Updates to AAMI’s ST79 Steam Sterilization Standard

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Martha Young, MS, BS, CSPDT
Martha L. Young, LLC
marthalyoung1@aol.com
Updates to AAMI’s ST79 Steam Sterilization Standard

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marthalyoung1@aol.com

Thank You

• Photos
  • Lena Cordie, Key Surgical
  • Steve Kovach and Ray Taurasi, Healthmark
  • Rose Seavey, Seavey Healthcare Consulting, LLC
Program Objectives

- Identify which AAMI ST79 is available in your department so you can update or purchase the more current recommended practice
- Discuss the most recent amendment (e.g., A3:2012) published Nov 2012
- Discuss the 10 things your organization can do now to improve reprocessing
- Describe the new documents being developed by AAMI

What Does AAMI Stand For?

Association for the Advancement of Medical Instrumentation
Purpose of AAMI

- Assist health care professionals and industry in United States and abroad with the
  - Use
  - Acceptance, and
  - Advancement of medical technology
- Includes developing sterilization practices for hospitals as well as industrial sterilization practices

AAMI Organization

- Nonprofit organization
- Founded in 1967
- Nearly 6000 members around the world
- Common goal of members
  - Increase understanding and beneficial use of medical instrumentation
AAMI Organization

• Recognized as the foremost voluntary standards-setting organization in the United States
• AAMI Standards and Recommended Practices represent a national consensus

American National Standard Institute (ANSI)

• Organization
  • Approves AAMI standards as American National Standards
  • Coordinates the
    • Development and promotion of all United States voluntary standards
    • Officially represents the United States in international-standards setting
      • Seat on International Standards Committees (ISO)
Examples of Harmonized Standards

- So far only a few AAMI standards developed for Medical Device manufacturers have been harmonized with ISO
- Standards for health care facilities have not been harmonized because of major differences in sterilization practices between the United States and parts of Europe

Examples of a Harmonized Standard

- ANSI/AAMI/ISO 11140-1:2005 (R) 2010
  - *Sterilization of health care products—Chemical Indicators—Part 1: General requirements*
  - Specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances
AAMI Recommended Practice

- Usually oriented toward healthcare professionals
  - Useful to manufacturers to understand environment where medical device is used
- Used mainly by SP, OR, and ICPs
- Address procedures and practices to ensure
  - Safe and effective use of device(s)
  - Maintenance of device performance characteristics
- Example
  - ANSI/AAMI ST58 Chemical sterilization and high-level disinfection

Implementation

How an AAMI Document is Developed

- Meet two times a year (DC or Baltimore)
- Have added conference calls in between meetings
- Respond to all submitted comments
- AAMI staff member for each committee
  - Procedural expert
  - Compiles comments
  - Prepares documents for voting and publication
Committee Members

- Medical device industry
- Health care organizations
  - IAHCSMM, APIC, AORN
- Facilities and individual professionals
  - Users
- Government representatives
  - FDA
- Academics, scientists
- Individual experts/consultants

Implementation

- Due process
  - Everyone with an interest has the right to participate and express a viewpoint
    - Many viewpoints and types of expertise
  - No single person or interest group can unduly influence the process
  - All comments must be reviewed and responded to
Implementation

How an AAMI Document is Developed

• Reaching **consensus**
  • Substantial agreement (more than majority)
  • Unanimous agreement is often achieved
  • Committee ballot and public review
• AAMI board review and approval
• ANSI board review and approval
• Publication
  • Reviewed every 5 years for updating

Continuous Maintenance

• ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
• The purpose of continuous maintenance is to permit standards and guidelines to
  • Evolve and be updated on a regular basis (as opposed to a fixed multi-year cycle)
• As such, proposals for revisions to ST79 are sought from interested and knowledgeable parties
Objective 1

Identify which AAMI ST79 is available in your department so you can update or purchase the more current recommended practice.

