason, it is essential to use water of the correct quality for each stage of the chain of events in processing, point-of-use treatment, manual, ultrasonic, automated cleaning, final rinse, and steam generation.

Table B.1—Tables of risk factors and effects

Water Quality	Secondary Factor	Point-of-use Rinse	Cleaning Agent Soak and Manual Cleaning	Final Rinse
General	Water Temperature			
	Cold Water (<16 °C /<60 °F)	Less chance of blood coagulation and protein denaturation	Hinders cleaning agent action*	Less effective rinsing
		User's hands become cold (manual cleaning)		
	Tepid Water (16-38 °C /60-100 °F)	Effective cleaning/removal of blood-based soil	Cleaning agent action may be less than optimal*	No effect
	Warm Water (38-45 °C /100-113 °F)	May cause some coagulation, decreased cleaning/removal of blood-based soil	starting to come into optimal temperature range* for cleaning agent	No effect
	Hot Water (45-55 °C /113-131 °F)	Coagulation of blood-based soil	optimal temperature range* for cleaning agent	No effect
	Water above 55 °C /131 °F/	Coagulation of blood-based soil	Cleaning agents may be too hot, and enzymes start to denature*	No effect
		Scalding of technicians/discomfort (manual cleaning)		

Water Quality	Secondary Factor	Point-of-use Rinse	Cleaning Agent Soak and Manual Cleaning	Final Rinse
Utility Water	Water Purity			
	Low Conductivity	Helps to loosen soil	Allows use of less cleaning agent*	Improved rinsing
	High Conductivity	Soil is more difficult to remove	Requires more cleaning agent*	Hinders rinsing performance
		May leave deposits		
	High TOC	Soil is more difficult to remove	Requires more cleaning agent*	May leave film on instruments
	High chloride	May corrode metal (e.g., instruments, pans, carts)		
	High metal ion content	May cause metal deposits on instruments (e.g., rust, color changes, corrosion)		
Critical Water	Water purity			
	In specification	Helps to loosen soil, adds cost for water production	Allows use of less cleaning agent, adds cost for water production*	Optimal rinsing, decreased potential for instrument spotting, staining, and corrosion
	Out of specification	See Utility Water	Cleaning performance diminished*	See Utility Water
NOTE 1 Tepid water is also recommended for use in eye wash stations/safety showers. See ANSI Z358.1				
*NOTE 2 Refer to cleaning agent manufacturer's written IFU or literature provided by the manufacturer.				

B.2 Sterilizer vacuum water supply

Only Utility Water should be used for sterilizer vacuum water supply, since Critical Water adds no advantages, adds cost, and may cause decreased lifetime of plumbing and pump components.

Table B.2— Impact of water temperature on sterilizer vacuum water supply pump performance

Water Temperature	Pump Performance
Cold (<16 °C /60 °F)	Optimal
Tepid (16-38 °C /60-100 °F)	Decreased pumping speed
Warm (38-45 °C /100-113 °F)	Greatly decreased pumping speed
Hot (45-49 °C /113-120 °F)	Not recommended
Above 49 °C /120 °F	Not recommended

B.3 Sources of water quality-based risk

B.3.1 Utility Water

The municipal water authority supplies a report on an annual basis. It should be checked to ensure that the following situations are not present.

— Particulates from lack of filtration;

— Municipal water supply not compliant with EPA limits or exceed recommended levels for contaminants in this standard and;

— Temporary excursions above acceptable limits (not found in the annual report in general).

Other risk sources include:

— Old piping;

— Piping with dead legs and;

— Water main breaks.

B.3.2 Critical Water

The system for production of Critical Water is monitored and periodically maintained for proper function. If it is not, the Critical Water produced may not meet the expected levels of purity.

Other issues with Critical Water are:

— Incorrect plumbing material (anything but stainless steel or plastic piping);

— System design does not provide a loop through which the Critical Water flows and is disinfected, with sample ports at points of use and;

— Ineffective disinfection.

B.3.3 Bacterial or endotoxin loading

In cases of high bacterial loading due to conditions outside the health care facility, this issue can become internal as well. Inactivation of the bacteria solves the problem of potentially infectious bacteria, but the endotoxin left behind are problematic in their own right. In either case, the system may need to be disinfected and flushed to return it to a bacteria/endotoxin-controlled state and meet the performance qualification specifications for the specified water quality.

B.3.4 Risks to personnel

The processing of reusable medical devices has a number of risks inherent to it that can affect the personnel carrying out the work. A partial list is given in the following Table B.3.

Table B.3—Work-related risks to staff

Item	Risk to Staff Member
Water Pressure	Release of water at high pressure can result in injury, especially to the eyes of health care personnel should they be hit by a jet of water.
Cleaning Agents/Disinfectants	While not strictly a water quality issue, exposure to these chemical mixtures, which are used in conjunction with water for processing, can result in chemical burn injury or eye damage. This can take place during transfer of the cleaning agent or disinfectant solution to the use vessel, or when diluted for use, by direct contact with skin, nasal passages or eyes.
Water Temperature	Hot water can result in personnel burns. Water delivered to a faucet outlet should not exceed 49 °C (120 °F).

Annex C
(informative)

Automated Endoscope Reprocessor (AER)

Incoming water for AERs should be assessed to verify that the appropriate water quality levels are achieved. For final rinse in an AER, the water entering the AER should meet the AER manufacturer's written IFU. This recommendation would align the processing procedure for automated and manual processing and would minimize the risk of re-contaminating the disinfected device.

Manufacturers of AERs do recommend that filters and water be regularly monitored, but few practical methods or recommendations are available to users. Current guidance, according to AAMI ST91 [9] provides guidance for when to monitor for water quality per the AER manufacturer. Additional guidance for how to monitor is provided in ISO 15883-4. AAMI ST91 recommends against routine environmental sampling but suggests instead that this type of monitoring be done only when a problem is identified, as in the case of an outbreak. The guidelines from APIC and the CDC do not recommend routine testing of tap water except to monitor for *Legionella* [20], [42].

C.1 Automated processing

Semi-critical devices may be processed using high-level disinfection at a minimum. Both critical and semi-critical medical devices may be processed using liquid chemical sterilization. The quality of water that should be used to process devices that will not be packaged but will be sterilized with a liquid chemical are provided in Table C.1. An example is the processing of flexible endoscopes. Stages 1, 2, and 3 are currently done manually. [31], [72], [79] Steps 4 and 5 may be performed by means of an automated reprocessor known as a liquid chemical sterilant processing system (LCSPS). These systems generate water of a quality suitable to the types of medical devices they are intended to process (e.g., flexible endoscopes or other heat-sensitive devices, such as respiratory tubing).

Table C.1—Water quality for LCSPS

Stage in Process	Function	Water Quality
1. Point-of-use treatment	Reduce the level of soil to prepare the device for transport for subsequent decontamination and ensure that clinical soil is not allowed to dry on the device or inside lumens	Utility Water is acceptable, at a temperature not exceeding 45 °C (113 °F).
2. Cleaning with cleaning agent solution	Remove patient organic and inorganic material (clinical soil) that is not removed by point-of-use treatment (Stage 1)	Utility Water is acceptable to dilute cleaning agent, unless otherwise directed by the cleaning agent manufacturer's written IFU.
3. Post-wash rinse	Remove cleaning agent residues and any loosened clinical soil	Utility Water is acceptable as incoming water to an AER, unless otherwise indicated by AER manufacturer's written IFU. Water changes and multiple rinses may be indicated.
4. Dilution of liquid chemical sterilant (if applicable) and liquid chemical exposure	Sterilization	Water quality for sterilant dilution is defined by the AER manufacturer written IFU for dedicated chemistries and by the sterilant manufacturer's

Stage in Process	Function	Water Quality
		written IFU if a non-dedicated chemistry.
5. Final rinse after liquid chemical sterilization	Remove residual LCS and reduce likelihood of pyrogens on device	In the case of HLD and LCS processed devices that will not be used immediately, sterile water or water that meets sterile water criteria should be used for the final rinse so as not to contaminate the device.
Note: The term “gross soil” removal may be used in cleaning validation protocols and referenced in medical device manufacturer’s written instructions for processing at point of use. This term may be variably interpreted by users and validation technicians. Because this terminology is not quantifiable, this document does not use the term “gross soil”. The use of “gross soil” makes it impractical to consistently and effectively validate manufacturer’s cleaning instructions and difficult to evaluate whether the needed level of “gross soil” removal is achieved at the point of use.		

Annex D
(informative)

Water used in cleaning and moist heat processes

The types of water used in cleaning and thermal disinfection are defined in Clause 7.3 and Clause 7.4. The factors that affect efficacy of cleaning are less well defined in these sections. This annex is provided to assist in interpretation of the contents of those sections and, potentially, optimization of cleaning and disinfection processes.

The best water for cleaning is Critical Water. This has downsides related to cost and capacity, but it provides the least interference with the action of cleaning agents, is the best solvent available for soluble instrument contamination, and will not leave residues when dried. However, if the system is not specified for Critical Water, its use may lead to damage to the plumbing or automatic washer. Refer to the manufacturer's written IFU for clarification.

With this in mind, real-world solutions do not generally include the use of Critical Water in all steps due to the downsides described above. To come to the best compromise with the real-world, non-ideal situation, it is essential to verify that Utility Water, where used, is well within the allowable range for Utility Water contaminants, see Table 2, Clause 6.2. This may require filtration or softening of the feedwater, but both are inexpensive relative to instrument damage, corrosion, or delayed cases.

D.1 Cleaning

The following sections discuss the process steps in more detail and define optimal water usage for the process stages.

Cleaning: The typical cleaning process in the U.S. consists of the following stages:

1) Initial rinse;
2) Soak;
3) Enzymatic cleaning agent;
4) Intermediate Rinse #1;
5) Neutral cleaning agent (in automatic washers);
6) Intermediate Rinse #2 and;
7) Final rinse/thermal disinfection (in automatic washers).

The effect of water type and temperature in each of these stages is discussed in the following subsections.

Initial rinse: Initial rinse is done to begin removing clinical soil and to prepare the item for the following steps.

Soak: Soaking is done to hydrate and loosen up patient soil on the instrument. In order to not coagulate blood or denature proteins, making the process more difficult or less effective, hot water is to be avoided. If Utility water is used, it has the least possible cost for the facility.

Hard water or water with high TOC are potential problem sources in this step since deposition of inorganic (hard water) or organic (high TOC) contaminants can result from their use. And removal/hydration of soil may be less effective since the water already has excessive solutes.

Enzymatic cleaning agent: break down organic clinical soil, making it easier to remove, and the surfactants in the cleaning agent help to solubilize the digested soil residue and aids in soil penetration, emulsification and maintains

suspension. Enzymes are biological systems and have two important aspects related to temperature that bear heavily upon their use.

Enzymatic activity is dependent upon the following parameters: temperature, concentration, contact time, water quality, and pH. Therefore, running at the highest temperature that the enzymes can tolerate and that does not denature the soil, making it harder for the enzymes to break down, is the best course of action to get the best cleaning in the least time for this process. But, being biological systems, enzymes have an upper temperature limit beyond which they themselves begin to denature. The critical success factor for enzyme wash stage temperature is to find the upper limit where these three factors balance out at an optimal level.

Utility water in which the contaminant levels are at the lower end of the ranges will not interfere with the enzymatic cleaning process. High contaminant levels, such as TOC, will interfere with the enzymatic cleaning process.

Intermediate Rinse #1: Rinsing after use of an enzymatic cleaning agent removes soil broken down by the enzymatic cleaning process. It should be done using Utility Water at the same temperature as the enzyme wash to avoid reheating in later steps, or, if different, a little colder for the same reasons discussed in the soak section. This stage can be done using Utility water.

