Take the Lead in Infection Prevention
What to Look For in Your Sterile Processing/Central Sterile Supply (SP/CSSD) Department
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Objectives

After completion of this self-study activity, the learner will be able to:
1. Identify what to look for related to personal protective equipment, usage of cleaning agents, and monitoring tools for steam sterilizers and mechanical cleaning equipment when conducting infection control rounds in SP/CSSD.
2. Identify which standards and recommended practices to use when updating policies and procedures and how to acquire them.
3. Develop a policy and procedure for loaner trays and recalls.
4. Discuss the importance of keeping instructions for use (IFU) up-to-date and methods for doing so.
5. Explain the importance of certification.

Test Questions

1. The Centers for Disease Control and Prevention expects infection preventionists to conduct infection control rounds annually in Sterile Processing (SP/CSSD).
   A. True  B. False

2. Fluid-resistant masks do not need to cover the nose when worn in the decontamination area.
   A. True  B. False

3. The type of water and its temperature has no effect on the performance of cleaning agents.
   A. True  B. False

4. The biological indicator process challenge device (BI PCD) used to monitor every implant loads should contain a BI and a Class 5 integrating chemical indicator and the implant should not be released until the BI results are known.
   A. True  B. False

5. It is important to have up-to-date manufacturers’ instructions for use (IFU) to ensure medical devices are being properly cleaned, packaged, and sterilized.
   A. True  B. False

6. Mechanical cleaning equipment should be monitored weekly (preferable daily) during routine use to verify the effectiveness of the cleaning process.
   A. True  B. False

7. The most current Association for the Advancement of Medical Instrumentation (AAMI) ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities was published in 2006.
   A. True  B. False

8. The International Association of Central Service Materiel Managers (IAHCSMM) published a Sample Policy and Procedure for the Management of Loaner Instrumentation that suggests loaner trays arrive in the healthcare facility at least two (2) business days prior to the scheduled case and three (3) business days prior to the scheduled case for a first-time vendor set.
   A. True  B. False

9. The policies and procedures for reprocessing should be the same no matter where the sterilizer is located (e.g., the operating Room, ambulatory surgery center, clinic, etc).
   A. True  B. False

10. If a physical monitor, chemical or biological indicator indicates a steam sterilization process failure all loads processed back to the last negative BI should be recalled and reprocessed.
    A. True  B. False
The CDC expects infection preventionists to take a leading role in ensuring the healthcare facilities sterilization processes meet standards and recommended practices, and reprocessing instructions for use (IFU). This is done by conducting infection control rounds at least annually. The Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 states:

“Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented. Document all deviations from policy. All stakeholders should identify what corrective actions will be implemented. Category 1B”1

The objective of the infection control rounds is to identify correctable variances in:

- Operator competency;
- Documentation of sterilization records for each cycle including:
  - Type of sterilizer and cycle used
  - Load identification number
  - Load contents
  - Exposure parameters (e.g., time and temperature)
  - Operators initials
  - Physical, chemical and biological indicator test results
  - Bowie-Dick test results;
- Sterilizer maintenance records of service;
- Visual inspection of wrapping materials; and
- Traceability of load contents.

The rounds should identify improvement activities to ensure operators are adhering to established standards.1

Performing a risk assessment with personnel in the sterile processing/central sterile supply department (SP/CSSD) will help identify risks that are being taken each day that could lead to a sterilization process failure. A risk analysis would identify those risks so they could be eliminated before a sterilization process failure occurs.

The goal is to prevent healthcare-associated infections (HAIs) which include surgical site infections (SSI). The CDC has stated:

“Inadequate sterilization of surgical instruments has resulted in SSI outbreaks… The importance of routinely monitoring the quality of sterilization procedures has been established. Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.”2

The Joint Commission (TJC) emphasizes the importance of preventing surgical site infections in their National Patient Safety Goal NPSG.07.05.01. The Element of performance for this goal is:

“Implements policies and practices aimed at reducing the risk of surgical site infections. The policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Center for Disease Control and Prevention [CDC] and/or professional organization guidelines).”3

This inservice will provide some high level practices and information to develop policies and procedures for the SP/CSSD. The information proved includes standards and recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI), The Association of periOperative Registered Nurses (AORN) and the Centers for Disease Control and Prevention (CDC).

