PRACTICE GUIDANCE TIPS

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# Ten Key Points the Infection Preventionist Needs to Know about AAMI

## BACKGROUND

The Association for the Advancement of Medical Instrumentation®(AAMI) is a nonprofit organization founded in 1967 whose mission is to advance safe and effective technology to improve health. AAMI is a primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI's key focus areas are sterilization and disinfection, medical device manufacturing, and healthcare technology management. AAMI is an accredited standards development organization by The American National Standards Institute (ANSI).

AAMI standards, technical information reports (TIRs), and other documents are developed by more than 200 technical committees and working groups. The committees and working group members are comprised of users, industry, regulatory (i.e. Food and Drug Administration) and general interest stakeholders (i.e. The Joint Commission (TJC), Det Norske Veritas (DNV) or Accreditation Association for Ambulatory Health Care (AAAHC)).

This document is intended to assist IPs in selecting, interpreting, and utilizing advisory documents regarding processing medical devices/ equipment.

## TOP TEN KEY POINTS

1. AAMI is one of several professional organizations (such as the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) and the Association of Perioperative Registered Nurses (AORN) that provide guidance for processing medical devices. To select which guidance document(s) a facility chooses to implement, IPs need to identify which evidence-based guidelines (EBG) (i.e., Center for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)) and/or consensus documents are required. The guidance a facility must follow can be found within program-specific documents from regulatory agencies like The Centers for Medicare and Medicaid Services (CMS), State Operations Manuals, or a State's Department of Health. Accrediting agencies (i.e. TJC/AAAHC/DNV) may also require specific EBG or consensus documents, though some accrediting bodies are less prescriptive than others. IPs should be able to explain the process for assessing and selecting guidance documents. Regulatory and accrediting agencies will hold the healthcare facility accountable for implementing and following the required practices in the standard the facility chooses.

   *It is up to the facility to decide which evidence-based guidelines and/or consensus documents they follow if they are not required by CMS or an accrediting agency. IPs should know which documents are required for their facility to comply with.*

2. AAMI creates guidance documents through a consensus body (working group), which "approves the content of a standard and whose vote demonstrates evidence of consensus" (ANSI Essential Requirements). Consensus documents differ from evidence-based guidance because they may or may not be supported by peer-reviewed scientific evidence. AAMI documents are considered consensus documents.

   *IPs should understand the difference between regulation, evidence-based guidelines, and consensus documents when writing their own policies, procedures, guidance, and SOPs.*

3. AAMI publishes both Standards and Technical Information Reports (TIR).

| AAMI Standard | AAMI TIR |
|---|---|
| • A consensus document that provides requirements, specifications, or guidelines to ensure safe use and management of medical devices and health technologies.<br>• Standards are typically **reviewed every five years** by a working group.<br>**(Reference: What are Standards \| AAMI)** | • An interim statement by a working group to develop a standard.<br>• A statement of expert opinion.<br>• It may also give advice on how a standard should be implemented.<br>• It cannot include "must"/"shall" statements.<br>• TIRs are typically **reviewed every three years** to determine if the document should be maintained, withdrawn, revised or advanced to become a standard.<br>(Reference: What are Standards \| AAMI, https://www.aami.org/standards/how-are-standards-developed/standards-policies-and-procedures-intro/additional-procedures-for-development-and-maintenance) |

   *IPs should understand the difference between an AAMI Standard (ST) and Technical Information Report (TIR). A TIR is usually developed to address an issue **prior** to it becoming a standard.*

4. In the foreword section of each AAMI document, the objectives of the guidance and specific terminology are outlined. Typically, "shall" statements are **required**, while "should" statements are **recommendations**. Other terms are clearly defined to express permission or possibility.

   *IPs should understand what elements in the standard are required or recommended. When performing gap assessments against current practice, IPs could prioritize the required statements by initially searching for "shall" statements.*

5. The "scope" section of each guidance document outlines the inclusion and exclusion criteria of the document. This section will inform the IP of when and how the guidance should be applied.

