

Infection Control Resource

Vol. 5 No.1

Prevention Strategies for IC Practitioners and Professional Nurses

In this issue

Medical devices or patient-care equipment that enter normally sterile tissue or the vascular system or through which blood flows must be sterilized before each use. Sterilization means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. Dr. Japp in her article states that infection control professionals can be advocates for sterile processing, and the first step is to have a thorough understanding of what the correct sterilization processes are and how to correctly apply each process, whether it takes place in a healthcare facility or at an outside processor.

The phlebotomist is a vital member of the clinical laboratory team and an integral member of the health care team. The threat of AIDS, hepatitis, and risks to all segments of society from other infectious diseases has dramatically emphasized the need for quickly expanding training programs, while maintaining the highest possible standards of instruction and continuing education for these health care professionals. The National Phlebotomy Association (NPA) has been instrumental in helping to expand training and education programs and in promoting across-the-board national standard of certification for all phlebotomists. *Infection Control Resource* has convened members of the NPA to discuss key issues in phlebotomy practice.

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Sterilization processes: What every infection control practitioner needs to know

by Nyla "Skee" Japp, RN, PhD, CSPDM

The art of sterilization is a complex process and cannot be completed merely by waving a magic wand. Not following the correct processes can be detrimental to the patient, as the device that we are assuming is safe for the patient may in all actuality cause severe illness or even death. How do we ensure that a device is safe for patient use? We must begin by having a thorough understanding of what the correct sterilization processes are and how to correctly apply each process, whether it takes place in a healthcare facility or at an outside processor. Moreover, clinicians should be encouraged to select medical devices and drugs that have been sterilized using the highest quality sterility method.

The first step: cleaning

The sterilization process begins with the first step, which is cleaning. Cleaning is defined as the removal of contamination from an item to the extent necessary for further processing or for the intended use.¹ The Occupational Safety and Health Administration defines decontamination as the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens and microorganisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.² The first consideration is to request the cleaning and sterilization instructions from the original equipment manufacturer (OEM) for the device being cleaned.

Sterilization processes

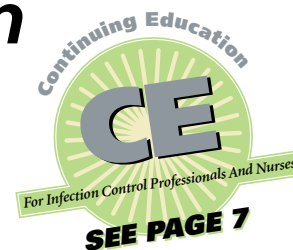
Today many ways are used to sterilize medical devices, but they can be classified into two main modalities: terminal sterilization or aseptic processing. Terminal sterilization means that

objects undergo a validated process that kills any living microorganisms before use, and the objects will remain sterile (in their packaging) until use. Aseptic processing involves sterile components and packaging assembled in environments as sterile as possible.

It should be noted that aseptic sterilization is not considered a terminal sterilization process. With terminal processes, the sterility assurance level is 10^{-6} , but the sterility assurance level of aseptic processes is 10^{-3} . Terminal sterilization is especially important both for drugs and for medical devices entering a patient's body, such as surgical scalpels, hypodermic needles, syringes, etc. An IV flush syringe is an example of a medical device that can be either aseptically or terminally sterilized depending on the manufacturer. Aseptically filled IV flush syringes use sterile syringes that are filled with a filtered solution in a clean room that minimizes the amount of particles in the air, but it is not a sterile environment (or clean room). Terminally sterilized IV flush syringes are filled in a class-100 clean room. Once the syringes are filled aseptically, they are then terminally sterilized in a steam autoclave. Manufacturers that terminally sterilize IV flush syringes (saline and heparin) include Covidien, and Excelsior Medical. Because of the low sterility assurance level, and because numerous infections and drug recalls have been attributed to aseptic sterilization processes, the Food and Drug Administration is considering making terminal sterilization the minimum level for sterilization.

