



2025 Updates on Standards for Sterile Processing

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16 March 2025

AAMI 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.

AAMI Description

AAMI supports the healthcare sterile processing community through its role as a **convenor of standards development activity**. Standards are crucial to sterile processing and help to ensure patient safety. But what exactly is a standard, how are they created and used, and what is the difference between recommendations and requirements? What **new standards and guidance** have been published recently, and **what's under development now** that your sterile processing department should be aware of?

AAMI Objectives



Understand what voluntary consensus standards are.



Discuss why and how standards are developed and implemented.



Learn about new and upcoming AAMI and ISO standards for sterile processing in health care facilities.

AAMI 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 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.



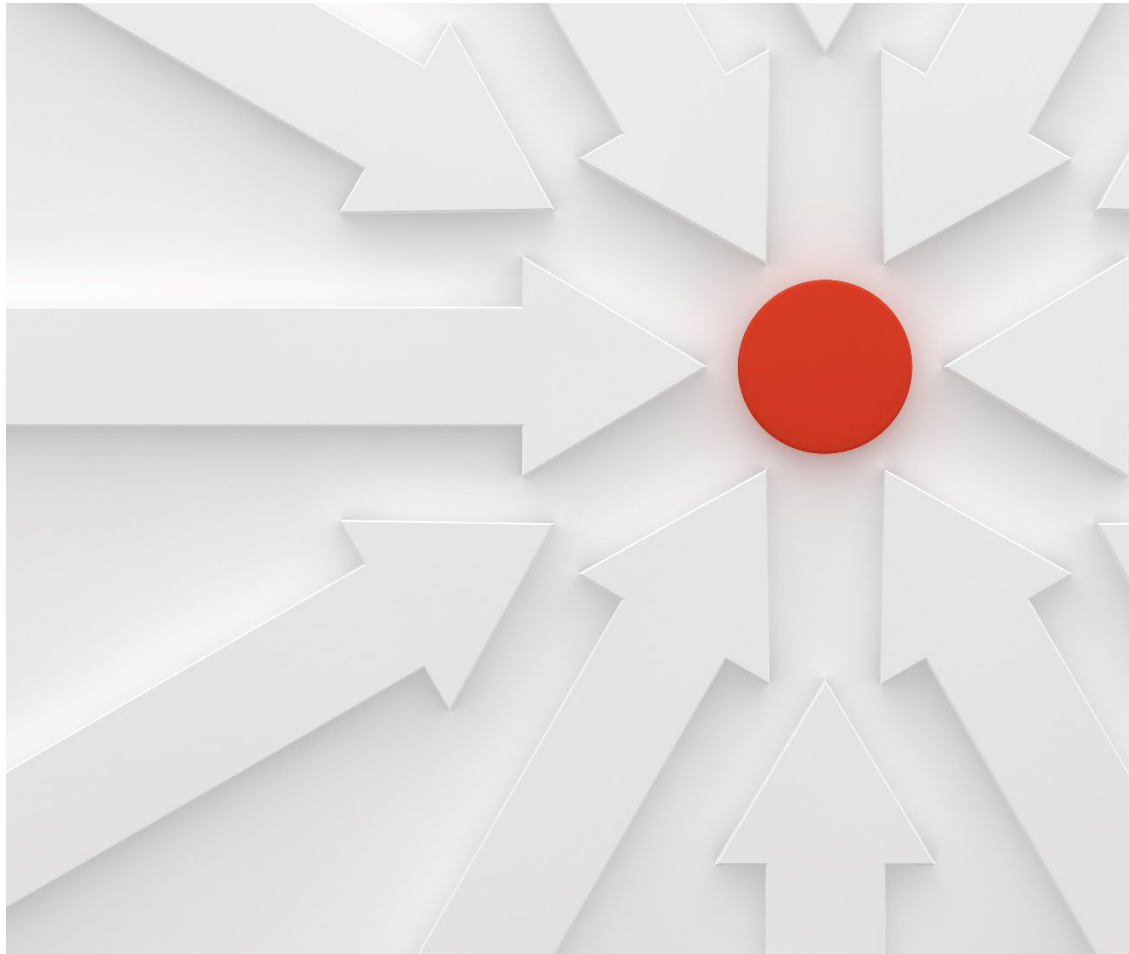
Develops U.S. standards and technical documents.



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 ⁱ 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



WORDS MATTER!

