Standards and Guidelines Update

Matthew J Arduino, MS, DrPH, FSHEA, M(ASCP)

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Healthcare Systems Strengthening and Training Branch
Division of Healthcare Quality Promotion

Keys to remember

- Most of these are voluntary unless adopted by CMS and accrediting body
- If facilities adopt Guidelines and Standards then CMS, TJC, and the other accrediting bodies will evaluate your practice to see if they are being followed

Overview

- **New AAMI Standards**
  - AAMI. Water for processing Medical Devices. ANSI/AAMI ST108:2023
  - AAMI. Reprocessing of hemodialyzers. ANSI/AAMI RD47:2020
  - AAMI. Water testing methodologies. AAMI/TIR58:2021
  - AAMI. Water for processing medical devices. ANSI/AAMI ST91:2021
  - AAMI. Flexible and semi-rigid endoscope processing in health care facilities. ANSI/AAMI ST91:2021
- **ASHRAE**
  - ASHRAE. Risk management for building water systems: physical, chemical and microbial hazards. ANSI/ASHRAE 514:2023
- **Practice Guidelines**
  - Day LW, et al. Multisociety guideline on reprocessing flexible GI endoscopes and accessories. *Gastrointestinal Endoscopy* 2021; 93(1):11-22,E6
- **Near Future**
  - SHEA Expert Guidance: Strategies for High Level Disinfection and Sterilization

Water for Processing Medical Devices

- **Standard evolved from AAMI TIR 34:2014**
- **Defines water quality for reprocessing medical devices, instruments, and steam for sterilizers**
- **Two types of water are defined:**
  - Facility water
  - Critical water

What does AAMI ST108 cover

- **Roles and responsibilities**
  - Facilities and Biomed Engineering
  - Device reprocessing personnel
  - Surgery personnel
  - Water treatment Specialist
  - Infection Preventionist
- **Risk analysis**
- **Categories of water**
- **Water quality selection and requirements**
- **Water treatment systems**
- **System qualifications:**
  - Operations
  - performance
- **Routine Monitoring**
- **CQI**
- **Water treatment system maintenance**
- **Special Considerations**

Water for Processing Medical Devices

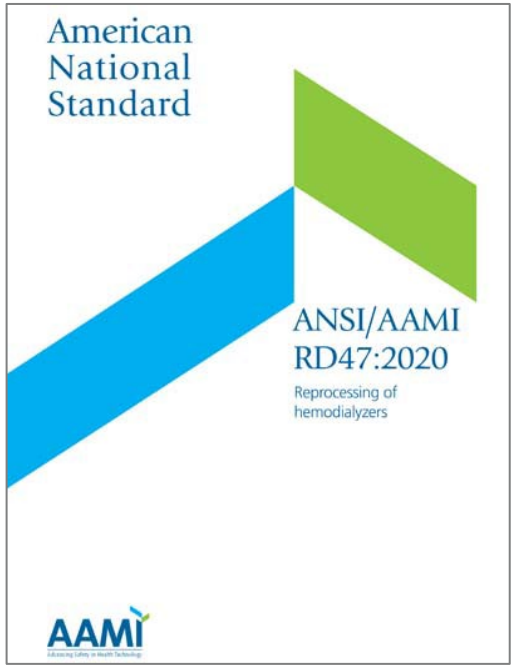
Three Categories of Water Quality

- **Utility Water:** may or may not be equivalent to your tap water; (See table on water quality parameters); **mainly used for flushing, washing, and intermediate rinsing (e.g., rinsing between cleaning and disinfection).**
- **Critical Water:** This is purified water (See table on water quality parameters); water used as final rinse for items that undergo High-level disinfection
- **Steam:** Measured analytes in the condensate (See table on water quality parameters; Steam used for sterilization of instruments, medical devices, and other items

Water Quality Parameters

Measurement	Units	Utility Water	Critical Water	Steam
pH @ 25ºC	pH	6.5-9.5	5.0-7.5	5.0-9.2
Total alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500	<10	NA
Endotoxin	EU/mL	NA	<10	NA
TOC	mg/L	NA	<1.0	NA
Color and turbidity	Visual	Colorless, clear without sediment	Colorless, clear without sediment	Colorless, clear without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<q
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphates	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total hardness	mg CaCo3/L	<150	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

