Disinfection & Sterilization in the Ambulatory Surgery Center
9500+ Patients Potential Exposed to Hepatitis B, Hepatitis C, or HIV
Objectives

- Define important components in cleaning, disinfection, and sterilization
- Identify methods for cleaning, disinfection, or sterilization
- List risks of failure to properly clean, disinfect, or sterilize equipment
- Discuss importance of coordinated approach
Definitions

Clean - Remove visible foreign material
- Presoak – Sterile water and/or Enzymatic spray at point of use
- Manual – under water, hand scrub with low foam detergent

Decontamination - Remove pathogenic organisms and make equipment safe for handling
- Mechanical – ultrasound, washer sterilizer

Sterilization - Kill all microbes
- Steam – autoclave (pre-vacuum and/or gravity)
- Immediate Use
- Chemical – Glutaraldehyde, Ethylene Oxide, Hydrogen Peroxide, Peracetic Acid

Sanitize - Reduce microbial load on inanimate objects to relatively safe level
- Endoscopes
4 Methods

Sterilization – targets all microorganisms & spores. No effect on prions

High-level disinfection – targets all microorganisms except spores

Intermediate-level disinfection – destroys most virus and most fungi but not spores

Low-level disinfection – destroys vegetative bacteria, some viruses and fungi, but not spores or Mycobacteria
Regulations

Federal Insecticide, Fungicide, Rodenticide Act 1947 (FIFRA)

Specified
- Use Dilution
- Contact Time
- Method of Application
- Safety Precautions

Environmental Protection Agency (EPA)
- Disinfectants
- Including High Level Disinfectants
- Liquid Chemical Sterilants

Food and Drug Administration (FDA)
- Antiseptics

Occupational Safety and Health Administration (OSHA)

Bloodborne Pathogen Rule 1991
- Require EPA registration
- Disinfectant must be tuberculocidal
- Rule amended in 1997 - disinfectants must be effective against HIV & HBV
Spaulding Classification System

**Critical** – objects which penetrate sterile tissue or blood must be **Sterile**
- instruments, cutting endoscopes and accessories, cardiac and urinary catheters, and needles

**Semi-critical** – objects that touch mucous membranes or non-intact skin require **High level disinfection**
- respiratory and anesthesia equipment, bronchoscopes, and GI endoscopes

**Non-critical** – objects that only touch intact skin require **Intermediate & Low level disinfection**
- OR beds and linens)
Workflow for Sterile Processing

- Physical separation between a decontamination and processing area
- Decontamination → Preparation and Packaging → Sterilization and Processing → Distribution and storage
- Temperature & Humidity
  Decontamination area: 60 – 73 and 30% - 60%
  Sterile Processing: 72 – 78 and 30% - 60%
  * Not to exceed 70% in sterile storage
  * Must be documented 24/7
- Use of require PPE
- Transport soiled instruments closed container that is labeled as biohazardous
Decontamination

- Manual cleaning is the most critical step to prevent infection
- Pre-treating at point of use is recommend (sterile water soak or enzymatic solution)
- Disassemble anything that can be
- Brush lumens, channels, crevices, and joint; UNDER water to prevent splashing
- Follow manufacturers recommendation

Infection Control Considerations:
1) Proper use of required PPE to prevent exposure to contaminates and/or microorganisms
2) Routine cleaning of washer sterilizer with documentation
3) HAND HYGIENE
Sterilization

Steam

• **Pre-vacuum:**
  Sucks air out of the chamber
  Vacuum pressure at 273F for 18 minutes
• **Gravity displacement:**
  Air is force out of the chamber through drain
  Drain closes at 270F and cycle runs 60 minutes
• **Immediate Use:**
  Sterilized for use right now – not stored

Infection Control Considerations:

1) Wet wrappers are considered contaminated & should not be used
2) Never immediate use sterilize implants
3) Routine cleaning of autoclaves with documentation
4) Negative Biologicals for all implants
Indicator and Integrator

Chemical
1 – External heat (tape, locks)
2 – Pressure (Bowie Dick)
3 & 4 – Time and temperature
5 & 6 – Time, temperature (270F), Pressure, and steam/moisture

