Welcome!

Topic: Part II – Review of key information from ST79, Sections 3 - 9
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Housekeeping
- Questions
  - Mute feature (*7 = unmute; *6 = mute)
  - "Chat" feature
- Technical difficulties
- CE Credits
- Pod session follow-up

For more information: www.3M.com/3MSterileU

Disclosure Statement

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3M Sterilization Tech Line 1-800-441-1922 Option "2"
Objectives

- Describe recommended practices related to decontamination, packaging and preparation
- Describe the different types of steam sterilization processes and cycle parameters

ST79, Sections 3-9

- Design considerations (3.1 –3.4)
- Personnel considerations (4.1 – 4.6)
- Receiving (5.1 – 5.3)
- Handling, collection, and transport of contaminated items (6.1–6.5)
- Cleaning and other decontamination processes (7.1 – 7.7)
- Packaging, preparation, and sterilization (8.1 –8.12)
- Installation, care, and maintenance of sterilizers (9.1 – 9.7)

Related Annexes (Sections 3-9)

- Annex A – Examples of work place design
- Annex B - Infection transmission
- Annex C - CJD
- Annex D - User verification of cleaning processes
- Annex E - Selection and use of chemical disinfectants
- Annex F - Thermal disinfection
- Annex G - Devices returned to the manufacturer
- Annex H - OSHA blood borne pathogen standard
- Annex N - TASS
Section 3 - Design Considerations

- Work area design and functional workflow
- Physical facilities
- Housekeeping procedures

Examples of Workplace Design (Annex A)

Sample illustrations
- Typical small hospital
- Medium-sized hospital
- Regional processing center
- Ambulatory surgery facility
- Dental facility

Work areas separated by walls, partitions
- Space proportioned to expected volume
- Floors and walls
  - Level, and able to withstand frequent cleaning
- Ceilings
  - Flush surface, with recessed and enclosed pipes
- Doors and windows kept closed
  - (Including pass through windows)
- Handwashing stations conveniently located
  - Clean, and decontamination areas
- Eye wash stations
  - Within 10 seconds travel time
  - Ability to flush for 15 minutes
Section 3 - Design Considerations

- Traffic patterns
  - Dirty to clean
  - Restricted to authorized personnel
- Temp and humidity levels monitored and recorded daily (3.3.6.5)
  - Temperature
    - 68-73°F clean areas
    - 60-65°F decontamination areas
  - Humidity
    - 30-60% in work areas
    - Not over 70% in sterile storage areas
- Housekeeping (3.4)
  - Separate cleaning equipment for decontamination
  - All areas cleaned daily (should be the same as in OR)

Section 4 – Personnel considerations

- General rationale
- Qualifications
- Training and continuation education
- Health and personal hygiene
- Attire
- Standard/transmission-based (enhanced) precautions

Section 4 – Personnel considerations

- Qualifications (4.2)
  - Supervisor
  - Sterile Processing personnel
- Training and continuing education (4.3)
  - Sterile Processing personnel
  - Service personnel
  - Other personnel
- Health and personal hygiene (4.4)
- Attire (4.5)
- Standard/transmission-based precautions (4.6)
Section 4 – Personnel considerations

Attire (4.5.1)
- Clean uniforms donned at facility
  - Laundered in the facility if contaminated
- Shoes clean, non-slip soles and sturdy
  - Prevent injury from dropped items
- Head and facial hair cover
- No jewelry or wrist watches
- Change into street clothing if traveling between buildings and leaving the campus

Section 4 – Personnel considerations

Decontamination area (4.5.2)
- Appropriate PPE – EYE PROTECTION
  - Protection against liquid splashes and of microorganisms and chemicals
  - Goggles, full-length face shields
  - Still need to wear a mask if use a face shield
- Appropriate PPE – GOWNS
  - Protect from splash and splatter
  - Liquid-resistant covering with sleeves
  - Change if gets wet or soiled

Section 4 – Personnel considerations

Decontamination area (4.5.2)
- Appropriate PPE – MASKS
  - Fluid-resistant to protect from splash or splatter
  - Cover nose and mouth
  - Donned mask is considered contaminated
    - can spread microorganisms if worn around the neck, stuffed into a pocket, or perched on the forehead
Decontamination area (4.5.2)

- Appropriate PPE - GLOVES
  - Prevent punctures, contact with microorganisms, decrease cross-contamination
  - General purpose heavy-duty, water proof, long and cuffed
  - Pick up sharps with forceps and discard in puncture-resistant container
  - Still need to wash hands

