

HSPA



2025

LOUISVILLE



HSPA/AAMI Update on Standards and How They Impact Sterile Processing

Amanda Benedict, AAMI

Damien Berg, HSPA

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Introductions



Amanda Benedict, MA, SES-CSP, 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) through SES.



Introductions



Damien Berg is the Vice President of Strategic Initiatives for the Healthcare Sterile Processing Association (HSPA). Berg, an IAHCMM Past-President of the board of Directors (2018-2019) and a veteran Sterile Processing leader who most recently served as a regional manager for UCHealth in Northern Colorado. He has over 29 years of Sterile Processing and OR experience serving in multiple roles SPD Tech, SPD Manager, SPD Director, Scrub Tech, GI Tech, and Combat Medic.

He has a degree in Business Administration and Healthcare Management and extensive experience working closely with leadership within healthcare organizations and various regulatory bodies, and participates in standards setting groups such as the Association for the Advancement of Medical Instrumentation (AAMI) to develop American National Standards, international standards (i.e., ISO), and technical documents.

In addition, he serves on the Executive Committee for the World Federation of Hospital Sterilization Science (WFHSS). He is an international speaker and Sterile Processing representative on a global scale, such as at chapter events, legislative/advocacy meetings, and numerous conferences.



Description

This presentation provide a timely update on newly published AAMI (and ISO!) standards and other technical documents for sterile processing, take an advance look at new or revised standards and technical information reports currently under development, and provide insight into how they will impact the work being done in sterile processing across the country and globe.



Objectives



GAIN AN UNDERSTANDING OF THE AAMI STANDARDS DEVELOPMENT PROCESS AND HSPA'S ROLE IN THOSE ACTIVITIES.



UNDERSTAND THE CHANGES AND KEY TAKE AWAYS FROM THE LATEST STANDARDS AND HOW THEY WILL IMPACT YOUR PRACTICES



LEARN WHAT NEW AAMI DOCUMENTS ARE BEING ACTIVELY WORKED ON AND HOW YOU CAN BE PART OF IT.



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.



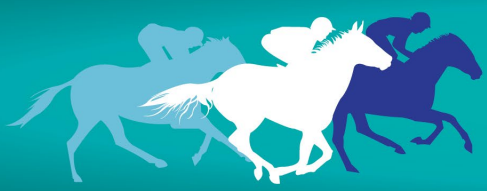
Administers technical committees of ISO and IEC.



Develops U.S. standards and technical documents.



Convenes a global community of health technology standards professionals.



