



# Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Setting

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## Objectives

After completion of this self-study activity, the learner will be able to:

1. Order AORN documents for your reference library.
2. Integrate the AORN Recommended Practices for Sterilization in Perioperative Practice Settings into your policies and procedures to meet the JCAHO Leadership Standards.
3. Develop a policy and procedure for using flash sterilization according to the AORN Recommended Practices for Sterilization in Perioperative Practice Settings.
4. Develop a quality control program for sterilization processes based on the AORN Recommended Practices for Sterilization in Perioperative Practice Settings.

*Many thanks to the team at 3M Health Care for working with Managing Infection Control to provide the following accredited course. IAHCSSM has awarded one and one-half (1.5) contact points for completion of this continuing education lesson toward IAHCSSM re-certification. The CBSPD has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication, and to be used only once in a re-certification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 121.*

*Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of Managing Infection Control.*

## Test Questions

True or False

1. AORN recommended practices are approved by the Board of Directors after members and others are allowed to comment.
2. Providing surgical items free of contamination is one measure for preventing surgical wound infections.
3. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Leadership Standard states policies and procedures must be based on the least stringent licensure requirements, laws, rules and regulations.
4. Do not follow packaging system manufacturers' instructions for preparation and sterilization.
5. Flash sterilization should not be used as a substitute for insufficient instrument inventory because of the increased risk of infection to the patient.
6. Use a rapid-action biological indicator result to release an implant in an emergency situation when flash sterilization is unavoidable.
7. Steam sterilizers should be tested at least weekly and preferably daily with a biological indicator.
8. Low-temperature liquid peracetic acid sterilizers should be tested at least weekly and preferably daily with a biological indicator.
9. Sterilization process indicators (chemical indicators) should not be used in each package to be sterilized and included with items being flash sterilized.
10. Policies and procedures should be developed using the AORN recommended practices for sterilization to establish authority, responsibility and accountability, and to serve as operational guidelines.

## Introduction

The Association of periOperative Registered Nurses (AORN) develop recommended practices through the AORN Recommended Practices Committee. The proposed recommended practices are presented to members and others for comments. After the comment period, the recommended

practices are finalized and approved by the AORN Board of Directors. The Recommended Practices for Sterilization in Perioperative Practice Settings was effective January 1, 2006.

The AORN recommended practices “are intended as achievable recommendations representing what is believed to be an optimal level of practice.” Each healthcare facility will need to determine the degree to which the recommended practices can be implemented within its policies and procedures. These recommended practices “are intended as guidelines adaptable to various practice settings.” The practice settings include:

- ▶ Traditional operating rooms
- ▶ Ambulatory surgery units
- ▶ Physicians’ offices
- ▶ Cardiac catheterization suites
- ▶ Endoscopy suites
- ▶ Radiology departments
- ▶ Other areas where operative and other invasive procedures may be performed.

### Purpose of Recommended Practice

These recommended practices provide guidelines for the sterilization of surgical items (i.e., instruments, supplies, equipment, medical devices). The creation and maintenance of an aseptic environment has a direct influence on patient outcomes. A major responsibility of the perioperative registered nurse is to minimize patients’ risks for surgical wound infections. The expected outcome of primary importance to this recommended practice is outcome O10, “The patient is free from signs of Infection.” One of the measures for preventing surgical wound infections is to provide surgical items that are free of contamination at the time of use. This can be accomplished by subjecting them to a sterilization process. Steam, ethylene oxide (EO), low temperature gas plasma, peracetic acid, ozone, and dry heat are sterilization methods that are used in the healthcare environment. Sterilization of each item to be processed must be validated by the product manufacturer. Directions for sterilizing items should be reviewed in consultation with the manufacturers of the sterilizer and the item to be sterilized. Each sterilization method, and some instrumentation, has limitations; these limitations should be identified before purchasing and using any sterilizer. Sterilization provides the highest level of assurance that surgical items are free of viable microbes.”<sup>1</sup>

As leaders in the healthcare setting, you are responsible for meeting the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Leadership Standards. This standard (LD.1.30 and LD.4.20) states that a hospital must provide care, treatment and services in accordance with applicable licensure requirements, law, rules and regulations. Policies and procedures must be based on the most stringent of these so that optimal patient care is achieved.