If a manufacturer has validated that the residue of an enzymatic process does not interfere with subsequent steps of the cleaning process, this stage may be omitted.

Cleaning agent: The cleaning agent step typically uses a cleaning agent to remove inorganic soil that the enzymatic cleaning agent cannot. It also removes residual digested soil that the rinse (if performed) did not. Since this is not a biological process, the temperature of the stage can be increased to increase the process rate, up to the temperature limit of the cleaning agent solution as provided in the manufacturer's written IFU. This stage can be done using Utility water. Excessive hardness and/or TOC will interfere, since cleaning agents can be overloaded by either contaminant type. Excessive hardness can be offset by inclusion of ingredients intended to bind metal ions or compounds of calcium and magnesium in solution.

Intermediate Rinse #2: Rinsing after use of a cleaning agent removes the remaining soil left on the instruments from the previous cleaning steps. It should be done at the same temperature as the neutral wash to speed up heating in the final rinse/thermal disinfection stage.

D.2 Thermal disinfection

Final rinse/thermal disinfection: Critical water is required for the final rinse/thermal disinfection stage of cleaning to remove residual soil, cleaning agent, etc. and to avoid the risk of recontamination prior to HLD or sterilization. If suds are visible prior to the final rinse and thermal disinfection, a second intermediate rinse #2 with Utility Water may be needed. Lubricant is normally added to the final rinse water and the volume used should be the minimum recommended by the manufacturer's written IFU to be effective for the smooth operation of instruments, and not feel slippery to touch.

The steps described above are for automated cleaning. For manual cleaning, the sample principle applies. However, only the soak, enzymatic, and final rinse (without thermal disinfection) steps are utilized.

D.3 Steam sterilization

Steam (moist heat) sterilization is achieved by exposing the items to be sterilized with saturated steam under pressure.

In a health care facility, steam can be provided for steam sterilization in two ways. Often, where health care facilities use steam for heating purposes and other process supply, steam will be taken from this centralized system for sterilization purposes as well. Steam obtained by this source is called "Plant" or "House" steam. Since the medical device processing area could be some distance from the central steam supply, the steam may pass through an extensive distribution system before being received at the sterilizer.

An alternative steam supply can be generated in closer proximity to the sterilizer and this steam can be produced with a high purity water source. This method of steam supply is called either "Process" steam (steam created with Critical

Water as the steam feedwater) or "Clean/Pure" Steam (steam generated using a pure steam generator fed with water for injection).

Steam quality and purity both impact sterilizer performance. Normally, steam “purity” is reported as the solids content.

The physical characteristics of steam, defined as:

- steam dryness–the portion of steam that is saturated steam (water vapor) with the remainder assumed to be liquid water (steam condensate)

- superheat–a measure of excess energy contained in the steam compared to the energy expected for saturated steam

- non-condensable gas content–the amount of non-condensable gas in the steam expressed as volume percentage as 100 % x [V non-condensable gas / (V condensed steam – V non-condensable gas)]

Measuring either steam purity or quality requires careful sampling of steam to assure representative sampling of the steam and the steam must be condensed to a liquid condensate prior to analysis. Guidance on steam quality can be reviewed in detail in [8] and to find methods for sampling in EN 285.

Steam quality can be significantly impacted by the distribution system from the steam generator to the sterilizer. This is important to both plant and clean steam systems. Once steam is generated it immediately begins to cool as it is distributed to end users. As this cooling occurs, a portion of the steam begins to condense to form a liquid condensate. The condensate can be very aggressive to distribution piping and lead to corrosion. A properly designed steam system contains steam/water separation equipment to remove the naturally occurring condensate (e.g., steam traps). These devices are mechanical and require regular maintenance and inspection. If the steam/water separation equipment fails, it is possible for the steam and condensate mixture to be introduced to the sterilizer causing potential wet packs and/or staining of the load. Check the sterilizer manufacturer’s written IFU regarding the water quality/type that should be used to feed the steam generator.

Steam purity is, as stated above, measured relative to total dissolved solids content, and may also be reported in more detail per the requirements of Table 2 and Table 4. The issue at hand is the use of the correct terminology to describe the type of steam provided. There are three terms of art. These are:

- **clean steam:** defined by Parenteral Drug Association (PDA) and in USP 24 as steam generated using “a pure steam generator (PSG) when fed with water for injection.”;

- **process steam:** is typically produced in health care with a stainless steel boiler fed with Critical Water; carbon steel generators can be supplied with softened water. Refer to manufacturer’s written IFU for the appropriate quality of feedwater, and;

- **plant** or **house steam:** is produced in the typical manner found in health care settings using Utility water as the feedwater, with or without chemical treatment.

The steam purity decreases from top to bottom in this list. The steam purity needed is defined by the application (i.e., “is it good enough?”). In the case of a well-managed house steam system with proper engineering controls for steam delivery, house steam is good enough. Process steam is the next step up, which provides advantages in reducing the likelihood of staining. Clean steam is never found in health care applications, and compared to process steam, does not offer any advantages that would make it worth the effort to use.

The water supply to sterilizers may be used directly or indirectly in the sterilization process.

Steam sterilizers used in health care facilities fall into two general categories: table-top sterilizers and hospital sterilizers fixed installation sterilizers. Table-top steam sterilizers are used extensively in office-based practices and in specialty areas. Table-top steam sterilizers can have self-contained water reservoirs that recirculate the water from cycle to cycle within the sterilizer. Because recirculating water reservoirs can become contaminated, strict attention should be given to cleaning the reservoir and replacing the water supply. For table-top steam sterilizers that have nonrecirculating water

systems, a fixed number of cycles can be run before the reservoir water should be replaced. Users should carefully follow the sterilizer manufacturer's written IFU as chemicals in the supply water can adversely affect the materials from which the sterilizer is constructed. See also [6].

Fixed-installation systems are provided with integral steam generators or are connected directly to the building steam supply. Steam sterilizers with integral steam generators are usually connected to the building water supply system. The chemistry of the local water supply often varies seasonally. The local water supply is usually chemically treated by the local water authority, which should provide a complete water chemistry analysis on request. Compliance of the local water with the requirements for the steam generator should be verified at installation and reverified periodically over the life of the equipment.

Fixed-installation sterilizers connected directly to the facility's steam distribution system can be viewed as having a relatively large steam supply, but that steam supply is generated and maintained economically for purposes having little in common with steam sterilization conditions. The steam boilers in most hospitals are designed to efficiently generate high-temperature and high-pressure steam to serve heating, ventilation, and air-conditioning (HVAC) systems and laundry and food-service applications. Critical Water may be appropriate as feedwater for boilers used to supply sterilizers if the materials used in the boiler and sterilizer are compatible with the quality requirements ranges.

Critical Water should be used to rinse critical devices before sterilization to help reduce the amount of endotoxin on the sterilized device and to lessen the chance of a pyrogenic or other adverse patient reaction because sterilization methods are not effective at inactivating endotoxin.

Steam purity is affected by the quality of the feedwater. Pretreatment of the feedwater may be necessary to produce steam that does not cause deposition of residuals when used for steam sterilization of medical devices. As pointed out in a review of water for steam generation in steam sterilization [33], water used to generate saturated steam for steam sterilization needs to be closely monitored to ensure that ions, carbon dioxide, other gases, silicates, and conductivity are at or below prescribed levels. Although concerns have been raised regarding endotoxin in steam ([60], [68], [85]), studies by [52] and [92] have demonstrated that despite microbial contamination of the water used to generate steam, devices exposed to the steam and the steam condensate did not have significant endotoxin levels. Therefore, routine monitoring of endotoxin levels in water used to generate steam is not warranted. Additional information on treatment of incoming water is provided in Annex E.

Noncondensable gasses (NCGs), defined as gasses that cannot be liquified by compression under the conditions of temperature and pressure used during the sterilization process. They can be simplistically described as air in a steam supply. Low levels of NCGs contained in the steam supply to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process and lead to inconsistencies in the performance of the sterilizer and Bowie-Dick test results. High levels of NCGs contained in the steam supply to sterilizers can result in unsterile loads.

Annex E
(informative)

Water treatment technologies

E.1 Introduction

If water characteristics do not meet the requirements specified in Table 2, the water can be treated by various technologies to provide an enhanced quality suitable for a given stage of device processing. The treatment of water to reduce or control the microbial load (bioburden) is intended to reduce the risk that the medical device:

a) does not acquire extraneous viable and non-viable microorganisms, and endotoxin in excessive quantities before disinfection or sterilization; and

NOTE Low bioburden helps ensure the effectiveness of disinfection and sterilization processes.

b) is not contaminated by viable microorganisms if a final rinse is required after the high-level disinfection or sterilization process.

The treatment of water to modify its inorganic and organic content is intended to:

a) prevent damage to the medical device (e.g., corrosion, salt deposits, materials degradation);

b) prevent inactivation of cleaning agents, disinfectants, and sterilants that require dilution; and

c) remove organic molecules that could cause pyrogenic reactions or other adverse effects in patients or damage the instruments or their usability.

In general, the water treatment process should be effective, reliable, and economical. The design of the water treatment system should take into account the desired quality of the water; the characteristics of the incoming water; and the volume, flow rate, and frequency of use. Importantly, no water treatment system will work for long without proper scheduled monitoring and maintenance, which requires cooperation and efficient communication between device processing personnel and water maintenance personnel. Categories of water quality are defined in Section 6 with appropriate levels for the quality of water for the stages of medical device processing.

E.2 Water treatment technologies

Individual water treatment technologies are designed to perform a specific task (e.g., a water softener is designed to remove scale forming ions). In some instances, technologies are substitutes or alternatives for one another (e.g., a water softener vs antiscalant chemicals). In other instances, these technologies are capable of performing multiple tasks (e.g., Reverse osmosis (RO) is designed to remove dissolved organic and inorganic contaminants, as well as filter out microorganisms). Depending on the quality of the tap water being fed to the water treatment system and the desired quality of water to be produced, these technologies can be used as the sole means of water treatment. In other cases, these technologies will be utilized together in a configured system. When used together, the technologies are typically arranged in succession, with the downstream technology improving the water quality produced by the upstream technology – or technologies – preceding it. Some examples of water treatment technologies, equipment, and their function are described in the following subsections.

NOTE Not all water treatment systems are configured in the same way. The specific, local circumstances such as feedwater quality, volume of water to be treated, space constraints, environmental considerations, quality of water to be produced, etc. will dictate which water treatment technologies are best to use and in what combination. This will also inform which technologies are not well suited, or in some cases, not necessary.

E.2.1 Sediment filters

Permanent, back-washable sediment filters (also known as bed filters or media filters) are located at or near the beginning of the water treatment system and are intended to remove suspended particulate materials from incoming water. Although a single filtration medium may be used, bed filters known as multimedia filters are more commonly selected. These units contain multiple layers, each layer retaining progressively smaller particles. In this way, the bed is used to its fullest extent: the largest particles are removed in the first layer contacted by the water, and the smallest particles in the final layer.

As the bed accumulates particulate material, open passages begin to clog and resistance to flow through the filter increases. Ultimately, the increased resistance to flow will lead to a reduction in water supply to downstream components. So that this situation does not arise, bed filters are cleaned by periodic backwashing, which is accomplished either manually or by means of a timer-actuated control valve. Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet. These values can be used to determine the dynamic pressure drop across the filter (delta pressure, or ΔP), which serves as an index of resistance to flow and provides a basis for setting the frequency of backwashing.