AAMI's role in standards development

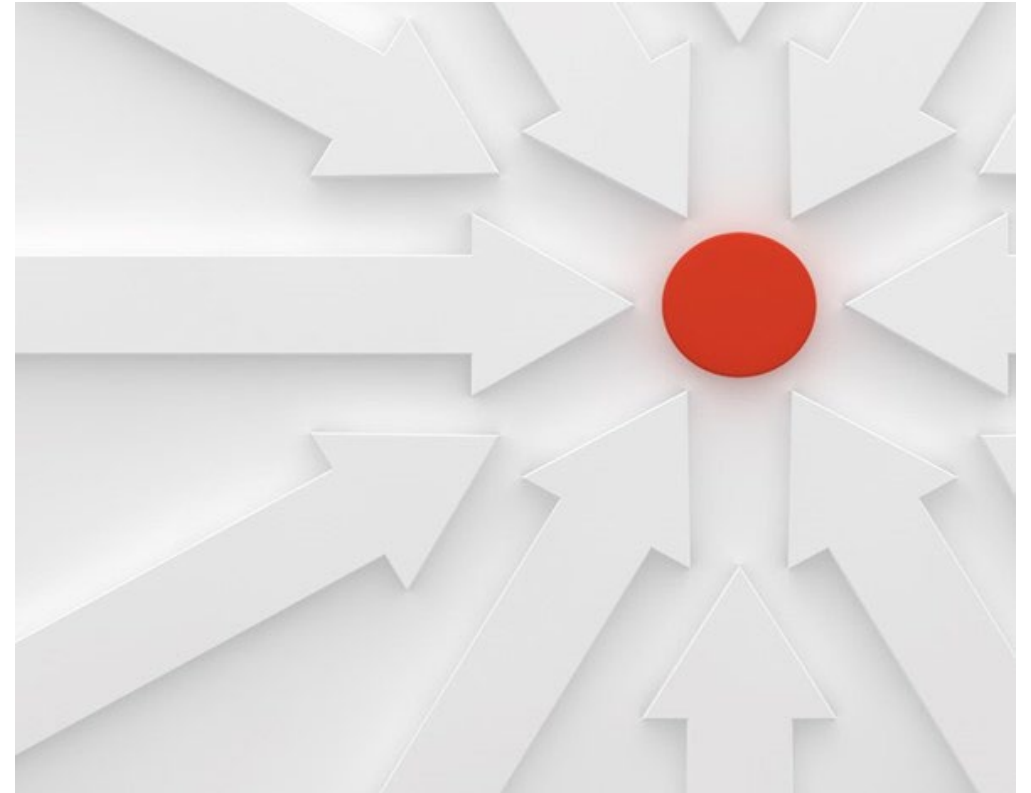


AAMI is the primary source of consensus standards, both national and international, for the medical device industry.



AAMI's 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”



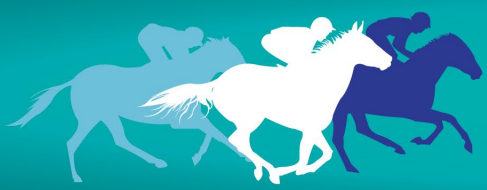
About AAMI standards and technical documents

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?

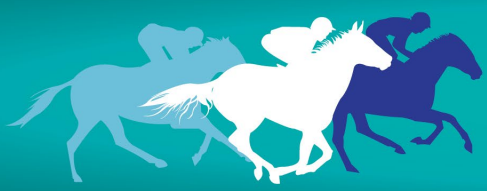
A statement of consensus that **establishes technical specifications** and **provides a common language**.

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 for sterile important for 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!



- Why HSPA believes it is important to participate in standards development
- How HSPA participates (vote, comment, frequently co-chair, raise issues for awareness and to help address gaps in guidance)
 - Individual SPD experts can participate directly



Decoding standards



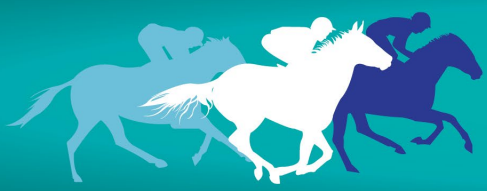
WORDS MATTER!

