Top Ten Sterilization Issues in an Ambulatory Surgery Center

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Objectives
After completion of this self-study activity, the learner will be able to:
1. Identify 10 key areas in cleaning and sterilization that a Centers for Medicare and Medicaid Service (CMS) surveyor may evaluate during a site visit to an ambulatory surgical center (ASC).
2. Describe proper practices and documentation requirements in these key areas.
3. List three primary sources for professional guidance in cleaning and sterilization practices and documentation.

Test Questions
1. When space is limited, patient care items may be stored in the decontamination room.
   A. True   B. False
2. The area where surgical items are decontaminated should have negative air pressure with room temperature between 16-18°C (60-65°F).
   A. True   B. False
3. All sterile items received from a manufacturer can be stored indefinitely under event related sterility conditions.
   A. True   B. False
4. Centers for Medicare and Medicaid Service (CMS) requires that someone with infection prevention training [preferably a certified professional (CIC)] oversee the sterilization program.
   A. True   B. False
5. All items once opened in the operating area must be cleaned, rinsed and sterilized with the same process as ones actually used in the procedure.
   A. True   B. False
6. For qualification testing of a table-top sterilizer, a biological indicator (BI) should be placed inside a process challenge device (PCD) that is representative of the same type of package or tray that is routinely processed.
   A. True   B. False
7. Small items secured in paper-plastic peel pouches should be placed inside wrapped trays or containers for effective sterilization.
   A. True   B. False
8. If you change lot numbers of the sterilized biological indicators (BIs) during the day then you need to run another positive BI control with the same lot number.
   A. True   B. False
9. Each package in a sterilization load should be labeled with the sterilization date, the sterilizer number, and the number of items in the load.
   A. True   B. False
10. CMS allows the use of wrappers or containers for flash sterilization as long as all manufacturers’ instruction for the devices are followed.
    A. True   B. False

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Introduction

For many Ambulatory Surgery Centers (ASCs) the Centers for Medicare and Medicaid Service (CMS) surveys will be the first time any agency of any type has entered their facilities to inspect their environment and practices. It can be overwhelming! I have had the opportunity to assist multiple ASCs in preparing for these inspections in a variety of U.S. settings (e.g., orthopedic, eye, plastic surgery, general surgery). I have come across some common environment and process issues that are not up-to-date with current recommendations and guidelines. These issues may lead to citations when CMS walks in the door. In this document, we will look at the “Top Ten” sterilization issues often observed in ASCs. Please note that these concerns are not limited to just ASCs. Any facility that performs decontamination and sterilization processes can be guilty of noncompliance in these areas. Also, note that there are other concerns both related to this scope of practice that we will not discuss today. For example, one area where noncompliance is often seen is that of safe injection practices. More information on these recommendations can be found at the following Web site: http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html.

Spatial Concerns With the Decontamination Room

Many ASCs (and hospitals) over time have not proportionately increased space for physical processing of contaminated equipment as their workloads increased. So today, these areas are frequently of poor design and less than ideal. I have also seen ASCs who have adapted inappropriate spaces not meant for decontamination (e.g., hallways, closets, etc.) and are now unable to use proper workflow to move items progressively from being contaminated to being safe to handle. According to the guidelines and recommendations the decontamination room should be a restricted area where only those working should enter. This area should contain only dirty contaminated items and the equipment necessary to decontaminate them. The Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79:2006, A1:2008 and A2:2009, section 3.3.6 states that physically the room should contain:

- Enough space to accommodate the activity that takes place there;
- Floors and work surfaces that are easy to clean and dry. Carpet should not be used in these work areas;
- Ceilings that are constructed to create a flush surface with recessed, enclosed pipes and fixtures. The ceilings should be constructed of materials that are not of particulate- or fiber-shedding composition such as seen in drop down ceiling with particleboard panels;
- Equipment in the room should be constructed to limit areas where soil and organisms could hide. Limit bulletin boards, art works, etc;
- Good general lighting and special lighting over work areas that may include magnifiers with light for better visualization of fine and delicate instruments should be present while cleaning;
- Eyewash stations should be available within 10 seconds travel time. They should have the ability to flush a site for 15 minutes if needed; and
- Housekeeping cleaning supplies for this area should be separate from those used in clean prep or patient areas. These areas should be cleaned daily as you would for all other patient care areas in the facility. A low level disinfectant should be used according to manufacturers’ instructions. A copy of these instructions along with the chemicals material safety data sheets (MSDS) should be easily accessible. Staff should be comfortable with the information in both of these directives.2