Voluntary unless incorporated by reference into regulation

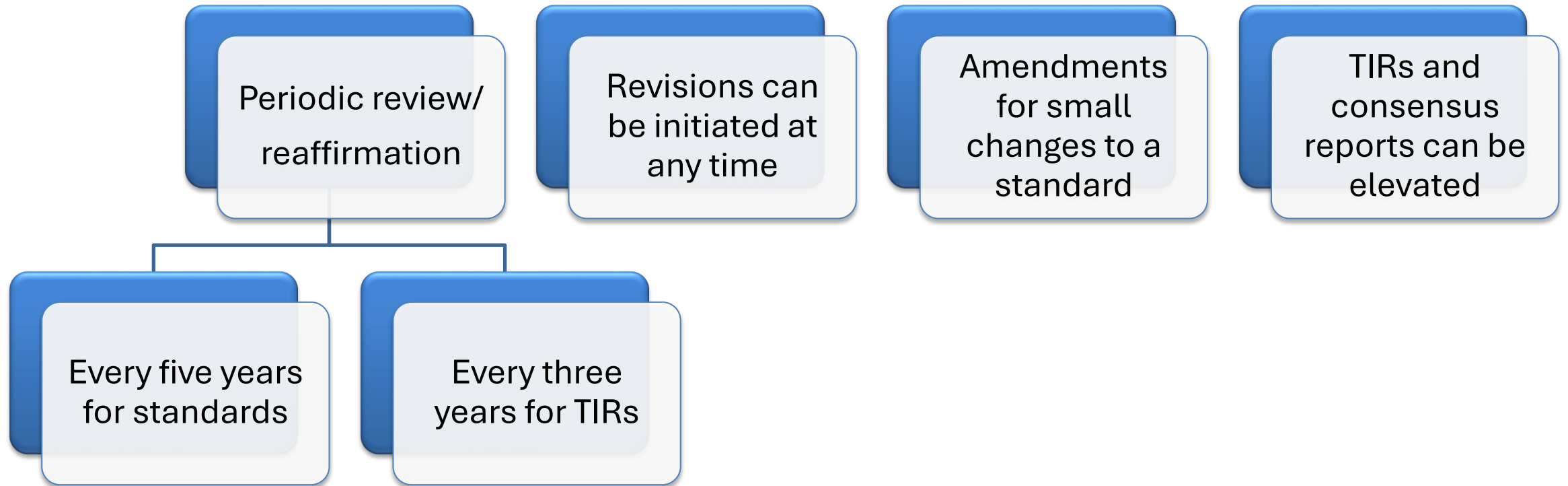
Following standards can help to ensure safe and effective practices that meet accreditation requirements

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



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(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*

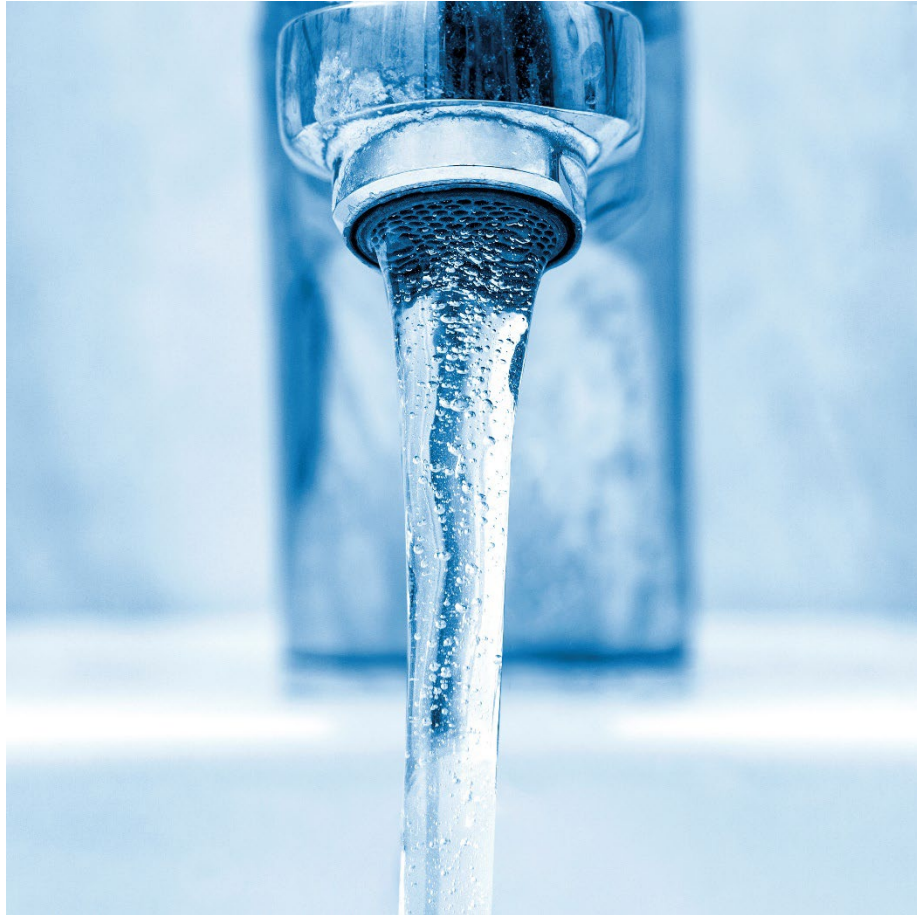
ISO 15883-3: 2024, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*



