Handout
For Your Information

Obtaining Contact Hours and Providing Comments
Log in to the Learning Center at My AORN to complete the evaluation at the close of the event.

AORN is provider-approved by the California Board of Registered Nursing, Provider Number CEP 13019, 1.0 contact hour.

Notice
AORN does not endorse any commercial company’s products or services. Any and all commercial products referenced or displayed in this program are expected to conform to professional medical/nursing standards. Inclusion in the program does not constitute or guarantee an endorsement by AORN of the quality or value of such product, or of the claims made by the manufacturer.

No responsibility is assumed by AORN, Inc. for any injury and/or damage to persons or property as a matter of products liability, negligence or otherwise, or from any use or operation of any standards, recommended practices, methods, products, instructions, or ideas contained in the materials herein, or referenced in this program. Because of rapid advances in medicine and health care sciences, independent verification of any diagnoses, treatment, medication, and/or individualized care referenced in conjunction with this program should be made. The material contained herein is not intended to be a substitute for the exercise of professional medical or nursing judgment.

The content of this program and contained in this publication is provided on an “as is” basis.

TO THE FULLEST EXTENT PERMITTED BY LAW, AORN, INC. DISCLAIMS ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR THIRD PARTIES RIGHTS, AND FITNESS FOR A PARTICULAR PURPOSE.

Copyright
Copyright 2021 AORN, Inc. AORN’s training and educational materials are protected under federal copyright and trademark law. Only registered attendees may use our materials. Any unauthorized use of our materials is strictly prohibited. Violations of these requirements or of our valuable intellectual property rights may incur substantial penalties, including statutory damages of up to $150,000 for a single willful violation of AORN’s copyrights.

Speakers are responsible for the content of their presentations and for obtaining permission to use any copyrighted material. AORN is not responsible for and does not assume any liability for presentations.
Disclosure

Jacqueline Daley, HBSc, MLT, CIC, CSPDS, FAPIC
Senior Manager Infection Prevention, Mission Hospital, Mission Viejo, California
Infection Prevention Consultant

Educational Consultant
  • 3M
  • Stryker - Sage
  • Boston Scientific
Polling Question

Is your ASC
1. Free-standing facility?
2. Affiliated with a hospital or health system?
3. Do not know

Learning Objectives

▪ Identify standards and guidelines impacting the practice of infection prevention.
▪ Discuss key areas of focus related to infection prevention and the environment of care.
▪ Define best practices for processing devices, instruments and equipment that has a direct impact on infection prevention.
Ambulatory Surgery Centers (ASC)

- Ambulatory surgery centers [ASC] are modern healthcare facilities focused on providing same-day surgical care, including diagnostic and preventive procedures.\(^1\)
- Regulated by state and federal government
- Free-standing, physician owned
- Hospital owned and licensed
- Presents opportunities for increased patient and surgeon satisfaction and lower costs
- Need for improved compliance monitoring and better reporting mechanisms
- Heightened awareness for infection prevention practices


Infection Control Assessment of Ambulatory Surgical Centers
Schaefer, MK et al. JAMA. 2010;303(22):2273-2279

**Objective:** To describe infection control practices in a sample of ASCs

**Main Outcome Measures:** Proportion of facilities with lapses in each infection control category.

**Results:** Overall, 46/68 ASCs (67.6%; 95% confidence interval [CI], 55.9%-77.9%) had at least 1 lapse in infection control.

- 12/68 ASCs (17.6%; 95% CI, 9.9%-28.1%) had lapses identified in 3 or more of the 5 infection control categories
- **Common lapses:** using single-dose medication vials for more than 1 patient (18/64; 28.1%; 95% CI, 18.2%-40.0%),
- Failing to adhere to recommended practices regarding reprocessing of equipment (19/67; 28.4%; 95% CI, 18.6%-40.0%), and
- Lapses in handling of blood glucose monitoring equipment (25/54; 46.3%; 95% CI, 33.4%-59.6%)
- **Other lapses** – Hand hygiene and use of PPE; environmental cleaning (high-touch surfaces in and out of OR)

**Conclusion:** Among a sample of US ASCs in 3 states, lapses in infection control were common.
Medicare-Certified ASCs - Based on data provided by the CMS May 2020