Decontamination area (4.5.2)

- Decontaminate reusable PPE at least daily and between employees
  - when the integrity of reusables is compromised they cease to function as a protective barrier and must be discarded
- Replace torn gloves immediately
- Remove all disposable PPE prior to leaving the decontamination area, being careful not to contaminate scrub suit or skin
- Wash hands prior to leaving the decontamination area

Section 5 – Receiving

- General rationale
  - Receiving of purchased or loaner items
    - No external shipping containers in the preparation or sterile storage area
    - Newly purchased instruments/rigid sterilization container systems should be inspected and decontaminated
    - Sterile disposable items — preparation/sterile storage areas
- Disposition of sterile items (issued but not used)
  - Issued to a controlled environment, (e.g. OR) may be returned to sterile storage if the integrity of the package has not been compromised
  - Opened, or have damaged packaging, should be reprocessed through decontamination
Section 6 – Handling, collection, and transport of contaminated items

- General rationale
- Separation of waste and reusable items at point of use
- Care and handling of contaminated reusable items at point of use
- Containment
- Transport

Transport (6.1 – 6.5)

- Point of Use
  - Gross soil should be removed
  - Waste and reusable items separated
- Carts, reusable covers, bins and other containers should be decontaminated after each use.
- Dedicated soil lifts should be periodically decontaminated
- Items kept moist in the transport container
  - Towel moistened with water, foam, spray, or gel product
  - Avoid transporting in liquid

Transport Between Buildings and Off-site (6.5.6, 6.5.7)

- Vehicles should provide for complete separation of contaminated items from clean and sterile items.
- Transportation vehicles should be completely enclosed and decontaminated between trips
- Procedures for packaging and transporting contaminated items off-site for processing must comply with applicable DOT and state regulations.
Section 7 – Cleaning and other decontamination processes

- General rationale
- Policies, procedures, and manufacturers’ Instructions
- Presoaking
- Disassembly
- Cleaning
- Microbicidal processes
- Servicing and repair of devices in the health care facility

Presoaking and Disassembly (7.3, 7.4)

- Presoaking with a specialized product (e.g., an enzymatic solution) is recommended
- Thoroughly rinse after presoaking
- Instruments composed of more than one part should be disassembled
  - Care should be taken to ensure that all small parts are contained.
- Sterilization container systems should have filters, labels and locks removed

Manual Cleaning (7.5.3.2)

- Brushes and other cleaning implements should be specifically designed for use on medical devices
  - Single-use
  - If reusable, be decontaminated at least daily
- The device manufacturer should provide information regarding brush size for cleaning devices with lumens
- Brush and flush under water
- If item cannot be immersed - clean in a manner that will not produce aerosols
Section 7 – Cleaning and other decontamination processes

Mechanical Cleaning (7.5.3.3)

- Types
  - Utensil and cart washers,
  - Washer-sanitizers,
  - Pasteurization equipment,
  - Washer-disinfectors,
  - Washer decontaminators,
  - Washer-sterilizers

- Ultrasonic cleaners:
  - De-gassed prior to use
  - Clean items of gross soil before placing in ultrasonic
  - Use recommended ultrasonic detergent (low foaming)
  - Lid must be kept closed (aerosolization)
  - Water must be changed frequently

Section 7 – Cleaning and other decontamination processes

Mechanical Cleaning (7.5.3.3)

- Regular PM should be performed according to MFG instructions upon installation, weekly (preferable daily) during routine use, and after major repairs.
  - Outside the scope of routine preventive maintenance, and significantly affects the performance of the equipment
  - Examples of major repairs
    - Replacement of the water pump(s),
    - Detergent delivery system,
    - Heating system,
    - Water delivery system,
    - Water treatment system,
    - Computer control or an upgrade to software.