Evidence-Based Guideline

(Consolidated Text)
## ANSI/AAMI ST79
### Recommended Practice

<table>
<thead>
<tr>
<th>If You Have This AAMI Document</th>
<th>What To Purchase</th>
<th>What To Download Free</th>
</tr>
</thead>
</table>

**Most up-to-date**

Download A3:2012 PDF
Regulations & Recommended Practices Establish State-of-the-Art for Sterile Processing

The Joint Commission National Patient Safety Goals

- NPSG.07.05.01
- “Implement evidence-based practices for preventing surgical site infections.”
- Element of performance
- “Implements policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Center for Disease Control and Prevention [CDC] and/or professional organization guidelines).”

The Joint Commission. 2013 Hospital Accreditation Standards (HAS)
Every Facility that Utilizes a Steam Sterilization Process Should Follow AAMI ST79 Recommended Practices

Hospitals
ASCs
Clinics
Doctor Offices

The Joint Commission

• Joint Commission Online July 2011
  • Surveyors received in-depth training on sterilization processes through AAMI
    • Before training cited 10% noncompliance for HLD/sterilization*
    • After training cited 40% noncompliance for HLD/sterilization*
  • Survey to ANSI/AAMI ST79
  • Expect most up-to-date ANSI/AAMI ST79 to be available to employees

http://www.jointcommission.org/assets/1/18/conline_July_20_11.pdf

Objective 2

Discuss the most recent amendment
A3:2012
Published Nov 2012

Immediate-Use Steam Sterilization

• IUSS replaces the term Flash sterilization throughout AAMI ST79
  • Now it matches
    • Multi-Society Position Paper
Immediate-use steam sterilization (IUSS) should meet the following criteria:

- Have been through a cleaning process consistent with all devices processed within the facility
- Once cleaned place in a container or package intended for IUSS
  - “Sterilizing unwrapped items is not recommended.” (8.6.2.1)

- Cycle selection based on written IFUs from manufacturers of
  - Device, sterilizer, and container
Common Statement About IUSS Use in Healthcare Facilities

We use rigid sterilization containers and run a 270-275°F (132-135°C), prevacuum steam sterilization process in our OR so we no longer use IUSS.

Is this an IUSS CYCLE?

Introduction and Overview

IUSS should meet the following criteria:

• Cycle selection includes:
  • Type of cycle
    • Gravity-displacement or dynamic-air removal
  • Dynamic-air removal should be used unless gravity cycles recommended by device manufacturer (8.6.2.1)
Introduction and Overview

IUSS should meet the following criteria:

• Cycle selection includes:
  • Temperature
    • 270-275°F (132-135°C)
  • Time
    • Standard (270-275°F, 4 min) or
    • Extended (270-275°F, 10 min) (8.6.2.1)

Remember

• Time
  • The same time should be used for IUSS as for terminal sterilization and in every location that sterilization takes place
  • Follow the device manufacturer's IFU
Introduction and Overview

IUSS should meet the following criteria:

- Cycle selection includes:
  - Dry time:
    - 0 to 1 minute so contents wet
  - Containerize
  - Transfer immediately using aseptic technique
  - Open immediately, do not store for later use unless indicated by containment device manufacturer (8.8.5)

Common Statement About IUSS Use in Healthcare Facilities

We use rigid sterilization containers and run a 270-275°F (132-135°C), prevacuum steam sterilization process in our OR so we no longer use IUSS.

YES THIS IS AN IUSS CYCLE IF DRY TIME IS 0-1
Introduction and Overview

Immediate-Use Steam Sterilization (IUSS) should meet the following criteria:

• “Implants should not be sterilized for immediate use.” (not new)

Definitions

2.15 chemical indicators (CIs) and 10.5.2.1 General considerations for CIs

• Definitions of 6 classes of CIs based on ANSI/AAMI/ISO 11140-1:2005, Sterilization of health care products—Chemical indicators—Part 1: general requirements
  • Class 1 Process indicators
  • Class 2 Bowie-Dick test indicators
  • Class 3 Single-variable indicators
  • Class 4 Multi-variable indicators
  • Class 5 Integrating indicators
  • Class 6 Emulating indicators
Definitions

2.15 chemical indicators (CIs) and 10.5.2.1 General considerations for CIs

Note 1

- Explaining that the 6 classifications found in ANSI/AAMI documents are different than the classifications of CIs used by medical device manufacturers when filing a 510(k) document

