



AAMI Sterile Processing Standards Update: What the OR Needs to Know

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AAMI Introductions



Amanda Benedict, MA, SES-CSP, SES Fellow, 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 both 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 has served as the committee manager of ISO/TC 198, *Sterilization of health care products*, since 2015. She continues to hold leadership roles within the American National Standards Institute (ANSI) governance committees and SES – The Society for Standards Professionals.

Ms. Benedict has 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 (SES-CSP) and is a Fellow of SES.

AAMIⁱ Description

During this session, attendees will gain a comprehensive understanding of what standards are, how they're developed, and their importance for practice and professionals. We'll walk through an overview of AAMI standards and technical documents for health care sterile processing and key information for the OR. Lastly, we'll take a look ahead to currently developing new/revised standards and technical documents for sterile processing to help the OR prepare for what's coming soon and the potential impact on practice.



AAMI Objectives

1

Understand what voluntary consensus standards are, and why and how standards are developed and implemented.

2

Increase knowledge of key AAMI sterile processing standards and guidance documents and their implications for the OR.

3

Gain awareness of standards/guidance under development and their potential impact on practice.

AAMI AAMI's unique role

- **AAMI brings together a diverse community of more than 14,000 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 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.



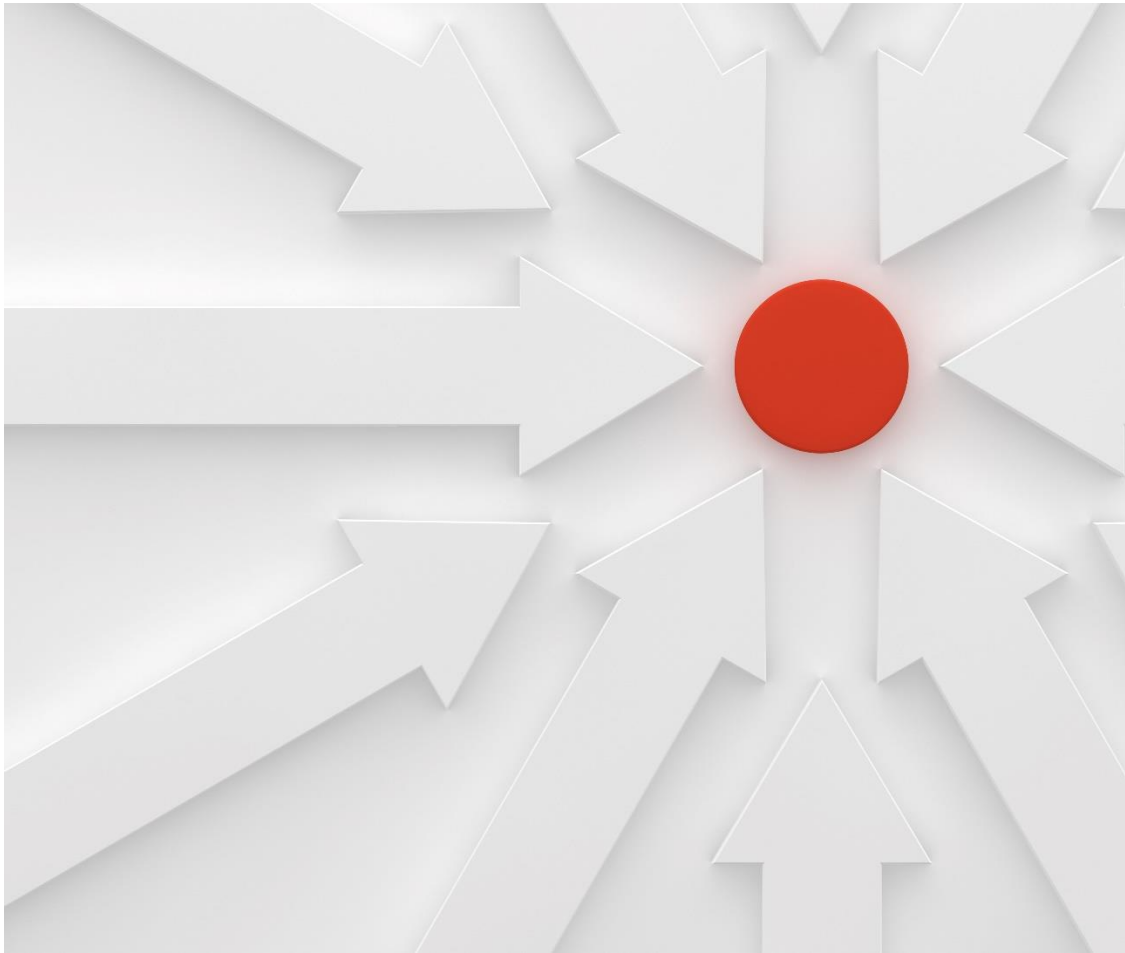
Develops U.S. standards and technical documents.



