AAMI Sterility Assurance
Nancy Chobin, RN, AAS, ACSP, CSPM, CFER
President/CEO Sterile Processing University
Copyright 2019
Sterile Processing University, LLC

Objectives
- To provide an overview of the relevant AAMI standards that direct processing practices
  - ST-79
  - ST-58
  - ST-77
  - TIR-12
  - ST-91

AAMI
- Association for the Advancement of Medical Instrumentation
  901 N. Glebe Rd.
  Arlington, VA 22203
- TEL: (703) 525-4280
- Web: www.ammi.org

AAMI
- Publishes national standards
- Must be approved by AAMI and ANSI (American National Standards Institute)
- Then becomes ANSI/AAMI National Standard
- Also publishes TIR (Technical Information Reports)
- Committees co-chaired by manufacturer and a user.

AAMI
- Anyone can become a member
- Then sign up for participation on Committees
- As a Committee member you have a vote on each document and input into the document’s contents

Current Documents
- ST-79 “Comprehensive Guide to Steam Sterility and Sterility Assurance in Healthcare Facilities”
- Includes former standards ST46, ST-35 (Decontamination); Ambulatory Care (ST-42); Flash Sterilization (ST-37) and Rigid Containers (ST-33)
- Published 2017

Major Changes
- 3.3.5.5 Heating, ventilation, and air conditioning (HVAC) operating parameters
- The health care organization should identify which version of ANSI/ASHRAE/ASHE
170 will be used based on when the HVAC system was initially installed or last upgraded.

- The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within the rooms throughout the facility where sterile processing occurs.

8 HVAC
- Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas.
- Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.
- If a variance in the HVAC parameters occurs, sterile processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or other designated personnel) should conduct a risk assessment. The sterile processing department is defined by ANSI/ASHRAE/ASHE 170 as a critical area.

9 Temperature
- General work areas – 68-73 deg. F. (20-23 deg.C.)
- Decontam – 60-65deg F(16-18 deg. C.)
- Sterilization access room –75-85 deg. F. (24-29 deg.C.) (or as recommended by equipment mfr)
- Sterile storage/support areas – 75 deg. (maximum -24deg.C.)
- Fans should not be permitted
- These are being re-considered by AAMI
- Consider “cooling vests” for SPD staff in Decontam

10 Sterilizer Access Room
- Need to refer to your sterilizer manufacturer’s User Manual regarding their recommended temperature for this area.
- Monitor and document – may interfere with correct operations of your sterilizers.

11 Unloading Sterilizers
- 10.3.1 Unloading sterilizers having a chamber volume larger than 2 cubic feet
- Terminally sterilized items should be allowed to cool to room temperature before handling.
- An infrared gun or temperature-sensing device may be used to verify that sterilized items have reached a defined temperature (e.g., 24°C [75°F]).
- The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used.

12 More Changes
- Cleaning verification tests should be performed DAILY (sonics and washers)
- Sonic solution should be changed after EACH USE (facility defines a use)
Separate multi-level sets so that all surfaces are exposed to impingement action.

- Instruments and devices should not be treated with any additional chemical (e.g., alcohol, disinfectant wipes) unless such treatment is specifically recommended in the manufacturer’s written IFU.

- MANUAL CLEANING - change the solution after every use (a “use” should be defined in the health care facility’s policies and procedures).

13 **Reminder .................**
- All cleaning cloths should be lint-free even in Decontam
- Do NOT use terry cloth towels or wash cloths due to lint generation
- Sponges are only permitted if single use

14 **Cleaning Steam Sterilizers**
- Sterilizers should be inspected and cleaned DAILY according to the manufacturer’s written IFU.
- Examples of items requiring daily care and/or cleaning are recording charts, printers, printer ribbons, marking pens and ink, door gaskets, the chamber drain screen, the internal chamber, and external surfaces.
- Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer’s written IFU.
- NOTE; contact your sterilizer mfr to see if they will give you a letter stating weekly cleaning of the chamber is sufficient.

