

Technical Information Report

AAMI TIR34: 2014/(R)2017

Water for the reprocessing
of medical devices

Water for the reprocessing of medical devices

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AAMI

Abstract: This technical information report (TIR) covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidelines for selecting the water quality necessary for the reprocessing 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, pasteurization, reverse osmosis, sediment filters, sterilization, ultrafiltration, water filtration, water quality, water softening, water treatment

AAMI Technical Information Report

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation AAMI Water Quality for Medical Device Reprocessing Working Group

This technical information report (TIR) was developed by the AAMI Water Quality for Medical Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval. At the time this TIR was published, the Water Quality for Medical Device Reprocessing Working Group had the following members:

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Foreword

This technical information report was developed by the AAMI Water Quality for Medical Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this TIR is to provide guidelines to personnel involved in medical device reprocessing on the quality of water that should be used in various stages of medical device reprocessing. It is also intended to provide guidelines to water service maintenance personnel on establishing and monitoring water treatment systems. This second edition has been changed to reflect two water categories instead of the four previously specified. There are also many updates and organizational enhancements.

The concepts incorporated in this TIR should not be considered inflexible or static. The recommendations presented here will be reviewed and updated periodically to reflect new information and technical developments regarding water quality and treatment in medical device reprocessing.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203-1633.

Introduction

Water quality is an important consideration in all stages of medical device reprocessing. Ensuring adequate water quality in device reprocessing requires collaboration between the personnel who reprocess medical devices and the personnel who establish and maintain the water treatment system. Because the needs of these two groups are distinct, this technical information report (TIR) contains:

- a) sections in the main text that provide guidance for personnel involved in medical device reprocessing on the selection of the recommended water quality for each stage of medical device reprocessing for each category of medical device; and
- b) annexes that provide technical information to water maintenance personnel (i.e., personnel who are involved in water treatment and distribution in the facility) to guide them in setting up and monitoring water treatment systems.

Water can be treated by a variety of methods that yield different levels of water quality. In general, as the chemical quality of water improves, its microbial content could increase unless the system is closely monitored to prevent microbial overgrowth. Gram-negative bacteria and nontuberculous mycobacteria can grow in any type of water, including tap, softened, deionized (DI), reverse osmosis (RO) treated, and distilled water. The rate of growth and the microbial levels attained are a function of the amount of organic contaminants in the water. The importance of monitoring water quality to prevent problems with microbial overgrowth cannot be overemphasized.

This TIR defines two levels of water quality suitable for medical device reprocessing, and it describes the water treatment processes that can be used to obtain the correct water quality. To provide optimal water for medical device reprocessing, reprocessing personnel and water maintenance personnel should collaborate with administrative personnel to implement the following procedures:

Step	Procedure	What to Do	Who is Responsible
1	Assessment of water quality	The tap water from the public utility source should be analyzed by an accredited facility with expertise in water quality to determine whether the water requires treatment and, if so, what type of treatment. This analysis should take into account seasonal variations in water quality.	Water maintenance personnel
2	Implementation of water treatment process	On the basis of the assessment in Step 1 and in consultation with an accredited facility with expertise in water quality, personnel should ensure that treatment processes are implemented to provide the type of water quality needed for the medical device reprocessing needs of the facility.	Water maintenance personnel in conjunction with device reprocessing personnel
3	Assurance of proper water quality for the various stages in medical device reprocessing	Medical device reprocessing areas should be audited to determine whether water of the correct quality is being used for the devices being reprocessed in each area. If not, the water treatment should be modified as necessary.	Device reprocessing personnel in conjunction with health care technology management personnel
4	Ongoing monitoring of water quality	Where applicable, monitoring procedures should be established to ensure that the treated water is of adequate quality for medical device reprocessing. Water maintenance personnel and device reprocessing personnel should communicate effectively to ensure that action is taken when inadequate water quality is detected.	Water maintenance personnel in conjunction with device reprocessing personnel

This TIR was developed using information on the reprocessing of medical devices labeled for reuse. There might be regulatory requirements or other issues associated with reprocessing single-use devices that were not considered in developing this TIR (see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm).

