

Steam Sterilization



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Steam Sterilization - Study Guide #13

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Description of Study Guide Topic

This study guide will review important principles of steam sterilization, cycle performance, steam quality and purity, equipment maintenance and process monitoring.

Overall Purpose of the Study Guide

To discuss the important principles of sterilization and methods of monitoring the process, and to enrich the healthcare professional's knowledge of the process.

Objectives

Upon completion of this independent study, the participant will be able to:

1. Review the basics required for steam sterilization.
2. Discuss sterility assurance monitoring requirements for steam sterilization.

Intended Audience

This study guide provides for independent study for those persons who need to improve their understanding of steam sterilization: Central Service managers and technicians, perioperative nurses, surgical technologists, infection control professionals, etc.

Introduction

Saturated steam under pressure is the oldest and most common agent used in healthcare facilities for sterilizing heat- and moisture-stable medical/surgical instruments, devices and supplies. We have come a long way since the first pressure steam sterilizer was built in 1880 by Charles Chamberlain, a colleague of Louis Pasteur. Chamberlain's sterilizer was quite simple and very much resembled a household pressure cooker.

Many variations occurred along the way, but 1933 was the year that marked the beginning of modern sterilization in the United States. The Amsco Corporation introduced the first automated pressure steam sterilizer in which performance was controlled by the measurement of temperature by a thermometer in the chamber drain line. Since those days, we have made significant advances in sterilizer equipment technology, but the basic principles and theory of steam sterilization remain the same.

For purposes of discussion of general concepts, this educational program focuses on steam sterilization used in healthcare environments. Other moist heat sterilization methods are used in the industry when necessary to protect the integrity of the product being sterilized; including mixtures of steam and air or steam, air and water. These other methods will not be covered here.

Sterilization is a complex process based on the proper execution and successful coordination of a number of procedures, including:

- > Cleaning and rinsing the items thoroughly
- > Preparation, assembly and packaging of the items
- > Proper loading of the packs for sterilization
- > Proper operation of a well-maintained sterilizer to deliver the correct parameters for sterilization
- > Preparation and delivery of high-quality steam

The major problems that can interfere with the successful completion of the steam sterilization process are:

- > Problems with steam characteristics, such as saturation, purity, or supply
- > Incomplete air removal from the packs and the chamber
- > Equipment malfunctions
- > Personnel error

Steam Characteristics

Steam sterilization is accomplished by using moist heat in the form of saturated steam under pressure. It is still the fastest, most dependable, most easily produced and most economical method of killing all microorganisms. Moist heat or steam, used under controlled conditions, can kill microorganisms much more quickly and efficiently than can dry heat, and at a lower temperature.

- > Steam coagulates a microorganism's cell protein (protoplasm) to kill it, in much the same way as the white of an egg coagulates when you poach it in boiling water at 212°F (100°C)
- > Frying an egg using dry heat would require at least 700° F (371°C) and would take longer

Cell destruction using dry heat oxidizes or incinerates the microorganisms to kill them.

What is saturated steam? Very simply, it is a combination of heat, energy and water. When you watch a pot of water boil, you see small bubbles rise to the surface of the water and burst. The bubbles contain saturated steam. The saturated steam used for sterilization can be produced by several methods, depending on the type of sterilizer you are operating.

Steam Quality

Steam "quality" or saturation is described in terms of the presence of water as a wet mist or water droplets. The most important thing to remember is that the steam quality, or moisture content of the steam, is critical for effective sterilization. A minimum of 97% saturated steam, with no more than 3% liquid content, or water, is considered best for steam sterilization. If the moisture content is higher, the result will be wet packs at the end of the sterilization cycle. If the moisture content of the steam is too low, the steam can become superheated. Superheated steam may be at the correct temperature, but is too dry to be effective for steam sterilization. (Remember, dry heat takes longer to kill microorganisms.) Superheated conditions, besides being ineffective, can prematurely deteriorate fabrics and some medical devices.

Steam Purity

The purity of the steam is also important; the steam must be free of:

- > Any solid impurities that can build up in the steam lines, like rust, sludge, pipe scale deposits from hard water, and packing or gasket materials used in plumbing
- > Liquid impurities that can come from feed water additives used to control the pH level and retard scaling and corrosion in the boiler

- > Vapor impurities that can come from the chemical additives used to prevent corrosion in steam lines

Opinions vary on whether or not these impurities are a significant problem with respect to sterilization, but such impurities can stain items.

Amine additives are intended to be carried over with the steam and when correctly used, will not harm the load. Clean steam lines that are properly trapped and the proper use of chemicals will prevent carrying over impurities into the sterilizer that can stain, spot, or damage fabrics and medical devices used in patient care. Some industrial and pharmaceutical applications require that the steam generation be done without the use of any boiler water treatment. Sterilizers that operate from self-contained boiler systems or small, remote boilers may have specific requirements concerning feed water characteristics and boiler maintenance to ensure safe, reliable operation.

Variations in steam pressure may affect temperature come-up time and uniformity within the sterilizer chamber. Pressure variations may come about because of clogged filters, poorly engineered piping, or excessive demands on the steam supply. In cold climates, problems may occur at the beginning of the winter; such problems are often traceable to a marginal steam supply that is overloaded when it is called upon to supply building heat.

Steam production may be monitored and maintained by personnel who are far removed from the actual sterilization process, even by public utilities such as electrical power companies. Correcting steam supply problems generally requires the assistance of trained maintenance personnel or the engineering staff. The sterilizing department must be able to communicate their requirements for steam quality, purity, and pressure to the steam producer.

Types of Steam Sterilization Cycles

Properly prepared steam is used differently in gravity displacement and prevacuum sterilization cycles.

Gravity Displacement Cycle

In gravity displacement sterilization, the incoming steam displaces residual air through a drain in the bottom of the sterilizer chamber.

Whether a gravity displacement or a prevacuum cycle is used, the basic sterilization cycle consists of three basic segments:

- > The conditioning phase
- > The exposure phase
- > The exhaust phase

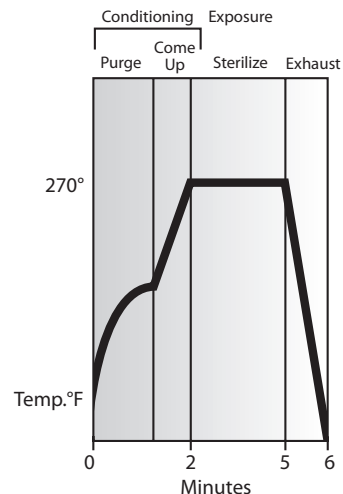
Conditioning Phase

The conditioning phase is the part of the cycle when air is removed, steam enters and the load is heated. In a gravity displacement sterilizer, the following sequence of events occurs during the conditioning phase:

1. The steam comes from its source and enters the sterilizer jacket, which is the space between the sterilizer chamber wall and the outer shell. Steam in the jacket keeps the inner chamber wall hot, which prevents condensation of steam on the chamber wall and assists in drying at the end of the cycle.

