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## Preparing for a Joint Commission Survey

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## Objectives

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

1. Identify areas to focus improvement activities to prepare for a Joint Commission survey.
2. Develop or update policies and procedures related to the environment, cleaning process, equipment, housekeeping, sterile storage, outdates and stock rotation, and quality control of the high-level disinfection and sterilization process based on recommended practices.
3. Develop or update a policy and procedure on loaner instrumentation based on the International Association of Healthcare Central Service Materiel Management (IAHCSMM) policy and procedure.
4. Develop or update a policy and procedure on immediate-use steam sterilization based on recommended practices and the Multi-society position statement on Immediate-Use Steam Sterilization.

## Test Questions

- 1 **The Joint Commission (TJC) surveyors are not focusing on the cleaning, disinfection, and sterilization areas within a healthcare facility.**  
A. True B. False
- 2 **Department humidity should ideally be 50% to prevent absorbent material such as wrappers and peel pouches from becoming dried out which could create superheated steam and a sterilization process failure.**  
A. True B. False
- 3 **Use the water quality recommended in the instrument manufacturer's instructions for use (IFU) for rinsing the instruments during the cleaning process.**  
A. True B. False
- 4 **Read symbols, dates, and statements on packages so you know which products to use first and which are no longer usable.**  
A. True B. False
- 5 **The water in eye wash stations should be between 13°C and 38°C (60°F and 100°F).**  
A. True B. False
- 6 **Air should flow into the soiled/decontamination area (negative pressure)(in) from the preparation and packaging area (positive pressure)(out) to prevent air contaminants from entering the clean areas.**  
A. True B. False
- 7 **The lot control numbers of the biological indicator test and control vial should match and be documented.**  
A. True B. False
- 8 **If recommended by the test strip manufacturer's instructions for use, perform quality control testing on each new bottle of MRC/MEC test strips before the strips are placed into routine use.**  
A. True B. False
- 9 **Releasing implants before the biological indicator (BI) results are known is unacceptable and should be the exception, not the rule.**  
A. True B. False
- 10 **AORN recommends the use of containment devices to avoid contamination of instruments processed by immediate-use steam sterilization.**  
A. True B. False

## Introduction

The Joint Commission (TJC) issued a position statement on steam sterilization on June 15, 2009.<sup>1</sup> In this position statement TJC said surveyors will be looking more closely into all aspects of the sterilization method or cycle. This includes cleaning and decontamination, sterilization, storage, and return of instruments to the sterile field. The surveyors will be observing the process and asking for manufacturer's instructions for use (IFU) for instruments, the sterilizer, wrapping or packaging, and chemical and biological indicators. As a result of TJC position statement a task force was convened of 12 organizations to discuss the specific issue of "flash sterilization." The result was a Multi-society position statement on Immediate-Use Steam Sterilization (formerly known as "flash sterilization").<sup>2</sup>

In October 2009 TJC made a change to the Infection Control standard IC.02.02.01 that discussed the responsibility of the organization to reduce the risk of infections associated with medical equipment and devices. This change was first published in the 2010 standard and exists in the 2012 standard.<sup>3</sup> The Element of Performance (EP) 1 was changed to state "Hospital implements infection and control activities when cleaning and performing low-level disinfection." Intermediate and high-level disinfection used to be in EP 1 but they joined sterilization in EP 2. EP 2 addresses intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. Intermediate and high-level disinfection were moved to EP 2 to reflect the concern TJC and Centers for Disease Control (CDC) have for these procedures if done incorrectly.<sup>4</sup>

As a result of TJC's emphasis on cleaning, disinfection, and

sterilization the surveyors received in-depth training in 2010 on the sterilization process through the Association for the Advancement of Medical Instrumentation (AAMI) based upon the ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.<sup>1</sup> ANSI/AAMI ST79 is now the reference document for surveys.<sup>5</sup>

To assist you in preparation for TJC survey, the Association for the Advancement of Medical Instrumentation published in 2011 *Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys*.<sup>6</sup> The purpose of this guidance document is to help health care professionals prepare for an accrediting agency survey as it relates to the sterile processing of surgical instruments and other medical devices in health care settings.<sup>6</sup> This is an excellent reference for preparing for surveys for TJC and other organizations.