- FDA recognition of chemical indicators is limited to
  - Class 1 Process Indicators
  - Class 2 Indicators for use with special tests
  - Chemical Integrators
  - Have resistance characteristics consistent with the “Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators,” issued 12/19/2003
Definitions

Annex O

• Comparison of the difference between ANSI/AAMI/ISO and FDA classifications on chemical indicators
  • CIs can meet both FDA and ANSI/AAMI/ISO performance characteristics since most CIs are also sold OUS
    • For example a CI may meet the FDA chemical integrator FDA performance requirements and the ANSI/AAMI/ISO Class 5 integrating indicator performance requirements

2.15 chemical indicators (CIs) and 10.5.2.1
General considerations for CIs

Note 1

• How does this affect your practice?
  • It does not affect your practice
  • The recommendations for the type and use of chemical indicators have not changed (Table 6 and 7, 10.5.2, 10.5.4, 10.6)
Work area design and functional workflow

3.2.1a Definitions of work areas

- Central service department was changed to **sterile processing area**
  - Not every facility has a department
- Sterile processing area is any location in a facility that:
  - Processes and controls medical supplies, devices, and equipment whether sterile or not sterile
- ASC, clinic, office-based practice

3.2.2 Key issues to be considered in the design of decontamination:

- "Is there sufficient number of appropriately placed hand sanitizers?"
- "How will the loaner instrumentation be received? How much space will be required and how will receipt be documented?"
Work area design and functional workflow

3.2.2 Key issues to be considered in the design of decontamination:

pp) “Are there any specific needs for instrumentation, such as for leak test checking, dental drills, and robotics?”

qq) How will IFU be accessed or located?”

Special area requirements and restrictions

3.3.7.1 Decontamination area

• “The decontamination area is only utilized to process medical/surgical instrumentation and equipment. Dietary service items should not be processed in this area.”

• Added section
  • Need for an area for receipt of loaner instrumentation (space and paperwork)
3.3.7.1 Decontamination area

- Where prolonged standing is required
  - Should use anti-fatigue mats (OSHA)
- Final water rinse (manual or automatic washers)
  - Deionized, distilled, or RO water
  - Prevents staining and contamination of instruments

3.3.7.2 Decontamination equipment

- New section
  - Discusses maintenance of the equipment according to the manufacturer’s written IFU
  - Ensures optimal performance of equipment
3.3.7.3 Preparation area

- The preparation area should include space for:
  
h) processing table made of nonporous materials (e.g., stainless steel) should be ergonomic and preferably height adjustable

3.3.7.5 Sterile storage

- Used to store sterile and clean products that have been removed from external shipping containers
- “Hand hygiene facilities should be accessible to the sterile storage area.”
- Traditional hand washing or waterless hand hygiene agents
3.3.7.6 Break out area

- New section
  - Location of break out area to remove items from external shipping, carton dust and debris will not enter sterile processing area
  - Adjacent to a surgical or supply processing area

3.3.8 Emergency eyewash/shower equipment

- Plumed eyewashes/facewashes and showers
  - Should activate weekly to ensure flushing fluid is available
  - Verify water temperature
    - 15°C to 43°C (60°F to 100°F)
  - Document routine testing
4.5.2 Decontamination area
• “Liquid-resistant shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other potentially infectious materials.”

Handling, collection, transport of contaminated items
6.3 Care and handling of contaminated reusable items at point of use
• Identify instruments that need repair with a tag so not used
7.4.1 Sorting and disassembly of instrumentation
• “Instruments identified for repair will remain segregated throughout the decontamination process.”
Handling, collection, transport of contaminated items

6.3 Care and handling of contaminated reusable items at point of use

• Placement of instruments in containers, instrument, or transportation pan
  • Protect scopes and delicate instruments from damage
  • Segregate sharp instruments
  • Heavy instruments on bottom
  • Delicate instruments on top

Incorrect Handling, Collection and Transportation

Heavy instruments stacked on top of more delicate instruments
Handling, collection, transport of contaminated items

6.3 Care and handling of contaminated reusable items at point of use

- Keep instruments moist with water or instrument precleaner to prevent biofilm formation
  - Moist towel
  - Instrument spray for pretreatment
- Reduces instrument corrosion, pitting, and rusting