Terminal sterilization approaches

There are two approaches to terminal sterilization: high temperature and low temperature. High-temperature methods involve either dry



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Symposium

Board members of the National Phlebotomy Association discuss trends and issues in phlebotomy practice

Moderator

Diane Crawford, CPT (NPA)
Executive Director, National Phlebotomy Association (NPA)

Panelists

Jeffrey A. Blood, BS, CPI (NPA)
Michael Delph, BA, MPS, CPT (NPA)
Alma Haupt, CPT (NPA)
Deloris Lynch, CPT (NPA)

The phlebotomist is a vital member of the clinical laboratory team whose main functions are to obtain patients' blood specimens by venipuncture and microcollection and to transport other clinical specimens. The field of phlebotomy has greatly expanded in the past several years, and the role of this integral member of the healthcare team has recently been brought into much sharper focus. The threat of AIDS, hepatitis, and risks to all segments of society from other infectious diseases has dramatically emphasized the need for quickly expanding training programs while maintaining the highest possible standards of instruction and continuing education for healthcare professionals. The National Phlebotomy Association (NPA) has been instrumental in helping to expand training and education programs and in promoting across-the-board national standards of certification for all phlebotomists. *Infection Control Resource* has convened members of the NPA to discuss key issues in phlebotomy practice.

What steps should or could be taken to standardize phlebotomy training from state to state?

Blood: This is an issue that I've felt passionate about since I started teaching students who had trained elsewhere and were coming for advanced training in preparation for the national exam. We've created a model program here in Connecticut that includes introductory, advanced, and prac-

What's needed is to standardize the training requirements and the hours of instruction and practice offered by health facilities, vocational schools, and community colleges.

- Delph -

tical and clinical training that doesn't occur in programs that offer only didactic training. I've been working with the NPA and experts in the field to create our own training text and procedural guidelines to address this disparity.

Delph: What's needed is to standardize the training requirements and the hours of instruction and practice offered by health facilities, vocational schools, and community colleges. This can help pave the way toward licensure or certification so that phlebotomists are better prepared to work in hospitals, commercial labs, clinics, large medical offices, and blood banks. We must put an end to one-weekend hands-on phlebotomy training workshops.

Haupt: Yes, standardization is important. We need a focus group to establish state, regional, and national standards for training and certification. It could be comprised of representatives from national and regional phlebotomy associations, accreditation boards, training programs and schools, and other related professional organizations. I'd also like it to include professors and instruc-

tors of phlebotomy science as well as currently certified phlebotomists.

Lynch: We need to create some buzz, to get the healthcare industry to wake up to standardizing phlebotomy training and licensing or certification. The art of phlebotomy is a major part of quality of healthcare. The bare essence of life is in the blood, and the methods and techniques for collecting this essence should be standardized. Demand for phlebotomists is heavy, so institutions are training people on the job or having staff take quick phlebotomy courses without certification. These courses and the on-the-job training are temporary stopgaps; they don't train phlebotomists to meet the professional standards required in the field.

Do you feel that a phlebotomist should be licensed by the state, much as LPNs and nurses are?

Lynch: Yes, I do. An article published in 2004 in *The Washington Post* made an interesting observation: "Unlike your hairdresser, your cosmetologist and even the aromatherapist down the street—most of whom are licensed by some authority—the person probing for a vein may have only a few days of on-the-job training." Phlebotomy is a "delicate microsurgical procedure; therefore, phlebotomists must have significant training." The profession of phlebotomy is currently not treated as a profession, and phlebotomists' work ethics, morale, and overall attitude are not of the highest standard. I think that licensure or certification by the state, administered by a governing agency such as the NPA, is necessary and would enhance phlebotomists' qualifications and expertise.

Haupt: I, too, feel that phlebotomists should be licensed by states. They should meet individual state requirements in education and should take state board examinations.

Blood: I think that national certification, without state boundaries, is more beneficial to our constituents, many of whom have CNA (Certified Nursing Assistant), HHA (Home Health Aide), EMT (Emergency Medical Technician) certifications or nursing backgrounds and appreciate the national concept. National certification also presents us with a better opportunity to standardize training through our governing body:

the NPA.

Delph: I feel that many of the national certification agencies are the best way for a phlebotomist to achieve certification. I do think that standards in several areas need to be established. The training in each school should be uniform, and when a phlebotomist seeks certification, it is important that all national certification agencies require the same practical as well as written tests.

Lynch: Since the establishment of certification and formal training for phlebotomists in 1978, there have been many certifying agencies and other organizations that have taken on this role, but the NPA is the leader in this industry. My view is that the NPA should be the governing agency.

To renew membership in the NPA, phlebotomists must annually undertake a certain amount of professional development. Are current requirements adequate?

