Using Observation and Audit Tools to Improve Quality Outcomes

by Cynthia Hubbard, RN, BS

Objectives
After completion of this self-study activity the learner will be able to:
1. Identify the infection risk posed to patients by contact with medical devices that have not been effectively reprocessed.
2. Discuss The Joint Commission ongoing quality monitoring in their Elements of Performance.
3. Develop an understanding of the interrelated elements for effective sterilization included in the recommended practices of the Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79).
4. Develop routine observation and quality monitoring auditing tools in your environment.

Test Questions
1. The Joint Commission requires a hospital’s infection prevention and control plan to include a written description of surveillance activities designed to minimize, reduce or eliminate the risk of infection.
   A. True    B. False
2. Improperly cleaned and sterilized medical devices not only pose risks for the person seeking health services, but they also carry the risk for person-to-person transmission of infections.
   A. True    B. False
3. The Centers for Medicare and Medicaid Services (CMS) advise ambulatory surgery centers to perform regular self audits.
   A. True    B. False
4. The ANSI/AAMI ST79 recommended practice states audits that are conducted on a regular basis can enhance the department’s quality processes.
   A. True    B. False
5. The steam quality used in sterile processing should have a dryness value between 90% -95% .
   A. True    B. False
6. Per ANSI/AAMI ST79 recommended practice the ventilation system in soiled and decontamination areas should ensure that air flows into the area (under positive pressure); with a minimum of six air exchanges per hour.
   A. True    B. False
7. Quality monitoring of mechanical washing equipment includes verifying that spray arms achieve full rotation and that the nozzles are clean to ensure effective cleaning action.
   A. True    B. False
8. The effectiveness of the sterilizer drying cycle should be evaluated by controlled, random sampling and opening selected sets at the completion of the drying/cooling time.
   A. True    B. False
9. Any sterilized set containing moisture or that has visible water inside the container is considered contaminated.
   A. True    B. False
10. Each load of implants is monitored with a process challenge device containing a biological indicator and a Class 5 integrating indicator and the load is quarantined until the BI is negative.
    A. True    B. False

Introduction
The Joint Commission (TJC)
Many people are at risk of developing an infection from contact with medical equipment, devices or supplies while seeking health services. TJC notes, “Failure to properly clean, disinfect, or sterilize, and use or store medical equipment, devices, or supplies in a manner that will not cause infection or illness to patients, health care workers, or other persons.”
Education & Training

equipment, devices, and supplies not only poses risks for the person seeking health services, but also carries the risk for person-to-person transmission of infections. To maintain a reliable system for controlling this process, TJC emphasizes using standardized practices to orient, train and ensure competency of all healthcare workers reprocessing medical equipment, devices and supplies; then reinforcing these processes (for example, posting a list of the manufacturers’ step-by-step guidelines) and using ongoing quality monitoring to evaluate your effectiveness. Elements of Performance must document compliance with the infection standard goal to minimize the possibility of infection transmission associated with the use of medical equipment, devices and supplies. Additionally, the hospital’s infection prevention and control plan must include a written description of surveillance activities to minimize, reduce or eliminate the risk of infection.

Centers for Medicare & Medicaid Services (CMS)

In a recent report, Medicare-certified Ambulatory Surgery Center (ASC) growth in the United States during 2001-2008 increased by more than 50 percent and currently there are more than 5,000 ASCs participating in the Medicare program. In 2007, these ACSs performed more than 6 million procedures with services extending beyond traditional surgery to include endoscopy, pain injections, and dental procedures. A study, originally published in the JAMA June 9, 2010 issue, reports the results of a CMS survey, (using an audit tool), that assessed compliance with five specific infection prevention and control practices, including hand hygiene and equipment reprocessing, in facilities in Maryland, Oklahoma and North Carolina between June - October 2008.

Twelve of 62 facilities (19.4 percent) were noted to have a lapse in adherence to hand hygiene or appropriate use of personal protective equipment (i.e., gloves); nineteen of 67 facilities (28.4 percent) failed to adhere to recommended practices regarding reprocessing of surgical equipment. Overall, the researchers found that 39 of 68 (57.4 percent) pilot ASCs surveyed over five months in 2008 were ultimately cited for deficiencies in the infection prevention and control areas surveyed. Of further interest, the percentage of inspections with infection prevention and control deficiencies during this pilot was more than 6-fold greater than the number reported to CMS nationally during the 12-month period from October 1, 2006 to September 30, 2007.