Extra supplies that are used in the decontamination process should not be removed for use in other areas of the facility. In the Centers for Disease Control’s (CDCs) 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health-care Settings section II. J. and AAMI ST79, section 3.2.3 it is noted that clean and dirty equipment should be separated.1,2 Consider that the drawers, cupboards and open shelves near the decontamination work sink are all contaminated by aerosolization of soiled cleaning liquids or by persons accessing items from those areas. If others must access the extra items and there is not a clean storage area outside the decontamination room, a close cupboard might be placed at the door to the area, far away from the sink. It should be labeled clean storage to remind everyone not to touch it with soiled hands or gloves.

Patient care items should never be stored in the decontamination area. The room or space used for decontamination should not be used for clean processing unless absolutely necessary. Even then, a facility is at risk of being cited by CMS since it would be very difficult to validate that staff are maintaining “clean” and “dirty” areas. If space is so limited that the decontamination room has to be used for clean processing, the workflow should move from dirty to clean and the recommendations noted above should be implemented and enforced as much as possible. It is not acceptable to use an area for decontamination, clean it and then use the same space for cleaning as noted in AAMI ST79 section 3.2.3. First of all, we all know that in a day-to-day work environment staff will not take the time to clean the area before placing clean equipment on it and second of all it would be difficult to document that this is actually your protocol.
A CSM surveyor may:
- Ask to see the decontamination and clean room for processing items.
- Open all doors and drawers to look to see what is stored in each room.
- Inspect walls, ceilings and floors for proper construction and cleanliness.

- Request the healthcare worker to “describe the flow of items from the OR suite to the sterilizers.”

**Ventilation, Temperature and Humidity**

Proper air movement and moisture is key to limiting the risk of movement of microorganisms from dirty areas to clean. Many ASCs again have adapted spaces not meant for decontamination and have a difficult time implementing and monitoring this air movement in order to maintain proper ventilation and air humidity.

AAMI ST79 in section 3.3.6.4 states that air in a decontamination room should be under negative pressure with at least 10 air exchanges per hour. A surveyor can quickly check this by holding the door into a room open about one inch and holding a tissue up to the opening. If negative air pressure is available the tissue should flow inward. Air should be vented directly outside from these work areas as well. In one facility I recently reviewed, the air vent into the room was perceived years ago to be “noisy” by the staff so they placed a piece of cardboard into the vent to block the noise. Meanwhile, they were blocking the air intake to the room changing the airflow from a negative to a strong positive!

On the other hand, preparation and packaging areas along with the sterilization rooms should be positive pressure. In these rooms you want the dirty air outside your clean work area to remain outside the room; so if you used the same technique as above the tissue would blow away from the sterilization room. AAMI and the Association of periOperative Registered Nurses (AORN) have developed specific air parameters for each work area. See Table 2 for ventilation requirements for these functional areas which are in section 3.3.6.4 of AAMI ST79.

AAMI ST79 states in sections 3.3.6.5 and 3.3.6.6 that for worker comfort and to reduce the risk of microbial growth, especially molds, temperatures in the decontamination area should fall

<table>
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<tr>
<th>Functional area</th>
<th>Airflow</th>
<th>Minimum number of air exchanges per hour (ANSI/AAMI ST79)</th>
<th>Minimum number of air exchanges per hour (AIA, 2001)</th>
<th>All air exhausted directly to the outdoors?</th>
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<td>Negative (in)</td>
<td>10</td>
<td>6</td>
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<td>Sterilizer equipment access</td>
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<td>10</td>
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<tr>
<td>Sterilizer loading/ unloading</td>
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<td>10</td>
<td>---</td>
<td>Yes</td>
</tr>
<tr>
<td>Restrooms/ housekeeping</td>
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between 16-18°C (60-65°F) and in the general work areas between 20-23°C (68-73°F), both with a relative humidity at 30 percent to 60 percent. Higher relative humidity can promote microbial growth and a lower relative humidity may adversely affect some sterilization parameters (such as steam penetration) and the performance of some products (such as biological and chemical indicators).

The air pressure, air exchanges, temperature and humidity should be regularly monitored by internal staff and at least annually by an outside contracted company. Documentation of such monitors should be available. Staff should be able to recite proper readings and know what to do if they are outside acceptable parameters. In one facility that I visited recently, month after month staff documented in a well-developed log table that the temperature was not proper; however, no action was ever documented to these outliers.

