Infection Preventionists and SPD

What every infection preventionist should know about the sterile processing department

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Objectives

After completion of this self-study activity, the learner will be able to:
1. Explain the importance of the infection preventionist (IP) doing routine rounds in the sterile processing department (SPD).
2. Discuss current standards and recommended practices related to personnel and design considerations, cleaning and disinfecting, packaging, sterilization monitoring, flash sterilization, sterile storage, transportation, and traffic control.
3. Discuss the need for a loaner instrumentation program.
4. Develop a check list for what to look for when doing rounds in sterile processing.

Test Questions

True or False. Circle the correct answer.

1. Sterile processing professionals should follow all manufacturers’ written recommendations for reprocessing surgical instruments and medical devices.
   A. True   B. False

2. It is recommended that only sterile processing supervisors be certified as a condition of employment.
   A. True   B. False

3. All sterilization processing should be under a centralized control with consistent policies and procedures.
   A. True   B. False

4. The most important job in SPD is decontamination.
   A. True   B. False

5. The maximum weight limit for instrument sets is 35 pounds.
   A. True   B. False

6. Currently, neither AORN nor AAMI recommended practices address the use of Class 6 Emulating Indicators.
   A. True   B. False

7. Biological Indicators (BI) directly measure the lethality of the sterilization process because they contain spores and are considered the definitive monitor for routine sterilizer efficacy testing, releasing implants, sterilizer qualification testing and product testing.
   A. True   B. False

8. Flash sterilization should not be used as a substitute for sufficient instrument inventory.
   A. True   B. False

9. Contaminated items from the OR should be kept moist and transferred to SPD in containment devices as soon as possible.
   A. True   B. False

10. Implants can be released for use before the results of the biological indicator is available.
    A. True   B. False

Introduction

As healthcare providers, the most important thing we do is provide safe care to our patients. Therefore, a major responsibility of any healthcare provider is to minimize patient risks. This is particularly important in regard to surgical site infections (SSI). One critical way to minimize risks to patients is to present items that are free of contamination, or sterile, at the time of use.

The sterile processing department (SPD) plays a major role in patient safety and its importance cannot be overestimated. This role takes knowledgeable, responsible people and a workplace that facilitates effective and efficient processing to properly perform these tasks. Thus, it is essential that infection preventionists (IP) understand and support the roles and responsibilities of SPD for the sake of patient safety.
This article will cover current standards and recommended practices related to SPD, including topics such as:

- Personnel;
- Design considerations;
- Water quality;
- Cleaning and disinfecting;
- Packaging;
- Sterilization monitoring;
- Flash sterilization;
- Sterile storage;
- Transportation;
- Traffic control; and a
- Loaner instrumentation program.

The IP can use this information to assess the SPD when doing rounds within their facility for compliance with best practice to ensure that items processed in that department are safe for patient use.

### Standards and Recommended Practices

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

AAMI’s newest steam sterilization publication, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2008) is a complete guideline for all steam sterilization activities in healthcare facilities. AAMI has combined five recommended practices into this new standard. No matter what the size of the facility or the size of the sterilizer, this is a “must-have” resource for all healthcare personnel who work with steam sterilization. This is the publication that every SPD and operating room (OR) should have in their reference library.

The five recommended practices incorporated into the new standard are:

- ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*;
- ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use*;
- ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*;
- ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*.

AORN’s newest edition of Perioperative Standards and Recommended Practices (RP) is another “must-have” tool for SPD and the OR. This book contains many recommended practices related to SPD such as 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.

Every ICP should have access to both of these great resources. The ordering instructions for both of these resources follow this inservice.

### Personnel Considerations

Today’s SPD demands critical thinking skills. Surgical instruments and reprocessing/sterilization instructions are more complicated than ever. Responsibility for performing sterilization processes should be assigned to competent individuals who have knowledge of all aspects of disinfection and sterilization procedures and safety precautions.

Sterile processing professionals should follow all manufacturers’ written recommendations for reprocessing surgical instruments and medical devices. The manufacturer’s written instructions should describe which items need to be taken apart and put together, if they require lubrication, how they are cleaned, whether they need to go through the ultrasonic, and what type of sterilization process is recommended, etc. The manufacturer’s recommendations should be on file and available to all staff.