15 **More Changes**
- Water quality – tap water now called “utility water”
- Treated water (e.g. sterile, RO) now called “critical water”
- Chemical indicators now referred to as TYPES, not classes.
- An emergency eyewash cannot be located on a decontamination sink.

16 **More Changes**
- Instrument lubricants should only be used if recommended by the instrument/device manufacturer (e.g. implants, eye instruments)
- Need mechanisms to verify automated dosing systems working as well as manual systems (i.e. pumps in bottles).
- All detergents/chemicals must be rinsed off after each step (e.g. after spraying, after pre-soaking, after sonication)

17 **Changes**
- Verify all parameters met on mechanical washers including correct cycle used.
- If a printout, must be signed and saved.
- Cups, small bowls should not be placed inside basin sets unless they can be oriented to ensure drainage of condensate.
- The table with the sterilization cycles and temperatures has been removed – must
Hand Washing

- Sinks should be located at or near all areas in which instruments and other devices are cleaned, decontaminated, prepared and in all support areas
- Decontam sinks should be separate from hand-wash sinks
- Hands free operated equipment preferred
- Can use alcohol-based, waterless hand products but only if hands not visibly soiled.

Instrument Air

- Instrument air: (Previously called compressed air or medical air):
- A medical gas that falls under the general requirements for medical gases as defined by the NFPA 99: Health Care Facilities Code, is not respired, is compliant with the ANSI/ISA S-7.0.01, Quality Standard for Instrument Air, and is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40° F (-40° C).
  
- Instrument Air

- Instrument air may be supplied from cylinders, bulk containers and/or medical air compressors.
- The definition of a medical air compressor (per NFPA) is a compressor that is designed to exclude oil from the air stream and compression chamber and that does not, under normal operating conditions or any single fault, add toxic or flammable contaminants to the compressed air.
- No computer “air”, Nitrogen or hair dryers permitted.

Instrument Air

- Items should be dried for steam and low temperature sterilization processes (e.g. Sterrad)
- AAMI only recommends instrument air for drying sets
- Avoid drying cabinets

Requirements

- Instruction manuals- for all processing equipment should be available and kept as long as equipment in use
- Preventive maintenance program
- Calibration of equipment (under PM)
- Record keeping – documentation of PM and repairs
- Environmental sanitation
  - SPD should be cleaned daily
  - Ensure cleaning of vents, ceiling tiles, etc. done as needed.

Sterile Storage

- Facilities may wish to continue to independently monitor the temperature and humidity levels.
- If the temperature or humidity levels are above or below the levels specified for the SPD area, the discrepancies should be reported to the SPD manager or supervisor.
Sterile Storage

- The length of time sterile packages and other items (e.g. biological and chemical indicators, packaging materials) can remain in temperatures and humidity levels above the recommendations for the facility need to be determined by the facility in conjunction with Infection Prevention, SPD and the Operating Room.
- A small variance for a short amount of time might not be significant.

Sterile Storage

- Larger variances for longer periods of time could be clinically significant.
- Refer to the IFUs for your sterile product (e.g. packaging, medical and surgical pre-sterilized items) to determine the recommended temperature and humidity levels for storage.
- Depending on the packaging system used and other factors, items may have to be discarded (i.e. pre-sterilized product) or reprocessed.

Sterile Storage

- Large volume centralized locations are sterile processing areas and central stores.
- Decentralized locations where small quantities of sterile items are stored close to treatment/procedure areas that are outliers to areas described above can be managed through staff surveillance during the regular course of performing their duties.
- Examples of these decentralized locations could include labor and delivery areas without C-section procedures, imaging areas, emergency department (small storage), etc.
- Staging of sterile items outside of procedure room (like an operating room) for a limited period of time would also apply

Personnel Considerations

- Supervisory Personnel
  - All preparation and sterilization activities, including decontamination, inspection, preparation, packaging, sterilization, storage, and distribution, should be supervised by competent, qualified personnel.
  - Personnel assigned to supervisory functions should be prepared for this responsibility by education, training, and experience. Minimum recommended qualifications include
    - a) successful completion of a central service management certification examination;
    - NOTE—the Certification Board for Sterile Processing and Distribution (CBSPD) (148 Main Street, Suite D-1, Lebanon, N.J. 08833; 800-555-9765; http://www.sterileprocessing.org); the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078; http://www.iahcsmm.org); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013; http://www.health.gov/nhic/).