In May 2011 at the International Association of Healthcare Central Service Materiel Management (IAHCSMM) annual meeting in Louisville, KY, the Joint Commission made a presentation on their new emphasis for 2011 which continues to apply in 2012.

John Eiland, the surveyor who spoke stated that TJC will have an engineer at every site for 2 days in sterile processing (SP), clinics etc. for the survey. The surveyor will use the National Fire protection Agency (NFPA) 101 manual.<sup>5</sup> In addition the speaker said to read the ANSI/AAMI ST79 Section 3 on Design considerations and Section 9 on Installation, care, and maintenance of sterilizers to prepare for the survey.<sup>5</sup> Other comments made in this inservice are from personal communications with healthcare facilities who have had surveys.

## Environment concerns

### Temperature and humidity

TJC is interested in knowing what is the temperature and humidity in the different areas of the department.<sup>5,7</sup> ANSI/AAMI ST79 Section 3.3.6.5 and Section 3.3.6.6 discuss the temperature and humidity requirements for work areas. The temperatures recommended are:

- General work areas – 20°C to 23°C (68°F to 73°F);
- Decontamination – 16°C to 18°C (60°F to 65°F);
- Sterilization equipment access rooms – 24°C to 29°C (75°F to 85°F);
- Sterile storage and personnel support areas – may be as high as 24°C (75°F).<sup>9</sup>

Work areas need to be comfortable for workers, especially in decontamination, and cool and dry enough to minimize bioburden.

Humidity should be between 30% to 60%. The humidity in

sterile storage should never exceed 70%. The ideal relative humidity is 50% (not below 35%).<sup>8</sup> This humidity needs to be maintained to prevent absorbent material such as nonwoven and woven wrappers and peel pouches and biological (BIs) and chemical indicators (CIs) from drying out. If packaging dries out it can create superheated steam in a steam sterilizer which could lead to a sterilization process failure. If BIs become desiccated they become more resistant to steam sterilization which could lead to positive BIs. The response of CIs may be slowed down as a result of storage in low humidity. Ensure that all packaging, BIs, and CI are stored according to their instructions for use (IFU). ANSI/AAMI ST79 Section 8.3.1 states that "packaging materials should be held at room temperature [20°C and 23°C (68°F and 73°F)] and at a relative humidity ranging from 30-60% for a minimum of 2 hours" before use.<sup>8</sup>

Independent temperature and humidity monitors should be in each location with the data read and recorded daily by personnel in order to detect changes in temperature and humidity that could frequently occur and effect comfort and the result of the sterilization process.

### **Water quality**

TJC is concerned about water quality because it is important in the cleaning of medical devices.<sup>5,7</sup> ANSI/AAMI ST79 Section 7.5.4 discusses the importance of water quality in the rinsing of instruments whether they are cleaned manually or mechanically. Devices “should be thoroughly rinsed to ensure that loosened debris and detergents are adequately removed.”<sup>8</sup> Tap water can be used first to ensure the use of copious volumes of water but the final water rinse should be done with treated water according to the medical device manufacturer’s IFU. The IFU may recommend deionized, distilled, or reverse osmosis (RO) water with the objective of minimizing staining and contamination of instruments with microorganisms from the tap water source. To eliminate pyrogens from the final rinse, “regular maintenance of the water treatment process is essential.”<sup>8</sup>

### **Ventilation (air flow and air exchanges)**

TJC surveyors have been checking the air flow rate between the decontamination/soiled area and preparation and packaging at the pass through window using a facial tissue.<sup>7</sup> Healthcare facilities have been cited because the air flow was not correct. Air should flow into the soiled/decontamination area (negative pressure)(in) from the preparation and packaging area (positive pressure)(out) to prevent air contaminants from entering the clean areas. The air in the areas under negative pressure “should be exhausted to the outside via a nonrecirculating system.”<sup>8</sup> This information is discussed in ANSI/AAMI ST79 Section 3.3.6.4.<sup>8</sup>

Negative air flow (in) with a minimum of 10 air exchanges per hour should occur in the following areas:

- Soiled/decontamination;
- Sterilizer equipment access;
- Sterilizer loading/unloading;
- Restrooms/housekeeping.<sup>8</sup>

Positive air flow (out) with a minimum of 10 air exchanges per hour should occur in the following areas:

- Preparation and packaging;
- Textile pack room.<sup>8</sup>

Clean/sterile storage should be a positive air flow (out) with a minimum of 4 air exchanges per hour.<sup>8</sup>

Ventilation controls bioburden and environmental contaminants to ensure the effectiveness of the sterilization process. TJC surveyors have also asked if engineering provides the department with reports showing airflow rates.<sup>7</sup> The facility should determine an appropriate

frequency for testing and this information should be sent to the sterile processing department to add to the documentation records of temperature and humidity to prepare for a survey and to ensure correct ventilation at all times.

### **Separation of dirty/clean/assembly**

TJC surveyors have sited healthcare facilities for having a physical setting in which the automated endoscope reprocessor (AER) is in the same room where the cleaning takes place.<sup>7</sup>

TJC wants the AER to be located in a different room from cleaning to prevent cross-contamination or recontamination of the scopes after processing.<sup>5</sup>

ANSI/AAMI ST79 Section 3.2.3 addresses functional workflow patterns.

“The sterile processing department should be designed to separate areas in which contaminated items are received and processed from areas in which clean items are packaged, sterilized, and stored. Functional work areas should be physically separated by walls or partitions to control contaminants generated during the phases of reprocessing. Work area design also should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas.

**NOTE** – In office-based facilities, physical separation of functional work areas (e.g., the decontamination and clean/sterile areas) is desirable, but spatial separation could be satisfactory if accompanied by good workflow patterns, airflow characteristics, and work practices. See Figure 2.”<sup>7</sup>

If you cannot physically separate the two activities in the endoscopic area then do a risk analysis and determine what changes you can make to the entire process to prevent cross-contamination or recontamination of the endoscopes and be prepared when TJC surveyor arrives. Improving functional separation through airflow patterns or separation of activities are some suggestions in ANSI/AAMI ST79.<sup>8</sup> The results of a survey may present an opportunity for the modification or construction of a new area that meets the recommended practices for separation of contaminated endoscopes from processed and stored endoscopes.

Departments have also been cited by TJC surveyors because the door and pass through window between clean and dirty was open.<sup>7</sup> ANSI/AAMI ST79 Section 3.2.3 recommends a “pass-through window that is at equal counter height between the decontamination and clean processing areas.”<sup>8</sup> Both the door and pass through window need to be closed to maintain the airflow needed to prevent contaminants from escaping to the clean side.

The objective of separation of dirty/clean/assembly is to limit environmental contamination by containment which limits the bioburden on devices to be high-level disinfected or sterilized.

**Traffic patterns and related attire if appropriate**

TJC surveyors are observing traffic patterns and related attire in sterile processing.<sup>5</sup>

ANSI/AAMI Section 3.2.4 discusses that traffic in decontamination, preparation and packaging, sterilization processing, sterile storage, and distribution should be restricted to authorized personnel.<sup>8</sup> Policies and procedures should specify criteria for authorized entry, movement and attire with the objective of preventing microorganisms from being carried into the area and to protect personnel and visitors from microorganisms present on contaminated items being processed in the decontamination area. If entry is necessary, personnel protective equipment (PPE) is required (Section 4.5). The PPE worn will depend on the area accessed and activities performed. At a minimum clean uniforms provided by the facility should be worn and not uniforms worn in from the outside. Other PPE can include protective gloves, protective attire, eye protection, and face masks.

**Eye wash stations**

TJC expects the water temperature in the eye wash stations to be between 13°C and 38°C (60°F and 100°F). ANSI/AAMI ST79 Section 3.3.8 addresses emergency eyewash/shower equipment. No water temperature is discussed but it states that “ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they are designed to flush both eyes simultaneously, and that they have a “hands-free, stay open” feature once activated.”<sup>8</sup>

Eye wash stations are required by OSHA for immediate use in locations where chemical such as cleaning agents, disinfectants, and low temperature sterilization chemicals such as ethylene oxide, hydrogen peroxide, and ozone are used. The eyewash station should be marked with a highly visible sign and employees should be able to reach the station in 10 seconds. If a strong acid or strong caustic solution is used the eyewash station should be immediately adjacent to the hazard. The eyewash station should be maintained according to the manufacturer’s IFU and tested routinely for proper operation. To be prepared for a JC survey the temperature should be checked and documented.