The AORN recommended practices for sterilization in perioperative settings should be part of your reference library and reviewed when establishing policies and procedures, as should be the recommended practices developed by the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control (APIC), the American Society for Healthcare Central Service Professionals (ASHCSP), the International Association of Healthcare Central Service Materials Management (IAHSCMM) and the Centers for Disease Control (CDC).

This inservice will provide information about the AORN Recommended Practices for Sterilization in Perioperative Practice Settings that can be used to develop policies and procedures. Purchasing the AORN Recommended Practice Book will provide you with a more comprehensive look at all the AORN recommended practices. (See details for how to purchase on p. 120.)

### Recommended Practice I

*“Items to be sterilized should be decontaminated in a controlled environment and in accordance with the device manufacturer’s written instruction.”*

- ▶ Control room temperature, humidity, ventilation and physical separation of decontamination from sterilization processes.
- ▶ Use standard precautions in decontamination.
- ▶ Wear appropriate personal protective attire.
- ▶ Use cleaning procedures that minimize the possibility of contamination.

AORN states that “environmental controls and standard precautions reduce personnel exposure to hazardous materials.” The AORN’s *Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment* and *Recommended Practices for Cleaning and Processing Endoscopes and Endoscope Accessories and the Multi-society guideline for reprocessing flexible gastrointestinal endoscopes* should be followed for the cleaning and drying of items so that the reliability of the sterilization method is not affected by microorganisms on items, as well as soil, oils and other materials that may shield the sterilant from contacting the items.<sup>2-4</sup> AAMI recommended practices also provide information on controlling the environment, protecting employees and proper decontamination of medical devices.<sup>5-7</sup>

### Recommended Practice II

*“Items to be sterilized should be packaged according to the guidelines established in AORN’s “Recommended practices for selection and use of packaging systems.”<sup>8</sup>*

Prepare and package items to achieve and maintain sterility to the point of use:

- ▶ Follow the Association for the Advancement of Medical Instrumentation (AAMI) guidelines for density of wrapped packages.<sup>5</sup>
- ▶ Consult with packaging system manufacturers about preparation, configuration, sterilization recommendations and the ability of the packaging to allow for aseptic presentation.
- ▶ Hold instruments open and unlocked.
- ▶ Consider the type of instruments, total set weight, and density during preparation and assembly.
- ▶ Do not place paper/plastic peel pouches in a container or wrapped set because this type of packaging has not been validated by the manufacturer of the container.

The AORN recommended practices related to instrument sets and containers are:

- ▶ Weight should be specified by the manufacturers of the surgical instruments, sterilizer and container systems.
- ▶ Follow the container system manufacturer's written instructions for maximum weight, set preparation, sterilizer loading procedures, exposure times and drying cycles.
- ▶ Sets more than 20 pounds are known to be difficult to dry without lengthy drying times.
- ▶ Consult the National Institute for Occupational Safety and Health (NIOSH) published lifting equation to calculate a recommended weight for specified, two-handed lifting tasks.<sup>9</sup>

Due to the concerns by the Food and Drug Administration (FDA), AORN and other healthcare professional organizations (AAMI, APIC, ASHCSP, IAHCMM) about the use of containment devices, including permissible tray weights and sterilization instructions, a new AAMI document has been developed. ANSI/AAMI ST77 *Containment devices for reusable medical device sterilization* will be published in 2006.<sup>10</sup> This standard covers the minimum labeling and performance requirements for rigid sterilization container systems and for instrument cases, cassettes and organizing trays that a device manufacturer needs to provide a healthcare facility. The labeling and performance requirements should provide information to ensure effective cleaning, preparation, sterilization, storage and aseptic presentation of medical devices in container systems.

Instruments must be correctly prepared and packaged and the appropriate sterilization cycle parameters used in order for effective sterilization to occur. With the variety of steam sterilization cycle times, temperatures and dry times, it is important to obtain in writing from the medical device manufacturer (MDM) the appropriate parameters. After a thorough review, you should adjust your sterilization process to accommodate the various parameters to ensure effective sterilization. If the MDM's instructions for sterilization are different from those recommended by the sterilizer manufacturer, the MDM's instructions should be followed.