Personnel Considerations

- Processing personnel – qualified individuals who are properly trained and certified (as a condition of employment and within 2 years of employment)

29

30 \textbf{General Attire for SPD}

- Shoes worn in the department should be clean, should have non-skid soles, and should be sturdy enough to prevent injury if an item drops on the foot. \textit{Shoes cannot have any open areas} (including back).
  - Shoe covers are only needed to cover shoes that do not remain at the facility.
  - All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering.
  - Jewelry should not be worn on the hands or wrists in the decontamination, preparation, or sterilization area.
  - Undergarments should not be visible beneath scrubs (AORN)
  - Use of warm-up jackets (snapped closed) recommended to contain fallout from bare arms (AORN)

31 \textbf{Attire}

- Scrub suits \textbf{ARE NOT} to be taken home for laundering NOR worn to or from work.
- If a scrub suit becomes soiled, it must be changed prior to resuming duties.
- Bouffant type head covers are to be worn in all areas of the department. When applied, hair should be completely contained inside the head cover. Cloth headcovers are not permitted unless they are changed and laundered daily.
- Artificial (false) eyelashes are not permitted; they can fall off into sets.
- Facial body piercings must not be visible or be covered (e.g. with a bandaid).

32 \textbf{General Attire}

- No nail polish, artificial nails. Nail length should not exceed \(\frac{1}{4}"\) beyond the finger tip.
- The policy on use of cover apparel when employees leave the department to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations.
- Employees should change into street clothes whenever they leave the health care facility or when traveling between buildings located on separate campuses.

33 \textbf{Dress Code}

- It is the responsibility of the sterile processing staff to ensure compliance with the departmental dress code for all staff and visitors.
- This includes the Decontamination Area dress code.
- Report all instances of non-compliance to the Manager.

34 \textbf{General Considerations}

- Newly purchased/repaired items – clean, inspect before placing into use
- Manufacturer's instructions – the reusable medical device mfr. is responsible for ensuring that the device can be effectively cleaned and sterilized.
- Personal electronic devices should not be brought into the processing areas. Exceptions should be noted in the organization’s policies.
Physical Monitors - Section 13.5.1 of AAMI ST79

- Physical monitors should be used to monitor sterilizer performance. These include time, temperature, and pressure monitors.
- Rationale - Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record by means of charts, printouts, or digital data.
- Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken.

Chemical Indicators - Section 2.10

- Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.
- Six ‘types’ of CIs are described in AAMI ST79:2017 (the new term ‘type’ of CI replaces the older term ‘class’ of CI).
- Guidance on using internal and external CIs is provided in Section 13.5.2.2 and on Bowie-Dick testing in Section 13.7.6.

Biological Indicators

- Biological indicators contain a known number of live microorganisms and are used to assess the adequacy of a sterilization cycle.
- Section 13.5.3.1 states, “Health care personnel should select BIs that consist of spores of Geobacillus stearothermophilus that comply with ANSI/AAMI/ISO 11138-3 and that are suitable for use in the specific sterilization cycle.”
- Rationale - “Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.”

