# Principles of Industrial Moist Heat Sterilization

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**Abstract:** This Technical Information Report provides tutorial information to industrial users of moist heat sterilization to supplement the requirements of ANSI/AAMI/ISO 11134, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization* (AAMI, 1993). The TIR also provides definitions of terms and a bibliography.

**Keywords:** bioburden method, commissioning, cycle development, lethality, microbiological challenge, moist heat, overkill method, process control, steam sterilization, sterilization cycles, sterilization validation, validation

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This Technical Information Report (TIR) was developed by the AAMI Industrial Moist Heat Sterilization Working Group, under the auspices of the AAMI Sterilization Standards Committee. Much of the information provided in this TIR was published previously in the American National Standard, *Guideline for industrial moist heat sterilization of medical products* (ANSI/AAMI ST25—1987). Portions of the American National Standard were later incorporated into the International Organization for Standardization (ISO) standard, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization* (ISO 11134—1993). The ISO standard was adopted as an American National Standard, superseding ANSI/AAMI ST25, and published by AAMI in 1993.

The ISO standard establishes minimum requirements for industrial moist heat sterilization and does not include much of the tutorial or explanatory information provided in the original American National Standard. This TIR recapitulates and amplifies that information to provide further guidance to industrial users of moist heat sterilization. Additional information on related subjects may be found in the references listed in the bibliography.

Comments on this Technical Information Report are invited and should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

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# PRINCIPLES OF INDUSTRIAL MOIST HEAT STERILIZATION

## 1 Introduction and scope

**1.1** This Technical Information Report (TIR) is mainly intended to provide tutorial information to industrial users of moist heat sterilization to supplement the requirements of ANSI/AAMI/ISO 11134, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization* (AAMI, 1993). The ANSI/AAMI/ISO standard was developed with a focus on medical devices. However, in its context as a U.S. national standard, ANSI/AAMI/ISO 11134 is applicable to all manufactured health care products sterilized by means of moist heat sterilization. As such, the standard can be considered to be an umbrella document encompassing moist heat sterilization process requirements and guidance applicable to drugs, biologics, and other nondevice solution products as well as to medical devices.

**1.2** This TIR covers the following general topics:

a) *Product and process considerations:* Section 3 describes the interrelationship of product and process, the major types of moist heat sterilization cycles, and microbiological and engineering aspects of process development.

b) *Validation:* Section 4 covers the elements of validation (commissioning, verification of process specifications, and performance qualification) and addresses such issues as vessel equivalency, the minimum number of replicate cycles, and decision-making criteria for revalidation.

c) *Routine processing:* Section 5 covers process control, change control and revalidation, preventive maintenance of equipment, and safety issues.

**1.3** This TIR also provides definitions of terms, a bibliography, and annexes containing supplementary information.

NOTE—This TIR does not cover moist heat sterilization in health care facilities, nor does it address performance requirements for industrial moist heat sterilizers. Although annex D lists a number of pertinent Food and Drug Administration (FDA) and International Organization for Standardization (ISO) publications, this TIR does not provide substantive guidance on U.S. or international regulatory requirements related to industrial moist heat sterilization processing.

## 2 Definitions of terms

**2.1 air-steam mixture:** uniform mixture of air and saturated steam used for sterilization.

NOTE—Air is used to compensate for pressures generated within sealed containers that exceed saturated steam pressures.

**2.2 bioburden:** population of viable microorganisms on a raw material, component, finished product, and/or package.

**2.3 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.

**2.4 D value:** exposure time required under a defined set of conditions to cause a 1-logarithm or 90% reduction in the population of a particular microorganism.

**2.5 F value:** measure of the microbiological inactivation capability of a heat sterilization process.

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**2.6 $F_0$ value:** F value calculated at 121.1° C (250° F) with a z value of 10 K and a D value of 1.0 minute.

**2.7 moist heat:** heat that is derived from water, either as a liquid or as steam under pressure.

**2.8 moist heat sterilization:** process of using moist heat to produce a sterile product.

**2.9 primary packaging:** element of the packaging system that maintains the sterility of the product.

**2.10 saturated steam:** water vapor at a temperature corresponding to the boiling point of the source liquid.

**2.11 sterile:** state of being free from viable microorganisms.

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

**2.12 sterilization:** validated process used to render a product free of all forms of viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of 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.

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

NOTE—Validation covers three activities: commissioning, verification of process specifications, and performance qualification.

**2.14 z value:** number of degrees of temperature required for a 1-logarithm change in the D value.

## 3 Product and process considerations

### 3.1 General

Moist heat sterilization has many applications throughout the medical industry, ranging from the sterilization of pharmaceutical products to the processing of medical devices and *in vitro* diagnostic products. However, certain sterilization process conditions may adversely affect the product and/or its packaging. This section of the TIR covers elements of product and packaging design that are of major concern and worthy of consideration before the manufacturer uses or recommends moist heat sterilization of the product.

