Welcome!

Topic: Part I – AAMI ST79 Recommended Practice
Facilitator: Jamie Melahn, 3M Marketing
Diane Koch, 3M Marketing
Speaker: Dorothy Larson, Technical Services

Housekeeping
- Questions
  - Mute feature (*7 = unmute; *6 = mute)
  - "Chat" feature
- Technical difficulties
- CE Credits
- Post session follow-up

For more information: www.3M.com/3MSterileU

Disclosure Statement

Dorothy Larson
Technical Service Representative
3M Infection Prevention Division
dmlarson2@mmm.com

3M Sterilization Tech Line 1-800-441-1922 Option ‘2’
Objectives

- Describe what AAMI is and the need for recommended practices
- Describe how to order a copy of ST79

AAMI ST79 Recommended Practice

- What are Recommended Practices?
- Who belongs to AAMI?
- How are the AAMI Standards developed?
- Are AAMI ST79 Recommended Practices voluntary?
- How do AAMI Standards relate to ANSI and ISO Standards?

What is AAMI?

The Association for the Advancement of Medical Instrumentation (AAMI)

- A voluntary, nonprofit organization
- Writes recommended practices and standards
- Purpose is to assist health care professions and industry with the use, acceptance, and advancement of medical technology
What are Recommended Practices?

ANSI/AAMI ST79 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”

- Provides procedures and practices to help ensure safe and effective use of a device
- ST79 is a resource for all health care personnel who use steam to sterilize
- Guidelines are intended to be achievable

Who belongs to AAMI?

- Representatives from
  - Medical device industry
  - Healthcare facilities
  - Research and teaching facilities
  - Healthcare organizations (AORN, APIC, IAHCSMM)
  - Government representatives (FDA, EPA)
  - Academic scientists
  - Individual experts

Standards Development

- Follows a due process and consensus
  - All with an interest can participate; No single person or interest group can unduly influence the process
  - Substantial agreement among interested parties; more than majority w/ committee ballot and public review
  - Consensus document
Are AAMI ST79 Recommended Practices voluntary?

- Yes, unless they are adopted by a regulatory authority (i.e. State of New Jersey)
- The application of the recommended practice is solely within the discretion and professional judgment of the user
- Manufacturers are not obligated to comply with a standard unless they claim so in their labeling

How do AAMI Standards relate to ANSI and ISO Standards?

- **ANSI/AAMI**
  - ANSI - American National Standards Institute
    - Coordinates the development and promotion of U.S. voluntary standards, representing the U.S. in setting international standards
- **ANSI/AAMI/ISO**
  - International Standards Organization
  - Writes standards that apply across the world

Why is the AAMI ST79 Recommended Practice needed?

Efficacy of Steam Sterilization
(AAMI ST79 Introduction – Overview)

- Lowering and limiting bioburden
- Appropriately preparing devices
- Selecting the correct sterilization parameters
- Maintaining the sterility of sterilized items until used
Why is the AAMI ST79 Recommended Practice needed?

- Promote sterility assurance
- Quality of care
- Policy and procedure development
- Informed of new technologies

Regulations & Recommended Practices Establish State-of-the-Art for Sterile Processing

Key Groups Influencing Practice

- The Joint Commission (TJC)
- Occupational Safety & Health Administration (OSHA)
- Environmental Protection Agency (EPA)
- Association of periOperative Registered Nurses (AORN)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
Terminology in ST79

A) Necessary, Need, Suggest
   OR
B) Must, Should, May, Can

“MUST”

- "Must" is used only to describe unavoidable situations, including those mandated by government regulation.

Examples:
1) The decontamination area must have an emergency eyewash/shower station
2) To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process
"SHOULD"

- "Should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

Example: Paper-plastic pouches should be used for small, lightweight, low-profile items.

"MAY"

- "May" is used to indicate that a course of action is permissible within the limits of the recommended practice.

Examples:
1) Humidifiers may be installed to maintain the recommended humidity level seasonally
2) Sterility maintenance covers (dust covers) may be used to protect and extend the shelf life of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling before use.

"CAN"

- "Can" is used as a statement of possibility and capability.

Example: Container systems can be cleaned by either manual or mechanical means.
ANSI/AAMI ST79
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

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 & amb facilities

ANSI/AAMI ST37
Steam sterilization: Steam sterilization of patient care items for immediate use

ANSI/AAMI ST33
Safe handling and biological decontamination of devices in facilities & nonclinical settings

ANSI/AAMI ST33
Guidelines for reusable rigid sterilization containers for EO and steam sterilization in facilities

ANSI/AAMI ST79
ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Published in 2006
- Updated using a continuous maintenance process
- Amendment 1 approved August, 2008
- Amendment 2 approved July, 2009
Now ST79:2010 & A1:2010 (Consolidated text)

Contact AAMI to order ANSI/AAMI ST79:2010 & A1:2010,
Comprehensive guide to steam sterilization and sterility assurance in health care facilities (Consolidated Text)
• Order Code: ST79 or ST79-PDF by credit card
• Price/AAMI Member Price: $240/$120 (available at member price through AORN)
• Call 1- 877-249-8226
• Internet: http://marketplace.aami.org
• Fax: 301-206-9789
• Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MD 20701-0211

ST79 Contents – what’s inside?

ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Cover page
- Contents
- Committee representation/members
- Forward
- Introduction
- Standards discussion: Sections 1-12; incl. Tables, Figures
Immediate-Use Steam Sterilization/Flash

Multi-society Position Statement on Immediate-use Steam Sterilization (IUSS)

- Evolution of flash sterilization
- "Immediate use" i.e. item is removed from sterilizer and aseptically transferred to the sterile field
- Personnel should be knowledgeable and competent
- Standardized practices should be implemented
- Critical reprocessing steps (cleaning, decontamination, and aseptic transport) must be followed
- Device manufacturer's written reprocessing instructions should be followed


Immediate-Use Steam Sterilization/Flash

Multi-society Position Statement on IUSS Position Statement Endorsements

- AAMI will include this statement with all new purchases and updates to ST79
- Statement with endorsing logos available as a free download on the AAMI website:
Immediate-Use/Flash Sterilization

Process designed for the steam sterilization of patient care items for immediate use
- High temperature (270-275°F/132-135°C)
- Gravity or dynamic-air-removal
- No dry time
- No storage


Flash Sterilization

Packaging includes
- Perforated, mesh bottom, open surgical tray
- Rigid sterilization container system
- Protective organizing case
- Single-wrapped surgical tray, “express cycle”

Ref: ANSI/AAMI ST79:2010 and A1:2010, Section 10.7.4.1

ST79 - Annexes

Annex D
(Informative)
User verification of cleaning processes

Annex N
(Informative)
Toxic Anterior Segment Syndrome (TASS) and the processing of intraocular surgical instruments
ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Sections 1-2 Introduction: Scope / Definitions and abbreviations
Section 3: Design considerations
Sections 4-6: Personnel considerations / Receiving / Handling, collection, and transport of contaminated items
Section 7: Cleaning and other decontamination processes
Sections 8-9: Packaging, preparation, and sterilization / Installation, care, and maintenance of sterilizers
Sections 10-12: Quality control / Quality process improvement / New product evaluation

Sections 1 - 12

- General Rationale
  - Overview of information within a section

- Rationale
  - Provides the reason for recommendation

- NOTE
  - Clarification statements

Section 1 - Scope

1 Scope
1.1 General

NOTE – For purposes of this recommended practice, “health care facilities” means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term “hospital” is sometimes used in this recommended practice; in all circumstances, this term should be taken to encompass all other health care facilities.
Fun Fact!

- Just for fun, I did a quick search of ST79 and noted how often the term hospital is used!
- What would you guess? Approximately
  A) 15 times
  B) 35 times
  C) 50 times

Section 1 - Scope

1.2 Inclusions
In addition to the definition of terms, bibliography, and informative annexes, this recommendation specifically addresses:
- functional and physical design criteria for sterile processing areas;
- staff qualifications, education and other personnel considerations;
- processing recommendations;
- installation, care, and maintenance of steam sterilizers;
- quality control; and
- quality process improvement

1.3 Exclusions
- Lists things that ST79 does not cover
Section 2 – Definitions and abbreviations

Examples -

2.9 Bowie-Dick test: Diagnostic test of dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air-re-entrainment.

2.12 CDC: Centers for Disease Control and Prevention.

2.55 heat sink: Heat-absorbent material; a mass that readily absorbs heat.

2.125 terminal sterilization: Process whereby product is sterilized within its sterile barrier system.

Part I – AAMI ST79 Recommended Practice Summary

- AAMI standards are developed to assist health care professions and industry with the goal of improving the safety of medical instrumentation and advancing medical technology.
- Sterilization is complex! ST79 sets forth guidelines for facility design, work practices, and process controls to help ensure sterile items are consistently produced.
- Understand/adhere to ST79 recommended practices to enhance department efficiencies.
- All health care facilities should have an up-to-date copy of ANSI/AAMI ST79:2010.

QUESTIONS

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Reference:

Association for the Advancement of Medical Instrumentation (AAMI)

Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Other Resources:

- 3M™ Sterile U
  - http://www.3M.com/SterileU
- 3M Helpline: 1-800-228-3957
- 3M Sterilization Tech Line: 1-800-441-1922 option “2”
- AAMI: www.aami.org
- AORN: www.aorn.org