## Some equipment and implants may require prolonged exposure or drying times.

### Recommended Practice III

*“Saturated steam under pressure is the preferred method and should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacture.”*

- ▶ Follow steam sterilizer manufacturers' written instructions for operating the sterilizer.
- ▶ Since steam sterilizers vary, verify your cycle requirements against the sterilizer manufacturer's written instructions for the specific sterilizer and load configurations.
- ▶ Compare the written instructions for any sterilization container with the sterilizer manufacturer's written instructions. Some equipment and implants may require prolonged exposure or drying times (see comments above).
- ▶ Have sterilizer equipment manuals readily available to the sterilizer operator.

Cool packages before handling to avoid compromising the barrier properties of the packaging material and contaminating the contents and avoid placing warm or hot items on cool or cold surfaces.

*“When hot and cold surfaces are brought together, moisture condenses from both inside and outside the package. If liquid breaches the packaging material, items inside the package are considered unsterile.”<sup>1</sup>*

Refer to the AORN's *Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment* when processing high-risk tissue known or suspected to be contaminated from Creutzfeldt-Jakob disease (CJD).<sup>2</sup>

### Recommended Practice IV

*“Flash sterilization should be used in selected clinical situations and in a controlled manner. Use of flash sterilization should be kept to a minimum.”*

Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method, and should not be used as a substitute for insufficient instrument inventory.<sup>1</sup>

“Flash sterilization should be considered only if all of the following conditions are met:

- ▶ The device manufacturer's written instructions are available and followed.

- ▶ Items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats and other substances.
- ▶ Lumens are flushed with the cleaning solution and rinsed thoroughly.
- ▶ Items are placed in a sterilization container or tray in a manner that allows steam to contact all instrument parts.
- ▶ Measures are taken to prevent contamination during transfer to the sterile field.
- ▶ Documentation of cycle information and monitoring results is maintained to provide for tracking of the flashed item(s) to the individual patient.”<sup>1</sup>

The AORN recommended practices states: “Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process. It is essential that all steps in the sterilization process be performed in a conscientious manner.”<sup>1</sup>

The recommended practice also discusses the necessity for proper cleaning, decontamination, packaging and wrapping,

handling and transportation of unwrapped packages, and the use of specialized flash sterilization containers and preparation of lumens. The AORN recommended practices also directs you to follow written instructions for sterilization process parameters from both the medical device and sterilizer manufacturers.

The AORN recommended practices states: “**Flash sterilization should not be used for implantable devices.** Implants are foreign bodies, and they increase the risk of surgical site infections. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices. **When an implantable device is sterilized at a healthcare facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known.** If an emergency situation makes flash sterilization unavoidable, **a rapid-action biological monitoring device should be used along with a class 5 chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result.** After the rapid-action negative

result is obtained, the implant can be released for use in the immediate situation. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required. If the biological indicator is later determined to have a positive result, the surgeon should be notified as soon as the results are known.”<sup>1</sup>

As stated by Janet Schultz in “Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities” in *Managing Infection Control*, January 2004, possible patient outcomes include a higher degree of risk of infection because:

- ▶ “First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- ▶ “Second, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of infection.

- ▶ “Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- ▶ “Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient.”<sup>11</sup>

In addition: “The mortality rate (deaths) associated with infected total hip replacements approaches 50%, from the infection itself and from the complications associated with the resulting impaired mobility, such as blood clots and pneumonia.”<sup>11</sup>

For the above reasons, an implant should not be flash sterilized or released for patient use before the rapid-action biological indicator result is known.

This AORN recommended practices also states:

- ▶ Monitor the sterilizer function with mechanical (now referred to as physical), chemical and biological indicators to meet all monitoring standards.