2. The steam enters the chamber from the jacket and forms a layer above the air.
3. As more and more steam is admitted, the air is pushed out through the chamber drain. Trapped air is the biggest enemy of steam sterilization. Steam will sterilize only surfaces that it can touch. Prepare, package and load all items so that air can be removed and steam can penetrate and then be removed from every surface to be sterilized.
4. As the air is pushed out of the chamber, the load is warmed and the chamber temperature is sensed at the thermostatic trap in the chamber drain line.
5. When all of the cool air is pushed out, the trap closes.
6. Pressure is increased inside the chamber to achieve the desired sterilizing temperatures. Saturated steam produced by the boiler (or generated within the sterilizer chamber in tabletop units) will be at the temperature of boiling water at sea level 212°F (100°C). This temperature is not sufficient for sterilization, so the temperature must be raised. To do this, the steam is put under pressure.
7. Steam pressure from the boiler to the sterilizer should be 50-80 pounds per square inch (psig) as read on the steam line gauge. Steam pressure measured in the jacket and chamber should be equal during the exposure phase of the sterilizing cycle. The chamber pressure is displayed on a pressure gauge or a computer printout. It takes 15 psig to achieve a sterilizing temperature of 250°F (121°C), or 27 psig for 270°F (132°C) and 30 psig for 274°F (134°C). All of these pressures are gauged pressures, meaning they are in addition to the approximately 15 psig that the earth's atmosphere exerts on all surfaces at sea level.

NOTE: Because atmospheric pressure is less at higher elevations, the steam pressure on the chamber gauge will have to be increased approximately one half pound for every 1,000 feet above sea level to be able to achieve sterilizing temperatures. Your service technician will make that adjustment. If you are having trouble reaching sterilizing temperature, check to see that the steam pressure is high enough.



Exposure Phase

When a set temperature is reached within the sterilizer chamber, the exposure phase begins. The exposure time of the sterilization cycle is the length of time it takes for a particular load of items to be sterilized. Because sterilizers vary in design and performance characteristics, always verify cycle parameters against the sterilizer

manufacturer's written instructions for the specific sterilizer and load configuration being used.

The most common temperature and time parameters for wrapped goods in a gravity displacement cycles are:

- > 15-25 minutes of exposure at 270-275°F (132-135°C)
- > 30 minutes exposure time at 250°F (121°C)

If the exposure time you are accustomed to using for wrapped goods in a gravity displacement cycle at 250°F (121°C) is 30 minutes, this includes:

- > 12 minute heat up – the time needed to heat up the load. (The load lags or is slower to heat up than the steam that is free in the chamber)
- > 12 minute kill time – the scientifically determined time required to kill highly resistant microorganisms at 250°F (121°C)
- > A six minute safety factor, which is 50% of the kill time

When you use a higher set temperature, the exposure time will be shorter. Check your operator's manual for the exposure times at higher temperatures.

If a sterilization container system is used as packaging, consult the container manufacturer's written recommendations regarding exposure time. The use of rigid sterilization container systems may affect come-up and exposure times in steam sterilizers depending on the efficiency of air removal from and steam penetration into the containers.

The inherent design of some medical devices (e.g., some air-powered instruments) can hinder air removal and steam penetration, making sterilization more difficult and requiring longer exposure times. The device manufacturer is in the best position to specify the conditions necessary for steam sterilization of such devices.

Exhaust Phase

The exhaust phase of the sterilization cycle is when steam is removed from the chamber; air is injected through a filter that removes contaminants and the load is dried and brought back to atmospheric pressure. Once the chamber pressure is brought back to atmospheric pressure, the end-of-cycle signal sounds and the chamber door can be opened. Steam sterilization of liquids requires special preparation and procedures, especially in the exhaust phase of the cycle. Improperly prepared liquids or improper sterilization cycles can result in serious injury to the sterilizer operator. Always consult the operator's manual before attempting to steam-sterilize liquids.

Prevacuum Cycle (a Dynamic Air Removal Cycle)

Prevacuum steam sterilizers are sometimes also called "Hivacs." This type of sterilization cycle depends upon pressure and vacuum excursions at the beginning of the sterilization cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system. A higher operating temperature is used and the exposure time is shorter than a gravity displacement cycle.

Conditioning Phase

In prevacuum cycles, air is mechanically pulled from the chamber during the conditioning phase. Mechanical air removal via a vacuum pump, or an ejector system, is faster than gravity displacement of air and it removes air more efficiently. Thus, sterilization temperatures are reached more rapidly. Remember that air is displaced, or pushed out of the chamber, during the introduction of steam in the gravity displacement cycle.

There are usually a series of injections of steam and then chamber evacuations to remove both air and steam, so you will notice the temperature and pressure going up and down several times before the sterilizer indicates the exposure phase has begun.

Exposure Phase

In prevacuum cycles, the exposure time and total cycle time are shortened. The exposure time for wrapped goods using a prevacuum cycle at 270°F (132°C) is four minutes. A four minute cycle would include:

- > A one minute heat-up time
- > Two minutes of kill time
- > A one minute safety factor

Exhaust Phase

In a prevacuum sterilizer, steam is actively pulled from the chamber during exhaust at the end of the sterilizing cycle.

Steam Flush-Pressure Pulse (a Dynamic Air Removal Cycle)

The steam flush-pressure pulse (SFPP) cycle is another type of dynamic air removal cycle that conditions the load above atmosphere pressure. It does not pull a vacuum at the beginning of the cycle. The exposure time and temperature are the same as for the prevacuum cycle, which is the other dynamic air removal cycle used in healthcare facilities. The SFPP cycle and prevacuum cycle are considered equivalent with regard to the sterilization process and the use of biological and chemical indicators.

Everyone who has responsibility for steam sterilizer operations must fully understand how to operate the sterilizer and how to select the correct parameters for sterilization. When all of the principles of product preparation and sterilizer operation are applied properly, steam sterilization is designed to provide a significant level of sterility assurance. There is less than a one in a million chance that a microorganism will survive the process.