Delph: Since the National Phlebotomy Association was established in 1978, it has been the only organization concerned with all aspects of educating and certifying the nation's phlebotomists. In the name of continuous quality improvement, the NPA needs to again take the lead in improving the list of requirements. In order to take annual renewal to the next step, the following strategies should be considered: regional conferences, online presentations/discussion, and online computer-based training and testing.

Lynch: Michael is right; the NPA is the organization that was and still is concerned with the educating, training, good work ethics, and professionalism of phlebotomists. But today's phlebotomists need more interaction, they need to be accountable, they need to be placed in a position where they have to comply with the annual or semi-annual development requirements of a governing organization and their employers.

Haupt: In addition to the NPA's current requirements for annual professional development, phlebotomists should be required to create or to participate in community-based activities that provide educational training for those in need of instruction in point-of-care testing, such as daily glucose testing, which involves selecting proper blood-collection sites, correctly using monitoring equipment, and inserting and disposing of

Issues with safety features for straight needles have caused the overuse of more expensive butterflies when a straight needle could have been used effectively.

- Blood -

lancets.

Blood: This issue of CEUs (Continuing Education Units) and types of continuing education will remain under discussion as we experience changes in multidisciplinary roles in healthcare and technology.

How effective are the products made by manufacturers for the prevention of accidental needlesticks? What recommendations do you have for manufacturers?

Haupt: Products for the prevention of accidental needlesticks are currently adequate. I'd like to see manufacturers include in the labeling a message promoting a culture of safety. They could also provide posters to be displayed in work areas, break rooms, locker

rooms, and training areas.

Blood: I've had the opportunity to try many protective needle models since the Needlestick Safety and Prevention Act took effect in 2000, and none has been perfect. For instance, one model can exit the site blunt, but the safety mechanism is difficult to engage and moves the needle forward, causing venous wall damage. Another model stays sharp when exiting the insertion site and has to be clicked in place, almost inviting the phlebotomist to use the other hand. Issues with safety features for straight needles, along with inadequate training, have caused the overuse of more expensive butterflies when a straight needle could have been used effectively.

Delph: Studies show that most needlestick injuries occur during disposal. Keeping that in mind, I'd say that most sharps-disposal containers with needle-removal features are up to the task (figure 1); however, more companies need to show their commitment and join the National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI). One factor to be considered is cost: whether it's for hospital or clinic or freelance phlebotomist, the equipment should be within a reasonable price range.

Lynch: Manufacturers have been effective in inventing and producing safe products. OSHA (Occupational Safety and Health Administration) has greatly influenced this with its regulations and requirements. The decision is now with the purchasers. I also suggest that manufacturers stop producing the standard non-safe instruments.



Figure 1. Sharps Disposal Unit (Covidien)

To prevent accidental needlesticks, what areas of procedure and training do health-care facilities need to improve?

Blood: The procedural aspects of phlebotomy present the greatest overall risk to the phlebotomist and the client. The challenge is the variety of settings where phlebotomy procedures are performed and the fact that the person performing the phlebotomy might not have been trained extensively or be experienced enough to avoid injury.

Delph: To start, we need to continue enforcing the Needlestick Safety and Prevention Act, which outlines the need for employers to select safer needle devices and to involve employees in identifying and choosing these devices. In fact, the act requires employers to adopt technology and practices that protect healthcare workers against sharps injuries. As per a recent publication by OSHA, other possible solutions can be found in the areas of control programs and decontamination. Six things I would recommend: (1) Ensure that employees select the container(s) that work for them as well as for the facility. Test and evaluate several to select the right type. (2) Do not let cost be a factor. Safety of employees and the patients they serve should be the first priority. (3) Ensure that the phlebotomist is free of pressure (for example, an unreasonable number of patients to be seen in a day) and that work can proceed smoothly (for example, special needs of patients should be considered when scheduling tests). (4) Ensure that all lab procedures and exposure-control plans are kept current. (5) Require phlebotomists to complete initial and refresher training in a timely manner. (6) Issue sharps containers or make them available at cost to phlebotomists working for private paramedical companies. Once the container is full, the paramedical company should dispose of the container.