Total = 5,886


Specialties Performed in Medicare-Certified ASCs

- Other: 2,141 (37%)
- Orthopedic: 2,304 (36%)
- Ophthalmology: 2,806 (36%)
- Endoscopy: 1,894 (32%)
- Plastic: 1,751 (30%)
- Podiatry: 1,694 (29%)
- Otolaryngology: 1,424 (24%)
- Obstetrics/Gynecology: 1,209 (21%)
- Dental: 492 (9%)

Based on data provided by the Centers for Medicare & Medicaid Services (CMS), June 2019

Objective 1

Identify standards and guidelines impacting the practice of infection prevention.
Practices are influenced and dictated by
Regulators

Local and State Regulations

Standards, Guidelines and Professional Bodies

Sponsored by

Supported by

AORN | HOT TOPIC VIRTUAL FORUM
Prioritizing Infection Prevention in the ASC

AORN Foundation
Relevant Standards - AAMI

- ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities
- AAMI TIR34:2014/(R)2017 Water for the reprocessing of medical devices
- ANSI/AAMI ST90:2017, Processing of health care products - Quality management systems for processing in health care facilities
- AAMI TIR63: 2014/(R)2017 Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection
- AAMI TIR55:2014 Human factors engineering for processing of medical devices
- ANSI/AAMI ST40/(R) 2018 Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities

Relevant Guidelines

- Association of perioperative Registered Nurses (AORN)
  - Guidelines for Perioperative Practice
- CDC/HICPAC Guidelines
  - Disinfection and Sterilization in Healthcare Facilities (Updated May 2019)
  - Hand Hygiene in Healthcare Settings
  - Prevention of Surgical Site Infections
  - Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. (Updated July 2019)
  - Environmental Infection Control in Healthcare Facilities. (Updated July 2019)
- CDC/HICPAC Guidelines (cont’d)
  - Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care
- Other specialty surgical society/organization
  - Guidelines for the cleaning and sterilization of intraocular surgical instruments

Relevant Standards and Guidelines - Endoscopy

- American Society of Gastrointestinal Endoscopy (ASGE)
  - Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA)
  - Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes
- Association for the Advancement of Medical Instrumentation (AAMI)
  - ANSI/AAMI ST91: 2015 Flexible and semi-rigid endoscope processing in health care facilities
- CDC / Healthcare Infection Control Practices Advisory Committee - January 25, 2017

CMS Documents / CMS Requirements

- State Operations Manual (SOM)
- Conditions of Participation (COPs)
- Conditions for Coverage (CfCs)
- Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet
- Establish a program for identifying and preventing infections
- Maintaining a sanitary environment
- Reporting outcomes to appropriate authorities.
- Active surveillance program
  - Specific procedures for prevention,
  - Early detection, control and investigation of infectious and communicable diseases in accordance with the recommendations of nationally-recognized infection prevention authorities, such as the Centers for Disease Control and Prevention (CDC).

Objective 2
Discuss key areas of focus related to infection prevention and the environment of care.
Environmental Reservoirs

- Surfaces and equipment are potential reservoir for transmission
  - Contamination as a result of the patient and healthcare worker hands
    - Over bed tables, bedrails, furniture, call bell, light switches, doorknobs, counters where medications and supplies are prepared, IV poles, patient monitoring equipment (e.g., keyboards, control panels), equipment such as thermometers, stethoscopes, blood pressure cuffs, sink handles, edges of privacy curtains, transport equipment (e.g., wheelchair handles), etc.