Sterilizer Cleaning and Maintenance

Achieving successful sterilization also requires that routine and preventive cleaning and maintenance be performed on the sterilizer as scheduled. Proper maintenance of equipment minimizes sterilizer downtime and helps prevent sterilizer malfunctions.

The sterilizer manufacturer should provide detailed and complete information about necessary routine and preventative maintenance procedures, including the frequency at which these procedures should be performed. Perform maintenance as specified in these written instructions.

Routine Maintenance

Routine Inspection

Give particular attention to inspection, maintenance and replacement of components that are subject to wear, such as recording devices/pens, door gaskets and chamber drain screens. The door gasket keeps a tight seal to prevent steam from escaping and to prevent air from entering the chamber when the door is locked. It should be free of soil, cracks and tears. A clean chamber drain is essential because air and steam cannot be successfully removed from the chamber if it is clogged. Have the manufacturer's representative show you the location of the drain, how to remove the chamber drain screen and then how to back-flush the screen under running water to remove lint or anything else that may have collected in it. If a chamber drain cleaning is recommended, have the manufacturer's representative show you how to do it properly. To protect yourself from hot chamber walls and fixtures, always use caution and wear long protective gloves when cleaning the chamber drain screen and the chamber drain.

Cleaning the Sterilizer

Inspect and clean sterilizer walls, carts and shelves regularly according to the manufacturer's written instructions. Soil buildup can be difficult to remove if allowed to remain too long and a dirty chamber can impair drying. Examples of items requiring daily inspection are:

- > Door gaskets
- > Chamber drain screen
- > The internal chamber
- > External surfaces
- > Recording charts and pens

Perform weekly or other prescribed inspection and cleaning using methods and cleaning agents specified in the manufacturer's written instructions.

Remember, the chamber walls and fixtures will be hot. Always turn off the steam supply and allow the chamber to cool before attempting to clean the chamber walls. Also allow cart and carriage surfaces to cool before cleaning. Periodic inspection and cleaning reduces the frequency of sterilizer malfunction. Cleanliness also reduces the risk of accidental contamination of sterile material. Consult your sterilizer manufacturer for appropriate cleaning methods and cleaning agents.

Preventive Maintenance

Preventive maintenance is critical to keeping your sterilizer running properly, much like changing the oil in your car or rotating the tires. Periodic maintenance, including lubrication and replacement of appropriate parts, must be carried out regularly and by a qualified individual. The maintenance program may be in-house or may be contracted with the sterilizer manufacturer or other qualified service company. The frequency of maintenance will depend on how often the equipment is used and may vary from institution to institution; consult the manufacturer's instructions for guidance.

Gauges

Such items as pressure and temperature gauges, timers, controls and recording devices must be calibrated as specified in the manufacturer's instruction manual.

Tasks that require special tools or calibration equipment that are not available in the healthcare facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility.

Record Keeping

Retain maintenance and repair files for a specified period of time, as established by local, state, or federal regulations. Keep a separate maintenance and repair record for each sterilizer. Provide sufficient information to identify the sterilizer and to establish a continuous history of all scheduled and unscheduled service. Include at least the following:

- > Dates on which service was requested and completed
- > Model and serial numbers of the sterilizer
- > Location of sterilizer
- > Description of service and type and quantity of parts replaced
- > Results of biological testing
- > Name of the person requesting the service and reason for service request
- > Signature and title of person acknowledging completed work

Accurate and complete records are required for process verification and are useful when malfunctions occur.

Monitoring Steam Sterilization

A complete monitoring program for steam sterilization includes physical, chemical and biological monitoring. The AAMI standards document "Comprehensive guide to steam sterilization and steam assurance in health care facilities" (ANSI/AAMI ST79:2006) provides additional information.

Physical Monitoring (a.k.a., Mechanical Monitoring)

Physical control monitors are used to verify time, temperature and pressure recordings during the sterilization cycle. They permit the earliest possible detection of major equipment malfunctions because they can be evaluated even while the cycle is in progress. Physical monitors allow real-time assessment of sterilization cycle conditions. They usually provide permanent records by means of chart recordings or computer-driven printouts. Everyone must know how to read these gauges, chart recorders and/or printouts.

Physical monitoring involves the following procedures:

1. At the beginning of the cycle, ensure that the chart recorder is marked with the date and the sterilizer identification number and that the pen is properly aligned. If a computer printer records

your cycle parameters/results, check previous printout for any problems. Always inspect previous cycle documentation for satisfactory cycle completion.

2. As the cycle progresses, visually inspect the monitors to see that the appropriate parameters are being reached.
3. Once the sterilization cycle is completed, and before items are removed from the sterilizer, examine the record to verify that cycle parameters were met.
4. Verify that this inspection took place by signing the documents required by your facility's policies or procedures. This also permits later identification of the operator, if necessary.

If recording devices are unavailable, monitor the time and temperature gauges during the cycle, document at the end of the cycle that cycle parameters were met and sign the documentation.

Information recorded from each sterilization cycle should include:

- > Load number
- > Contents of the load
- > Exposure time and temperature, if not provided by a recording chart
- > Name of the operator
- > Results of biological monitoring, if applicable

Documenting the process records cycle performance and establishes accountability.

Common problems detected by physical monitoring include inadequate temperature, vacuum, exposure time and drying time. If physical monitoring records indicate any malfunction or suspicious operation, notify the department head or designee. If the malfunction cannot be corrected immediately (for instance the wrong cycle time and/or temperature were chosen), terminate the cycle in accordance with the manufacturer's instructions. Consider the load nonsterile and remove the sterilizer from service. Do not restore the sterilizer to operation until the exact cause of the malfunction has been identified and remedied.

Chemical Monitoring

Chemical indicators are physical or chemical devices employed to monitor one or more sterilization process parameters for the purpose of detecting failures in packaging, loading, or sterilizer function. Some chemical indicators contain chemical substances in the form of a solid pellet that melts at a specific temperature. Others consist of paper strips that have been impregnated with dyes or other chemicals that change color in the presence of specified parameters. The Association for the Advancement of Medical Instrumentation (AAMI) has defined six basic classes of chemical indicators: throughput indicators, Bowie-Dick type indicators, single parameter indicators, multiparameter indicators, integrating indicators, and emulating indicators.

Classes of Indicators

AAMI and ISO recognize six classes of chemical indicators. Each class has different performance specifications. The use and application for indicators in Classes 1 through 5 can be found in AAMI ST79:2006. However, use recommendations for Class 6

indicators have not been incorporated into ST79. The following list details the definitions for each type of chemical indicator:

- > **Class 1 – Process Indicators** - Process indicators are intended for use with individual units (e.g. packs or containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They are designed to react to one or more of the critical process variables.