Biological
- Daily
- Steam – *Geobacillus stearothermophilus*
- Dry heat- *Geobacillus stearothermophilus*
- ETO – *Bacillus atrophaeus*
- Low temperature technologies (H2O2 gas) – *Geobacillus stearothermophilus*
- Adhere to Manufacturer’s Quality Controls recommendations
Failed Biologic Indicator

- Immediately take sterilizer out of service
- Notify director and infection control
- Quarantine all loads since failure and reprocess
- Begin investigation
  - Verify integrity of biologic indicator
  - Verify mechanical indicator (print out)
  - Verify operator input
    - Correct cycle selection
  - Verify correct plant operations
    - Loss of steam
    - Power loss
- Repeat biologic indicator in 3 consecutive runs
  - If any positive – call manufacturer for service
Chemical Sterilization

Used on heat and moisture sensitive equipment

- Gluteraldehyde
  - Point of use. No storage allowed
  - Cold sterilization
  - Takes 10 hours
  - Bad for instruments
  - Not a recommended form of sterilization

- ETO (ethylene oxide)
  - Gas concentration, temperature, humidity
  - Long cycle: 2-5 hours of exposure
  - Aeration required for 8-10 hours
  - Human carcinogen
  - Environmental hazardous
Chemical Sterilization

- Hydrogen peroxide gas plasma (Sterrad)
  - Requires synthetic packaging. No cellulose
  - Some devices with narrow long lumens cannot be processed (See manufacturer’s recommendations for length and diameter)
  - Dry sterilization; no aeration time required
  - Cycle time 75 minutes
  - Environmental sound

- Peracetic Acid (Steris)
  - Point of use. No storage allowed.
  - Small loads
  - Immersible instruments only
  - Temperature 120F – 130F
  - Corrosive to instruments and people
Sterile Storage

- Event related shelf life – consider the product sterile until an event causes it to become contaminated. Packaging evaluated before use for integrity
  - Tear or opening in packaging
  - Water damage

- Time related shelf life – consider item sterile for set period based on wrapping/packaging material. Once expiration date is passed, item must be removed from service. Discard or reprocess. If manufacturer has placed expiration date on package, item has time related shelf life.
Sterile Storage

- Segregated, protected area
- Covered shelving
- Solid surface bottom shelf
- Temperature control (68-75)
- Humidity control (30%-70%)
- Air exchange per hour
- 8-10 inches off floor
- 18 inches below ceiling
- 2 inches from outside wall
Cleaning of Washer & Autoclaves

• Washer:
  - Remove spray arms & rack
  - Flush arms to remove build up
  - Clean bottom of chamber to ensure drainage

• Autoclaves:
  - Daily drain strainer checks to prevent clogs
  - Monthly chamber cleaning to remain deposit
  ** May need to be more frequent based on local water conditions
Total Joint Sterilization

Knee replacement huh? I'm pretty sure Thunder wasn't told that was an option.
Infection Control Considerations

- All sets should be brought in 48 hours in advance; at minimum 24 hours
- All sets need to be separated into 25 pound instrument sets
- All sets must be processed through the washer sterilizer
- All implants must be processed with a biological indicator
- All sets must be ran with a Class 5 integrator
- Never accept sterilized sets in dust covers
- Never immediate use for a dropped implant
Endoscope Sterilization

“Do you sterilize your instrument after each use?”

“Well, I know my endoscopes are sterilized after every use, but I have no idea who does it.”
Infection Control Considerations

• Leak testing performed before placed in cleaning solutions

• Manual cleaning ASAP in fresh cleaning solution
  * Not allowed to dry
  * Brush channels, raise and lower elevator
  * Tap water rinse

• Kept damp or wet but not submerged during transport to decontamination

• Clean within 1 hour or follow delayed processing instructions
  * Delayed processing – label with procedure end time
Infection Control Considerations