Reprocessing of Hemodialyzers



- AAMI. Recommended practice for reuse of hemodialyzers. Arlington, VA, AAMI 1993
- AAMI. Reprocessing of hemodialyzers. ANSI/AAMI RD47:2020

AAMI Developed a Recommend Practice then a Standard

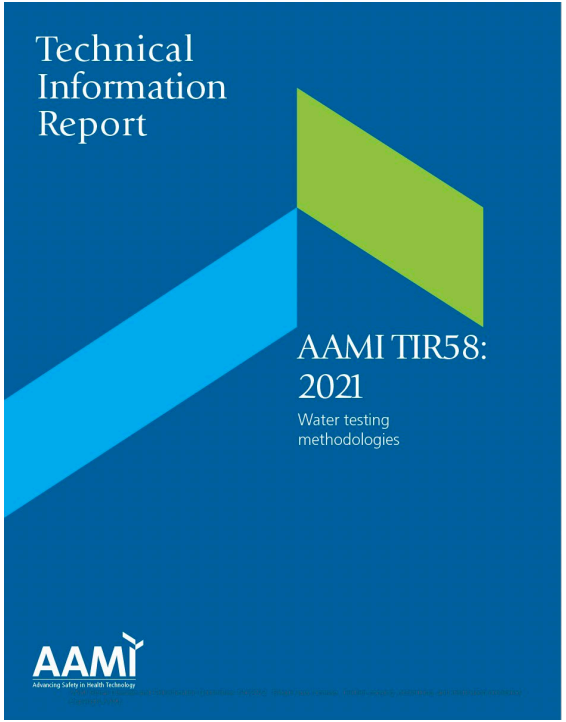
- The basic procedure for dialyzer reprocessing involves four steps: rinsing, cleaning, performance testing, and disinfection and sterilization.
- Dialyzer processing may be performed manually or with the use of automated equipment
- Currently performed in low and middle-income countries (LMICs)
- Some of the LDO's and Baxter Renal Care Division own facilities and provide care in LMICs (eg., Latin and South America, Asia, Eastern Europe, Middle East, Africa)

Dialyzer Reuse

- As of 2020, the three largest dialysis organizations in the United States do not perform reuse in any of their facilities
- According to NHSN annual facility survey – no U.S. hemodialysis facilities have reported reprocessing dialyzers
- Reuse is still performed in other parts of the world, particularly in countries with limited resources to dedicate to kidney replacement therapies
- No longer cost effective in the US

AAMI TIR 58 Water testing Methodologies

- **Audience: Hemodialysis facilities and their laboratories**
- **Additional information and background related to recommendations in ANSI/AAMI/ISO and ANSI/AAMI Standards regarding contaminants in water**
- **Contains laboratory test methods and depending on complexity and instrumentation required what can be performed at the facility and what requires sending to a Laboratory**



Testing Methodologies

- TIR does not supersede *Standard Methods for the Analysis of Water and Wastewater*
- The reader is advised to reference the FDA approval as appropriate or those tests that CMS requires FDA approved tests (eg endotoxin)
- Document does not include sampling recommendations
- Helps facility make operational decisions and prevent patient injury.
- Format contains two tables (Table 1 is a guide to Table 2 Methodologies)

Table 1—Guide to Table 2—Water testing methodologies

4.1 Column 1	4.2 Column 2	4.3 Column 3	4.4 Column 4	4.5 Column 5
Lists elemental, organic and microbial contaminants with their chemical symbol or commonly used acronym. These are used for testing during the design, operational monitoring, and/or troubleshooting phases of a water treatment and distribution system lifecycle.	Lists Maximum Allowable Levels, Action Limits and/or clinically significant levels for each contaminant, as applicable, from ANSI/AAMI, ANSI/AAMI/ISO and other reputable documents and references.	Describes the documented clinical symptoms and levels of the contaminant at which the symptoms occur when a hemodialysis patient is exposed.	Describes effects the contaminant can have on the various components involved in production of water used to prepare dialysis fluid/dialysate and delivery of dialysis fluid/dialysate to the hemodialysis patient during a hemodialysis treatment. Systems affected could include the water treatment system, concentrate preparation and storage, water and concentrate delivery systems and dialysate proportioning by the hemodialysis machine.	Describes the various test methods that can be used to detect or test for a given contaminant. The test method should be sensitive enough to detect below the maximum allowable contaminant levels as described in the applicable ANSI/AAMI or ANSI/AAMI/ISO standard. Known interference problems associated with certain test methodologies are noted.