E.2.2 Greensand filters

Greensand filters are used to treat feedwater that contains excessively high levels of iron and/or manganese. The media is able to oxidize manganese and iron present in the water upon contact due to the formulated filtration media, made from a naturally mined material, glauconite, coated with manganese oxide.

E.2.3 Bag filters

Bag filters are designed to remove larger, relatively coarse suspended particulate matter from incoming water, often where the municipal supply connects to the building's internal piping infrastructure. The filters are often designed to handle high flowrates and volumes of water to be treated. Water containing suspended particles passes through the filter material from the inside out, trapping the particles inside the bag. A bag filter normally has a connection for a high-pressure inlet on the top and the filtered water exits at the sides and bottom. A metal or plastic housing holds the bag in place during operation.

E.2.4 Filter cartridges

Filter cartridges consist of a cylindrical cartridge of the filter medium with a central drainage core. The cartridge is contained within a filter housing with seals to separate the incoming water and filtered water streams. Although cartridge filters may be installed at the inlet to a water system, their usual application is as a final filtration step prior to RO or final filtration as microbial control in the water system distribution loop. These final filters have a 0.2 microns absolute rating or smaller and validated for bacterial and endotoxin removal and designed per ASTM F838-15a [16], a concentration of at least 10^7 CFU/cm^2 of effective filtration area (EFA), for bacterial retention and are constructed of a specialized material (e.g., positively charged) for endotoxin retention.

E.2.5 Softeners

Water containing calcium or magnesium can form relatively hard deposits and is termed hard water. Water passed through a softener will exchange the calcium and magnesium ions with sodium ions and yield soft water. Softeners will also remove other polyvalent cations, most notably iron and manganese, although they are somewhat limited in this regard. Softeners in water systems are used to minimize hard-water deposits and can be used as an option to prevent damaging sensitive RO membranes and to prevent calcium deposition on reprocessing equipment or devices.

The basic construction of a softener is a cylinder or vessel housing a volume of insoluble spheres or beads, termed resin, attached to which are sodium ions. During operation, the supply of exchangeable sodium ions is progressively reduced, being replaced by calcium and magnesium ions. When all sodium ions have been used, the resin bed has reached a condition referred to as exhaustion. Softeners should be restored before they reach exhaustion; that is, new exchangeable sodium ions are placed on the resin by a process known as regeneration.

Automatically regenerated softeners also include brine tanks, from which saturated sodium chloride solution is drawn during regeneration; a control valve regulates regeneration and service cycles.

E.2.6 Antiscalent

Antiscalants, also known as scale inhibitors, are chemicals added to the feedwater of a water treatment system to minimize the potential for scale deposits to form on the surface of reverse osmosis membranes. The presence of anitscalents inhibits the reaction between calcium, magnesium, and bicarbonate which allows these minerals, and the antiscalant chemical, to be rejected by the reverse osmosis process and discharged down the drain via in the reverse osmosis system's waste stream.

E.2.7 pH adjusting chemicals

If water characteristics do not meet the requirements specified in Table 2, the water can be treated by various technologies to be more suitable for a given stage of device processing.

E.2.8 Granular activated carbon adsorption

Activated carbon is commonly used as pretreatment to reverse osmosis units and deionization equipment. Reactivated carbon should not be used for medical processing applications. Granular activated carbon (GAC) is a principal means of removing both free chlorine and chloramines, as well as certain organic compounds from feedwater. Granular activated carbon is produced by roasting charcoal from coconut shells or coal at very high temperatures. The activation process significantly enhances the surface area of the carbon due to the creation of tiny pores throughout the media volume. Organic compounds are adsorbed into the pores of the carbon matrix and retained through ionic, polar, and Van der Waals forces. The surface of activated carbon reduces free chlorine to chloride and carbon dioxide, while chloramines are catalytically reduced to ammonia, nitrogen, and chloride. The large surface area of the activated carbon enables significant quantities of organic material to adsorb through ionic, polar and Van der Waals forces.

E.2.9 Sulfite salts

Sulfite salts (e.g., sodium sulfite, sodium bisulfite, sodium metabisulfite) are dry chemicals which, when dissolved in solution, react with both free and combined forms of chlorine to remove these compounds from the feedwater.

E.2.10 Reverse osmosis

Reverse Osmosis is a filtration technology which utilizes high pressures and specialized, semi-permeable membranes wound in a series of layers in a spiral to remove, to a high degree, a wide range of impurities from water including ionic contamination, organic compounds, bacteria, and endotoxin.

In the process of reverse osmosis, the RO membrane under pressure has water fed in a cross-flow manner. Typically, 50-75 % of feedwater passes through the membrane as permeate (i.e., product water) and the rest exits via a concentrate (concentrated waste) stream that contains the salts, organics and particulate matter rejected by the membranes.

RO membranes are typically made out of a thin polyamide film and are stable over a wide pH range, however, they can be damaged by oxidizing agents such as chlorine and fouled by organics or colloids. Pretreatment, such as granular activated carbon (GAC), is usually required to protect the membrane. When well-maintained, an RO unit can reject approximately 95 to 97 % of inorganic, organic, and microorganism contamination. However, it should be noted that reverse osmosis is not well suited for removing dissolved gases in water, as these gases pass through the pores of the RO membranes.

RO systems have become widely used in medical device water purification systems, in large part because of the ability of these systems to remove dissolved inorganic solutes, bacteria, and bacterial endotoxin.

E.2.11 Deionization

Deionization (DI) is an ion exchange process that removes both anions (negatively charged ions) and cations (positively charged ions) from water. During the exchange process, hydroxide ions replace other incoming water anions and hydrogen ions replace other incoming water cations; the hydroxyl and hydrogen ions then combine to form treated water. DI treatment is very effective at removing ionized contaminants, but has no capability for removal of non-ionized substances (e.g., bacteria and endotoxin). DI systems may contain anion and cation resin in separate vessels, known

as dual-bed systems; or they may have both resin types mixed together in a single vessel, known as mixed-bed or unibed systems.

Systems that include DI as a component should also contain carbon adsorption and ultrafiltration. In such systems, carbon is placed upstream of the deionizer to remove free chlorine and chloramines that are damaging to ion exchange resin, and ultrafiltration is placed downstream of the deionizer to remove bacteria and endotoxin that may originate in the DI resin bed. The usual application for DI is as a polisher to RO or as a standby process for use in the event of RO system failure. Use of DI as the primary means of purification is not recommended because of the inability of DI and ultrafiltration to remove certain low-molecular weight or toxic bacterial products.

DI has a finite ion exchange capacity that, when exhausted, will require regeneration of the resin. This is commonly done through the use of portable exchange tanks that water treatment companies provide as a service. Prior to exhaustion, tanks are taken away to a regeneration facility and replaced with freshly regenerated tanks. Water quality meters are used to monitor water quality and will signal when the ion exchange resin has exhausted.

E.2.12 Electrodeionization

Electrodeionization (EDI), also referred to as Continuous Electrodeionization (CEDI) and Continuous Deionization (CDI), is a water treatment process that uses a combination of ion-exchange resins, ion-exchange membranes and direct current to continuously deionize water without the need for chemicals.

EDI modules consist of a set of chambers filled with ion exchange resins and separated by ion-exchange membranes. As water enters the EDI module an electrical field is applied to force ions to flow through the resins and across the membranes. Ions are not permanently bound to the media but instead are collected into concentrate streams which can be directed to drain or recycled. The deionized water can be used directly or undergo further treatment for enhanced water purity.

It is important that the ionic contaminant levels in the feedwater to EDI systems are closely monitored to avoid overloading the module. For this reason, EDI is commonly used as a downstream “polishing” technology after RO. EDI systems are also highly susceptible to chlorine oxidation, so it is important that the feedwater be dechlorinated.

E.2.13 Ultraviolet (UV) disinfection

A UV disinfector typically consists of a UV lamp mounted in a quartz tube contained within a stainless steel tube. As water flows through the area between the quartz and stainless steel tubes, the water, bacteria and any other microorganisms contained within is irradiated. The microorganisms’ DNA and RNA polymerase are damaged by the absorbed electromagnetic radiation, which inhibits replication and provides a very effective means of microbial control. UV however can create a by-product of endotoxin and must be followed by a 0.2 micron charged membrane absolute rated filter.

E.2.14 Ultrafiltration

Ultrafilters are membrane-based separation devices that can be used to remove particles as small as 1,000 daltons (e.g., bacteria and endotoxin); thus, ultrafilters are well suited to remove both bacteria and endotoxin. Ultrafilters should be placed in water systems at locations downstream of deionization, if DI is the last process in a water treatment system or following ultraviolet irradiation.

Ultrafiltration membranes used for processing applications are typically constructed in either a spiral-wound (“jellyroll”) configuration or in a hollow-fiber configuration. Spiral-wound ultrafilters are usually operated in a cross-flow mode, with a fraction of the feedwater being forced through the membrane and the remainder being directed along the membrane surface to drain. As with RO, cross-flow filtration is intended to minimize membrane fouling. Hollow-fiber ultrafilters are typically housed in vessels similar to those used for cartridge sediment filters are operated in a dead-end (not cross-flow) mode. In the case of hollowfiber ultrafilters, they should be constructed of a positively charged material for endotoxin retention.

E.2.15 Distillation

Distillation is the oldest and simplest method of purifying water. The process is most beneficial in removing dissolved inorganic compounds, bacteria, bacterial endotoxin, viruses, and cysts. In a distillation process, membrane

breakthrough or other mechanical failures that could cause bacteria or endotoxin to be present in the water are not of concern.

Distillation involves heating water to the boiling point (100 °C /212 °F) in a vessel (still) and converting the water into steam. The steam passes into a condenser, where it is cooled (condenses) back into the liquid phase (distillate) and collected in a reservoir. Inorganic salts, bacteria, viruses, and high-boiling organics remain behind in the still. Batch-type stills require manual filling; in automated stills, fresh water is added continuously. A portion of the water in an automated still is continuously sent to drain to help reduce mineral deposits. Pretreatment of incoming water is sometimes necessary to reduce system maintenance and to improve the quality of the distillate. Pretreatment can include passing the water through a mixed-bed DI cartridge (which removes hard-water components), a carbon filter (which removes dissolved organics), or both. Stills are typically constructed of stainless steel, tin-coated copper-brass, aluminum, and glass.

All distillation units require descaling and removal of precipitated solids in order to maintain equipment efficiency. The frequency of these procedures depends on the hardness of the feedwater and on whether pretreatment is used. Acidic chemicals are used to dissolve the scale without damaging the still and its heating elements.

Distilled water is typically stored before use. Storage guidelines should be followed to ensure that the water is not recontaminated (see Annex C).

Table G.2 describes substances found in untreated water, processes of removal, and elements of water treatment and distribution systems known to increase concentrations.

E.2.16 Ozone disinfection

Ozone is a naturally occurring substance and a very powerful oxidizing agent, readily removing organic and microorganism contaminants in water. Ozone is a molecular compound consisting of three oxygen atoms (O_3), two of which form the basic oxygen molecule (O_2) and a third oxygen atom, often referred to as a free radical, which easily detaches from the ozone compound and reattaches to other molecules, breaking down their structure and destroying them.

Ozonation of water is performed using a machine called an ozone generator. There are several styles of ozone generators, each using a slightly different method to produce ozone; however, the end product is the same. As the ozonated air is injected into the water stream, typically at a concentration of 0.2 to 0.5 mg/L, for a contact time of 10-minutes, biological contaminants within the water will become oxidized and destroyed. Destruction of established biofilm could require a longer exposure time or a higher concentration of ozone.