• Visually inspected after manual cleaning
• Mechanical processing according to manufacturer’s instructions
  * Processor is approved for cleaning scopes
  * Soaking for high-level disinfection no longer recommended
  * Positioned so all surfaces come in contact with the solution
• Rinse with sterile water or alcohol
Endoscopes Storage

• Not stored in procedure rooms
• Stored in a drying cabinet
  - Hanging; not touching the bottom of the cabinet
  - Laying flat; must have blow out device connected
• If drying cabinet not available – cabinet MUST have HEPA filtered air with positive pressure
• Storage time established by multidisciplinary team: IP, endo nurse, SPD, endoscopist
• Cleaning verification testing determines the number of days consider “sterile”

Hospital or third party reprocessor is regulated the same as original equipment manufacturer

A device labeled for single use is considered a new device if reprocessed. The reprocessor is considered the manufacturer.

As a new device, all federal (FDA) controls regarding the manufacture and marketing of the device apply.
## Survival Rates

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Survival Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>24-48 hrs</td>
</tr>
<tr>
<td>MRSA</td>
<td>63 days</td>
</tr>
<tr>
<td>VRE</td>
<td>58 days</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>33 days</td>
</tr>
<tr>
<td>C. diff spore</td>
<td>5 months</td>
</tr>
<tr>
<td>Pseudomonas</td>
<td>7 hours</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>7 days</td>
</tr>
<tr>
<td>Norovirus</td>
<td>12 days</td>
</tr>
<tr>
<td>SARS</td>
<td>24-72 hrs</td>
</tr>
<tr>
<td>Candida sp.</td>
<td>3 days</td>
</tr>
<tr>
<td>Parainfluenza</td>
<td>10 hrs</td>
</tr>
</tbody>
</table>
Staff Consideration

• Provide comprehensive training for all staff assigned to process medical/surgical instruments
• Provide access instructions for use (IFUs) for all instruments and equipment
• To achieve and maintain competency
  • Hands on training
  • All work supervised until documented competency
  • Includes review of written instruction to assure compliance and uniformity
  • Conducted at hire and annually
Infection Control Role

• Periodic review of policies and procedures
• Annual review of disinfectants
• Regular review
  • Expired items
  • Flash sterilization logs
  • Sterilization monitor logs
  • Temperature and humidity logs
• Observations
  • Hand hygiene
  • Proper personal protective equipment
  • Validation of processes
# STERILE PROCESSING & HIGH-LEVEL DISINFECTION ROUNDS TOOL

<table>
<thead>
<tr>
<th>STANDARDS</th>
<th>Compliant</th>
<th>Compliant</th>
<th>N/A</th>
<th>DESCRIPTION/COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. ADMINISTRATIVE REQUIREMENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Manufacturers’ written instructions current, readily available to staff, and followed for:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Equipment</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Instruments</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Cleaning solution</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. All sterilization and reprocessing policies and procedures readily available for staff</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Orientation and annual education performed and documented</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Demonstrated knowledge of and documented competence</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Continuing education at regular intervals</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Training for all new instrumentation, devices, and equipment</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Equipment maintenance records maintained</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Sterilization records storage follows the facilities record retention policy</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Management of loaner instrumentation program in place</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Consistently adhering to dress code (facial hair covered, facility laundered scrub attire)</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Hands are washed after removing PPE</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. PPE readily accessible, worn and removed as indicated</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Regularly auditing and documenting adherence to cleaning disinfection, sterilization and device storage procedures</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>II. POINT OF USE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Disposable sharps are separated from reusable items</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Delicate instruments are kept separated</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Instruments are kept moist prior to transport and decontamination</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td>Note: If used instruments are pre-soaked in enzymatic solution at point of use, they are transported inside a closable container in a manner preventing spilling/cross contamination.</td>
</tr>
<tr>
<td>1. Instruments are not cleaned in hand sinks or scrub sinks</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Contaminated items are properly contained during transport</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Containment devices are appropriately labeled with biohazard warning symbols or identified by color</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transport devices are decontaminated between each use</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------</td>
<td>-----</td>
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<td></td>
</tr>
<tr>
<td>1.</td>
<td>Time between use and decontamination is minimized</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### III. DECONTAMINATION ROOM