The surveyors concluded that although CMS inspections play an important role in assessing and improving infection prevention and control practices, ASCs must also take a more active role. To assist that effort, CMS has made the ASC infection prevention and control audit tool available online. Facilities can review it to ensure that their policies reflect best practices and that staff understand and follow the procedures outlined in their written policies. Additionally, CMS advises ambulatory surgical centers to perform regular self-audits.

“If the findings by Schaefer et al (Referenced in JAMA, June 9, 2010;303[22]:2273-2279) are generalizable, then among the estimated more than 6 million patients who undergo procedures in ASCs annually in the United States, it is possible that several million patients could be at potential risk for healthcare-associated infection each year.”

ANSI/AAMI ST79 Recommended Practice

The objective of this recommended practices document, last updated in 2009, is to guide us toward desirable reprocessing-related performance to ensure effective sterilization. All of its provisions are to be considered and applied in the light of professional judgment and experience to your setting.

The primary focus of the ANSI/AAMI ST79 recommended practice is to define and explain best practices in these interrelated areas: facility design considerations; personnel considerations; receiving; handling, collection and transport of contaminated items; cleaning and other decontamination processes; packaging, preparation and sterilization; installation, care and maintenance of sterilizers; quality control and quality process improvement.

“In its broadest sense quality control involves continuous supervision of personnel performance, work practices and ongoing verification of adherence to established policies and procedures.” Using observation and audits to check compliance with your current procedures and standards helps ensure consistency over time, as the same elements are checked and deficiencies acknowledged and addressed. Also, any omissions or out-of-date procedures can be identified. Any member of the team can be entrusted to make the observations and, indeed, this often is a great educational tool as it brings up questions and clarifies procedures.

The ANSI/AAMI ST79 recommended practice reinforces that policies and procedures form the heart of quality control. They must be based on the recommendations of medical device manufacturers, the sterilizer manufacturer and evidence-based guidelines. Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up addressing problems.

Applying the Concepts

In the interests of convenience and time savings for anyone wanting to use auditing tools in your environment, the following examples are inspired by and formatted from the primary provisions of the ANSI/AAMI ST79:2006, A1:2008 and A2:2009 document.
### Observation and Audit of: Design Considerations and Physical Facilities

**Section 3 Design Considerations**

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#### Work area design
- Walls or partitions separate functional work areas

#### Functional workflow patterns
- Work moves from dirty to clean
- Pass through windows and doors are kept closed

#### Traffic Control
- Only authorized persons in the area

#### Adequacy of Space
- Space is proportionate to the volume of work; what adjustments are needed for safe working conditions?

#### Mechanical systems are functional
- Source of distilled or deionized water
- Oil-free medical compressed air and/or nitrogen sources
- Vacuum systems

#### Electrical
- Sterilization processing equipment is on emergency power
- Power requirements are as specified for each piece of equipment

#### Steam for sterile processing
- Steam dryness is at a value between 97% - 100% (checked by Facilities Engineering)
- Periodically assess sterilization loads for the presence of “wet packs”

#### Utility monitoring/alarm systems for steam, water, electricity, and air connected to the processing equipment should be in place to alert to failures
- Utility monitoring and alarm systems are functional (checked by Facilities Engineering)

#### Emergency eyewash/shower equipment and hand-washing sinks
- Locations are expedient for both decontamination and clean areas
- Units are functional and checked per schedule
- There is no standing water on floors

#### General area requirements
- Floors are level
- Ceiling is finished with enclosed fixtures
- Surfaces of walls, ceiling and floors is non-shredding and washable without damage
- Soiled and decontamination areas are under negative pressure so that air flows into the area with a minimum of 10 air exchanges per hour
- Air should flow from areas of positive pressure to areas of negative pressure
- General work area temperatures are controlled between 20°C - 23°C (68°F -73°F); temperature is recorded daily in each area
- Relative humidity is controlled between 30% - 60% in all work areas except Sterile Storage where it should be 70%; relative humidity is recorded daily in each area
- Lighting is effective in areas where instruments are manually cleaned and inspected (e.g., 1,000 lux)
- Lighting is appropriate for the age of workers in the area
- Lighting fixtures are selected and mounted to focus the light in front of workers; they should not be working in their own shadows
- The design of lighting fixtures should minimize the accumulation of dust
- Alcohol-based hand hygiene agents used have an alcohol concentration of more than 60% by volume (to be effective)

#### Summary—Issues to monitor
1.  
2.  

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**Observation and Audit of: Personnel Considerations**