AAMI offers detailed guidance on personnel considerations regarding qualifications, training and education.

### QUALIFICATIONS (SECTION 4.2)

#### Supervisory personnel (Section 4.2.1)

“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.” At the very least the supervisor should:

- a) be certified in sterile processing management;
- b) demonstrate current knowledge and sufficient relevant experience in the healthcare setting;
- c) participate in continuing education programs and courses on the following topics:
  - federal and local regulations;
  - personnel and material management;
  - financial management;
  - leadership and management skills;
  - infection control;
  - safety;
- d) demonstrate comprehensive understanding of relevant state and federal regulations, particularly Occupational Safety and Health Administration (OSHA) bloodborne pathogens exposure control plan and engineering and work-practice controls.
It is imperative that SPD supervisors maintain competency by participating in continuing educational offerings. In addition, they should actively participate in healthcare committees such as infection control, risk management, quality improvement, safety, product evaluation, and standardization.1

Sterile processing personnel (Section 4.2.2)

Sterile processing responsibilities should only be assigned to qualified individuals who have demonstrated competencies in all areas.

Qualifications include demonstrated knowledge of and documented competence in:

a) all aspects of decontamination: sorting, disassembly/reassembly, manual and mechanical cleaning methods, microbicidal processes, equipment operation, standard/transmission-based precautions, and engineering and work-practice controls;

b) the operation of all sterilizing systems used by the healthcare facility;

c) principles of sterilization and infectious disease transmission; infection control, and all aspects of sterilization; and

d) worker safety as it relates to medical device processing and sterilization.

“It is recommended 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.” See Figure 1 for examples of certifications.

TRAINING AND CONTINUING EDUCATION (SECTION 4.3)

Sterile Processing personnel (Section 4.3.1)

Sterile processing staff should receive initial orientation as well as on-the-job training to establish the worker’s competency-based knowledge and skills. The orientation must cover the department policies and procedures about infection control, safety, attire, personal hygiene, and compliance with state and federal regulations. They should also receive continuing education at regular intervals to review and update their knowledge and skills and to maintain their competency and certification. Employees should also receive training for all new instrumentation, devices and equipment.1

ATTIRE (SECTION 4.5)

General considerations (Section 4.5.1)

Uniforms that are provided by the healthcare facilities should be worn by all personnel entering the decontamination, preparation, sterilization, and sterile storage areas. These uniforms, usually known as scrubs, 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). Scrubs that are visibly contaminated must be laundered in the facility’s laundry.

“Shoes worn in the department should be clean, should have non-skid soles, and should be sturdy enough to prevent injury if an item drops on the foot. All head and facial hair except for eyebrows and eyelashes should be completely covered with a surgical-type hair covering. Jewelry and wrist-watches should not be worn in the decontamination, preparation, or sterilization area.” See Figure 2.

Decontamination area (Section 4.5.2)

Personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with long sleeves. This could be a backless gown, jumpsuit, or surgical gown. If there is any risk of splash or aerosols, personnel protective equipment (PPE) should include a high-filtration-efficiency face mask (this statement was updated to recommend fluid-resistant masks which is more appropriate in the AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness) and eye protection. PPE used to protect the eyes from splash and aerosols could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles. See Figure 3 for proper PPE.

Following manufacturer’s instructions, reusable gloves, glove liners, aprons, and eye-protection devices should be decontaminated at least daily or before it is used by another employee. Heavy-duty, waterproof gloves will greatly decrease the potential for puncture, limit the microbial burden on hands, and decrease the risk of cross contamination.1

“Before leaving the decontamination area, employees should remove all protective attire, being careful not to contaminate the clothing.
beneath or their skin, and wash their hands.” Once used, face masks are considered contaminated and should not be worn hanging around the neck, stuffed into a pocket or perched on the forehead.

Design Considerations

In some facilities the physical processing area is frequently less than ideal. Some challenges are lack of space, lack of equipment, poor design or inappropriate location. This can be the result of many things such as OR growth, technology advancements, poor maintenance, old facilities, lack of planning with new facilities or construction. Nonetheless, AAMI has detailed guidelines for the design and maintenance of processing areas. The following is a summary of design considerations found in ANSI/AAMI ST79, Section 3.