E.2.17 Hot-water disinfection

Hot water may be used to control bacterial proliferation in water storage and distribution systems. For effective bacterial control, water temperatures and exposure times in the range 80 °C to 90 °C (176 °F to 194 °F) and 10- to 30-minutes are used.

NOTE Water should be cooled to room temperature before use.

Hot-water disinfection systems can be used only in systems constructed from heat-resistant materials, such as crosslinked polyethylene and stainless steel.

E.2.18 Chemical disinfection

Chemical additives can also be used to control bacterial proliferation in water treatment systems. Examples of commonly used chemicals are chlorine, sodium hypochlorite, hydrogen peroxide, and peracetic acid. Some chemicals added to a water system could degrade materials, so the effect of a chemical on the system should be evaluated before it is used. For optimum effectiveness, some chemical disinfectants require an upper pH limit lower than what is allowable in Table 2. The pH of the water should be controlled for the effective performance of the chemical that is used for disinfection.

Table E.1—Summary of water treatment methods

Water treatment system component options		What it does		Location in water treatment system		Design considerations	
		Removes	*Adds*	*Place before*	*Place after*	*Advantages*	*Disadvantages*
Pretreatment	**Green sand depth filter**	Iron and manganese by oxidation and filters out the precipitates:	n/a	Initial water treatment step	Tap water sources	Prevents iron and manganese from precipitating on softener and DI resins and inactivating them	
	Water softener	Magnesium Calcium Barium Strontium	Sodium	Coarse filter Carbon or bisulfite	Tap water sources	Prevents hard water scaling and deposits from forming on the equipment and reprocessed device	Need for monitoring and replacement Sheds particles
	Submicron filter[1]	Particles >0.2, 0.2, or 0.5µm	n/a		DI Any water treatment component that can generate bacteria		May shed particles
	pH adjustment	Aids removal of dissolved carbon dioxide by converting carbon dioxide to carbonate that RO can exclude Aids removal of colloids	Acid or base (usually NaOH)	RO	Softener		
	Activated carbon[2]	Chlorine Chloramines Organics	Carbon fines and Bacterial endotoxin (normally removed by submicron filtration following the carbon filter)	Softener (for high organics in incoming water; reduces ability of carbon to remove TOC) RO DI	Softener (keeping chlorine in during softening helps control microorganisms)	Protects RO and distillation from fouling organics. It does not remove hard-water deposits. Protects RO membranes and DI resins of degradation by chlorine	Supports bacterial growth, which increases endotoxin levels, and may cause fouling of filters and RO membranes. If chloramine is used instead of hypochlorite, can react to create amines, which are hard to remove; requires strong cation exchanger
	Metabisulfite injection	Chlorine Chloramines	Metabisulfite	RO DI	Softener pH adjustment	Neutralizes chlorine Bacteria growth problems less likely	
Purification	**Reverse osmosis (RO)**	Anions, cations, colloidal silica Bacteria Endotoxin Colloids Organics		Storage tank	Softener Chlorine removal pH adjustment to 8-8.5 to reduce carbon dioxide to bicarbonate Coarse and submicron filters	Reliability	Rate of production Storage tank may be needed Capital cost Maintenance Resistivity not as high as DI
	Deionization (DI)[3,4]	Anions, cations Retards silicon Strong base deionizer can remove silica	Some bacteria and bead fines	Final purification process or ultrafilter	Chlorine removal Coarse filter	Rate of production Efficiency of ion removal High resistivity	Potential for silicon breakthrough Potential to magnify fluoride if resin becomes overloaded Microbial growth Endotoxin generation due to bacterial growth Need to exchange or regenerate resins
	Cation exchange resin	Cations	Some bacteria and bead fines	Final purification processes or ultrafilter	Chlorine removal	Rate of production Efficiency of ion removal	
	Anion exchange resin	Anions, cations Retards silicon Strong base deionizer can remove silica	Some bacteria and bead fines	Final purification process or ultrafilter	Chlorine removal	Rate of production Efficiency of ion removal High resistivity	Reacts with chlorine to produce trimethylamines
	Distillation	Anions, cations Bacteria	n/a	Storage tank	Softener	Simple operation	Rate of production low for the dollar cost Energy input high

Water treatment system component options		What it does		Location in water treatment system		Design considerations	
		Removes	*Adds*	*Place before*	*Place after*	*Advantages*	*Disadvantages*
		Endotoxin Organics					
	Ultrafiltration	Anything larger than the molecular weight cutoff of the membrane	n/a		All other purification needs (where needed to remove bacteria and endotoxin)	Bacteria and endotoxin removal	Cost Can mask upstream purification problems Microbial breakthrough
Distribution	**UV**	Kills bacteria	Inactivated bacteria becomes endotoxin	Used following a component that has high bacterial counts			Must be followed by an ultrafilter due to endotoxin generation
Distribution	**Ozone**	Kills bacteria			Used to disinfect the water system during routine disinfection steps	Very effective antimicrobial	Must monitor ambient levels
Distribution	**Steam/hot water**	Kills bacteria			Used to disinfect the water system during routine disinfection steps	If designed into the water system, a very easy-to-use method of disinfecting the distribution loop	
Distribution	**Chemical disinfection**	Kills bacteria			Used to disinfect the water system during routine disinfection steps		Requires rinsing of the distribution system prior to use

NOTE 1 Submicron filters may not be absolute bacteria filters (they must be rated and validated as absolute); if not, they can only be relied on to reduce bacteria levels.

NOTE 2 Carbon tanks should be designed for backwashing and/or hot water disinfection.

NOTE 3 Deionization without RO or distillation is unreliable for endotoxin removal or must rely on careful monitoring of ultrafilters.

NOTE 4 Deionization is not recommended after RO for cleaning of medical devices. Extremely high resistivity is not critical for these applications, and DI reintroduces microbial and endotoxin contamination to the RO water.

Annex F
(informative)

Water treatment system design

F.1 Water treatment system design

A wide range of treatment can be used to modify the chemical, biochemical, and microbial content of water during water treatment, delivery, or storage. Table E.1 provides a summary of water treatments, identifying the purpose, placement, advantages, and disadvantages of each. All the water treatment processes listed in Table E.1 require ongoing maintenance and periodic testing to verify proper water quality. Water quality is the result of one water treatment process or a combination of multiple water treatment processes. It is important to ensure that if the overall water treatment process includes a method that removes chlorine from the water (e.g., an activated carbon water treatment process), the overall process includes other stages that will reduce microbial proliferation because water without chlorine provides an excellent opportunity for microbial replication.

Some health care facilities have central water treatment facilities to provide water for various hospital areas. Access to this type of water source in the processing area could be a practical and cost-effective way to provide water for certain stages in medical device processing. Alternatively, local point-of-use (POU) water treatment units can be installed in the processing area. If water is provided from a central facility, it is important that the water quality available at the POU be monitored to ensure that after transit through the distribution network, the water still meets the necessary specifications. Water testing at the POU also ensures that the distribution system does not become contaminated, which could ultimately create problems in the central treatment facility. Combinations of hospital-produced water and POU water may also be used. In some cases, a health care facility might soften the entire water supply; however, additional water treatment may be needed to produce Utility Water and almost certainly to produce Critical Water.

F.1.1 General design considerations

Not all water systems are configured in the same manner. Depending on the quality of the local feedwater supply and other site-specific factors such as space constraints, environmental considerations, operational expense, etc., some of the technologies listed above may or may not be used in the water system design.

A trained water treatment design professional, with knowledge of the local feedwater conditions, should be involved in the configuration of an appropriately configured system

Water treatment systems designed to produce Critical Water should be designed in a manner that inhibits the proliferation of microorganisms. This includes the use of technologies designed to control microorganisms (i.e., UV light, submicron filtration, positively charged filters, RO, ultrafiltration), minimization of stagnant areas, like dead legs, within the distribution loop, continuous recirculation, and periodic cleaning and disinfection of water treatment equipment and distribution piping using disinfectants.

Consideration should be given to the expected actual volume of water consumption during normal operational use of reprocessing equipment, not just the calculated maximum capacities according to the equipment's manufacturer's literature. This water volume usage assessment should account for instantaneous demand (e.g., multiple washer-disinfectors operating at the same time), as well as total per shift and per day water consumption values. This will help optimize the sizing of the water treatment system and avoid it becoming over-designed and larger than necessary. This well also aid in ensuring minimum flow velocities in the distribution loop are met to inhibit or reduce the formation of biofilm and proliferation of microorganisms.

Adequate space should be provided for the water treatment system to ensure it can be appropriately and safely monitored and serviced, as well as adhere to local plumbing and electrical codes.

F.2 Typical water system configurations

F.2.1 Water systems designed to produce Utility Water

Utility Water is water that comes from the tap that may require further treatment to achieve the specifications in Table 2. This water is mainly used for flushing, washing, and rinsing between cleaning and disinfection/sterilization. Water systems designed to produce Utility Water are focused on removing or significantly reducing dissolved inorganic contaminants, especially those that contribute to an increased level of hardness and alkalinity of the tap water, as well as affecting pH. The primary objective of water systems designed to produce Utility Water is the prevention of scale formation as well as interference with cleaning chemistries.

EXAMPLE: Typically, water systems designed to produce Utility Water consist of particulate filtration and some form of softening (e.g., water softener). De-chlorination (typically carbon filtration) may also be used to prevent oxidation of the ion exchange resin contained within a water softener. Other technologies, such as RO, may be utilized for feedwaters where the inorganic levels are higher, or in areas where regenerating water softeners are not allowed or ill-suited unless used after chemical high-level disinfection as a final rinse, bacteria and endotoxin limits are not specified for Utility Water (see Table 2), continuous recirculation of Utility Water is not generally required, nor are downstream microbial control technologies such as ultraviolet (UV) disinfection and/or sub-micron filtration or ultrafiltration.

Figure F.1 is an example of a general water treatment process for incoming water to produce water that is acceptable for use in medical device processing.

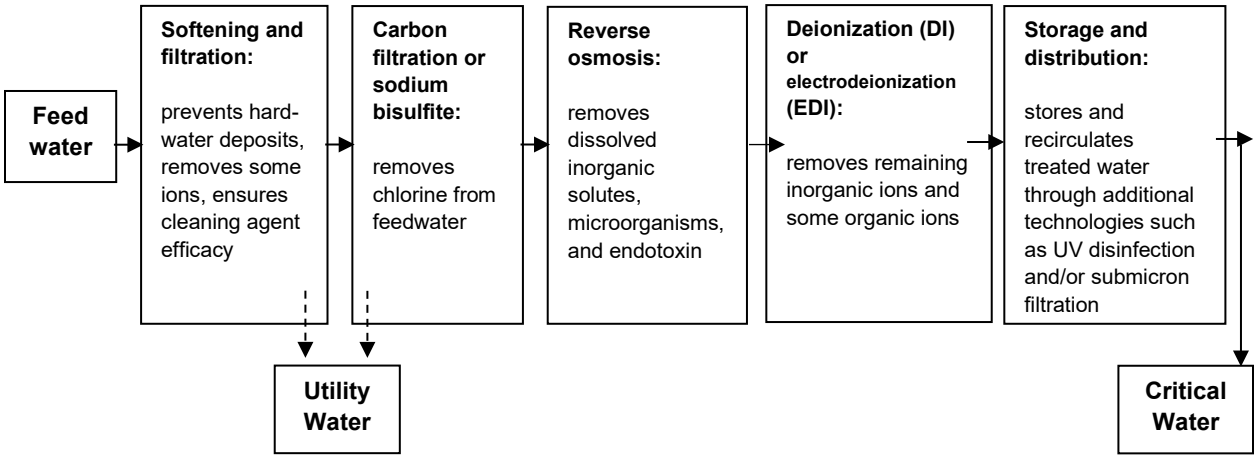


Figure F.1—Example process flow diagram (PFD)

NOTE Actual configuration may vary depending on local feedwater quality, site-specific conditions, and any applicable regulatory restrictions. Water treated according to the above example may or may not meet the criteria spelled out in Table 2 (See Annex E). See Annex E.

