

Sterile Environments

Design Concepts

Sterile Environments

A sterile environment is created to improve and maintain the quality of air and also to provide a non-favorable condition for biological or bacterial growth.

A sterile environment is an environment that lacks living organic material. Sterilization is the act of destroying all living organisms.

Methods of Sterilization

Dry Heat Sterilization (Autoclave) is accomplished by exposing items to dry heat in an enclosed environment or chamber at elevated temperatures ranging from 315-340°F for a specific exposure time. The equipment used in manufacturing and surgical operating usually is dry heat sterilized.

Steam Sterilization (Steam-pass) is a process capable of destroying all forms of microbial life on inanimate surfaces and is employed when the highest level of assurance that an item will be safe to handle is desired. Sterilization is accomplished by exposing items to saturated steam at high temperatures ranging from 270-285°F for a specific exposure time. This is considered an easy way of sterilization as steam is usually available in the facility.

Cold Sterilization (surface cleaning/spraying with disinfectants) provides three levels of disinfection: low-level disinfection, which kills most bacteria, some viruses and some fungi, but cannot be relied on to kill resistant organisms such as tubercle bacilli or spores; intermediate-level disinfection, which inactivates mycobacterium tuberculosis, vegetative bacteria, most viruses and most fungi, but does not necessarily kill bacterial spores; and high-level disinfection, which destroys all microorganisms with the exception of high numbers of bacterial spores.

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Filtered sterilization (HEPA filter for air and ultra-filtration for process liquid) uses special types of membrane filters, with very low porosity in the range of 0.1 μm to 0.3 μm . These filters are used to extract the microorganism from liquids or gases.

Classification of Environments

A sterile room or so called clean room is an environment where airborne particulates are controlled through an exchange of highly filtered air using a high efficiency particulate air (HEPA) filtering system, and through minimization of activities that generate particles.

In addition to particle control, the clean room is temperature- and humidity-controlled to 70°F, 45% RH. Industry practice classifies room air quality in the following categories:

Class 100 is an international definition of air quality, which requires that no more than 100 particles of size 0.5 micron or above should be present per cubic foot of air. However, maintaining a Class 100 sterile room is a difficult task, requiring stringent controls and strict monitoring. Class 100 is considered a sterile environment.

Class 10,000 maintains fewer than 10,000 particles larger than 0.5 microns in each cubic foot of air space.

Class 100,000 maintains fewer than 100,000 particles larger than 0.5 microns in each cubic foot of air space.