Water for the reprocessing of medical devices

1. Scope

1.1 General

This TIR addresses how to determine the water quality needs for reprocessing various categories of medical devices at various stages of reprocessing and how to assess, generate, monitor, and maintain water meeting those requirements.

1.2 Inclusions

This TIR covers the quality of the water used to clean, rinse, disinfect, and sterilize medical devices. It defines water types on the basis of hardness, pH, microorganism levels, endotoxin levels, and other characteristics. The following specific topics are covered:

- a) Importance of water quality and effective water treatment
- b) Categories of water quality for medical device reprocessing
- c) Selection of water quality
- d) Water treatment systems
- e) Monitoring of water quality
- f) Strategies for microorganism control
- g) Personnel considerations
- h) Continuous quality improvement
- i) Troubleshooting water quality issues

This TIR also provides definitions of terms and a bibliography. The annexes contain technical details pertaining to water treatment and monitoring for the benefit of water maintenance personnel.

1.3 Exclusions

This TIR does not cover the water requirements for hemodialysis applications. See ANSI/AAMI/ISO 13959, ANSI/AAMI/ISO 11663, and ANSI/AAMI RD47.

This TIR does not address water treatment performed within medical washers, washer–disinfectors, or automated endoscope reprocessors (AERs); it covers only the water coming into such equipment. The internal filtering or other additional treatment performed within a medical washer, washer–disinfector, or AER is the responsibility of the equipment manufacturer. However, it is in the best interest of reprocessing personnel to be informed of the internal water treatment apparatus and of the equipment manufacturer to take into account the water quality recommendations of this document. See the ANSI/AAMI and ISO 15883 series of documents.

2. Definitions and abbreviations

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

2.1 anion: Negatively charged atom or molecule.

2.2 ATP assessment: Method using adenosine triphosphate (ATP) to indirectly measure viable microbial load.

2.3 automated endoscope reprocessor (AER): Machine intended to disinfect or sterilize loads containing endoscopes.

NOTE—Some AERs have provision for reprocessing accessories.

2.4 bacterial endotoxins test (BET): Assay for measuring endotoxins by combining a liquid test sample with *Limulus* amoebocyte lysate (LAL) reagent and measuring the resulting proportional reaction by visual, turbidimetric, chromogenic, or other validated means of detection.

2.5 bioburden: Population of viable microorganisms on or in product and/or sterile barrier system.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (cfus) per single item.

2.6 biofilm: An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002).

NOTE 1—The biomass may consist of multiple bacterial species, yeast species, or both.

NOTE 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 *glycocalyx*) and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

2.7 bladder tank: Pressurized tank that has an internal bladder, is part of the water path, and maintains pressure and flow during peak use times.

2.8 cation: Positively charged atom or molecule.

2.9 chemical sterilization: Validated process that uses a chemical agent and is designed to render a product free of viable microorganisms.

2.10 chloramines: Compounds formed by the reaction of aqueous chlorine with ammonia.

2.11 chlorine, combined: Chlorine that is chemically combined, as in the case of chloramine compounds.

NOTE—There is no direct test for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference.

2.12 chlorine, free: Concentration of residual chlorine in water that is present as dissolved gas (Cl_2), hypochlorous acid (HOCl), and/or hypochlorite ion (OCl^-).

NOTE—The three forms of free chlorine exist together in equilibrium. Their relative proportions are determined by the pH and temperature of the water.

2.13 cleaning: Removal of contamination from an item to the extent necessary for further reprocessing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent 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.

2.14 CLSI: Clinical and Laboratory Standards Institute.

2.15 conductivity, water: Measure of the concentration of ions in solution.

NOTE—Conductivity is measured by a conductivity meter and described in microsiemens/centimeter (cm).

2.16 critical devices: 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.

2.17 cross-flow filtration: Process in which viable or nonviable particles 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.

2.18 deadleg: With respect to water distribution systems, piping that is more than six times as long as it is wide and that does not have constant water flow.