**Other**

TJC surveyors have also checked to see if you have:

- A disaster plan;
- Evacuation procedures for areas in which ethylene oxide sterilizers are used;
- Emergency exit maps that match and are consistent;
- Fire extinguishers that are not blocked;
- Staff that know where fire alarm pull stations are located;
- Adjustable (ergonomics) workstations;
- Ability to weigh trays (check to ensure  $\leq 25$  pounds) and have a log to document the weight;
- Peg boards that are not made of absorbable surfaces (paint to ensure not absorbable).<sup>5,7</sup>

**Cleaning process**

Cleaning is a top priority for TJC surveyors. They have asked healthcare facilities if loaner instruments are received at least 24 hours ahead of time for cleaning and processing and whether loaner instruments are processed in the same manner as other instruments in all areas of the healthcare facility following the instrument manufacturer’s IFU.<sup>7</sup> The IAHCMM Sample Policy & procedure for Loaner Instrumentation recommends that healthcare facilities require receipt of loaner trays at least two (2) business days prior to the scheduled case and three (3) business days for first-time vendor-loaned sets for inservicing, inspecting and processing.<sup>11</sup> This is considered the amount of time required to properly process the instruments using the manufacturer’s IFU.

TJC surveyor may ask for a copy of the manufacturer’s IFU and observe the cleaning process, including PPE.<sup>7</sup> The surveyor may also observe if rigid containers are being broken down and washed according to the manufacturer’s IFU.<sup>7</sup> Most manufacturers

recommend that the filter retention plates be removed from the container for washing. TJC surveyor may observe if you are using the correct amount of cleaning agent and diluting it properly.<sup>7</sup> This may require the use of a graduated cylinder to determine if the amount of cleaning agent dispensed is correct and a marking of the sink to ensure the correct amount of water is added.

ANSI/AAMI ST79 Section 7 Cleaning and other decontamination processes is an excellent resource for information on the cleaning process.<sup>8</sup> Follow the instrument, mechanical cleaning equipment, cleaning agent, and cleaning tools instructions for use to ensure proper cleaning of all items. And remember that the cleaning process needs to be the same in the OR and ASC as it is in SP. There are no short cuts and there are monitoring tools available to assist in determining if the cleaning process is effective. These tools are discussed in ANSI/AAMI ST79 Annex D.<sup>8</sup>

## Equipment

TJC is interested in the use/function, recalibration, ongoing/periodic cleaning and maintenance of equipment, including contractor servicing.<sup>5</sup> ANSI/AAMI ST79 Section 9 discusses Installation, care, and maintenance of sterilizers and is the section used for this part of the survey. This section covers the care and maintenance procedures applicable to steam sterilizers which are important to minimize sterilizer downtime and prevent sterilizer malfunctions. “The manufacturer’s maintenance schedule and procedures should be followed, whether the sterilizer is new, remanufactured, refurbished, or reconditioned.”<sup>8</sup> The manufacturer’s instruction manual should be available to internal and external personnel who may perform the required services.

Routine care of sterilizers is discussed in ANSI/AAMI Section 9.4. “Sterilizers should be inspected and cleaned daily according to the manufacturer’s written instructions (see 9.2).”<sup>8</sup>

Ongoing daily care and cleaning includes the following components of the sterilizer:

- Recording charts;
- Printers;
- Printer ribbons;
- Marking pens and ink;
- Door gaskets;
- Chamber drain screen;
- Internal chamber, and;
- External surfaces.<sup>8</sup>

Weekly or periodic care of components of the sterilizer should be performed as recommended in the sterilizer manufacturer’s written instructions for use.