NOTE 1 The test method should be sensitive enough to detect below the maximum allowable contaminant levels in water as described in Tables 1 and 2 of ISO 23500-3, *Water for hemodialysis and related therapies*, 2019.

NOTE 2 SW = U.S. EPA Solid Waste Methods; SM = Standard Methods; CMS = Centers for Medicare and Medicaid Services

NOTE 3 Unless a chemical contaminant is part of the AAMI profile, an EPA testing laboratory that is licensed by their state for the contaminants in question should be consulted.

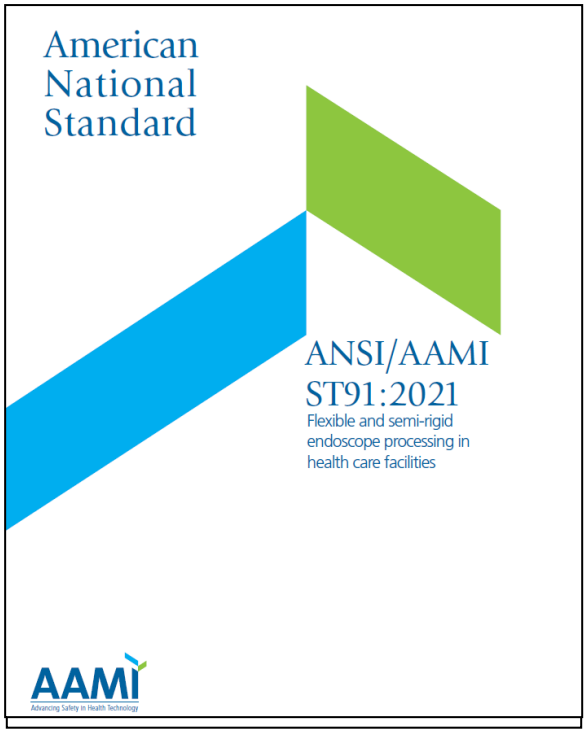
AAMI Contaminants and testing methodologies included and discussed

- **Chemical contaminants**
  - Disinfectants
  - Trace elements
  - Physiological analytes
  - Water quality indicators (eg., Tannins, lignin, Silt density Index, turbidity)
- **Microbiological contaminants**
  - Total plate count
  - Endotoxin Assay
  - Algae, Cyanobacteria
  - Fungi
  - biofilm

Why are endoscope reprocessing standards and guidelines important

- **Multiple types of scopes associated with transmission of ARO's**
  - Duodenscopes, Gastroscopes, Cystoscopes, and Ureteroscopes
- **Scopes are complex devices with narrow channels and places for organisms to hide**
- **They are difficult to clean**
- **At a minimum High-level disinfection is required for reprocessing**
- **Use of antifoaming agents (eg., simethicone) during endoscopy procedures can cause reprocessing failures**
- **Scope damage is also noted to cause reprocessing failures**
- **Transmission of pathogens have been implicated with reprocessed scopes**

Standard vs Clinical Practice Guideline



MULTISOCIETY TASK FORCE ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes and accessories

Lukejohn W. Day, MD,[1] V. Raman Muthusamy, MD, MAS,[2] James Collins, BS, RN, CNOR,[3] Vladimir M. Kushnir, MD,[4] Mandeep S. Sawhney, MD, MS,[5] Nirav C. Thosani, MD,[6] Sachin Wani, MD[7]