Is the staff wearing proper personnel protective equipment (PPE) when cleaning/decontaminating surgical instruments?

The use of PPE in the decontamination area is a requirement of the OSHA blood-born pathogen regulation (29 CFR 1910.1030) to minimize exposure to blood-borne and other disease-producing organisms.4

The general attire for this area recommended in ANSI/AAMI ST79 Section 4.5.1 includes:

- Clean uniforms provided by and donned at the facility;
- Clean, non-skid soled shoes sturdy enough to prevent injury if an item such as a sharp is dropped (no holes in shoes please);
- A surgical type hair covering that completely covers all head and facial hair (except for eyebrows and eyelashes); and
- No jewelry or wristwatches.4

ANSI/AAMI ST79 Section 4.5.2 recommends the following PPE:

- Liquid-resistant covering with sleeves (i.e., backless gown, jumpsuit, or surgical gown)
  - To protect from the risk associated with splash or splatter
  - Change if get wet or soiled
- Liquid-resistant shoe coverings
  - If there is a potential for shoes becoming contaminated and/or soaked with blood and other potential infectious materials
- General-purpose utility gloves (heavy-duty, waterproof, long, and cuffed)
  - To decrease chance of puncture, limit microbial burden on hands, and decrease risk of cross-contamination
  - Pick up sharps with forceps and discard in puncture-resistant container
  - Still need to wash hands

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• Fluid-resistant face mask
  – To protect from the risk associated with splash or splatter
  – Cover nose and mouth
  – Do not hang a used mask around neck, stuff into a pocket or perch it on a forehead after use because the mask is considered contaminated
• Eye protection (goggles, full-length face shields, or other devices that prevent exposure to splash from all angles)
  – To protect from the risk associated with splash or splatter
  – Reduce the risk of eye contact with microorganisms and eye injury from hazardous chemical agents
  – Still need to wear a face mask

Reusable PPE should be decontaminated at least daily and between employees. Torn gloves should be replaced immediately, all disposable PPE should be removed carefully so as not to contaminate the scrub suit or skin prior to leaving the decontamination area, and hands should be washed prior to leaving the decontamination area.

Role of infection preventionists
Your role is to ensure the appropriate PPE is available and worn correctly to protect employees. Periodic unannounced walk throughs are a good way to identify those employees who are not wearing their PPE appropriately. Watch for face masks not covering their nose.

Are cleaning agents being used according to label instructions?

If the written IFU of the manufacturer of the device or cleaning agent are not followed the reusable medical device may not be clean. Cleaning agents are discussed in ANSI/AAMI ST79 Section 7.5.2.2. The cleaning agent “should be compatible with the medical device to be cleaned as well as the materials used in the cleaning equipment.” The cleaning agent “should be easily removable from the medical device by rinsing with readily available water of defined properties so the device does not retain residual chemicals in amounts that could be harmful to patients, damage the device itself, or create other hazardous situations.”

The cleaning agent IFU should be followed to ensure:
• Use within shelf life
• Correct dilution - more is not always better!
• Correct type of water is used to dilute solution
  – Specific water hardness and pH
• Correct water/solution temperature is monitored to ensure enzymes are not inactivated

Are sterilization monitoring tools being used and the results documented?

At the IAHCSMM annual meeting in May 2012, TJC stated that surveyors are finding that healthcare facilities are not running a BI at least weekly, using the appropriate biological indicators (BIs) or BI process challenge devices (BI PCDs) for the appropriate cycles, BI test and control results are not being recorded, and the BI test and control are not from the same lot. ANSI/AAMI ST79 Section 10 addresses these issues and all the quality control that should be used for monitoring the steam sterilization process. As I stated before, TJC surveys will be surveying for performance that meets this recommended practice.

For routine monitoring of the steam sterilization process BIs in a PCD should be used “at least weekly, but preferably every day that the sterilizer is in use (see 10.7).” Every load containing implants (see 10.6.1) should be monitored with a BI inside a PCD and the ‘implants should be quarantined until the results of the BI testing are available.” The BI PCD for implant loads should contain a BI and a Class
5 integrating indicator, not a Class 6 emulating indicator. (ANSI/AAMI ST79 Section 10.6.1) (4) TJC will be surveying to see that implants are not released until the Bi is negative and if they are that the surgeon authorizes the release of the implant and the ANSI/AAMI ST79 Annex L Exception form is used.  