- ▶ Record the physical parameters for each cycle and verify the results before the item is transferred to the point of use.
- ▶ Monitor flash sterilization cycles daily with devices according to manufacturers' written instructions.<sup>5,7</sup>
- ▶ Use a sterilization process monitoring device with each load to be flash sterilized.<sup>5,7</sup>
- ▶ Documentation should be traceable to each patient
  - Information on each load
    - Device(s) processed
    - Patient receiving item(s)
    - Reason for flash sterilization

Monitoring devices, including biological indicators, provide information to demonstrate that conditions for sterilization have been met. More information about the use of these devices is discussed in Recommended Practice XIV and in the 2002 ANSI/AAMI ST46 *Steam sterilization and sterility assurance in health care facilities* and the 1996 ANSI/AAMI ST37 *Flash Sterilization: Steam sterilization of patient care items for immediate use* recommended practice.<sup>5,7</sup>

### Recommended Practice V

*“Ethylene oxide (EO) sterilization is a low-temperature process that may be used for sterilization of heat- and moisture-sensitive surgical items.”*

This recommended practice states:

- ▶ Follow the manufacturer's written instructions to determine if the item is compatible with EO and what the sterilization parameters are.
- ▶ Load items in baskets or on loading carts to ensure free circulation and penetration of EO.
- ▶ Clean and dry all items, including lumens, before packaging for EO sterilization.
- ▶ Documentation of the cycle includes:
  - Temperature
  - Exposure time
  - Relative humidity
  - Sterilant concentration
  - Lot number of items
  - Contents of load
  - Results of mechanical (now referred to as physical), chemical and biological monitors

Additional information on the use of EO can be obtained from the AAMI *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*, ANSI/AAMI ST41, 1999 and the 1998 *Ethylene oxide use in hospitals: A manual for health care personnel* from the American Society for Healthcare Central Service Professionals of the American Hospital Association.<sup>12-13</sup>

### Recommended Practice VI

*“Items sterilized in EO sterilizers should be properly aerated in a mechanical aerator to remove EO.”*

In addition to the above recommended practices for EO, the following are also recommended:

- ▶ Complete aeration must be done before items can be safely used.
- ▶ “Whenever possible, EO-sterilized items should be processed in sterilizers that have an integrated aeration cycle.”
- ▶ When transferring items to a separate aerator, handle as little as possible before aeration; pull, rather than push, the cart to direct the EO vapors away from personnel.
- ▶ Use butyl rubber or neoprene gloves when handling EO-sterilized items.
- ▶ Aeration times depend upon the following variables:
  - “item composition and size,
  - item preparation and packaging,
  - density of load,
  - type of EO sterilizer used,
  - type of aerator used, and
  - temperature penetration pattern of the aerator’s chamber.”<sup>1</sup>
- ▶ Aeration times should be provided by the medical device and the packaging systems manufacturer and should be followed.
- ▶ Never interrupt an aeration cycle to remove items for use. This could cause patient or personnel injury.
- ▶ Document all aeration cycle parameters.

### Recommended Practice VII

*“A program for monitoring occupational exposure to EO must be established.”*

The AORN recommended practice states:

- ▶ Ensure a safe work environment by using an EO monitoring program complying with Occupational Safety and Health Administration (OSHA) regulations.
- ▶ Determine personnel’s EO airborne exposure concentration by monitoring and sampling according to OSHA regulations to ensure exposure does not exceed the OSHA action level of 0.5 ppm as an 8-hour time weighted average and the STEL of 5 ppm over a 15-minute period.
- ▶ Document monitoring and maintain records for the duration of employment plus 30 years after termination.
- ▶ Personnel should be informed of EO health and safety procedures upon assignment and at least annually.

- ▶ Follow OSHA regulations for periodic physical assessments.
- ▶ Inform employees of the facility’s emergency spill plan.