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

*“One product, one standard,
one test worldwide”*

- 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.





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!

AAMI 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.



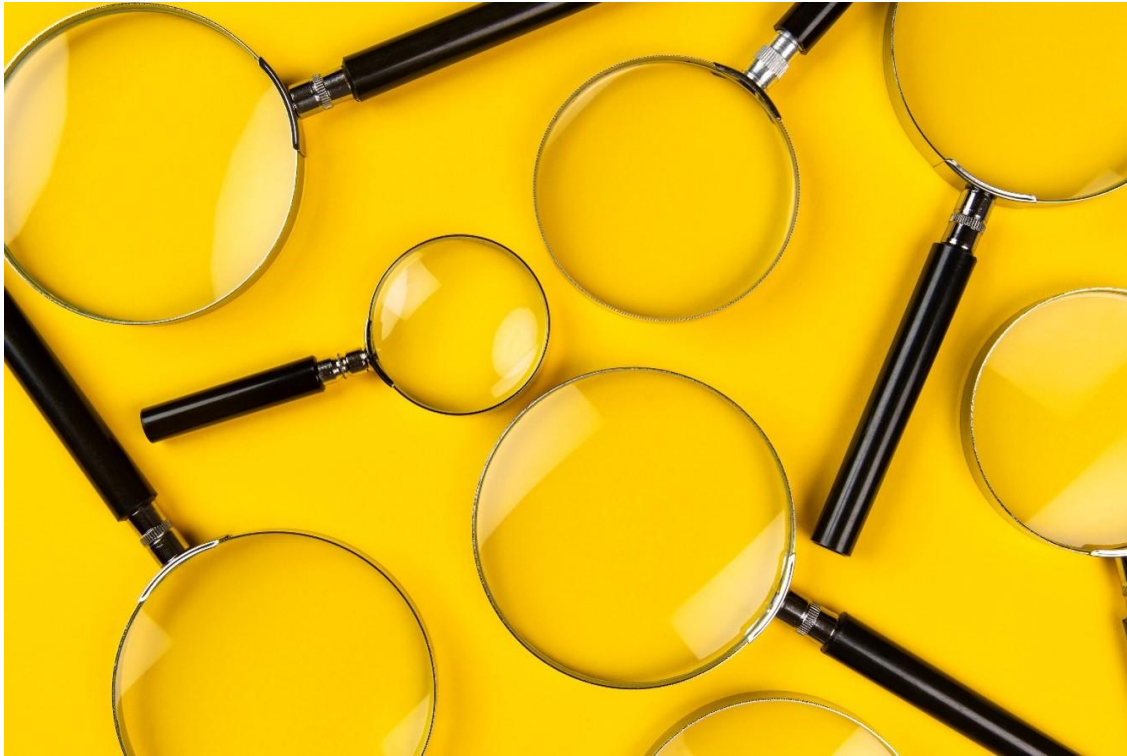
Why are standards important for health care professionals?

- **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!

AAMIⁱ Decoding standards



WORDS MATTER!