Process Challenge Devices (PCDs)

- Section 13.5.4, “A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.”
- The PCD may contain only a BI, only a Type 5 or Type 6 CI, or a BI and a Type 5 CI.
- While facility-assembled PCDs are used to monitor table-top sterilizers, ST79:2017 recommends the use of commercially available BI PCDs to monitor sterilizers larger than 2 cubic feet. (Section 13.7.2.1)

Routine Load Release

- When removing a processed load from a steam sterilizer, staff should make a decision about whether to release the load after careful evaluation of the available data.
- This data includes: the physical monitor (i.e. the print-out), which is checked to verify the cycle parameters were met; and the inspection of the external chemical indicators.
• All packages should have a Type 1 external CI, unless the internal CI is visible for inspection.
• Internal CIs are inspected by the person opening the set. AAMI ST79 recommends, “One or more internal chemical indicators should be placed within each package, tray, or rigid container”

**Routine Load Release**
• These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters”. (Section 13.5.2.2.2 )
• Guidance on routine load release is split into two subcategories: nonimplant loads and implant loads.
• Nonimplant loads: Loads that do not contain an implant should be monitored using physical monitors, chemical indicators, and may be monitored with a Process Challenge Device (PCD) containing: a BI; a BI and a Type 5 CI; a Type 5 CI; or a Type 6 CI. The use of a PCD is optional.

**Routine Load Release**
• Implant Loads: As biological indicators are the only monitoring tool that demonstrate the lethality of the sterilization process, AAMI ST79:2017 continues to recommend that implant loads be monitored with a PCD containing a biological indicator and a Type 5 integrating indicator.
• The implant should be quarantined until the BI result is available. (Sections 13.5.3.2 and 13.6.3)
• In defined emergency situations, the implant can be released on the basis of the Type 5 integrator contained within the PCD but the BI should still be incubated and the result documented. (Section 13.6.3)
• ST79:2017 provides an example Exception Form for emergency load release documentation in Annex K.

**Routine Sterilizer Testing**
• A robust quality assurance program should include routine efficacy testing using BI PCDs.
• If a sterilizer is designed to be used for multiple types of cycles, AAMI ST79 recommends testing each cycle type used.
• The recommended frequency for routine sterilizer efficacy monitoring with a BI PCD is at least weekly, but preferably every day that the sterilizer is used.
• Guidance on the specific BI PCD to be used is provided in three sections.

**Routine Sterilizer Testing**
• Sterilizers larger than 2 cubic feet - The use of a pre-assembled, disposable BI PCD, equivalent in challenge to the AAMI 16-towel PCD, is recommended.
• AAMI ST79 comments that disposable PCDs “provide standardization and reduce variability and potential for error”.
• The PCD is placed in a loaded chamber in the area most challenging to sterilant penetration.

**IUSS Testing**
• Note that AAMI ST79:2017 does not have a separate section on routine monitoring of
IUSS cycles.
• All IUSS cycles are to be performed in closed, rigid containers validated for IUSS.
• Sterilizers used for IUSS have a chamber size larger than 2 cubic feet, routine testing of dynamic-air-removal IUSS cycles falls under this section i.e., they should be monitored with a pre-assembled, commercially available BI PCD.
• In IUSS cycles, routine testing may be done in an empty chamber.
• IUSS containers must be cleaned after each use according to the IFU – cannot “wipe out”.
• Must receive container testing annually.

Tabletop Sterilizer Testing
• Table-top sterilizers (have less than or equal to 2 cubic feet in chamber size.
• To monitor table-top sterilizers, the user assembles a representative BI PCD. For example, if items are pouched for sterilization, the BI PCD is created by placing a BI, a CI and an instrument in a pouch. Routine testing is done in a fully loaded chamber
• All routine and qualification testing is done with FULLY LOADED chambers.

Gravity Cycles
• For routine monitoring of gravity-displacement cycles, a representative of the same type of tray to be routinely processed by gravity-displacement cycles should be selected to serve as the PCD.
• Each type of tray configuration routinely used for gravity-displacement cycles should be tested separately.”
• The PCD should be placed on the bottom shelf of an otherwise empty chamber.