- Eliminating the reservoir
  - Eliminate or contain the reservoirs of agents
  - Depopulate the environment / space
  - Interrupt the transmission of infection
  - Protect the host (patient, visitors, staff) against infection and diseases


Survival of Organisms on Surfaces

Survival of Organisms on Surfaces

- Clostridioides difficile spores – 5 months
- E. coli – 1.5 hours to 16 months
- Enterococcus species including VRE – 5 days to 4 months
- Klebsiella species – 2 hours to >30 months
- Pseudomonas aeruginosa – 6 hours to 16 months; on dry floor – 5 weeks
- Staphylococcus aureus including MRSA – 7 days – 7 months

Life span of organisms on surfaces

Kramer et. Al. BMC Infectious Diseases 2006;6:130
Survival of Organisms on Surfaces

- *Acinetobacter* species – 3 days to 5 months
- Hepatitis A Virus – 2 hours to 60 days
- Hepatitis B Virus – >1 week
- HIV – >7 days
- Influenza Virus – 1-2 days
- Rhinovirus – 2 hours – 7 days
- *Candida auris* – 14 days
- SARS-CoV 2 – 2 hours to 5 days

Kramer et al. BMC Infectious Diseases 2006;6:130

Transmission of Microorganisms through Contaminated Surfaces

- Cleaning procedures based on risk of pathogen transmission
  - Frequency
  - Method
  - Process

*Colonized surfaces can serve as direct sources for transmission to a second patient or in an indirect source in healthcare-related hands or equipment.

Content source: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP). Page last reviewed: October 13, 2020. Accessed 11/7/2020
Products for Environmental Cleaning

➢ EPA registered
➢ Intermediate to low-level disinfectants
  ▪ Accelerated hydrogen peroxide
  ▪ Quaternary Ammonium compounds (Quats)
  ▪ Sodium hypochlorite
  ▪ Peracetic acid-hydrogen peroxide
➢ Label claims
  ▪ Tuberculocidal
  ▪ Virucidal
  ▪ Fungicidal

➢ Disinfectant wipes vs. bucket method
➢ Wet time should be 10 minutes or less
➢ Care should be taken in selecting cleaning implements
  ▪ Impact of laundering vs use of a disposable
  ▪ Microfiber cloths
  ▪ Sponge cloths
  ▪ Cotton cloths

Assessment of Cleaning and Cleanliness

• Methods for assessing cleaning practice
  ▪ Direct performance observations
  ▪ Visual assessment / inspection
  ▪ Fluorescent markers

• Methods for assessing the level of cleanliness
  ▪ Measuring the residual bioburden (i.e., ATP)
  ▪ Bacteriological culture of the surface itself using a swab or contact agar plate method

Content source: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP)] Accessed 10/24/2020
Structured Approach

1. **Observe / Audit / Monitor environmental cleaning and disinfection**
   - Review product dilutions – Is it per the directions of the MIFU
   - Surface application – With what and how?

2. **Use cleaning verification**
   - ATP
   - Fluorescence markers
   - Bacterial culture

3. **Provide feedback and recommendations to key stakeholders**
   - Education – Back to Basics
   - Role of Technology

---


---

Safe Injection Practices

Sharp Safety
Safe Injection Practices

- Perform proper hand hygiene
- Medication preparation should be clean and free of blood, body fluids and contaminated equipment
- Preparing and administering injectable medications.
- Cleanse the access diaphragms of medication vials with 70% alcohol before inserting a device into the vial.
- Never administer medications from the same syringe to multiple patients, even if the needle is changed or the injection is administered through an intervening length of intravenous tubing.
- Never reuse a syringe to enter a medication vial or solution.
- Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient.
- Do not combine the leftover contents of single-use vials for later use.
- Do not use fluid infusion or administration sets (e.g., intravenous tubing) for more than one patient.
- Dedicate multidose vials to a single patient whenever possible. If multidose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle).
- Date multidose vials when opened and discard after 28 days (not the expiration date) or at anytime contamination is suspected.
- Dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.
- Adhere to federal and state requirements for protection of HCP from exposure to bloodborne pathogens.
- Needleless or safety engineered devices should be employed whenever possible.

