

ETHYLENE OXIDE STERILIZATION GLOSSARY

TECHNICAL TIP #14

Below is an alphabetical list of terms that may be used in discussions of ethylene oxide (EO) sterilization as recognized by medical device manufacturers inspected by the U.S. FDA. All definitions or explanations are to be taken as applied specifically in the context of EO sterilization processing.

Aeration

Part of the sterilization process during which ethylene oxide and/or its reaction products desorb (outgas) from the medical device until predetermined levels are reached. This may be performed within the sterilizer and/or in a separate chamber or room.

Aeration Area

Either a chamber or a room in which aeration occurs. The temperature in the aeration area is elevated and controlled to assure that the aeration process is accelerated and repeatable. Air is recirculated in the room to maintain good heat distribution with a portion of the air stripped off and cleansed with the pollution control equipment. The stripping of the air reduces the amount of free ethylene oxide resident in the rooms, thus prevents recontamination of product load.

AAMI

Abbreviation for the Association for the Advancement of Medical Instrumentation. AAMI generates guidelines which are used in the industry for validating, monitoring, and performing routine EO sterilization processes.

ANSI/AAMI/ISO 11135:2007

International Organization for Standardization (ISO) Guidance document which has been adopted and published by AAMI (and ANSI) to address validation and routine control of ethylene oxide sterilization.

Bacteriostasis/Fungistasis Test

Test performed to evaluate the presence of microbial growth inhibiting properties of a health care product. This test assures that any reaction of the growth medium with the different materials used in the manufacture of the device will not mask or prevent growth from any viable organism remaining on the device after being subjected to a sterilization process.

Batch

Defined quantity of bulk, intermediate, or finished product that is intended or purported to be uniform in character and quality, and which has been produced during a defined cycle of manufacture.

Bioburden

Population of viable microorganisms on a raw material, component, finished product, and/or package. Unlike the gamma irradiation process, bioburden data is not utilized in ethylene oxide sterilization to determine the sterilization process. It is

collected to quantify the amount of product contamination, which is then compared to the population of the biological indicator used in the EO sterilization process.

Biological Indicator

Inoculated carrier contained within its primary pack ready for use and providing a defined resistance to the specified sterilization process. The biological indicator referenced in the United States Pharmacopeia (USP) for monitoring the ethylene oxide process is *Bacillus atrophaeus*.

Calibration

Comparison of a measurement system or device of unknown accuracy to a measurement system or device of known accuracy (traceable to national standards) to detect, correlate, report, or eliminate by adjustment, any variation from the required performance limits of the unverified measurement system or device. All critical measuring devices utilized on ethylene oxide sterilizers which may impact the quality of the process are calibrated to traceable national or international standards.

Chamber

Enclosed area which only accommodates sufficient product to fill the sterilizer. EO chambers are constructed of steel or stainless steel and are designed to withstand the extreme pressures and elevated temperatures utilized in the EO sterilization process.

Commissioning

Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification and that it functions within predetermined limits when operated in accordance with operational instructions. All EO sterilization equipment which complies with ANSI/AAMI/ISO 11135 is commissioned.

Conditioning

Treatment of product within the sterilization cycle, but prior to sterilant admission, to attain a predetermined temperature and relative humidity. This part of the sterilization process may be carried out either at atmospheric pressure or under vacuum (see also preconditioning).

Critical Parameters

Parameters identified as being essential to the sterilization process and requiring monitoring.

Culture Conditions

Stated combination of conditions, including the growth medium with the period and temperature of incubation, used to promote germination, outgrowth, and/or multiplication of the microorganisms for a biological indicator. This must be specified by the BI manufacturer.

Cycle Completion

Point after completion of the sterilization process at which the sterilization load is ready to be removed from the chamber. In EO sterilization, cycle completion occurs after the final air break phase of the process.

D-Value

Time (expressed in minutes) required to achieve inactivation of 90 percent of a population of a test organism under stated exposure conditions. Also referenced as the D10 Value or decimal reduction value.

Development

Process of refining a prototype design or process to meet established product criteria.