Preventive maintenance should be done according to the sterilizer manufacturer’s written instructions for use and by a qualified individual. ANSI/AAMI ST79 recommends in Section 9.5:

“Simple charts showing the location and replacement dates of components will show trends in deterioration and provide a framework of a preventive maintenance program. The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained (see 9.7).”<sup>8</sup>

Calibration should only be performed by qualified personnel to ensure effective and reliable sterilization (see Section 9.6).<sup>8</sup>

It is important to document what and when preventive maintenance and calibration was performed by either internal or external personnel from the sterilizer manufacturer or a contractor service. “These records can be either in paper or electronic format and should be kept for each sterilizer (see ANSI/AAMI ST79 Section 9.7)”<sup>7</sup> The documentation “should be maintained by the supervisor responsible for the equipment, by the hospital engineering staff, by the service person or organization that performed the servicing, and/or by whoever else is deemed appropriate by the health care facility.”<sup>8</sup>

Documentation should be kept for the life time of the sterilizer. Maintaining documentation will assist sterile processing in trouble shooting steam sterilization processes. Other departments will need the documentation “to identify the equipment and to establish a continuous history of all scheduled and unscheduled service.”<sup>8</sup>

## Housekeeping

TJC will survey the cleanliness of the department.<sup>5</sup> They are asking about the frequency of departmental cleaning including:

- Daily versus deep cleaning;
- Behind closed doors and under racks;
- Hidden corners and high level flat spaces;
- Behind and around automatic cleaning equipment;
- Sterilizers access room including the tops of sterilizers, and;
- Is the “dirty” room clean?<sup>5</sup>

ANSI/AAMI ST79 Section 3.4 briefly discusses housekeeping procedures. Housekeeping procedures in sterile processing “should be the same as those used to clean operating and delivery rooms and should ensure a high level of cleanliness at all times.” This includes:

- Cleaning the floors and horizontal work surfaces at least daily;

- Cleaning on a regular scheduled basis and more often if needed:
  - Walls;
  - Storage shelves;
  - Air intake and return ducts;
- Replacing stained ceiling tiles and repair leaks that caused stain, and;
- Cleaning lighting fixtures or covers every 6 months.<sup>8</sup>

Separate housekeeping tools should be used for decontamination and clean areas to avoid transferring contaminants from “dirty” to “clean” areas and surfaces. Clean up your act because TJC surveyor will be wearing white gloves.

## Sterile storage

TJC is interested in the security of storage areas, how cardboard boxes and shipping containers are handled, that items are stored in sterile storage 18 inches below the bottom of the deflector plate of sprinklers, and the bottom shelf of each rack has a solid bottom.<sup>5,7</sup>

ANSI/AAMI ST79 discusses sterile storage in Section 8.9. Sterile items should be stored at least:

- 8 to 10 inches above the floor;
- 18 inches below the ceiling or level of the sprinkler heads;
- 2 inches from outside walls.<sup>9</sup>

If the bottom shelf of an open-shelf (wire) cart is used there should

be a physical barrier between the shelf and traffic or housekeeping activities to prevent contamination of the items. “Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas. (See also 5.2.1)”<sup>8</sup> Shipping containers have been exposed to potentially high microbial contamination and corrugated cartons generate and are reservoirs for dust. Traffic should be restricted to authorized personnel wearing appropriate attire. (ANSI/AAMI ST79 3.2.4 and 4.5)<sup>8</sup> The objective is to protect the sterility of stored products by controlling the environment and handling of the sterile item (i.e., do not crush, bend, compress or puncture).

## Outdates and stock rotation

TJC is interested in outdating and stock rotation and the ability of employees to read the symbols on sterile purchased items to ensure they are not used beyond the date listed by the manufacturer of the product.<sup>5,7</sup>

ANSI/AAMI ST79 Section 8.9.3 discusses shelf life. “There should be written policies and procedures for how shelf life is

determined and how it is indicated on the product.”<sup>8</sup> Train employees to read symbols, dates, and statements on packages so they know which products to use first and which are no longer usable. Also train personnel to inspect packages that say “Do not use if package is open or damaged” before the package is released.

