New and Upcoming Standards for Sterile Processing

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Introductions

- Amanda Benedict, MA, CStd, is AAMI's Vice President, Sterilization, focusing on ensuring strategic alignment and expansion of resources and programs for the extensive community of sterilization and sterility assurance professionals. Her work includes promoting upstream and downstream initiatives relative to AAMI's Sterilization Standards portfolio, overseeing AAMI's support of the Kilmer Conference and adjacent collaborative activity, and serving on the Board of Directors of the Society for Sterility Assurance Professionals.

- Previously, Ms. Benedict served as AAMI's Vice President, Standards from 2020-2023, oversaw the strategic and operational functions of AAMI's expansive and dynamic Standards program and portfolio, managed the national and international work program for the AAMI Sterilization standards portfolio from 2015 until 2022, and led AAMI and ISO standards activities in quality management for medical devices from 2022 until early 2024. She continues to serve in leadership roles within the American National Standards Institute (ANSI) and SES – The Society for Standards Professionals.

- Ms. Benedict holds a Bachelor of Arts in psychology and a Master of Arts in education and human development from the University of Maryland, College Park. She holds a Career Professional Standards Certification (CStd) through SES.

AAMI Description

One of AAMI's best roles to support the healthcare sterile processing community is as a convenor of standards development activity. Standards are crucial to sterile processing and help to ensure patient safety. But what is a standard and why are they so important? What is the difference between recommendations and requirements? What new and forthcoming standards for sterile processing do YOU need to be aware of to ensure that your department is prepared?

AAMI Objectives

1. Understand what voluntary consensus standards are;
2. Discuss why and how standards are implemented;
3. Learn about new and developing AAMI standards for sterile processing in health care facilities.

AAMI's unique role

- **AAMI brings together a diverse community of more than 10,000 healthcare technology professionals united by one important mission—the development, management, and use of safe and effective health technology.**

- **AAMI is uniquely positioned to:**
  - Support the healthcare community in development, management and use of safe and effective healthcare technology.
  - Convene diverse groups to solve problems.

AAMI's role in standards development

- **Accredited** by American National Standards Institute (ANSI) to write American National Standards.
- **Administers** U.S. Technical Advisory Groups (TAGs) to the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) committees – responsible for U.S. participation in committees and U.S. votes on documents.
- **Administers** technical committees of ISO and IEC.
- **Develops** U.S. standards and technical documents.
- **Convenes** a global community of health technology standards professionals.

AAMI's role in standards development

AAMI is the primary source of consensus standards, both national and international, for the medical device industry.

AAMI Standards Philosophy

- Standards should be developed only where there is a **clear need**.
- Standards should be based on **current technology** and **consensus.**
- Requirements should be **performance-based**; design standards should be avoided**.**

"One product, one standard, one test worldwide"

About AAMI standards and technical documents

- Three types of national documents
  - American National Standards
  - AAMI Technical Information Reports (TIRs)
  - Consensus Reports (CRs)
- “User” documents and industry documents
- All developed through a consensus process!

What's a standard?

- A statement of consensus that **establishes technical specifications** and **provides a common language.**
- Provides a **minimum essential** threshold.
- A **foundation** for technology development and innovation**.**
- A basis for **conformity assessment.**
- A means to **facilitate** market entry and trade.

Why are standards important for sterile processing?

- **Codification** of fundamental terms and processes.
- Provides a recipe for **repeated, reproducible processes.**
- Enhances **professional mobility and portability of skills.**

STANDARDS ARE ESSENTIAL TO ADVANCING THE PROFESSION!

Decoding standards

- Voluntary unless incorporated by reference into regulation
- Following standards can help to ensure safe and effective practices that meet accreditation requirements
- For facilities that choose to conform with a standard:
  - “Shall” means a requirement
  - “Should” means a recommendation
  - “May” means permissible
  - “Can” means possible
  - “Must” is used to refer to a regulation

Life Cycle of an AAMI Standards Document

- Periodic review/reaffirmation
  - Every five years for standards
  - Every three years for TIRs
- Revisions can be initiated at any time
- Amendments for small changes to a standard
- Consensus reports can be progressed to a standard or TIR

What's new in AAMI (and ISO) health care sterile processing standards and technical documents?

