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WATER QUALITY DEFINITIONS

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

Biofilm: An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily.

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

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.

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).

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.

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.

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

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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 amebocyte lysate (LAL). See also bacterial endotoxins test (BET) and pyrogen.

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—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 more than 180 ppm.

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

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

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.

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.

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.

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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.

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.

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

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

Sterile: Free from viable microorganisms.

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.

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.

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

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

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.

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

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.

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