## Quality control

### **Test strip and chemical monitoring devices**

TJC surveyor is interested in seeing the data from the quality control (QC) testing of the MRC/MEC test strips used to measure the minimum recommended concentration/minimum effective concentration (MRC/MEC) of the high level disinfectant.<sup>5,7</sup> This testing should be done according to the test strip manufacturer’s IFU but is not required by all test strip manufacturers. In general, the testing is done when a new bottle of strips is opened. Pass and fail solutions are prepared and the strips need to correctly detect the results of both solutions before the new bottle of strips can be placed into routine use. ANSI/AAMI ST58 Section 9.3.3 discusses solution test strips and chemical monitoring devices:

“Health care personnel should use the appropriate test strip or chemical monitoring device to test the LCS/HLD solution. The solution should be tested before each use (ASGE and SHEA, 2003). If the test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should not be used.”<sup>9</sup>

TJC surveyors will also check the shelf life of the MRC/MEC test strips and the high-level disinfectant and they will ask for the QC test strip data so you need to document that testing.<sup>8</sup>

### **Biological (BI) and chemical indicators (CI)**

TJC surveyor will be checking to ensure that:

- BI used is correct for the cycle being tested (follow BI manufacturer’s IFU);
- Lot numbers of the BI test and control vials match and are documented.<sup>5,7</sup>

They will also ask how often do you run BIs and Bowie-Dick tests, will check the BI records for all sterilization processes in both SP and the OR, and will ask to see documentation for the last recall.<sup>8</sup>

ANSI/AAMI ST79 discusses the routine testing procedure for steam sterilizers, including the correct BI process challenge device (BI PCD) and the use of controls in Section 10.7.<sup>8</sup>

For controls:

“Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator to verify the presterilization viability of the spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature.”<sup>8</sup>

ANSI/AAMI ST79 Section 10.5.3.2 states steam sterilizers should be monitored routinely with a BI PCD weekly, preferably daily (each day the sterilizer is used).<sup>8</sup> If a steam sterilizer is designed to be used for multiple types of cycles then:

- each type of cycle should be routinely tested because each cycle creates a different challenge to air removal and steam penetration
  - gravity-displacement at 132°C to 135°C [270°F to 275°F];
  - gravity-displacement at 121°C [250°F];
  - dynamic-air removal at 132°C to 135°C [270°F to 275°F];
  - flash or immediate-use at 132°C to 135°C [270°F to 275°F];
  - flash or immediate-use with single wrapper or other packaging.<sup>8</sup>

A note states that if you are running both a 4 and a 10 minute dynamic-air removal sterilizer at 132°C to 135°C [270°F to 275°F], then only the shortest sterilization time needs to be tested.<sup>8</sup>

In addition for implants:

“BIs within PCDs should be used to monitor every load containing implants (see 10.6.1); implants should be quarantined until the results of the BI testing are available (CDC, 2008).<sup>8</sup>

ANSI/AAMI ST79 Section 10.6.3 discusses:

“Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. (See Annex L for examples of an implant log and an exception form).”<sup>8</sup>

TJC wants the exception form used and a department of surgery policy with multidisciplinary input in place that addresses who can authorize early release of implants.<sup>5</sup> TJC suggests it be a surgeon but that a signature is not required on the exception form.<sup>5</sup> Many hospitals do require the surgeon’s signature to stress the importance of making this decision to release implants before the BI results are available.

The use of BI PCDs for steam sterilizer qualification testing is discussed in ANSI/AAMI ST79 Section 10.8.<sup>8</sup>

In ANSI/AAMI ST79 Section 10.7.6 it states a Bowie-Dick test “should be carried out each day the sterilizer is used before the first processed load.”<sup>8</sup> ‘The Bowie-Dick test also should be carried out during sterilizer qualification (10.8).’<sup>8</sup>

ANSI/AAMI ST79 also addresses recall in Section 10.7.5 entitled Actions to take when biological indicators, chemical indicators, or physical monitors indicate failure in a sterilization process.<sup>8</sup>

“If the cause of the failure is immediately identified (usually operator error) and confined to one load or one item in the load (i.e., an item with a nonresponsive internal CI), the cause of the failure should be corrected and the load should be reprocessed. If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in those loads should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service for further investigation of root causes. See Figure 12 and Table 8 for guidance on how to conduct this investigation.”<sup>8</sup>

Following the recommended practices for usage of BIs and CIs and quarantining implants until the BI results are available will ensure the effectiveness of the sterilization process and improve patient safety.