F.2.2 Water systems designed to produce Critical Water

Critical Water is water that is extensively treated to ensure that microorganisms and inorganic and organic materials are removed from the water. Critical Water is mainly used for the final rinse after high-level disinfection and/or for critical devices prior to sterilization. Critical Water may also be used to feed sterilizers with on-board steam generators.

- Water systems designed to produce Critical Water typically consist of three aspects:
  - Pretreatment (particulate filtration, softener or antiscalant system, carbon filter or sodium bisulfite system);
  - Primary treatment;
  - Storage and distribution.

The purpose of pretreatment is to protect the main treatment components from harmful substances. Whether certain pretreatment steps are needed and the order in which these steps should be performed depend on the characteristics of the incoming tap water and on the principal treatment process that will be used. For example:

a) If the incoming tap water contains high levels of iron or manganese, these ions can precipitate on the resin beads in softener or DI beds, reducing bed capacities; consequently, filtration through green sand might be necessary. If the incoming tap water has low iron and manganese content, green sand filtration might not be necessary for the water quality identified for the application.

b) Softening before chlorine removal helps protect the softened water from microbial growth. However, chlorine degrades softener beads, reducing capacity. If the incoming tap water has high chlorine levels and the process depends largely on activated carbon to remove it, it might be advantageous to place the activated carbon before the softener. If the incoming water does not have high chlorine, it might be preferable to place the softener before the activated carbon to attain more microbiological protection of the softened water.

For example, most RO membranes cannot withstand chlorine or chloramines so these chemicals must be removed before the water enters the RO unit. Pretreatment also prevents certain substances from plugging the RO or other filters.

F.2.2.1 Primary treatment equipment

Primary treatment equipment can include RO, DI, EDI, and distillation. RO removes most ionic species from the water. RO also removes microorganisms, endotoxin, 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 deionization. RO does produce treated water relatively slowly, so a storage tank may be needed. The capital costs are considerably higher for RO than for DI, but the system does not require the frequent resin exchange or regeneration that the DI process does require, unless deionization polishing is required downstream. RO systems should be regularly tested and disinfected to minimize bacterial growth.

Deionization can produce a large volume of water on demand and has a relatively low initial capital cost; however, DI resins should be periodically regenerated or replaced. In some cases, DI tanks are provided by a vendor and replaced by that vendor when the resistivity reaches a certain level. Resistivity monitors should be used with DI tanks to continuously monitor water quality. Deionization removes both positively and negatively charged ions very effectively. Of the three most common treatment processes (DI, RO, and distillation), deionization produces water with the highest resistivity (i.e., lowest conductivity). Resistivity of water increases in proportion to the removal of ions, so high resistivity indicates that there has been effective removal of ions. Deionization does not effectively remove noncharged or weakly charged species, such as some organic compounds and silica, nor does it remove microorganisms or endotoxin. 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 are needed after DI to ensure the microbiological quality of the water produced which can include molecular filtration treatments that remove pyrogenic molecules, submicron filters that remove microorganisms, or ultrafilters.

Distillation relies on the vaporization and condensation of water to remove dissolved and suspended substances. Distillation effectively removes microorganisms, endotoxin, organic compounds, and colloids. Various styles of stills are available. This water treatment method generally requires more energy to operate than RO or DI. Treated 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, soft or deionized water is used to feed a distillation unit to keep the amount of scaling to a minimum.

Alternative water treatment processes, such as RO/DI, with proper preventative maintenance, can remove microorganisms as well as inorganic components. Proper maintenance of an RO distribution system is critical as the distribution network can become contaminated with microorganisms and subsequently develop biofilm on the inner surfaces of the piping.

F.2.2.2 Storage tanks, distribution equipment, and piping

Systems may include storage tanks, distribution piping and pumps, and bacterial and endotoxin controls.

F.2.2.2.1 Storage

Due to the relatively slow generation of water from primary treatment such as RO, it is common to have a storage tank to hold the water produced by the RO. Storage tanks accommodate peak demands and production expansion but require a vent and microbial retentive air filter due to rising and lowering water levels. Water in a storage tank is in an environment exposed to atmospheric gases as well as a standing or minimally circulating situation. If this water is subsequently used to generate steam, the return line should be below the water line to avoid aerating the water and increasing the likelihood of adding non-condensable gasses into the water creating high non-condensable gas levels in the steam. The addition of non-condensable gases can cause noncompliance with the requirements of AAMI ST79:2017 Section 3.3.3.2 [8] and potentially cause Bowie-Dick test or sterilization failures.

When used, storage tanks should have a conical or bowl-shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2 µm air filter. The filter should be changed on a regular schedule according to the manufacturer's written IFU. A means should be provided to effectively disinfect any storage tank installed in a water distribution system. Internal spray mechanisms can facilitate disinfection and rinsing of a storage tank.

Water storage tanks for water produced should be monitored for bacteria levels and endotoxin levels (see Annex G.4).

The system should have a fully drainable, properly sized storage tank to provide needed water storage as defined by the end user. If a specific volume is not known, it is suggested that the storage tank be sized to hold at least 1 to 2 hours of water. Care must be made to not undersize but at the same time not to oversize the storage tank. Systems should have the ability to divert water to drain when water quality falls outside of the defined parameters. Systems should also include a means of notifying end users when this occurs.

F.2.2.2.2 Distribution system

The function of the water distribution system is to distribute water from the purification system to its points of use. This Annex provides detailed information on the construction of storage devices, distribution systems, and bacterial control devices. As chlorine is often removed in the purification process, it is a critical consideration in system design and bacterial control measures.

After water has been treated, it is necessary to maintain the water quality and prevent microbial contamination and growth. Water should be distributed using a loop through which the water flows and returns to its starting point. Maintenance of water quality is generally accomplished by routine disinfection of the distribution loop and continuous recirculation of the water through the distribution system.

F.2.2.2.3 Distribution piping

Distribution piping should be constructed of material compatible with high purity water, typically Schedule 80 PVC, polypropylene, or high-density polyethylene. Stainless steel pipe is not commonly used in water treatment system design for medical device processing applications except for steam lines. There should be no dead-legs (i.e., piping that is more than 3-5 times as long as its internal diameter and that does not have constant water flow). Dead-legs in the pipework should be minimized through appropriate design, and as a guide should not significantly exceed three times the branch diameter as measured from the ID pipe wall to center line of the point-of-use valve where significant stagnation potential exists. The number of threaded or glued socket joints with gaps should be minimized because they create entrapment areas for microbial growth. A constant water flow of more than three feet per second (3 to 5FPS is the desired range of return velocity) will minimize the formation of biofilm on the piping. A fully recirculating loop is required to ensure continuous flow of water and the return velocity to the water treatment system origin or storage tank should be monitored with a flow meter to determine 3 to 5 FPS under a full load of water usage. Providing a slight slope to the water distribution system will enhance water quality by enabling the water to drain out without pooling, minimizing the formation of biofilm caused by improper drainage. Water flowing through the distribution system can be disinfected

by UV treatment. The distribution pipes can be disinfected with hot water, ozone, or various chemical additives, (e.g., sodium hypochlorite (bleach), hydrogen peroxide, or peracetic acid).

NOTE Treatment agents should be used with caution. For example, those chemical disinfectants containing chlorine might not be compatible with materials and filters within the distribution system and, consequently, could cause premature degradation. It has been demonstrated that residual chlorine is extremely difficult to neutralize and remove from a water system. Therefore, it is recommended that prior to use, all sanitizers and disinfectants used on water distribution systems should be evaluated for material compatibility.

F.2.2.2.4 Distribution pumps

Distribution pumps should be designed to meet the needs of the water systems under full demand while routinely ensuring enough flow through the loop to maintain 3 to 5 FPS on the loop return. The loop return should have a flow meter to be able to determine the return velocity rate. Variable frequency drive (VFD) pumps are favored, when possible, to ramp up and down to maintain adequate flows.

F.2.2.2.5 Bacterial and endotoxin controls

Several devices or methods are available to help control the proliferation of bacteria and endotoxin in the distribution loop. These devices become more important when the chlorine has been removed from the water system.

A UV light is recommended for most applications to help control bacteria; however, this may not be needed in every case if the system is properly disinfected on a monthly schedule and routinely the bacteria testing results come back below 10 CFU.

Every system must have a properly sized final loop filter of ≤0.2 micron or tighter/smaller (absolute rated, not nominal rated), with endotoxin removal capabilities necessary to achieve endotoxin specification as defined in Table 2. This filter should be located at the point of connection to the loop supply and sized to meet or reasonably exceed the intended flow rate of the loop.

The system should be thoroughly labeled to indicate the system flow for treated, untreated, and drain piping and the system should have a Piping and Instrumentation Diagram (PI&D) that matches the actual installation.

Ozone can be used to control bacterial proliferation in water storage and distribution systems. Ozone can degrade many plastic materials, including polyvinylchloride and elastomeric o-rings and seals. Therefore, ozone should only be used for bacterial control in systems constructed from ozone-resistant materials or at a frequency that will not induce damage in less ozone-tolerant materials.

Hot water may be used to control bacterial proliferation in water storage and distribution systems. For effective bacterial control, use water temperatures and exposure times in the range 80 °C to 90 °C (176 °F to 194 °F) and 10- to 30-minutes. Hot-water disinfection systems can be used only in systems constructed from heat-resistant materials, such as crosslinked polyethylene and stainless steel.

NOTE The water system should be allowed to cool to room temperature before use.

Chemical additives can also be used to control bacterial proliferation in water storage and distribution systems. These methods are not the only acceptable methods. Other chemicals may be used to remove suspended solids, to remove chlorine compounds, to adjust pH, and to remove carbonate compounds. Subsequent processing steps might be required to remove the added chemicals.

Chemicals added to a water system could degrade materials. The effect of a chemical on the system should be evaluated before it is used. The water system should be designed to control and monitor the chemical additives and their reaction products to ensure removal. The water system monitoring program should address the chemical additives and their reaction products.

NOTE The water system configuration may vary depending on local feedwater quality, site-specific conditions, and any applicable regulatory restrictions.

F.3 Questions that users should ask when selecting a water treatment system

When selecting a water treatment system, the multidisciplinary team should ask the following:

Does the facility know the following characteristics about the municipal water supply?

- Yearly chemical fluctuations of the municipal supply.
- Yearly microbial levels.
- Yearly organic and inorganic contaminants and levels.
- Municipal water treatment process and has it prospectively monitored to verify the quality.
- Yearly temperature range.

Other considerations:

- Piping was selected based on the disinfectant.
- Water quality requirements for each piece of processing equipment/system has been met.
- Water quality requirements for each medical device to be processed has been met.
- Water quality can be monitored for each processing step and/or equipment.
- Audits are regularly conducted to provide current data and status of water quality.
- Designation of an individual tasked with ensuring water quality based on audit data.
- Water system has been evaluated for maximum expansion ability.
- Establishment of a written plan with criteria which requires the water treatment plan to shut down, and the process to bring the system back to normal operation.

Annex G
(informative)

Routine monitoring of water treatment equipment & produced water quality

G.1 Overview of monitoring needs

G.1.1 Equipment monitoring

To ensure effective performance of the water treatment system, and to avoid unnecessary equipment failures or system shutdowns, all water treatment components should be monitored for proper functionality on a regular basis. Table G.1, Table G.2, and Table G.3 list examples of specific water treatment equipment to be monitored and what parameters to be monitored.

