EDUCATION

STERIS UNIVERSITY

Staying Current with ANSI/AAMI ST79

One Integrated Approach to Healthcare.

STERIS

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Learning Objectives

Upon completion of this program, you will be able to:

- Describe the intended purpose of ANSI/AAMI ST79
- Identify the new and revised material in ANSI/AAMI ST79

AAMI

- *Association for the Advancement of Medical Instrumentation (AAMI)*
- Founded in 1967
- Nonprofit organization
- Diverse community of approximately 7,000 professionals united by one important mission:

  The development, management, and use of safe and effective health technology.

AAMI
Advancing Safety in Healthcare Technology

AAMI, continued

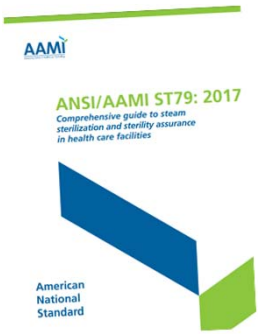
- 100 technical committees and working groups
  - Produce Standards, Recommended Practices (RPs), and Technical Information Reports for medical devices
- Standards and RPs represent national consensus
- Many approved by ANSI
- Essential to the overall mission of AAMI is the
  - Continued increase in the safe and effective application of current technologies to patient care and
  - Encouragement of new technologies

AAMI, continued

- Voluntary standard
  - Recommends to the device manufacturer the information that should be provided with or on the product
- Recommended practice
  - Provides guidelines for the use, care, and/or processing of a medical device or system
- Surveying bodies look for compliance

ANSI/AAMI ST79

- Covers steam sterilization in health care facilities
- Promote sterility assurance
- Guide healthcare personnel in the proper use of processing equipment



Why Was ST79 Edited in 2017?

- Initial edition of ST79 = 5 documents
- Last updated 2013
- Disconnected and disorganized
- Sometimes difficult to find the information
- Rationales mixed in with directives
- Redundancies
- Substantial editing required

In the Past

- **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*

2017 Edits: Birds-Eye View

- Reorganization
  - Cleaning/disinfection (decontamination)
  - Preparation and assembly (prep and pack)
  - Packaging
  - Sterilization
- Rationales and references
- Stem sentence format
  - 'Should' followed by bullets (e.g., a, b, c)
- Definitions
  - Additions
  - Deletions
  - Separation of rationale from definition
- AAMI document edits are no longer continuous but are now on a 5 year edit cycle. AORN follows the same pattern.

Chapter Reorganization

ST79:2013	ST79:2017
Chapter 7: *Cleaning and other decontamination processes*	**Chapter 7:** *Cleaning, disinfection, and other decontamination steps*
Chapter 8: *Packaging, preparation, and sterilization*	**Chapter 8:** *Preparation and assembly of instruments*
Annex P: *Moisture Assessment*	**Chapter 9:** *Packaging*
Annex Q: *Comparison of the differences between AAMI and FDA classifications on chemical indicators*	**Chapter 10:** *Sterilization*
	Chapter 11: *Storage and transportation*
	Annex P: *General considerations for cleaning and disinfection*
	Annex Q: *Alternatives for keeping cool in the sterile processing environment*

Stem Sentence Example: Traffic Control

- ***Written policies and procedures regarding traffic control should:***

a) limit access to restricted areas to authorized personnel;

b) specify criteria for authorized entry, movement within processing areas, and attire;

c) establish a dress code for all personnel and visitors who enter restricted areas (see also 4.5); and

d) specify the responsibility and authority for enforcing traffic-control policies and procedures.

- *Rationale:* Personnel and visitors can carry microorganisms into processing areas, thus increasing the potential for environmental contaminants in these areas. It is important to protect personnel and visitors from the microorganisms present on contaminated items being processed in the decontamination area.

Definition Without a Word/Term

ANSI/AAMI ST79:2013

The definition:

"… filtered, medical-grade, compressed air"

ANSI/AAMI ST79:2017

The term: *Instrument Air*

The definition:

- Medical gas that falls under the general requirements for medical gases as defined by NFPA 99 (*Health care facilities code)*
- is not respired
- is compliant with the ANSI/ISA 7.0.01 (Quality standard for instrument air)
- is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40˚C (-40˚F)

Term without a Definition is it *Loaner* or *Loaned*?