2.19 decontamination: According to the Occupational Safety and Health Administration (OSHA), “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” (29 CFR 1910.1030).

NOTE—The term is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood.

2.20 deionization (DI): Water treatment process that uses specially manufactured ion-exchange resin to remove ionized salts from the water.

NOTE—DI typically does not remove organics, viruses, or bacteria, except through “accidental” trapping in the resin. When DI is used, it is advisable to follow the deionizer with a bacterial filter to ensure that the treated water does not contain high levels of bacteria. See A.2.7.

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

NOTE—Depth filters are often used as prefilters to remove large particles and to extend the service life of subsequent filters.

2.22 disinfection: Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

NOTE—Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

2.23 distillation: Water treatment process that uses phase change to purify water.

NOTE—For purposes of this TIR, distilled water is considered to be water generated from a properly maintained still on-site, not bottled water labeled as distilled.

2.24 empty bed contact time (EBCT): Measure of how much contact occurs between particles (e.g., activated carbon) and water as the water flows through a bed of the particles.

NOTE—EBCT in minutes (min) is calculated from the following equation:

$$\text{EBCT} = (7.48 \times V)/Q$$

Where:

V is the volume in cubic feet (ft³) of particles in the bed, and

Q is the flow rate (gallons/min) of water through the bed.

2.25 endotoxin: High-molecular-weight complex that is associated with the cell wall of Gram-negative bacteria, is pyrogenic in humans and specifically interacts with *Limulus* amoebocyte lysate (LAL). See also **bacterial endotoxins test (BET)** and **pyrogen**.

2.26 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 (United States Pharmacopeia [USP] standard reference material).

NOTE—FDA’s reference endotoxin EC-6, USP Lot G, 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 (Poole, et al., 1997).

2.27 EPA: U.S. Environmental Protection Agency.

2.28 FDA: U.S. Food and Drug Administration.

2.29 green sand: Manganese-containing zeolite used to remove soluble iron and manganese from water.

NOTE—The manganic ion form in the zeolite oxidizes ferrous and manganous ions in water to their insoluble ferric and manganic forms. The resulting manganous ion in the zeolite can be regenerated to the manganic ion form with potassium permanganate.

2.30 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 (CaCO₃) equivalents.

NOTE—Soft water is 0 to 60 ppm CaCO₃, moderately hard water is 60 to 120 ppm, hard water is 120 to 180 ppm, and very hard water is more than 180 ppm.

2.31 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 treated water.

NOTE—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.

2.32 high-level disinfectant (HLD): Liquid chemical sterilant (LCS) used for a shorter exposure time than required for sterilization, under otherwise identical conditions.

2.33 high-level disinfection: Complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores (CDC 2008)

NOTE—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.

2.34 hydrophobic: Not readily absorbing water; insoluble in water.

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

2.36 *Limulus* amebocyte lysate (LAL): Reagent made by lysing amebocytes of the horseshoe crab, *Limulus polyphemus*, and used to detect and quantify endotoxin.

2.37 lipopolysaccharide (LPS): Gram-negative bacterial cell wall component typically composed of lipid A, a core polysaccharide, and an O-side chain. See also **endotoxin**.

2.38 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.

2.39 low-level disinfection: Process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores.

2.40 microfilter: Filter designed to remove particles in the range of 0.1 to 3 microns in diameter.

2.41 microorganism: Entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses.

NOTE—A specific standard might not require demonstration of the effectiveness of the sterilization process in inactivating all types of microorganisms, identified in the definition above, for validation and/or routine control of the sterilization process.

2.42 noncritical devices: Medical devices that contact only intact patient skin. Examples include bedpans, reusable anesthesia masks, and blood pressure cuffs.

2.43 nonpyrogenic: Term used to describe a health care product that does not induce a fever.

NOTE—*Nonpyrogenic* may also be used to describe and label health care products that contain endotoxin levels less than specified limits.

2.44 nonpyrogenic water: Water that does not contain endotoxin exceeding a specified endotoxin limit.

2.45 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 min.

2.46 pH level: Number denoting alkalinity or acidity.