Lynch: I supervise an outreach laboratory program of a major hospital and I manage full-time, part-time, temporary, and contractual personnel. I agree that we must meet the challenge of enforcing the Needlestick Safety and Prevention Act; this includes not re-capping needles, discarding the needle holder with the needle after use, using both gloves without tearing off a finger to palpate, etcetera.

Haupt: I'd like to see a yearly awareness day, where accidental-needlestick preven-

I agree that we must meet the challenge of enforcing the Needlestick Safety and Prevention Act; this includes not re-capping needles, discarding the needle holder with the needle after use, using both gloves without tearing off a finger to palpate, etc.

- Lynch -

tion would be a seminar topic. The seminar would review prevention techniques, discuss best practices for blood collection, have vendors available to demonstrate their latest safety devices and equipment. Time would be set aside to recruit staff members to create a safety culture council.

To what extent should phlebotomists participate in drafting and implementing measures to limit exposure in healthcare facilities?

Haupt: Phlebotomists should actively participate in determining procedures and implementing such measures. Their interactions with other staff as well as their daily contact with and observation of patients can inform the decision-making process.

Delph: All employees, full-time or not, who are covered by the Needlestick Safety and Prevention Act should be active participants. If they are involved, the healthcare facility will get their buy-in and adherence to general infection-control principles and hygiene measures.

Lynch: Most facilities have established committees or teams that meet to discuss

and develop exposure-control plans. I feel that phlebotomists should be a part of this process from the beginning to the end, as they are the front-line employees who will utilize the plan in conjunction with other healthcare workers.

Blood: The unfortunate reality is that not many individuals trained in phlebotomy are in management roles in healthcare institutions; phlebotomy is not part of nursing curricula or extensively taught in medical school. That's why it's imperative that we continue to work on mandating training and certification for anyone involved in this profession, and on encouraging continuing education of certified phlebotomists so that they can ascend to decision-making positions in the industry and can influence policy and procedure.

Crawford: Thank you all for a very informative discussion.

Diane Crawford CPT (NPA) has over 40 years experience in the field of phlebotomy practice. In 1978, Ms. Crawford founded the National Phlebotomy Association and is currently the organization's chief executive officer. Ms. Crawford has been a tirelessly crusader for the certification of phlebotomists and for improving the training and education of phlebotomists. She has spoken at numerous public and medical meetings on the practice of phlebotomy

Jeffery A. Blood, BS, CPT (NPA), has been a phlebotomist and phlebotomy instructor for 30 years. He has held several supervisory positions in the department of phlebotomy at Yale New Haven Hospital, CT. Included in his many activities; Mr. Blood is the phlebotomy instructor for the Connecticut Department of Health, Yale University and the National Kidney Foundation (CT).

Michael A. Delph BA, MPS, CPT (NPA), has been a phlebotomist, phlebotomy instructor and board member of the National Phlebotomy Association for over 13 years. He is employed by the DOE in Upton NY in the criminal justice lab as a manager in the training and qualifications section. Additionally, Mr. Delph is the dean of criminal justice department at the Katherine Gibbs School in Melville, NY.

*Alma Haupt CPT (NPA)
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Deloris A. Lynch, CPT (NPA), has over 30 years' experience as a phlebotomist, phlebotomy supervisor, and phlebotomy instructor. She is currently employed at MedStar Diagnostic Laboratories at the Washington Hospital Center in DC. Ms. Lynch is a board member of the National Phlebotomy Association (NPA) and until recently was the continuing education regional director for the NPA.

Sterilization processes: What every infection control practitioner needs to know — continued

heat or saturated steam under pressure. Low-temperature processes involve ethylene oxide (EO) gas, gas plasma (e.g., Sterrad), peracetic acid (e.g., Steris), ozone, gamma radiation, and electron beams.

Dry heat (terminal process)

Dry-heat sterilization is not widely used in healthcare facilities because of the high temperatures and long exposure times required. One advantage that dry heat sterilization has is the ability to sterilize powders, oils, petroleum-based items, and unassembled needles and syringes. Some hospitals use dry-heat sterilization to sterilize talcum powder used in some thoracic surgical procedures.