A CSM surveyor may:
• Ask to see documentation of air movement, temperature and humidity monitoring.
• Question staff, “Do you know what the temperature in this room should be? How do you know if it is at that temperature?”
• Perform the “tissue check” of the air movement in and out of these rooms.

Sterile Storage

Often with space constraints, ASCs need to be creative in storing their clean and sterile items. As noted earlier, these items should be stored separately, preferably in a different room, from contaminated or “dirty” items. Today, the shelf life of sterile items is usually event-related and dependent on the amount and type of handling, packaging, storage conditions, and transportation the package has to endure. AAMI ST79 states in section 8.10.1 that prior to use, each package should be inspected. Some prepackaged sterile items from a manufacturer may have an expiration date so these packages should be inspected, reviewed and rotated on a regular basis.

In the clean room, sterile packages should be stored in a way that reduces the potential for contamination. In a recent review, I looked under a sink in the clean storage room and found leaky pipes dripping on the blue wrap that the staff uses for packaging items prior to sterilization. AAMI ST79 states in section 8.9.2 of AAMI ST79 that the bottom shelf should be solid, or contain a physical barrier between the shelf and the floor and traffic and housekeeping activities. This criteria is needed to protect items on the lowest shelf from becoming contaminated with splashing when the floor is wet moped every night. Heavy instrument packages should not be stacked due to the possibility of compression. If a package is compressed, it can force air and microorganisms into the package, cause seals to burst, or puncture the package according to section 8.9.2 in AAMI ST79.

Outside shipping containers and corrugated cardboard boxes should never be allowed in the sterile storage area. (AAMI ST79 section 8.9.2) Shipping containers are exposed to unknown and potentially high microbial contamination and corrugated cardboard serves as a generator of and reservoir for dust. An easy way to check for these boxes is to look for shipping labels. If a shipping label is visible, this surface was exposed to the environment and could easily be dirty. I have seen cardboard boxes stored in clean areas that look great to the naked eye. However, once you look a little deeper, you could peel apart the layers of the cardboard and find mold and mildew in the interior. Instead items should be removed from the cardboard boxes and stored in washable, labeled easy to access plastic containers. The CDC addresses this in the Guideline for Environmental Infection Control in Health-Care Facilities, 2003 under the section on Controlling Waterborne Microbial Contamination.

The recommended temperature for all sterile storage areas is 24°C (75°F) and they require at least four air exchanges per hour, and a controlled relative humidity that does not exceed 70 percent (AAMI ST79 section 3.3.65, 3.3.6.6). Remember too that this area should be accessible only to staff who know how to handle sterile items properly.

A CMS surveyor may:
• Measure the distance of the shelved sterile items from the ceiling, floor and outside walls.
• Look for expiration dates on pre-packaged sterile items.
• Inspect sterile items on the shelf looking for breakdown, holes, water stains, pressure stacking, etc.
• Check the storage boxes for dust using the “white glove” test.
• Question staff, “Do you know of any items that have expiration dates on them? How do you keep on top of these expirations?”
Staff Education and Dress Codes

As in most healthcare facilities, staffing is of concern in ASCs. It is not unusual for one or two people to be trained to do decontamination and sterilization processes by the previous person who was trained by his/her predecessor and so on. Over time the information may not be as accurate as it should be! For example, it is not uncommon when staff are questioned on how to properly run an old piece of equipment that they say, “Well, that is what I was told and I never questioned it!”

Facilities should maintain orientation material and a checklist of what information was taught by whom. CMS requires that someone with infection prevention training [preferably a certified professional (CIC)] oversee this program so documentation of his/her involvement in the training should also be available. CMS may also question leadership to see if they have made available the opportunity for staff to become certified in sterile processing or at least attend seminars on these pertinent topics outside of the facility. There are constant changes and updates in decontamination and sterilization so it is imperative that staff be given the appropriate training.

In an ASC, it is also not unusual for staff to be cross-trained in many areas. I have often seen nurses move from the scrub nurse in the operating room (OR) to the decontamination specialist, to the sterilization technician, to the purchasing agent and then back into the OR all within a few hours. All such personnel need to have proper education in all of these areas in order to maintain standardized effective care of the patient and equipment. On the other hand, I have also been in some clinic surgery settings where only one person has been trained to do the decontamination and sterilization processes. This too can lead to problems if that person is unable to attend to the job due to illness, vacation, etc. In this setting, some documented cross training of individuals would be beneficial.

