NATIONAL STANDARDS

Recently Published


AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by e-mail to receive a PDF copy of the draft. These copies are free.

Published documents proposed for reaffirmation can be purchased from the AAMI Store.

Comments due December 9

AAMI ST98, *Cleaning validation of health care products -- Requirements for development and validation of a cleaning process for medical devices* (proposed new American National Standard). This standard covers the requirements to validate cleaning processes that are developed by the medical device manufacturer for processing medical devices and applies to all medical devices that require cleaning prior to each clinical use of that device. This includes any medical device that might be used clinically, or processed, in any setting such as health care facilities, home, and use by first responders, etc. Contact: Amanda Benedict.

Comments due January 6, 2020

AAMI EQ56, *Recommended practice for a medical equipment management program* (proposed revision of an American National Standard). This recommended practice specifies minimum criteria for a management program designed to minimize certain risks associated with equipment used during routine care of patients in a health care organization. The recommended practice addresses the structure of the program, documentation requirements, staffing, and resources allocated to those responsible for maintaining medical equipment. Contact: Patrick Bernat.
New Work

AAMI EQ, Medical Equipment Management Committee. The committee is working on the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs*. This standard seeks to provide a recommended framework for new or established education programs in health care technology management (HTM). Contact: Patrick Bernat.


AAMI ST/WG 40, Hospital Practices Steam Sterilization. The working group is working on the developments of AAMI TIR109/Ed.1, *External transport of medical devices processed by health care facilities*. This document will provide guidance for health care facilities regarding the transportation of medical devices from one facility to another; includes the safe method of transport for contaminated items and the maintenance of integrity of sterilized items. Contact: Amanda Benedict.

Consensus Body Members Needed

The committees listed below are seeking new members in the indicated stakeholder interest category to participate in the development of their documents. Definitions of the various stakeholder groups are:

**User:** An individual or organizational representative, who purchases, utilizes or receives the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare; individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.

**Industry:** An individual or organizational representative involved in the commercial production, promotion, sale, use or distribution of materials, products, systems, or services covered in the scope of technical documents developed by AAMI; this interest category includes manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.

**Regulatory:** An individual or organizational representative involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI; this interest category includes those representing federal, state, local, foreign, or other government entities.

**General interest:** An individual or organizational representative with a general material interest in the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI and who does not fit into any of the preceding categories; this interest
category can include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.

Please contact the staff person indicated for more information on how to join.

AAMI EQ, Medical Equipment Management Committee. The committee is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ110/Ed.1, Guidance for health care technology management education programs. Contact: Patrick Bernat.

AAMI ST/WG 95, Water Quality for Reprocessing Medical Devices. The working group is general interest, user, and regulatory stakeholders to participate in the development of AAMI ST108/Ed.1, Water for the processing of medical devices. Contact: Amanda Benedict.

AAMI ST/WG 40, Hospital Practices Steam Sterilization. The working group is seeking regulatory and general interest stakeholders to participate in the developments of AAMI TIR109/Ed.1, External transport of medical devices processed by health care facilities. Contact: Amanda Benedict.

UPCOMING MEETINGS

AAMI Committees and U.S. TAGs
Open meetings of AAMI committees and U.S. Technical Advisory Groups (TAGs) are listed here and at the AAMI website (www.aami.org). Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department (standards@aami.org) indicating the name and date of the meeting so that staff can contact you in the event of a last-minute cancellation.

December 2019

AAMI/SM-WG05, Device Security Working Group (open meeting – registration required). 2-3 December, 9:00am – 5:00 pm, Arlington, VA. Contact: Wil Vargas.

AAMI/WV, Waveform Testing Committee (open meeting – registration required). 3 December, 1:00pm – 4:00pm, Arlington, VA. Contact: Kelly Hunget.

AAMI/EC, ECG Committee (open meeting – registration required). 4 December, 9:00am – 11:00am, (via web). Contact: Hae Choe.

AAMI/ID, Infusion Device Committee (open meeting – registration required). 4-6 December, 9:00am-5:00pm, Arlington, VA. Contact: Jennifer Moyer.

AAMI/SM-WG03, Interoperability Working Group (open meeting - registration required). 4-5 December, 9:00am – 5:00 pm, Arlington, VA. Contact: Wil Vargas.
**AAMI Standards Monitor Online**  
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**AAMI/DF, Defibrillator Committee** (open meeting – registration required). 5 December, 9:00am – 5:00pm, Arlington, VA. **Contact: Hae Choe.**

**AAMI/PC, Cardiac Rhythm Device Management Committee** (open meeting – registration required). 5 December, 9:00am-5:00pm, Arlington, VA. **Contact: Jennifer Moyer.**

**AAMI/CP, Combination Products Committee** (open meeting – registration required). 6 December, 9:00am – 5:00pm, Arlington, VA. **Contact: Hae Choe.**

**AAMI/SM-WG01, Software Working Group** (open meeting - registration required). 10 December, 10:00am – 4:30 pm, Arlington, VA. **Contact: Wil Vargas.**

**INTERNATIONAL STANDARDS**

Information on draft international standards under ballot can be found in ANSI Standards Action.

**International Committee and Working Group Meetings**

Call or email the indicated staff person at AAMI for more information about upcoming international standards meetings.

**December 2019**

ISO/TC 198, Sterilization of health care products and affiliated working groups (closed meetings), 2-6 December 2019, 9:00 h to 17:00 h, Seoul, Korea. **Contact: Amanda Benedict.**

**January 2020**

ISO/TC 210/JWG4, Small bore connectors (closed meeting), 9-10 January 2020, 9:00 h to 17:00 h, Luebeck, Germany. **Contact: Colleen Elliott.**

ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care and related WGs (closed meetings), 13-17 January 2020, 9:00 h to 17:00 h, Luebeck, Germany. **Contact: Colleen Elliott.**

**March 2020**

ISO/TC 215, Health informatics and related WGs (closed meetings), 25 March – 3 April 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia. **Contact: Joe Lewelling.**

**April 2020**

IEC/SC 62A/WG 33, CAG - Chairman Advisory Group (closed meeting), 23-24 April 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia. **Contact: Hae Choe.**

IEC/SC 62A/WG 20, Environmental protection (closed meeting), 27-28 April 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia. **Contact: Hae Choe.**
AAMI Standards Monitor Online
22 November 2019

Stand out among your peers by earning a Certified Industrial Sterilization Specialist certification in each of the three specialties: Ethylene Oxide | Radiation | Moist Heat. As in most professions, taking the initiative to earn and maintain a credential shows an individual’s devotion to the field, specialized knowledge base, and pride in professional development.

An interested and eligible candidate for the CISS certification programs should have a keen understanding of the following topic areas relating to the specialty of their choice:

- Quality Management Systems
- Sterilization Agent, Process, and Equipment Characterizations
- Product and Process Definition
- Validation
- Routine Monitoring, Control, and Product Release
- Maintaining Process Effectiveness

Start preparing now for the next testing window that will be held November 1-15! For more information regarding eligibility, exam content, and the application process, visit www.aami.org/aci and click on the ACI Certification Candidate Handbook. To reach an ACI representative, email aci@aami.org.

Call for Nominations – AAMI Awards 2020

Each year the medical technology community recognizes leaders and innovators whose efforts have moved the industry forward. We need your help! Nominate yourself or leaders in the industry. Award winners may receive monetary prizes, a plaque commemorating their achievements, and will be celebrated by their peers at the 2020 AAMI Exchange in New Orleans, LA. For more information, visit the AAMI Awards page. Questions – email awards@aami.org.