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

Gastrointestinal (GI) endoscopy is highly effective for the prevention, diagnosis, and treatment of many digestive diseases.[1] Endoscopes used in endoscopy are complex, diverse, and essential devices that require meticulous cleaning and reprocessing in strict accordance with manufacturer guidelines before being reused on patients. Multiple risks are associated with endoscopic procedures; one such risk includes patients developing an exogenous infection (ie, pathogen introduced through a contaminated device).[2] Exogenous infections in endoscopy are attributed to a myriad of causes. In general, pathogen transmission related to standard end-viewing endoscopes are associated with a failure to follow established cleaning and disinfection/sterilization guidelines for endoscopes, accessories, or associated equipment or with the use of defective equipment.[3–5] On the other hand, exogenous infections have occurred in patients undergoing specialized procedures using duodenoscopes, despite following established reprocessing protocols[6–10]; such observations and findings have raised questions about the optimal methods for the cleaning and disinfection of these unique devices. At the same time, in recent years, concerns have been raised that many of these infectious risks to patients may be underestimated as a result of under-reporting or non-recognition. Consequently, this information highlights the need for clear, evidence-based reprocessing guidelines.

Gaps and variation in implementing infection prevention practices are common in endoscopy units across the United States,[11] and compliance with reprocessing guidelines is inconsistent. Such variation emphasizes the need for standards and updates to infection control guidelines as it relates to GI endoscopes. Several guidelines have covered the topics of safety in endoscopy units,[12] antibiotic prophylaxis before endoscopy,[13] and standards for minimizing nonendoscopic infections and developing an infection control program in endoscopy units[7]; together, these guidelines aid in improving infection control practices within endoscopy units. Given the rising concerns of endoscope-related infections, it is imperative to evaluate the current literature and standards for endoscope reprocessing. This guideline contains expanded details related to the critical reprocessing steps of cleaning and drying and incorporates recent evidence as it pertains to improving the reprocessing of GI endoscopes.

SPAULDING CLASSIFICATION FOR MEDICAL DEVICES AND LEVEL OF DISINFECTION

The classification system first proposed by Dr E. H. Spaulding in 1957 divides medical devices into categories based on the risk of infection involved with their use.[14]

0016-5107/$36.00
https://doi.org/10.1016/j.gie.2020.09.048

Standard vs Clinical Practice Guideline

STANDARD

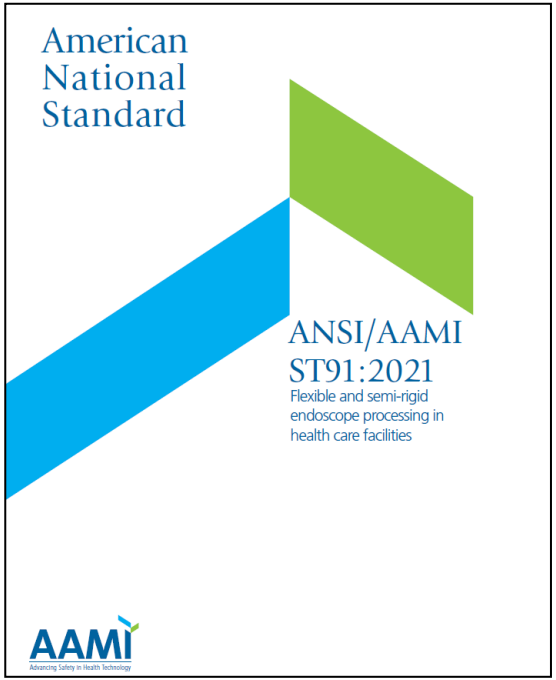
- **Based on consensus:** Standards committee includes manufacturers, professional societies, medical device reprocessors, academics, practitioners and FDA.

CLINICAL PRACTICE GUIDELINE

- **Based on grade evidence based on publications:** committee includes representation from GI Societies, in addition to APIC and SHEA

ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities

- **Committee representation:**
- **FDA**
- **Manufacturers**
- **Practitioners (Nurses, Physicians)**
- **Healthcare Sterile Processing Association**
- **Academics**



6 New takeaways from ST91:2021

- Implement height-adjustable equipment:

  "Sinks should be height-adjustable so that personnel do not have to bend over to clean endoscopes. An ideal decontamination sink is height-adjustable, approximately 36 inches (91 cm) from the floor."