These types of indicators are typically, single-variable, external indicators, such as sterilization tape, but may include some internal indicators.

- > **Class 2 – Indicators for use in Specific Tests** - Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/ sterilization standards.

An example of this type of indicator would be the Bowie-Dick test that is designed to test for air removal in vacuum-assisted steam sterilizers.

- > **Class 3 – Single variable indicators** - A single-variable indicator is designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process as a stated value (SV) of the chosen variable.

This type of indicator would not be a typical indicator used for steam sterilization, but it is an indicator used for sterilization methods such as hydrogen peroxide gas plasma.

- > **Class 4 – Multi-variable indicators** - A multi-variable indicator is designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variables.

This type of indicator provides additional monitoring of the sterilization cycle. It reacts to two of the critical parameters, or variables, in the sterilization process (time, temperature, saturated steam) that have been chosen by the manufacturer. The more information gathered about what occurred in the sterilization cycle, the more confidence there is that the sterilization process was successful.

- > **Class 5 – Integrating Indicators** - Integrating indicators are designed to react to all critical process variables. The condition at which the indicator will demonstrate a passing condition is equivalent to or exceeds the performance requirements published in the ANSI/AAMI/ISO 11138 series for biological indicators.

This type of indicator is correlated to the performance of a biological indicator and reacts to all of the critical variables in the sterilization process (time, temperature and saturated steam). It must demonstrate passing conditions at points in the sterilization process where a biological indicator is dead. It must also show a failed response at the point in the sterilization cycle where a biological indicator is alive. Class 5 integrating indicators may be used as indicator strips, challenge packs or in combination with biological indicators.

- > **Class 6 – Emulating indicators** - Emulating indicators are cycle verification indicators that are designed to react to all critical variables for specified sterilization cycles. The indicator demonstrates a passing condition after

the required lethality of the sterilization cycle has been achieved. Class 6 indicators emulate the sterilization cycle.

This type of indicator or emulator measures all of the critical variables/parameters of steam sterilization and has a tighter tolerance. This means that it measures even more of the cycle than the currently used Class 5 integrator.

This classification system of chemical indicators refers primarily to indicator strips, but it also applies to challenge packs containing chemical indicators. When used for load monitoring, the challenge packs provide an immediate confirmation of a sterile load. At minimum, a Class 5 indicator must be used in these packs. Alternatively, a Class 6 emulating indicator may be used. The Class 6 provides a greater assurance than the Class 5 integrating indicator.

Chemical indicators should be used within each sterilized package and should be placed into the area most difficult for the steam to reach. Internal chemical indicators can not be retrieved without compromising the sterile integrity of the packaging and thus must be retrieved and interpreted at the time of use, giving the person who opens the sterilized package an indication that the sterilant appeared to have reached the indicator. Everyone using sterilized items that have chemical indicators included must know how to correctly interpret the response of the indicator.

Load-record cards are also equipped with chemical indicators (typically Class 1 or Class 4). These cards provide a place to document each package that has been prepared and labeled for each specific sterilization cycle. Among other details, load records allow you to keep track of how many of each item were in the load and where they came from. In the event of the sterilization cycle failure, you will know where to go to retrieve the items and what you are looking for.

Choosing a Chemical Indicator

Obtain data from indicator manufacturers on the reliability, safety, and performance characteristics of their particular products. Certain broad performance considerations may be used to evaluate different types and brands of indicators:

- > **Readability:** the ease with which the user can judge the endpoint response, such as the predetermined shade of a color that the indicator should finally achieve by the end of the sterilization cycle
- > **Reliability:** a combination of its reproducibility (precision or consistency) and achievement of its design target (or accuracy)
- > **Selectivity:** the specific exposure conditions the indicator is designed to monitor and how the development of its endpoint response will be affected by specific changes in other conditions
- > **Stability:** susceptibility to adverse effects of prolonged storage or unsuitable storage conditions (e.g., extremes of temperature or humidity or light exposure) either before or after being used to monitor a sterilization process
- > **Safety:** tendency to release hazardous substances to sterilized items, personnel, or the environment. The choice of a chemical indicator depends greatly on the specific needs, resources, and sterilization equipment of the individual healthcare facility

Interpreting Chemical Indicators

Chemical indicators enable you to verify only that products have been subjected to certain processing conditions; no chemical indicator verifies that an item is actually sterile.

After processing, compare the response of the chemical indicator to an endpoint described by the manufacturer. Inadequate or incomplete reaction of the chemical indicator may be indicative of a sterilization process problem (e.g., incorrect choice of packaging, improper packaging or loading technique, or sterilizer malfunction).

If interpretation of the indicator suggests inadequate steam processing, do not use the contents of the package. Immediately inform the appropriate supervisor. A single, nonresponsive, or inconclusive chemical indicator may indicate that the entire load is nonsterile, or it may be that errors in loading or packaging resulted in sterilization failure in some, but not all, packages in the load.

Supervisors must exercise professional judgment in determining whether or not to recall an entire load. They must take into account all factors having a bearing on the efficacy of the cycle and all performance indicators; including the results of physical monitoring (time and temperature recordings), the results of chemical indicators elsewhere in the load, and if applicable, the results of biological monitoring. If biological monitoring was performed, but the results are not yet available, the remaining packages from the same load should be quarantined and not used until the results of the biological indicators are obtained. Class 5 integrating indicators may be used as indicator strips, challenge packs or in combination with biological indicators.

Develop written policies and procedures for the recall of supplies from issued or stored loads in cooperation with your institution's infection control committee. To ensure patient safety, these recall procedures must expedite the retrieval of items that are suspected to be nonsterile and must ensure adequate follow-up actions.

Bowie-Dick Testing

The original test pack is constructed with surgical towels and is described along with the test protocol in the AAMI document "Comprehensive guide to steam sterilization and steam assurance in health care facilities" (ANSI/AAMI ST79:2006). Commercial tests are available that are generally easier to use and are more accurate. Newer technology has allowed for some Bowie-Dick tests to be used as a diagnostic tool.

Biological Monitoring

Biological monitoring is the most critical part of monitoring the steam sterilization process. The purpose of biological monitoring is to test the ability of a sterilization cycle to kill microorganisms.

When deciding which biological indicator to purchase, consider the information provided in the AAMI document "Process Challenge Devices/Test Packs for Use in Health Care Facilities," which is referenced in this Study Guide. Also, obtain information from the manufacturer on the biological indicator's reliability, safety and performance characteristics, as well as written instructions on storage, handling, use and microbiological testing of their product.