### 3.2 Product considerations

#### 3.2.1 General

When planning to process a product by moist heat sterilization, it is important to ensure that the product will function safely and effectively and that the package which protects it will remain intact after exposure to the temperatures, pressures, and high humidity of the sterilization process. In the case of a reusable product, it is necessary for safety and effectiveness to be maintained after exposure to the maximum specified number of reprocessings, including decontamination, assembly/packaging, and sterilization, as applicable.

#### 3.2.2 Materials selection

Careful selection of materials during the development of the product design or of subsequent changes will help ensure that permeability, physical properties, dimensions, raw material content, and rate of heat degradation will be appropriate for a product simultaneously exposed to heat, moisture, and pressure changes in the chamber.


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### 3.2.3 Fitments and closures

Fitments and closures that are required to be sterile may be pretreated (presterilized to reduce bioburden) or designed to retain the moisture needed to achieve sterilizing conditions in the moist heat sterilization process. If pretreatment is not used, it is important to ensure that the product or component has been designed to allow adequate moisture into the product through the sterilization process or from the product itself (as in the case of a product with a rubber closure or other component that can be assembled wet). See also "Pretreatment and preconditioning," later in this section.

For products carrying United States Pharmacopoeia (USP) label claims, there are specific requirements for fitments and closures (see the current edition of the USP).

## 3.3 Package considerations

### 3.3.1 General

The major purpose of the package of a medical device or diagnostic product is to maintain the sterile barrier until it is used. During sterilization, it is essential that the package be able to tolerate the process parameters with no adverse affect on product quality or package integrity.

### 3.3.2 Packaging design criteria

The following design criteria are important in the selection of the primary package for a product that will be sterilized or processed using moist heat:

a) *Permeability:* For sterilization to be achieved, the moist heat in the chamber must permeate the package and, if applicable, the product. If air removal is a part of the sterilization process, the package must also permit air evacuation without damage. Before the final sterilization cycle is selected, it is essential to ensure that the package that will be in place during sterilization is adequately permeable.

   In the case of nonpermeable materials, the materials and/or design must allow adequate heat transfer to the product so that internal product moisture will act as the sterilant.

b) *Materials:* Materials selection will be influenced by many factors, including availability, cost, type of package opening, package configuration, and the end use of the product. Early evaluation of materials against the prospective sterilization process parameters will minimize delays due to production and sterilization process failures.

c) *Strength:* The package needs to be strong enough (in its materials, seals, and design) to withstand the sterilization process, as well as shipping and storage conditions, over the specified shelf life of the product. The required strength of the package will be dictated by the size, weight, and shape of the package contents and by the other intended packaging layers.

d) *Sterility maintenance:* If the product itself maintains a sterile barrier, then the primary package need not provide this protection. However, where the package is intended to maintain the sterile integrity of the product, the microbial barrier properties of the package are important and ought to be thoroughly evaluated to ensure that the sterility of the product will be maintained throughout its life. Guidance on this subject is provided in ANSI/AAMI/ISO 11607—1997, *Packaging for terminally sterilized medical devices.*

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The secondary and tertiary packages provide additional physical protection during handling, shipping, and distribution of the product and thus facilitate maintenance of the sterile barrier of the product in the primary package. If the product will be sterilized with packaging layers in addition to the primary package, it is important to evaluate the above criteria as well as the impact of moisture and temperature/pressure changes during the sterilization process.

### 3.3.3 Packaging validation

The effectiveness of the primary packaging is demonstrated during packaging validation, which provides documented evidence of the package's barrier properties and integrity. (See ANSI/AAMI/ISO 11607—1997.)

If the effectiveness of the packaging material as a sterile barrier has not been established (i.e., it is a new type of packaging material), it will be necessary to perform challenge testing to validate the barrier properties of the material. For an established packaging material, it will be sufficient to maintain on file literature from the manufacturer documenting physical and microbial barrier characteristics.

It is also necessary to validate the capability of the packaging and sealing processes to reliably deliver a satisfactory seal while maintaining other attributes of package quality. Important factors to consider when designing a validation program include the following:

a) The packaging materials used during validation studies ought to be representative of those that will be used in routine production.

b) Evidence will be needed to demonstrate that the sealing process does not adversely affect the function of the product or package and that the package can be opened and the product presented according to specifications.

c) The experimental protocol should include qualification runs with the sealing equipment at the appropriate specification limits for temperature, dwell time, and pressure that provide the most severe challenge to the sealing process.

d) It will be necessary to calibrate instruments used to monitor and record sealing process parameters before and after qualification runs.

e) It will be necessary to establish the reproducibility of the packaging process over successive runs under specified operating conditions.

f) The test methods used to measure the quality of the seal need to be validated, and the test instruments need to be calibrated. Among the typical tests are seal strength, seal width, and visual appearance.

g) After package integrity is validated, it is important to demonstrate that it is maintained before, during, and after the sterilization process, during distribution, and for the expected useful life of the sterile product.