NEW!: ANSI/AAMI ST108:2023, *Water for the processing of medical devices*

- Elevation of AAMI TIR34, *Water for the reprocessing of medical devices*
- Categories of water
- Water quality for mechanical washers
- Water quality monitoring requirements
- Multidisciplinary team member recommendations, roles & responsibility
- Special considerations for disruptive events
  - Construction or extended shutdown
  - Boil alerts
  - Interruptions in service
  - System repair, modification and/or routine maintenance

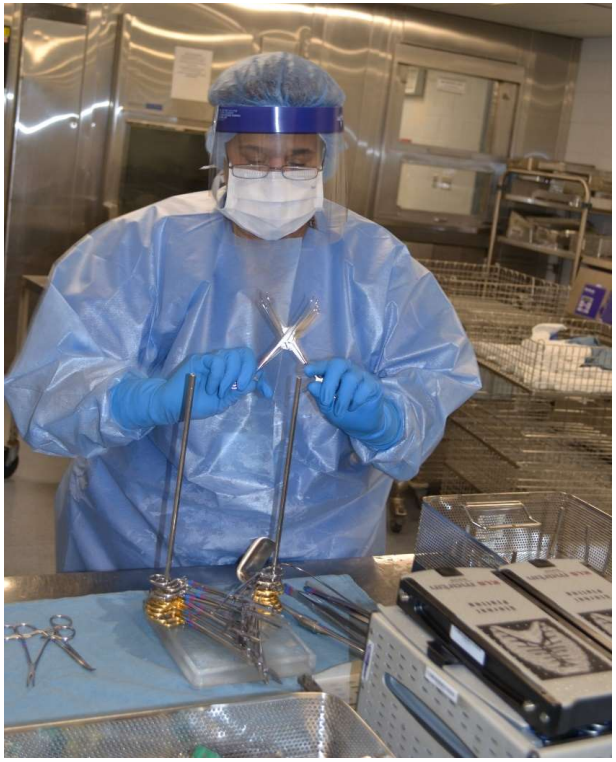
REVISED!: AAMI PB70:2022, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*

Surgical Gown–E:

- Specialized gown which provides extended protection of critical zones

Non-surgical protective gowns, such as Decontamination Gown:

- Intended for use in decontamination purposes
- Barrier performance of at least Level 3



PB70:2022 – Hoods

- Head and neck covering with or without an integrated face shield
- Critical zone
  - Entire front of the hood assembly extending past the face to the ears, but not over the ears

PB70:2022 – Togas

- Combination of a **protective gown** with an **integrated hood** with a **face shield**
- Hood performance level at least 1
- Critical zones are chest, arms, hood
- Detailed information on the barrier performance of each critical zone component of togas can be obtained from the manufacturer.

PB70:2022 – Other protective apparel items

Aprons, Footwear Covers, Sleeves, Protective Headwear (hats & caps)

- Barrier performance of at least Level 1.
- Seams between protective and non-protective areas have no barrier requirements.

PB70:2022 – Packaging Labeling

- Labeled with contents
- Labeled with class of barrier
- Labeling descriptions
  - a) full coverage gown;
  - b) non-protective back gown; or
  - c) open back gown

PB70:2022 – Attire Labeling

- Labeled with class of barrier performance
- Attire having back panels that do not meet at least the requirements for Level 1 barrier performance shall be prominently labeled with a warning stating “Back is Non-Protective”

NEW(ISH)!: ISO 17665:2024, *Sterilization of health care products – Moist heat – Requirements for the development, validation and routine control of a sterilization process for medical devices*

- Combination and revision of old ISO 17665 series of documents
- Primarily for industry
- New edition includes annex for health care facility applications
- Likely to be adopted nationally and by the EU

NEW!: ISO 22441:2022, *Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*

- Addresses VH2O2 (VHP) processes
- Primarily for industry
- Also includes content for health care facility applications
- Recognized by the FDA
- Likely to be nationally adopted

What's coming soon from AAMI?