Enzyme Foam Not Covering All the Surfaces

Poor transportation: Damaged instruments
Correct Transportation

- Wet towel covering instruments
- Biohazard sign
- Contained and kept moist

Cleaning

7.5.2 Cleaning agent
- Calculate volume of cleaning sink or other solution container (e.g., transport bin, basin, etc) to determine appropriate dilution rates
- Ensure consistent and accurate cleaning chemistry is used
7.5.2 Cleaning agent

- Follow manufacturer’s written IFU for water/solution temperature
  - Routinely monitor and document (7.5.3.2)

- 7.5.3.2 Manual cleaning and 7.5.6 Cleaning of instruments
- Lumens should be brushed with a brush of
  - Appropriate type, size (diameter and length)
  - Bristle type and material
- Followed by flushing with cleaning solution and then preferable treated water
7.5.3.2 Manual cleaning and 7.5.6 Cleaning of instruments

- Nylon cleaning implements preferred
- Stainless steel designed specifically for surgical instrument jaws and box locks may be used following manufacturer's written IFU

7.5.3.3 Mechanical cleaning

“Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. When evaluating or changing to a new type of cleaning chemistry and after all major repairs, all cycles used should be tested to ensure the cleaning chemistry and cleaning action are effective.”
Cleaning

7.5.5 Verification of the cleaning process

- “Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes.”
- Use methods that are able to measure organic residues (see Annex D)
  - ATP
  - Protein
  - Hemoglobin

Objective 3

Discuss the 10 things your organization can do now to improve reprocessing
AAMI/FDA Medical Device Reprocessing Summit

• Oct 11-12, 2011 at FDA
• Address challenges recently highlighted by FDA on reprocessing of reusable medical device
  • Focus was cleaning
• Presentations and Reprocessing Summit
  Publication available at:
  http://www.aami.org/reprocessing/materials.html

AAMI Horizons

• Sterilization and Reprocessing
  A Matter of Patient Safety
  • Spring 2012
  • http://www.aami.org/publications/Horizons/
10 Things To Improve Reprocessing Now

• This list emerged from the 2011 AAMI/FDA Medical Device Reprocessing Summit
  • Presentations
  • Audience
  • Discussions
  • Follow-up input

AAMI Horizons, Spring 2012

10 Things To Improve Reprocessing Now

• Intended to
  • Inspire
  • Serve as a refresher on some basics
  • Does not replace standards, regulations, or internal policies
  • Can implement immediately without waiting for other actions, such as long-term standards and research

AAMI Horizons, Spring 2012
#1 The Basics

- Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes, and must be performed:
  - Before each patient use
  - According to the device manufacturer’s written instructions for use (IFU)
- For more information, go to [www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm)

AAMI Horizons, Spring 2012

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#2 The Right Tools

- Have readily available in reprocessing areas:
  - IFU
  - All cleaning implements and equipment required by the IFU

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Right Tools

Mechanical cleaning equipment
  • Washer-disinfector/decontaminator
  • Ultrasonic
  • Utensil and cart washer
• Cleaning agents
• Water-soluble instrument lubricants
• Treated water
• Cleaning verification monitors (equipment and instruments from equipment)

Right Tools

Manual cleaning method
  • Appropriate sinks
  • Cleaning agents
    • Way to measure adequate dilution
    • Way to measure time at temperature to record
  • Correct size and type of brushes
  • Water-soluble instrument lubricants
Right Tools

Manual cleaning method
• Treated water
• Air and/or lint-free cloths
• Cleaning verification monitors for individual instruments

#3 Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization

• The following areas should be represented:
  • Operating room
  • Infection prevention and control
  • Healthcare technology management (biomed)
  • Endoscopy
  • Risk management and quality
  • Education
  • Materials management (I would include Sterile Processing)

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#4 Share lessons learned

- Remind senior management and safety officers that it costs much less to “do it right the first time.”
- Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.