NOTE—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.

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

NOTE—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).

2.48 potable water: Water that has been treated and delivered in a manner so that it meets EPA guidelines as suitable for drinking.

2.49 precleaning: Initial stage in reprocessing in which water (or detergent solution) is used to rinse or soak medical devices so that gross levels of any secretions or tissues are removed from patient-used medical devices or other instruments before a more thorough cleaning process is undertaken.

2.50 pyrogen: Fever-producing substance. Pyrogens are most often lipopolysaccharides from Gram-negative bacteria. See also **endotoxin**.

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

2.51 reprocess: To prepare a device, instrument, or piece of equipment for reuse by any or a combination of the following processes: precleaning, cleaning, disinfection, sterilization, and rinsing at appropriate stages.

2.52 resistivity: Ability of water to resist the flow of electricity; a measure of the resistance of water and the inverse of conductivity.

NOTE—Resistivity is measured by a resistance monitor and described in megohms-cm (MΩ-cm).

2.53 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.

2.54 rinsing: Process of flushing with fluid (usually tap water) the exterior or interior of any lumens of a medical device to remove organic and inorganic material at various stages in medical device reprocessing.

2.55 semicritical devices: Medical devices that contact intact mucous membranes or nonintact 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.

2.56 softening: Technique that removes ions that cause water to be hard (usually calcium and magnesium, but iron ions may also be removed by softening).

2.57 sterilant or sterilizing agent: Physical or chemical entity, or combination of entities, that has sufficient microbicidal activity to achieve sterility under defined conditions.

2.58 sterile: Free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. See **sterilization**.

2.59 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—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.

2.60 sterilization process: Series of actions or operations needed to achieve the specified requirements for sterility.

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

2.61 storage tank: Tank in which water is stored for future use, typically at the user's facility.

NOTE—Because of the potential for bacterial growth and biofilm formation, the use of storage tanks is discouraged.

2.62 submicron filter: Mechanical filtration process that has the capacity to retain particles or organisms that are less than 1 micrometer (µm) in diameter.

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

NOTE—The efficacy of microbial kill depends on the temperature and exposure time. For a more detailed discussion, see Annex E.

2.64 total dissolved solids (TDS): Sum of all ions in a solution, often approximated by means of electrical conductivity or resistivity measurements.

NOTE—TDS measurements are commonly used to assess the performance of water treatment systems. TDS values are often expressed in terms of CaCO₃ or NaCl equivalents (ppm).

2.65 total organic carbon (TOC): Measure of both natural and synthetic organic substances that are residual from natural plant and animal decomposition (ASTM D5196-06).

2.66 ultrafilter: Membrane filter with a pore size in the range 0.001 to 0.05 µm.

NOTE—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.

2.67 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

2.68 water purity: Indication of the extent to which impurities (e.g., dissolved organic and inorganic solids and microbial contaminants, ionic, and chemical) have been removed.

2.69 water quality: Descriptor of the levels of various impurities present in water.

NOTE—For example, tap water meets defined water quality standards that ensure that the levels of inorganic chemicals, microorganisms, and radionuclides are within levels that do not pose a risk to the public when ingested (Benner, 2004). For medical device reprocessing, the water quality needed at various stages in the process varies; for example, initial rinsing with tap water is recommended, but final rinsing of cleaned medical devices might require treated water that meets more stringent criteria for ions, microorganisms, organics, and dissolved solutes.

2.70 water treatment system: Collection of water purification devices and associated piping, pumps, valves, and gauges that together produce purified water of a specified quality and deliver it to the point of use.

2.71 wound filter: Filter consisting of two layers of membrane welded together, with one end inserted into a hollow tube. The membranes are wrapped around the tube in a spiral. The layers are arranged and adhered along the lengthwise and widthwise edges so that, in use, unfiltered fluid passing through one spiral surface of the filter unit, into one spacer layer, should pass through a filter layer before passing out of the construction through the opposing spiral-end surface. Wound filters are typically used in reverse osmosis and ultrafiltration.