REVISION: AAMI ST58, *Chemical sterilization & high-level disinfection in health care facilities*

- Incorporates ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*
- Expanded low temperature sterilization recommendations
- Reconfigured to have two sections that are process specific
  - High-level disinfection and liquid chemical sterilization
  - Terminal low temperature sterilization

NEW: AAMI TIR99, *Processing of dilators, transesophageal and ultrasound probes in health care facilities*

- Provides guidance for the appropriate processing of dilators and ultrasound probes in health care facilities making them safe for patient care.
- Intended to provide clear and comprehensive information and direction for health care personnel in the processing of these devices and accessories.

REVISION: AAMI TIR79, *ST79 self-audit assessment for health care facilities*

- Based on the recommendations in ANSI/AAMI ST79:2017/(R)2022
- Revision incorporated the recommendations from the four amendments developed in 2020

What's currently under development at AAMI?

NEW: AAMI TIR109, *External transport of medical devices processed by health care facilities*

Comprehensive guidance on externally transporting medical devices that are used at one healthcare facility to another or to a centralized healthcare operated processing facility, either for use, sterilization, disinfection or decontamination.

[Continued] AAMI TIR109, *External transport of medical devices processed by health care facilities*

- Centralized processing becoming more prevalent
- Low temperature sterilization centralized to one facility
- Increased amount of outpatient clinics that require sterilization support

[Continued] AAMI TIR109, *External transport of medical devices processed by health care facilities*

Areas to address

- Clean/sterile transport
- Contaminated transport
- Types of containers for transport
- Transport vehicles

[Continued] AAMI TIR109, *External transport of medical devices processed by health care facilities*

Areas to address

- Security of items
- Documentation
- Tracking of items
- Preparation of items to transport

AAMI/ADA ST113, *Comprehensive guide for steam sterilization and sterility assurance for dental facilities*

- Joint development between AAMI and ADA
- Based on ANSI/AAMI ST79:2017
- Goal to provide a usable handbook for private practice dentists
- Participate through AAMI or ADA

[Continued] AAMI/ADA ST113, *Comprehensive guide for steam sterilization and sterility assurance for dental facilities*

Proposed changes:

- Align language to dental settings
- Remove content specific to hospitals (e.g., boilers)
- Remove recommendations pertaining to loaned instruments
- Remove references to carts
- Remove references to textiles and basins
- Use only dental examples

REVISION: AAMI ST77, *Containment devices for reusable medical device sterilization*

- General updates based on outcome of periodic review
- Still opportunity to get involved

TIRs and Amendments in development

- AAMI TIR117, *Guidance for processing tattoo machines and accessories in the healthcare setting*
  - Status:
    - Work has not started yet on this TIR.
    - Aiming to have co-chairs in place and begin work in April/May
- AAMI TIR118, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*
  - Status:
    - A task group is working on a first draft
    - ST-WG61 will meet this week to review progress and discuss next steps
- AAMI TIR119, *Guidance on Healthcare Implementation and Use of ANSI/AAMI ST108:2023*
  - Status:
    - A task group is working on a first draft
    - ST-WG95 will meet this week to progress WD-1 and circulate it for comment before September meeting
- Amendment to ANSI/AAMI ST90, *Processing of health care products—Quality management systems for processing in health care facilities*

Potential New Activity?

- Revision of AAMI TIR11, *Selection and use of protective apparel and surgical drapes in health care facilities*
- Assessment for ANSI/ANSI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities*
- Guidance on cleaning of patient care equipment outside of the sterile processing department

Is ANSI/AAMI ST79:2017/(R)2022 being revised?

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Opportunities to Add Your Voice to Standards

- Join a committee or working group
- Attend a standards group meeting
- Submit comments during public review
- Propose an idea for a new standard, TIR or consensus report

For more information:

- AAMI's Website (www.aami.org)
- *AAMI Sterilization News Brief*
- *AAMI News*
- *AAMI Standards Monitor Online*
- Contact AAMI Standards Program at standards@aami.org

Questions?

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