Voluntary unless incorporated by reference into regulation

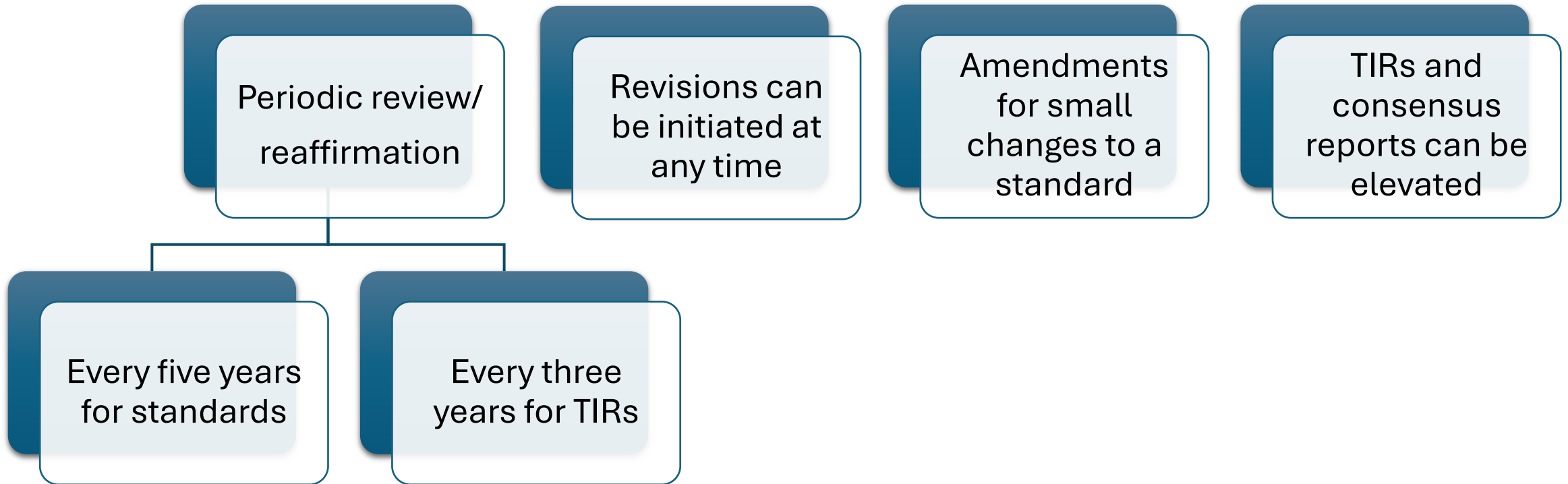
Following standards can help to ensure safe and effective practices that meet accreditation requirements

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





Newly published AAMI and ISO 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 is becoming more prevalent
- Low-temperature sterilization centralized to one facility
- Increased amount of outpatient clinics that require sterilization support



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[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



American
National
Standard

**ANSI/AAMI
ST58:2024**

Chemical sterilization and high-level
disinfection in health care facilities



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.





Other recently published AAMI and ISO health care sterile processing standards and technical documents



REVISION: AAMI TIR79:2024, *ST79 self-audit assessment for health care facilities*

Based on the recommendations in ANSI/AAMI ST79:2017/(R)2022.

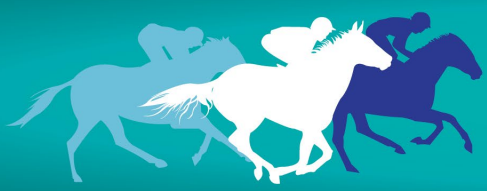
Revision incorporated the recommendations from the four amendments developed in 2020



**NEW(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
- Adopted by the EU
- Likely to be adopted nationally and by the US





REVISIONS: ISO 15883 series, Washer-disinfectors

ISO 15883-1: 2024,
*Washer-disinfectors —
Part 1: General
requirements, terms and
definitions and tests*

ISO 15883-2: 2024, *Washer-
disinfectors — Part 2:
Requirements and tests for
washer-disinfectors
employing thermal
disinfection for critical and
semi-critical medical
devices*

ISO 15883-3: 2024,
*Washer-disinfectors —
Part 3: Requirements and
tests for washer-
disinfectors employing
thermal disinfection for
human waste containers*

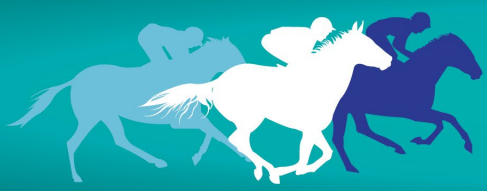
NEW!: ANSI/AAMI ST108:2023, *Water for the processing of medical devices*

- 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





Nearing publication at AAMI



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



GENERAL UPDATES BASED ON
OUTCOME OF PERIODIC REVIEW



DOCUMENT NEARING
FINALIZATION



What's under development for sterile processing at AAMI and ISO?