Control Vials
• In each case, it is recommended that a control BI, having the same lot code as the test BI, be incubated each day a test BI is incubated.
• Acceptance criteria includes a negative result for the test BI and a positive result for the control BI.
• The control may be incubated for additional time to get a visual color change. (Recommended)

TIR-12
• Designing, Testing, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers

TIR-12
• Addresses design considerations and provides information on
  • Decontamination
  • Disinfection
  • Sterilization practices commonly used in HCFs
• Manufacturers recommendations now called manufacturers’ instructions for use or IFUs
• Assists manufacturers in validating reprocessing procedures they recommend
• Will guide them in choosing procedures that can be replicated in HCFs

51 ST-81
• Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

52 ST-81
• Sets requirements for manufacturers for labeling their products and for providing re-processing instructions
• Both TIR-12 and ST-81 are for manufacturers but HCF personnel will find them useful to see if your device manufacturer is complying with the regulations

53 Compliance
• Device manufacturers must provide information to you to facilitate your reprocessing the devices they made.
• According to the FDA, the only way the FDA can take any action is to receive complaints, properly filed on MEDWATCH Form 3500.

54 Compliance
• To make the reporting easier, the FDA has provided a website that goes directly to the Form. They also provide instructions on exactly how the Form should be completed. The website is:
  • https://www.accessdata.fda.gov/scripts/medwatch

55 ST-58R
• “Chemical Sterilization and High Level Disinfection in Health Care Facilities”

56 ST-58R
• Published November 2013
• Merges and updates two existing AAMI documents:
  • ANSI/AAMI ST-58 (Safe Use and Handling of Glutaraldehyde-Based Products in Health Care facilities)
  • TIR-7 – Chemical Sterilants and High Level Disinfectants: A Guide to Selection and Use

57 ST-58R
• Covers all chemical sterilants (except ETO)
• High level disinfectants currently available for use
  • Glutaraldehyde solutions
  • hydrogen peroxide solutions
  • Ortho-phthalaldehyde (OPA) solutions
  • Peracetic acid solutions

58 ST-58R
• HLDs covered (continued)
  • Sodium hypochlorite solutions
- Chemical vapor sterilants using formaldehyde and alcohol (dental offices)
- Hydrogen peroxide gas plasma sterilization
- New formulation of ozone sterilization not included

59 **ST-77 Rigid Containers**
- AAMI document for rigid containers and organizing trays (ST-77), 2013
- “Containment Devices for Reusable Medical Device Sterilization”
- Covers design, performance and labeling criteria for reusable rigid sterilization containers, instrument cases and cassettes and organizing trays intended for use in containing medical devices for sterilization

60 **Organizing Trays**
- Includes Synthes, etc trays
- How to clean items inside?
- How to prepare set?
- Sterilization parameters?
- Can loaner sets be placed inside a rigid container?
  - Only if the loaner manufacturer has validated and provided written instructions.

61 **ST-91**
- Endoscope document
- Published April, 2015
- Being updated, may be revised by end of 2018

62 **Water Quality**
- “Water for the Reprocessing of Medical Devices” TIR 34 (2014)
- Addresses quality of water for cleaning and rinsing
- Is not a national standard

63 **Other New Documents**
- Loaner Instruments - TIR
- Human Factors - TIR
- ST-90 - Processing of health care products - Quality management systems for processing in health care facilities
- New TIR starting on TEE and Ultrasound Probes

64 **Conclusions**
- AAMI is a standard setting organization
- The minimum practice level is AAMI
- You should have at least ST-79 on hand
- Work with OR, Risk Management and Infection Prevention to comply with AAMI
- SPD Manager is responsible for all cleaning, sterilization and HLD activities
- Must be knowledgeable in all AAMI standards

65 **Conclusions**
• Need to understand importance of AAMI standards
• JC and other professional organizations recognize AAMI as the expert
• In a court of law AAMI is the standard you must meet

66 Contact Information
• Nancy Chobin
• TEL: 908-735-8944 (office)
• Website:
  • www.SPDCEUS.com
  • Email: Nancy @ SPDCEUS.com

67 References