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HEALTHCARE PURCHASING NEWS

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## *Learning Objectives*

1. ***Describe some basic AAMI performance areas of knowledge required for optimal sterile processing functions***
2. ***Discuss key elements required for optimal sterile storage and materials management***
3. ***Explain the importance of an OR/SPD taskforce, how to establish one, and how to develop some practical tools for successful communication***

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# The magic door –

## *Sterile processing behind the scenes*

*by Arthur Henderson, RN, BA, CNOR and Michele McKinley, LVN CRCST*

The Operating Room team arrives in surgery and the day begins. Shift report and room assignments are given, and then the room is wiped down before the first case is opened in each room. The sterile supplies and instruments are set around the room. All expiration dates, indicators and package integrity are checked. The room is secured and supplies and instruments are opened. The operating room team has done everything possible to ensure the patient receives the highest standard of care. Or have they?

The surgeon and OR staff use the instruments, which are then transported to the sterile processing department (SPD). Do they know what happens to these soiled instruments once they have left the control of their area? The path from "point of use" to "set up for the next case" is a cycle filled with many potential risks they may not be aware of.

Typically the SPD is located on a lower level of the facility behind closed doors. It's an area that few surgical personnel tend to venture to unless they have an urgent need to find something for an imminent surgical case. Since the surgical staff (and their patients) are highly dependent on the reliability and quality of sterile "products" they receive from behind these magic doors, it is in their best interest to have a good understanding of what goes on there and why. More importantly, perioperative personnel should understand the expertise required to perform to 'best practices' standards, and what surgical staff can do to facilitate the sterile processing function.

## So much to know

Does the surgical staff know if their SPD has quality controls in place to ensure a consistent, sterile product? Do they know what is being monitored, and what the results of the monitoring are? Is there good communication between the OR and SPD to address any deficiencies that could impact patient care? Are these deficiencies reported immediately, or does the notification wait until the next staff report? What should SPD customers be looking for and expect from their sterile processing experts? These questions are merely a sampling of what could be asked.

Fortunately, there are several professional bodies that offer guidance and standards of practice that can inform everyone on the perioperative team about best practices.


For example, the Association for the Advancement of Medical Instrumentation (AAMI) provides *Regulatory Guidelines for all Sterile Processing Functions*. All healthcare facilities are expected to develop processes that adhere to these guidelines. SPD assessments and audits should be based on these guidelines to ensure compliance, be in a continued state of readiness, and most importantly, to assure that products for patient use are held to the highest quality standard.

Some key SPD performance areas everyone should be aware of, as cited in the AAMI Guidelines, include:

### 1. Quality

Quality checkpoints and audits should be performed at key points of the process flow e.g., decontamination, assembly, packaging, sterilization, and sterile storage. Once audits are performed this information should be used to develop action items lists for process improvement. Trending of the data

should provide a baseline by which to measure and monitor your performance. The results of these audits and measurements should be reported to appropriate departments (AAMI ST79:2006 11.2).

### 2. Doing the right thing

Each employee should know their role and how they impact the patient as a member of the perioperative team. There should never be a doubt that the professionalism of the staff would ensure that all breaches in sterility would be handled appropriately; e.g., if a one-of -a-kind sterile item is needed for a procedure and is dropped on the floor, would the staff immediately communicate that the item was contaminated or would they go ahead and put it on the case cart or deliver it to the customer since no-one witnessed the item falling (Central Service Technical Manual, Seventh Edition; Chapter 1, Page 16; Ethics)?

### 3. Education

All staff should be assessed for competency in all tasks being performed in the sterile processing areas on a scheduled basis (AAMI ST79:2006 4.3.1).

### 4. Personnel

All sterile processing staff should adhere to appropriate attire policy and procedures including hygiene, artificial nails, jewelry, etc. All people entering the department must wear appropriate attire (AAMI ST79:2006 4.5.1).