GENERAL RATIONALE (SECTION 3.1)

From both safety and cost-effectiveness standpoints, all instrument processing functions should be performed in one department. If centralization of sterilization processing is not possible, all sterilization processing should be under a centralized control with consistent policies and procedures.

FUNCTIONAL WORKFLOW PATTERNS (SECTION 3.2.3)

The area where contaminated items are received and processed should be physically separated from areas in which clean items are packaged, sterilized and stored. Decontamination equipment that mechanically processes items and then automatically unloads them into the clean side is recommended. See Figure 4.

The workflow should be designed so that items are moved progressively from being contaminated to being safe to handle. A pass-thru window, between the decontamination area and the clean area is recommended. See Figure 5.

PHYSICAL FACILITIES (SECTION 3.3)

Space requirements (Section 3.3.1)

Processing space needs are frequently underestimated. Space should be provided in proportion to the expected volume and the amount of products that will be stored in this area.

Table 1. Ventilation Requirements for Functional Areas

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

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Floors and walls (Section 3.3.6.1)
Floors and walls should be level and be constructed of materials that will withstand frequent cleaning with chemical agents. Carpet is not appropriate in work areas.

Ceilings (Section 3.3.6.2)
Ceilings in work areas should be constructed to create a flush surface with recessed, enclosed pipes and fixtures. “Ceilings should be constructed of materials that are not of particulate- or fiber-shedding composition.”

Ventilation (Section 3.3.6.4)
In general, the clean areas (sterilization, preparation, packaging and sterile storage) should have positive airflow ventilation and the soiled and decontamination areas should be under negative pressure. See Table 1.

Temperature (Section 3.3.6.5)
The temperature in the work areas should be comfortable for properly attired personnel. In general work areas should be between 20°C and 23°C (68°F and 73°F) and in the decontamination area the temperature should be between 16°C and 18°C (60°F and 65°F).

Relative humidity (Section 3.3.6)
Relative humidity should be controlled between 30 percent and 60 percent in all work areas. In the sterile storage area, the relative humidity should not exceed 70 percent (see Figure 6). Higher relative humidity can promote microbial growth and a lower relative humidity may adversely affect some sterilization parameters (such as steam penetration) and the performance of some products (such as biological and chemical indicators).

HOUSEKEEPING PROCEDURES (SECTION 3.4)
Areas where any aspects of decontamination, preparation, or sterilization are performed should receive the same housekeeping procedures as the operating room to ensure a high level of cleanliness at all times.

Water Quality
Water quality and effective water treatment is a huge issue for SPD. The two main goals of water treatment in medical device reprocessing are to prolong the life of medical instrumentation and, more importantly, minimize the risk of patient infection resulting from contaminated medical devices.

The IP, along with SPD personnel, should confirm with the facilities engineering department that the water quality supplied to each piece of equipment meets the manufacturers’ requirements. In 2007, AAMI published a Technical Information Report (TIR) on Water for the reprocessing of medical devices. This TIR provides guidelines on the quality of water that should be used on various stages of medical device reprocessing. Some of this information can also be accessed in the “Water Quality and its Impact on the Decontamination Process” by Scott Lyon in Managing Infection Control, Oct:2008.

Cleaning and Disinfection
The most important job in SPD is decontamination. If the medical device is not effectively cleaned, the sterilant cannot penetrate the material contaminating the item and sterilization will not occur. If it is not clean; it cannot be sterilized!

Blood and body fluids can cause pitting; therefore, cleaning of surgical instruments should occur as soon as possible after use. Instruments should be decontaminated in an area separated from locations where clean activities are performed. All instruments opened in the OR should be decontaminated even if they have not been “used.” Instruments should not be decontaminated in scrub or hand sinks because the sink and faucet can become contaminated.

Mechanical cleaning equipment is recommended because it provides a higher level of cleaning and thermal activity than manual methods. The SPD should follow all surgical instrument and medical device manufacturers written validated instructions regarding types of cleaning methods (automatic or manual), cleaning agents, and disassembly procedures. Because of the possibility of aerosolization of microorganisms, brushing lumens and other items should occur under water.

Packaging
The intention of any sterilization packaging is to allow sterilization of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination. Sterilization packaging systems are classified by the Food and Drug Administration (FDA) as a Class II medical device.