What is a Biological Indicator?

According to the AAMI document "Comprehensive guide to steam

sterilization and steam assurance in health care facilities” (ANSI/AAMI ST79:2006), “A **biological indicator** is a test system containing viable microorganisms providing a defined resistance to a specified sterilization process.”

Further, the U. S Food and Drug Administration (FDA) says that “a biological sterilization process indicator is a device intended for use by a healthcare provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization” (FDA, 2003).

Does a negative biological test result prove that everything in the load is sterile? It is important to understand that a biological indicator is used to determine if the set sterilization cycle parameters were sufficient to kill the test microorganisms.

Remember that a negative biological result does not prove that everything in the load is sterile or that they were all adequately exposed to sterilization conditions.

The probability of sterilization of an item(s) is not only dependent on a properly functioning sterilization cycle, but also properly decontaminated, assembled, wrapped and loaded items, so that they can all be adequately exposed to sterilization conditions.

Which test microorganism is used to monitor steam sterilization cycles?

Spores of *Geobacillus stearothermophilus* that comply with the AAMI/ANSI standard “Sterilization of Health Care Products-Biological Indicators-Part 3: Biological Indicators for Moist Heat Sterilization” (AAMI/ANSI/ISO 11138-3:1995), are used.

Geobacillus stearothermophilus is not harmful to humans.

This spore/microorganism is incorporated into a process monitoring device to test steam sterilization cycles.

What are process monitoring devices (PCD) and how are they configured?

“A PCD is an item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process” (ANSI/AAMI ST79:2006).

The conventional biological indicator is a carrier (usually a spore strip/disc) that is inoculated with *Geobacillus stearothermophilus*, placed into its primary pack (which is a self-contained unit that also houses a unit of growth media) and is ready for use. This self-contained unit is used by itself to test flash sterilization cycles and is contained in a prescribed AAMI test pack or equivalent commercially-prepared test pack to monitor the wrapped goods steam sterilization cycles. Death of the *Geobacillus stearothermophilus* indicates that appropriate parameters for sterilization were achieved.

- > A biological indicator with enzyme-based, early-readout capability is also available. Its construction is essentially the same as the conventional biological indicator, however, a non-fluorescent substrate is incorporated into the media. After sterilization and a rapid incubation time, a special reader may detect fluorescence indicating an enzymatic

breakdown of the non-fluorescent substrate, predicting a steam sterilization process failure. If no enzyme is detected, fluorescence will not occur, predicting that the biological spores will not grow upon further incubation

Is a rapid enzymatic indicator a biological indicator?

A rapid enzymatic indicator contains enzymes that have been isolated from spore-forming bacteria. This is not a biological indicator due to the lack of bacterial spores. The enzymes have a temperature- and pH-sensitivity that is similar to the microorganism that they came from. When the enzyme is exposed to steam sterilization conditions, its activity is lost over time and correlates to the destruction of *Geobacillus stearothermophilus*. Incubation is not required because there is no microorganism included in this test material, but an activation solution is applied to the sterilized test material and the color change indicates a positive or negative result.

When is it necessary to biologically monitor steam sterilization cycles?

According to AAMI (ST79), conventional biological indicators should be used to monitor steam sterilization cycles under the following conditions. The use of rapid enzyme indicators is not acceptable under these circumstances because the best way to verify the lethality of a sterilization cycle is to kill large populations of microorganisms that are resistant to steam sterilization.

- > Upon installation of a new sterilizer
- > After relocation of an existing sterilizer
- > After a sterilizer malfunction
- > After a sterilizer process failure that is indicated by a positive biological test
- > After major repairs to a sterilizer that are outside the scope of routine or preventative maintenance. For example, a major repair would be: weld repairs to the sterilizer chamber/pressure vessel, repair of chamber door or major plumbing assembly, rebuilds or upgrades to the sterilizer controls
- > After repairs to the steam generator/delivery system
- > When performing periodic quality assurance testing of items that you routinely sterilize

ROUTINE biological monitoring of steam sterilization cycles is also the standard, as well as additional biological monitoring when **IMPLANTABLE** medical devices are in a load.

Which process monitoring device should I use to perform routine biological monitoring of steam sterilization cycles and loads with implantable medical devices? How often do I need to do it?

Conventional biological indicators and enzyme-based early-readout indicators can each be used to routinely monitor steam sterilization cycles and serve as the basis for release of sterilized items for use, including implantable medical devices.

- > Routine monitoring is performed in a sterilization load, at least weekly, preferably every day the sterilizer is in use (testing every sterilizer and type of sterilization cycle used)
- > Every sterilization load that contains **IMPLANTABLE** medical devices must be biologically monitored. For maximum sterility assurance, implantable medical devices should be quarantined until negative biological test results are confirmed.

If I use an enzyme-based early-readout indicator, do I need to do anything else to verify the performance of a steam sterilization cycle?

Yes, according to AAMI (ST79), the use of this method of monitoring requires that the performance of the sterilization cycle be periodically verified by one of two methods. Use one of the following test methods at least weekly, but preferably every day that the sterilizer is used.

- > Continue incubation of the enzyme-based early-readout indicator following the manufacturer's instructions. The amount of time necessary to ensure that any surviving microorganisms will grow out will be specified by that manufacturer
- > You may use a conventional biological test pack to verify sterilizer performance

Details regarding monitoring steam sterilization cycles can be found in AAMI ST79:2006).

Constructing a Biological Test Pack

The biological test pack recommended for use has been tested by sterilizer manufacturers in cooperation with AAMI. Testing conditions and parameters are clearly spelled out in the AAMI document mentioned earlier.

Construct the test pack using 16 freshly laundered reusable huck or absorbent surgical towels in good condition. Each towel should be approximately 16 x 26 inches in size. Do not iron these towels because ironing removes too much moisture from the textile which can result in superheating and inhibit the sterilization process.

Use the following procedure to construct and test a biological test pack:

1. Fold each towel lengthwise in thirds and then widthwise in half.
2. Place the towels, one upon the other, with the folds opposite each other to form a uniform stack that is approximately nine inches x nine inches x six inches high.
3. Place one or more biological indicators between the eighth and ninth towels, toward the center of the pack, along with a chemical indicator.
4. Carefully tape the stack, keeping it approximately six inches high. Do not use a wrapper.
5. If properly constructed, the test pack will weigh approximately three pounds and should have a density of approximately 11.3 pounds per cubic foot.