Status of New AAMI ST Projects (April 2025)

| | Approved Work Item (AWI) | Working Draft (WD) | Committee Draft for Vote (CDV) | Final 15-Day Review | AAMI Standards Board Approval | Publication |
|----------|--------------------------|--------------------|--------------------------------|---------------------|-------------------------------|-------------|
| TIR116 | | WD-3 | | | | |
| ST113 | | WD-2 | | | | |
| TIR118 | | WD-3 | | | | |
| TIR124-1 | | WD-1 | | | | |
| TIR124-2 | | WD-1 | | | | |
| TIR117 | | WD-1 | | | | |
| TIR119 | | WD-1 | | | | |
| TIR121 | | WD-1 | | | | |
| TIR122 | | WD-1 | | | | |
| TIR127 | AWI | | | | | |

Status of AAMI Revision and Amendment ST Projects (April 2025)

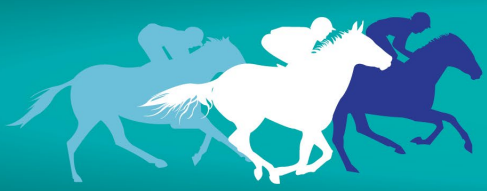
| | Approved Work Item (AWI) | Working Draft (WD) | Committee Draft for Vote (CDV) | Final 15-Day Review | AAMI Standards Board Approval | Publication |
|----------------|--------------------------|--------------------|--------------------------------|---------------------|-------------------------------|-------------|
| TIR12 | | WD-1 | | | | |
| TIR52 | | WD-1 | | | | |
| ST72 | | WD-1 | | | | |
| ST90 Amendment | | WD-1 | | | | |
| ST91 Amendment | | WD-1 | | | | |



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
- The goal is 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





TIRs and Amendments in development

- AAMI TIR117, *Guidance for processing tattoo machines and accessories in the healthcare setting*
 - Status:
 - 1st working draft circulated to working group for comment in February; still under review.
 - AAMI ST-WG45 will likely meet in September to resolve comments and discuss next steps.
- AAMI TIR118, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*
 - Status:
 - 3rd working draft will be circulated to working group for comment in May/June.
 - AAMI ST-WG61 will meet in September to resolve comments and discuss next steps.
- AAMI TIR119, *Guidance on Healthcare Implementation and Use of ANSI/AAMI ST108:2023*
 - Status:
 - 1st working draft circulated to working group for comment
 - ST-WG95 will meet 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*
 - 1st working draft circulated to working group for comment.
 - ST-WG86 will meet in September to resolve comments and discuss next steps.



TIRs and Amendments in development (Cont)

- Amendment to ANSI/ANSI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities* – development of an assessment
 - Status:
 - Work is underway! 1st working draft circulated to working group for comment.
 - ST-WG84 will likely meet in September to resolve comments and discuss next steps.
- 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:
 - 1st working draft circulated to working group for comment.
 - ST-WG61 will meet in September to resolve comments and discuss next steps.



New activity in ISO/TC 198

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



PROPOSED BY FRANCE
(AFNOR)



WILL BE DEVELOPED BY
ISO/TC 198/WG 17,
CLEANING



*EVERY COUNTRY THAT
PARTICIPATES WILL FORM A
NATIONAL MIRROR
COMMITTEE AND NOMINATE
NATIONAL EXPERTS TO THE
INTERNATIONAL WG*

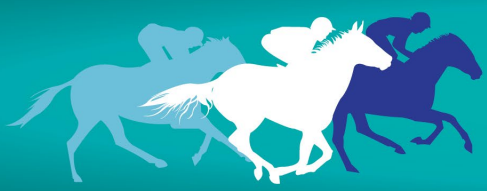


Is ANSI/AAMI ST79:2017/(R)2022 being revised?



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Make your voice heard! Opportunities to influence 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
- HSPA Process Magazine "Up to Standards"
- HSPA Insights



Questions?

Damien Berg, dberg@myhspa.org

Amanda Benedict, abenedict@aami.org