Further information on EO monitoring of personnel can be obtained from the AAMI *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*, ANSI/AAMI ST41, 1999 and the 1998 *Ethylene oxide use in hospitals: A manual for health care personnel* from the American Society for Healthcare Central Service Professionals of the American Hospital Association.<sup>12-13</sup>

### Recommended Practice VIII

*“Low-temperature gas plasma sterilization methods may be used for moisture-stable, moisture-sensitive, and heat-sensitive items.”*

The AORN recommended practice states: “When using a low-temperature gas plasma sterilization system, the manufacturer’s written instructions for use, monitoring, and maintenance should be followed.”<sup>1</sup>

The newest recommendations for monitoring low-temperature gas plasma, ozone or any gaseous chemical sterilizer is in *Chemical sterilization and high level disinfection in health care facilities*, ANSI/AAMI ST58, 2006.<sup>14</sup> Section 9.5.4.3 Frequency of use of biological indicators and process challenge devices, p. 41 states: “Process challenge devices containing appropriate BIs should be used for sterilizer qualification, testing during initial installation of the sterilizer, after relocation, major repairs or malfunctions of the sterilizer, and after sterilization process failures (see 9.5.4.4). For periodic quality assurance testing of representative samples of actual product being sterilized (see 9.7), BIs should be placed in actual products not in PCDs.

“A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle (see 9.5.4.5). Each load containing implantable devices should be monitored and, whenever possible, quarantined until the results of the BI testing are available. When documented medical exceptions dictate, it may be necessary to release an implantable device before the BI results are known. Release of a device before the results of the BI are known should be documented. See Annex M for examples of an implant log and exception form.”

The AORN recommended practice also says: “Documentation of items that can and cannot be processed in hydrogen peroxide gas plasma should be obtained from the device and sterilizer manufacturer.

“Sterilization of devices to be processed in hydrogen peroxide gas plasma should be validated by the device manufacturer. Devices to be sterilized should comply with the sterilizer manufacturer’s lumen claims relating to diameter and length of the device.”<sup>1</sup>

### Recommended Practice IX

“Sterilization systems using peracetic acid as a liquid sterilant may be used for heat-sensitive surgical items that can be immersed.”

The AORN recommended practice related to liquid peracetic acid systems that “should be considered a just-in-time sterilization process and should not be used for items to be stored and used at a later time without additional processing”<sup>1</sup>, states:

- ▶ Follow the sterilization system manufacturer’s written instructions for use, maintenance and monitoring.
- ▶ Clean and process endoscopes and accessories according to the AORN *Processing Endoscopes and Endoscope Accessories and the Multi-society guideline for reprocessing flexible gastrointestinal endoscopes*.<sup>3</sup>
- ▶ Use items immediately because they are wet, and the cassette or container is not hermetically sealed to prevent contamination.
- ▶ The medical device manufacturer should validate the process using the sterilizer manufacturer’s written instructions.
- ▶ Items that can and cannot be processed should be documented by the medical device and sterilizer manufacturer.

Further information on the usage of liquid peracetic acid systems can be obtained in *Chemical sterilization and high level disinfection in health care facilities*, ANSI/AAMI ST58, 2006.<sup>14</sup>

## Sterile packages should be stored under environmentally controlled conditions to maintain the shelf life of packages.

### Recommended Practice X

“Sterilization systems using ozone may be used for moisture-stable, moisture-sensitive heat-sensitive items.”

- ▶ Follow the sterilization system manufacturer’s written instructions for use, maintenance and monitoring.
- ▶ Consult manufacturer’s written instructions for specific use limitations including lumen length and diameter.

See Recommended Practice VIII for more information on the monitoring of ozone systems in addition to the AAMI recommended practice *Chemical sterilization and high level disinfection in health care facilities*, ANSI/AAMI ST58, 2006.<sup>14</sup>

### Recommended Practice IX

“Dry-heat sterilization should be used to sterilize anhydrous items (i.e., waterless) items that can withstand high temperatures.”

The AORN recommended practices state:

- ▶ Use, maintain and monitor according to the sterilizer manufacturers’ written instructions.
- ▶ Small containers and package density should be kept as low as possible for easy heat penetration.
- ▶ Closed containers or cassettes should be biologically monitored to determine the time needed for sterilization.
- ▶ Most types of tape cannot be used in this process.
- ▶ To avoid burns, use insulated gloves or handles when removing items from the sterilizer, and cool packaging before further handling.

The recommended practice says to consider purchasing commercially available pre-sterilized oils and powders before purchasing a dry-heat sterilizer.