**Section 4 Personnel considerations**

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<tr>
<td><strong>Qualifications, training and continuing education</strong></td>
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<tr>
<td><em>Experience of supervisor and staff is appropriate for level of responsibility</em></td>
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<tr>
<td><em>Initial orientation and area training is completed and documented</em></td>
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<tr>
<td><em>Supervisors demonstrate knowledge of regulations, OSHA, principles of management and are certified or otherwise appropriately credentialed</em></td>
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<tr>
<td><em>Training is provided for new devices, instrumentation, and equipment and is documented</em></td>
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<tr>
<td><em>Continuing education is provided on facility-approved schedule for the subject matter; attendance is documented</em></td>
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<tr>
<td><em>All personnel demonstrate knowledge of principles of sterilization, infection prevention, and all areas of sterile processing</em></td>
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<tr>
<td><em>All personnel are certified within two years of employment</em></td>
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<tr>
<td><strong>Health/personal hygiene</strong></td>
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<tr>
<td><em>Written policies on personal hygiene are known and practiced</em></td>
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<tr>
<td><em>No artificial nails; nail polish is not worn</em></td>
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<tr>
<td><em>Uniforms or other garments that become soiled or wet during wear are changed immediately</em></td>
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<td><em>Immunizations, including hepatitis B, are current. A signed hepatitis B vaccine declination statement, required by OSHA, is on file for any employee who declines the immunization</em></td>
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<tr>
<td><em>Hand washing is effectively performed as per procedure</em></td>
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<tr>
<td><strong>Attire</strong></td>
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<tr>
<td><em>Facility provided/laundered attire is donned at work and removed before leaving the unit at the end of shift</em></td>
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<tr>
<td><em>Shoes worn in the work area are clean, with non-skid soles, and are sturdy enough to prevent injury</em></td>
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<tr>
<td><em>All head and facial hair (except for eyebrows and eyelashes) is completely covered with approved surgical-type hair covering</em></td>
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<tr>
<td><em>Jewelry and wristwatches are not worn in decontamination, preparation, or sterilization areas</em></td>
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<tr>
<td><em>Fluid-resistant face mask is worn covering the nose in decontamination along with eye protection, general purpose utility gloves and liquid-resistant covering with sleeves</em></td>
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<tr>
<td><em>Face masks not worn hanging around neck, stuffed into a pocket, or perched on the forehead because they are considered contaminated after use and can promote the spread of infection</em></td>
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<tr>
<td><em>PPE is worn and removed as prescribed; those working in areas where items are flash-sterilized also wear a liquid-resistant face mask</em></td>
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<tr>
<td><em>Once removed, contaminated PPE and equipment is placed in a clearly marked container or designated area for storage, washing, decontamination, or disposal</em></td>
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<tr>
<td><strong>Standard/transmission-based precautions</strong></td>
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<tr>
<td><em>OSHA blood borne pathogen exposure control plan is understood</em></td>
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<td><em>Engineering and work practice controls are understood</em></td>
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**Summary—Issues to monitor**

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August 2010
### Observation and Audit of: Handling, Collection and Transport of Contaminated Items;
Cleaning and Other Decontamination Processes


Section 6 Handling, collection and transport of contaminated items; Section 7 Cleaning/decontamination processes; Annex E Selection & use of chemical disinfectants; Annex N (Informative) Toxic anterior segment syndrome and the processing of intraocular surgical instruments

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#### Separation of waste and reusables
- Secured, dedicated containers/segregated areas are provided for holding the various categories of soiled materials, such as textiles, instruments and equipment
- Waste and sharps are disposed of at the point of use into appropriate containers
- Soiled materials are contained during transport

#### Transportation schedules and routes
- A regular pickup schedule, appropriate for the volume of soiled materials, is maintained
- The route for soiled materials pickup avoids public areas and patient transport

#### Policies and procedures
- Exist for all major categories of reusable items and all methods of decontamination and are current (as defined by Infection Prevention and Control policy)

#### Manufacturers’ instructions—the reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned, and disinfected or sterilized. If there are no specific instructions in the product labeling, contact the manufacturer directly to provide a documented reprocessing method.
- Current written manufacturers’ instructions, with photos or product diagrams, are available in work areas
- Current written manufacturers’ instructions are used to reprocess all medical devices

#### Presoaking
- Follow device manufacturers’ written instructions
- Vertically soaking lumened instruments prevents air bubbles
- Frequently changing the cleaning solution keeps the bioburden low