### 5. Environment

All areas of Sterile Processing should be checked for cleanliness of the areas, equipment, workstations, etc. Sterile storage areas should be checked for any possible breach to sterility including dust, moisture, proximity to floors and walls, and controlled traffic patterns. Workstations should be free of food, drinks and personal items. Temperature and humidity must be monitored in each area to comply with AAMI Recommendations (AAMI ST79 2006 3.3). Temperature in general work areas should be 68 – 73° F, decontamination 60 – 65° F and sterile storage should not exceed 75° F (AAMI ST79 2006 3.3.6.5). Humidity for all areas should be between 30% and 60%, with sterile storage not to exceed 70% (AAMI ST79 3.3.6.6). Air exchanges should be monitored and the traffic flow should go from dirty to clean (AAMI ST79 3.3.6.4).

## The other "magical" process: materials management

The provision and sterile storage of hospital supplies also requires a significant level of knowledge. In most facilities the materials department is separate from the SPD. Surprisingly, the sterile storage area is often treated as a simple warehouse, which can create issues that compromise instrument sterility. Employees working in the materials area are not always sterile processing technicians, nor are they necessarily trained in the appropriate handling of sterile product. There is valuable guidance, however, in the *AAMI Guidelines for all Sterile Processing Functions*.

Some important topics surgical and sterile processing teams should review include:

1. Quality audits; should be performed for review of sterile packaging for breaches in sterility (AAMI ST79: 2006 11.2).
2. Sterile storage; In some instances, due to location or lack of knowledge, sterile storage is improperly treated as a mini-warehouse (AAMI ST79:2006 8.9.2). Common points of non-compliance are;
   a. Outside, cardboard boxes being stored next to sterile packaged items (AAMI ST79:2006 8.9.2).
   b. Staff not wearing appropriate attire e.g., uniforms, head coverings, etc. (AAMI ST79:2006 4.5.1).
   c. Drinks and food at workstations; have you ever noticed Cheetos® stains on your packages (AAMI ST79:2006 4.6)?
   d. Improper hand-washing (no sinks available) prior to handling sterile packages (AAMI ST79:2006 3.3.6.8).
   e. Lack of traffic control (external department have access) (AAMI ST79:2006 3.2.4).
   f. Items dropped on the floor and placed on case carts or pushed with foot to move to the back of the case cart (AAMI ST79:2006 8.9.2).
3. Temperature, humidity and air flow are typically not monitored in sterile storage areas, but they should be. Although environmental monitoring guidance is not included in the recommended guidelines for sterile storage, materials management should be aware of the need to monitor the sterile storage area because, as AAMI states, "bacteria thrive at high temperatures; relative humidity higher than those recommended can promote microbial growth and thus increase bioburden" (AAMI ST79:2006 3.3.6.5, 3.3.6.6, 3.3.6.4).

Another professional organization that offers guidance, perioperative standards and recommended practices is the Association of periOperative Registered Nurses (AORN). AAMI and AORN complement one another in their guidance for optimal sterile storage. Both organizations discuss proper package storage and handling, limiting exposure to moisture, dust, and excessive light, and avoiding temperature and humidity extremes.

## Knowledge is power, and so is great communication

It is essential that the OR and SPD recognize that they are a team and understand that their mutual success, and the quality of their patients' outcomes, depends on the development of a collaborative working relationship. An OR/SPD taskforce provides a valuable forum these teams can use to jointly identify opportunities for improvement.

Here are some key recommendations that will encourage taskforce success:

a. Team participants should be from all levels of staff, not just management. Sometimes the front-line staff have some valuable ideas, and this forum gives them a chance to express them.
b. Identify a common objective goal (e.g., all instruments will be sterile and on time for the scheduled procedures).
c. Leave emotion at the door no matter how frustrated you are.
d. Do not blame or point fingers.
e. Rather than criticizing or belittling another person's idea, discuss the logical reasons why you think it will not work and come to a general consensus to move ahead or table the idea.
f. Develop action items lists with deadlines and assignments.
g. Share meeting minutes with the rest of the OR and SPD teams so everyone is working toward the same goals.

## Tools for success

The nurturing of the OR/SPD relationship is not a once-a-month task; it requires a daily commitment to improvement. It is not always feasible to discuss areas of concern in

*See **SELF-STUDY** on page 44*

Self-Test Answers: 1. A, 2. B, 3. A, 4. B, 5. A, 6. E, 7 A, 8. C, 9. E, 10. E.