Voluntary unless incorporated by reference into regulation

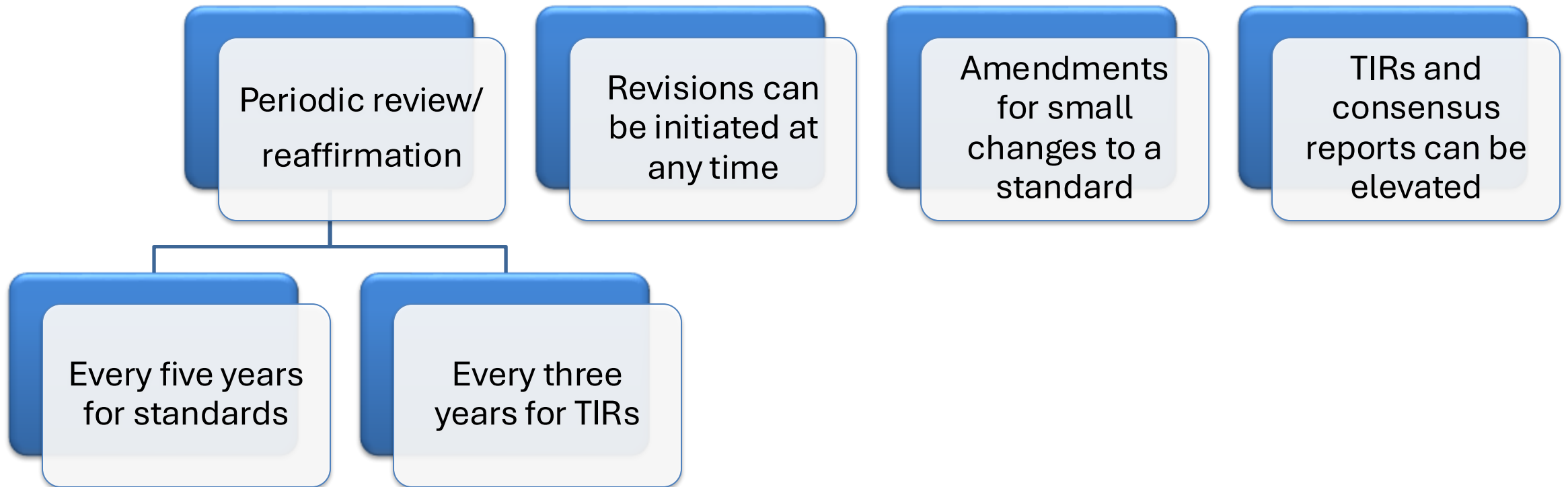
Following standards can help to ensure safe and effective practices that meet accreditation requirements

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





**“Foundational” AAMI health care
sterile processing standards**



ANSI/AAMI ST79:2017/(R)2022, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, & A1:2020, A2:2020, A3:2020, A4:2020

- Provides guidance on:
 - a) functional and physical design criteria for sterilization processing areas;
 - b) staff qualifications, education, and other personnel considerations;
 - c) processing recommendations;
 - d) installation, care, and maintenance of steam sterilizers;
 - e) quality control;
 - f) product evaluation; and
 - g) quality process improvement.
- Applicable to all health care facilities, including, but not limited to, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, dental offices, and other areas where sterile products are reprocessed, stored, and used.



ANSI/AAMI ST79:2017/(R)2022, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, & A1:2020, A2:2020, A3:2020, A4:2020

- Heating, ventilation, air conditioning guidance: points to the version of ANSI/ASHRAE/ASHE 170 that was current when the HVAC system was initially installed or last upgraded.
- Revised attire and PPE recommendations.
- Enhanced hand hygiene recommendations.
- Preparation and packaging recommendations, including improved diagrams for sequential double wrapping and simultaneous double wrapping.
- Immediate use steam sterilization (IUSS) guidance is minimized.
- Point-of-use treatment recommendations.
- Recommendations for transport of contaminated instruments.



