3M℠ Health Care Academy

Introduction to the revised AAMI ST79

Objectives

1. Discuss the committee's goals for this revision to AAMI ST79
2. Review industry consensus on HVAC recommendations and related changes in AAMI ST79
3. Discuss key changes to the quality control recommendations in AAMI ST79

Discuss the committee's goals for this revision to AAMI ST79

Why the revision?

- Goals for new edition
  - Provide critical content in consistent format
  - Make it easy to access immediate need information
  - Be the go-to document for processing devices used in invasive procedures
  - Provide current/up to date information about processing

Why?

- Goals
  - Inform wide range of professionals
    - SPD
    - OR
    - Dental
    - Infection Preventionists
    - Vendors
    - Accrediting organization

Why?

- Goals
  - More user friendly
  - Improve format - edit –
    - Consistency
    - Flow to mirror work flow
    - Clean up redundancies, misplaced information,
    - Update references
    - Increasingly base on evidence

Why?

Overriding goal is:

- Facilitate best practice to ensure positive patient outcome
  - Absence of infection
  - Absence of injury
- Facilitate best practice to ensure safe work environment and practice to protect staff from injury or infection
  - Absence of infection
  - Absence of injury

Five Original Documents

ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*

- ANSI/AAMI ST42, *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities*
- ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use*
- ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*
- ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*

Clean-up

- Ensure that the definitions include only what is in the text
- Ensure that there are definitions for terms found in the text
  - Instrument air, Critical water
- Update definitions (Chemical Indicators now “Types” – not Class)
- Remove rationale from directives
- Place educational material in the annex
- Reorganize chapters for cleaning and disinfection, prep and pack and sterilization

Clean-up – Example of the Old Format

3.3.6.3 Doors

Doors should be made of a durable material that can withstand constant bumping from back tables and carts and that can be cleaned frequently. Doors should open easily following the one-way directional workflow and should not have thresholds.

Rationale: Carts and back tables are constantly being pushed from one area to the next, through the stages of processing from dirty to clean. Doors require frequent cleaning. It is cumbersome for personnel to pull open a door and push a cart through it. The constant bumping of doors by carts eventually wears away the finish. Bumping against a threshold can cause carts to spill or necessitate picking

Example of New Format

3.3.5.4 Doors

Doors should:

a) be made of a durable material that can withstand impacts from back tables and carts and that can be cleaned frequently; and

b) open easily following the one-way directional workflow and should not have thresholds.

Rationale: Carts and other equipment are constantly being pushed from one area to the next, through the stages of processing from dirty to clean. Doors require frequent cleaning. It is cumbersome for personnel to pull open a door and push a cart through it. The constant bumping of doors by carts eventually wears away the finish. Bumping against a threshold can cause carts to spill or necessitate picking up the cart to traverse the threshold.

Old Format

4.3.2 Service personnel

Education and training programs for service personnel should include information on the hazards associated with blood-borne pathogens, the requirements of the OSHA standard on occupational exposure to blood-borne pathogens (29 CFR 1910.1030), the importance of vaccinations as protective measures, standard/transmission based precautions, protective work practices, the use of PPE, emergency procedures, and procedures to follow if an exposure occurs.

Rationale: Education and training are the most important aspects of a program intended to protect employees and users from a potential health hazard.

New Format

Education and training programs for service personnel should include:

a) information on the hazards associated with blood-borne pathogens;
b) the requirements of the OSHA standard on occupational exposure to blood-borne pathogens (29 CFR 41 1910.1030);
c) the requirements of the OSHA Hazard Communications Standard;
d) the importance of vaccinations as protective measures;
e) standard and transmission-based precautions;
f) protective work practices;
g) the use of PPE;
h) emergency procedures; and
i) procedures to follow if an exposure occurs.

Rationale: Education and training are important aspects of a program intended to protect employees and users from a potential health hazard….

Keeping Cool

Lowering ambient temperature is not the most effective way to reduce body temperature !

When wearing PPE (especially fluid resistant or plastic) not enough skin is exposed to allow perspiration to evaporate and cool the body

ST79:2017 Annex Q

Keeping Cool in Decontam

Incorporate work/rest cycles – shorten work periods

Maintain hydration

Wear cooling device

bandana, skull cap, headband, vest, scarf, towel

Frequent breaks – apply cool water or ice to body pulse points

AAMI ST79:2017 Annex Q

Cooling products

Pictures courtesy of Healthmark Industries.

Discuss key changes to the quality control recommendations in ST79:2017

Sterilization

10.2.2 Sterilization cycles

The sterilizer manufacturer's written IFU should be followed for operation of the sterilizer and indications for use.

a) Differences between the programmed cycle and the cycle parameters recommended by the device manufacturer should be investigated and, if possible, reconciled before the items are sterilized. If differing instructions cannot be resolved, the device manufacturer’s IFU should be followed.

b) If a rigid sterilization container system or a sealed containment device designed for IUSS is used as packaging, the container system manufacturer’s written IFU regarding exposure time should be consulted and reconciled with that of the sterilizer manufacturer.