OSHA Bloodborne Pathogens Standard

- Implement an exposure control plan with details on employee protection measures.
- Plan must also describe how to use
  - engineering and work practice controls,
  - personal protective clothing and equipment,
  - employee training,
  - medical surveillance, hepatitis B vaccinations, and other provisions as required
- Engineering controls
  - Primary means of eliminating or minimizing employee exposure
    - Includes the use of safer medical devices, such as needleless devices, shielded needle devices, and plastic capillary tubes.
- Process controls
  - Hands-free zones

NOTE 1 — Volume of red 40 dyne/cm synthetic blood delivered to white blotter papers.
NOTE 2 — Based on documented whole blood concentrations of infected patients.
What is an Infection Control Risk Assessment (ICRA)?:

- Tool used by the healthcare facility to identify and document risk of spreading disease during construction and renovation activities
- Focuses on decreasing the risk of infection
- Protect patients, hospital staff and visitors from infection
- ICRA goes from the start of the project until the space is occupied
- Coordinating/weighing knowledge about infection, infectious agents, and care environment-anticipating the impact

CDC Guidelines for Environmental Infection Control in Health-Care Facilities (2003) Last update: July 2019
https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf
Objective 4

Define best practices for processing devices, instruments and equipment that has a direct impact on infection prevention.
Environment of Care – Facility Design

- Centralize as much as possible
- Processing equipment requirements
- Instrument air for drying
- Sterilant requirements (e.g., steam, low temperature)
- Space constraints – potential issues
  - Work to be done in the space
  - Separation of clean and dirty
  - Workflow – clean to dirty to clean
    - Traffic control
    - Storage requirements – clean, sterile
    - Floors, walls, ceilings (stained tiles)
    - Lighting – Illuminance recommendations
- Emergency eyewash/drenching shower equipment
  - Plumbed to deliver warm water
  - Activate weekly to prevent stagnation
  - Risk assessment for HCW related to exposure with chemicals
- HVAC - Temperature, humidity, pressure relationships – Policies referenced
  - Temperature, humidity, air flow
  - Soiled work room temperature
  - Humidity (high/low prolonged periods of time)
  - Airflow patterns should not allow air contamination to enter clean areas
    - Pressure – direction of airflow (negative)
    - Air exchange
  - When out of range
    - Small variance, short time – No significance
    - Larger, longer variance - Critical thinking, multidisciplinary team decision
    - Action plans

Focus on Workflow

- AORN – When sterilization is performed within the surgical suite, a sterile processing room shall have
  - Separate clean and decontamination areas, which may be rooms or areas
  - Decontamination and clean spaces that are separated by one of three methods
    - a wall with a door or pass through
    - a partial wall or partition at least 4 feet high and width of the counter, or
    - 4 feet between instrument washing sink and area where instruments are prepared for sterilization
  - When same pathway must be used for clean/sterile and contaminated instruments and supplies
    - Ensure that all contaminated supplies are contained (leak proof) and labeled
    - Try to separate transport – clean and contaminated by time
    - Separate sink for instruments and for handwashing
    - Use drop-in sinks when additional sinks needed

AORN Guidelines for Perioperative Practice, AORN, Denver, CO. 2018
OSHA CFR 1910.1030 Bloodborne Pathogens
Personnel Considerations

- Policies and procedures
- Qualifications
  - Supervisors and processing personnel
- Education and training
  - Initial orientation, continuing education and in-service training
  - Documented competency
  - Certification
- Health and personnel hygiene
  - Hand hygiene (closely monitored by accreditation agencies)
  - Nails – polish / length/ natural or artificial
  - Storage requirements for alcohol-based hand rubs
  - Attire
  - Personal protective equipment
  - Safety Data Sheet (SDS)
    - Eye wash station (plumbed) / shower equipment (documented checks regularly)


Manufacturer’s Instructions

- Manufacturer’s written instructions for use (MIFU) are an integral part of instrument and device processing
  - Should be available for cleaning agents, disinfecting agents, packaging, instrument, devices and equipment (AERs, Sterilizers, etc.)
  - Should be up to date / most recent
  - Easily accessible to processing staff
  - Should be followed to allow for consistent processing of the same device/instrument every time
  - Multi-disciplinary team should develop instructions for cleaning, disinfection and/or sterilization should there not be one available from the manufacturer
  - IFUs should be reviewed prior to purchase of instrument, devices and equipment to ensure they are clear and easy to follow
  - Available in hard copy or electronic
Cleaning, Disinfection and Sterilization

Spaulding Classification

Critical devices
• Instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body, and products with sterile fluid pathways.
  ▪ Examples - surgical instruments, needles, transfer forceps, cardiac catheters, implants etc.
  ▪ High degree of risk of transmission of infection if contaminated and, therefore, must be sterile at the time of use.