#### Disassembly
- Follow device manufacturers’ written instructions
- Sort per procedures; remove trash and linens from instrument sets
- Disassemble rigid sterilization containers and remove disposables and tape

#### Cleaning—must be appropriate for a particular contaminated device, and depends on the biohazard that the device presents. Procedures should reflect knowledge and application of the critical, semi-critical and noncritical designations to determine processing needs. There is also an understanding of the special processing needed for prions.
- Follows device manufacturers’ written instructions
- Note that chemicals are not causing corrosion in ultrasonic cleaning equipment, washer-disinfectors, or washer-sterilizers;
- Residual chemicals are easily removed from medical devices by rinsing with readily available quality water
- Follows the device manufacturers’ instructions to determine the appropriate cleaning agent and also the cleaning agent manufacturers’ instructions for use
- Immersible devices are cleaned under water to minimize aerosolization
- Uses lukewarm water/detergent solutions (27°C - 44°C [80°F - 110°F], but not exceeding 60°C [140°F]) to prevent coagulation and assist in protein removal
- The temperature of the soaking solution is monitored and documented
- Only non-abrasive cleaning compounds and implements are in the area and used
- Only clean (prefer disposable, single-use) tools are used in the cleaning process
- All reusable brushes are disinfected or sterilized at least daily and of the appropriate size for the tasks
- Towels are also clean and lint-free
- Cleaning solutions are changed frequently (e.g., after each set of instruments).
- Final rinses are performed with treated water; saline is not used

#### Rigid sterilization container systems
- Follows the rigid sterilization container systems manufacturers’ written instructions
- Container is disassembled before it is cleaned
- After cleaning inspect for cleanliness and damage to nuts, bolts, screws, rivets, filter retention mechanisms, gaskets, and permanent filters

#### Instrument Cleaning
- Instruments are maintained as free of gross soil as possible during surgical or other health care procedures
- Cleaning and decontamination begins as soon as possible after items have been used

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### Instrument Cleaning

- Delicate instruments and devices requiring special handling are separated from general instruments and utensils.
- A designated cleaning area and equipment dedicated to the cleaning of intraocular surgical instruments is identified and these instruments are processed separately from general surgical instruments.
- Intraocular surgical instruments are maintained in a moist state before cleaning in order to prevent the drying of OVDs and surgical debris onto or within them.
- The sterile, distilled or deionized water recommended by the instrument manufacturer used to clean/rinse intraocular surgical instruments is discarded after each use.
- If an ultrasonic cleaner is used to process intraocular surgical instruments, it is emptied, cleaned, rinsed, and dried after each use.
- Instruments or devices composed of more than one part are disassembled, and all jointed instruments are open to make sure that all surfaces are effectively cleaned.
- Use of clinical-soil-dissolving enzymatic cleaners to prevent coagulation of blood onto the device are used per manufacturers’ instructions.
- Air-powered instruments are not immersed in solution.
- Water-soluble instrument lubricants, specifically designed for compatibility with sterilization, may be used; the manufacturers’ instructions for use are followed (instrument lubricants containing mineral oil or other oil bases are not used).

### Microbial processes—includes disinfection and sterilization by thermal or chemical means

- The use of a microbiological process is determined by the medical device manufacturer.
- Appropriate process selection is made for each item requiring microbial processing.
- Liquid chemical sterilant/high-level disinfectants (LCS/HLD) labeling provides information on the safe and effective product use, including lot number, expiration date, active ingredients, concentrations, dilution or activation required prior to use, contact time and temperature.
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses is prohibited in work areas where there is a risk of occupational exposure to chemical or biological materials.
- Verify that mechanical equipment is functioning properly by monitoring temperatures and using appropriate testing methods; document results.
- Verify that mechanical equipment spray arms achieve full rotation and that the nozzles are clean to ensure effective cleaning action.

### Repair of devices in the facility

- Clinical engineers and biomedical equipment technicians are not exposed to infectious agents when they repair devices.

### Summary—Issues to monitor

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**Observation and Audit of: Packaging, Preparation, and Sterilization**


**Section 8 Packaging, preparation, and sterilization**

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### Selection of packaging materials

- Packaging is held for two hours at (20°C to 23°C [68°F to 73°F]) and 30-60% for temperature and humidity equilibration of packaging materials in the preparation area to permit adequate steam penetration and to avoid superheating.