See AAMI TIR12 and FDA guidance document (2015) for information about sterilizer cycles. For a specific sterilizer, consult that sterilizer manufacturer’s written IFU.

Sterilization

Table 4 and Table 5 – ST79:2013

Table 4

Time and temperature parameters for gravity-displacement steam sterilization cycles in health care facilities

Table 5

Minimum cycle times for dynamic air-removal steam sterilization cycles

THESE TABLES ARE NOT PROVIDED IN AAMI ST79:2017

Sterilization

Tables removed because

- User should consult IFU – cycles vary
- Old tables listed unwrapped cycles – goal to eliminate unwrapped cycles (recognize not entirely possible immediately)
- Mention of extended cycles has been eliminated
  - Check with device and sterilizer manufacturer – reconcile or go with device

Sterilization

AAMI ST79:2013

Sections on gravity-displacement cycles and dynamic air removal cycles for unwrapped porous and non porous items

AAMI ST79:2017

No content on unwrapped cycles

Immediate Use – AAMI ST79:2017

Sterilization for immediate use

IUSS should not be used for purposes of convenience or as a substitute for sufficient instrumentation. Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

IUSS should be kept to a minimum and should be used only in urgent clinical situations.

AAMI ST79:2017 Sec 10.2.3

Immediate Use - AAMI ST79:2017

Items processed by IUSS should:

a) be decontaminated as specified in Section 7;

b) be placed in a rigid sterilization container system that is intended for the cycle parameters to be used;

c) be used immediately and not stored for later use or held from one procedure to another; and

d) be identified as IUSS.

AAMI ST79:2017 Sec 10.2.3

Monitoring IUSS

- A BI test pack as described in 13.7.2.1 or a commercially available disposable BI PCD should be used to test the dynamic-air-removal cycle for IUSS.
- Monitoring of IUSS cycles may be done in an empty chamber (Table 1)

AAMI ST79:2017 Table 1 and Sections 13.7.2.1 and 13.8.4

Monitoring IUSS

- When performing qualification testing of gravity cycles for IUSS, place one BI and one or more CIs in the tray configuration that has been selected to be tested. The PCD (BI challenge test tray) should be of appropriate size for the sterilizer being tested. The BI(s) and CI(s) should be located in the most difficult-to-sterilize portion of the PCD.
- NOTE—The open surgical tray, rigid sterilization container system, protective organizing case, or single-wrapped surgical tray should be a product that has been validated by the manufacturer for use in sterilization.

AAMI ST79:2017 Table 1 and Sections 13.7.4 and 13.8.4

Monitoring Recommendations

Table 1—Sterilization process monitoring recommendations

Routine load release (see 13.5 and 13.6)		Routine sterilizer efficacy monitoring (see 13.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 13.8)	Periodic product quality assurance testing (see 13.9)
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal CI monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Type 5 integrating indicator • a Type 5 integrating indicator • a Type 6 emulating indicator	Physical monitoring of cycle External and internal CI monitoring of packages Monitoring of every load with a PCD containing a BI and a Type 5 integrating indicator	Physical monitoring of cycle External and internal CI monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In IUSS cycles, monitoring may be done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber, if applicable (see 13.7.6)	Physical monitoring of cycle External and internal CI monitoring of packages For sterilizers larger than 2 cubic feet and for IUSS cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6)	Physical monitoring of cycle Placement of BIs and, CIs within product test samples

NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

Internal Chemical Indicators

- One or more internal chemical indicators should be placed within each package, tray, or rigid container.
- Type 5 or Type 6 chemical indicators recommended
- Internal CIs placement:

  a) one CI is visible to the person opening the package;

  b) CIs are in the area or areas considered least accessible to steam penetration”

AAMI ST79:2017 Section 13.5.2.2.2

Cleaning - AAMI ST79:2017

- When using an automated chemical delivery system/device or sink proportioner, the automated doser should be routinely verified or calibrated. Calculation of sink volume might or might not be necessary
- Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded. (previously daily testing was preferred)

    Ultrasonic

    Washer disinfector

AAMI ST79:2017. Sec. 7.6 and 7.6.4.5.

Key Learnings

- ST79:2017 is available for purchase
- New edition provides critical content in consistent format
- May need to revise policies on:
  - Monitoring HVAC performance parameters
  - Frequency of testing mechanical cleaning equipment
  - Monitoring of pre-vac IUSS cycles

Questions?

References

Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79:2017. Arlington, VA. 2017.

Thank you