The Bi manufacturer’s IFU should be followed to ensure the correct Bi and Bi PCD is run for the type of sterilizer and cycle parameters being tested in addition to the information on how to incubate the Bi test and control.

A chemical indicator (CI) (Class 1) should be affixed on the outside of every package or rigid container system unless the internal CI is visible to distinguish between processed and unprocessed items. An internal CI (Class 3, 4, 5, or 6) should be placed on the inside of each package, tray, or containment device to indicate the sterilant penetrated the package. It should be noted that Class 6 emulating indicators are cycle-specific; that is, they should be used only in the specific cycles for which they are labeled. (ANSI/AAMI ST79 Section 10.5.2.2.2) (4)

The CI manufacturer’s IFU should be followed to ensure the correct CI is used for the type of sterilizer and cycle parameters to be tested and the CI results are interpreted correctly so a package or rigid container system that was not processed or incorrectly processed is not used on a patient.

Recommended practices and the IFUs of the monitoring product should be followed and personnel should be trained and competent to use and read the results of physical monitors, CIs and BIs. Using a rapid readout Bi PCD in every load and quarantining the load until the Bi is negative will eliminate recalls and the chance that an incorrectly processed medical device is used on a patient.

Role of infection preventionists

As an IP you need to stay on the cutting edge of new monitoring technology and confirm the products are being used according to the manufacturers’ IFU and recommended practices. The results of these monitoring tools provide data to change policies and procedure to eliminate sterilization process failures and SSIs.

During a Joint Commission (TJC) survey, the surveyor may ask to see copies of current manufacturers’ instructions for use (IFU) to see how accessible they are to the end-users. They may ask for a copy of a specific IFU and follow the processing of the instruments from cleaning/decontamination through sterilization. (5) This could be part of a surgical instrument tracer.

Ideally the IFUs are on a computer based system that is available at multiple work stations within the department, throughout the facility, and at offsite locations that do processing. IFUs in a 3 ring binder in the manager’s office are not easily accessible to the end-users and not up-to-date with the new computerized technology. TJC would like to see a process improvement plan that shows a timeline for computerized based access to IFUs if not presently available. (5)

The other concern about IFUs is how to keep them up-to-date. Keeping them up-to-date could almost be a full time job because IFUs may change and you may never be informed by the company of those changes. Requiring an IFU to accompany loaner instruments each time they arrive in the facility, preferably before they arrive, and reviewing to see if they have changed will assist in ensuring you have the most up-to-date IFU at least for loaner instruments. Corporate websites may also provide IFUs.

Another option is using a service that provides for a reasonable fee up-to-date IFUs. A company called Best Practice Professionals, Inc. (www.onesourcedocs.com, 1-800-701-3560) can assist you in obtaining IFUs. The web site describes the oneSOURCE Document Site as “an online, electronic binder of Manufacturers’ Instruction for Use documents for equipment and surgical instruments, with a search engine that provides multiple paths to needed documents.” Searching is done by “Instrument Catalogue Number, Manufacturer or Description — It’s that easy!” This system can be used as a facility wide electronic binder by all departments in the healthcare facility.

Before altering the IFU for any reason, contact the corporate Sterility Assurance or Quality Assurance Services of the manufacturer to see if the changes you want to make (e.g., such as changes in the cleaning, packaging, or sterilization cycles or processes) have been validated and request that information in writing. If the change you want to make has not been validated by the medical device manufacturer it is risky to make a decision to continue with the idea and could result in improperly process medical devices and poor patient outcomes.

Role of infection preventionists

An infection preventionists who has access to up-to-date IFUs can use that information during infection control rounds to ensure reprocessing instructions are current and accurate and correctly implemented. (1)
What is their practice for monitoring of the mechanical cleaning equipment?

If instruments are not properly cleaned they cannot be disinfected or sterilized. Therefore, the healthcare facility should be following the recommended practices for monitoring the cleaning effectiveness of mechanical cleaning equipment.