The AAMI recommended practice *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST40, 2004 is a reference for additional information on the use of table-top dry heat sterilizers.<sup>15</sup>

### Recommended Practice XII

“The shelf life of a packaged sterile item is event related.”

The AORN recommended practice states the following events could compromise a package so it is no longer sterile:

- ▶ “multiple handling that leads to seal breakage or loss of package integrity,
- ▶ moisture penetration, and
- ▶ exposure to airborne contaminants.”<sup>1</sup>

Shelf life is event-related, not time-related, and these recommended practices should be in place before event-related sterility is a policy. In addition, “sterile packages should be stored under environmentally controlled conditions” to maintain the shelf life of packages.<sup>1</sup>

### Recommended Practice XIII

“Transportation of sterile items should be controlled.”

Written policies and procedures should be in place to ensure the quality of sterile packages are maintained during transportation. The AORN recommended practice is to transport items in covered or enclosed carts with solid-bottom shelves to protect them from environmental contaminants along the transportation route. Since loss of sterility is event-related (depends on amount of handling, conditions during transportation and storage, and the quality of the packaging material), “an evaluation of these conditions should occur before policies and procedures on the transportation of sterile items are written for perioperative practice setting.”<sup>1</sup> Written policies and procedures should be in

place to address how to maintain package sterility and prevent physical damage to packages in transportation.

### Recommended Practice XIV

*“A quality control program should be established.”*

AORN recommended practices state that a quality control program should be established to enhance personnel performance and monitor sterilizer efficacy to promote patient and employee safety. The program should include:

- ▶ “orientation programs,
- ▶ continuing education,
- ▶ documented competency, and
- ▶ tracking of unusual occurrences.”<sup>1</sup>

The following information about the sterilization process should include:

- ▶ Sterilizer maintenance and repair history;
- ▶ Sterilization process monitoring by mechanical (now referred to as physical), chemical or biological indicators with chemical and biological indicators used in a process challenge device where appropriate;
- ▶ Air-removal testing (i.e., Bowie-Dick test) of prevacuum steam sterilizers;
- ▶ Visual inspection of packaging materials;
- ▶ Lot control and traceability of load contents.

The following information should be recorded for each sterilization cycle:

- ▶ Sterilizer identification
- ▶ Type of sterilizer and cycle used
- ▶ Lot control number
- ▶ Load contents
- ▶ Critical parameters of the process
- ▶ Operator’s name
- ▶ Results of monitoring

One of the most frequently asked questions is how long sterilization process records should be maintained. AORN recommended practices states: “All records should be maintained for a time period specified by the health care facility’s risk manager and in compliance with local, state, and federal regulations. Accurate and complete records are required for process verification and are useful in sterilizer malfunction analysis.”<sup>1</sup>

### Mechanical monitors:

Mechanical monitors (now referred to as physical monitors) should be used to verify if time, temperature and pressure recordings are within manufacturers’ established parameters. They should be read and reviewed at the end of each cycle, and hardcopy records should be signed by the operator.

### Sterilization process indicator:

“A sterilization process indicator should be used in each package to be sterilized and included with items being flash sterilized.” If the indicator (chemical indicator) is not visible from the outside of the package, then a separate indicator is placed on the exterior of the package. AORN recommends the use of sterilization process indicators to detect procedural errors and equipment malfunctions but not as a way to verify sterility. The external process indicator distinguishes between processed and non-processed items and “the color change should be verified before opening.”<sup>1</sup>

### **Internal process monitors:**

Internal process monitors “show that the sterilant was able to penetrate the package, exposing the package contents to conditions of sterilization.”<sup>1</sup> View the internal chemical indicator before placing the item on the sterile field. “If the interpretation of the external or internal process monitors suggest inadequate processing, the item should not be used.”<sup>1</sup>

### **Biological indicators:**

Monitor wrapped cycle with a biological indicator in an appropriate process challenge device (i.e., test pack). Follow the AAMI standard for quality assurance testing of rigid containers. Test flash cycles with a biological indicator in an open mesh pan and/or in a flash container to simulate in-use conditions.

