NATIONAL STANDARDS

Recently Published

AAMI TIR38:2019, *Medical device safety assurance case guidance*
Purchase from: http://my.aami.org/store/detail.aspx?id=TIR382019PDF

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 or click on the indicated URL to download the draft. These copies are free.

Published documents proposed for reaffirmation can be purchased from the AAMI Store: http://my.aami.org/store/.

Comments due April 8

AAMI CDV-1 ST8, *Hospital steam sterilizers* (revision of existing American National Standard). Applies to steam sterilizers that are intended for use in hospitals and other health care facilities. Covers minimum labeling, safety, performance, and testing requirements for steam sterilizers that have a volume greater than 56.63 L (2 ft3), have automatic controls, generally use an external steam source (but might also have an integral electric boiler), and provide a means for automatically recording time and temperature. Contact: abenedict@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/document?document_id=16807&wg_id=PUBLIC_REV

Comments due March 18

AAMI CDV-4 ST72, *Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing* (revision of existing American National Standard). Specifies general criteria to be applied in the determination of bacterial endotoxins (pyrogens) on sterilized or sterilizable healthcare products, components or raw materials. Endotoxin methodologies covered include both qualitative (limit) methods and quantitative (end-point) methods. Excludes determination of pyrogens other than bacterial endotoxins. Contact: jmoyer@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/document?document_id=16024&wg_id=PUBLIC_REV

AAMI/ISO FDIS 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging* (revision of existing American National Standard). Specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. Contact: hchoe@aami.org.

AAMI/ISO FDIS 11607-2, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes* (revision of existing American National Standard). Specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized and maintain sterility to the point of use. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems. Contact: hchoe@aami.org.

New Work

AAMI/SM-WG03, Interoperability Working Group The committee is working on the revision of AAMI 2700-1/Ed. 1 (formerly ASTM F2761), *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*. This standard specifies general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE). This is the first of a series of standards which establishes requirements for design, verification, and validation processes of a model based integration system for an Integrated Clinical Environment. Contact: wvargas@aami.org.

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 ST/WG 8, Microbiological Method – seeking users. This committee is working on the revision of AAMI ST72, *Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing*. Contact: jmoyer@aami.org.

AAMI ST/WG 43, Hospital Steam Sterilizer – seeking users. This committee is working on the revision of AAMI ST8, *Hospital steam sterilizers*. Contact: abenedict@aami.org.

AAMI/CN/WG01, Luer activated valves. The committee is working on development of AAMI/CN27, General requirements for luer activated valves (LAVs) incorporated into medical devices for intravascular applications. Contact: celliott@aami.org.

AAMI/PB, Protective Barriers Committee – seeking users. The committee is working on the revision of AAMI/PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Contact: abenedict@aami.org.

AAMI/SM-WG03, Interoperability Working Group – seeking users and general interest. The committee is working on the revision of AAMI 2700-1/Ed. 1, *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*. Contact: wvargas@aami.org.

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). Agendas for open meetings are usually available from AAMI Central. (Visit https://standards.aami.org/higherlogic/ws/public*, find the committee or working group and look under "Upcoming Shared Events" or "Recently Shared Documents"). 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.*

March 2019

[CANCELLED] AAMI/MC, Mechanical Circulatory Support Systems Committee (open meeting – registration required), 8 March 2019, 9:00 h to 17:00 h, Arlington, VA. Contact: cbernier@aami.org.

AAMI/CV, Cardiac Valve Prostheses Committee (open meeting – registration required), 12-14 March 2019, 9:00 h to 5:00 h, Omni Riverfront Hotel, New Orleans, LA. Contact: cbernier@aami.org.

Sterilization Standards Week (advance registration REQUIRED – https://services.aami.org/SSW/), 18-21 March 2019, 08:00 h – 17:30 h, AAMI, Arlington, VA. Contact: abenedict@aami.org.

April 2019

AAMI/CP, Combination Products (open meeting – registration required), 12 April 2019, 9:30 – 4:30, AAMI, Arlington, VA. Contact: hchoe@aami.org

AAMI/DP, Medical Device Particulates (open meeting – registration required), 17-18 April 2019, 9:00 – 5:00, AAMI, Arlington, VA. Contact: cbernier@aami.org.