Section 7 – Cleaning and other decontamination processes

Rinsing (7.5.4)

- After cleaning (manual and mechanical) items should be thoroughly rinsed
  - Copious amounts of tap water can be used
  - Final rinse should be performed with free flowing treated water
Section 7 – Cleaning and other decontamination processes

Microbicidal process (7.6)
- Chemical disinfection
- Chemical sterilization for decontamination
- Thermal (hot water) disinfection
- Thermal sterilization for decontamination
- Terminal sterilization
- Chemical sterilization
- Thermal terminal sterilization
- Flow chart for microbicidal processes (7.6.1)

Section 7 – Cleaning and other decontamination processes

Thermal Disinfection (hot water) (7.6.2.3)
- Thermal disinfection is accomplished with automated equipment, such as:
  - Washer-sanitizers,
  - Pasteurization equipment,
  - Washer-decontaminators, and
  - Washer-disinfectors
- The level of disinfection achieved depends on the water temperature and contact time

Section 7 – Cleaning and other decontamination processes

Servicing and Repair of Devices in the Healthcare Industry (7.7)
- Device manufacturers:
  - Provide training for their service personnel, and
  - Instructions to users to help prevent exposure
- HC institutions:
  - Provide PPE, and
  - P&P to ensure service personnel not exposed to infectious agents
- Service personnel include:
  - Manufacturers' representatives,
  - In-house clinical engineers and biomedical technicians, or
  - Third-party service providers
Section 7 – Cleaning and other decontamination processes

Infection Transmission – Annex B

- Purpose of decontamination process is prevent the transmission of disease
- Understanding the chain of infection:
  - Helps to develop and implement policies and procedures
  - Reduce the risk of infection transmission

Section 7 – Cleaning and other decontamination processes

Processing of CJD-contaminated Patient Care Equipment - Annex C

- Provides general guidance for reprocessing instruments and medical devices exposed to patients known or suspected to have Creutzfeldt-Jakob disease (CJD)
- Not readily inactivated by conventional disinfection and sterilization procedures

Section 7 – Cleaning and other decontamination processes

User Verification of Cleaning Processes – Annex D

- Cleaning verification by users should include:
  - Visual inspection and assessment:
    - External surfaces, inner housing, and channels
    - Testing the cleaning efficacy of equipment, and
    - Monitoring key cleaning parameters (e.g., temp.)
- Manufacturers should provide users with cleaning verification tests that enable them to quickly test medical devices directly after cleaning
  - Table D.1 and D.2 currently available test methods

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Section 7 – Cleaning and other decontamination processes

TASS (Highlights Annex N)

- Specified concentration of the recommended cleaning agent
- Final rinsing sterile, distilled, or deionized water
- Single-use brushes should be used and disposed
- Sterilize per instrument manufacturer recommendations
  - Avoid immediate-use steam sterilization (flash)

Section 8 – Packaging, Preparation, and sterilization

- General rationale
- Selection of packaging materials
- Package configurations and preparation
- Preparation and assembly of surgical instrumentation
- Loading the sterilizer
- Sterilization parameters
- Monitoring sterilization cycles (covered in Section 10)
- Unloading the sterilizer
- Sterile storage
- Distribution (general)
- Transport of sterile packaged items
- Aseptic presentation

Selection of packaging materials (8.2)

- Match packaging to the item and inventory requirements
  - The package must remain sterile in storage; selection of the packaging material is basic to meeting this goal
- Training required
  - Sterilization method and the medical devices to be sterilized affect the choice of materials
  - Manufacturer’s test data and instructions for use
  - Base packaging procedure and policy on the manufacturer’s instructions for use and expiration
  - Not all packaging materials are effective for all sterilization methods
Section 8 – Packaging, preparation, and sterilization

Package configurations and preparation (8.3)

- Reusable woven textile
- Disposable nonwoven materials
- Peel pouches/dust covers
- Rigid sterilization containers

Environmental factors
- Before use hold packaging at room temperature (20°C – 23°C [68°F to 73°F]) and a relative humidity of 30–60% for at least 2 hours.
  - If packaging is to dry, superheating may occur.

Inspection of materials
- Examine packaging materials prior to use.
- Wrap snug to prevent low spots that could collect condensate on the exterior of the package, but not too tightly to impede process.
- Repack, replace chemical indicators (CIs).
- Dispose of peel pouch contents if gauze or cotton balls.

Review the sterilizing cycle conditions
- Drying cycle length and temperature
- Set contents, weight, & density (especially metal mass)
- Loading of the sterilizer and position of wet pack

Reprocess after detecting the error or probable cause of the wet pack

Perform process audits to ensure adherence to procedures.
Section 8 – Packaging, preparation, and sterilization

Package configurations and preparation (8.3)

- Types of package labels (8.3.2)
  - Process indicators (Class 1 CIs)
  - Product identification and lot number
  - Expiration statement label
- Securely affix labels to packages so they stay throughout the course of handling to use
- If using a marking pen, write only on the attached label or indicator tape with non-toxic ink

Closures (8.3.3)