3. The importance of water quality and effective water treatment

3.1 Introduction

The overall goals of water treatment in medical device reprocessing are to prolong the life of medical instrumentation, to ensure effectively functioning instrumentation, and, more importantly, to help minimize the risk of adverse patient outcomes arising from contaminated medical devices. This section of the TIR is intended to help users understand the major considerations associated with the quality of water used in medical device reprocessing in health care facilities and the general principles of water treatment.

3.2 Major impacts of adverse water quality on medical device reprocessing

3.2.1 General considerations

The primary objective of medical device reprocessing is to ensure that a device is safe for patient use and does not cause an adverse event in the patient. Adverse patient events to which inadequate water quality can contribute include the following:

- a) Device malfunction during a patient procedure (e.g., corrosion of a surgical instrument because of salt or other water deposits 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 inside the mechanism because of inadequate cleaning stemming from inactivation of the detergent by water of improper quality)
- b) Toxic effects and tissue irritation resulting from residuals on a device or implant that was reprocessed using water of inadequate quality (e.g., pyrogenic reactions could occur as a result of high levels of endotoxin or other pyrogenic agents left as residuals from water that contained high microbial levels; residual salts from water used for the final rinse could be converted by ethylene oxide [EO] to toxic residues)
- c) Patient infection resulting from the use of contaminated devices (e.g., salt or organic deposits from the water used in reprocessing could inactivate the disinfectant or sterilant or could protect microorganisms from the disinfection or sterilization process; a disinfected or sterilized device could transmit an infection if rinsed with water containing unacceptable levels of microorganisms) (see Table 1)
- d) Ineffective cleaning/disinfection because of chemical integration with water contaminants. Water contaminants can bind with the detergent surfaces, preventing them from dispersing soils.
- e) Noncondensable gases (NCGs), defined as gases 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 in Bowie-Dick test results.

It is important that personnel who reprocess medical devices or use them in patient procedures understand the water quality issues that can contribute to adverse patient events and be aware of some of the gross indicators that suggest that there could be problems with the water quality. Monitoring water quality is a prospective process meant to confirm that control strategies are working properly. Monitoring is not a process to prevent biofilm development but rather to indicate when control strategies might require review or remedial action. Inadequate water quality could contribute to residue left on a scope (e.g., film on a scope that adversely affects lens optics).

In the preparation of water for use in medical device reprocessing, two general characteristics need to be considered: the microbial level in water (3.2.2) and the inorganic and organic components of water (3.2.3).

3.2.2 Microbial level in water

The water used at each stage of reprocessing should not increase the bioburden of the devices being processed. Water entering the facility from the public utility is usually chlorinated to prevent microbial replication. Even in chlorinated 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, chlorinated water might contain other inorganic components that will damage medical devices during reprocessing, thereby necessitating water treatment, such as DI, to remove these components. Such treatment will also remove the chlorine; consequently, any microorganisms present will have a significantly greater ability to replicate. Alternative water treatment processes, such as RO, will remove microorganisms as well as inorganic components, thereby reducing the microbial load in the water. However, the RO distribution network could become contaminated with microorganisms and subsequently develop biofilm on the inner surfaces of the piping; in this case, the water will still have unacceptable microbial levels when it is used in medical device reprocessing despite having been properly treated initially.

Because of these considerations, it is necessary to assess the microbial level of water used for device reprocessing in the facility to ensure that it is acceptable. It is necessary to monitor bacterial levels in tap water, softened water, and deionized water only when systems are installed, modified, or repaired or if problems are identified (see Table 1 and Table 6). Once the microbial level is at an acceptable level (i.e., the level is < 100 colony-forming units per milliliter [cfus/mL]), then monitoring is no longer required. However, it is necessary to monitor microbial levels in “Critical Water” (see 4.2) at intervals that should conform to the recommendations of Table 1 and Table 6. Rapidly addressing unacceptable microbial levels in the water distribution system is critical to keeping biofilm to a minimum.

