AAMI ST-79 Update 2017

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Objectives

- Understand the major AAMI ST-79 standard that changes published October 2017.
- Review your facility’s compliance with these changes.
AAMI

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AAMI Publication Orders

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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.
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 Document

- 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.
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.
Temperature

- General work areas – 68-73 deg. F. (20-23 deg. C.)
- Decontam – 60-65 deg. F. (16-18 deg. C.)
- Sterile storage/support areas – 75 deg. (maximum - 24 deg. C.)
- Fans should not be permitted
- These are being re-considered by AAMI
- Consider “cooling vests” for SPD staff in Decontam
Sterilizer Access Room

- **Sterilization access room** – 75-85 deg.F. (24-29 deg.C.) (or as recommended by equipment mfr)
- 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.
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.
  - 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.
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]).

- Use according to the IFU
IFUs

- Do you have ALL of them?
- Who reviewed them for accuracy?
- Where are they located? Copy in Decontam? Sterilization Area?
- Can you fully comply with them?
  Do you even have a sonic? It is capable of cleaning an entire set?
- Remember, when you fail to comply with an IFU, you are using a product off label and are totally responsible for the safety and efficacy of the device.
More Changes

- Cleaning verification tests should be performed DAILY (sonics and washers)
- **MANUAL CLEANING** - change the solution after every use (a “use” should be defined in the health care facility’s policies and procedures).
- 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.
Reminder

• All cleaning cloths should be lint-free even in Decontam
• Do NOT use terry cloth towels or wash cloths due to lint generation
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.
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.
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 chemicals must be rinsed off after each step (e.g. after spraying, after pre-soaking, after sonication)
Types of Proportioners
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 follow the device mfrs IFU
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 Compressors.** Instrument air is a support gas used to operate surgical tools, ceiling booms, etc., in lieu of nitrogen.
- All **instrument air compressor** packages are complete per NFPA99, and are designed to reduce the amount of field labor required for installation.
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” 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
- Routine care of sterilizers – cleaning by users
- 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.
General Attire for SPD

- All personnel entering the decontamination, preparation, sterilization, and sterile storage areas should wear **clean uniforms that are provided by and donned at the facility.**
- 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. **Shoes cannot have any open areas** (including back).
  - Shoe covers are only needed to cover shoes that do not remain at the facility.
  - Shoe covers still required in Decontamination area
General Attire for SPD

- 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 scrub (AORN)
- Use of warm-up jackets (snapped closed) recommended to contain fallout from bare arms (AORN)
Attire

- 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. (AORN)
- Facial body piercings must not be visible or be covered (e.g. with a bandaid) (AORN).
General Attire

- No nail polish, artificial nails. Nail length should not exceed \( \frac{1}{4} ” \) beyond the finger tip. (AORN the tips should be no longer than 2 mm (0.08 inch).

- Employees should change into street clothes whenever they leave the health care facility or when traveling between buildings located on separate campuses.
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.
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.**
Chemical Indicators – Section 2.1

- 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).
- At a minimum a Type 4 CI should be used.
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.”
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 (e.g. gravity and pre-vacuum).
- 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 (steam).
Low Temperature Sterilization

- Biological monitoring is recommended daily (whenever used) preferably each cycle.
- EACH cycle type being used must be biologically tested whenever used.
- Large incidence of non-compliance
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.
Biological Monitoring

- **NOTE:** In previous versions of ANSI/AAMI ST79, sterilizers used for immediate-use steam sterilization (IUSS) required a different type of PCD than the PCD used for the sterilizers in the SPD area.
- This change was based on the way sterilization was historically performed in surgery.
BI Monitoring

- With the enactment of IUSS, however, the sterilization cycles used in surgery are the same as those used in SPD; therefore, the sterilization challenge is the same.
Biological Monitoring

- The routine biological monitoring process challenge device (PCD) or test pack for immediate-use steam sterilizers falls under the same testing methods as for routine biological monitoring of sterilizers larger than two cubic feet.
BI Monitoring

- Before being exposed to the sterilization cycle, a biological test pack (PCD) should be labeled to identify the date, the sterilizer, and the cycle being tested.
- The PCD should be positioned in the chamber over the drain line on a rack in an empty chamber.
- A normal cycle should be run, according to the sterilizer and device manufacturers’ written IFU.
- Upon completion of the sterilization cycle and cooling of the PCD, the BI(s) and CI(s) should be removed from the PCD and their identification recorded.
- The CI manufacturer’s written IFU for interpretation of CI results should be followed.
BI Monitoring

- There is no BI PCD for gravity IUSS cycles.
- Contact your IUSS container mfr for guidance on BI testing of gravity IUSS cycles using their container.
- May need to place 1-2 BI vials and CIs in the immediate use container.
- Process on gravity IUSS cycle.
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 pouches 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.
Tabletop 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)
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
Can loaner sets be placed inside a rigid container?

• Only if the loaner manufacturer has validated and provided written instructions.
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
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
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References