   *IPs should review the scope section of each guidance document before attempting to implement the guidance. IPs will need to know what is specifically included vs. excluded from the document to accurately apply the guidance.*

6. AAMI documents always contain a section of definitions used throughout the specific document. It is important to review the AAMI definitions to ensure proper interpretation and implementation of the guidance. For example, in ANSI/AAMI ST91:2021 the term "reprocessing" was transitioned to "processing" and "pretreatment" was transitioned to "point of use treatment."

   *To properly interpret and implement an AAMI guidance document, IPs should be knowledgeable about current terminology and its meaning.*

7. There are multiple AAMI sterilization and disinfection standards. Some of the key guidance documents used in healthcare settings are included below:

| Title | Focus |
|---|---|
| **ANSI/AAMI ST79: 2017** ***Comprehensive guide to stream sterilization and sterility assurance in healthcare facilities*** | • Provides comprehensive guidance for sterile processing facility design, personnel, all steps of steam sterilization process from receiving to packaging, quality improvement processes and how to properly evaluate new products.<br>• Does NOT cover specific construction and performance criteria for steam sterilizers. |
| **ANSI/AAMI ST 58: 2013** ***Chemical sterilization and high-level disinfection in healthcare facilities*** | • Provides comprehensive guidelines for the selection and use of liquid chemical sterilants (LCS), high level disinfectants (HLD) and gaseous chemical sterilizers that have been cleared by the FDA for use in hospitals and other healthcare facilities.<br>• Does NOT cover steam sterilization, processing single use medical devices or devices that might have been exposed to prions. |

   *The IP should partner with sterile processing experts/departments to review required and recommended elements.*

8. AAMI publishes guidance for processing flexible and semi-rigid endoscopes.

| Title | Focus |
|---|---|
| **ANSI/AAMI ST 91: 2021** ***Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities*** | • Provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible and semi-rigid endoscopes used in health care facilities.<br>• Does NOT include processing of rigid endoscopes, transesophageal echocardiogram (TEE) probes, endocavity ultrasound probes or devices labeled for single use only; and specific construction or performance criteria for steam sterilizers. |

*IPs are encouraged to review the document to determine if their facilities will adopt the AAMI standard. If adopted, IPs should review all the "must" and "shall" statements to ensure compliance.*

9. AAMI has the following document outlining environmental standards.

| Title | Focus |
|---|---|
| **ANSI/AAMI ST 108: 2023** ***Water for the processing of medical devices*** | It is a revision/replacement of TIR 34. Its purpose is the selection and maintenance of effective water quality suitable for processing medical devices. It gives guidance on water treatment and storage, water distribution/storage, quality control procedures, consideration for ongoing maintenance, monitoring and the formation of a water management team. |

*IPs are to be knowledgeable of requirements, "shall" statements in ST 108 and participate in a gap analysis against their current practice at their organization. A key goal is to reduce/eliminate endotoxin and/or bacteria.*

**10.** Some relevant new TIRs in development include:

| Title | Focus |
|---|---|
| **TIR 99: *Dilators, transesophageal and ultrasound probes processing in health care facilities*** | This document provides guidance for the level of disinfection required for ultrasound probes/transducers based on Spaulding classification and intended use. |
| **TIR 119: Guidance of Healthcare Implementation and Use** | This document is being created to assist with implementation of ANSI/AAMI ST 108: 2023 *Water for the processing of medical devices.* |
| **TIR 109: *External transport of medical devices processed by health care facilities*** | This document provides guidance for health care facilities related to the external transportation of medical devices from one facility to another facility. It provides guidance on maintaining the integrity of sterilized items and provides a safe method of transport for contaminated, decontaminated, and/or sterile items. |

*IPs should stay up to date on new releases by referring to the AAMI website. The Standards Monitor Online (*https://www.aami.org/standards/standards-monitor-online) contains updates specific to AAMI guidance documents.

This document is a product of the APIC Practice Guidance Committee. Please contact crpi@apic.org with questions.