### Package considerations and preparation

- Packaging materials are inspected for integrity prior to use.
- Labeling information is written only on the plastic side of peel pouches.
- Inks in marking pens are nontoxic and smear-proof.
- A tab is created for easy removal of the indicator tape on reusable wrappers.
- Rubber bands or tape are not used to hold instruments together in a group; tip protectors are steam-permeable.
- If double pouching is practiced, use only paper–plastic pouches validated by their manufacturer for this use.
- Paper–plastic pouches are not used in wrapped sets or containment devices unless the practice is validated by the packaging manufacturer and verified by product testing in your sterilizers.

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<table>
<thead>
<tr>
<th>Package considerations and preparation</th>
<th>If it is necessary to flush the lumen of an instrument, use distilled or deionized water. Multipart instruments are disassembled for sterilization unless the device manufacturer provides validated instructions to the contrary.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument prep and assembly</td>
<td>A maximum weight limit of 25 pounds for containerized instrument sets. Instruments are carefully inspected for cleanliness, flaws, or damage and dried before packaging. Instrument functionality tests are performed per procedure. Perforated or wire-mesh-bottom trays are inspected for any sharp edges, nicks, etc. All jointed instruments are assembled open or in unlocked position with ratchets not engaged. Instruments composed of more than one part/sliding pieces/removable parts are disassembled unless the device manufacturer specifies otherwise. Items with concave surfaces and/or broad, flat surfaces that will retain water are placed on edge to drain condensate. Rigid sterilization containers are used in accordance with the manufacturers’ instructions re: set prep and assembly.</td>
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<tr>
<td>Loading the sterilizer</td>
<td>Similar items requiring the same cycle parameters (i.e., sterilization exposure time and temperature, cycle drying and/or cool-down time) are grouped together. Metal items are placed below textile or paper-plastic packs on the loading cart. Use baskets to facilitate placing paper-plastic pouches on edge with the proper spacing for adequate sterilant penetration. Wrapped/unwrapped instrument sets in perforated trays or rigid containers are placed so that the tray bottom is parallel to the loading cart shelf. All fabric packs are placed perpendicular to the loading cart shelf. Solid-bottom pans, bowls, and trays are positioned tilted on edge and oriented in the same direction. Drying is evaluated by controlled, random sampling and opening selected sets at the completion of the drying/cooling time.</td>
</tr>
<tr>
<td>Sterilization parameters</td>
<td>Sterilizer manufacturers’ written instructions for cycle parameters are compared with medical device manufacturers’ instructions and any discrepancies resolved. The correct cycle parameters for rigid sterilization containers are selected and verified based on the results of product testing. Sterilization of specialty instruments and devices, such as drills, may require extended exposure times; sterilization parameters of all complex instruments are verified with the device manufacturer. Before flash sterilization is used this process is verified as appropriate by the instrument manufacturer. Sealed containment devices used in flash sterilization, and an appropriate PCD (process challenge device), are authorized by the device manufacturer.</td>
</tr>
<tr>
<td>Unloading the sterilizer</td>
<td>The sterilizer door is opened for a time at the end of the sterilization cycle, before the containers are removed, to prevent condensation formation. Sterilized items remain on the cart to cool and are not touched during the cooling process. A minimum 30 minutes cooling time is recommended; the cart is placed in a low traffic area without close proximity to air-conditioning or other cold-air vents. Items or packs removed from a table-top sterilizer are visibly dry. Flash-sterilized items are used immediately, not stored for later use. The handling of all newly-sterilized items is minimized; visibly inspect them as they are removed from the sterilizer cart.</td>
</tr>
<tr>
<td>Sterile storage—The contamination of a sterile item is event-related, and the probability of contamination increases over time and with increased handling. Apply sterility maintenance covers to completely dry and cool sterilized packages. Sterile items are stored at least 8 - 10 inches above the floor; at least 18 inches below the ceiling or sprinkler heads and at least 2 inches from outside walls. Carts have a physical barrier between the bottom shelf and traffic or housekeeping activities on the floor. Outside shipping containers and corrugated cartons are not used as containers in sterile storage areas. Written policies and procedures exist for the storage, handling, rotation, and labeling of container systems and other sterile packs.</td>
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### Sterile storage
The contamination of a sterile item is event-related, and the probability of contamination increases over time and with increased handling.

- There are written policies and procedures for determining shelf life and how it is indicated on the product’s packaging.

### Distribution/Transport of sterile items
All containers/carts used to transport sterile items are cleaned after each use as contamination is picked up from the environment during transport outside of sterile storage areas.