Some of the newest recommendations related to packaging that the IP should be aware of include the following:
**Instrument set weights.** Due to ergonomic, sterilization and drying issues, both AAMI and AORN recommendations agree on a maximum weight limit of 25 pounds including the wrap or container.\(^1\)\(^6\) See Figure 7 on page 88.

**Containment devices.** 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. The practice of confining instruments in paper-plastic pouches and then including them in wrapped or containerized sets has not been validated as appropriate and efficacious by packaging and container manufacturers. However, small perforated, mesh-bottom baskets, absorbent, single-layer flat wrap, or appropriate foam products may be used.\(^1\) See Figure 8.

**Placement of inventory sheets.** Count sheets should not be placed inside wrapped sets or rigid containers. 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.\(^5\) 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. Another is to computerize the entire process and print out the count sheets in the OR when the case carts arrive since they are not required to be sterile. See Figure 9.

**Placement of Chemical Indicators (CI).** A CI should be placed inside each package and an external chemical indicator affixed outside each package.\(^1\)\(^6\) The CI should be placed in the geometric center not on the top of a wrapped pack or tray (see Figure 10).\(^5\) Two CIs should be placed inside rigid containers, one in each of two opposite corners of the inside basket (see Figure 11).\(^5\) If the container is multi-level a CI should be placed in two opposite corners of each level. In multi-level wrapped sets, a CI should be placed on each level (see Figure 12).\(^5\)

**Sterilization Monitoring**

SPD relies on three types of monitors for sterilization; physical monitors, chemical and biological indicators. All

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**Figure 7.** Instrument tray being weighed.

**Figure 8.** Containment device.

**Figure 9.** Inventory sheets on outside of containment devices.

**Figure 10.** Class 5 Integrating Indicators in geometric center not on top of wrapped tray.

**Figure 11.** Two Class 5 Integrating Indicators inside rigid containers—one in each of two opposite corners.

**Figure 12.** Class 5 Integrating Indicator on each level of a multi-level wrapped set.
three of these monitors are important for quality assurance.

PHYSICAL MONITORS

Sterilizer graphs, gauges and printouts are considered the physical monitors. These devices provide real-time assessment of the sterilization conditions and provide permanent records. Sterilizers that do not have recording devices should not be used.1 “At the end of the cycle and before items are removed from the sterilizer, the operator should examine and interpret the chart or printout to verify that all cycle parameters were met and initial it to permit later identification of the operator.”1

CHEMICAL INDICATORS

Chemical indicators (CI) are intended to react to one or more of the parameters required for the specific sterilization process. The six classes of CIs are defined below.

- **CLASS 1**: Process indicators used externally to distinguish between processed and unprocessed items.9 An example is indicator tape used on the outside of each package, commonly referred to an external chemical indicator.1,6

- **CLASS 2**: Bowie-Dick type tests specifically designed for testing dynamic-air-removal sterilizers.8 Should be used daily and for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failures.1,6

- **CLASS 3**: Single-variable CI designed to react to a single critical variable of the sterilization process, usually time.8 May be used as an internal chemical indicator but Class 4 and 5 provide more information.1

- **CLASS 4**: Multi-variable CI designed to react to two or more of the critical variables of the sterilization process.8 Used as an internal chemical indicator.1

- **CLASS 5**: Integrating indicator designed to react to all critical parameters of the sterilization process. The performance of integrating indicators is correlated to the performance of a biological indicator (BI).8 Used as an internal chemical indicator, may be used inside a PCD to release loads that do not contain implants and should be used inside the BI process challenge device (PCD) to monitor implant loads.3 Do not release the implant load until the BI result is available.1,6

- **CLASS 6**: Emulating indicator designed as a cycle specific indicator.9 Currently, neither AORN nor AAMI recommended practices address the use of Class 6 CIs.1,6,7

The use of Class 5 CI integrating indicators is strongly recommended because it monitors all the parameters for the cycle, not just one or two.7

