

December 2008

The self-study lesson on this central service topic was developed by 3M Healthcare. The lessons are administered by KSR Publishing, Inc.

Earn CEUs

The series can assist readers in maintaining their CS certification. After careful study of the lesson, complete the examination at the end of this section. Mail the complete examination and scoring fee to Healthcare Purchasing News for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available on the Internet at www.hpnonline.com.

Certification

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

For additional information regarding certification contact CBSPD - 2 Industrial Park Road, Suite 3, Alpha, NJ 08865 (www.sterileprocessing.org). For more information Direct any questions to *Healthcare Purchasing News* (941) 927-9345, ext 202.

Learning Objectives

1. Identify current recommended practices and standards related to Sterile Processing.
2. Compare current SPD processes with best practices according to AORN and AAMI.
3. Identify what to look for and questions to ask regarding compliance with best practices when doing rounds in Sterile Processing.

Sponsored by:



3M Health Care

SELF-STUDY SERIES

Sponsored by **3M Health Care**

The infection preventionist and SPD must partner for safe patient care

by Rose Seavey, RN, BS, MBA, CNOR, CSPDT

Patient Safety is every healthcare provider's responsibility. The Sterile Processing Department (SPD) plays a very significant part in patient safety, especially as it relates to surgical patients. One significant way the SPD can minimize risks to patients is to ensure items are free of microbial contamination, i.e. sterile, at the time of use.

It is critical that Infection Preventionists (IPs) understand and support the roles and responsibilities of the SPD for the sake of patient safety. By understanding the latest standards and recommended practices, the IP will be better able to partner with SPD. These standards and recommended practices cover SPD design considerations and traffic control, training and certification of personnel, device processing (including cleaning and disinfecting, packaging, sterilization monitoring, flash sterilization, sterile storage and transportation) and the need for a well managed loaner instrumentation program.

Recommended practices and standards

The two major resources for standards and recommended practices for SPD are The Association of periOperative Registered Nurses (AORN) and The Association for the Advancement of Medical Instrumentation (AAMI).

AORN's 2008 Edition of *Perioperative Standards and Recommended Practices* includes many Recommended Practices (RPs) pertinent to SPD. For instance, the RPs on: High-Level Disinfection; Cleaning and Processing of Endoscopes; Cleaning and Care of Instruments and Powered Equipment; Selection and Use of Packaging Systems; and Sterilization in the Perioperative Practice Setting all contain valuable guidance.

AAMI's *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities* (ANSI/AAMI ST79: 2006) is a complete guideline for all steam sterilization activities in healthcare facili-

ties. These standards are considered a must have for SPD and all healthcare personnel who work with sterilization. Every SPD, Operating Room (OR) and IP should have access to both of these great resources.

This article reviews some of the guidance provided in these resource documents so you'll be better informed next time you do rounds in the SPD.

Personnel considerations

Surgical instruments and medical device reprocessing and sterilization instructions are more complicated than ever. Following these instructions demands critical thinking skills. Only individuals with proven competencies should be assigned to perform disinfection and sterilization procedures.

Manufacturers' written recommendations for reprocessing surgical instruments and medical devices should be on file and routinely followed.^{1, 3, 4, 5} These written instructions should specify if items need to be disassembled or lubricated, provide directions for cleaning (including whether the device requires ultrasonic cleaning), and specify the type of validated sterilization process.¹

Supervisory personnel qualifications

"All preparation and sterilization activities, including decontamination, inspection, preparation, packaging, sterilization, storage, and distribution, should be supervised by competent, qualified personnel. Personnel assigned to supervisory functions should be prepared for this responsibility by education, training and experience".¹

Those responsible for supervision should:

- a. be certified in Sterile Processing Management;



- b. demonstrate current knowledge and sufficient relevant experience;
- c. participate in continuing education programs on the following topics:
- federal and local regulations,
 - personnel and material management,
 - financial management,
 - leadership and management skills,
 - infection control,
 - safety,
 - principles and methods of sterile processing; and
- d. demonstrate comprehensive understanding of relevant state and federal regulations, particularly Occupational Safety and Health Administration (OSHA's) blood-borne pathogens exposure control plan and engineering and work-practice controls.¹

In addition, they should participate in healthcare facility committees such as infection control, risk management, quality improvement, safety, product evaluation, and standardization.¹

Technician qualifications

SPD technicians should demonstrate knowledge of and documented competence in:

- all aspects of decontamination;
- the operation of all sterilizing systems used by the healthcare facility;
- principles of sterilization and infectious disease transmission; and
- worker safety as it relates to medical device processing and sterilization.