- Adequate protection is maintained during transport to minimize the potential for damage.
- All clean or sterile items transported through uncontrolled environments are in covered or enclosed carts with a solid bottom shelf.
- Reusable carts and cart covers for transport vehicles are cleaned after each use.
- Items are carefully placed inside plastic or paper bags or boxes.
- Heavy items are not placed on top of sterile packages.
- Carts of sterile packages are secured within transportation vehicles to prevent damage or contamination.
- Transport vehicles (motorized or manual) that are loaded and ready for transport are not left unattended in unsecured areas.

### Aseptic presentation
Basic aseptic techniques and principles of sterilization are the same for all sterile packaging systems.

- Any set containing moisture or that has visible water inside the container system is considered contaminated.
- Prior to placing sterilized items on the sterile field, the bottom of the wrapper or container is visually inspected for integrity and moisture.
- The external and the internal Cls are checked for the appropriate endpoint response before sterilized items are transferred to the sterile field.
- The integrity and proper alignment of plates, filters or valves in containers are inspected before the contents are used (see manufacturer’s instructions).
- The contents of a sterile package should be aseptically transported to the sterile field.

### Summary—Issues to monitor

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**Observation and Audit of: Installation, Care, and Maintenance of Sterilizers**


**Section 9 Installation, care, maintenance of sterilizers**

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**Routine care**

- Sterilizers are inspected and cleaned daily (including items like door gaskets, the chamber drain screen, etc) according to the manufacturers’ written instructions

**Preventive maintenance**

- Preventive maintenance is carried out by qualified individuals and records are maintained for the life of the sterilizer

**Calibration**

- Periodic calibration (including items like pressure and temperature-sensing devices, timers, controls, and recording devices) is performed as specified in the manufacturers’ instruction manuals and the results are documented

**Record keeping**—accurate and complete records are required for process verification and are useful in malfunction analysis

- Maintenance records are kept for each sterilizer; records include sufficient information to identify the equipment and establish a continuous history of all scheduled and unscheduled service.
- Sterilization records are retained in accordance with the policy and procedure established by the individual health care facility

**Summary—Issues to monitor**

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Observation and Audit of: Quality Control and Quality Process Improvement
Section 10 Quality control; Section 11 Quality process improvements; Annex D User verification of cleaning processes

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**Monitoring mechanical cleaning equipment**
- All Bowie-Dick testing is conducted every day, before the first processed load, in a dynamic-air-removal steam sterilizer
- One Bowie-Dick test (Class 2 CI) is placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber
- A lot number is assigned to each flash sterilization load and a load record is generated for each sterilization cycle
- Implants are fully traceable to the patient
- Sterilizers without recording devices are not used
- Results of all monitors are satisfactory and recorded per policy and procedure
- sterilization process monitoring—includes four components: monitoring of every package and sterilization load; routine monitoring of sterilizer efficacy; qualification testing (see ANSI/AAMI ST 79 Tables 6, 7 and 10.8); and periodic product quality assurance testing
- User verification of cleaning processes
- Verification tests recommended by the equipment manufacturer are performed per policy as part of the overall quality assurance program
- Performance outcomes include clean surfaces and adequate fluid flow in equipment with adaptors for lumens
- Mechanical cleaning equipment is tested upon installation, weekly (preferably daily) during routine use, and after major repairs
- The results of monitoring and verifying cleaning processes are documented
- The readouts and cycle printouts (if available on your machines) are reviewed and initialed

**Lot control numbers**—lot identification enables personnel to retrieve items in the event of a recall and to trace problems
- Each item or package intended for use as a sterile product is labeled with a lot control identifier
- A lot number is assigned to each flash sterilization load and a load record is generated for each sterilization cycle
- Implants are fully traceable to the patient
- Sterilizer records
- As defined in policy and procedures, data about each sterilization cycle is recorded and maintained
- Results of biological testing are retained
- Results of Bowie-Dick testing are retained
- Response of the CIs placed in PCDs are retained
- Reports of inconclusive or nonresponsive CIs found later in the load are retained
- Record-retention policy directive is followed

**Expiration dating**
- All sterilized items are labeled with a control date for stock rotation and the following statement (or its equivalent): "Contents sterile unless package is opened or damaged. Please check before using."