### Table 2. Frequency of Use of Biological Indicators1,6,9

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Biological Indicator</th>
<th>Frequency of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Weekly, preferably daily, and with each load containing implantable devices which should be quarantined until the BI results are available. Also use for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failure and product testing.</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td><em>Bacillus atropheus</em></td>
<td>Every load</td>
</tr>
<tr>
<td>Low temperature</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Daily, preferably each load, and with each load containing implantable devices which should be quarantined until the BI results are available. Also use for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failure and product testing.</td>
</tr>
<tr>
<td>hydrogen peroxide</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Daily, preferably each load, and with each load containing implantable devices which should be quarantined until the BI results are available. Also use for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failure and product testing.</td>
</tr>
<tr>
<td>gas plasma</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Daily, preferably each load, and with each load containing implantable devices which should be quarantined until the BI results are available. Also use for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failure and product testing.</td>
</tr>
<tr>
<td>Ozone</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Daily</td>
</tr>
<tr>
<td>Liquid peracetic acid</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Daily</td>
</tr>
<tr>
<td>Dry-heat</td>
<td><em>Bacillus atropheus</em></td>
<td>Weekly, preferably daily, and with each load containing implantable devices which should be quarantined until the BI results are available. Also use for sterilizer qualification testing after sterilizer installation, relocation, malfunction, and sterilization process failure and product testing.</td>
</tr>
</tbody>
</table>
BIOLOGICAL INDICATORS

“The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle.”¹ See Table 2 on page 93 for frequency of use of BIs.

Many facilities are choosing to monitor sterilizer efficacy with every load and quarantining that load to eliminate recalling all items processed since the last negative BI. A major advantage of monitoring every load with a BI is the insurance that every load sterilized is monitored. This way each patient gets the same standard of care.

Documentation establishes accountability and therefore, information for every sterilization cycle should be documented. The following information should be recorded for each cycle:

- 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, BI).¹,⁶

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

Flash Sterilization

Flash sterilization could increase the risk of infection to patients because of pressure on staff to eliminate one or more steps in the cleaning and sterilization process. For that main reason, flash sterilization should be kept to a minimum. Flashing should be used only when there is insufficient time to process by the preferred wrapped method. “Flash sterilization should not be used as a substitute for sufficient instrument inventory.”⁶

IMPLANTS SHOULD NOT BE FLASHED

Flash sterilization is not appropriate for implantable devices. Implants are foreign bodies, and they enhance the risk of surgical site infection. Alert planning, proper packaging, and inventory management in collaboration with suppliers can minimize the need to flash sterilize implantable medical devices.⁶

If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a Class 5 CI. The implant should be quarantined on the back table until the rapid-action indicator provides a negative result.⁶

DOCUMENTATION OF FLASH LOADS

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

- items(s) processed;
- patient receiving the device(s);
- cycle parameters used (e.g., temperature, duration of cycle);
- date and time the cycle is run;
- operator identification; and
- reason for flash sterilization.⁶

Sterile Storage

The shelf life of sterile items is event-related and dependent on the amount and type of handling, packaging, storage conditions, and transportation. Sterile packages should be stored in a way that reduces the potential for contamination. The recommended temperature for all sterile storage areas is 24°C (75°F) and they require at least four air exchanges per hour, and a controlled relative humidity that does not exceed 70 percent. This area should be accessible only to staff who know how to handle sterile items properly.¹

Sterile items should only be stored on or in designated shelving, counters, or containers. Sterile items should be stored according to the following recommendations:

- 18 inches below the ceiling (or level of sprinkler head) because adequate space is needed for air circulation and to ensure the effectiveness of sprinkler systems;
- 8 inches to 10 inches above the floor to prevent contamination during cleaning; and
- 2 inches for outside walls because of condensation that may form on interior surfaces of outside walls.¹,⁶

The bottom shelf should be solid, or contain a physical barrier between the shelf and the floor. Heavy instrument packages should not be stacked due to the possibility of compression. If a package is compressed, it can force air and microorganisms into the package, cause seals to burst, or puncture the package.¹

Outside shipping containers and corrugated cardboard boxes should never be allowed in the sterile storage area. Shipping containers are exposed to unknown and potentially high microbial contamination and corrugated cardboard serves as a generator of and reservoir for dust.¹,⁶

Transportation

Sterile items should be transported in a manner that will protect them from puncture or contamination. Because sterility is event-related, 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 and transported to the decontamination area or soiled utility area as soon as possible.
Many facilities are requesting loaners to be in the facility at least 24 hours before the scheduled case in which they will be used.