ANSI/AAMI ST79 Section 7.5.3.3 discusses the mechanical cleaning equipment that needs to be monitored. Equipment that “removes soil and microorganisms through an automated cleaning and rinsing process” that needs to be monitored includes:

- Utensil and cart washers;
- Washer-sanitizers, pasteurization equipment;
- Washer-disinfectors, washer-decontaminators, and washer-sterilizers; and
- Ultrasonic cleaners.

“Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repair.” (ANSI/AAMI ST79 Section 7.5.3.3) The monitoring recommendations in the AORN Recommended Practice for Care and Cleaning of Surgical Instruments and Powered Equipment Recommendation XXII.a. is similar to the AAMI recommendation. A major repair is defined in ANSI/AAMI ST79 Section 7.5.3.3 and 10.2). This monitoring recommendation is similar to the biological indicator monitoring recommended for steam sterilizers.

Daily and preventive maintenance is discussed in ANSI/AAMI ST79 Section 7.6.2.3 and is vital to the proper function of all mechanical equipment. Monitoring mechanical cleaning equipment verifies that the daily and preventive maintenance was performed, the correct solutions were connected and dispensed, the equipment was correctly loaded, and the correct cycle was run.

Annex D, Table D.2 in ANSI/AAMI ST79 discusses the tests available for healthcare facilities to verify the efficacy of mechanical cleaning equipment such as washer disinfectors. Tests that use blood and protein markers are the most common. Manufacturers of the test systems suggest placing the test inside the basket in the mechanical cleaning equipment in an empty load.

In addition to this monitoring, each cycle printout should be reviewed and initialed (similar to sterilizers), test results should be documented, and “ideally, cleaned medical devices should be traceable to the patients on whom they are used.” (ANSI/AAMI ST79 Sections 7.5.3.3 and 10.2)

The care of ultrasonic cleaners is discussed in ANSI/AAMI ST79 Section 7.5.3.3 and AORN Care of Instruments Recommendation X. A number of monitoring tools are available to verify the cleaning effectiveness of ultrasonic cleaners. For example, the author observed an ultrasonic cleaner used to process the da Vinci® Surgical System instruments being tested with cleaning verification monitors which included a monitor to test for cavitation (sufficient energy and conditions are correct), an irreversible thermometer to check temperature, a monitor to verify cleaning effectiveness, and a monitor to check the effectiveness of fluid flow for cleaning lumens. All the monitors showed a pass except the lumen test monitor. It was determined that the pump was not working so no fluid was flowing through the lumens. No one knew what the last cleaning verification test was run or how many da Vinci lumened instruments had been processed in this ultrasonic while it was not functioning. This is a major risk for infections and an example of why monitoring of the cleaning process is so important.

Annex D, Section D.1 in ANSI/AAMI ST79 says cleaning verification by users should also include “monitoring key cleaning parameters (e.g., temperature).” Water temperature in any of the mechanical cleaning equipment could be monitored using irreversible thermometers and remote sensing equipment. There is no recommended frequency for this monitoring as of yet but it should be considered. The author observed irreversible thermometers being used inside a case cart. The thermometers indicated the cleaning solution and water were not contacting all surfaces, specifically under the top of the cart and in the back. The equipment was adjusted to correct the problem and retested. If this testing had not been done the case carts would have continued to be improperly cleaned. The temperature monitors can be used in any of the mechanical cleaning equipment to determine if the correct temperature is being reached in all locations which may not be indicated by the physical monitors, if available.

Visual inspection has been the most common method used to inspect the cleanliness of individual instruments but the limitation is that you cannot see biofilm or microbes, biological residues, or inside lumens. (ANSI/AAMI ST79 Section Annex D, Section D.1) Annex D, Table D.1 discusses tests available to assess the efficacy of cleaning of medical devices. Tests that utilize ATP and protein markers are the most common. These tests can be used routinely to test individual instruments after manual washing, sonication, or the mechanical cleaning process to ensure they were effectively cleaned.

As with biological indicator monitoring of sterilizers, the more often you monitor the mechanical or manual cleaning process the quicker detection and correction of cleaning process failures which minimizes the number of patients that could be involved as a result of a process failure. Monitoring the efficacy of the mechanical cleaning equipment more often (preferably daily, possibly every load) creates a greater assurance that instruments are clean and can be effectively sterilized.

