STERIS UNIVERSITY

A Guide For Interpretation of AAMI Standards

university.STERIS.com

Disclosures

1. **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
2. **Conflict of interest:** Employee of STERIS.
3. **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
4. **Non-commercial company support:** None.
5. **Alternative/Complementary therapy:** None.

Continuing Education

- STERIS Corporation is an approved provider of continuing nursing education by **CBRN** – provider # CEP 11681 and an approved Administrator Education Unit (AEU) and Infection Prevention Control (IPCH) provider by **BASC** – provider # 1417.
- This program is approved for:
  - **0** hour(s) of GI Specific content credit by **ABCGN** (American Board of Certification for Gastroenterology Nurses),
  - **0** AEU(s) & **0** IPCH(s) by **BASC** (Board of Ambulatory Surgery Certification), and
  - **0.5** contact hour(s) of continuing education credit
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **HSPA** (Healthcare Sterile Processing Association).

Learning Objectives

- Describe the differences between AAMI standards and professional organization guidelines
- Define key terms used to interpret the standards
- List the common AAMI standards and technical information reports used in healthcare

The Association for the Advancement of Medical Instrumentation

"AAMI leads global collaboration in the development, management, and use of safe and effective health technology."

Education | Certifications | Standards, Guidelines, Technical Reports | Technical Committees

AAMI		Professional Organizations
Multiple Disciplines	Disciplines	Single Discipline
National Standards	Documentation	Guidelines
International Representative	Representation	Regional Representative

What Is An AAMI Standard?

"*…provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.*" AAMI

- Consensus document
- Voluntary

3 Reasons To Follow AAMI Standards

1. Diverse Background of the Technical Committee
   - Medical Device Manufacturers
   - Regulators
   - Clinicians
   - Academicians
   - Medical Associations

3 Reasons To Follow AAMI Standards

1. Diverse Background of the Technical Committee
2. "Go-to" resource for accrediting organizations

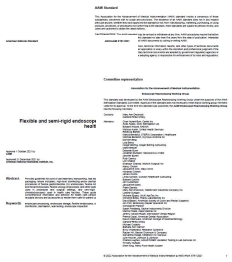
3 Reasons To Follow AAMI Standards

1. Diverse Background of the Technical Committee
2. "Go-to" resource for accrediting organizations
3. State regulation

Blueprint Of A Standard

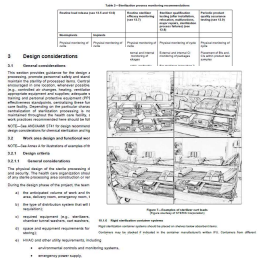
AMMI Standard's Structure

- Disclaimers and Copyright
- Table of contents
- Glossary of equivalent standards
- Committee members
- Foreword
- Introduction



AMMI Standard's Structure

- Scope
- Definitions and abbreviations
- Body of Information
- Annex – Informative
  - Non-mandatory
  - Informative



Rationale

- The 'why'
- Clarification

8.4 Basins and basin sets

Basin sets should

a) be prepared so that all basins are placed in the same direction;

b) be processed with nonlinting absorbent material between nested basins; and

c) be assembled so as to permit air removal, steam penetration, and steam removal during the sterilization and drying process.

Small items such as medicine cups should not be placed inside basin sets unless they can be oriented to ensure drainage of condensate.

Rationale: Separating basins with absorbent material enhances adequate air removal and passage of steam to all surfaces, and facilitates drying. Nonlinting materials are recommended because lint can be introduced into a patient's wound and cause a foreign-body reaction. Proper alignment of basins, to prevent them from acting as reservoirs for moisture, is essential to achieving sterility.