AAMI/BSI/FDA International Standards Conference (register: https://www.aami.org/isc), 24-25 April, 09:00h to 17:00h, Hyatt Regency, Reston, VA.

June 2019

SM-WG05 - Device Security Working Group (open meeting – registration required), 10-11 June 2019, 9:00 – 5:00, AAMI, Arlington, VA. Contact: wvargas@aami.org.

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in ANSI Standards Action: http://www.ansi.org/news_publications/periodicals/standards_action/standards_action.aspx?menuid=7

International Committee and Working Group Meetings

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

February 2019

ISO/TC 198/WG 11, General criteria for sterilization processes and sterilizing equipment (closed meeting), 25-26 February, 09:00 h to 17:00 h and 08:30 h to 16:00 h, Arlington, VA, USA. Contact: abenedict@aami.org.

ISO/TC 198/WG 3, Moist heat sterilization (closed meeting), 27-28 February-1 March 2019, 9:00 h to 17:00 h, Arlington, VA, USA. Contact: abenedict@aami.org.

ISO/TC 150/SC 6/WG 4, Implantable infusion pumps (closed meeting), 27-28 February-1 March 2019, 9:00 h to 17:00 h, Arlington, VA, USA. Contact: jmoyer@aami.org.

ISO/TC 150/SC 2/WG 8, Cardiac occluders (closed meeting), 28 February – 1 March 2019, 9:00 h to 17:00 h, Arlington, VA USA. Contact: cbernier@aami.org.

March 2019

IEC/SC 62D – ISO/TC 173/JWG 4, Hospital beds (closed meeting), 4-6 March 2019, 9:00 h to 17:00 h, Arlington, VA, USA. Contact: hchoe@aami.org.

IEC/SC 62A, Common aspects of electrical equipment used in medical practice, (MTs and WGs to work on Amendment 2 to IEC 60601-1) (closed meetings), 11-15 March 2019, 9:00 h to 17:00 h, Xi'an, China. Contact: hchoe@aami.org.

April 2019

IEC/SC 62A/JWG 4-ISO/TC 210/JWG3, Medical device usability (closed meeting), 2-4 April 2019, 9:00 h to 17:00 h, Prangins, France. Contact: wvargas@aami.org.

ISO/TC 210/JWG1, Application of risk management to medical devices (closed meetings), 10-12 April 2019, 9:00 h to 17:00 h, Norrmalm, Sweden. Contact: wvargas@aami.org.

IEC/SC 62A/WG 20, Environmental protection (closed meeting), 16-18 April 2019, 9:00 h to 17:00 h, Frankfurt, Germany. Contact: hchoe@aami.org.

ISO/TC 84/WG 16, Drug delivery system requirements for paediatrics and other demographics (closed meeting), 30 April – 1 May 2019, 9:00 h to 5:00 h, Arlington, VA USA. Contact: cbernier@aami.org

May 2019

ISO/TC 150/SC 2/WG 1, Cardiac valves (closed meeting), 17-19 May 2019, 9:00 h to 5:00 h, Amsterdam, the Netherlands. Contact: cbernier@aami.org.

June 2019

ISO/TC 198/WG 1, Industrial ethylene oxide sterilization (closed meeting), 17-18 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: lwaggoner@aami.org.

ISO/TC 198/WG 9, Aseptic processing (closed meeting), 24-27 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: abenedict@aami.org.

ISO/TC 210/WG6, Application of post market surveillance systems to medical devices (closed meetings), 24-26 June 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: wvargas@aami.org.

October 2019

ISO/TC 150/SC 2 and related working groups, Cardiovascular implants and extracorporeal systems (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: cbernier@aami.org.

ISO/TC 150/SC 6 and related working groups, Active implants (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: jmoyer@aami.org

---

MISCELLANEOUS

Introducing our new Standards FAQs page!

Please visit the AAMI website at www.aami.org/standardsfaqs to quickly get answers to commonly asked questions. If your question and answer is not listed on the website, please complete and submit the online form and someone will get back to you within three business days. Please note that as a standards developing organization accredited under ANSI, AAMI is procedurally prohibited from providing interpretations of standards and/or interpreting whether specific actions are in conformance with the standards. We do not have the technical expertise on staff to advise about specific practices and can only point you to content in the standards that might be helpful.

For questions of a technical nature, we suggest you reach out to any number of consultants in the AAMI Buyers Guide that can be found on www.aami.org.