Contaminated instruments should only be transported in containers, devices or carts labeled as biohazard and should be separated from the delivery of clean and sterile supplies.\(^1\,\!^6\)

Leak-proof, puncture-resistant closable and labeled containers must be used for devices that have sharp edges capable of penetrating the container or skin. Items must be kept moist in the transport container by adding a moist towel (water, not saline) or using a foam, spray or gel product, specifically intended for this use.\(^1\)

**Off-site transportation**

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

**Traffic Control**

Only authorized personnel in specific attire should be allowed in areas where decontamination, preparation and packaging, sterilization processing, sterile storage, and distribution are carried out. Proper traffic control practice minimizes the potential for contamination in the processing area and protects personnel and visitors from the microorganisms present on contaminated items in the decontamination area.

The responsibility and authority for enforcing traffic-control of policies and procedures, and compliance methods should be specified in writing. Visitors in SPD should comply with the dress code stated in the policies and procedures.\(^1\)

**Loaner Instrumentation Program**

The use of loaner instrumentation/implants has become common practice in healthcare facilities. There is an increasing need to borrow instruments, implants and other devices from vendors and neighboring facilities. Technology is constantly changing. Sometimes a procedure is done so infrequently that a facility cannot afford to purchase the instruments. Sometimes it is due to particular requirements for specialties such as pediatrics. Whatever the reason, 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 manufacturers’ written recommendations by the receiving healthcare facility before use. The SPD needs 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 in which they will be used. In addition, if there are 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 are packaged and sterilized by another healthcare organization, the borrowing facility will not have access to the sterilization records. In addition, they cannot verify the quality of any previous processing or conditions during transportation and storage. Consequently, the items should be completely reprocessed following the instrument manufacturer’s written instructions before use.\(^1\,\!^6\)

Following the procedure, the items should be disassembled, decontaminated and inventoried before returning to the vendor or loaning facility.

Managing loaner instrumentation entails planning. A well written policy with controls for enforcement and consequence should be developed in collaboration with SPD, the operating room, infection control, risk management, surgeons, vendors, quality and patient safety. Emphasis should be placed on developing a standardized system that will allow all involved parties to access information easily.\(^10\)

**Summary**

A major responsibility of any healthcare provider is to minimize patient risks and SPD plays a major role in patient safety. For patients’ safety sake, the IP should be familiar with current best practices in SPD. The information in this article will help the IP to assess the SPD for compliance with best practices. This author strongly suggests IPs do rounds at least every six months in the SPD to ensure best practices are being followed.

**SPD rounds should include, but are limited to, the following:**

- Personnel;
- Design considerations;
- Water treatment;
- Cleaning and disinfecting;
- Packaging;
- Sterilization monitoring;
- Flash sterilization;
- Sterile storage;
- Transportation;
- Traffic control; and a
- Loaner instrumentation program.
Every facility should have a copy of the most recent recommended practices to refer to. Ideally, the IP should have a copy of the AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* recommended practice and the AORN Recommended Practices for Sterilization in the Perioperative Practice Setting, (see below for ordering information). All “sterile” items must be sterile at the time of use and remember … if it is not clean you cannot sterilize it.

**Ordering Information**

**AAMI**
- ANSI/AAMI ST79:2008, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
  - Order code: ST79 or ST79-PDF
  - Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made.
  - 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:
  1. Internet: http://marketplace.aami.org
  2. Call: 1-800-332-2264, ext. 217 or 1-703-525-4890, ext. 217
  3. Fax: 703-525-1424
  4. Mail: AAMI, Customer Service Center, 1100 N. Glebe Road, Suite 220, Arlington, VA 22201-5762

**AORN**
- AORN Perioperative Standards and Recommended Practices can be purchased through AORN as can the AAMI ST79 recommended practice using the following options:
  1. Internet: www.aorn.org/bookstore/ordering.htm
  2. Call: 1-800-755-2676 ext. 1 or 303-755-6304 ext. 1 (Monday-Friday, 8 a.m. to 4:30 p.m. Mountain Standard Time)
  3. Fax: 303-750-3212
  4. 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. A CD-ROM of the standards is available for the first time this year.

**References**


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For additional information regarding Certification contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call 908-788-3847 or visit the Web site at www.sterileprocessing.org.

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   PO Box 25310, Scottsdale, AZ 85255-9998
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