## Immediate-use steam sterilization (IUSS)

IUSS “is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized in a manner that minimizes its exposure to air and other environmental contaminants.”<sup>2</sup> TJC has cited healthcare facilities for not using containment devices for IUSS.<sup>7</sup>

AORN says in Recommendation IV.a.2. for flash or IUSS to avoid contamination of the items during transportation to the sterile field:

“Items are placed in a closed sterilization container or tray, validated for flash sterilization, in a manner that allows steam to contact all instrument surfaces.”<sup>10</sup>

TJC has asked if items processed by IUSS have been tracked to the patients.<sup>7</sup> ANSI/AAMI ST79 Section 10.3 states “Flash sterilization of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained.”<sup>8</sup>: This traceability is especially important because “the consequences of implant-related infections are particularly severe and result in increased morbidity and mortality.”<sup>8</sup>

## Certification

Surveyors have asked facilities to point out who is certified and some surveyors have congratulated those individuals.<sup>7</sup> TJC has not cited healthcare facilities for not having certified employees but TJC understands the importance of certification and so should your healthcare facility. 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.”<sup>8</sup> 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 (IAHCMM)  
213 Institute Place, Suite 307, Chicago, IL 60610  
312-440-0078  
<http://www.iahcsmm.org>.

Orientation and 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. TJC requires documentation of training and continuing education. Certification is a method to determine initial competency.<sup>3</sup>

## Summary

Following the recommended practices from AAMI, AORN, and CDC and being aware of what TJC is looking for in a survey will help

you prepare for TJC survey and more importantly improve patient care.

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9. Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities*. ANSI/AAMI ST58:2005.
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11. IAHCMM Sample Policy & Procedure for Loaner Instrumentation and IAHCMM Position Paper on the Management of Loaner Instrumentation, June 2011  
Available free at:  
[http://www.iahcmm.org/CurrentIssues/Loaner\\_Instrumentation\\_Position\\_Paper\\_Sample\\_Policy.html](http://www.iahcmm.org/CurrentIssues/Loaner_Instrumentation_Position_Paper_Sample_Policy.html)

**Answers**

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

**Martha Young, BS, MS, CSPDT**

*Martha Young, BS, MS, CSPDT, is president of Martha L. Young, LLC, providing SAVVY sterilization solutions to health-care 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 IAHCSCMM, 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 [marthayoung1@aol.com](mailto:marthayoung1@aol.com).*

**Sterile Process and Distribution CE Information**

CE Applicant Name: \_\_\_\_\_

City: \_\_\_\_\_

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](http://www.sterileprocessing.org).

IAHCSMM has awarded 1.5 contact hours 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.

- |                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> <li>1. Make a photocopy of this form.</li> <li>2. Print your name, address and daytime phone number and position/title.</li> <li>3. Add the last 4 digits of your social security number or your nursing license number.</li> <li>4. Date the application and sign.</li> <li>5. Answer the true/false CE questions. <b>Keep a copy for your records.</b></li> </ol> | <ol style="list-style-type: none"> <li>6. Submit this form and the answer sheet to:<br/>3M Infection Prevention<br/>Attn: HC4160<br/>RR Donnelly Fulfillment Services<br/>585 Hale Avenue North<br/>Oakdale, MN 55128-9935</li> <li>7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.</li> <li>8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly's receipt of the application.</li> </ol> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Application** *Please print clearly or type.*

Name: \_\_\_\_\_

Daytime phone: (        ) \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Position/Title: \_\_\_\_\_

City: \_\_\_\_\_

Social Security or Nursing License Number: \_\_\_\_\_

State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Date application submitted: \_\_\_\_\_

Country: \_\_\_\_\_

Signature: \_\_\_\_\_

Offer expires March 2017



**Infection Prevention Division**  
**3M Health Care**  
 3M Center, Building 275-4E-01  
 St. Paul, MN 55144-1000  
 U.S.A.  
 1 800 228-3957  
[www.3M.com/infectionprevention](http://www.3M.com/infectionprevention)

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