The AORN recommended practice also states: “Additional monitoring of three consecutive sterilization cycles should be performed after installation, major repair, redesign, or relocation of sterilizers. This testing is performed in an otherwise empty sterilizer. Pack should be placed in the area(s) of the sterilizer least favorable to sterilization, as identified by

the sterilizer manufacturer. If a steam sterilizer is intended to be used for multiple types of cycles (e.g., gravity displacement, dynamic air removal, flash), each sterilization mode should be tested.”<sup>1</sup>

“A biological indicator (preferably a process challenge device) should be included in all loads containing an implant(s), and implant(s) should be quarantined until the results of the biological indicator are known.”<sup>1</sup>

Qualified personnel should interpret the results of the tests and controls included in the sterilization records. Control vials should be from the same lot number as the test vial.

“Positive biological indicators should be reported immediately so that appropriate action can be taken. Accurate interpretation and immediate reporting of positive results promotes safe patient care.”<sup>1</sup>

In the event of a positive biological indicator:

- ▶ First read the sterilizer printout to determine if the parameters were met.
- ▶ Review chemical indicators for proper color or other change.
- ▶ Subculture the positive biological indicator.

- ▶ Retrieve and reprocess items processed back to the last known negative biological indicator.
- ▶ Document all actions.

### Additional monitoring requirements:

- ▶ **Steam sterilizers** should be tested with *Geobacillus stearothermophilus* spores at least weekly and preferably daily.
- ▶ **Prevacuum sterilizers** should be tested daily with a Bowie-Dick test in an empty chamber, and three consecutive tests should be run whenever the sterilizer is installed, relocated or undergoes a major repair.
- ▶ **Ethylene oxide sterilizers** should be tested with *Bacillus atrophaeus* spores every load.
- ▶ **Low-temperature hydrogen peroxide gas plasma sterilizers** should be tested at the same interval as other sterilizers in the facility. The spore of choice for this testing today is *Geobacillus stearothermophilus*.
- ▶ **Ozone sterilizers** should be tested with *Geobacillus stearothermophilus* spores at the same interval as testing of other sterilizers in the facility. Consult with the sterilizer manufacturer.
- ▶ **Low-temperature liquid peracetic acid sterilizers** should be tested daily with *Geobacillus stearothermophilus* spores. Follow the sterilizer manufacturer's written instructions.
- ▶ **Dry-heat sterilizers** should be tested with *Bacillus atrophaeus* spores when installed after major repairs. Tabletop gravity convection units should be monitored with spores at least once per week. Mechanical convection (i.e., forced air) dry-heat sterilizers should be monitored according to the manufacturers' recommendations.

More information about the monitoring of the sterilization process can be obtained from ANSI/AAMI ST46, 2002, *Steam sterilization and sterility assurance in health care facilities*, the ANSI/AAMI ST37, 1996, *Flash Sterilization: Steam sterilization of patient care items for immediate use* recommended practice and the ANSI/AAMI ST58, 2006, *Chemical sterilization and high level disinfection in health care facilities*.<sup>5,7,14</sup>

*“Preventative maintenance on sterilizers should be performed by qualified personnel on a scheduled basis.”*

- ▶ Inspect and clean the sterilizer chambers, carts and exterior surfaces as outlined by the written instructions of the manufacturer to minimize downtime and prevent malfunctions.
- ▶ Keep maintenance records
  - “date of service;
  - sterilizer model and serial number;
  - sterilizer location;
  - description of malfunctions;
  - name of person and company performing maintenance;
  - description of service and parts replaced;
  - results of biological validation and testing, if performed;
  - results of air-removal test results and, where appropriate, the name of the person requesting the service; and
  - the signature and title of the person acknowledging the completed work.”