Semi-critical devices
• Instruments or objects that contact intact mucous membranes or non-intact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body.
  ▪ Examples: noninvasive flexible and rigid fiberoptic endoscopes, endotracheal and aspirator tubes, bronchoscopes, laryngoscopes, respiratory therapy equipment, cystoscopes, vaginal specula, and urinary catheters
  ▪ Semi-critical devices should be sterilized; if not possible or feasible, the device, at a minimum, must be subjected to a high-level

http://www.aami.org/newsviews/newsdetail.aspx?ItemNumber=5243&isPhoto=0&isTrue
Understand basic definitions?

**Cleaning**
- Removal of organic soil
- Microbes and soil can still be present
- Device can still be infectious

**High-Level Disinfection (HLD)**
- Microbial kill under defined conditions
- Spores are not killed
- Effectiveness dependent on meticulous cleaning

**Sterilization**
- Kills all living organisms including spores
- Effectiveness dependent on meticulous cleaning

---

**High-Level Disinfection (HLD)**

- Staff knows difference between HLD and sterilization and can verbalize
- Semi-critical items, at a minimum, undergo HLD
- Automated (use of automated endoscope reprocessor (AER))
  - IFU available
  - Pre-cleaning of equipment
  - Documentation

**Manual Processing**

- Glutaraldehyde/OPA
  - IFU readily available
  - Bin covered
  - Solution in bin or receptacle dated – when activated, when expired
  - Solution remaining in bottle – expiration label
  - Quality control test performed and documented
  - MEC tested before each use and documented
  - Temperature monitored

---

http://www.cdc.gov/hicpac/Disinfection_Sterilization/cleaning.html
Water Quality

In wine there is wisdom, in beer there is freedom, in water there is bacteria.

Benjamin Franklin

• Water quality is extremely important for all stages of instrument and device processing
  ▪ Assess, treat and monitor
• Selection of water of the appropriate quality is important for:
  ▪ Cleaning contaminated medical devices
    • Manual and washer-disinfectors
    • Ultrasonic cleaners
    • Cart washers
  ▪ Diluting detergents and high-level disinfectants
    • Automated endoscope reprocessors (AER)
  ▪ Rinsing devices such as items that will be sterilized or high-level disinfected

• Water needs to be free of contaminants such as:
  ▪ Waterborne pathogens (Pseudomonas aeruginosa/Nontuberculous mycobacteria/Stenotrophomonas maltophilia, Legionella spp., etc.)
  ▪ Endotoxin / Biofilm
• Were you shut down during the pandemic?
  • Did you flush water systems?
  • Do you have a water management program?
  • Do conduct routine water testing?

Water, Water, Everywhere but can’t use a drop!

AAMI TIR34:2014 Water for reprocessing medical devices
Point of Use (POU) Treatment

- Wiping and flushing of instrumentation used during a case in the OR / procedure room
- Keeping instruments moist based on manufacturer’s instructions and facility policy and procedure until they reach processing area
- Multi-part instruments should be opened and disassembled according to manufacturer’s instruction for use
- Transportation from POU to processing areas
  - Pre-approved transportation routes
  - Sharps transport violates OSHA requirements
- Cleaning of equipment prior to removal

Focus on Handling, collection, and transport of contaminated items

- Reusable items should be separated from waste at the point of use. Contaminated disposable items should be discarded into an appropriate container; puncture-resistant containers must be used for sharps.
- All items contaminated with blood, body fluids, and tissue must be placed in a leakproof container before transport.
- Contaminated reusable items should be contained in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items.
- The procedures for packaging and transporting contaminated items off-site for processing must comply with applicable Department of Transportation (DOT) and state regulations.

Cleaning, disinfection (microbicidal processes), and other decontamination steps

- Policies and procedures
  - The health care organization should establish policies and procedures for all methods of cleaning and decontamination of reusable items.
  - Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up to address problems.
    - Maintains consistency and effectiveness of the cleaning and decontamination processes consistent with applicable standards and recommended practices.
    - Audits of the process can help to identify gaps so methods can be identified to improve the process.
  - In all cases, always follow the manufacturer’s written instructions.


