

Definitions

Definitions from ANSI/AAMIST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, were pulled from the Definitions and Abbreviations section, Section 2, pages 4-11. See below for citations.

ANSI/AAMIST79:2017, Section 2, 2.12 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

ANSI/AAMIST79:2017, Section 2, 2.14 containment device: Instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

ANSI/AAMIST79:2017, Section 2, 2.16 critical water: Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [RO] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or for steam generation.

ANSI/AAMIST79:2017, Section 2, 2.19 cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

ANSI/AAMIST79:2017, Section 2, 2.37 exposure time: Period for which the process parameters are maintained within their specified tolerances. In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

ANSI/AAMIST79:2017, Section 2, 2.47 health care facility: Specialized facility where professionals deliver services utilizing medical devices.

ANSI/AAMIST79:2017, Section 2, 2.55 instructions for use (IFU): Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device.

ANSI/AAMIST79:2017, Section 2, 2.50 immediate-use steam sterilization (IUSS): Sterilization method that involves the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team. ¹

ANSI/AAMIST79:2017, Section 2, 2.55 Instructions for use: Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device. [added at the end: defined within the Food Drug & Cosmetic Act.]

ANSI/AAMIST79:2017, Section 2, 2.33 event-related sterility maintenance: Sterility maintenance that is not based on expiration dating but rather on factors such as the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling.

ANSI/AAMIST79:2017, Section 2, 2.67 Medical Device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease.
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap.
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception; and
- which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

ANSI/AAMIST79:2017, Section 2, 2.82 packaging system: Combination of the sterile barrier system and protective packaging.

ANSI/AAMIST79:2017, Section 2, 2.10 rigid sterilization container: Sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

ANSI/AAMIST79:2017, Section 2, 2.104 shelf life: When the term is used with respect to a sterilized medical device, the period of time during which the item is considered safe to use.

ANSI/AAMIST79:2017, Section 2, 2.108 steam quality: Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water) and the level of non-condensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process).

ANSI/AAMIST79:2017, Section 2, 2.109 steam sterilization: Sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent.

ANSI/AAMIST79:2017, Section 2, 2.111 sterile barrier system: Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

ANSI/AAMIST79:2017, Section 2, 2.114 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization. SAL is normally expressed as 10^{-n} . A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item.

ANSI/AAMIST79:2017, Section 2, 2.116 sterilization: Validated process used to render a product free from viable microorganisms.

ANSI/AAMIST79:2017, Section 2, 2.117 sterilization cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

ANSI/AAMIST79:2017, Section 2, 2.125 terminal sterilization: Process by which the product is sterilized within a sterile barrier system that permits storage for use at a later time.

ANSI/AAMIST79:2017, Section 2, 2.129 user verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.

ANSI/AAMIST79:2017, Section 2, 2.131 validation: Documented procedure performed by the device manufacturer for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

FDA definition of Medical Devices:

medical device: as defined within the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

Two terms in our 510(k) which are misconstrued for IUSS:

The terms, Immediate Use and Use Immediately: occurring or accomplished without delay; following or preceding without a lapse of time. (Merriam Dictionary.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/immediate>. Accessed 08 December 2022.