Role of infection preventionists

As an infection preventionists you want to ensure everything is being done to prevent HAIs. Monitoring all the mechanical cleaning equipment at an interval that minimizes the number of patients that could be involved with a cleaning process failure will help you meet this goal in addition to having policies and procedures that meet the AAMI recommended practices.
TJC says that all policies and procedures should be aligned with evidence-based guidelines and/or professional organization guidelines. Here is a list to help you keep policies and procedures current and up-to-date with standards and recommended practices.

The following ANSI/AAMI recommended practices and technical information reports (TIR) should be used for developing these policies and procedures:

- **Ethylene oxide sterilization in health care facilities.** ANSI/AAMI ST41:2008
- **Chemical sterilization and high-level disinfection.** ANSI/AAMI ST58R:2005 (presently in revision and not for sale).
- **Process challenge devices and/test packs for use in health care facilities.** TIR31:2009

ANSI/AAMI ST79 is a continuous maintenance document so a free PDF of amendments is available when they are published. Be sure to check to see if you have the most up-to-date version of the recommended practice. TJC surveyors have been trained on and will be using ANSI/AAMI ST79 as a reference during surveys. They expect each facility to have an up-to-date recommended practice available for personnel to access.


ANSI/AAMI recommended practices can be ordered at http://marketplace.aami.org or by phone at 877-249-8226 or 1-240-646-7031. ANSI/AAMI ST79 can be ordered through AORN and IAHCSSM at membership prices.

A free PDF of A2:2011 and future amendment(s) may be downloaded by visiting http://www.aami.org/publications/standards/st79.html which also includes information on how to update your copy of ANSI/AAMI ST79 when free amendments are available. The amendments can be printed and saved to your hard drive. Watch for the next set of amendments (A3:2012) to be published in November 2012.

The 2012 AORN Perioperative Standards and Recommended Practices has the following chapters that are good references for writing SP/CSSD policies and procedures:

- Cleaning, Handling, and Processing Anesthesia Equipment;
- High-Level Disinfection;
- Cleaning and Processing Flexible Endoscopes and Endoscope Accessories;
- Cleaning and Care of Surgical Instruments and Powered Equipment;
- Selection and Use of Packaging Systems for Sterilization;
- Sterilization.

The AORN Perioperative Standards and Recommended Practices, 2012 can be purchased through AORN using the following options:

- Internet: www.aorn.org
- Call: 1-800-755-2676 x 1 or 303-755-6304 x 1 (Monday-Friday, 8AM to 4:30PM mountain standard time)
- Fax: 303-750-3212
- By mail: AORN, Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA

The updated AORN Recommended Practice for Sterilization, 2012 was not finished in time for the 2012 book publication but will be in the 2013 version. It can only be purchased now using the following option:

- ANSI website: http://webstore.ansi.org/default.aspx
  In the search box at the top, enter “AORN MAN-864B-2012” where it says “Enter document number…”
- Click “Go”


**Role of infection preventionists**

An infection preventionists needs to stay on the cutting edge of standards and recommended practices to assist periodic review of policies and procedures.
Does the department have a policy for use of Loaner Trays?

If any of these events have happen recently in your healthcare facility then it is time to develop a policy for loaner trays or buy some teeth into the one you have. Have you ever received sets:

- The same morning as the case is scheduled;
- Too late to quarantine implants until the BI is negative;
- You have never seen before and you have had no in-servicing in OR or SP/CSSD and do not have the equipment in house to process the instruments;
- Without inventory sheets;
- With missing or broken instruments;
- With instrument trays cracked or broken; or
- With dirty instruments?

If you have been confronted with even one of these events then the International Association of Central Service Materiel Managers (IAHCSMM) has some help for you. The Orthopedic Council of IAHCSM published in June 2011 the following documents.