Packaging materials used in dry-heat sterilization include heat-resistant glass objects (e.g., Petri dishes, test tubes, small jars), stainless steel trays, aluminum foil, nylon films, and cotton muslin if the chamber temperature does not exceed 400°F (205°C).³ Dry heat cannot be used with fabrics and rubber, as the materials will deteriorate during the sterilization cycle.

Biological monitoring of the sterilization process should be done at least weekly and the results of the monitoring documented. The spore used in monitoring dry-heat sterilization is *Bacillus atrophaeus*. (Monitoring is discussed in more depth below.)

Dry-heat sterilization requires that a given temperature be reached and maintained for a specific period. There are two types of dry-heat sterilizers. As air within the chamber of a *gravity convection sterilizer* is heated, it rises and displaces cooler air, which descends into the lower part of the chamber. This circulation pattern causes inconsistent temperatures within the chamber, making it difficult to monitor the sterilization process. The *mechanical convection sterilizer* is thus preferred. It contains a blower that actively forces heated air throughout all areas of the sterilizer chamber. This creates a uniform temperature and equal transfer of heat throughout the load, making this process the easier method to monitor. With this advantage, the mechanical convection sterilizer is the preferred sterilizer in many facilities using dry-heat sterilization.

Steam (terminal process)

In healthcare, the fastest and most economical method is steam sterilization. It has been used for many years and is recognized as effective. The three main modes of steam sterilization are gravity displacement, dynamic air removal, and steam-flush pressure-pulse.

Low sterility assurance levels and numerous infections and drug recalls have been attributed to aseptic sterilization processes. The FDA is considering making terminal sterilization the minimal level.

Today's steam sterilizers come in many sizes and offer several cycle selections. Small *table-top sterilizers* are used most often in clinics and dental offices. They generate their own steam using distilled or de-ionized water. Each day before the sterilizer is used it should be checked to ensure that there is enough water in the sterilizer reservoir for the number of loads to be processed.

Flash sterilizers are often found in operating rooms, labor and delivery rooms, and areas where invasive procedures are performed. Flash sterilization should never be considered except for emergency sterilization of instruments when there is not adequate time for terminal sterilization.

Gravity displacement

Gravity displacement steam sterilizers use a passive air-removal cycle, which means that as the steam rises, the heavier air is displaced from the sterilizer and its load. If air is not removed from the chamber of the sterilizer and the items being processed, sterilization cannot take place.

Liquids may be sterilized in a gravity displacement sterilizer due to the slow exhaust of the sterilizer. Cycle times will differ, however, depending on the volume of liquid being sterilized. Biological indicators should be run with all liquid cycles.

Table 1. Lumen measurements that determine suitability for ozone sterilization

Internal diameter	Maximum length of device
≥ 2 mm	≤ 250 mm
≥ 3 mm	≤ 470 mm
≥ 4 mm	≤ 600 mm

The critical variables of steam quality are the dryness of the steam (expressed as a dryness fraction) and the level of noncondensable gas (expressed as a fraction of volume). Steam dryness should be between 97% and 100%, and noncondensable gas should be at a level that will not impair steam penetration into the sterilizer's load.¹

Dynamic air-removal / pre-vacuum

Dynamic air-removal sterilizers, often referred to as pre-vacuum sterilizers, usually operate at higher temperatures than gravity displacement sterilizers. Pre-vacuum sterilizers actively remove air by means of a built-in vacuum pump. The higher temperature normally will decrease the overall sterilization time of the cycle. When a dynamic air-removal system is used, a Bowie-Dick test must be done to ensure that there are no air leaks in the sterilizer.

Liquids cannot be processed using a dynamic air-removal sterilizer.

Steam-flush pressure-pulse

Steam-flush pressure-pulse sterilizers use a repeated sequence of steam flushing and pressure pulsing to remove air from the sterilizer chamber and processed items. As with a pre-vacuum sterilizer, air is readily removed from the sterilizer chamber and its load; the difference lies in the fact that the steam-flush pressure-pulse process is not susceptible to air leaks, making air-removal tests unnecessary. Air removal occurs above atmospheric pressure so no vacuum is required.

Washer-sterilizers (non-terminal process)

Washer-sterilizers for instruments are often found in sterile-processing and decontamination areas, clinics, and surgery centers. For the most part they are utilized for decontaminating instruments prior to cleaning. This process does not provide a terminal sterilization cycle. All items processed in a washer-sterilizer must still be cleaned and sterilized using either a terminal process or a flash sterilization process.