Dress code and protective equipment for the personnel in these areas can also be a challenge in an ASC. This information is discussed in AAMI ST79 section 4.5.2. Decontamination workers should be wearing clean, facility-provided uniforms, non-skid shoes, and head and facial hair covers. This section also covers personal protective equipment (PPE) which should include:

- Long-cuffed utility gloves;
- Liquid-resistant coverings with sleeves such as backless gowns, surgical gowns or jumpsuits; and
- Fluid-resistant face masks and eye protection (safety goggles, full face or eye shields).

Jewelry and wristwatches should NOT be worn in the decontamination, prep or sterilization areas. Nails should be natural, short and clean. No artificial nails. Again, if you have staff cross-trained to work in multiple areas of the surgery center, these requirements must be enforced for all staff.

A CMS surveyor may:

- Ask to see orientation materials for a recent new hire.
- Check PPE and dress codes of staff as they work in the different areas.
- Review education and certification records of persons responsible for infection prevention activities.

Cleaning/Disinfection of Devices

In most small and average size ASCs cleaning of instruments is done manually or by ultrasonic cleaners. All reusable devices and instruments must be cleaned, disinfected or sterilized according to the manufacturers’ recommendations. Surveyors will often walk into a sterile processing area, choose a reusable device and ask to see the facilities protocol as well as the manufacturers’ recommendations for handling. They will expect these instructions to match each other. Facilities should have copies of the manufacturers’ recommendations easily accessible for all devices. These recommendations can be obtained from the manufacturer’s representative, the local supplier of the devices or, more often, they are available on line under the manufacturers’ Web page. These instructions should be copied or scanned and placed in a binder or an easily accessible computer file. Staff should be comfortable with the information on the instructions and where to find them. If the facility flashes instruments, surveyors will also expect to see a listing of devices that can be flashed next to the sterilizer for staff to consult prior to sterilizing.
Physical monitors such as recorders, displays, digital printouts and gauges that provide real-time measurements of time, temperature and pressure are a critical component of a steam sterilization monitoring program.

All items once opened in the operating area must be cleaned, rinsed and sterilized with the same process as the ones actually used in the procedure. I have seen nurses separate the used devices from the unused items and only wash the used ones. They would then combine the sets in a tray ready for sterilization. The unused devices could easily have been contaminated in the OR suite or in the transportation to decontamination and must be handled the same as the used devices.

For manual cleaning, appropriate sinks should be available. AAMI ST79 notes in section 3.3.7.1 that the sink should have three sections: soaking, washing and rinsing. If you don’t need to soak the instrument you could get by with one sink with two sections. Low foaming detergents should be used to provide a clear view beneath the water surface. This can reduce the risk of accidents with sharp items. This detergent should be measured to provide the most effective cleaning according to manufacturers’ instructions. Don’t forget that your bottles of disinfectant should be labeled with name and expiration dates of the chemicals. Sharp and delicate instruments should be separated from the rest of the devices prior to cleaning. Cleaning and brushing of devices should be performed under the water level to avoid splashing and aerolization. These brushes should be disposed of or decontaminated daily. (AAMI ST79 section 7.5.3.2)

When using an ultrasonic cleaner, it is important to avoid splashing and aerolization as well. The AORN Recommended Practices for Sterilization in Perioperative Practice Settings, 2010, section X.c.11 states that these machines should be operated with lids closed during the cleaning and rinsing process and the cleaning solution changed before it becomes heavily soiled and at a minimum of daily. At this time the ultrasonic cleaner should be emptied, cleaned, rinsed with sterile water, and the chamber wiped down with alcohol or another disinfectant according to the equipment manufacturers’ recommendations. (AORN section X.c.11) If processing eye instruments clean the ultrasonic cleaner preferably after each use or at least daily using the above procedure according to the American Society of Cataract and Refractory Surgery Recommended practices for cleaning and sterilizing intraocular surgical instruments, 2007. Check with the equipment manufacturer to ensure that a alcohol rinse is not contraindicated. If the ultrasonic cleaner does not have a lid, management can have one made to fit. Again, only use the ultrasonic according to manufacturers’ instructions, have those instructions handy and make sure your day-to-day protocols match the manufacturers’ recommendations.