**Physical monitors**
- Physical monitors (time, temperature, and pressure recorders, displays, digital printouts, and gauges) are checked before each cycle to ensure they are working and after each cycle to verify that the parameters of the selected sterilization cycle have been met
- Results of all monitors are satisfactory and recorded per policy and procedure
- Sterilizers without recording devices are not used
- If physical monitors detect malfunctions, corrective action is taken

**Chemical indicators (CIs)**—used to detect sterilization failures resulting from incorrect packaging, incorrect sterilizer loading, or sterilizer malfunctions. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. CIs are used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process.
- External and internal chemical indicator monitoring is used for each item sterilized
- CIs are used in accordance with the CI manufacturer’s instructions
- All CIs are interpreted in accordance with the CI manufacturer’s instructions
- CIs are placed in that area(s) of the package, tray, or containment device considered to be least accessible to steam penetration
- A Bowie-Dick test (Class 2 CI) is conducted every day, before the first processed load, in a dynamic-air-removal steam sterilizer
- One Bowie-Dick test (Class 2 CI) is placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber
- Users are trained and knowledgeable about performance characteristics and demonstrate competency in interpreting CIs

**Biological indicators (BIs)**—are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements.
- All BIs are used in accordance with the BI manufacturer’s instructions for storage, handling, use, and microbiological testing
- BIs are incubated in the appropriate incubator, read at the specified interval and disposed of per manufacturer’s directions
- Each day that a test BI is run, at least one BI from the same lot, not exposed to the sterilant (control), is incubated in each incubator to verify the viability of the spores, BI media and the performance of the incubator

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### Biological indicators (BIs)

- BIs along with a Class 5 integrating indicator within PCDs are used to monitor every load containing implants.
- Implant loads are quarantined until the results of the BI testing are available.
- Emergency situations are defined and documented when the implant is released before the BI results are available.
- BIs are used for periodic quality assurance testing of representative samples of actual products being sterilized and before newly purchased or loaner sets are placed into routine use.

### Process Challenge Devices—PCDs

<table>
<thead>
<tr>
<th>Release criteria for nonimplants</th>
<th>Release criteria for implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>User-assembled PCDs are prepared and used according to policy and procedure.</td>
<td>Biological indicators (BIs)—are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements.</td>
</tr>
<tr>
<td>Commercially available PCDs are used, stored, handled, and interpreted according to manufacturers directions.</td>
<td>Various types of BIs are available, each with different response characteristics and incubation requirements.</td>
</tr>
<tr>
<td>Every load of implants is monitored with a PCD containing a BI and a Class 5 integrating indicator.</td>
<td>For routine release of nonimplantable loads, the PCD contains a BI, or a BI and a Class 5 integrating CI, or a Class 5 integrating CI.</td>
</tr>
<tr>
<td>For routine release of nonimplantable loads, the PCD contains a BI, or a BI and a Class 5 integrating CI, or a Class 5 integrating CI.</td>
<td>The BI PCD is placed on the bottom shelf of an otherwise empty sterilizer, in the area least favorable to sterilization, for routine sterilizer monitoring of a flash sterilizer.</td>
</tr>
<tr>
<td>The BI PCD is placed on the bottom shelf of a full sterilizer, in the area least favorable to sterilization, for routine sterilizer monitoring of a table-top or sterilizer larger than 2 cubic feet.</td>
<td>The BI PCD is placed on the bottom shelf of a full sterilizer, in the area least favorable to sterilization, for routine sterilizer monitoring of a table-top or sterilizer larger than 2 cubic feet.</td>
</tr>
</tbody>
</table>

### Routine load release

- Every sterilization load is physically monitored.
- Every packaged item is labeled externally with a process indicator (Class 1 CI) and contains an internal CI (Class 3 CI, Class 4 CI, or Class 5 CI).
- A BI PCD is used, as per procedure.
- The decision to release a load is made by an experienced, knowledgeable person at the conclusion of the sterilization cycle.
- Loads that do not meet the criteria for release are clearly identified and not mistakenly distributed.

### Sterilization process failures

- Facility policy and procedures are followed in the case of a sterilization process failure.
- The designated management person is notified of any suspected sterilization process failure.
- If CIs, BIs or physical monitors fail, the load is quarantined, the sterilizer is removed from service and the cause of the failure is investigated.
- If the cause of the failure is immediately identified (usually operator error), the cause is corrected and the load is reprocessed.
- If the cause of the failure is not immediately identified, the load is quarantined and all loads back to the last negative BI are recalled, the cause is identified and corrected.
- After a major repair of any type of sterilizer or the utilities connected to the sterilizer, qualification testing is satisfactorily completed prior to the sterilizer being returned to service.