ANSI/AAMI ST79:2017/(R)2022, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, & A1:2020, A2:2020, A3:2020, A4:2020

Four amendments published in 2020:

- A1 - Environmental Services/Fans/Food and Drink
- A2 - Inspection of insulated instruments
- A3 - Modification of content pertaining to frequency of cleaning for routine care of sterilizers for sterile processing areas in health care facilities
- A4 - Content addressing recording BI lot numbers in sterilizer records for sterile processing in health care facilities



ANSI/AAMI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities*



- Additions to point-of-use treatment
- Workflow and traffic control
- Cleaning verification expanded
- Revised leak testing recommendations
- Expanded transport section
- Recommendations for water quality
- Sterilization vs. high-level disinfection
- Expanded drying recommendations
- Revised storage requirements
- Multidisciplinary team involvement (e.g., reprocessing equipment and cleaning agents, use of alcohol, risk assessment for storage, new product evaluation, etc.)



**Newly published AAMI health care
sterile processing standards and
technical documents**



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 addressed:

- 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 addressed:

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





REVISION!: ANSI/AAMI ST58:2024, *Chemical sterilization and high-level disinfection in health care facilities*

- Incorporated 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



AAMI **NEW!**: AAMI TIR99:2024, *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 TIR79:2024, *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





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*

- Expanded the types of PPE included in this standard
 - **Surgical Gown–E**
 - **Non-surgical protective gowns, such as decontamination gowns**
 - **Togas** (combination of a **protective gown** with an **integrated hood** with a **face shield**)
 - **Hoods**
 - **Aprons, footwear covers, sleeves, protective headwear (hats & caps)**
- Describes barrier performance levels
- Defines critical zones
- Specifies package and attire labeling requirements





**Currently under development at AAMI
and ISO**



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



AAMI TIRs and Amendments in development

- AAMI TIR117, *Guidance for processing tattoo machines and accessories in the healthcare setting*
 - Status:
 - Working drafts circulated to working group for comment.
 - ST-WG45 met in September to resolve comments and discuss next steps.
- AAMI TIR118, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*
 - Status:
 - Working drafts circulated to working group for comment.
 - ST-WG61 met in September to resolve comments and discuss next steps.
- AAMI TIR119, *Guidance on Healthcare Implementation and Use of ANSI/AAMI ST108:2023*
 - Status:
 - Working drafts circulated to working group for comment.
 - ST-WG95 met in September to resolve comments and discuss next steps.

AAMI TIRs and Amendments in development

- Amendment to ANSI/ANSI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities* – development of an assessment
 - Status:
 - Working drafts circulated for comment.
 - ST-WG84 likely to meet virtually prior to March.
- AAMI TIR121, *Guidance on cleaning and disinfection of patient care equipment in patient care areas to render safe for handling and next patient use*
 - Status:
 - Working drafts circulated for comment.
 - ST-WG61 met in September to resolve comments and discuss next steps.
- Amendment to ANSI/AAMI ST90, *Processing of health care products—Quality management systems for processing in health care facilities*
 - Working drafts circulated to working group for comment.
 - ST-WG86 met in September to resolve comments and discuss next steps.



New activity in ISO/TC 198



PROPOSED BY
FRANCE
(AFNOR)



DEVELOPED BY
ISO/TC 198/WG
17, *CLEANING*

ISO 25224, Sterilization of health care products — Sampling and culturing for reusable, thermolabile flexible endoscopes



*PARTICIPATING COUNTRIES
NOMINATE NATIONAL EXPERTS
TO THE INTERNATIONAL WG*

AAMI ⁱ What about ANSI/AAMI ST79?



YES – ST79 is now under revision!

- Full revision process
- Projected to take ~3 years
- Very early stage now

Get involved!

AAMI ⁱ What else is coming?

- New/innovative technologies
→ new guidance
 - Alternative sterilization modalities
 - UV
 - 3-D printed devices
 - AI
- US TAG to ISO/TC 304,
Healthcare organization management





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

AAMI For more information:

- AAMI's Website (www.aami.org)
- *AAMI Sterilization News Brief*
- *AAMI Standards Monitor Online*
- *AAMI BI&T*
- Contact AAMI Standards Program at standards@aami.org

AAMI Questions?

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