<table>
<thead>
<tr>
<th></th>
<th>Are instruments pre-cleaned or soaked soon after use?</th>
<th>YES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Clean and dirty areas and processes separate and do not cross over</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Cleaning brushes are reusable and in good working condition; disinfected daily or cleaning brushes are discarded after use</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Brushing occurs under water</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>
| 1. | Appropriate cleaning and decontamination solutions:  
   a. Dilution measuring cups and lines in the sink for accurate measuring  
   b. Expiration dates labeled  
   c. Solution labeled with appropriate hazardous warning symbols | YES |   |
| 1. | Instruments are not cleaned in hand sinks or scrub sinks | YES |   |
| 1. | Water quality meets manufacturers requirements | YES |   |
| 1. | Disinfectant concentration is tested per manufacturer’s recommendations | YES |   |
| 1. | Weekly Instrument Washer Tests performed and documented or more frequently as recommended by the manufacturer. | YES |   |
| 1. | Supplies necessary for cleaning all instruments and devices are easily available, adequately stocked and in good condition | YES |   |
| 1. | If microsurgical ophthalmic instruments are used, they are cleaned separately from other surgical instruments per manufacturer’s written instructions. |   |   |
| 1. | Staff can describe all processes related to decontamination | YES |   |
| 1. | Ultrasonic cleaners solution is changed daily and ultrasonic cleaned daily |   |   |
| 1. | Staff wear appropriate PPE |   |   |
| 1. | Floors, walls, ceilings, back splashes and work surfaces are constructed of materials that can stand frequent cleaning |   |   |

### IV. INSTRUMENT PREPARATION

<table>
<thead>
<tr>
<th></th>
<th>Supplies necessary for packaging and wrapping all instruments and devices are easily available, adequately stocked (integrators, packaging, wrapping, tape, protectors, markers, etc.)</th>
<th>YES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Hand hygiene dispenser present</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Items are properly packaged, wrapped, and properly identified</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Labeling on indicator tape, patient record cards or plastic side of peel packs</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Instrument set weights not over 25 pounds</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>
Double pouching should not be performed without written instructions from the pouch manufacturer indicating that the practice has been validated and the pouch in question has been cleared by the FDA for this purpose. If double peel packs are used, the pack is NOT folded over.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Internal and external chemical indicators (CI) used for all packages</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Geometric center of wrapped packages</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Two opposite corners in rigid containers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. On all levels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

V. STERILIZATION

1. Cleaning schedule for sterilizers in place | YES |   |

For dynamic air-removal sterilizers, daily Bowie Dick testing in an empty chamber

1. Instruments sterilized in open position (e.g., scissors) | YES |   |

Sterilization load record consisting of: date, load #, sterilizer #, operator’s name, items, quantity of each item, biological indicator lot # (if needed), biological control lot #. | YES |   |

A process (policy and procedure) in place to ensure proper reprocessing of loaner instruments from vendors or other medical facilities to include vendor is approved/certified to provide these services. | YES |   |

Implants are monitored with an internal and external Chemical Indicators and monitored with a Process Control Device containing a biological indicator and a Class 5 integrating indicator. | YES |   |

Implantable devices are quarantined until BI results are negative | YES |   |

Biological indicator failure equipment recall process in place and reported to Infection Control Designee. How frequent are recalls? | YES |   |

Sterilization monitors Weekly, preferably daily (ie, each day the sterilizer is used), monitoring with a PCD containing a BI; the PCD also may contain a CI | YES |   |
| a. The same lot number is used for the control and the processed BI | YES |   |
| b. Chemical Indicators are used in every load | YES |   |