All personnel performing sterile processing activities should be certified in Sterile Processing as a condition of employment. Personnel should successfully complete a SPD certification examination within the first two years of employment and remain certified during their employment.¹

Attire

The healthcare facility should provide scrubs to be worn by all personnel entering the decontamination, preparation, sterilization, and sterile storage areas. These uniforms should be donned at the facility and changed daily or more often as required (i.e. when wet, grossly soiled, or visibly contaminated with blood or body fluids).

All head and facial hair except for eyebrows and eyelashes should be completely covered. Jewelry, including watches, should not be worn in the de-

contamination, preparation, or sterilization area.¹

Staff working in Decontamination should wear Personal Protective Equipment (PPE). PPE includes general-purpose utility gloves and a liquid-resistant covering with long sleeves such as a backless gown, jumpsuit, or surgical gown. The PPE should include a high-filtration-efficiency face mask and eye protection if there is any risk of splash or aerosols. Eye protection for splash and aerosols could include goggles or full-length face shields that protect from all angles.¹ See Figure 1 for a picture of appropriate PPE:



Design considerations

All instrument processing functions should be performed in one department for both safety and economic reasons. If centralization of sterilization processing is not possible, all sterilization processing should be under a centralized control and standardized with consistent policies and procedures.

The workflow should be designed so that items are moved progressively from being contaminated to being safe to handle. A pass-through window, between the decontamination area and the clean area, is recommended for items that

require hand washing.¹ See Figure 2 for a typical pass-through window:



In general, the clean areas should have positive airflow and the soiled and decontamination areas should be under negative pressure. The temperature in clean areas should be between 68°F and 73°F. Because of the need for PPE in the decontamination area it should be kept between 60°F and 65°F. Humidity should be controlled between 30% and 60% in all work areas.¹ In addition to temperature and humidity recommendations, AAMI ST79 provides recommended ventilation requirements (see Table 1, below).

Cleaning and disinfection

If a medical device is not effectively cleaned, it cannot be sterilized! Therefore, decontamination is one of the most important steps in instrument reprocessing. Cleaning of surgical instruments should occur as soon as possible after use. All instruments opened in the OR should be decontaminated even if they have not been "used."³ Instruments should not be decontaminated in scrub or hand sinks because the sink and faucet can become contaminated.¹

Mechanical cleaning equipment is recommended because it can deliver higher temperatures than manual cleaning methods. SPD should follow all surgical instru-

Table 1 – Ventilation requirements for functional areas

Functional area	Airflow	Minimum number of air exchanges per hour (ANSI/AAMI ST79)	Minimum number of air exchanges per hour (AIA, 2001)	All air exhausted directly to the outdoors?
Soiled/ decontamination	Negative (in)	10	6	Yes
Sterilizer equipment access	Negative (in)	10	10	Yes
Sterilizer loading/ unloading	Positive (out)	10	—	Yes
Restrooms/ housekeeping	Negative (in)	10	10	Yes
Preparation and packaging	Positive (out)	10, down-draft type	4	No
Textile pack room	Positive (out)	10, down-draft type	—	No
Clean/sterile storage	Positive (out)	4, down-draft type	4	No

Reprinted from ANSI/AAMI ST79:2006 with permission of the Association for the Advancement of Medical Instrumentation, Inc. (C) 2006 AAMI www.aami.org. All rights reserved.

ment and medical device manufacturers' written validated instructions regarding cleaning methods, cleaning agents, and disassembly procedures.³ Lumens should be brushed under water to avoid aerosolization of microorganisms.¹

Packaging

Current recommendations state a Chemical Indicator (CI) should be placed in the geometric center of wrapped packages. Two CIs should be used inside rigid containers, one in each of two opposite corners of the inside basket. Each level within the tray or containment device should have internal CIs. Each sterile package should have an external CI placed on the outside of the package.⁴