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 bloodstream or other sterile body sites. A report documented *Pseudomonas aeruginosa* infections associated with the use of transrectal, ultrasound-guided transducer assemblies (CDC, 2006). As a result of this report, FDA issued a public health notification stating that these medical devices are critical and should be sterilized unless there are parts that cannot withstand the rigors of sterilization, in which case high-level disinfection may be used (FDA, 2006a). In addition, FDA recommended that sterile water—not tap water—should always be used to rinse such devices after high-level disinfection.

Microbial level is measured as the number of cfus per mL of water.

3.2.3 Inorganic and organic components of water

3.2.3.1 General considerations

A number of water characteristics contribute to unacceptable organic and inorganic levels: bacterial endotoxin, total organic carbon (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 (Monson, et al., 1992). (See also Kreisler, et al., 1992; Mamalis, et al., 2006; Hellinger, et al., 2006; Werner, et al., 2006; and Annex N of ANSI/AAMI ST79.) 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 1) before sterilization.

Individually or in combination, these characteristics can cause changes in the appearance or color of water (e.g., the water might appear cloudy). If the water used in reprocessing does not look clear and colorless, there is likely to be a problem that should be corrected. See Section 4 for the characteristics of water of the two quality categories.

3.2.3.2 Bacterial endotoxins

Bacterial endotoxins are organic compounds that are derived from the cell walls of bacteria and that, when introduced into the human body, can cause a fever-like (pyrogenic) reaction and other adverse effects. Unlike microorganisms, endotoxins are not reliably destroyed by disinfection or sterilization processes. Therefore, if the incoming water used for cleaning and rinsing has high levels of endotoxins, residual endotoxins might remain on reprocessed devices. The source of endotoxins is often the overgrowth of Gram-negative bacteria in water. The exact threshold of endotoxins 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 endotoxins (e.g., *Salmonella* species, *E. coli*, or some other Gram-negative bacteria); the amount of endotoxins 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. (1999) demonstrated that intravenous injection of 1 to 4 nanograms/kilogram (ng/kg) of purified endotoxins 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 endotoxins (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.

Residual endotoxins are a concern for medical devices that will contact the patient’s bloodstream, cerebrospinal fluid, or the anterior chamber of the eye (Mamalis, et al., 2006). See also 3.4 and 4.2.

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

3.2.3.3 Total organic carbon

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 reprocessing, water

residuals can discolor the device and interfere with the effectiveness of detergents, disinfectants, or sterilants. Also, high organic carbon levels provide nutrition to microorganisms and can contribute to microbial overgrowth in the water.

3.2.3.4 pH

The pH of water used in device reprocessing 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 detergents (especially enzymatic detergents), disinfectants, or sterilants used in reprocessing (i.e., the water pH is not compatible with the detergent, disinfectant, or sterilant).

3.2.3.5 Water hardness

Hard water is caused by the presence of dissolved salts (typically calcium and magnesium) that deposit as hard mineral layers (lime-scale) when the water is heated or evaporated. Very hard water can decrease the effectiveness of most detergents and disinfectants; for example, components of hard water bind with detergent surfactants, preventing them from dispersing soils. Very hard water can also adversely affect the performance of medical washers and medical washer–disinfectors (e.g., by fouling electrical heating elements and heat-exchange components, reducing heat-transfer efficiency, increasing water-heating costs, and depositing lime-scale 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 high-level disinfectants (HLDs) and liquid chemical sterilants (LCSs) that are diluted to in-use concentration or diluted in the course of reuse.

Water hardness is indicated by the concentration of CaCO_3 in the water.

3.2.3.6 Ionic contaminants and resistivity

An ion is an electrically charged atom or molecule. The ions of importance in water for medical device reprocessing are chloride, iron, copper, and manganese. Excessive chloride can cause corrosion pitting. Excessive iron, copper, or manganese (called heavy metal ions) can tarnish stainless steel instruments (i.e., cause blue, brown, or iridescent surface coloration). Pitting causes a rough surface that prevents adequate cleaning and allows microorganisms and organic material to accumulate, which, in turn, can cause adverse patient effects.

The ionic content of water is indicated directly by the measured concentration of the individual ions and indirectly by the measured resistivity of the water. Resistivity is the ability of water to resist the flow of electricity.