- Change the way you think about sink design:

  Sinks should be deep enough to allow complete immersion of the endoscope to minimize aerosolization. The size of the sink should be adequate (i.e., a minimum of 16 inches x 30 inches) to ensure that the endoscope can be positioned without tight coiling and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on the back.

- Implement a borescope to inspect high-risk endoscopes
- Implement lighted magnification for inspection
- Enhance manual cleaning procedures
- Better anti-fatigue mats

Flexible and semi-rigid endoscope processing

- **Design of endoscope processing area**
  - Work-flow: Unidirectional flow;Separation of Dirty and clean. Flow is from dirty to clean; and separate secure clean storage area
  - Height adjustable work surfaces and sinks sufficient to accommodate endoscope length
  - Anti fatigue mats
  - Utility and critical water
- **Environmental cleaning**
- **Personnel**
  - Frequency of education, training and competency verification; Documentation; PPE use hand hygiene, standard precautions, equipment
- **Decontamination Process**
  - Point of use treatment; Appropriate cleaning methods for the device; endoscope, cleaning equipment and cleaning solutions follow IFUs, leak testing, visual inspection, boroscope inspection, cleaning verification
- **HLD, Liquid chemical sterilization, and terminal sterilization systems for flexible endoscopes**
  - Manual vs Automated (AERs); endoscope drying considerations; Terminal sterilization by gaseous or vaporized chemical sterilization processes (EtO, VHP, HP-O_3)

Flexible and semi-rigid endoscope processing

- **Sterile endoscope sheaths and protective microbial barrier**
  - Endoscope sheaths are available and FDA-cleared for use only with specified endoscopes
- **Processing of endoscope accessories**
  - Processing certain reusable endoscope components, such as air/water and suction valves, biopsy port covers, water bottles, and tubing, requires the same level of inspection, cleaning, and high-level disinfection or sterilization as the endoscopes themselves. If compatible, valves should be subjected to sterilization
- **Storage of processed endoscopes**
- Methods that employ active drying are preferred; use of storage cabinets
- **Transport of processed endoscopes**
  - Aseptic transport of scopes; placed in a clean, covered, solid protective container that is nonporous, leak-proof on its sides and bottom, puncture-resistant, and large enough to accommodate a single endoscope; those that were sterilized should be transported in the container

Flexible and semi-rigid endoscope processing

- **Quality Control**
  - Identification of storage location, age status of each scope
  - Records for visual inspections and testing of equipment; P&P for the use of cleaning verification tests
  - Procedures for microbial surveillance; scope tracking (traceability) and equipment auditing;
  - A method for tracking infections
- **Device repair and loaned scopes**
  - Point of use detection and communication; Processing area detection and communication
  - Health care facility point of repair transfer; Return to health care facility from repair;
  - Use of loaned endoscopes during microbial surveillance; Quality measures
- **New product evaluation**
  - Establish a multidisciplinary committee with representation from those who will be affected by the new product.
  - Ease of understanding IFUs; safety; ROI; personnel education; environmental impact, etc

Multi-society guideline on reprocessing flexible GI endoscopes and accessories recommendation categories (see table 2, pp 14-17)

- **Staff training and competency**
- **GI Endoscope processing**
  - Precleaning/point of use treatment
  - Leak testing
  - Manual cleaning phase
  - Exterior and interior inspection during reprocessing
  - Disinfection of flexible GI endoscopes
  - Single HLD vs repeat HLD
  - Eto Sterilization vs HLD
  - Optimal parameters for drying
- **Endoscope storage**
- **Efficacy of Microbiological surveillance of scopes**
- **Endoscope maintenance**
- **Endoscopy unit infection control leadership**
- **Endoscopy and COVID-19**

https://www.giejournal.org/article/S0016-5107(20)34851-3/fulltext

Clinical questions addressed by the multisociety guidelines on flexible scope reprocessing

Four grade questions:

- Is there a benefit of repeat HLD?
- Is there a benefit of EtO sterilization compared to single HLD on reprocessing GI scopes?
- What is the main maximum storage time for a GI scope during which it would remain clean and patient ready?
- What is the efficacy of microbiological surveillance in detecting contamination in fully reprocessed endoscopes?