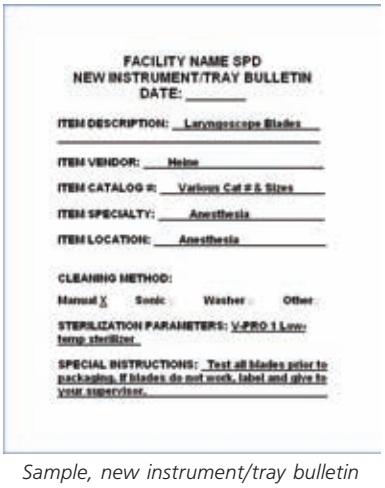
***SELF-STUDY*** *from page 43*

real time, but it is important to not let these potential problems go unreported. They can fester and create more anger and frustration. To keep track of issues, practical communication tools can provide a reporting mechanism and a convenient way to disseminate information in an objective manner, which allows both departments to improve processes. Some examples of communication tools are:

1. Using count sheets and labels to identify non-conformities. The OR staff can document these on the count sheet and turn it in to the SPD for tracking and trending. This can be a useful way to identify educational needs on an individual or departmental basis.
2. Developing communication bulletins that can be shared with both departments; e.g.
   a. Quality Bulletin – can be used to identify a non-conformity that you would want to share with the entire team.
   b. Information Bulletin – can be used to notify staff of tray revisions, location changes, additions of new items, etc.
   c. New Tray/Instrument Forms – can be used to notify staff of a new tray/instrument addition and provide pertinent information to both departments.

## Visiting isn't just for fun

When each department moves beyond its own departmental "comfort zone," its staff gains an understanding of how their roles impact the other department. The OR staff should be active in sharing their knowledge through in-services, reviewing their sets with SPD team members so they can easily identify the instruments, understand what they are used for, and learn why it is important to have them set up and prepared in a certain manner.



FACILITY NAME SPD
NEW INSTRUMENT/TRAY BULLETIN
DATE: _____

ITEM DESCRIPTION: Laryngoscope Blades

ITEM VENDOR: Heine

ITEM CATALOG #: Various Cat # & Sizes

ITEM SPECIALTY: Anesthesia

ITEM LOCATION: Anesthesia

CLEANING METHOD:

Manual X Sonic Washer Other

STERILIZATION PARAMETERS: V-PRO 1 Low-temp sterilizer

SPECIAL INSTRUCTIONS: Test all blades prior to packaging. If blades do not work, label and give to your supervisor.

*Sample, new instrument/tray bulletin*

To facilitate SPD member visits to the OR, a formal rotation can be established that allows each SPD technician to spend a day in the surgical suite observing procedures. This allows the technicians to see how the instruments are used and what happens if there are deficiencies within the sets. The SPD supervisor can also assign a different person in the department each day to answer the phone calls from the OR and to make deliveries to the surgical suite. This also fosters a team environment as the OR staff gets to know everyone in the SPD. The more the SPD staff ventures into the OR, the better they will understand why their attention to detail is so critical.

## There's no magic to it

There is no magic needed to assure high quality sterile products, as long as all members of a hospital's perioperative team (OR staff, SPD personnel, materials management team) understand the risks that could potentially compromise the end product. Sharing knowledge and expertise will enable facilities to establish appropriate monitoring programs and ensure the best possible outcomes for their patients. Maintaining appropriate SPD quality measures and audits also helps OR staff to feel confident in the quality of the sterile processing functions that are not under their control, and in the sterile products they receive for use. HPN

FACILITY NAME
INFORMATION BULLETIN
HARMONIC BLADE WRENCH
DATE

PLEASE NOTE

The Harmonic Blade Wrench is not a disposable item

They are having to be replaced on a routine basis which is a cost to the OR/SPD Budget