- Use sterilization indicator tape
- Latch on rigid containers
- NO pins, paper clips, rubber bands, staples, etc.
- Use elastomer bands if recommended by the packaging manufacturer
- Tip protectors should be steam-permeable, fit loosely and used according to the manufacturer’s IFUs

Preparation and assembly of surgical instrumentation (8.4)

- Sterilize in perforated or wire-mesh-bottom trays or containment devices (rigid organizing trays or rigid sterilization containers)
- Remove excess moisture from cleaning and rinsing using filtered, medical-grade, compressed
- Remove and replace disposable items (e.g., towels, gauze)
Section 8 – Packaging, preparation, and sterilization

Preparation and assembly of surgical instrumentation (8.4)

- Jointed instruments should be open or unlocked with ratchets not engaged
  - Racks, pins, stringers and other devices can be used to hold instruments in the open position
- Multipart instruments should be disassembled
- Position to allow sterilant to come into contact with all surfaces and water to drain from concave surfaces
- Do not hold instruments together with rubber bands
- Heavy instruments placed so do not damage delicate items

Rigid sterilization containers

- When using a rigid container system, contain all items in the basket or tray within the container system
- “Small, basket-type accessory containers with covers or lids (e.g., nail or bone-screw holders), protective organizing baskets, trays, or cases, (e.g., microsurgical instrument cases, air-powered equipment sets, orthopedic instrument organizing sets) should be placed into rigid sterilization container systems only if the container has been specifically designed and tested for that purpose.” (8.4.4)
Rigid sterilization containers

- Check latching mechanism or closure to make sure it is functioning properly and remains secure
- The sealing or mating surfaces should not be dented or chipped
- Screws and rivets on filter retention mechanisms and fasteners should be secure, not distorted or burred
- The filter media should be examined for integrity
- Gasket should be pliable, securely fastened, no breaks or cuts

Follow medical device manufacturer’s IFU for set preparation and assembly

Verify that the container system and the medical device to be sterilized have been tested and validated for the cycle recommended

Use only in cycles recommended

Place instrument trays flat -
- Maintain distribution of metal mass
- Allow air removal
- Sterilant penetration
- Condensate drainage
- Drying
- Keeps instruments in orderly arrangement and from getting damaged
Section 8 – Packaging, preparation, and sterilization

Loading the sterilizer – Paper-plastic pouches (8.5.2)
- Load in a loose fashion
- Place on edge with the plastic side of one pouch facing the paper side of the other pouch
- Avoid laying peel pouches on top of each other

Section 8 – Packaging, preparation, and sterilization

Loading the sterilizer – Basins / Textile packs
- Basins: tilt on edge and orient in same direction for
  - Displacement of air
  - Rapid, even distribution of steam throughout the load
  - Prevention of condensate pooling
- Textile packs
  - Lay on their edge so all fabric is perpendicular to the shelf
  - do not stack on top of each other
  - Pack loosely so that sterilant can circulate

Section 8 – Packaging, preparation, and sterilization

Loading the sterilizer – Rigid Containers
- Place on shelf below absorbent items to prevent wetting of absorbent items by condensate
- Do not stack unless recommended by MDM
- Do not stack containers from different MDM
Section 8 – Packaging, preparation, and sterilization

Sterilization parameters (8.6)

- Gravity Displacement
- Dynamic-Air-Removal by
  - Prevacuum: Series of pressure and vacuum excursions
  - Steam-flush pressure-pulse (SFPP): Series of steam flushes and pressure pulses above atmospheric pressure

Choose based on the written IFU from the
- Medical device manufacturer
- Packaging manufacturer
- Sterilizer manufacturer

Investigate and resolve if the parameters do not agree

Minimum cycle times at 250°F/121°C for gravity displacement steam sterilization cycles for sterilizers > 2 cubic feet

<table>
<thead>
<tr>
<th>Load Contents</th>
<th>Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>30</td>
</tr>
<tr>
<td>Textile packs</td>
<td>30</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>30</td>
</tr>
</tbody>
</table>
### Sterilization parameters (8.6)

<table>
<thead>
<tr>
<th>Load Contents</th>
<th>Temp</th>
<th>Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>270°F/132°C</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>3</td>
</tr>
<tr>
<td>Textile packs</td>
<td>270°F/132°C</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>3</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>270°F/132°C</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>3</td>
</tr>
</tbody>
</table>