To avoid preparing your own packs and to ensure consistency of pack assembly and performance characteristics, consider using disposable biological test packs. Use these disposable tests just as you would use the towel pack you prepare yourself. Just be sure that the manufacturer can prove that its performance is equivalent to the 16-towel test pack. This test is performed in a fully loaded chamber with the test pack sitting flat (so all layers of towel are sitting one upon the other), on the bottom sterilizer shelf over the drain.

Installation Testing

After installation and before a sterilizer is put into service, it is necessary to perform installation testing. Performance of a steam sterilizer is a function not only of its design, but also of the steam generation and distribution systems with which it is used, the electrical system and other mechanical systems unique to a particular facility. The compatibility of the sterilizer with these systems, and thus its overall effectiveness, can only be verified in the environment in which it will be used.

To perform an installation test or to test after major repairs, use the following procedure for both gravity displacement and prevacuum cycles:

1. Prepare three biological test packs.
2. Place one of these packs flat on the sterilizer shelf, so that all layers of the towels sit one upon the other (not on edge) in the area of the chamber that is least favorable to sterilization. (This area, or "cold point," varies with sterilizer design, but is normally in the front, bottom shelf of the sterilizer, over the drain). Place it alone in the sterilizer, because if any air is in the chamber it will seek to be in that lone pack.
3. Run a normal sterilization cycle performing this test three consecutive times, using a fresh pack each time. Allow 30 minutes between each cycle to achieve "fresh start" conditions.
4. At the end of the cycle, carefully handle the biological test pack with protective gloves to avoid heat hazards.
5. Remove the biological indicator from the pack and handle it carefully to avoid contaminating it.

Routine Biological Testing

To perform routine testing, again position the pack flat on the lower shelf, over the drain, but this time in a fully loaded chamber during normal sterilization processing.

Testing Control Samples

Before using a new lot of BIs, take a sample from each new lot or box to run a control test. Do not sterilize it. Handle and incubate it according to the manufacturer's instructions. The control should show positive growth to prove that the test microorganisms are alive and ready for test. Retest controls weekly according to the manufacturer's instructions. AAMI recommends running a control every day.

Incubation of Biological Indicators

Closely follow the biological indicator manufacturer's instructions for incubation. Incubate *Geobacillus stearothermophilus* at the correct temperature, generally 131°F (55°C), using a special incubator. If the sterilization cycle was ineffective, the test organism should grow during incubation. Evidence of a properly functioning sterilization cycle is no growth of the test microorganism. All biological indicator results, including results from controls, must be interpreted by a qualified individual and must be included in the sterilizer records.

If you find positive growth, take the sterilizer out of service. Report it to your supervisor, who will check the physical monitors and chemical indicators to see if they indicate a faulty process and will consult with sterilizer maintenance personnel to determine the cause of failure.

Ask the lab to identify whether or not it is a *Bacillus* growing or if it is a microorganism that may have contaminated the specimen after sterilization. The lab will use the following test procedures as described in the ANSI/AAMI ST79:2006 and by the manufacturer of the biological indicator:

1. Make two subcultures from the recovered culture.
2. Incubate one subculture at 95-99°F (35-37°C) and the other at 131-140°F (55-60°C) for 24-48 hours.
3. Prepare smears of the incubated subcultures, stain them by Gram's method and examine them microscopically.
4. The test is positive for *Geobacillus stearothermophilus* if microscopic examination reveals Gram-positive spore-bearing rods and if the incubation studies demonstrate growth at 131-140°F (55-60°C) but no growth at 95-99°F (35-37°C).

If it is determined that a sterilization failure did occur, all products sterilized since the last good biologic test was performed must be considered nonsterile, be retrieved if possible and reprocessed.

A faulty sterilizer can not be made operational without identifying and correcting the underlying problem; merely extending the cycle time or increasing the cycle temperature, for example, is not appropriate. After a major repair of any type of steam sterilizer, Qualification Testing must be completed. Qualification Testing includes three consecutive test cycles be run with a PCD containing a BI, one right after the other, in an otherwise empty chamber (see AAMI ST79:2006, 10.8.1). After a major repair to a dynamic-air-removal sterilizer, Qualification Testing must also be completed, which includes three consecutive Bowie-Dick test cycles run in an empty chamber, one right after the other and the test sheets examined (see AAMI ST79:2006, 10.7.6.1). The test results should be obtained (i.e., the BI should be incubated according to the BI manufacturers instructions) and be determined to be satisfactory before the sterilizer is returned to service.

A major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel, replacement of the chamber door, vacuum pump, a major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, does not require Qualification Testing before the sterilizer is returned to service. Verification of the sterilizer's operation according to the sterilizer manufacturer's specifications is sufficient (ANSI/AAMI ST79:2006).

Bowie-Dick Type Tests

There is one more important detail to monitor: the ability of the mechanical air removal device used during the prevacuum cycle (a type of dynamic air removal cycle) to efficiently remove air from the chamber.

Bowie-Dick type tests are designed to test for efficiency of air removal from the chamber and will also detect any air leaking into the chamber through faulty fittings or bad gaskets. Most modern prevacuum sterilizers have an air leak test built right into the system. If undetected, air leaks or insufficient air removal can defeat steam sterilization in a prevacuum cycle. Find out how it works and when to use it from your manufacturer's representative.

Remember, the Bowie-Dick type test is used only on prevacuum cycles. A Bowie-Dick test pack must be constructed as follows:

1. Fold freshly laundered, 100% cotton, absorbent, surgical towels to a size not smaller than 9 by 12 inches.
2. Stack the folded towels 10-11 inches high. (The total number of towels may vary from test to test, depending on towel thickness and wear.)
3. Place a commercially prepared test sheet into the center of the pack.
4. Wrap the stack with a single, loosely applied, reusable or disposable nonwoven wrapper.

NOTE: You can purchase disposable Bowie-Dick type tests that generally provide a more consistently prepared test pack, but they should be scientifically proven to be equivalent in performance characteristics to the one you prepare yourself.

5. It is advisable to run an empty cycle before the test to heat up the sterilizer and blow through any condensation that may have collected in the steam lines.
6. Place the test pack flat so the layers of fabric sit one upon the other on the lower shelf of the sterilizer, over the chamber drain. Nothing else should be in the chamber. (If air is not removed by the mechanical air removal device, it will collect in this lone pack.)
7. Run a prevacuum cycle with an exposure time of three and a half minutes. If your sterilizer does not have half-minute settings, four minutes may be used, but do not exceed four minutes at 273°F (134°C) or the test result may be invalid. Drying is omitted.
8. After the test is performed, carefully handle the hot pack to remove the test sheet or commercial indicator.
9. Look at the test sheet or indicator for complete and consistent color change; the color in the center should be the same as that at the edges. (Residual air or air that leaks into the chamber is normally "entrained," or carried by the in-rushing steam, to the center of the load.) Consult the manufacturer of the test for information regarding appropriate color change parameters.
10. If evidence of an air pocket is found, report it to your supervisor and retest the sterilizer. Have maintenance examine the sterilizer to determine the cause of test failure and repair it if appropriate. Do not use the sterilizer to perform prevacuum cycles until you get a satisfactory Bowie-Dick test.