- IAHCSMM Position Paper on the Management of Loaner Instrumentation
- IAHCSMM Sample Policy and Procedure

These documents are available for no charge at: http://iahcsmm.org/CurrentIssues/Loaner_Instrumentation_Position_Paper_Sample_Policy.html

These documents discuss the responsibility of the surgeons, operating room (OR), sterile processing department (SP/CSSD), and sales representatives to develop a partnership to define and enforce responsibilities to ensure patient safety. The most important recommendation is the delivery time for loaner trays. IAHCSMM recommends the following:

- “Healthcare facility requires receipt of loaner trays at least two (2) business days prior to the scheduled case.” (sales rep)
- “All first-time vendor sets require three (3) business days for inservicing, inspecting and processing.” (sales rep)

This will allow SP/CSSD enough time to follow all the steps in the IFU (which should arrive before the loaner trays) and not take short cuts in processing to meet the OR deadlines and to quarantine the implants until the BI results are available. For this to work, buy-in must be obtained from administration, OR, surgeons, IP, risk management, and SP/CSSD. The facility and vendors should be educated on the policy and there should be consequences if the policy is not followed. For example, the third time a vendor does not supply instruments on time then their products will not be used in the future.

Role of infection preventionists

Infections preventionists need to own this loaner tray policy to prevent short cuts from being taken in the processing of loaner trays that do not arrive in time for all the cleaning, monitoring, and sterilization steps to be performed according to IFUs and recommended practices. This is another tool to fight HAIs.

Is the SP/CSSD staff certified? Are newer employees working toward certification?

ANSI/AAMI ST79 Section 4.2 recommends that “all personnel performing sterile processing activities be certified as a condition of employment. At a minimum, all such personnel should successfully complete a central service certification examination within two years of employment and should maintain that certification throughout their employment.” Certification can be obtained from:

- Certification Board for Sterile Processing and Distribution (CBSPD)
  - 148 Main Street, Suite C-1, Lebanon, NJ 08833
  - 800-555-9765
  - http://www.sterileprocessing.org
- International Association of Healthcare Central Service Materiel Management (IAHCSMM)
  - 213 Institute Place, Suite 307, Chicago, IL 60610
  - 312-440-0078

Orientation, on-the-job training, and continuing education are important to prevent operator errors and protect employees from potential safety hazards and ensure policies and procedures are adhered to. Competency testing of employees where they demonstrate knowledge provides verification of qualifications and workplace training. TJC requires documentation of training, continuing education, and competency. Certification is a method to determine initial competency but continuous competency also needs to be determined and documented.

Surveyors have asked facilities to point out who is certified and some surveyors have congratulated those individuals. TJC has not cited healthcare facilities for not having certified employees but TJC understands the importance of certification and so should your healthcare facility.

Role of infection preventionists

Ensure competency testing provides hands-on training, supervision until competency is documented, and regular retesting of competency. Support the certification of SP/CSSD staff. Certified and competent staff will help you fight against HAIs.
What is the department procedure for a recall in the event of a sterilization process failure (e.g., a positive BI result)?

Each healthcare facility should have written policies and procedures for the recall of items from an issued or stored sterilization process. (ANSI/AAMI ST79 Section 10.11.1) These policies and procedures “should be developed for compliance with the Safe Medical Device Act of 1990 as it pertains to failures of reusable medical devices (i.e., The Medical Device Reporting [MDR] regulations of 21 CFR 803).” (ANSI/AAMI ST79 Section 10.11.1)

ANSI/AAMI ST79 in Section 10.7.5 discusses the actions to take when biological indicators, chemical indicators, or physical monitors indicate a steam sterilization process failure. If any of these three indicators identifies a failure of the sterilization process and the cause of the failure is immediately identified (usually operator error such as running the wrong cycle for the load contents) and is confined to the one load, the cause of the failure should be corrected, and the load reprocessed.

If the cause cannot be immediately identified (which is the case in most situations):

- Quarantine the load;
- Take sterilizer out of service to investigate the root cause of the failure;
- Recall all loads back to the last negative biological indicator;
- Retrieve and reprocess the items from those loads; and
- Arrange for corrective action.4

When you understand the recall procedure you can appreciate the advantage of running a rapid readout BI in every load and only having to deal with the reprocessing of one load of medical devices instead of the recall and reprocessing of 20 to possibly 40 or more loads. Running a rapid readout BI in each load and quarantining until the BI results are negative ensures quick detection of sterilization process failures, reduces patient risk, saves money, and increases peace of mind.