### Table-top sterilizers

<table>
<thead>
<tr>
<th>Load Contents</th>
<th>Temp</th>
<th>Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwrapped instruments on tray or glassware</td>
<td>270°F/132°C</td>
<td>≥3</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>≥3</td>
</tr>
<tr>
<td>Wrapped trays of instruments, instruments in peel pouches</td>
<td>270°F/132°C</td>
<td>≥5</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>≥5</td>
</tr>
<tr>
<td>Packs, wrapped</td>
<td>250°F/121°C</td>
<td>≥30</td>
</tr>
</tbody>
</table>

### Immediate-Use Steam Sterilization (Flash)

- Process designed for the steam sterilization of patient care items for immediate use
- High temperature  
  (270-275°F / 132-135°C)
- Gravity or dynamic-air-removal
- No dry time
- No storage
Sterilization parameters (8.6)

Immediate-Use Steam Sterilization (Flash)

Packaging includes:
- Perforated, mesh bottom, open surgical tray
- Rigid sterilization container system
- Protective organizing case
- Single-wrapped surgical tray

Minimum Immediate-Use (Flash) Cycle Times for Gravity Steam Sterilization Cycles

<table>
<thead>
<tr>
<th>Load Contents</th>
<th>Temp</th>
<th>Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwrapped nonporous items</td>
<td>270°F/132°C</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>3</td>
</tr>
<tr>
<td>Unwrapped nonporous &amp; porous items in mixed load</td>
<td>270°F/132°C</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>275°F/135°C</td>
<td>10</td>
</tr>
</tbody>
</table>

Extended cycles

- Cycles whose time is extended beyond the minimum steam sterilization cycles
- Sterilization of specialty instruments and devices, i.e. drills, could require extended exposure times
  - Some manufacturers do not recommend immediate-use sterilization
- Device manufacturer’s written instructions should be followed!
Section 8 – Packaging, preparation, and sterilization

Unloading the sterilizer (8.8)

- Maintain items on sterilizer cart until adequately cooled
- Do not touch during the cooling process
  - Could wick bacteria from hands into packaging
- Place sterilizer cart in a low traffic area, no air-conditioning or cold-air-vents
- Do not transfer warm items to a cool cart → could result in condensate forming and contamination
- May open door slightly at end of cycle to reduce the potential for condensation formation
- Items sterilized immediate-use sterilization are to be used immediately, not stored for later use

Section 8 – Packaging, preparation, and sterilization

Unloading the sterilizer (8.8)

- Minimize handling of all sterile items
- Visually inspect for
  - Tears
  - Wet packages
- For items dropped on the floor and integrity of its packaging compromised, return to decontamination area for reprocessing

Section 8 – Packaging, preparation, and sterilization

Sterile storage (8.9)

- Store sterilized items in a separate area until distributed for patient care use. Environmental conditions for sterile storage include
  - Controlled temperature 24°C (75°F)
  - Four air exchanges/hour
  - Relative humidity not to exceed 70%
  - Authorized traffic
  - Positive air flow (out)
Section 8 – Packaging, preparation, and sterilization

Sterile storage (8.9)

- Inventory is protected from contamination
  - Store at least 8–10 inches from the floor, 18 inches below ceilings and 2 inches from outside walls
  - Storage on carts or shelves:
    - Cleanliness standards, solid bottom shelf
    - Store so not crushed, bent, compressed
    - Stack containers if recommended by MDM
    - Store heavy instruments in middle for ease of handling and do not stack

- Shelf life is event related and depends on
  - Quality of packaging material
  - Storage conditions
  - Conditions during transportation
  - Amount of handling

- Label each product
  - Expiration date or statement such as: “Contents sterile unless package is open or damaged. Please check before using.”

- Sterility maintenance covers may be used to extend shelf life of items that could be subjected to environmental challenges or multiple handlings before use

Distribution (8.10)

- Prevent sterile packages from contamination

- Avoid:
  - Dragging,
  - Sliding,
  - Crushing,
  - Bending,
  - Compressing,
  - Puncturing
Section 8 – Packaging, preparation, and sterilization

Transportation of sterile packaged items (8.11.1)

- Protect items from puncture; and contamination by
  - Moisture
  - Excessive humidity
  - Condensation (caused by exposure to temperature extremes)
  - Insects and vermin
  - Dust and dirt
  - Excessive air pressures
  - Microorganisms