A Bowie-Dick test should be a part of installation testing for prevacuum cycles and should be performed three consecutive times before any prevacuum sterilizer is put into service. Also conduct a Bowie-Dick type test before the first load of goods to be processed every day or, if you are sterilizing loads 24 hours a day, at the same time of day every day for consistency. Allow 30 minutes between each cycle to achieve "fresh start" conditions.

NOTE: The Bowie-Dick test is not used to monitor the steam-flush pressure pulse (SFPP) cycle in STERIS equipment because this cycle operates above atmospheric pressure.

Summary

All of this material is important to the understanding of the steam sterilization process and how to monitor it properly, but it only

touches the surface. Consult the references listed in the bibliography to further enhance your knowledge regarding steam sterilization.

It is your responsibility to know as much as you can about the process of steam sterilization. Every step you take should be toward successful sterilization.

Glossary

Absorbent Towel

An all cotton towel having a plain weave with only the warp yarns tightly twisted.

Amine

Any of a class of compounds derived from ammonia by replacement of one or more hydrogen atoms with organic groups.

Biological Indicator

A calibrated population of bacterial spores (of high Indicator resistance to the mode of sterilization being monitored) on or in a carrier, put up in a package which maintains the integrity of the inoculated carrier and which is of convenience to the ultimate user, that serves to demonstrate whether sterilization conditions were met.

Bowie-Dick Type Test

A diagnostic test of a sterilizer's ability to remove air from the chamber and prevent air re-entrainment.

Challenge Pack

A pack used in installation, qualification and ongoing quality assurance testing of hospital sterilizers.

Chamber

The portion of the sterilizer in which materials are steam-processed and that is sealed off when the door is closed.

Chemical Indicator

A physical or chemical device employed to monitor one or more Indicator process parameters of the sterilization cycle in order to detect failures in packaging, loading, or sterilizer function. The chemical indicator usually consists of a sensitive chemical or ink dye that may vary in sensitivity from product to product.

Cleaning

The removal, usually with detergents and mechanical action, of all adherent visible soil (e.g., blood, protein substances and other debris) from the surfaces, crevices, serrations, joints and lumens of instruments, devices and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Downtime

A period of time when a sterilizer is nonoperational.

Dry Heat

Hot air or other gases (such as superheated steam) lacking sufficient moisture to condense and transfer heat efficiently.

Endpoint

The point during exposure of a chemical indicator to a process at which a characteristic (physical or chemical) change is observed indicating that certain known or minimum exposure conditions have occurred.

Entrainment

The collecting or transporting of solid particles or a second fluid or vapor by the flow of the primary fluid or vapor at high velocity.

Exhaust Phase

The part of the sterilization cycle during which steam is removed from the chamber, air is injected through a filter that removes contaminants and the load is dried and brought back to atmospheric pressure.

Exposure Phase

The total continuous, elapsed time during which the sterilizer operates at the pre-selected sterilizing temperature.

Gravity Cycle

A type of sterilization cycle that uses the injection of steam displacement at a measured rate to displace residual air through a drain cycle located in the floor of the sterilizer chamber, near the door.

Heat-Up Time

The time required for the entire load to reach the selected sterilizing temperature after the chamber has reached that temperature. Heat-up time is the same as temperature penetration time.

Jacket

The portion of a steam sterilizer, surrounding and affixed to the chamber, through which steam is circulated and which functions to maintain temperature in the chamber.

Mechanical Indicator

A device that indicates sterilization cycle conditions, including time, temperature and pressure. Also known as a physical indicator.

Physical Indicator

A device that indicates sterilization cycle conditions, including time, temperature and pressure. Also known as a mechanical indicator.

Pressure Gauge

A device attached to the chamber or jacket of a steam sterilizer. It is used to indicate, usually in pounds per square inch gauge (psig), the pressure in the chamber or jacket.

Prevacuum Sterilizer Cycle

A type of dynamic air removal steam sterilization cycle that depends upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system; usually the higher the operating temperature 270°F to 276°F (132°C to 135°C), 285°F to 290°F (141°C to 144°C), the shorter the exposure time and the accelerated drying of fabric loads.

Rehydration

A process of adding moisture to linen by laundering before sterilization.

Rigid Container

Specifically designed steel, plastic, or anodized aluminum receptacles used to package items for sterilization, usually surgical instruments. The lid and/or bottom surface contain a steam-or gas-permeable, high-efficiency microbial filter.

Steam Flush Pressure Pulse Cycle

A type of dynamic air removal steam sterilization cycle that conditions the load above atmospheric pressure to remove air and introduce steam.

Steam Purity

A quantitative measure of contamination of steam caused by dissolved solids, volatiles, or particles in vapor or by tiny droplets that may remain in the steam following primary separation in the boiler.

Steam Quality

The ratio of the weight of dry steam to the weight of dry saturated steam and entrained water. For example, if the quality of the steam has been determined to be 97%, the wet steam mixture delivered from the boiler is composed of three parts by weight of water, usually in the form of a fine mist, and 97 parts by weight of dry, saturated steam. A minimum quality of 97% saturated steam, with no more than 3% liquid content (water), is considered best for steam sterilization.

Sterile

The state of being free of all living microorganisms; in practice, usually described as the probability of a surviving microorganism being one in one million.

Sterilizer

The equipment used to sterilize materials or devices by direct exposure to the agent of choice (e.g., steam, ethylene oxide gas or vapourous hydrogen peroxide).

Sterilization

A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

Superheating

Occurs when dehydrated textiles are subjected to steam sterilization. Moisture is taken from the steam to hydrate the textiles. The sterilization environment may become too dry and superheating may occur, which can prevent effective steam sterilization. Therefore, there is a need to launder textiles to rehydrate them before resterilizing.