AAMI and AORN recommend a maximum weight limit for instrument sets of 25 pounds, which includes the wrap or container. Heavier containers cause sterilization, drying and ergonomic issues.^{1,4} See Figure 3, an instrument set being weighed:



Figure 3

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. Small perforated, mesh-bottom baskets, absorbent, single-layer flat wrap, all-paper bags, or appropriate foam products that have been validated for the application may be used to contain small items within a container.¹

Instrument inventory sheets should not be placed inside wrapped sets or rigid containers. Currently, there is no available research regarding the safety of toners and/or various papers subjected to any sterilization method. Chemicals used in the manufacture of paper and toner ink pose a theoretical risk of reaction in some sensitized individuals.² Another issue is the possibility of fibers shedding from the various papers used for inventory sheets. One suggestion is to place the inventory sheets on the outside of the package by taping to wrapped packages or wrapping them around the handle of

a rigid container. See Figure 4- inventory sheets on outside of pans:



Figure 4

Sterilization monitors

The Sterile Processing Department relies on three types of monitors for sterilization: physical monitors, chemical indicators, and biological indicators. Quality assurance measures require the use of all three types of sterilization monitors.

Physical monitors consist of sterilizer graphs, gauges, and printouts. These devices provide a real-time assessment of the sterilization process and serve as permanent records. Sterilizers that do not have recording devices should not be used.¹

Chemical indicators (CIs) are intended to react to one or more of the parameters required for the specific sterilization process. There are 6 classes of CIs:

- Class 1 - Process indicators used externally to distinguish between processed and unprocessed items.² (e.g. indicator tape used on the outside of packages)
- Class 2 - Indicators for use in specific tests.² (e.g. Bowie-Dick type tests designed for dynamic-air-removal sterilizers)
- Class 3 - Indicators designed to react to a single critical variable of the sterilization process.²
- Class 4 - Multi-parameter indicators designed to react to two or more of the critical variables of a sterilization process.²
- Class 5 - Designed to react to all critical variables of a sterilization process. The performance of these integrating indicators is correlated to the performance of a biological indicator.²
- Class 6 - Designed as a cycle specific emulating indicator. ² Currently, neither AORN nor AAMI recommended practices address the use of Class 6 CIs.

The use of Class 5 integrating indicators is strongly recommended because they monitor all the variables for the cycle, not just one or two.⁶

Biological Indicators (BIs), which contain a large number of highly resistant bacterial spores,

provide a direct measure of the lethality of a sterilization process and are considered the definitive monitor for sterilizer efficacy testing and the release of implants.^{1,6}

Numerous facilities are opting to monitor sterilizer efficacy by using a BI with every load. If a sterilization recall is necessary, all items going back to the last negative BI must be recalled. Using a BI with every load is a major advantage. In regards to patient safety, monitoring every load with a BI ensures every item sterilized is monitored with a BI and that provides the same standard of care for every patient.

Documentation of each sterilization cycle should include:

- sterilizer identification,
- type of sterilizer and cycle used,
- lot control number,
- load contents,
- critical parameters for specific sterilization method,
- operator's name, and
- results of the sterilization process monitors (i.e., Physical, CI, and BI).^{1,5}

Sterilization records should be maintained for a time specified by the facility's policies and in compliance with local, state, and federal regulations.^{1,5}

Flash sterilization

Flash sterilization should be kept to a minimum and used only when there is insufficient time to process by the preferred wrapped method. When items are flash sterilized, there could be an increased risk of infection to patients because of pressure on staff to eliminate one or more steps in the cleaning process. "Flash sterilization should not be used as a substitute for sufficient instrument inventory".⁵

Implants should not be flashed

Implants are foreign bodies, and they enhance the risk of surgical site infection. Careful planning, proper packaging, and inventory management in partnership with suppliers can help

Table 2: Frequency of Use of Biological Indicators^{1,5}

Sterilization Method	Biological Indicator	Frequency of Use ⁵
Steam	Geobacillus stearothermophilus	Weekly, preferably daily and each load containing implantable devices.
Ethylene oxide	Bacillus atropheus	Every load
Low temperature hydrogen peroxide gas plasma	Geobacillus stearothermophilus	Daily, preferably with each load and each load containing implantable devices
Ozone	Geobacillus stearothermophilus	Daily, preferably with each load and each load containing implantable devices
Liquid peracetic acid	Geobacillus stearothermophilus	Daily
Dry-heat	Bacillus atropheus	Weekly, preferably daily and each load containing implantable devices

reduce the need to flash sterilize implantable medical devices.⁵

In an emergency situation, in which flash sterilization is unavoidable, a rapid-action biological monitoring device should be used in conjunction with a Class 5 CI. The implant should be quarantined on the back table until the rapid-action BI provides a negative result.⁵