### Routine sterilizer efficacy monitoring

- A BI PCD (may also contain a CI) is used weekly, preferably daily (each day the sterilizer is used).
- Routine sterilizer efficacy testing is done for each type of cycle used.
- Routine sterilizer efficacy monitoring for table-top sterilizers and sterilizers larger than 2 cubic feet is performed in a fully loaded chamber.
- In flash sterilization cycles, monitoring is done in an empty chamber.
- Routine sterilizer efficacy testing in flash sterilizers includes a separate test for each type of tray configuration normally used in addition to each type of cycle used.
- For dynamic-air-removal sterilizers, daily Bowie-Dick testing is done in an empty chamber prior to any loads being processed.
- Satisfactory physical monitoring of each cycle.
- Satisfactory external and internal CI monitoring of all packages.
- All BIs are negative and controls are positive at appropriate time intervals.
- Results of all tests are satisfactory and recorded per policy and procedure.

### Qualification testing

- For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack.
- For sterilizers larger than 2 cubic feet, and for flash sterilization cycles, monitoring of three consecutive cycles in an empty chamber with a BI PCD (the PCD may also contain a CI).
### Qualification testing
- For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a BI PCD (the PCD may also contain a CI)
- Satisfactory physical monitoring of all cycles
- Satisfactory external and internal CI monitoring of all packages
- All BIs are negative and controls are positive at appropriate time intervals
- Results of all tests are satisfactory and recorded per policy and procedure

### Periodic product quality assurance testing of routinely processed items
- Prior to purchased or loaner sets being placed into routine use they pass product quality assurance tests
- Quality assurance testing of routinely processed items representing all product families is done
- Satisfactory physical monitoring of each cycle
- Placement of BIs and CIs within product test samples is documented
- Satisfactory external and internal CI monitoring of all packages
- All BIs are negative and controls are positive at appropriate time intervals
- Results of all tests are satisfactory and recorded per policy and procedure
- Product testing activity records are maintained, including the testing date, the name of the item, location of BIs and CIs within the tray, and the test results

### Periodic product quality assurance testing of rigid sterilization containers
- Prior to purchase and being placed into routine use, and at selected intervals thereafter, container systems pass product quality assurance tests
- Satisfactory physical monitoring of each cycle
- Placement of BIs and CIs within product test samples is documented
- Results of all tests are satisfactory and recorded per policy and procedure
- Product testing activity records are maintained, including the testing date, the name of the item, location of BIs and CIs within the tray, and the test results

### Product recalls
- Recall policies and procedures exist and expedite the retrieval of processed items suspected to be nonsterile
- Adequate follow-up actions are taken, such as quarantine of the sterilizer, sterilizer repair, notification of physicians and affected clinical departments, and patient surveillance
- The recall report identifies percentage of products located during the recall and provides verification that they were destroyed or reprocessed

### Risk analysis—Because sterility assurance is a probability function, it is assumed that at some time a failure will occur.
- The facility has identified the potential source(s) of a sterilization failure and estimated the likelihood that such failure(s) will occur
- The facility has assessed the consequences if failure(s) occur, and assessed how prepared it is to manage the failure(s)
- Sterilization process failures are managed by developing and implementing plans to control them
- An interactive dialogue exists between sterile processing, OR and infection preventionists that actively informs the other concerned parties (patients and doctors) in the event of a recall
- Risk analysis is performed at least annually and reevaluated whenever significant changes occur

### Summary—Issues to monitor
1. Quality monitoring by routine observation and use of an auditing tool is recommended by TJC, CMS and AAMI and can be used for ongoing education. When all members of the team value the same process details, better compliance with procedures is ensured, as shortcuts that put the patient at risk are viewed as a personal reflection of unacceptable practice. Using these audit examples as a starting point, you will soon be able to customize them and establish a culture of observation that supports their routine use.
2. As the ANSI/AAMI ST79 recommended practice sums it up, “There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to appropriate individuals or groups/teams.”

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References


Cynthia Hubbard RN, BS, is an author and independent nurse consultant. She has worked in the healthcare industry for over 30 years, including positions in ER nursing, occupational health nursing, Materials Management, and Central Service management at Saint Mary Hospital - Mayo Clinic in Rochester, Minn. Cynthia was a design consultant on national and international construction projects related to sterile processing, materials and waste management for 14 years with the Lech Bates Hospital Group of Littleton, Colo. After moving to Washington State in 2003 Cynthia served as the sterile processing manager at Sacred Heart Medical Center in Spokane during their surgical building addition. She is a recipient of the ASHCSP Educator of the Year Award.

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CEU Applicant Name ________________________________
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4. A 9. A
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