Ethylene oxide gas (terminal process)

Ethylene oxide has been used as a disinfectant for many years. Both EO and formaldehyde vapors have proved to be more lethal than other disinfectants because of their sporicidal properties. For healthcare facilities, the most important characteristic of EO is its efficacy in sterilizing materials that are too sensitive for high concentrations of moisture and/or heat. Following a sterilization cycle with EO, devices must be aerated, as materials retain varying amounts of the EO gas. No item should ever be removed from an aeration cabinet until the full aeration cycle has been completed.

Table 2. Chemical indicators: classes and practical applications

Class	ISO 11140-1: 2005 specifications	Applications
Class 1: Process indicators	Used with individual units (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units; designed to react to one or more of the critical process variables	Externally visible indicator tape or labels, load cards
Class 2: Indicators for use in specific tests	Used in specific test procedures as defined in relevant sterilizer/sterilization standards	Bowie-Dick-type cards used to evaluate sterilizer performance
Class 3: Single-variable indicators	React to a critical variable and indicate exposure to a sterilization process at a stated value (SV) of the chosen variable	Tubes containing chemical pellets that melt at specific temperatures, used to confirm that a specific temperature was reached at a specific location in the sterilizer chamber; may be used for pack-control monitoring but provide less information than class-4 or class-5 indicators
Class 4: Multi-variable indicators	React to two or more critical variables and indicate exposure to a sterilization cycle at SVs of the chosen variables	Used for pack control; are usually paper strips printed with a chemical indicator
Class 5: Integrating indicators	React to all critical variables; SVs equal or exceed performance requirements given in ISO 11138 series for biological indicators; must have SVs at 121°C, 135°C, and at least one more temperature in between; SV at 121°C <i>must</i> be ≥16.5 minutes to ensure performance is comparable to biological indicators in saturated steam	Can be an additional monitoring tool to release loads not containing implants if used in the appropriate challenge-test pack or process challenge device (PCD)
Class 6: Emulating indicators	React to all critical variables for specified sterilization cycles; SVs are generated from the critical variables of the specified sterilization process	Internal indicators for pack control; end-user must inventory a different Class-6 indicator for each sterilization cycle time and temperature; response of a Class-6 indicator does not necessarily correlate to a biological indicator, so Class-6 indicators cannot be used to monitor release loads that contain implants

The Occupational Safety and Health Administration has set limits on EO use. Monitoring of personnel and the immediate area, ventilation, and safety alarms are all requirements of this standard.

Gas plasma (terminal process)

Many healthcare facilities have moved from ethylene-oxide to gas-plasma sterilization because of the hazards associated with ethylene oxide and the monitoring required.

Gas-plasma sterilization can be used for endoscopic instruments, cameras, stereotactic devices, and fiber optic light cords. There are some limitations on this method of sterilization, depending upon lumen size and length of device. This method may not be used for devices with dead-end lumens, cellulose-based materials or items (e.g., trays) containing these materials, liquids, traditional adhesive labels, implants, and any devices that are labeled specifically as requiring gravity-displacement steam sterilization.

Peracetic acid (terminal process)

Peracetic acid sterilization is considered a wet process, meaning that it should be used only for immersible items that can fit

properly into sterilization containers with no pinching or bending to restrict flow, and for items that contact the sterilant can be made for the internal and external surfaces of the device being sterilized. Items undergoing this process must withstand a temperature of range of 122°F–133°F (50°C–56°C). Items being processed are not packaged, so care must be taken to avoid contaminating them after sterilization. This method of sterilization should be considered only for point-of-use or just-in-time sterilization.

Ozone (terminal process)

An emerging technology for low-temperature sterilization involves the use of ozone. Only electricity, water, and medical-grade oxygen are needed to produce ozone in a sterilization system. Because these components are readily available in hospitals, devices can be sterilized at low cost.

As with other forms of low-temperature sterilization, there are limitations on what can undergo this process. Lumened devices are limited to those with single lumens made of stainless steel. Internal lumen diameters control the length of an item acceptable for ozone sterilization (refer to Table 1). A de-

vice’s measurements must be verified with its manufacturer.