Quality Assurance
Sterilization Process Monitoring Devices

• Physical monitors
  ▪ Gauges, digital printout, time/temperature/pressure recorders
  ▪ Used on every cycle
• Chemical indicators (CIs)
  ▪ Six types (Type 2 is the Bowie-Dick test for dynamic air removal sterilizers)
  ▪ Used on or in all package, tray, containers, pouches
  ▪ Do not verify sterility
• External indicators – process indicators; distinguishes processed from unprocessed
  ▪ Tape, label, card, tamper evident device
• Internal indicators – reacts to one or more of the critical variable of sterilization
  ▪ Assist in the detection of potential sterilization failures (e.g., incorrect loading, sterilizer malfunction)
• Biological indicators (BIs)
  ▪ Consist of standard viable spores in or on a carrier
  ▪ Measures lethality of the sterilization process

Sterility Assurance = Physical + Chemical + Biological

Routine Sterilizer Efficacy Monitoring

• Biological Indicator
  ▪ Steam/VH2O2 – Geobacillus stearothermophilus
  ▪ EO – Bacillus atrophaeus
  ▪ Used within a process challenge device
• Process challenge device (PCD)
  ▪ May contain BI and/or CI (Type 5 or Type 6)
  ▪ Commercially available, disposable, preassembled challenge pack
  ▪ User-assembled challenge test pack or test tray
• Routine load release of non-implantable devices
  ▪ PCD containing BI; or PCD containing BI and Type 5 CI; or PCD containing Type 5 or Type 6 CI
  ▪ Steam sterilizer tested weekly, preferably every day the sterilizer is used.
  ▪ VH2O2 sterilizers – each cycle type tested at least daily, preferably every load
  ▪ EO sterilization – every load
• Routine load release of implantable devices
  ▪ PCD containing a BI and Type 5 CI in every load
  ▪ Load not released until the results of the BI is known

ANSI/AAMI ST79:2017 Secn 3.5.3, Secn13.5.4 and Table 2; ST41:2008/(R)2012 Secn 10.5.3, Secn 10.5.4 and Table 2
AORN Guideline for Sterilization, 2018. Recommendations XX.h.4 and XX.h.5
High-Level Disinfection

- Monitoring of LCS/HLD (Quality Control)
  - Monitored before each use
    - Time, temperature, minimum effective concentration
    - Visual inspection of solutions and discard if precipitates observed
  - Follow manufacturer’s written instructions for use (IFUs)
  - Most manufacturers provide solution test strips or chemical monitoring devices for use with their products.
  - Biological and traditional chemical indicators are generally not labeled for use to monitor effectiveness or labeled for such use
  - Follow the manufacturer’s written IFU for all FDA-cleared indicators recommended for LCS/HLD
  - Document the results

ANSI/AAMI ST58:2013 Secn 7.4, 9.3

Special Considerations
**Immediate Use Steam Sterilization (IUSS)**

- Used for urgent / emergent needs
  - Situations outlined in policies and procedures available
- Efforts to reduce IUSS
  - Not for convenience
  - Not routine or frequent practice
  - Not used due to lack of equipment
  - Not used for lack of time
  - Documentation
  - Not performed on implants
  - Not performed on patients suspected to have Creutzfeldt-Jakob Disease (CJD)

- Device IFU provide IUSS instructions
- Instruments decontaminated as for items that will undergo terminal sterilization
- Process monitoring is done with
  - Physical
  - Biological indicator
  - Chemical indicator
- Items aseptically transferred immediately from sterilizer to the point of use
  - Not stored for future use on another patient or day

ANSI/AAMI ST79:2017 10.2.3

---

**Loaner Instrumentation – Best Practices to Avoid Impact on the OR**

- Need to have Manufacturer’s written Instructions for Use (IFU) including reprocessing instructions
- Staff need to be trained on the trays (disassembly, cleaning, inspection, packaging and sterilization)
- Some IFU provide excellent guidance, while others are poorly written and do not give clear guidance on cleaning issues for specific complex instrumentation and problem areas.
- Unfortunately, the SPD staff may not know or have the time to investigate problematic items if trays do not arrive for reprocessing in a timely manner