References and Suggested Readings

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Review Questions

1. Steam sterilization is a complex process based on proper execution and successful coordination of a number of procedures, including:
 - A. cleaning of items to be sterilized
 - B. assembly, packaging, and loading for sterilization
 - C. sterilizer maintenance
 - D. all of the above
2. Moist heat kills microorganisms by:
 - A. oxidation
 - B. incineration
 - C. coagulation of cell proteins
 - D. denaturation of cell proteins
3. Steam quality refers to its:
 - A. moisture content
 - B. purity
 - C. temperature
 - D. pressure
4. The percentage of saturated steam that is considered optimal for steam sterilization is:
 - A. 3%
 - B. 95%
 - C. 97%
 - D. 100%
5. The part of the sterilization cycle when air is removed, steam enters the chamber, and the load is heated is called the:
 - A. conditioning phase
 - B. containment phase
 - C. exposure phase
 - D. exhaust phase
6. The basic difference between gravity displacement and prevacuum sterilization cycles is that in a prevacuum cycle:
 - A. incoming steam forces the air out of the chamber
 - B. a Bowie-Dick type test is not required
 - C. air is mechanically removed or pulled from the chamber
 - D. the sterilization cycle is slower
7. In order to attain effective sterilization temperatures, for every 1000 feet above sea level, the pressure to the sterilizer must be:
 - A. decreased by about 1 pound
 - B. decreased by about 1/2 pound
 - C. increased by about 1 pound
 - D. increased by about 1/2 pound
8. Generally speaking, when you increase the set sterilization temperature, you also:
 - A. increase the exposure time
 - B. decrease the exposure time
 - C. decrease the gauge pressure required
 - D. superheat the steam
9. When a sterilizer's end-of-cycle signal sounds, it means that:
 - A. the exposure phase is over
 - B. the exhaust phase has begun
 - C. the chamber has been brought back to atmospheric pressure
 - D. the items are cool enough to handle
10. Physical (mechanical) control monitors are used to verify that:
 - A. individual items are sterile
 - B. all residual air was removed from the chamber
 - C. sterilization parameters were reached in the chamber
 - D. sterilization parameters were reached within each pack
11. Class 2-5, Internal chemical indicators are used with each package you process to verify that:
 - A. sterilization took place
 - B. appropriate sterilization parameters reached the indicator within the pack
 - C. all remaining microorganisms were killed
 - D. all residual air was removed from the sterilizer
12. Class 1, External chemical indicators, or throughput indicators, should be included with:
 - A. each individual item to be sterilized
 - B. each package to be sterilized
 - C. each load
 - D. the first load of the day
13. Class 4, Internal multiparameter indicators are designed to be interpreted:
 - A. when you remove the pack from the sterilizer
 - B. upon distribution from sterile storage
 - C. at the time of use
 - D. after incubation in a laboratory setting
14. Your choice of a chemical indicator should be influenced by its:
 - A. safety
 - B. stability
 - C. readability
 - D. all of the above
15. The steam sterilization process is monitored using spores of:
 - A. *Bacillus subtilis*
 - B. *Geobacillus stearothermophilus*
 - C. *Streptococcus*
 - D. *Mycobacterium tuberculosis*
16. The microorganism used to test the steam sterilization cycle:
 - A. will produce disease in humans if you are not careful
 - B. does not produce disease in humans
 - C. is highly susceptible to steam sterilization
 - D. can be incubated at room temperature
17. A 16-towel biological test pack should be approximately:
 - A. 12 x 12 x 20 inches
 - B. 10 x 10 x 12 inches
 - C. 9 x 12 x 10 inches
 - D. 9 x 9 x 6 inches
18. For installation testing of a new sterilizer, a biological test pack should be placed:
 - A. in an otherwise empty chamber, on edge, in the front of the sterilizer
 - B. in an otherwise empty chamber, flat, in the back of the sterilizer
 - C. in a typical load, on edge, in the front of the sterilizer
 - D. in an otherwise empty chamber, flat, on the bottom shelf of the sterilizer above the drain

19. If a biological test indicates that a sterilization failure occurred, you must reprocess:
- A. all products sterilized since the last good biologic test was performed
 - B. the items in that load only
 - C. all items processed that day
 - D. all of those items must be discarded, not reprocessed
20. A Bowie-Dick type test is to be used to test successful air removal from:
- A. gravity displacement cycles only
 - B. prevacuum cycles only
 - C. both gravity displacement and prevacuum cycles
 - D. both types of sterilizers, after installation or major repairs only

- Answers to Review Questions & Section Sources:
- 1. D (Introduction)
 - 2. C (Steam Characteristics)
 - 3. A (Steam Quality)
 - 4. C (Steam Quality)
 - 5. A (Types of steam sterilization cycles – Gravity displacement cycle)
 - 6. C (Types of steam sterilization cycles – Prevacuum)
 - 7. D (Types of steam sterilization cycles – Gravity displacement cycle)
 - 8. B (Types of steam sterilization cycles – Gravity, exposure phase)
 - 9. C (Types of steam sterilization cycles - Gravity, exhaust phase)
 - 10. C (Monitoring steam sterilization – Physical monitoring)
 - 11. B (Monitoring steam sterilization – Chemical monitors, Class II-V)
 - 12. B (Monitoring steam sterilization – Chemical monitors, Class I)
 - 13. C (Monitoring steam sterilization – Chemical monitoring)
 - 14. D (Monitoring steam sterilization – Choosing a chemical indicator)
 - 15. B (Monitoring steam sterilization – Biological monitoring)
 - 16. B (Monitoring steam sterilization – Biological monitoring)
 - 17. D (Monitoring steam sterilization – Constructing a bio. test pack)
 - 18. D (Monitoring steam sterilization – Installation testing)
 - 19. A (Monitoring steam sterilization – Biological monitoring)
 - 20. B (Monitoring steam sterilization – Bowie-Dick testing)

Evaluation Form
Study Guide #13: Steam Sterilization

Last Name

First Name/M.I.

RN/LPN/LVN License Number (Circle one: RN - LPN - LVN)

Non-RN: License or Social Security Number

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To receive continuing education credit, please complete the evaluation form and mail, fax or e-mail the completed form to STERIS Corporation.

Rate on a scale of: 1=low 5=high

To what extent did the study guide meet the 2 stated objectives below?

- | | | | | | |
|--|---|----------------------------|----------------------------|----------------------------|----------------------------|
| 1. Review the basics required for steam sterilization cycle | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 2. Discuss sterility assurance monitoring requirements for steam sterilization. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 3. To what extent is this learning method easy-to-use? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 4. How much time was required to read the content, take the test, compare your answers and complete the evaluation form? | _____ hours _____ minutes | | | | |
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| 6. Was the content presented without bias of any commercial product or drug? | Yes _____ No _____ | | | | |

I have completed all the requirements for this entire activity (please sign and date).

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