Every biological record is checked for result and properly recorded | YES |   |

IUSS parameters are documented | YES |   |

IUSS cycles are checked daily to assure completeness | YES |   |
| 1. | Use of closed flash containers | YES |
| 1. | Aseptic transportation to point of use | YES |
| 1. | All IUSS is traceable to the patient | YES |
| 1. | IUSS log is maintained and includes reason for IUSS | YES |
| 1. | Volume of IUSS sterilization is tracked to determine need for intervention to reduce-not used as a substitute for insufficient instrument inventory. | YES |
| 1. | IUSS frequency and reason is report to the IC Committee and/or Quality Council with recommendations reported to MEC & GB. | YES |
| 17. | High Level Disinfection (HLD) | YES |
| 18. | Semi-critical equipment is high-level disinfected or sterilized | YES |
| 18. | Items are pre-cleaned according to manufacturer’s instructions or evidence-based guidelines prior to high-level disinfection | YES |
| 18. | Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection | YES |
| 18. | High-level disinfection equipment is maintained according to manufacturer instructions | YES |
| 18. | Chemicals used for HLD are prepared according to manufacturer instructions | YES |
| 18. | Temperature of HLD chemicals are checked and recorded per manufacturer’s instructions | YES |
| 18. | Chemicals used for HLD are tested for appropriate concentration according to manufacturer instructions or evidence based guidelines and are replaced before they expire | YES |
| 18. | Chemicals used for HLD are documented to have been prepared and replaced according to manufacturer’s instructions or evidence-based guidelines | YES |
| 18. | Equipment is HLD according to manufacturer’s instructions or evidence-based guidelines | YES |
| 18. | Items are rinsed according to manufacturer’s instructions | YES |
| 18. | Items that undergo HLD are dried before re-use | YES |
| 18. | HLD logs are in order | YES |
| 18. | Test strips are properly dated | YES |
| 18. | Control checks on test strips are performed and documented according to manufacturer’s instructions | YES |

VI. STERILE STORAGE

1. Sterile supplies stored at least 2 inches from the outside wall, 18 inches below the ceiling (or level of the sprinkler head), and 8-10 inches above the floor to prevent contamination from floor dust and cleaning | YES |
1. Bottom storage shelves of supply cart(s) are solid to prevent contamination from floor dust and cleaning

2. Sterilized items are stored and rotated with FIFO process (first in first out) by expiration date

3. Storage area is clean, dry adequate and integrity of packaging maintained

4. Sterile items separate from clean items

5. Staff can describe expiration dates and event related sterile storage

6. Heavy wrapped trays are not stacked

7. No web-edged or corrugated boxes

8. Space proportioned to expected volume

9. Inappropriate or unnecessary equipment and supplies are not present in the area

10. Ceiling flush surface, no shedding materials with recessed and enclosed pipes

11. Equipment maintenance records maintained

12. Functional work flow pattern (dirty to clean)

VII. PHYSICAL ENVIRONMENT

1. Area restricted to authorized personnel only

2. Flooring is in good conditions.

3. All surfaces are in good conditions with no areas impaired which may allow microbial growth.

4. Vents are clean and free of dust.

5. All areas have a functional work flow pattern (dirty to clean)

6. Doors and pass-through windows are kept closed when not in use

7. Cardboard boxes removed before items are brought to restricted areas

8. Temperature and humidity levels monitored and recorded daily

   a. 68-73 degrees F clean areas*

   b. 60-65 degrees F decontamination areas*

   Humidity

   a. 30-60% work areas*

   b. Less than 70% in sterile storage areas*

   * unless otherwise required by state regulations

9. Ventilation

   a. Soiled area, negative pressure (6 air exchanges per hour)

   b. Clean/sterile areas, positive pressure (10 air exchanges per hour)

10. Housekeeping procedures

    All areas cleaned daily (should be the same as in OR)

11. Separate cleaning equipment for decontamination
### Do processes appear efficient in SP with items/areas tidy and well labeled?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Environmental Services support is adequate—environment is clean and orderly |
|-----------------------------|--------------------------|
| YES | NO |

| Hand Hygiene supplies adequate and conveniently located in all areas (soap, water, lotion, and degermer) |
|-------------------------------------------------|--------------------------|
| YES | NO |

| Handwashing stations conveniently located in clean and decontamination areas |
|---------------------------------|--------------------------|
| YES | NO |

| Eye wash stations located within 10 seconds travel time to areas where hazardous chemical use occurs |
|-------------------------------------------------|--------------------------|
| YES | NO |

| No supplies are stored on the floor |
|-------------------------------------|--------------------------|
| | |

| Food and drink are absent from the work areas. |
|-----------------------------------------------|--------------------------|
| | |