Understanding Standard Speak

Specific Word Usage - Requirements

- **Shall and Shall Not** – Requirement
- **Should and Should Not** – Recommendation

"An integrating indicator shall be designed to react to all critical variables." (ANSI/AAMI ST79 pg. 163)

"Both the test and control BI lot numbers should be documented." (ANSI/AAMI ST79 pg. 86)

"Carpet should not be used in the processing areas." (ANSI/AAMI ST91 Section 4.3.4)

Specific Word Usage - Permission

- **May or May Not** – Permission

"Organizing containers and other organizing accessories may be placed in the set if they are designed and intended for sterilization." (ANSI/AAMI ST79 pg. 50)

"External shipping containers may have potentially high microbial contamination because of environmental exposure during transport." (ANSI/AAMI ST79 pg. 31)

Specific Word Usage – Possible

- **Can and Cannot** – Possibilities or capabilities
- **Might or Might Not** – Possibilities

Stacking can result in damage to the wrap caused by undue pressure from the weight." (ANSI/AAMI ST91 Section 11.3.2)

"Certain items might require special preconditioning procedures; the device manufacturer should be consulted for instructions. (ASNI/AAMI ST41 Section 8.3)

"Clean devices that cannot be immersed in a manner that will not produce aerosols;" (ANSI/AAMI ST79 pg. 45)

"The microbicidal process might not be effective if soil has not been first removed by cleaning". (ANSI/AAMI ST79 pg. 39)

Specific Word Usage - Must

- **Must** – external constraints or obligations outside of the document

Containment systems that must meet OSHA standards for contaminated items at the point of use.
(ANSI/AAMI ST79 pg. 13)

The reprocessing of single-use devices by health care facilities is regulated by FDA, and all premarket and postmarket requirements must be met if a health care facility chooses to reprocess a single-use device.
(ANSI/AAMI ST79 pg. 32)

NOT a substitution for Shall.

Types Of Choices

"Processing tables, which should be made of nonporous materials (e.g., stainless steel), ergonomic, and, preferably, height-adjustable;"
(ANSI/AAMI ST79 3.3.6.2 pg. 23)

"Internal chemical indicators should be Type 3 or Type 4 but preferably Type 4 because these types of CIs provide the user with more information on the critical hydrogen peroxide sterilization parameters."
(ANSI/AAMI ST91 8.3.3 c))

"Immediate-use steam sterilization should be kept to a minimum and should be used only in urgent clinical situations."
(ANSI/AAMI ST79 10.2.3 pg. 63)

"according to the manufacturer's written IFU"
(ANSI/AAMI ST79 throughout)

Making the choice

- Patient Safety
- Risk assessment

IFU	Cycle Parameters
Forceps	270°F for a minimum of 10 minutes, gravity cycle
Sterilization Pouch	270°F for 15 minutes, gravity cycle
Chemical Indicator	270°F for 15 minutes, gravity cycle
Steam Sterilizer	270°F for 15 minutes, gravity cycle

Making the choice

- Patient Safety
- Risk

Topics *store.aami.org*

- Biological Evaluation
- Dialysis
- Electromedical Equipment
- General Aspects of Medical Devices
- Healthcare Technology Management
- Human Factors
- Implants & Artificial Organs
- IT, Software, and wireless
- Quality Systems / regulatory Affairs
- Sterilization – Equipment
- Sterilization – Hospital
- Sterilization – Industrial
- Symbols

Sterile Processing Standards

Technical Information Reports

Format Options

Hard Copy
- Easy transport
- Dated

Electronic Document
- Dated
- Easy Search

e-Library
- Current
- Easy Search
- Affordable

Action Items

- Gain access to the current AAMI standards.
- Assess compliance with the AAMI standards.
- Implement a means to stay current.

References

- AAMI. (2023) *AAMI STANDARDS PROGRAM Policies and Procedures*. Association for the Advancement of Medical Instrumentation. https://www.aami.org/docs/default-source/standardslibrary/final-for-publication_aami-standards-program-policies-and-procedures-october-2021.pdf?sfvrsn=9c19c4ad_2
- AAMI (2023, June 28) *Standards and Technical Documents*. AAMI. https://www.aami.org/standards/committee-contacts/what-are-standards
- AAMI (2019) *AAMI Technical Document Development Overview*. Association for the Advancement of Medical Instrumentation. https://www.aami.org/docs/default-source/standardslibrary/aami-technical-document-development-overview-nov_2019.pdf

Questions?

Thank you!

Visit us at **university.steris.com**

Supporting a Strong Department
Developing **Future Leaders**

STERIS
UNIVERSITY