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Filthy Surgical Instruments

iWatch News by The Center for Public Integrity

*Filthy surgical instruments: The hidden threat in America’s operating room.*

Accessed on 2/22/2012 at:

#5 Written procedures

- Establish a formal program for reprocessing, including:
  - Written standardized policies and procedures
  - Chain of accountability
- Use industry experts to resolve conflicts between the IFU and facility policies

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Remember

- Policies and procedures are only as good as the information used to create them
- Need someone who is up-to-date on recommended practices
- Need up-to-date IFU for
  - Medical devices
  - Equipment (cleaning, sterilizers)
  - Cleaning agents
  - Packaging
  - Monitors (cleaning, BIs and CIs)
#5 Written procedures

- Written procedures should be developed and implemented for sterile processing reporting of:
  - Inadequate instructions
  - Equipment problems
  - In-service issues to the manufacturer
  - FDA's MedWatch program

#6 Standards matter

- Know the current standards, recommended practices, and IFU
AAMI Standards beyond ST79

• ST58:2005 Chemical sterilization and high-level disinfection in health care facilities (Being Updated)
• ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness (Start Updating 2013)
• ST65:2008 Processing of reusable surgical textiles for use in health care facilities
• TIR34:2007 Water for the reprocessing of medical devices
• TIR31:2009 Process challenge devices and test packs for use in health care facilities

Sterilization in Health Care Facilities

• 2013 Edition
• Contains ST79 and 11 other standards and TIRs
• Available at http://www.aami.org/publications/standards/ster.book1.html
Evidence-Based Guidelines

AORN Perioperative Standards and Recommended Practices (2013) for
- Sterilization in Perioperative Practice Setting
- Cleaning and Care of Surgical Instruments and Powered Equipment
- Cleaning and Processing of Flexible Endoscopes and Endoscope Accessories
- Selection and Use of Packaging Systems
- High-level Disinfection

Evidence-Based Guidelines

- Available at http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html
#7 Purchasing

- Sterile processing should be included in purchasing decisions for medical devices
  - Can the device be reprocessed appropriately with the facility’s existing resources

#8 Separate and standardize functions and locations

- Separate:
  - Central service (warehouse, stocking, etc) from reprocessing
  - Create standardized job descriptions and functions
#9 Training

- Train, train, train, and retrain
- Assess staff competencies
- Negotiate for training budget with cost/benefit analysis to prove value
- Partner with vendors for education
- Create a list of available continuing education units (CEUs) for staff to access

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#9 Training

- Work with human resources to create career ladders for certification and promotion
- Promote the importance of certification
- Note: In-service for loaded or new instruments should include reprocessing in-service area that is separate from (or in) sterile processing

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#10 Assessment

- Conduct an audit for compliance with standards and regulations, using any number of available tools and resources
- For more information go to; [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm)

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Additional Resource

ANSI/AAMI ST79

- 11 Quality process improvement
  - 11.2.2 Risk analysis
    - Related to sterilization process failure
    - Identify risks before a failure occurs
    - Tools to use to identify failures
      - Figure 12 Decision tree for conducting investigations of steam sterilization process failures
      - Table 8 Checklist for identifying reasons for failures
Table 8—Checklist for identifying reasons for steam sterilization process failures

- Operator errors (85%)
- Sterilizer (10%) or Utility Malfunctions (5%)

Personal Communication, Charles Hancock, President, Charles O. Hancock Associates, Inc.
Objective 4

Describe the new documents being developed by AAMI

New AAMI Documents

- New TIR documents being developed
  - Human Factors for Medical Device Reprocessing
  - Endoscope Reprocessing
  - Standardized Instructions for Use
  - TIR is not a recommended practice
  - Review of an important technical issue or healthcare practice, and
  - Statement of expert opinion released by a technical committee
Other New AAMI Resources

• Sterile Processing In Healthcare Facilities: Preparing for Accreditation Surveys
  • More info
• Building for the Future: Construction and Renovation of Sterile Processing Facilities
  • Book coming soon
  • Webinar series in January, February, and March
• Sterile Processing Benchmarks (SPB)
  • Web-based tool
  • More info

Questions?

Type your question in the Q&A box on the left side of your screen and press Enter

Or press *1 on your telephone keypad
Closing Reminders

• Please be sure to fill out the evaluation form at http://aami.confedge.com/ap/survey/s.cfm?s=ST79A3

• CBSPD and IAHCSMM are offering contact hours for this webinar. Please contact Jeanine Beisel at jbeisel@aami.org to obtain a letter of attendance needed to receive the contact hours from CBSPD and IAHCSMM.