3.2.4 Water temperature

In addition to the microbial level and the organic and inorganic components of water, water temperature is another important consideration; it can have a significant impact on the effectiveness of reprocessing. The temperature of the water affects the efficacy of precleaning, cleaning, rinsing, liquid chemical disinfection, and liquid chemical sterilization. In general, the appropriate temperature depends on the stage of reprocessing, as well as the medical device, cleaning agent, and cleaning equipment manufacturers' written instructions for use (IFU).

3.3 Treatment of water

3.3.1 General considerations

If the characteristics of the water do not meet the requirements specified in Table 1, water can be treated by various processes to provide a better quality of water, one suitable for each stage of reprocessing.

The treatment of water to reduce or control the microbial load (bioburden) is intended to

- a) help ensure that the medical device does not acquire extraneous viable microorganisms, non-viable microorganisms, and endotoxins in excessive quantities before disinfection or sterilization, and

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

- b) help ensure that the device is not contaminated by viable microorganisms if a final rinse is required after the 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.

The specifics of water treatment are provided in more detail in Section 6 and Annex A. 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 product water; the characteristics of the incoming tap water; and the volume, rate, and frequency of use. And, importantly, no water treatment system will work for long without monitoring and maintenance, which requires cooperation and efficient communication between device reprocessing personnel and water maintenance personnel. Categories of water quality are defined in Section 4, and recommendations for the quality of water for the stages of medical device reprocessing are provided in Section 5.

A water treatment system has three elements: pretreatment (3.3.2), a principal water treatment process (3.3.3), and distribution (3.3.4). The pretreatment part of a water treatment system—which could consist of iron filtration, depth filtration, softening, and carbon filtration—is intended to protect the principal water treatment components. The principal treatment process generally consists of DI, RO, distillation, or a combination of these processes. To maintain water quality, the distribution system should be designed appropriately and should be routinely disinfected by means of chemical treatment, ultraviolet (UV) light, ozone, heat, or a combination of these processes.

Microbiological quality (which refers both to the number of viable microorganisms and the level of microbiological constituents, such as endotoxins, cell wall proteins, and peptidoglycan) is an important consideration in the treatment of water to be used for reprocessing medical devices and should be controlled throughout the treatment process. Controlling microbiological water quality becomes a particular challenge after chlorine is removed from the incoming tap water. Chlorine or chloramines are added to the water by the municipality to retard bacterial growth in the tap water; once they are removed, the water is able to support bacterial growth.

Monitoring water quality is a prospective process intended to confirm that the control strategies are working properly. When monitoring indicates that control systems are not functioning properly, then corrective action is required (e.g., decontamination of lines, replacement of filters). Monitoring consists of both complex testing performed as part of the overall quality control system and simple tests (e.g., colorimetric test strips) that can be performed at the point of use (POU). Monitoring is discussed in detail in Section 7 and Annex B.

3.3.2 Pretreatment

NOTE—See Annex A for a detailed discussion of water treatment equipment.

The purpose of pretreatment is to protect the main treatment components from harmful substances. For example, some RO membranes cannot withstand chloramines so the chloramines should be removed before the water enters the RO unit. Pretreatment also prevents certain substances from plugging the RO or other filters.

Pretreatment could include

- a) green sand filtration to remove iron and manganese;
- b) cartridge (wound filter) filtration to remove suspended material;
- c) softening to remove calcium and magnesium;
- d) activated carbon filtration to remove chlorine, chloramines, and organic compounds;
- e) sodium bisulfite addition to remove chlorine; or
- f) sodium hydroxide addition to remove dissolved carbon dioxide gas.

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.

3.3.3 Principal water treatment processes

NOTE—See Annex A for a detailed discussion of water treatment equipment.

3.3.3.1 Deionization

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. Resistivity of water increases in proportion to the removal of ions, so high resistivity indicates that there has been efficient 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 endotoxins. Poor maintenance of the DI system can lead to microbial overgrowth that results in increased levels of microorganisms and endotoxin in the water. Additional treatment steps are needed after DI to ensure the microbiological quality of the treated water (e.g., filtration treatments that remove pyrogens, submicron filters that remove microorganisms, ultrafilters).