Other items that are not compatible with ozone sterilization include flexible endoscopes, implants, ampules containing liquids, natural rubber and latex, woven textiles, metals (including copper, zinc, nickel, brass, bronze) and metal foils, containers with cellulose filters, and single-use devices.

Gamma / e-beam irradiation (terminal process)

Gamma irradiation is a simple process in that the only parameter to control is exposure time, which in turn controls the radiation dose delivered to the item. Gamma rays have excellent penetration to the product. Gamma irradiation is not done in healthcare facilities but is used by medical industries for sterilizing a variety of items. No item quarantine is required after dose validation.

Electron-beam (e-beam) irradiation is a fast process that is sometimes done at the end of production. E-beam radiation causes less degradation to sensitive materials than does gamma radiation. Following successful dosimetry studies and microbiological validation of the dose, no product quarantine is required after sterilization.

Irradiation is the method preferred for many types of single-use devices used throughout health care.

Filtration and aseptic sterilization (non-terminal process)

Many liquids can be sterilized by passing them through membrane filters of 0.45 microns or smaller. In aseptic processing, products are filled or assembled using sterile components maintained under sterile conditions in cleanrooms or in isolators. Aseptic processing is used for items that are adversely affected by terminal sterilization (e.g., allograft tissues for surgical procedures). Infections have been documented in tissue processed by this method. Other items may be processed using this method if adversely affected by one of the terminal sterilization methods.

Sterilization quality assurance

Regardless of the sterilization method used, quality assurance is necessary in all healthcare facilities and with all manufacturers' products and drugs. The accurate sterilization of all medical devices is a critical aspect of infection control.

Mechanical / physical monitors

Mechanical and physical monitoring should include all recording graphs and charts as well as digital monitoring controls. Mechanical monitors may be the first indication that a sterilizer is malfunctioning.

Chemical indicators / integrators

Chemical indicators should be used on *all* trays, rigid containers, and packages to indicate if sterilization parameters were achieved during the process. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. Table 2 shows the various classes of indicators and their applications.

External chemical or exposure-control indicators allow at-a-glance distinction between processed and unprocessed medical devices. An indicator should be placed on the outside of each package unless the internal chemical indicator is visible.¹

Biological indicators

Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Biological indicators should be used within process challenge devices. Such indicators provide evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. While the performance of chemical-integrating indicators (i.e., Class 5) and enzyme-only indicators has been correlated to the perfor-

mance of biological indicators, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about attainment of critical parameters of the sterilization process.

Conclusion

Healthcare facilities are requiring that we optimize our processes without sacrificing quality. I believe that infection-control professionals can be advocates for sterile processing by stressing the importance of what we do as well as how we do it. I have no doubt that if every sterile-processing department were using the correct processes and selecting products with the most sterility assurance possible, the cost of healthcare could be reduced by millions of dollars otherwise spent on treating nosocomial infections. Litigation cases based on lack of sterility assurance would also be reduced. We can do a better job of delivering quality patient care in this country and beyond by ensuring that our sterile processes—for example terminal versus aseptic sterilization—and product selection are in line with the gold standards set by the Association for the Advancement of Medical Instrumentation, the Association of Perioperative Registered Nurses, the Certification Board for Sterile Processing and Distribution, and the International Association of Health Central Service Materiel Management.

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1. Association for the Advancement of Medical Instrumentation. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006.
2. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens. 21 CFR 1910.1030.
3. International Association of Health Central Service Materiel Management. *Central Service Technical Manual*. 7th ed. 2007.

Recommended reading

Sterile Processing University. *The Basics of Sterile Processing*. 2nd ed. Lebanon, NJ: Sterile Processing University, LLC. 2007.

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This continuing nursing education activity was approved by the Vermont State Nurses' Association Inc. (VSNA) an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.*

Provider approved by the California Board of Registered Nursing. Provider #1447.

This educational activity is available for Medical Technologists to earn continuing education credits. Certificate of completion can be submitted to the state board or certification agency.

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

1. List different sterilization methods.
2. Explain classes of chemical indicators.
3. Describe the differences between aseptic sterilization to terminal sterilization.
4. List the procedures and training healthcare facilities need to do to improve to prevent accidental needlesticks injuries.