### 3.3.4 Product labeling

Product labeling should provide adequate instructions for shipping, storing, opening, and using the product. The label should also provide a caution that opened or damaged packaging can no longer ensure the sterility of the product. For reusable products, additional information should be provided to assist the user in selecting a process


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which will ensure that the device is safe to use after it has been cleaned, decontaminated, repackaged, and resterilized (see AAMI, 1995a).

NOTE—If overlabels are used, it is advisable to evaluate their impact on package performance and on the ability of the process to deliver sterilization.

### 3.5 Family groupings

For purposes of validating sterilization cycles, families of products and packages can be defined based on similarities in material composition, product design, manufacturing process, intended use (required sterility assurance level [SAL] and biocompatibility), and primary package system design. (See annex A.)

### 3.6 Sterilization cycles

Many sterilization cycles have been developed for use in a moist heat environment with calibrated equipment that has been properly installed and validated. Among the processes commonly used in industrial moist heat sterilization are the following:

a) *Saturated steam—Vented systems:* This sterilization process is used for products that can tolerate process temperatures at saturated steam pressure and that allow effective air removal from and steam contact with the product.

b) *Saturated steam—Forced air removal:* This process is intended to sterilize products consisting of porous materials and/or items having cavities where air is difficult to remove.

c) *Air pressure systems:* Some product packaging cannot withstand the vapor pressure changes associated with moist heat sterilization. There are a number of available processes in which filtered compressed air is used to ensure that, for part or for the duration of the sterilization cycle, the pressure on the outside of the product equals or exceeds the inside pressure. These processes include cycles using air/steam mixtures, water spray, and water immersion.

See annex B for detailed guidelines on cycle operation.

### 3.7 Sterilization process development

#### 3.7.1 General

Moist heat sterilization is a process in which the rate of microbial destruction depends on thermal energy, time, moisture content, product bioburden, and the resistance of the bioburden. After the rate of microbial destruction has been described for a process, the time necessary to achieve the appropriate probability of sterility or SAL can be obtained by extrapolation. Different products may require different methods of developing and validating a cycle that will provide the SAL recommended for the product. The number of samples of product or simulated product required for process development and validation also may vary. Typically, 5 to 10 samples will be needed, but the specific number chosen will be dictated by the number required to achieve statistical confidence in the test results. The number chosen should be supported by documented rationale.

Two basic methodologies are used in the development of sterilization processes: the overkill method and the bioburden method.

NOTES

1. European Standard (EN) 556 requires that products labeled sterile have a SAL of $10^{-6}$. The information provided in this section is based on AAMI recommendations for industrial steam sterilization process development (AAMI, 1987).

2. Cycle development for closures involves special considerations and is discussed in the next section.

3. If the sterilization process must comply with European or ISO requirements, biological indicators to be used in sterilization process development should comply with the appropriate standards. A biological indicator in compliance with the American National Standard

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for biological indicators (AAMI, 1991) does not necessarily comply with the ISO standards for biological indicators (ISO 11138-1: 1994 and ISO 11138-3:1995).

### 3.7.2 Overkill method

Microbiological challenge populations used in cycle development and routine monitoring are usually not related to the presterilization bioburden. The term "overkill" refers to the fact that the microbiological challenge organism is more numerous and more resistant than the product bioburden.

The overkill methodology is based on the premise that the sterilization process will inactivate the microbiological challenge and provide an additional safety factor. Usually, this safety factor represents the inactivation of 12 logarithms of a microorganism with a $D_{121° C}$ of approximately 1.0 min and a z value of 10° C. For challenge microorganisms having different D values, the population can be adjusted to achieve equivalent lethality; that is, the more resistant the challenge microorganism, the lower the population that can be used. For example, the challenge characteristics of a $10^3$ population having a D value of 2.0 min, or a $10^5$ population with a D value of 1.2 min, are equivalent to those of a $10^6$ population with a D value of 1.0 min.