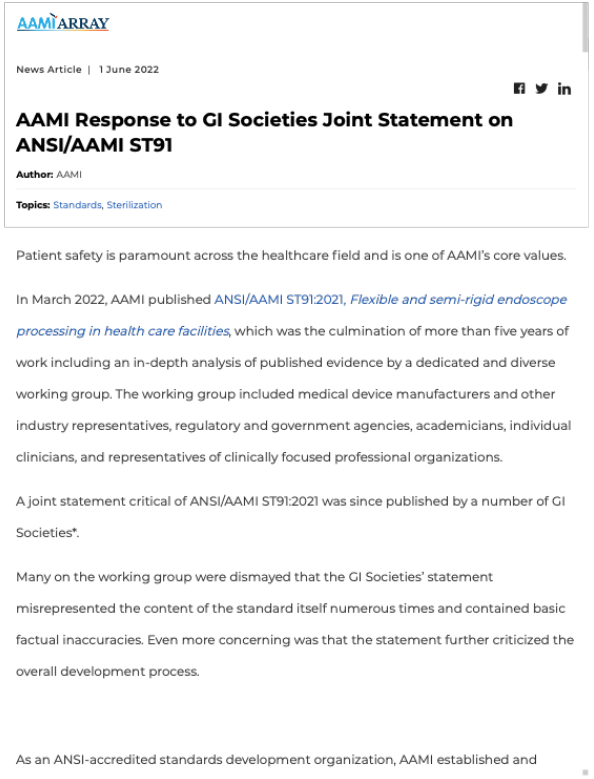
Non-grade clinical questions addressed by the multisociety guidelines on flexible scope reprocessing

1. What training and competencies are required for reprocessing staff?
2. What steps should be completed within the precleaning/POU treatment of endoscopes?
3. What is the optimal endoscopy unit layout and flow for the reprocessing of endoscopes?
4. What role does leak testing play in reprocessing?
5. What key elements should be completed during manual cleaning?
6. What is the role of inspection (exterior and interior)?
7. Are there optimal parameters for drying?
8. Is there a benefit to using alcohol in the drying of endiscopes?
9. What is the best method for storing endoscopes between uses?

Non-grade clinical questions addressed by the multisociety guidelines on flexible scope reprocessing

10. What is the optimal storage position of an endoscope in a storage cabinet?
11. Do accessories need to stored with an individual scope?
12. What is the frequency for replacing tubing used for insufflation of air, irrigation water, suction tubing, and waste vacuum cannisters?
13. Do water bottles used during a procedure have to be filled with sterile water?
14. Does the use of simethicone affect reprocessing?
15. What factors should be considered in the reprocessing of accessories and devices?
16. What P&P should endoscopy units follow in terms of endoscope maintenance?
17. What guidelines should endoscopy units follow in terms of loaner scopes?
18. What are the essential components of an endoscopy unit IPC leadership team?

There is Controversy regarding ST91 and the multisociety guidelines



AAMI ARRAY

News Article | 1 June 2022

AAMI Response to GI Societies Joint Statement on ANSI/AAMI ST91

Author: AAMI

Topics: Standards, Sterilization

Patient safety is paramount across the healthcare field and is one of AAMI's core values.

In March 2022, AAMI published ANSI/AAMI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities*, which was the culmination of more than five years of work including an in-depth analysis of published evidence by a dedicated and diverse working group. The working group included medical device manufacturers and other industry representatives, regulatory and government agencies, academicians, individual clinicians, and representatives of clinically focused professional organizations.

A joint statement critical of ANSI/AAMI ST91:2021 was since published by a number of GI Societies*.

Many on the working group were dismayed that the GI Societies' statement misrepresented the content of the standard itself numerous times and contained basic factual inaccuracies. Even more concerning was that the statement further criticized the overall development process.