Documentation of flash loads

Documentation of the cycle information and monitoring results should be maintained in a log (electronic or manual) so flashed items are traceable to the patient. Flash sterilization documentation should include:

- the item(s) processed,
- the patient receiving the device(s),
- the cycle parameters used (e.g., temperature, duration of cycle),
- the date and time the cycle is run,
- the operator identification, and
- the reason for flash sterilization.⁵

Sterile storage

Shelf life of sterile items is event-related. Sterility is dependent on handling, packaging, storage, and transportation. Sterile packages should be stored in a way that reduces the potential for contamination. The bottom shelf of storage units should be solid.

The recommended conditions for all sterile storage areas is a temperature of 68°F to 75°F (20°C to 24° C) and a relative humidity that does not exceed 70%. This area should be accessible only to staff who know how to handle sterile items properly.¹

Sterile items should be stored:

- 18" below the ceiling (or level of sprinkler head),
- 8-10" above the floor, and
- 2" from outside walls.^{1,5}

Heavy instrument packages should not be stacked. If a package is compressed it can force air and microorganisms into the package, cause seals to burst, or puncture the package.

Outside shipping containers and corrugated cardboard boxes should not be allowed in the sterile storage area because they may harbor microorganisms.^{1,5}

Transportation

Sterile items should be transported in covered or enclosed carts with solid-bottom shelves. If transported by hand, sterile packages that contain instrumentation should be kept parallel to the floor.¹

Contaminated items should be contained in leak-proof, puncture-resistant closable containers, labeled as biohazard, and transported to the decontamination area as soon as possible.³ Items must be kept moist in the transport container by adding a moist towel (water, not saline) or using a foam, spray or gel products intended for this use.

Off-site transportation

Transport vehicles used for off-site transportation should be completely enclosed and leak free. Clean and sterile items must be completely separated. All transport vehicles should be constructed of material that allows for proper decontamination processes.¹

Traffic control

Only authorized staff in specified attire should be allowed in areas where preparation and packaging, sterilization processing, sterile storage, and decontamination are carried out. Good traffic control practices minimize the potential for contamination in the processing area and protect people from the microorganisms present on contaminated items in the decontamination area. The responsibility for enforcing traffic-control policies and procedures and compliance methods should be specified in writing.¹

Loaner instrumentation program

The management of loaner instrumentation and implants is recognized as a major concern by many healthcare professionals. Borrowed instruments should be reprocessed according to the manufacturer's written recommendations by the receiving institution before use. The SPD should be given adequate time to inventory, inspect, clean, package and sterilize loaner instrumentation. Many facilities are requesting loaners to be in the facility at least 24 hours before the scheduled case for which they are to be used. In addition, if there are any implants, they must be quarantined until the BI reads negative. As with all sterilized items, loaner items should be traceable to the patient.

If loaner instruments come pre-sterilized by another healthcare organization, the borrowing institution will not have copies of the sterilization records and they cannot verify the quality of processing or conditions during transportation. Therefore, the items should be completely reprocessed and re-sterilized using the in-

strument manufacturer's written instructions before use.^{1,3}

Following the surgical procedure, the items should be disassembled, decontaminated, and inventoried before being returned to the vendor.

Managing loaner instrumentation requires planning. A sound policy with controls for enforcement and consequences for non-compliance should be developed in collaboration with the SPD, the Operating Room, Infection Control, Risk Management, surgeons, vendors, Quality and Patient Safety.

Summary

A major responsibility of any healthcare provider is to minimize patient risks. SPD plays a critical role in patient safety. The IP should partner with SPD on patient safety and be familiar with current best practices. The SPD manager should be a part of the Infection Control Committee. This article touched on some of the issues to look for when conducting rounds in SPD to include but not be limited to:

- personnel
- design considerations
- cleaning and disinfecting
- packaging
- sterilization monitoring
- flash sterilization
- sterile storage
- traffic control
- transportation
- compliance with the loaner instrumentation program.