G.1.2 Monitoring water quality produced

It is also important to monitor the water quality being produced by the water treatment systems on a regular basis. While water quality testing can be performed after each treatment technology, this is time consuming and is typically only done when trouble shooting the water treatment system or a particular piece of water treatment equipment. The focus of this annex is on the monitoring of the final quality of the water produced by the water treatment system after the last treatment step – for both Utility Water and Critical Water systems. Table G.2 and Table G.3 lists the quality measurement, type of testing, sampling site, and minimum frequency.

Note that the examples of acceptable methods provided is not an exhaustive list. Table G.3 can be used as a guideline for setting up a quality assurance monitoring program.

The alert levels can be identified using a method determined by the facility's interdisciplinary team, or can be calculated using the example provided below:

1) Determining the average (Avg) of the sample data.

2) Determining the standard deviation, σ, of the sample data.

3) Determining the upper control limit (UCL) by adding three times the standard deviation to the average of the sample data. UCL = [Avg + 3 σ]

4) Determining the lower control limit (LCL) by subtracting three times the standard deviation from the average of the sample data. LCL = [Avg - 3 σ]

G.2 Pretreatment equipment monitoring

G.2.1 Sediment filters

Sediment filters (e.g., cartridge filter, multi-media filter) should be monitored periodically. There is no easy test that can be used to determine the effectiveness of a sediment filter; however, pressure drop (delta pressure, or ΔP) across the filter can be used to determine when the filter is retaining particulate matter to the point where the filter will no longer allows the required water flow without an excessive reduction in pressure at the outlet of the filter. A sharp drop in pressure across the filter could indicate that the filter has ruptured and needs to be replaced. A backwash cycle may be used to remove particulate matter from the sediment filter. The equipment manufacturer’s written IFU for frequency of backwashing should be followed. Monitoring of a sediment filter should include verification that the timer used to initiate backwashing cycles is set to the correct time of day. The pressure drop (delta pressure, or ΔP) measurements and timer verifications should be recorded, trended, and periodically reviewed.

G.2.2 Softeners

Softeners should be monitored per the facility's quality management system. Monitoring consists of testing product water for total hardness. In the case of automatically regenerated softeners, monitoring also includes verification that the brine tank contains a sufficient supply of undissolved sodium chloride and that the control valve timer, when present, indicates the correct time of day.

Testing for hardness should be performed using an ethylenediaminetetraacetic acid (EDTA) titration test, with “dip and read” test strips, or a similar method. Regardless of the method chosen, the test accuracy and sensitivity should be sufficient to satisfy the hardness requirements of the RO machine manufacturer and will ensure that the softener is sized properly (i.e., that it has sufficient capacity, expressed as calcium carbonate equivalence). Water hardness test results should be recorded, trended, and periodically reviewed.

The softener brine tank should be monitored daily to verify that salt pellets are above the liquid level to produce the expected saturated salt solution in the brine tank. Salt designated as *rock* salt should not be used for softener regeneration because it is not refined and typically contains sediments and other impurities that could “poison” the softener resin or be a source of bacterial contamination.

The microbial load of softened or DI water will not be less than that of tap water because neither process reduces microbial levels. The microbial level might actually increase because of growth on the resin of the softener and DI bed. Therefore, neither softened nor DI water should be used for the post-disinfection rinse of high-level disinfected devices unless the water undergoes additional treatment (e.g., POU 0.2 µm or 0.1 µm filtration) and meets the requirements to be Critical Water (see Table 2).

G.2.3 Carbon adsorption

Carbon adsorption performance can be monitored by measuring free chlorine and/or chloramine concentrations in the water exiting the carbon beds. It is often simpler to sample the total chlorine (the sum of free chlorine and chloramines) and set a total chlorine maximum level of 0.1 mg/L than to analyze free chlorine and chloramines separately. Testing for free chlorine, chloramines, or total chlorine can be accomplished using the DPD-based test kits or “dip and read” test strips. Online monitors can be used to measure chloramine concentrations. Any test system used should have sufficient sensitivity and specificity to accurately read the minimum level required. Samples should be drawn when the system has been operating for at least 15-minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly. The results of monitoring free chlorine, chloramines, or total chlorine should be recorded on a log sheet, trended, and periodically reviewed.

Table G.1—Pretreatment equipment monitoring

Equipment	Parameters	Recommended minimal interval	Specification
Sediment filter	— Pressure drop across the filter — Filter expiration date	Daily	Pressure drops less than MRL[2]
Water softener brine tank	— Level of undissolved salt in tank[1]	Daily	Salt at MRL[2]
Carbon adsorption tanks	— Pressure drop across the filter — Filter expiration date	Daily	Pressure drops less than MRL[2]

NOTE 1 In test kits to measure the level of undissolved salt in the tank, DPD (diethyl-p-phenyanediamine) reacts with free chlorine to form a magenta color that is proportional to the concentration in the water sample. This color forms the basis of the test kits used to quantify chlorine concentration by means of visual comparison and instrumental analysis (colorimetry). In the presence of iodide ion, DPD also reacts with chloramines and can be quantified by the same methods.

NOTE 2 MRL = Manufacturer's recommended limit.

G.3 Primary treatment equipment monitoring

G.3.1 Reverse osmosis (RO)

RO systems should be monitored per the facility's quality management system using continuous reading monitors that measure conductivity (or total dissolved solids).

RO systems are not equipped with instrumentation that permits measuring levels of bacteria, endotoxin, or chemical contaminants. It is recommended that bacteria and bacterial endotoxin levels in RO water be measured at least monthly for compliance with the limits specified in Table 4. Analyses for chemical contaminants should be performed upon installation of the RO system, when membranes are replaced, and at least annually thereafter to ensure that established limits are met. Chemical analyses also should be performed when seasonal variations in source water suggest worsening quality or when rejection rates fall below 90 %.

All results of RO performance measurements should be recorded, trended, and periodically reviewed.

G.3.2 Deionization / electrodeionization

Deionizers should be monitored continuously using conductivity monitors that are temperature-compensated and equipped with audible and visual alarms. Conductivity meters should have a minimum sensitivity of 1 μS/cm. When deionizers are used as the primary method for removing inorganic contaminants (i.e., RO is not used), or when deionization is necessary to polish RO water, chemical analyses should be performed when the system is initially installed and at annual intervals thereafter. It is recommended that conductivity readings be recorded daily, trended, and periodically reviewed.

G.3.3 Filters / separators

Filter cartridges should be monitored periodically. There is no easy test for determining the effectiveness of a cartridge filter; however, differential pressure (delta pressure, or ΔP) across the filter can be used to determine when the filter is retaining particulate matter to the point where the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A sharp drop in pressure across the filter could indicate that the filter has ruptured and should be replaced. The equipment manufacturer's written IFU concerning when to replace cartridge filters should be followed. Replacement of the cartridge will usually be called for by an increase in differential pressure (delta pressure, or ΔP) to some specified value. The differential pressure (delta pressure, or ΔP) measurements should be recorded, trended, and periodically reviewed. Some filters may also have a useful life based on time.

Table G.2—Primary water treatment equipment monitoring

Equipment	Parameters	Recommended minimal interval	Specification
Reverse osmosis	— Product water conductivity or total dissolved solids — Product water flow rate (when RO is running)	Daily *using continuous monitors*	— Conductivity < MRL[1] — Project water flow rate > MRL[1] gpm
Deionizers	— Product water conductivity	Daily *using continuous monitors*	— Conductivity <MRL[1]
Filters/Separators	— Pressure drops across the filter, filter expiration date	Daily *using pre and post pressure gauges*	— Pressure drops less than MRL[1, 2, 3]
NOTE 1 MRL = Manufacturer's recommended limit. NOTE 2 Pressure increase can indicate clogging of the filter and need to change the filter. Refer to manufacturer's MRL. NOTE 3 Abrupt downward changes could indicate a rupture in the membrane.			

G.4 Storage tanks, distribution equipment, and piping monitoring

G.4.1 Water storage tanks

Water storage tanks should be monitored for bacterial endotoxin levels. Bacteria endotoxin levels should not exceed the levels specified in Table 4. Monitoring can be accomplished by taking a sample from the storage tank. It is recommended that bacterial endotoxin testing be conducted at least monthly. All bacterial endotoxin results should be recorded, trended, and periodically reviewed.

G.4.2 Distribution pumps

The water system's distribution pump(s) should be inspected periodically to ensure there are no visual or audible indications of a problem (e.g., excessive vibration, abnormal sounds). If the water system has a visual or electronic flow indication, this should be measured and compared to the distribution flow rate the water system is designed to produce.

G.4.3 Ultraviolet irradiators

Ultraviolet (UV) irradiators should be monitored for radiant energy output. UV irradiators are available equipped with radiant energy intensity sensors. A visual alarm or an output meter is an acceptable method of determining that the UV lamp is emitting sufficient radiant energy. UV irradiators should be monitored at the frequency recommended in the manufacturer's written IFU. Because the radiant energy decreases with time, annual lamp replacement is typically required. Periodic cleaning of the quartz sleeve might also be required, depending on the water quality. Monitoring results should be recorded, trended, and periodically reviewed.

G.4.4 Ultrafiltration

The performance of ultrafilters can be monitored by testing the water directly exiting the ultrafilter for bacterial endotoxin. Testing is recommended to be conducted at least monthly. In addition to periodic microbiological analyses, the pressure drop across the ultrafilter (delta pressure, or ΔP) should be measured using inlet and outlet pressure gauges. Such monitoring will indicate when membrane fouling has progressed to the point at which membrane replacement or cleaning is needed, and it is also necessary to ensure that the device is being operated in accordance with the manufacturer's written IFU.

G.4.5 Final cartridge filtration

For final cartridge filtration, the efficacy of microorganism removal is a function of the filtration cut-off. The efficacy of endotoxin removal is the positive charge of the filter's material of construction.

The smaller the pore size (e.g., 0.1 µm vs. 5 µm), the more efficient the filter is in removing even small forms such as mycoplasmas and viruses. However, the smaller the filtration pore size, the quicker the filter can become clogged and dysfunctional. The functional life of all filters is greatly improved if RO water is used as the source water instead of tap water. Generally speaking, 0.2 µm filters are most commonly used for the final end-stage microbial removal because they have a longer life span. The performance of final cartridge filters can be monitored by testing the water directly exiting the cartridge filter for bacteria and endotoxin. It is recommended that testing be conducted at least monthly for bacteria. For endotoxin, testing is recommended at system installation and once per year, unless bacterial levels indicate contamination exceeding specification at which point endotoxin testing should be conducted immediately. In addition to periodic microbiological and endotoxin analyses, the pressure drop (delta pressure, or ΔP) across the final cartridge filter should be measured using simple inlet and outlet pressure gauges.

G.4.6 Water distribution systems

Water distribution piping systems for Critical Water should be monitored for bacteria and endotoxin levels. Bacteria and endotoxin levels should not exceed the levels specified in Table 4 in Clause 10. Monitoring can be accomplished by taking a sample from the beginning and end of the water distribution loop and at the outlets supplying reuse equipment. If a bacterial filter is included in the water return line, samples should be drawn pre- and post-filter. For a newly installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits. All bacteria and endotoxin results should be recorded, trended, and periodically reviewed to ensure that action will be taken if the water quality does not conform to acceptable limits.

G.5 Bacterial control equipment

G.5.1 Ozone generators

Ozone generators should be monitored for ozone output at the level specified in the manufacturer's written IFU. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration. It is recommended that ozone concentration be measured each time disinfection is performed. An ozone-in-ambient-air test should be conducted periodically as recommended in the manufacturer's written IFU. Monitoring results should be recorded, trended, and periodically reviewed.