Please ensure it is not thrown away

Thank you,
SPD Management

*Sample information bulletin*

***Arthur Henderson, RN, BA, CNOR*** *is a clinical education specialist for STERIS Corporation. He is responsible for customer education, clinical support, troubleshooting, and issues concerning sterilization and infection control. Henderson has extensive experience in clinical education. He recently served as the clinical educator of perioperative services at a 460-bed acute care hospital in Southern California, responsible for developing an OR orientation program, developing and implementing an OR internship program for non-OR experienced nurses, coordinating performance improvement programs and overseeing staff development. He has over fourteen years of experience as a registered nurse and has worked in a variety of specialties including, GI, open heart and neurosurgery, and cardiothoracic intensive care. Henderson has an Associate Degree in Nursing from Kettering College of Medical Arts, Kettering, OH; a Bachelor of Arts in French/English from Atlantic Union College, South Lancaster, MA; a Certificate in Health Record Administration from Northeastern University, Boston, MA; and Alliance Français, Degree Moyen, Seminaire Adventiste du Saleve, Cologne, France. He is a Certified Nurse-Operating Room (CNOR) since 1994 and is a member of the Association of peri-Operative Registered Nurses (AORN), the Society for Gastroenterology Nurses and Associates (SGNA), and the Association for Professionals in Infection Control and Epidemiology (APIC). He is currently an American Heart Association CPR and ACLS Instructor.*

***Michele McKinley, LVN CRCST*** *is a clinical education specialist for STERIS Corporation, and is responsible for customer education, clinical support, troubleshooting, and issues concerning sterilization and infection control. McKinley has been in healthcare for 30 years, and was a site manager, interim manager and a consultant with STERIS Corporation's SterilTek™ sterile processing process improvement team for eight years. She is a licensed vocational nurse and has also been trained as an operating room technician. She has worked as a materials coordinator for the OR and was responsible for OR purchasing, inventory control, capital budget, charge master, maintenance and clean-up of OR supply inventory lists, instrument tray lists and preference cards. McKinley has led effective team building and process improvement efforts in total CS reorganization and improvement and has supervised specific areas of Joint Commission and state mandated inspections, flash sterilization reduction, loaner tray programs and tray reorganization.*

References:

1. *Recommended practices for Environmental Cleaning in the Perioperative Setting.* Standards, Recommended Practices, and Guidelines. Denver, CO; AORN, Inc; 2008: 375-376.

2. *Recommended practices for Sterilization.* Standards, Recommended Practices, and Guidelines. Denver, CO; AORN, INC; 2008: 587-588.

3. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* ANSI/AAMI ST79: 2006, Arlington, VA; Association for the Advancement of Medical Instrumentation, 2006.

4. Central Service Technical Manual. Seventh Edition, IAHCSMM 2007. International Association of Healthcare Central Service Material Management, 2007: 16.

# The magic door – Sterile processing behind the scenes

**Circle the one correct answer:**

1. **Perioperative personnel should understand the expertise required to perform to 'best practices' standards and what surgical staff can do to facilitate the sterile processing function because it affects surgical processes and their patients.**
   A. True B. False

2. **The SPD is visited by other departments frequently.**
   A. True B. False

3. **AAMI provides regulatory guidelines for all sterile processing functions.**
   A. True B. False

4. **All healthcare facilities are expected to develop processes that adhere to _____.**
   a. Hospital law
   b. AAMI guidelines
   c. AORN edicts
   d. Other hospitals' practices

5. **Quality audits are useful tools for continuing quality _____.**
   a. improvement
   b. graphing
   c. education
   d. sterilization

6. **What elements are used to routinely monitor the performance of the sterile processing department?**
   a. Quality
   b. Doing the right thing
   c. Education
   d. Environment
   e. All of the above

7. **It is an AAMI standard to show competency for all tasks performed in the SPD area.**
   A. True B. False

8. **The temperature in a decontamination area should be between _____.**
   a. 30 to 40 degrees
   b. 70 to 75 degrees
   c. 60 to 65 degrees

9. **Common points of non-compliance in sterile storage are:**
   a. Staff not wearing appropriate attire, e.g., uniforms, head coverings, etc.
   b. Drinks and food at workstations.
   c. Improper hand-washing (no sinks available) prior to handling sterile packages.
   d. Items dropped on the floor and placed on case carts or pushed with foot to move to the back of the case cart.
   e. All of the above.

10. **Environmental monitoring of the SPD, according to AAMI, should include:**
    a. Traffic flow should go from clean to dirty sides.
    b. All areas should be checked for cleanliness of the areas, equipment, workstations, etc.
    c. Sterile storage areas should be checked for any possible breach to sterility.
    d. Temperature and humidity must be monitored in each area to comply with AAMI Recommendations.
    e. b through d.

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