In addition, every IP should have access to the most the most recent AORN Recommended Practices and AAMI sterilization standards. **HPN**

Ordering Information:

AORN

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

- Internet: www.aorn.org/bookstore/ordering.htm
- 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
- Payment can be made by: VISA, MasterCard, American Express, or Discover, either online or by mail/fax/phone.

The infection preventionist and SPD must partner for safe patient care

Circle the one correct answer

- The two major resources for standards and recommended practices for SPD are AAMI and the FDA.
A. True
B. False
- It is recommended that sterile processing supervisors and technicians be certified as a condition of employment.
A. True
B. False
- All head and facial hair except for eyebrows and eyelashes should be completely covered when working in the preparation and sterilization areas.
A. True
B. False
- Infection Preventionists should be familiar with current best practices in Sterile Processing.
A. True
B. False
- The maximum weight for instrument sets is 25 pounds including the container or wrap.
A. True
B. False
- AORN and AAMI currently do not address the use of Class 6 Emulating Indicators.
A. True
B. False
- Biological Indicators (BI) provide a direct measure of the lethality of a sterilization cycle and are considered the definitive monitor for sterilizer efficacy testing and releasing of implants.
A. True
B. False
- Not having enough inventory is reason enough to use flash sterilization.
A. True
B. False
- Outside shipping containers and corrugated cardboard boxes should not be allowed in the sterile storage area because they may harbor microorganisms.
A. True
B. False
- Implants should be quarantined until the results of the biological indicator are available.
A. True
B. False

Presented by

HEALTHCARE
PURCHASING NEWS

Sponsored by

3M Health Care

Request for Scoring

- I have enclosed the scoring fee of \$10. (Payable to **KSR Publishing, Inc.** We regret that no refunds can be given. Multiple submissions may be paid with a single check.)

Detach exam and return to:

Continuing Education Division
KSR Publishing, Inc.
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
PH: 941-927-9345 Fax: 941-927-9588

Please print or type. Return this page only.

Name	
Title	
Hospital Name	
Mailing Address	
Apt/Suite	
City, State, Zip	
Daytime Phone	
E-mail	

SELF-STUDY SERIES

Sponsored by **3M Health Care**

AAMI

ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*

AAMI TIR34:2007, *Water for the reprocessing of medical devices*

Order code: TIR34

Also available in PDF format and as part of AAMI's electronic CD and subscription products.

AAMI documents can be purchased through AAMI by credit card using the following four options:

Internet: <http://marketplace.aami.org/eseries/ScriptContent/Index.cfm>

• Call: 1-800-332-2264, ext 217 or 1-703-525-4890, ext 217

• Fax: 703-525-1424

• Mail: AAMI, Customer Service Center, 1100 N. Glebe Road, Suite 220, Arlington, VA 22201-5762

References

1. The Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.* ANSI/AAMI ST79:2008.

2. The Association for the Advancement of Medical Instrumentation. *Sterilization of healthcare products - Chemical indicators - Part 1: General requirements,* ANSI/AAMI/ISO 11140-1:2005.

3. Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, Association of periOperative Registered Nurses. *AORN Standards and Recommended Practices 2008.*

4. Recommended Practices for Selection and Use of Packaging Systems. Association of periOperative Registered Nurses. *AORN Standards and Recommended Practices 2008.*

5. Recommended Practices for Sterilization in the Perioperative Practice Setting, Association of periOperative Registered Nurses. *AORN Standards and Recommended Practices 2008.*

6. Spry, C. *Using Steam Sterilization Monitors.* Managing Infection Control, June, 2008 Volume Eight Issue 6.

Rose Seavey, RN, BS, MBA, CNOR, CSPDT is the President/CEO of Seavey Healthcare Consulting, Inc, and formerly the Director of the Sterile Processing Department at The Children's Hospital of Denver. She was honored with AORN's award for



Outstanding Achievement in Clinical Nurse Education in 2001. She served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of ASHCSP National Educator of the Year award. Ms Seavey is a member of several AAMI working group committees that are developing recommended practices and is currently a co-chair for the ANSI/AAMI ST8, Hospital Steam Sterilizers, and ST55, Table-Top steam sterilizer's performance standards. In addition she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.