G.5.2 Hot water disinfection systems

Hot water disinfection systems for the storage tank and distribution loop should be monitored for temperature and time of exposure to hot water as specified in the manufacturer's written IFU. At minimum, hot water disinfection should be performed at least as often as is recommended in the manufacturer's written IFU. The water temperature should be recorded at the point farthest from the water heater; that is, where the lowest water temperature is likely to occur. It is recommended that the water temperature be measured each time a disinfection cycle is performed. A record verifying successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting the temperature and time requirements set and validated by the equipment manufacturer.

Table G.3—Storage and Distribution Equipment Monitoring

Equipment	Parameters	Special interval	Normal interval	Specification
Water storage tanks (for water produced)	— Water level — Visual inspection for leaks	N/A	Daily	Manufacturer’s recommended minimum tank level: maximum level to prevent overflow
Distribution pumps	— Excessive vibration — Unusual noise	N/A	Daily	N/A
UV disinfector	— Lamp on indicator	N/A	Daily	Lamp on indicated; intensity meter (if

Equipment	Parameters	Special interval	Normal interval	Specification
	— Intensity meter (if applicable)			applicable) according to MRL[1]
Final cartridge filtration	— Pressure drops across the filter — Filter expiration date	N/A	Daily	Pressure drops less than MRL[1, 4] (Abrupt downward changes could indicate a rupture in the membrane.)
Distribution piping system (for water produced)	— Microbial levels[2,3]	Weekly, until a pattern of consistent compliance with limits can be demonstrated	Monthly	N/A[2,3]

NOTE 1 MRL = Manufacturer's recommended limit.

NOTE 2 Bacterial levels should be determined when systems are installed, modified, or repaired. Monitoring is required only if problems are identified.

NOTE 3 Low levels of viable organisms do not guarantee endotoxin levels less than or equal to 10 EU/mL.

NOTE 4 Pressure increase can indicate clogging of the filter and need to change the filter. Refer to manufacturer's MRL.

Annex H
(informative)

Maintaining microbiological quality

H.1 Introduction

Microbial contamination control in water systems, particularly bacterial contamination control, is an important consideration. Many types of bacteria, including *Pseudomonas species, Legionella species, Stenotrophomonas species*, and nontuberculous *mycobacteria species* can survive and multiply in water systems, posing a significant infection risk. This Annex addresses strategies for the control of bacterial contamination and proliferation in water systems, as well as the routine collection and monitoring of bacterial contamination in water systems.

H.2 General considerations

The strategy for controlling the proliferation of microorganisms in water systems for device processing primarily involves proper system design, proper operation, and regular disinfection. Disinfection schedules should be designed to prevent bacterial proliferation, not elimination of bacteria once proliferation has occurred, to support compliance to specified microbial and endotoxin levels. Monitoring bacteria and endotoxin levels serves to demonstrate that the disinfection program is effective, not to indicate when disinfection should be performed. Gram-negative water bacteria, their associated lipopolysaccharides (bacterial endotoxin), and nontuberculous mycobacteria (NTM) most frequently come from the community water supply, and levels of these bacteria can be amplified depending on the water treatment system and the method of disinfection.

Water distribution pipes and storage tanks can serve as reservoirs of microbial contamination. Water systems frequently use pipes that are wider and longer than are needed to handle the required flow, thereby slowing the fluid velocity and increasing both the total fluid volume and wetted surface area of the system. Gram-negative bacteria in fluids remaining in pipes overnight multiply rapidly and colonize the wet surfaces, producing bacterial populations and endotoxin quantities in proportion to the volume and surface area. Such colonization results in the formation of biofilm that is difficult to remove once formed and that provides a barrier between the microorganisms and the chemicals that may be used during disinfection.

Biofilms are communities of microorganisms attached to surfaces. They form just about anywhere that a nonsterile fluid flows over a surface. Biofilm increases the ability of microorganisms to compete for nutrients and other resources. The complexity of biofilm depends on the degree of water or fluid movement and availability of nutrients. Slower water flows tend to form thicker biofilms, generally indicative of a greater diversity of microorganisms. As water velocity increases, the more difficult it is for microorganisms to attach and remain on the pipe surface, requiring a longer time for biofilm formation. Organisms living within a biofilm are shielded by an extracellular polymer or extracellular polymeric substances (EPS). This EPS provides the bacteria with some protection from the action of disinfectants. Biofilms can exist throughout a water distribution system. Once established in a distribution system, biofilm can be difficult to eradicate. Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but it should be performed at least monthly. If biofilm has formed, disinfection might be more effective if the pipes are treated with a descaling agent before disinfection is performed.

Additional measures can be taken to protect pipes from contamination. For example:

a) situating all outlet taps at equal elevation and at the highest point of the system so that the disinfectant cannot drain from pipes by gravity before adequate contact time has been achieved.

b) eliminating rough joints, dead-end pipes, and unused branches and taps that can trap fluid and serve as reservoirs of bacteria capable of continuously inoculating the entire system volume.

A storage tank in the distribution system greatly increases the volume of fluid and surface area available and can serve as a niche for water bacteria. Therefore, storage tanks are not recommended for use in processing water systems unless they are frequently drained and adequately disinfected. If the tank design and maintenance are not adequate to prevent bacterial proliferation, removal of the biofilm may require periodic scrubbing the interior tank walls. An ultrafilter should be used distal to the storage tank.

For critical devices, pyrogenic reactions are a significant consideration. Devices on which endotoxin (or other organic residues) or inorganics are present have been associated with Toxic Anterior Syndrome (TASS). Therefore, it is prudent to ensure that Critical Water (Table 2) is used for the final rinse of critical surgical instruments before steam sterilization. Duffy, et al. [51] found that when water treatment systems were improved to include deionization, filtration, and reverse osmosis, the pyrogenic reactions associated with the use of reprocessed intravascular critical devices dropped from 7.8 % to 0.5 %. The improvements in water treatment, along with changes in personnel training and in processing and water treatment maintenance procedures, led to a more than 300-fold decrease in endotoxin levels and a 5-fold decrease in bacterial counts. It was not possible to isolate the benefit from improvements in water treatment from the benefit gained from changes in processing procedures and personnel training. The pyrogenic reactions observed in this study may have been associated with elevated endotoxin levels in the rinse water, or they may have been caused by the cleaning agent bath, which was noted to be overgrown with bacteria. However, materials containing endotoxin (or other organic residues), or inorganics have been associated with TASS (see Annex M of ANSI/AAMI ST79 [8]). The FDA has expressed concern that endotoxin may contribute to TASS (FDA, 2006b [27]). The American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Registered Nurses (ASORN) have recommended that sterile water or deionized/distilled water be used to rinse ophthalmic surgical instruments (ASORN [19] and ASCRS [19]). Many manufacturers of ophthalmic surgical instruments also recommend that devices used for cataract surgery be thoroughly rinsed with sterile distilled water. Therefore, it is prudent to ensure that water of the recommended quality (Table 2) is used for the final rinse of ophthalmic surgical instruments before steam sterilization.

Only RO water is produced by a process that is expected to remove endotoxin. However, some endotoxin might be detected because of passage of the water through tubing that is not endotoxin-free. A medical device using a Critical Water final rinse containing less than 10 EU/ml will transfer only a fraction of that amount to a device. The amount of endotoxin left on the device after the rinse would yield far less than 20 EU remaining on its surface, which is the limit specified by USP <161> for transfusion and infusion assemblies and similar medical devices (USP [30]).

Tap and softened water is produced by processes unable to remove endotoxin and, therefore, should not be used for the final rinse of critical devices that contact the patient's bloodstream.

Although DI water is not produced by a process that removes endotoxin, it can be utilized to rinse critical devices if endotoxin levels are monitored and equivalent to levels for Critical Water as indicated in Table 2.

H.3 Microbiological quality - bioburden by colony forming unit (CFU)

H.3.1 Heterotrophic plate count

The following methods, obtained from American Public Health Association (APHA) [17], are considered appropriate for establishing trends in the number of CFUs observed in the routine microbiological monitoring of water. These three heterotrophic plate count (HPC) methods are the membrane-filtration method (L.1.4), the spread-plate method (L.1.5), and the pour-plate method (L.1.6). Combinations of incubation media, time, and temperature other than those recommended could occasionally, or even consistently, result in higher numbers of colony-forming units being observed.

Sample analysis should be initiated as soon as possible after collection to minimize changes in the bacterial population. The recommended maximum elapsed time between collection and analysis is 8-hours (maximum transit time 6-hours, maximum processing time 2-hours). When analysis cannot begin within 8-hours, maintain sample at a temperature below 4 °C but do not freeze. Maximum elapsed time between collection and analysis should not exceed 24-hours.

Low-nutrient media should be used for all HPC method (e.g., membrane-filtration, spread-plate, and pour-plate). Suggested media are Reasoner's 2A (R2A) agar or National Water Research Institute (NWRI) agar (heterotrophic plate count agar [HPCA]). The recipes for those media are provided in APHA [17]. Tryptic soy agar can also be used (Working Party of the Hospital Infection Society and the Public Health Laboratory Service [88].

Using a calibrated loop to apply the sample to the agar plate is not permitted. Dip samplers should not be used because they are not quantitative as to the volume of liquid analyzed. Blood and chocolate agars are not appropriate for this testing.

The HPC test is not intended to determine if the water is sterile (e.g., Critical Water that has been treated by ultramicron filtration), rather, it is a process indicator for water quality monitoring.

HPC might not provide a good measure of the presence of biofilm because the bacteria in biofilm are sessile, not free-swimming. However, erratic colony counts could indicate the presence of biofilm because biofilm sloughing can release of bacteria into the water. Currently, few practical methods are available for the routine detection of biofilm. Available methods include installing side streams (biofilm sampling devices) with removable coupons or rings that can be analyzed and scraping or swabbing internal pipe surfaces.

Biofilm is usually detected by a combination of laboratory procedures that includes viability staining (fluorescent staining) of surfaces and fluorescent, confocal, or scanning electron microscopy. Scrapings and removed sections of pipe can be sonicated and cultured using conventional methods (i.e., membrane-filtration or spread-plate techniques).

H.3.1.1 Membrane-filtration method

Utilize a 0.45 µm filter membrane to isolate bacteria from a sample. The filtered sample should yield a bacterial count between 20 to 200 CFU, achieved by either adjusting the sample volume or utilizing a dilution factor. A 100 mL sample portion should be filtered if a sample is expected to have a low bacterial count. Less than 100 mL sample portion should be filtered, or diluted prior to filtration, if the sample is expected to have a high bacterial count. Transfer the filter aseptically to an agar plate surface and incubate at a temperature between 30 to 35 °C. As these conditions may result in a slower growth rate, a longer incubation period may be required. Invert and incubate the agar plate at 30 to 35 °C for a minimum of 48-hours in a humid environment. The humid environment will prevent desiccation of the plate. Alternatively, incubation parameters which have been validated may be used. The highest bacterial counts are typically obtained by incubation periods between 5 to 7 days and at temperatures between 20 to 28 °C. However, extended incubation periods have disadvantages that may outweigh the higher counts obtained. The marginally higher baseline counts from extended incubation periods may not be particularly useful in detecting excursions or trends.

H.3.1.2 Spread-plate method

Aliquot a small volume, typically 1.0 mL, and spread evenly over the agar plate surface. Ensure the sample volume does not result in exceeding 300 CFU per plate. If 300 CFU per plate is exceeded, decrease the sample volume, or utilize a dilution factor. Invert and incubate the plate as described in Annex H.3.1.1.