Handling of instruments that need low temperature sterilization (e.g., ethylene oxide) can be a challenge for an ASC. Often these instruments are expensive and facilities have limited amounts of them so a quick turn-around time is crucial. I was recently at a facility that had developed a good process for outside sterilization with a local hospital’s sterile processing department. The ACS staff clean, disinfect and wrap the instruments according to the manufacturers’ instructions. They then label the pack and place it, along with the manufacturers’ instruction for sterilization, into a labeled tightly closed rigid plastic container. A standardized ASC form is also added. This form contains the date, pack contents and a place where the load sticker can be added. The container is sent to the hospital’s sterile processing department where the items are then sterilized and placed back into the clean plastic container along with the ASC form that now has the load sticker attached and is returned to the ASC. This stickered form is now documentation of sterilization in case there is a need to do a review of this information at a future date. Even though this form does not have the sterilization cycle parameters on it; if necessary, the ASC could follow up with the sterilizing facility for that information using the sticker load information.
A CSM surveyor may:

- Choose a reusable instrument and ask for the manufacturers’ instructions and your protocol for disinfection and sterilization of that instrument.
- Question a staff member, “Can you show me your process for manually cleaning a tray of instruments?”
- Ask for monitoring and preventative maintenance on your ultrasonic cleaner.
- Review your process for an instrument that needs sterilization outside of the facility.

**Table-top Steam Sterilizers**

Most ASCs use steam for sterilization. Table-top steam sterilizers are the most common type of steam sterilizer particularly in the smaller ASCs. Some of these sterilizers have been around for quite awhile and often the manufacturers’ written instructions are not available. Facilities should contact the manufacturer to obtain these instructions; if not available, a new table-top sterilizer should be purchased. In many cases the sterilizers are so old that the manufacture is not even in existence anymore. How does one know if they are running the equipment properly if they have no instructions from the sterilizer manufacturer?

AAMI ST79 definition 2.129 defines a table-top steam sterilizer as a compact steam sterilizer with a chamber volume of not more than two cubic feet. Most table-top steam sterilizers generate steam from water that the operator pours into a reservoir. There are some that are connected to a boiler system but these are not very common. For steam of acceptable quality the sterilizer manufacturers’ instructions must be followed regarding water purity requirements, filling and draining the reservoir, and general equipment cleaning and maintenance. (AAMI ST79 section 3.3.4.1) Manufacturers generally “recommend distilled or deionized water to help prevent mineral buildup in the steam generating system and to ensure the purity of the steam generated for sterilization.” (AAMI ST79 section 3.3.4.1)

Physical monitors such as recorders, displays, digital printouts and gauges that provide real-time measurements of time, temperature and pressure are a critical component of a steam sterilization monitoring program. After each cycle, a trained and knowledgeable operator should read and initial the physical monitor to verify that all cycle parameters were met. (AAMI ST79 section 10.5.10) Some older model table-top sterilizers do not have physical monitors. According to section 10.5.1 of AAMI ST79, “Sterilizers that do not have recording devices should not be used.”

As with all other types of steam sterilizers, qualification testing of table-top sterilizers should be conducted after sterilizer installation, relocation, major repairs and malfunctions, and after sterilization process failures if a major repair of the sterilizer or utilities is required. (AAMI ST79 section 10.7.5.1 and Figure 12) For qualification testing of a table-top sterilizer, a biological indicator (BI) should be placed inside a process challenge device (PCD) that is representative of the same type of package or tray that is routinely processed. AAMI ST79 section 10.8.3.1 states that the package should be selected from those most frequently processed and contain the items normally present during routine sterilization. For qualification testing the BI PCD should be run in three consecutive full loads and the load items should be quarantined until the BI results are negative.

Cleaning and preventative maintenance should also be performed and documented as recommended by the manufacturer.

A CMS surveyor may:

- Question a staff member, “Can you show me in the manufacturers’ instructions for your table-top sterilizer where it tells you what type of preventative maintenance needs to be completed on a regular basis?”
- Request water purity testing results.
- Ask to see the BI results of recent sterilizer qualification testing.

**Peel Pouches**

In an ASC, it is not unusual to see peel pouches used to contain small lightweight instruments for sterilization. The manufacturers of peel pouches should provide validated documentation that the specific pouches are FDA cleared for use with the specific sterilization systems and cycles that a facility is using.