Loaned items: Medical devices used in health care facilities that are not owned by the facility

- Formalized program
- Loaned instrumentation policy
- Decontamination of loaned instruments
- Avoiding the need for IUSS

Definitions & Abbreviations: New to Section 2

- Critical water
- Process failure
- Satellite sterile processing room
- Utility water

Definitions & Abbreviations, continued

Critical Water:

"*Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [(RO) or distillation] to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or for steam generation.*"

Definitions & Abbreviations, continued

Process Failure:

"*Condition in which one or more monitored parameters of cleaning, sterilization, or packaging is outside the defined specification for that parameter.*"

Definitions & Abbreviations, continued

Satellite sterile processing room:

"*Room located in departments outside the main sterile processing department (SPD), such as the operating room or obstetric department, which is designed and intended to be functionally equivalent to SPD for decontamination and sterilization of surgical instruments.*"

Definitions & Abbreviations, continued

Utility water:

"*Water that comes from the tap, for flushing, washing, or rinsing.*

Significant Revision: Environmental Controls

- No temperature and humidity parameters
- ANSI/ASHRAE/ASHE 170
- HVAC performance monitoring
- Multidisciplinary team
- Establish policies and procedures
- Conduct risk assessment

Environmental Control & Thermoregulation

- Healthy human body core temperature 98.6°F (37°C)
- Cool down:
  - Sweating and vasodilation
  - Eating/drinking cool foods/beverages
  - Cooling the body's pulse points(face, neck, chest, and limbs)
- Warm up:
  - Additional layers of clothing
  - Eating/drinking warm foods/beverages
  - Warming the body's pulse points

Revised Standard: Eyewash Station

- One intervening door
- Eyewash station should not be in a location that requires flushing of the eyes in a decontamination sink

Revised Standard: Ergonomic Considerations

"Ergonomic factors affecting worker safety and comfort should…"

a) "Adjustable counters…"

b) "Adequate space…"

c) "Anti-fatigue mats …"

Attire

- Gloves should:
  - Not be a medical examination glove
  - Be fitted and extend beyond the cuff of the gown
- Shoes should:
  - Be closed, no holes/openings
- Personal electronic devices should not be brought into the processing areas

General Considerations for all Devices and Utensils - Brushes

- **ST79:2013 - *Cleaning of instruments***: "*Reusable brushes should be disinfected or sterilized at least daily.*"
- **ST79:2017 - *General considerations for all devices and utensils:*** "*Reusable brushes should be cleaned after each use and disinfected or sterilized at least once a day.*"

Instrument Lubricants

"*Water-soluble instrument lubricants specifically designed for compatibility with sterilization may be used; the manufacturer's written IFU for use should be followed. Instrument lubricants containing mineral oil or other oil bases should not be used, except to lubricate the internal mechanism of powered instruments as specified by the manufacturer.*"

Instrument Lubricants, continued

Instrument lubricants should	Be specifically designed for the intended use and compatible with the processing method being use.
The lubricant manufacturer should:	Provide evidence to support material compatibility and biocompatibility for the intended use.
Device manufacturer's IFU should:	Be followed regarding the use of lubricants

Cleaning/General Considerations

- Brushing is a cleaning function and should only be done in the decontamination area and not in the clean (assembly) area
- If a medical device is found to be dirty upon inspection in the assembly area it should be returned to the decontamination area for recleaning

Cleaning Agents

Use cleaning agents recommended in the manufacturer's written IFU for the device. The cleaning agent should:

a) "be compatible with the medical device or container system…"

b) "efficacious on the types of clinical soil…"

Rinsing

- 2013 edition: 7.5.4 is dedicated to *rinsing*
- 2017 edition: No section is dedicated to rinsing

New in 2017 edition is the supporting rationale that recommends, thoroughly rinsing devices of precleaning solutions

Mechanical Cleaning, Disinfection, and Other Decontamination Steps

- 7.6.4.3.2: Maintenance of mechanical cleaning and disinfection equipment
- 7.6.4.3.3: Selection of mechanical cleaning and disinfection
- 7.6.4.3.4: Loading mechanical cleaning and disinfection equipment
- 7.6.4.3.5: Unloading mechanical cleaning and disinfection equipment
- 7.6.4.4: Ultrasonic