**Endoscope – Every Scope, Every Time**

- Quality Assurance program implemented (policies, competency, audit, oversight, IFUs, patient consent
- Dedicated personnel to process
- Competency on each type of scope and each manufacturer
- Instructions for processing - posted, be able to recite critical elements, accessories present
- Single use brushes (or decontaminated between each use)
- Debris not allowed to dry
- Point of use clean, leak test, pre-clean
- Quality monitoring policy current and implemented (manual cleaning)
- Drying - Alcohol flush / Drying Cabinet
- Hung vertical, not touching, vented cabinet, no cloth or chuck beneath scopes
- Tagged to identify processing date (or expiration date)

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td><strong>Brush all endoscope channels</strong></td>
<td></td>
</tr>
<tr>
<td>and components</td>
<td></td>
</tr>
<tr>
<td>Immerse endoscope completely</td>
<td>99</td>
</tr>
<tr>
<td>in detergent</td>
<td></td>
</tr>
<tr>
<td>Immerse components</td>
<td>99</td>
</tr>
<tr>
<td>completely in detergent</td>
<td></td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>96</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>84</td>
</tr>
<tr>
<td>Load and complete automated cycle</td>
<td>100</td>
</tr>
<tr>
<td>for high-level disinfection</td>
<td></td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>86</td>
</tr>
<tr>
<td><strong>Use forced air to dry endoscope</strong></td>
<td></td>
</tr>
<tr>
<td>Wipe down external surfaces</td>
<td>45</td>
</tr>
<tr>
<td>before hanging to dry</td>
<td>90</td>
</tr>
</tbody>
</table>

- Multiple steps skipped 45% of the time.
- Manual cleaning and automated high-level disinfection done correctly only 1.4% of the time
- ECR (automated cleaning and disinfection) performed correctly 75.4% of the time
Disinfection of Tonometers and other Ophthalmology Devices

Lack of compliance with reprocessing has been observed with the following items:
  • Tonometers
  • YAG laser lens
  • Eye specula

Record Keeping
Getting your material/documents in order is part of best practice!

- Policies and Procedures
  - Current, dated and signed
- Instructions for Use (IFU)
  - Intense focus
  - Organized
    - Electronic or paper
    - How are they filed?
    - Are they cross-referenced?
    - Do they cover all equipment, instruments and supplies?
- Accessible
  - If computerized staff must be able to work the program
  - Complete
  - Managed – management assigned
    - Process for currency
    - Process for obtaining

Sterile Storage, Transportation and Distribution
Quality in the Sterile Storage Area

- Store sterilized items in a separate area with adequate space until distributed for patient care use
- Restricted access / Controlled traffic
- Proper environmental conditions
  - Temperature, humidity and air changes
  - Positive pressure air flow (out)
  - No external shipping containers/corrugated cardboard
- Inventory is protected from contamination
  - Minimal handling
  - Store at least 8-10" from the floor, 18' below ceilings and 2" from outside walls
  - No storage on floor or windowsills
- Should not be stored next to sinks or under exposed water or sewer pipes or in locations where they may become wet

ANSI/AAMI ST79:2017, Section 11.1.1

Transportation of Sterile Packaged Items

- Items may be placed inside plastic or paper bags or boxes
- Reusable covers and carts should be cleaned after each use
- Check for leaks annually or more frequently
- Secure carts within vehicle
- Assess environmental conditions in vehicle both when in motion and not to see if condensate is a problem
- Decontaminate

“Sterile items should be transported in a manner that will protect the items from puncture and from contamination by moisture, excessive humidity, condensation caused by exposure to temperature extremes, insects, vermin, dust and dirt, excessive air pressures, and microorganisms.”

“All clean or sterile items being transported in uncontrolled environments should be in a covered or enclosed cart with a solid bottom shelf.”

“Vehicles used to transport sterile packages between health care facilities should provide for the complete separation of clean and sterile items from contaminated items.”