Differential Pressure

Difference in pressure between two adjacent pressure points. Differential pressures are utilized when calculating relative humidity and sterilant concentrations in EO sterilization.

Exposure Time

Time for which the sterilizer chamber is maintained within the specified range for temperature, sterilant concentration, pressure, and relative humidity. Also may be referred to as the time for which a medical device (load) is exposed at the specified sterilizing conditions.

Failure

Event in which a component does not perform one or more of its required functions within the specified limits under specified conditions.

Failure Analysis

Logical, systematic examination of an item to identify and analyze the probability, causes, and consequences of potential and real failures.

False Negative

Test result where a true positive was interpreted as negative, where microbial growth was present but not detected, or where viable microorganisms failed to grow.

False Positive

Test results where a true negative was interpreted as a positive, where growth resulted from extraneous microbial contamination, or where turbidity arose from an interaction between the sample and the test medium.

Final Package

Primary containment system, excluding shelf-cartons and shipping containers, that protects contents to the intended level over a specific period of time (i.e., a barrier to physical, microbial, or chemical challenges).

Flushing

Procedure by which sterilant is removed from the load and chamber by either multiple alternate admissions of filtered air or inert gas and evacuations of the chamber or continuous passage of filtered air or inert gas through the load and chamber.

Gas Filter

Nonshedding porous article placed in gas lines to remove particulate matter from gas streams prior to injection into the sterilizer.

Growth Promotion Test

Test performed to demonstrate that media will support microbial growth. For all sterility test performed in support of EO sterilization, all media are growth promotion tested per the requirements and procedures listed in USP.

Health Care Product

Term encompassing medical devices, medicinal products (pharmaceuticals and biologics), and in vitro diagnostics.

Inactivation

Loss of the ability of microorganisms to grow and/or multiply under specified culture conditions.

Indicator

Combination of the indicator agent and its substrate in the form in which it is intended to be used.

Inoculated Carrier

Carrier on which a defined number of test organisms have been deposited.

Installation Qualification

Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.

Installation Test

Series of checks and tests performed after installation of a sterilizer in the place of use.

Manufacturer

Natural or legal person packaging or sterilizing a medical device.

Medical Device

Any instrument, apparatus, appliance, 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;
- control of conception; and which does not achieve its principal 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.

Microbial Barrier

Ability of the packaging system to prevent the ingress of microorganisms under specified conditions.

Microbiological Challenge

Biological indicators, biological-indicator test packs, or inoculated product that contain known populations of microorganisms and can be used in testing sterilization cycles.

Negative Sterility Test

Sterility test samples which do not exhibit detectable microbial growth after incubation.

Nominal Population

The stated number of microorganisms on a biological indicator.

Overkill Sterilization Process

Process which is sufficient to provide at least a 12-logarithmic reduction or 12 D inactivation of an appropriately resistant biological indicator with an established D value.

Package Integrity

Unimpaired physical condition of a final package.

Parametric Release

Declaring product as sterile based on physical and/or chemical process data rather than on the basis of sample testing or biological indicator results.

Performance Qualification

Obtaining and documenting evidence that the equipment, as commissioned, will produce acceptable product when operated according to the processing specifications.

Positive Sterility Test

Sterility test samples which exhibit detectable microbial growth after incubation.

Preconditioning

Treatment of product prior to the sterilization cycle in a room or chamber to attain specified limits for temperature and relative humidity.

Preconditioning Area

Either a chamber or a room in which preconditioning occurs.

Primary Packaging

Element of the packaging system that maintains the sterility of the product.

Process Challenge Device

Object which simulates the worst case of conditions in the items of the goods to be sterilized.

- The device is so constituted that a biological indicator can be arranged in the place most difficult for the sterilant to reach. The design of the process challenge device depends on the kind of goods to be sterilized and the sterilization procedure. The biological indicator should not interfere with the function of the process challenge device.
- In some process challenge devices, an inoculated carrier may be used in place of a biological indicator.