NOTE 1 This method is less sensitive than the membrane-filtration method due to the decreased sample volume utilized.

NOTE 2 If adsorption of the samples into the agar is too slow, the 1 mL volume may be spread over two plates. In this case, the total number of colonies from both plates is used to determine the CFU/mL.

H.3.1.3 Pour-plate method

Aliquot a small volume, typically 1.0 mL, into a sterile Petri dish. Ensure the sample volume does not result in exceeding 300 CFU per plate. If 300 CFU per plate is exceeded, decrease the sample volume or utilize a dilution factor. Add molten agar, tempered to 52 to 55 °C, to the Petri dish and gently swirl to mix the sample and agar. Allow the mixture to solidify. Incubate the mixture as described in Annex H.3.1.1.

Note, the pour-plate method is less sensitive than membrane-filtrate due to the decreased sample volume utilized.

H.4 Microbiological quality – bacterial endotoxin test

H.4.1 *Limulus* amebocyte lysate (LAL)

Testing for bacterial endotoxin is generally performed by means of the *Limulus* amebocyte lysate (LAL) assay. Two basic types of LAL assay can be performed: the kinetic assay, which is available in a colorimetric or turbidimetric format, and the gel-clot assay. Alternatively, validated test methods to detect endotoxin or pyrogens may be used.

The LAL assay is described in ANSI/AAMI ST72 [7]. A positive control and a negative control should be run with each assay. The limits for endotoxin levels are given in Table 2.

H.5 How to perform water sampling

H.5.1 Sample collection

Critical Water samples, or other types of water when indicated, should be collected from several locations within the distribution system to provide a representative microbial water quality of the system. In general, samples should be collected at the beginning and end of the water distribution loop. A point of use in the distribution loop is a location where water enters equipment utilized to process medical devices. Where any storage tank is used, water should be sampled at the end of the purification process and the exit of the storage tank.

Samples should always be collected before disinfection of the water treatment system. If repeat cultures are performed after the system has been chemically disinfected (e.g., with hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before samples are collected. Before samples are collected, the storage tanks and distribution system should be drained and flushed until residual disinfectant is no longer detected. For new systems, the water should be cultured weekly until an established pattern has been determined. For established systems, the water can be cultured monthly unless a greater frequency is dictated by historical data at a given institution.

Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened, and the water allowed to run for at least 60 seconds before a sample is aseptically collected in a sterile, endotoxin-free container. The collection container should not be made of polypropylene, because polypropylene has been shown to inhibit endotoxin detection [78]. At least 100 to 300 mL of water should be collected. Sample taps should be treated with a general disinfectant (e.g., alcohol) prior to sampling and be completely dried to prevent contamination of the collected sample disinfectant residual from the sample tap. Bleach or other disinfectant solutions should never be used. Bacterial replication is prevented by holding the sample on ice, or at 4 °C, until it is delivered to the laboratory for testing.

H.5.2 Water sampling technique

Sampling Consistency: Sampling should be consistent in procedure and sampling locations to ensure the accurate monitoring of water quality.

Flushing: Sample points should be flushed commensurate to 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 possibility growing in these areas. A standardized flush before sampling can limit the microbial contribution from the sampling points.

Sampling containers: The appropriate sampling container should be used to collect the water sample. The container should be of the required quality not to introduce contamination into the test sample. For example, samples used in the sampling for bacterial endotoxin should be of the appropriate quality (e.g., pyrogen-free).

Sampling technique: Valves/taps/hoses used for sampling should be of the appropriate design to not contaminate the sample. For example, sampling locations do not provide a stagnant water environment when not in use and is accessible to the distribution loop disinfection process. Prior to sampling the sampling surfaces (e.g., valves, hoses) should be disinfected both externally and internally to reduce microbial contamination. Aseptic technique should be used for water collection.

H.6 Results exceeding specification

Microbial quality levels detected, and exceeding specification should lead to a repetition of the disinfection and sampling at the location to confirm the results. Upon confirmation of the exceedance, immediate action is required to reduce the microbial contamination.

The distribution loop should be disinfected using methods described in Annex E to ensure the microbial contamination is not being introduced through the distribution system. Automated instrument reprocessors (e.g., washer–disinfectors, washer–decontaminators, AERs) should be flushed with 1,000 ppm of a chlorine-releasing agent after the first instance of persistent unacceptable microbial levels is detected [88]. Other agents that could be considered for flushing include chlorine dioxide, peracetic acid, hydrogen peroxide, and super oxidized water. Before the unit is flushed with any of these agents, it is important to confirm with the reprocessor manufacturer that the components of the machine are compatible with the disinfectant to be used in its intended concentration. The levels should be monitored weekly by repeat testing until two successive counts show that baseline levels have been achieved.

If the microbial levels continue to exceed acceptable limits despite disinfection activities, a second system disinfection, combined with replacement of as much of the pipework as is practical, should be undertaken to remove biofilm. For the second round of disinfection, a higher concentration of chlorine-releasing agent (e.g., 10,000 ppm) or an alternative disinfectant should be used [88].

If contamination problems persist despite all efforts, the main water source should be investigated, and local authorities asked for input. This approach is based on the action plan outlined by the Working Party of the Hospital Infection Society and the Public Health Laboratory Service [88].

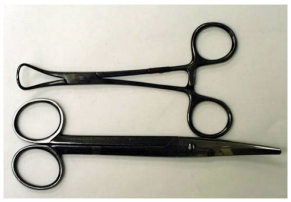
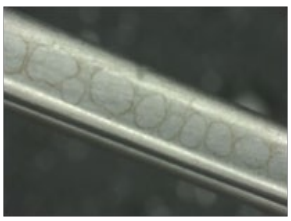
Annex I
(informative)

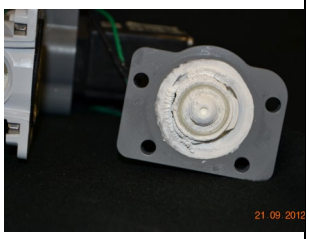
Typical presentation of water quality issues during the processing of medical devices

Poor water quality can lead to a variety of problems during medical device processing. Some of the more common problems, examples of their causes and recommendations to troubleshoot these problems are provided in Table I.1.

Table I.1—Examples of observed problems during medical device processing that can be caused by poor water quality

	Observed problem	Possible causes	Recommendations
	Ineffective cleaning or residual soil	— Soil allowed to dry on medical devices before cleaning; — Cleaning process not efficient; — Quality of water affects cleaning chemistry; — Medical devices difficult to clean; — Medical devices not fully opened or not disassembled and; — Medical device not loaded into a washer correctly.	— Review the handling of medical devices during clinical use and processing — Check the cleaning chemistry can handle certain water qualities (e.g., high water hardness) — Conduct water quality testing (particularly hardness) and consult with expert to assist in problem remediation
	Surface damages include: — Corrosion; — Pitting; — Rusting; — Stress cracking.	— Quality of medical devices and materials of construction — Physical damage during handling of the medical device — Allowing soil to dry on medical devices before cleaning — Exposure to some chemicals (e.g., saline solutions, chlorine, iodine, chlorinated water (especially when heated) — Incompatible water of cleaning chemistries (e.g., pH too high/low)	— Repair or discard damaged medical devices — Review the handling of medical devices during clinical use and processing — Monitor water quality — Testing (particularly pH, chlorine, and silicates) — Consult with expert to assist in problem remediation
	Loss of color	— Bleaching of colors over time, especially with colored anodized aluminum — Chlorinated water (especially, when heated) — Incompatible water, cleaning chemistries (e.g., pH too high/low),	— Review the handling of medical devices during clinical use and processing — Conduct water quality testing (particularly pH, chlorine, and silicates)

	Observed problem	Possible causes	Recommendations
		or bleach (chlorine solutions), or RO water (in some cases)	— Consult with expert to assist in problem remediation
	Gold-brown discoloration	Excessive heating to stainless steel surfaces combined with various water deposits Chromium oxide; development is often observed as a "rainbow" stain that develops over time (can include various blue-brown colors from the presence of copper and iron) — Phosphate layer developing on surface (from poor water quality and even some phosphate-containing cleaning chemistries that are not rinsed correctly). Often seen as orange-brown discoloration — Iodine residuals (mistakenly used for cleaning at the point-of-use)	— Review the handling of medical devices during clinical use and processing — Conduct water quality testing — Consult with expert to assist in problem remediation
	Orange-brown discoloration		
	Multicolored (i.e., rainbow) staining		
	Black or purple staining	— Commonly observed after steam sterilization, from high or low pH residuals remaining on the medical device following cleaning — Can be from water quality of insufficient rinsing or neutralization with low acidic or highly alkaline cleaning chemistries	— Review the medical device cleaning process (e.g., automated process, pH of final rinse water) — Conduct water quality testing — Consult with expert to assist in problem remediation
 	White, chalky spotting or deposits (may be associated with other colors such as green or red).	— Water hardness, observed following drying or steam sterilization — Can build up on surfaces over time. — This can often be combined with other chemical contaminants (e.g., copper and iron) to give different colors — Some cleaning chemistries can dramatically reduce these effects during cleaning processes — Similar deposits can also be caused by other chemical residuals (e.g., inadequate rinsing of cleaning chemistries or other water contaminants such as silicon oxide)	— Conduct water quality testing — Consult with expert to assist in problem remediation — Consider the use of cleaning chemistries that can tolerate high hardness levels and/or reduce water hardness by further treatment.

	Observed problem	Possible causes	Recommendations
	Biofilm development	— Slime development over time, often appearing as different colors (example shown in red) — Ineffective maintenance of medical devices/equipment — Biofilms are bacterial growth overtime and can be difficult to remove/ inactivate — Locations will include areas with inadequate contact during cleaning/disinfection and poor water draining (e.g., pooling)	— Review maintenance of medical devices and equipment, particularly when used or subjected to cleaning and disinfection — Review the treatment of water used for final rinsing of medical devices, particularly following disinfection
	Obstruction of water into automated processor water lines and valves by white, chalky build-up	— Clogged valve and water lines from a buildup of mineral deposits from water — Minerals in the water deposited on the surfaces of the water lines — High water volume using water with high mineral content results in a mineral build up	— Follow the equipment manufacturer's written IFU. If a specific water quality is required, perform a water analysis to ensure the adequate water quality is available

When troubleshooting potential problems, consider the following guidelines:

a) Examine the medical devices for the type(s) of damage observed and use Table I.1 as a guide to the cause.

b) Review all steps during the handling and processing of the medical device. Ensure that all the proper steps are undertaken in the cleaning and disinfection/sterilization processes. Looks for clues to medical device damage including:

— Allowing soil to dry on medical devices during transport;

— Use of saline or chlorine for point-of-use treatment or for transporting medical device (can lead to damage and rusting);

— Types of chemistries used for transport, cleaning or maintenance;

— How the chambers of washer-disinfectors or steam sterilizers look (rusting, deposits, color changes etc.);

— Damage seen before cleaning, after decontamination or following packaging/steam sterilization;

— Damage unique to some medical devices or all medical devices; and

— Is the problem observed all the time or periodically (this is typical with water quality).

c) Conduct water analyses. Consider all sources of water that could be used during medical device processing at the point-of-use, including: tap water (hot and cold, they can be different), any water source (e.g., softened water, reverse osmosis, distilled or deionized water), water used for steam production (in a boiler or water generator), steam condensate at the point-of-use. Consult with a water quality expert to aid in problem identification and resolution (e.g., cleaning chemistry, processing equipment or water purification suppliers).

d) Introduce water control processes and monitoring.

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