Inside the sterilizer, paper-plastic peel pouches should be placed on edge and oriented so that the paper side of one pouch faces the plastic side of the pouch next to it. (AAMI ST79, section 8.5.2) This ensures adequate steam penetration and air removal from each pouch. Also, AORN states that paper-plastic pouches should not be used within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, sterilant contact, and drying. (AORN RP Sterilization, II.c.) Due to the risk of inadequate air removal and steam penetration, it is not acceptable to use paper-plastic pouches inside wrapped trays or containers even if the pouch is not sealed.

For the purpose of confining small items within wrapped or containerized sets, a packaging material that allows adequate air removal and steam penetration, such as a paper-paper pouch or wire mesh basket, should be used. It is always important to confirm that packaging materials are being used in accordance with the manufacturers’ instructions and are FDA
cleared for that usage. Double packaging with paper-plastic pouches is acceptable as long as the outside pouch is big enough to prevent sterilization process failures due to inadequate air removal and steam penetration and is FDA cleared for that use. (AAMI ST79 section 8.3.4) Both pouches should be sealed and oriented in the same direction (i.e., plastic facing plastic).

A CMS surveyor may:
- Question staff, “Do you ever place peel pouches in wrapped sets or containment devices? If so, can you show me one?”
- Ask staff to show her/him how peel pouches are placed in the sterilizer.

**Chemical (CI) and Biological Indicators (BIs)**

Most surveyors will agree that the area where they find the most issues of noncompliance is with the chemical and biological indicators. When determining which BI should be used to monitor a steam sterilizer, it is important to first identify the type of sterilizer and the cycle temperature. I have audited facilities where one type of BI was used for all types of sterilizers and temperature cycles. Be sure to check with the BI manufacturers’ instructions for use to ensure you are using the correct BI for each type of sterilizer and cycle used. BIs are often classified by type of air removal used (i.e., gravity displacement or dynamic-air-removal) and temperature parameters.

Steam sterilizers of all kinds should be monitored with a BI PCD weekly, preferably every day the sterilizer is used. (AAMI ST79 10.5.3.2) All different cycle types used should be tested routinely. For example, if a table-top sterilizer is used to run cycles at both 250°F (121°C) and 270°F (132°C), then both of these cycles should be routinely tested with a BI PCD. AAMI ST79 section 10.5.3.2 states that unwrapped and wrapped cycles should also be tested routinely.²

There are no commercially available BI PCDs designed for table-top sterilizers so the user must make his or her own BI PCD that represents the most challenging package configuration in the load. (AAMI ST79 section 10.7.3.1)² The BI PCD should also contain one or more CIs and items normally present during routine sterilization. For example, if routine loads contain single instruments in peel pouches then the appropriate BI PCD is a BI and a CI along with a representative instrument.
in a peel pouch. If wrapped sets are also routinely processed, then a “dummy” wrapped set that contains a BI and one or more CIs and representative instruments should be used as the BI PCD. To my knowledge there are no FDA-cleared rigid sterilization containers for use in table-top sterilizers so instructions for this type of situation are not available. Contact the sterilizer manufacturer to see how to appropriately flash sterilize wrapped items.

The BI testing of a table-top sterilizer is conducted in a fully loaded chamber typically the first run of the day. (AAMI ST79 section 10.7.3.2) I have seen facilities run the BI in an empty chamber first thing in the morning to “get it over with.” The BI PCD should be placed in the “cold point” or area least favorable to steam sterilization. This area is typically the center of the load toward the front of the chamber but varies with sterilizer design; therefore, the manufacturer of the sterilizer should be consulted about placement of the BI PCD.

It is often confusing for staff members to understand the importance of running a positive control BI. So, to save time and money they just quit running them! Or they keep a drawer of BIs and when a new shipment comes in, they throw them all into the drawer with the others and mix up lot numbers! Again, educating staff to the purpose of the positive BI control should be documented in orientation and on a regular basis. To start with, the BI used for the positive control is not sterilized so the spores in it should be viable and give a positive result. AAMI ST79 section 10.7.3.3 states that the positive control should be from the same lot number as the BI used that day in your sterilizers. If you change lot numbers of the sterilized BIs during the day you need to run another positive BI control to match.

When the control yields a positive result, you are assured that your system is able to detect spores that survived the sterilization process for that specific lot number. If the positive control from a specific lot number does not read positive you may be getting false negative results from the BI you sterilized. Keep in mind that if you run two types of BIs and have several incubators or auto-readers you need to run a positive control for each BI type in each incubator or auto-reader used that day.