Instructions

1. Read both articles.
2. Complete the post-test. (You may make copies of the answer form.)
3. Complete the participant evaluation.
4. Mail or fax the complete answer and evaluation forms to address on back page. You can also take this test online at www.saxetesting.com.
5. To earn 1.2 contact hours of continuing education, you must achieve a score of 70% or more. If you do not pass the test you may take it one more time.
6. Your results will be sent within four weeks after the form is received.
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8. Answer forms must be postmarked by July 7, 2010 (nurses). No expiration for medical technologists.
9. Faculty Disclosure: No conflicts were disclosed.

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1. The first step in the sterilization process is:
 - a. packaging
 - b. disinfection
 - c. cleaning
 - d. chemical integrators
2. Packaging materials for dry heat may include:
 - a. muslin wrappers and glass jars
 - b. nylon films and peel pouches
 - c. peel pouches and aluminum foil
 - d. rubber and glass jars
3. The bacterial spore used for dry-heat sterilization monitoring is:
 - a. *Bacillus stearothermophilus*
 - b. *Bacillus atrophaeus*
 - c. either a or b
 - d. *Bacillus brevis*
4. Liquids may be sterilized in:
 - a. pre-vacuum autoclave
 - b. gravity-displacement autoclave
 - c. dry-heat sterilizer
 - d. Sterrad NX 200
5. Flash sterilization should be considered:
 - a. only for emergency cases
 - b. for routine use
 - c. when the facility cannot purchase the necessary inventory of instruments
 - d. not at all
6. For steam sterilization, the quality of dry-ness should be:
 - a. 85%–100%
 - b. 75%–85%
 - c. 97%–100%
 - d. 65%–75%
7. Sterilization with peracetic acid is considered a:
 - a. thermal process
 - b. outdated process
 - c. wet process
 - d. just-in-time process
8. Ozone sterilization can be used for:
 - a. natural rubber and latex
 - b. flexible scopes
 - c. liquids
 - d. stainless steel single-lumen devices
9. Class-3 chemical indicators are used to measure:
 - a. a single critical parameter of sterilization
 - b. multiple critical parameters of sterilization
 - c. all of the critical parameters of sterilization
 - d. only 5 critical parameters of sterilization
10. The National Phlebotomy Association
 - a. Wrote the National Needlestick Safety and Prevention Act
 - b. Was formed in 1988
 - c. Is the only organization concerned with all aspects of education and certification of phlebotomist
 - d. None of the above
11. The National Needlestick Safety and Prevention Act of 2000
 - a. Requires employers to adopt new technology and practices to prevent needlestick
 - b. Requires that employees are involved in the selection and evaluation of safer needle devices
 - c. Both A & B
 - d. None of the above
12. The Needlestick Safety and Prevention Act became effective in
 - a. 2000
 - b. 1991
 - c. 1995
 - d. 2004
13. Most needlesticks occur
 - a. When removing the needle for the packaging material
 - b. When disposing of an used needle
 - c. When removing the cap
 - d. When recapping the needle

Participant's Evaluation

What is the highest degree you have earned (circle one) ?

1. Diploma 2. Associate's 3. Bachelor's
4. Master's 5. Doctorate

Indicate to what degree this program met the objectives: Using 1 = Strongly disagree to 6 = strongly agree rating scale, please circle the number that best reflects the extent of your agreement to each statement.

	Strongly Disagree			Strongly Agree		
1. List different sterilization methods.	1	2	3	4	5	6
2. Explain classes of chemical indicators.	1	2	3	4	5	6
3. Describe the differences between aseptic sterilization to terminal sterlization.	1	2	3	4	5	6
4. List the procedures and training, healthcare facilities need to do to improve to prevent accidental needlesticks injuries.	1	2	3	4	5	6

How long did it take you to complete this home-study program? _____
What other areas would you like to cover through home study?

Name & Credentials _____
Position/Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____

Mark your answers with an X in the box next to the correct answer

1	A	B	C	D	9	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	A	B	C	D	10	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	A	B	C	D	11	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	A	B	C	D	12	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	A	B	C	D	13	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	A	B	C	D	14	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	A	B	C	D	15	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	A	B	C	D	16	A	B	C	D
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Resource Volume 5, No.1