### VIII. HANDLING AND DISTRIBUTION OF STERILE ITEMS

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Items transported are covered or contained during transport |
|-------------------------------------------------|--------------------------|
| YES | NO |

| Transport carts, if used, have a solid bottom shelf |
|---------------------------------|--------------------------|
| YES | NO |

| Carts and transport devices, covers, and containment devices are decontaminated between uses |
|---------------------------------|--------------------------|
| YES | NO |

| Unused items returned to inventory are inspected for package integrity |
|-----------------------------------------------------------------|--------------------------|
| YES | NO |

### REFERENCES:

- AORN Guidelines for Peri-Operative Practices 2018
- The Joint Commission Position Statement on Steam Sterilization, 2018
- Oregon Patient Safety Commission “Sterile Processing & High Level Disinfection Rounds Tool”
Joint Commission

EC.02.04.03 – The organization inspects, tests, and maintains medical equipment

4) The organization conducts performance testing of and maintains all sterilizers. These activities are documented

IC.02.02.01 – The organization reduces the risk of infections associated with medical equipment, devices, and supplies

1) Cleaning and performing low-level disinfection of medical equipment, devices, and supplies

2) Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies

5) When reprocessing single-use devices, the organization implements infection prevention and control activities that are consistent with regulatory and professional standards
• Chapter 7 – Infection Control

Subchapter 1D: Safe processes are used for the cleaning, decontamination, high-level disinfection, and sterilization of instruments, equipment, supplies, and implants

Subchapter 1F: Safeguards are in place to protect patients and others from cross-infection

Subchapter 1H: Medical devices for use with multiple patients are processed between patients according to the manufacturer’s instructions or nationally-recognized guidelines, whichever are more stringent

Subchapter 2H: Reprocessing of manufacturer-labeled single-use devices complies with FDA regulations and is limited to devices approved for reprocessing in accordance with FDA 510(k) clearance

• Chapter 10 – Surgical and Related Services

Subchapter 10K: The surgical environment contains safeguards to protect patients an others from cross-infection.
Survey Required Reportable to CMS

- Improper cleaning and disinfection of endoscopy
- Improper cleaning and sterilization of surgical instruments
- Insufficient (or no) monitoring and documentation of cleaning, high level disinfecting (HLD), and sterilization; failure to follow manufacturer’s instructions for use (IFUs)
416.42 Surgical Services

- That equipment is available for rapid “emergency” high-level disinfection/sterilization of operating room materials.
- That equipment is available are packaged, handled, labeled, and stored in a manner that ensures sterility e.g. in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- That temperature and humidity are monitored and maintained within acceptable standards of practice.

416.51 Infection Control

- HAI risk mitigation measure include addressing aseptic techniques used in surgery, including sterilization or high-level disinfection of instruments
TDSHS - 25 TAC 135

• 135.7(a) – All health care practitioners shall have the necessary and appropriate training and skills to deliver the services provided by the ambulatory surgery center.

• 135.11(b) – A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross infection, shall be assured through the provision of adequate space, equipment, and personnel.

11E – Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile
135.11(b)(12) – Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be developed, implemented and enforced.

A – Policies and procedures shall be developed following standards, guidelines, and recommendations issued by the AORN, APIC, CDC and, if applicable SGNA

B – Policies and procedure shall also address proper use of external chemical indicators and biological indicators

C – Performance records for all sterilizers shall be completed for a period of six (6) months

D – Preventive maintenance of all sterilizers shall be completed according to manufacturer’s recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least one year and shall be available for review to the facility within two hours of request by the department
Resources

• CDC – https://www.cdc.org
• WHO - http://www.who.int/
• FDA - https://www.fda.gov/
• OSHA – https://www.osha.org
• AAMI – http://www.aami.org
• AORN – https://www.aorn.org
• APIC – https://apic.org
• SGNA - https://www.sgna.org/