A decision tree for conducting investigations of steam sterilization process failures (Figure 12) and a trouble shooting checklist for identifying reasons for steam sterilization process failures (Table 8) are also part of ANSI/AAMI ST79 Section 10.7.5. In addition, Figure 12 shows what sterilizer testing is needed before the sterilizer is placed back into use.4

Role of infection preventionists

As an infection preventionist waging war against HAIs is a daily occurrence. Great tools to have are a recall procedure and routine monitoring frequency (e.g., every load monitoring with a rapid readout BI) that eliminates recalls and the risk that a patient will contact a non-sterile medical device.

Does your facility have standardized policies and procedures covering reprocessing done in both the SP/CSSD and other locations (e.g., the OR, affiliated Ambulatory Surgery Centers, clinics, etc)?

Sterilizers require the same quality control of the process, no matter the location. Policies and procedures should be standardized throughout the facility to ensure the sterilization process and patient care items produced are of the same quality and safe for patient use and to prevent SSI.3

As stated previously, policies and procedures should be based on evidence-based guidelines such as those from the CDC and/or professional organization guidelines, such as AAMI and AORN and standardized across the facility.3

TJC is using ANSI/AAMI ST79 recommended practices to survey facilities. Both TJC and CMS are surveying cleaning, disinfection, and sterilization activities. The sterilization process needs to be routinely tested with physical monitors, chemical and biological indicators, and the ANSI/AAMI ST79 recommended practices for cleaning/decontamination, disinfection, packaging, preparation, sterilization, installation, care, and maintenance of sterilizer’s, and sterile storage also need to be followed.

All of these activities need to be performed by experienced, knowledgeable people who should be certified by either the Certification Board (http://www.sterileprocessing.org) or IAHCSMM (www.IAHCSMM.org) to document competency and verify qualifications and workplace training as required by regulatory and accrediting agencies as previously discussed.

Role of infection preventionists

Infection preventionists should be involved in writing facility-wide standardized policies and procedures to ensure patients receive the same quality product no matter where the sterilizer or sterilization process is performed. This will save you time and assist in preventing SSIs.
Summary

Infection preventionists can lead through learning by keeping up-to-date on cutting edge technology, standards and recommended practices, and manufacturers’ instructions for use. Use this information for infection control rounds in SP/CSSD. The time to start is now.

References

3. The Joint Commission. 2012 Hospital Accreditation Standards (HAS).
6. Personnel communication with healthcare facilities who have had surveys.
Answers

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

Martha Young, BS, MS, CSPDT

Martha Young, BS, MS, CSPDT, is president of Martha L. Young, LLC, providing SAVVY sterilization solutions to healthcare manufacturers and facilities and a consultant for 3M. She retired from the 3M Infection Prevention Division, St. Paul, MN in 2009 after 31 years and has over thirty years of experience in the specialty area of cleaning/disinfection and sterilization. Ms. Young has lectured around the world, has numerous publications on infection prevention with an emphasis on how to improve the performance of the sterilization process, and writes a quarterly column for OR Manager. She is a member of IAHCSMM, AORN (Past Professional/Practice Issues Chair for AORN Speciality Assembly for Sterilization Processing and Materials Management from 2006-2010), APIC and a certified Central Sterile Processing and Distribution Technician. Additionally, Ms. Young is the APIC representative to AAMI and a voting member of several AAMI working groups developing recommended practices. In 2007 HPN acknowledged her as one of the “30 Pros Worth Knowing” who are the Most Influential in Healthcare Sterile Processing. Ms. Young can be reached at marthalyoung1@aol.com.

Ms. Young is an education consultant for 3M Health Care, Infection Prevention Division.
### Sterile Process and Distribution CE Information

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<th>CE Applicant Name:</th>
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Address:       State:     Zip Code:

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

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

IAHCSMM has awarded 1.5 approved contact points 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 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 Infection Prevention
   Attn: HC4160
   RR Donnelly Fulfillment Services
   585 Hale Avenue North
   Oakdale, MN 55128-9935
7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly’s receipt of the application.

### Application  Please print clearly or type.

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Offer expires November 2017