**Recently published 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*

- 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





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 (and VH2O2 is an established Category A sterilization method for medical devices)
- Likely to be nationally adopted



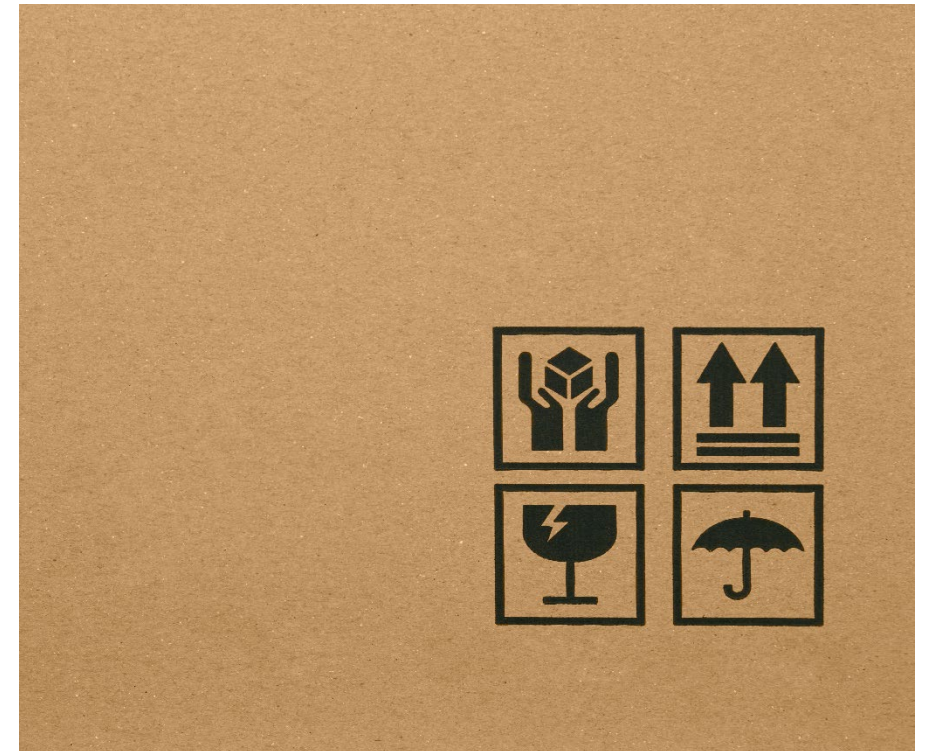
AAMI

Coming soon from 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 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: AAMI ST77, *Containment devices for reusable medical device sterilization*



GENERAL UPDATES BASED ON
OUTCOME OF PERIODIC REVIEW



DOCUMENT NEARING
FINALIZATION



AAMI

**Currently under development at AAMI
and ISO**

AAMI Status of New AAMI ST Projects

	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-2				
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

	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
- 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:
 - 1st working draft circulated to working group for comment.
 - ST-WG45 will meet this week to resolve comments and discuss next steps.
- AAMI TIR118, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*
 - Status:
 - 2nd working draft circulated to working group for comment.
 - ST-WG61 will meet this week 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 this week 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 this week 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:
 - Work is underway! 1st working draft circulated to working group for comment.
 - ST-WG84 not meeting this week; will likely meet in September.
- 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 this week to resolve comments and discuss next steps.

AAMI **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*

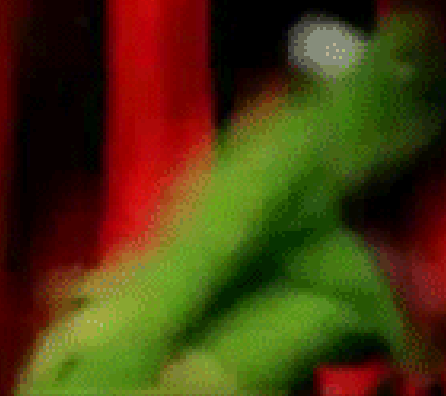


EVERY COUNTRY THAT PARTICIPATES WILL FORM A NATIONAL MIRROR COMMITTEE AND NOMINATE NATIONAL EXPERTS TO THE INTERNATIONAL WG



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

YES!





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 News*
- *AAMI Standards Monitor Online*
- Contact AAMI Standards Program at standards@aami.org

AAMI Questions?

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