3.3.3.2 Reverse osmosis

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

3.3.3.3 Distillation

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

3.3.4 Distribution

After water has been treated, it is necessary to maintain its quality and prevent microbial contamination and growth. Maintenance of water quality is generally accomplished by routine disinfection of the distribution loop and by continuous recirculation of the water through the distribution system. Piping should be constructed from stainless steel or a sanitary polymer that will provide a smooth surface to inhibit the formation of biofilm and to allow sanitization. There should be no deadlegs (i.e., piping that is more than six times as long as its diameter and that does not have constant water flow). A constant water flow of more than 3 feet per second will minimize the formation of biofilm on the piping. Providing a slight slope to the water distribution system will enhance water quality by enabling the water to drain out without pooling, thereby 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 sanitized or disinfected with hot water, ozone, or various chemicals, such as sodium hypochlorite (bleach), hydrogen peroxide, or peracetic acid.

NOTE—Treatment agents should be used with caution. For example, 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 all sanitizers and disinfectants used on water distribution systems should be evaluated for material compatibility before they are used.

3.4 Categories of medical devices

The quality of water needed for reprocessing is determined to some extent by the type of medical device. Medical devices can be placed into one of three categories, depending on the potential risk of infection associated with their intended use (Spaulding, 1968). 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 (CDC, 2008):

- 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, transfer forceps, cardiac

catheters, implants, gastrointestinal sphinctertomes, biopsy forceps, rigid endoscopes used for minimally invasive surgery, inner surface components of extracorporeal blood-flow devices such as heart-lung machines and 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 endotoxins (or any other substances that cause pyrogenic reactions, such as bacterial cell wall constituents) remain on the device at sufficient levels after reprocessing. To reduce the risk of pyrogenic reactions, the final rinse should be with water treated in a manner that will remove organic pyrogens.

- b) *Semicritical devices* are instruments or objects that contact intact mucosal membranes or nonintact 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 fiberoptic endoscopes, endotracheal and aspirator tubes, laryngoscopes, respiratory therapy equipment, and vaginal specula. Semicritical 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 that would be expected to destroy all microorganisms except for small numbers of bacterial spores. 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.

NOTE—Dental instruments that do not penetrate mucosal surfaces but come in contact with oral tissues are technically classified as semicritical. If they are heat-tolerant, however, CDC recommends that they should be steam sterilized (CDC, 2003).

- c) *Noncritical 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 roentgenographic machines (e.g., x-ray machines), rarely, if ever, transmit infections directly to patients. Consequently, depending on the particular item and degree of contamination, cleaning with a detergent and warm water might be adequate; some items might require some level of disinfection before reuse. Noncritical devices are frequently processed through washer-disinfectors that provide cleaning and thermal disinfection, making the device safe to handle.

Because noncritical devices do not usually pose a risk of pyrogenic reactions or infections in patients, the use of tap water is usually acceptable for all reprocessing stages.

NOTE—Tap water should have the characteristics outlined in Table 1 to be considered acceptable for the reprocessing of noncritical medical devices.

3.5 Stages of medical device reprocessing in which water quality is a consideration

The water used to reprocess a medical device needs to be of sufficient quality to ensure 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 reprocessing 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 detergent selected. Water is used for a number of rinsing stages (rinsing after precleaning, rinsing after cleaning, final rinsing), and the water quality suitable for these different stages might 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 reprocessing methods are indicated in Figure 1 and include heat sterilization (e.g., steam, dry heat); low-temperature gas sterilization (e.g., ethylene oxide, hydrogen peroxide gas plasma, chemical vapor, ozone); high-level disinfection (e.g., glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid, hypochlorous acid); pasteurization; and liquid chemical sterilization (e.g., glutaraldehyde, hydrogen peroxide, peracetic acid). Each of these methods will be addressed later in this TIR to provide guidance to users on water quality.