Transportation of sterile packaged items

- Clean or sterile items being transported in uncontrolled environments should be in a covered or enclosed cart with a solid bottom shelf
- Items inside plastic or paper bags or boxes for transport should be arranged within containers to prevent from damage, contamination
- Sterile packages with instruments transported by hand should be maintained in a position parallel with the floor
- Excessive and improper handling can damage the barrier qualities of the packaging materials
- Inspect sterile packages to identify damage to the integrity of the materials (tears, punctures, holes, moisture, stains, dust, evidence of insects, vermin)

Transportation of sterile packaged items

- Sterile packages to be transported from the point of processing to the point of use by means of a dedicated clean lift should be contained in a closed bin, a closed case cart, or a plastic bag. (8.11.4)
Section 8 – Packaging, preparation, and sterilization

Aseptic Presentation
- Sterile packages should be positioned on a separate dry, flat surface
  - at or above the level of the sterile field
  - at the edge of the surface nearest to the person who will be opening the pack
- Before opening packs, inspect external chemical indicator and physical integrity of the package
  - Rigid sterilization container systems, inspect
    - external latch filters, valves, and tamper-evident devices for integrity

Section 8 – Packaging, preparation, and sterilization

Aseptic Presentation
- Before removing sterile contents, check internal CIs for the appropriate endpoint response.
- Remove contents of package, avoiding contact with the table or external surfaces of the package
  - If packaging is a rigid sterilization container system, grasp inner basket handles with both hands and lift the basket above the container bottom
  - avoid contact with the upper rim of the container
  - For wrapped items and items in envelopes, avoid contact with the packaging

Section 9 – Installation, care, and maintenance of sterilizers

- General rationale
- Instruction manuals
- Installation
- Routine care
- Preventive maintenance
- Calibration
- Record-keeping
Section 9 – Installation, care, and maintenance of sterilizers

Routine Care (9.4)
- Inspected and cleaned daily, including
  - Recording charts
  - Ribbons
  - Printer ribbons
  - Marking pens and ink
  - Door gaskets
  - Chamber drain screen
  - Internal chamber
  - External surfaces
- Follow manufacturers instructions for other prescribed inspection and cleaning as specified in the written instructions

Preventive maintenance (9.5)
- Sterilizer manufacturer should provide written instructions for preventive maintenance of the equipment
- Maintenance should be carried out by a qualified individual
  - Attention to inspection, maintenance, and replacement of components subject to wear, e.g., recording devices, filters, steam traps, drain pipes, valves, and door gaskets
- Preventive maintenance and repair records should be retained
- Records of maintenance and repair should be maintained for the life of the equipment

Calibration (9.6)
- Periodic calibration should be performed as per manufacturer’s instruction manual
  - Document results
- Examples
  - Pressure and temperature sensing devices, timers, controls, recording devices
- Calibration should be performed following a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance
Section 9 – Installation, care, and maintenance of sterilizers

Record-keeping (9.7)

- A record of maintenance, paper or electronic format, should be kept for each sterilizer
- Records should be maintained by:
  - Supervisor responsible for the equipment,
  - Hospital engineering staff,
  - Service person or organization that performed the servicing,
  - And/or whoever else as deemed appropriate by health care facility
- Include sufficient information to identify the equipment and to establish a continuous history of all scheduled and non-scheduled service

Sterilizer maintenance - a minimum of the following information should be recorded:

- Date service was requested,
- Model and serial number of sterilizer,
- Location of equipment, incl. hospital ID if applicable,
- Name of individual from the health care facility who requested and authorized the service,
- Reason for service request,
- Description of service performed,
- Types and quantities of parts replaced,
- Name of person who performed the service,
- Date work was completed,
- Handwritten or electronic signature and title of person who acknowledged completion of the work, and
- Results of any post-maintenance testing, if needed, before returning sterilizer to service.
Reference:

Association for the Advancement of Medical Instrumentation (AAMI)

Comprehensive guide to steam sterilization and sterility assurance in health care facilities.


Contact AAMI to order ANSI/AAMI ST79:2010 & A1:2010,
Comprehensive guide to steam sterilization and sterility assurance in health care facilities (Consolidated Text)
- Order Code: ST79 or ST79-PDF by credit card
- Price/AAMI Member Price: $240/$120 (available at member price through AORN)
- Call 1- 877-249-8226
- Internet: http://marketplace.aami.org
- Fax: 301-206-9789
- Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MD 20701-0211

Other Resources:

- 3M™ Sterile U
  - www.3M.com/3MSterileU
- 3M Helpline: 1-800-228-3957
- 3M Sterilization Techline: 1-800-441-1922 option “2”
- AAMI: www.aami.org
- AORN: www.aorn.org