It is important to remember that the D values and z values of microbiological challenges and product bioburden can vary in different environments (e.g., solutions and different manufacturing sites) and in different containers and closures. Therefore, the selection of the initial microbiological challenge spore count or organism type is based on the resistance of the spore population under the conditions of use. The microbiological challenge is usually $10^3$ to $10^6$ of heat-resistant spores such as *Bacillus stearothermophilus.*

Because the efficacy of an overkill cycle is dependent upon the challenge organism presenting more resistance then the product bioburden, product samples are typically evaluated for bioburden during cycle development and at periodic intervals after production has begun.

Because the parameters of an overkill cycle are designed to be more severe than are required to achieve sterilization, the process may produce increased particulate levels, a more limited shelf life, and/or accelerated product degradation due to excessive thermal exposure. Consequently, extensive product/package testing during cycle development is necessary to ensure that product quality is not adversely affected by the sterilization process.

### 3.7.3 Bioburden method

There are two variations of the bioburden method: the absolute bioburden method and the combined bioburden/biological indicator method.

*Absolute bioburden:* This methodology requires that the product be screened for thermally resistant organisms, with the most resistant isolates selected for the purpose of challenging product sterilization. The initial resistance studies are performed by exposing actual product samples to the proposed cycle conditions at fractional time intervals. The product samples are then tested for microbial survival. From these data, the D values of the resistant isolates can be determined. Alternatively, bioburden organisms can be isolated, cultured, propagated on or into the product or a carrier, and then subjected to various fractional exposures at the proposed cycle conditions and tested for sterility. The D values of the isolates are then calculated. In this approach, it is important to understand that the resistance of the isolates may change during the propagation process.

When the absolute-bioburden method is used for cycle development, it is necessary to perform periodic bioburden resistance studies to ensure that product bioburden resistance has not changed. An extensive bioburden monitoring program is also required in order to establish the normal process control limits and to detect subtle changes in the raw materials, the product, and the manufacturing environment. Because of the impact of


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bioburden resistance on the efficacy of the sterilization cycle, it is important that bioburden testing frequency be addressed when modifications to the product or process are made.

Sufficient bioburden data should be obtained to establish a historical record. The frequency of bioburden monitoring depends on the quality and variability of the historical data, the kind of products being sterilized, the manufacturing process, and the type of sterilization process. However, it is common practice to monitor bioburden at least quarterly.

For periodic bioburden monitoring, either actual product samples or appropriate isolates may be evaluated, using one of the fractional exposure times from the initial resistance studies, to verify that the resistance has not shifted.

*Combined bioburden and biological indicators:* In this method, an organism known to be resistant to moist heat sterilization is used as the microbial challenge; examples include *Clostridium sporogenes, Bacillus coagulans, B. subtilis,* and *B. stearothermophilus.* The relative resistance and mean population of the biological indicator is compared to the resistance and population of bioburden associated with the product (as determined by enumeration and fractional exposure techniques). The objective is to demonstrate that inactivation of a predetermined level of microbial challenge microorganisms ensures a probability of survival no greater than the defined SAL. In other words, if the defined SAL is $10^{-6}$, then the challenge must ensure in combination of count and resistance that the probability of a bioburden survival is $10^{-6}$ or less.

## 3.8 Pretreatment and preconditioning

### 3.8.1 Pretreatment processes

The design of some complex products and closure systems prevents effective steam penetration in moist heat sterilization processes, resulting in a dry heat environment rather than a moist heat environment (see "Cycle development for closures and fitments"). At moist heat sterilization temperatures, the dry heat process is not very effective. To assure adequate sterilization, such products or components can be pretreated or presterilized to reduce bioburden.

NOTE—In some cases, presterilization is advisable because pretreatment processing and storage time may allow recovery of the bioburden population or may stress the bioburden in such a way as to alter its resistance.

Pretreatment is also used to reduce the bioburden of individual components for the purpose of reducing the sterilization processing of the final assembled product, or to kill contaminating organisms that are resistant to the desired final sterilization process.

Pretreatment can be performed by means of any method of sterilization or disinfection. A dry heat, moist heat, or radiation process is typically used. Process development is conducted in the accepted manner (see relevant AAMI or ISO standards), but the process need not be as rigorous as a terminal sterilization process because the requirement is for bioburden reduction, not sterility. For example, the microbiological validation of the process typically employs lower inoculation levels of the indicator organism.

### 3.8.2 Preconditioning process

Preconditioning most commonly involves the addition of moisture to product, components, and/or dry absorbent materials to create a moist heat environment in inaccessible locations or to prevent overheating or superheat conditions. As noted in the previous section, the design of some complex products and closure systems may inhibit effective penetration of moist heat. In addition, dry absorbent materials such as cellulose can absorb and condense excessive steam in the course of reaching equilibrium in water content. The heat from the condensing steam can cause temperatures inside absorbent loads to exceed the sterilization temperature. (See also Block, 1983.)

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