### Recommended Practice XVI

*“Policies and procedures for sterilization processes should be developed, reviewed periodically, and readily available in the practice setting.”*

Policies and procedure should be developed using the recommended practices for sterilization “to establish authority, responsibility, and accountability and serve as operational guidelines.”<sup>1</sup> Use the uniform perioperative nursing vocabulary to develop policies and procedures, and documented nursing interventions related to sterilization. For new technologies, healthcare personnel should “strictly follow manufacturers’ written instructions for the operation and maintenance of sterilization equipment” and be “aware of the occupational hazards that different sterilants may pose to patients, health care personnel, and the environment.”<sup>1</sup>

### Glossary

A glossary of terms is included in the standards.<sup>1</sup>

### Summary

The AORN Recommended Practices for Sterilization in Perioperative Practice Settings states “a major responsibility of perioperative nurses is to minimize patients’ risks for surgical wound infections. One of the measures for preventing surgical wound infections is to provide surgical items that are free of contamination at the time of use.”<sup>1</sup> Use the AORN recommended practices as a guideline for the sterilization of surgical items and to create and maintain an aseptic environment that has a direct influence on patient outcomes. That is your responsibility as a leader in your healthcare facility.

AORN Standards can be purchased through AORN using the following options:

1. Internet: [www.aorn.org/bookstore/ordering.htm](http://www.aorn.org/bookstore/ordering.htm)
2. Call: 1.800.755.2676 ext. 1 or 303.755.6304 ext. 1 (Monday-Friday, 8 a.m. to 4:30 p.m. MST)
3. Fax: 303.750.3212
4. By mail: AORN Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA

Payment can be made by:

1. VISA, MasterCard, American Express or Discover, either online or by mail/fax/phone.
2. By authorized PO, and AORN will bill you (\$100 minimum purchase). Sorry, we cannot accept POs for education conferences or services. (Not available for online orders.)

A CD-ROM of the standards is available for the first time this year. †

## AORN Specialty Assembly for Central Service, Sterile Processing Professionals

The Association of periOperative Nurses (AORN) has formed a new Specialty Assembly (SA) for Central Supply, Sterile Processing Professionals. This SA is being formed to give AORN members the opportunity to network about processing issues, including ambulatory and office-based surgery centers. The formation of this SA is a great opportunity for non-RNs to join AORN as associate members.

To join, complete the non-RN membership application for associate members by clicking the red “Join/Renew” button on the home page of the AORN Web site (<http://www.aorn.org>) and return to AORN. National dues are \$100, which includes membership in a local AORN chapter or a virtual chapter (eChapter) and the Central Supply/Sterile Processing Professionals SA. As an associate member you cannot vote, hold elective office or serve as a delegate. If you are already a member of AORN, you may also join this SA. Membership in each SA is \$15. If you need additional information about the Specialty Assembly, please contact Lorrie Briggs at 800.755.2676 ext. 367 or [lbriggs@aorn.org](mailto:lbriggs@aorn.org).

### References

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### ANSWERS

- |      |       |
|------|-------|
| 1. T | 6. T  |
| 2. T | 7. T  |
| 3. F | 8. F  |
| 4. F | 9. F  |
| 5. T | 10. T |

### Sterile Process and Distribution CEU Information

CEU Applicant Name \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_  
 State \_\_\_\_\_ Zip Code \_\_\_\_\_

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding CBSPD certification, contact: CBSPD, 2 Industrial Park Road, Suite 3, Alpha, NJ 08865 or call 908.454.9555 or visit [www.sterileprocessing.org](http://www.sterileprocessing.org).

IAHCSSM has awarded one and one-half (1.5) Contact Point for completion of this continuing education lesson toward IAHCSSM re-certification.

### Nursing CEU Application Form

This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the CE questions.
6. Submit this form and the answer sheet to:  
 Workhorse Publishing  
 Managing Infection Control  
 PO Box 25310, Scottsdale, AZ 85255-9998
7. Participants who score at least 70% will receive a certificate of completion within 30 days of Managing Infection Control's receipt of the application.

### Application

Please print or type.

Name \_\_\_\_\_  
 Mailing Address \_\_\_\_\_  
 City, State, Country, Zip \_\_\_\_\_  
 Daytime phone (        ) \_\_\_\_\_  
 Position/Title \_\_\_\_\_  
 Social Security or Nursing License Number \_\_\_\_\_  
 Date application submitted \_\_\_\_\_  
 Signature \_\_\_\_\_

*Offer expires May 2011*