“Transport carts and tables should be large enough for all packages to be placed securely in the appropriate position (flat) without extending beyond the edge of the cart shelf or table surface.”
Quality Control
Continuous Quality Improvement

• QC is critical to successful reprocessing and improve performance
• All facilities should have a comprehensive QC program
  ▪ Product identification and traceability to the patient (each item, package labeled with detailed content list; implants critical)
  ▪ Documentation and record-keeping (epidemiological tracking and assessment of reliability)
  ▪ Verification and monitoring of the cleaning process (devices and equipment)
  ▪ Monitoring of high-level disinfection and sterilization processes
  ▪ Product recalls
  ▪ Quality process improvement

ANSI/AAMI ST79: 2017 13.3.1; ST41:2008/(R)2012 10.3
Continuous Quality Improvement

- Encompasses the entire sterilization and / or high-level disinfection process
- Conducting regular quality audits/tracers and the infection prevention and control risk assessment.
  - Assess all components of the sterilization process for the ongoing ability to achieve the desired outcome of consistently delivering a sterile product to the user.
  - Use trended data – e.g., # BI tests / BI failures for each sterilizer, IUSS percentages, education compliance (percent attending or percent passing tests or competency measures), time and completeness of sterilizer preventive maintenance, ability to locate all items during recalls, and completeness of test records.
- Staff should have an understanding of goals and PI activities.


Medical Device Risk Analysis

“The sterilization risk [medical device processing] analysis should be part of the health care facility’s overall infection prevention and control risk analysis in accordance with accreditation agency requirements.”

- Risk assessment (FMEA) (potential, likelihood and consequences) - PROACTIVE
- Risk management (failures needing immediate attention and plan of action) - REACTIVE
- Risk communication (Recall procedure) – HARDWIRE LEARNING

“It should be performed at least annually and should be reevaluated whenever significant changes occur.”

ANSI/AAMI ST79:2017 14.2.3
# Risk Assessment and Prioritization - Example

**Establish top priorities**

<table>
<thead>
<tr>
<th>Infection Issues, Condition, Problem and Events</th>
<th>PROBABILITY (Likelihood of Occurrence)</th>
<th>Outcome Severity (Harm)</th>
<th>Preparedness</th>
<th>Risk Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent/High</td>
<td>Occasional/Med</td>
<td>Uncommon/Low</td>
<td>Rare/None</td>
<td>Life Threatening</td>
</tr>
<tr>
<td>SCORE</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Risk Priority

\[ \text{Probability} \times \text{Outcome} \times \text{Preparedness} = \text{Risk Priority} \]

**Rank the identified risk - Is the risk High, Moderate or Low?**

**Risk Prioritization - Determine what level of risk you are willing to accept?**

**High/Very High Risk – (e.g., \( \geq 12 \))**
- Risk reduction a priority / unacceptable
- Urgent implementation of risk reduction strategies in a defined time period
- May need to stop or restrict the activity / apply interim solutions until completed
- May be resource intensive to implement additional measures
- Monitor to ensure that control measures are hard wired to prevent harm

**Medium / Moderate Risk – (e.g., 7 - 11)**
- Can the risk be lowered to an acceptable level?
- Risk reduction strategies should be implemented promptly
- Monitor for increasing risk especially if harm could result

**Very Low (No Risk) / Low Risk – (e.g., \( \leq 6 \))**
- Acceptable
- No further action is necessary
- Monitor for increase in risk and current practices maintained
Summary

✓ Compliance with regulatory, standards, guidelines, recommended best practices are key to preventing infections in the ASC
✓ Accreditation Agencies and CMS Conditions of Participation expects that patient will be cared for in a safe and sanitary environment.
✓ The environment plays a key role in disease transmission and a program should be in place to address not only environmental cleaning and disinfection but also monitoring of the cleanliness.
✓ Staff are trained and competency documented to perform sterilization / high-level disinfection
✓ Policies and procedures are up to date, based on the most recent standards / guidelines and appropriately referenced
✓ Manufacturers instructions should be up to date and followed consistently to ensure positive outcomes
✓ Monitoring of the sterilization and high-level disinfection processes are necessary to be assured sterility of instruments and devices
✓ Pay close attention to storage, distribution and transport of sterilized items
✓ Conduct ongoing tracers / audits / assessments to ensure expected outcomes