As an ANSI-accredited standards development organization, AAMI established and

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GI SOCIETIES JOINT STATEMENT

AASLD · ACG · aga American Gastroenterological Association · ASGE American Society for Gastrointestinal Endoscopy

ASCRS American Society of Colon & Rectal Surgeons · SGNA Society of Gastroenterology Nurses and Associates, Inc.

GI Societies Joint Statement on ANSI/AAMI ST91: GI societies vote No on AAMI revisions on endoscopic processing

Changes to ST91 for flexible and semi-rigid endoscopes create obstacles to implement standards and offer impractical, inappropriate, or conflicting guidance.

EXECUTIVE SUMMARY

Our societies are committed to initiatives focused on eliminating healthcare-associated infections through improved education about evidence-based practices. Although the American Association for the Study of Liver Diseases (AASLD), American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), American Society of Colon and Rectal Surgeons (ASCRS), American Society for Gastrointestinal Endoscopy (ASGE), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), and Society of Gastroenterology Nurses and Associates (SGNA) appreciated the opportunity to engage in the discussion around the 2021 revision of ST91 flexible and semi-rigid endoscope processing in healthcare facilities, the joint GI societies remain con-

BACKGROUND

The Association for the Advancement of Medical Instrumentation (AAMI) is a private, membership-based organization of stakeholders with interests in medical instrumentation safety, care, and use. Members include device manufacturers, governmental agencies, healthcare delivery organizations, accrediting organizations, and independent consultants in the field.

AAMI standards often mirror guidelines of numerous other organizations and are available through membership, subscription, or purchase. Some AAMI standards are endorsed by the American National Standards Institute (ANSI). For endoscope reprocessing, the AAMI standard is 1 among several, including the "Multisociety guideline on reprocessing flexible GI endoscopes and accessories"[1] and those from the SGNA,[2] Association for Professionals in Infection Control and Epidemiology,[3] Association of periOperative Registered Nurses,[4] and Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee,[5] among others.

Highlights of the Controversy

AAMI's Response

- Consensus Standard developed by committee with broad representation (manufacturers, reprocessing personnel, physicians, nurses, FDA, academics and healthcare institutions)
- GI Societies' statement misrepresented the content of the standard itself numerous times and contained basic factual inaccuracies.
- As noted in the GI Societies Joint Statement, the process functioned exactly as designed by considering and, in many cases, incorporating the views of the GI society representatives
- The final language of ANSI/AAMI ST91:2021 was strengthened by the expression of viewpoints from all who participated in its development

Joint Societies Response

- **There are statements unsubstantiated by evidence**
  - Use of boroscopes for inspecting channels
  - cleaning verification tests after each use for all high-risk endoscopes are not approved for such use by the FDA
  - guidance for segregation of buttons and biopsy caps with associated endoscopes and/or labeling the buttons, endoscopes and biopsy caps to enable tracking of use per patient
- **Expressed discomfort with the disparities between the normative and formative sections of the standard**
  - Routine drying verification
  - inclusion of guidance relative to loaned endoscopes in the formative but not normative section of the standard

Summary

- **AAMI standards and TIRs have not been universally adopted**
  - Some healthcare facilities have evaluated ST108 Water for processing medical devices (cost benefit/risk assessment)
  - TIRs are not standards but can be useful sources of information
  - Documents are expensive (behind a pay wall)
- **AAMI documents are consensus standards the committees as required by ANSI involve representatives from all stakeholders**
- **Practice Guidelines are based on published evidence**
  - The multi-society guideline recommendations are mostly supported by low quality evidence; some recommendations are associated with moderate quality of evidence.

Guidance in Development

- SHEA Expert Guidance: Strategies for High Level Disinfection and Sterilization
- HICPAC Dental infection Control Guidelines (dental unit waterlines to be included)
- AAMI. Water testing methodologies. AAMI TIR58:2021
- AAMI. Hemodialysis distribution systems. AAMI TIR XX:XXXX

Protecting Patients and Healthcare Personnel

DHQP Inquiry (NCID/DHQP): hip@cdc.gov

For more information, contact CDC/ATSDR
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov www.atsdr.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

CDC ATSDR