Unloading Mechanical Washing & Disinfection Equipment

- Check cleaning verification and check correct cycle was run
- Inspect items for debris and wetness
- Check drain strainer

Ultrasonic Cleaning Equipment

Should:

a) used only for devices without contraindication

b) remove gross soil and detergents prior to use

c) use cleaning chemistry labeled for ultrasonic use

d) use fresh cleaning solution

e) thoroughly rinse with clean water

Ultrasonic Cleaning Equipment, continued

In addition to following the manufacturer's written IFU…

a) Request performance verification test methods from ultrasonic OEM

b) Perform cavitation testing daily

c) Degas solution as required

d) Avoid submerging plastics and soft metals

e) Keep the lid closed when in use

Ultrasonic Cleaning Equipment: Loading, continued

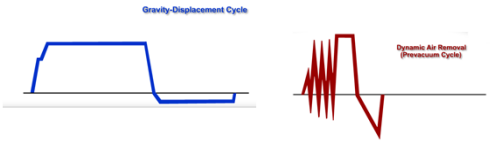
Remove the mats!

Verification of the Cleaning Process

"Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded."

Sterilization

Minimum parameter/cycle *time and temperature* steam sterilization tables removed



Unloading the Sterilizer

- Visually inspect sterile package for the following:
  - Holes
  - Package identification
  - Visual change or the external indicator
  - Moisture

Unloading Sterilizers Larger than 2 ft^3

Infrared gun or temperature sensing device Items

Chemical Indicators: It's Not A 'Class'; It's A 'Type'

- Type 1: Process indicator
- Type 2: Indicator for use in a specific test
- Type 3: Single critical process variable indicator
- Type 4: Multicritical process variable indicator
- Type 5: Integrating indicator
- Type 6: Emulating

Routine BI Monitoring of IUSS Cycles

A commercially available BI PCD may be used to test dynamic air removal.

Storage & Transportation

Refer to wrap manufacturer's IFU for guidance on stacking trays

Annex D: User Verification of Cleaning Processes

- Tables D.1 and D.2 (removed)
- Ultrasonic cleaners
  - Cavitation
  - Soil removal (external and internal)
- Mechanical/automated washers
  - Soil removal
- Chemical tests for residual soil markers
  - Protein
  - ATP
  - Hemoglobin

Annex P: Cleaning & Disinfection

- General Information
- FDA 'reprocessing' definition
- CDC's description of proper level of processing between patient use
- Elements of effective cleaning
- Types of soils
- Residual Soils
- Mechanical (automated) cleaning and disinfection
- Ultrasonic cleaning equipment
- Washer-pasteurizers
- Washer-disinfectors
- Single-chamber
- Multi-chamber
- Cart Washer/Disinfector

Annex Q: Thermoregulation: Alternatives for Keeping Cool in the Sterile Processing Environment

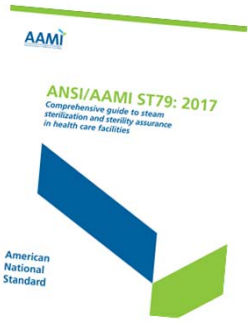
Alternative cooling methods:

- Workload distribution/work/rest schedule:
- *CBE* (Center for the Built Environment)*Thermal Comfort Tool*
- Worn under PPE (i.e., cooling vests)
- Bandanas, skull caps, or head bands
- Neck scarfs or towels
- Hydration

http://comfort.cbe.berkeley.edu/

Action Items

- Obtain a copy of ANSI/AAMI ST79 for your department and make it available to your staff
- Edit department policies and procedures to reflect ST79 edits; train staff accordingly



References

- Association of periOperative Registered Nurses (2017). *Guidelines for perioperative practice*. Denver, CO, Author.
- Association of the Advancement of Medical Instrumentation (2017). *ANSI/AAMI ST79:2017 Comprehensive guide of steam sterilization and sterility assurance in healthcare facilities*. Arlington, VA: Author.

Questions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