AAMI ST79 section 10.5.2.2 states an internal CI should be placed inside each package and an external CI should be placed on the outside of each item, unless the internal CI is visible. External CIs are used to distinguish items that have been processed through the sterilizer from items that have not been processed yet. Some peel pouches have a built in chemical indicator on the package. This can function as your external CI. Since they contain a chemical in their CI that could degrade, these peel pouches have expiration dates. Internal CIs provide information about whether or not the steam penetrated inside the package to the location of the instruments. The results of internal CIs should be interpreted by trained and knowledgeable healthcare professionals at the point of use before the items are used for patient care.

Where to place the CI in your larger sterilizers is more of a challenge. AAMI ST79 recommends an internal chemical indicator in each package, tray or rigid container system placed in the area least accessible to steam penetration. In section 10.5.2.2.2 it states:

“The CI should be placed in that area of the package, tray, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) considered to be least accessible to steam penetration; for a containment device, the manufacturer’s instructions for placement of the CI should be consulted. This location might or might not be the center of the package, tray, or containment device.”

The packaging systems recommended practice of AORN offers the most detailed guidance on the placement of internal chemical indicators. The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2010 in Recommendations IX 4-6 suggests the following placement of internal CIs:

- A CI in the geometric center (not on the top) of a wrapped pack or tray;
- Two CIs inside rigid containers, one in each of two opposite corners of the inside basket;
- Multi-level rigid containers should have a CI placed in two opposite corners (e.g., one in each of two corners) of each level; and
- A CI on each level of multi-level wrapped sets.

A CMS surveyor may:

- Question staff, “Can you show me the different types of BI monitors you have and in which sterilizer you use them?”
- Ask staff to describe how they use their CIs in specific types of packaging (i.e., peel pouches, rigid containers, etc.).
- Review BI results from BI PCDs for frequency of testing, lot number of tests and controls, and documentation.
- Request samples of all types of unused peel pouches looking for any that may contain expiration dates. The surveyor may then look for any that contain an imbedded external CI that could degrade and be expired.

**Documentation**

One practice often ignored over time is the proper documentation of a sterilized item. Each package should be traceable to the load in
which it was sterilized and ideally to the patient, especially an implant (AAMI ST79 section 10.3.1). This is usually accomplished by labeling each package in each load with the sterilization date, the sterilizer number, and the load number. If the sterility of a load is later called into question, it is important that all of the packages from that load can be identified and pulled from use. AAMI ST79 states in section 10.3.2 that “Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to their source.”

Labeling guns are now available to quickly and accurately place the proper labeling on each package. AAMI ST79 recommends in section 10.3.2 that the following information should be recorded and maintained for each sterilization cycle:

- The lot number;
- The specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towels, type/name of instrument sets);
- The exposure time and temperature, if not provided on the sterilizer recording chart;
- The name or initials of the operator;
- The results of biological testing, if applicable;
- The results of Bowie-Dick testing, if applicable;
- The response of the CI placed in the PCD (BI challenge test pack, BI challenge test tray, or CI challenge test pack) if applicable; and
- Any reports of inconclusive or non responsive CIs found later in the load.

The physical monitors (e.g., digital printout) for each cycle should be dated and signed by the operator and saved in the sterilizer records. Many of the old table-top sterilizers found in ASCs do not have printouts of the physical monitors. These table-top sterilizers should not be used since users are unable to note and document that the proper parameters have been met. In a recent review, I noted a sterilizer that had no printouts. When querying the staff, one nurse noted that these printouts were not necessary “since the table-top would just stop if the parameters were not met.” When asked she noted that this happened regularly! Additionally, a log of repairs and preventive maintenance should be maintained for each sterilizer. Sterilizer and load information may be maintained in a paper or electronic record keeping system.

In section 9.7 of AAMI ST79 it states: “A maintenance record, in either paper or electronic format, should be kept for each sterilizer.”

The maintenance record should include sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

- the date on which service was requested;
- the model and serial number of the sterilizer;
- the location of the equipment (hospital identification, if applicable);
- the name of the individual from the healthcare facility who requested and authorized the service;
- the reason for the service request;
- a description of the service performed (e.g., calibration, repair);
- the types and quantities of parts replaced;
- the name of the person who performed the service;
- the date the work was completed;
- the handwritten or electronic signature and title of the person who acknowledged completion of the work; and
- the results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.