Process Development

Documented program of studies which are performed to define the sterilization process based upon the product/packaging/loading pattern and/or equipment limitations.

Process Lethality

Capability of the sterilization process to destroy microorganisms.

Process Qualification

Obtaining and documenting evidence that the sterilization process will produce acceptable health care products.

Product

Generic term used to describe raw materials, intermediate products, subassemblies, and finished medical devices.

Product Compatibility

Ability of the sterilization process to achieve the intended results without detrimental effect on the product.

Product Qualification

Obtaining and documenting evidence that the health care product will be acceptable for its intended use after exposure to the sterilization process.

Qualification

Documented evidence that all prescribed design and performance requirements are met.

Recommissioning

Repetition of part of all of the commissioning test requirements for the purpose of reconfirming process reliability.

Reference Load

Specified sterilization load made up to represent the most difficult combination of products to be sterilized.

Revalidation

Repetition of part of all of the validation test requirements for the purpose of reconfirming process reliability.

Self-contained Biological Indicators

Biological indicator presented in such a way that the primary pack, intended for incubation, contains the growth medium required for recovery.

Simulated Product Load

Load that is used as an alternative to the actual product load and that represents an equal or greater challenge to the process.

Sterilant

Microbicidal agent in the physical form in which it is active.

Sterilant Injection Stage

Stage beginning with the first introduction of sterilant into the chamber and ending whenever the set operating pressure has been attained.

Sterilant Injection Time

Duration of the sterilant injection stage.

Sterilant Removal Time

Portion of the sterilization cycle in which sterilant is removed from the chamber and sterilization load, but not necessarily desorbed from individual products.

Sterile

Free from viable microorganisms. In practice, no such absolute statement regarding the absence of microorganisms can be proven (see sterilization).

Sterility

State of being free from viable microorganisms. In practice, no such absolute statement regarding the absence of microorganisms can be proven (see sterilization).

Sterility Assurance Level (SAL)

Probability of a viable microorganism being present on a product unit after sterilization. SAL is normally expressed at 10-n.

Sterility Test

Test performed to determine if viable microorganisms are present.

Sterilization

Validated process used to render a product free from viable microorganisms. In a sterilization process, the nature of microbial death is described by an exponential function. Therefore, the presence of viable microorganisms on any individual item can be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. The probability can be expressed as a sterility assurance level (SAL).

Sterilization Compatibility

Ability of the packaging material to both withstand the intended sterilization process and to allow attainment of the required conditions for sterilization within the final pack.

Sterilization Cycle

Defined sequence of operational steps designed to achieve sterilization that is carried out in a sealed chamber. Specifically for EO sterilization, the treatment in a sealed chamber comprising air removal, conditioning, injection of sterilant, exposure to ethylene oxide, and removal of ethylene oxide.

Sterilization Load

Goods that are to be or have been sterilized simultaneously in the same sterilization chamber.

Sterilization Process

All treatments which are required to accomplish sterilization, including preconditioning, the sterilization cycle, and aeration.

Sterilization Process Development

Studies conducted to develop a reproducible process by which the product can be sterilized to the desired probability of a nonsterile unit (PNSU) without damage.

Terminal Sterilization

A process whereby a product is sterilized in its final container and which permits the measurement and evaluation of quantifiable microbial lethality.

Test of Sterility

Test performed to determine the fraction of product units (or portions thereof) which are scored positive when subjected to defined culture conditions.

Test Organism

Microorganisms for the manufacture of inoculated carriers.

Usable Sterilizer Chamber Volume

Space inside the sterilizer chamber which is not restricted by fixed or mobile parts (loading units, pallets, etc.) and which is consequently available to accept the sterilization load. This is expressed in terms of height, width, and depth.

User

Person making use of the medical device.

Validation

A documented procedure for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications. Validation is considered as a total process that includes written protocol, evidence that the equipment as installed meets design criteria and specifications (equipment qualification), use of calibrated instruments to collect

data, and evidence that the equipment can deliver the process within specified tolerances under established operating conditions and is reproducible as demonstrated by replicate runs and process challenges (performance qualification).

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