A CMS surveyor may:

- Request to review physical monitors on recent sterilizer runs.
- Ask staff to show her/him load documentation from a run on a certain day of last month.
- Question staff, “When was the last day someone had to service a specific sterilizer? Can you show me the documentation?”

**Flash Sterilization**

Probably one of the most controversial areas in sterilization currently is with flash sterilization in the ASC. Audits of these facilities show that flash sterilization is quite common particularly in those facilities that do multiple short surgeries in
one day (i.e., cataracts, carpal tunnel). It is not unusual to see sets being flashed three or four times a day! In the past this practice was considered unacceptable. However, recently CMS clarified the confusion on this topic in a memo to state survey agencies. They noted that routine flash sterilization in ambulatory surgery centers is acceptable as long as the load is wrapped or contained and the facility follows manufacturers’ instructions for all the devices involved.7

CMS provided a list of seven questions that its surveyors can use to determine the appropriateness of a facility’s sterilization practices:
1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?"7

ASCs will not be cited for “properly using short sterilization cycles for wrapped/contained loads,” the memo stated.3 The routine flashing of unwrapped or uncontained loads, however, will be cited as a violation. Flashing such loads should only be done when there is “an urgent and unprecedented need for a specific device,” such as when an instrument is dropped and not for convenience. When up-to-date medical device manufacturers’ instructions for use are obtained you may find that short flash sterilization cycles are not an option anymore. In addition, table-top sterilizer instruction for use may not allow for flash sterilization using wraps or containers.

It is important to remember as well that flash sterilized items should be cleaned prior to sterilization with the same practices one uses for items being sterilized by other methods in your facility. I have heard nurses tell me for example that if an item falls to the floor during a procedure that they will just rinse it off and throw it in the flash sterilizer!

Even though labels are typically not used on flash sterilized items, a lot number should be assigned to each flash sterilization load and a load record should be documented for each flash cycle. According to AORN RP on Sterilization Recommendation IV.i.1., sterilization records for each flash load should include the following information:
- the item(s) processed;
- the patient receiving the item(s);
- the cycle parameters used (e.g., temperature, duration of cycle);
- the date and time the cycle is run;
- the operator information; and
- the reason for flash sterilization.4

Section 10.3.1 of AAMI ST79 emphasizes that implantable devices should not be flash sterilized. However, if flash sterilization of implantable devices is unavoidable due to an emergency situation, “full traceability to the patient should be maintained.”2

A CMS surveyor may:
- Ask a staff member to walk through their process when they need to flash an item.
- Ask to see the medical device and sterilizer manufactures’ instructions for flash sterilization.
- Review documentation of flash sterilization runs.
- See if he/she can track flash sterilized items back to a patient.

Summary

Proper cleaning and sterilization of items in the ambulatory surgery center plays a large role in the safety of these patients. Staff responsible for the infection prevention practices need to be diligent in maintaining proper procedures and documentation of activities. They also must stay current with the new scientific updates, regulatory standards and professional recommended practices that affect these practices. Key Web sites to assist in this education include:
- Purdue CRCST Self Study: https://www.continuinged.purdue.edu/lessons/

References

Peggy Prinz Luebbert, MS, MT(ASCP), CIC, CHSP is currently owner of Healthcare Interventions Inc. headquartered in Omaha, Neb., providing consulting in safety and infection prevention. Ms. Luebbert has multiple degrees in the healthcare field including a BS in chemistry, biology and medical technology along with a Master's Degree in pathology and adult Education. She has worked in infection prevention and safety for more than 25 years in multiple healthcare and corporate settings. She also maintains certifications in infection prevention and healthcare safety and has published and lectured extensively on the topic. Ms. Luebbert is a member of APIC and has had the opportunity to work with national and international organizations in setting standards of care in her area of expertise.

ANSWERS

1. B 6. A
2. A 7. B
3. B 8. A
5. A 10. A

Sterile Process and Distribution CEU Information

CEU Applicant Name ________________________________
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The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 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 recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the Web site at www.sterileprocessing.org.

IAHCSMM has awarded 1 Contact Point for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is 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 the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. KEEP A COPY FOR YOUR RECORDS.
6. Submit this form and the answer sheet to:
   3M Sterilization Assurance, Attn HC4160
   RR Donnelly Fulfillment Services
   585 Hale Ave N, Oakdale, MN 55128-9935
7. For questions contact craig@healthvie.com
8. Participants who score at least 70% will receive a certificate of completion within 30 days of healthVIE.com’s receipt of the application.

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