NATIONAL STANDARDS

Recently Published

ANSI/AAMI/UL 2800-1:2019, *Standard for Safety for Medical Device Interoperability*
Purchase from: http://my.aami.org/store/detail.aspx?id=UL280001

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 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.

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 April 29

AAMI CDV 2700-1, ***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*** (reaffirmation and redesignation American National Standard ASTM F2761-9:2013). This standard specifies the characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single high acuity patient. This standard establishes requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices. This series of standards establishes requirements for design, verification, and validation processes of a model-based integration system for an integrated clinical environment. This series of standards is intended to define the requirements essential for safety and thereby facilitate regulatory acceptance. Contact: wvargas@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.

AAMI Combination Products Committee. A new work item has been approved on the development of a technical information report (TIR), AAMI TIR105, *Risk management guidance for combination products.* This document will provide guidance for the assessing risks for combination products (as defined by the U.S. under 21 CFR 3.2(e)) throughout their total product lifecycle. This document is intended to provide recommendations on best practices, recognizing that risk management requirements may vary

across regulatory jurisdictions. For information on this project or to join the consensus body, contact hchoe@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/RD, Renal Disease and Detoxification Committee - seeking users. This committee is working on the revision of AAMI RD47, *Hospital steam sterilizers*. Contact: cbernier@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

Sterilization Standards Week (advance registration was REQUIRED and closed on 13 March 2019), 18-21 March 2019, 08:00 h – 17:30 h, AAMI, Arlington, VA. Contact: abenedict@aami.org.

April 2019

AAMI/ST/WG 3, Moist Heat Sterilization Working Group (open meeting), 3 April 2019, 11:00h to 12:30h, Skype meeting. Contact: abenedict@aami.org.

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.

May 2019

AAMI Renal Disease and Detoxification Committee (open meeting – registration required), 6 May 2019, 9:00-5:00h, AAMI, Arlington, VA. Contact: cbernier@aami.org.

AAMI/PC/WG 2, Transvenous Cardiac Leads (open meeting), 6-7 May 2019, 9:00–5:00h, Intercontinental San Francisco, San Francisco, CA. Contact jmoyer@aami.org.

AAMI/PC, Cardiac Rhythm Management Devices (open meeting), 7 May 2019, 9:00–5:00h, Intercontinental San Francisco, San Francisco, CA. Contact jmoyer@aami.org.

June 2019

AAMI/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.

AAMI/ID, Infusion Devices (open meeting – registration required), 11-13 June 2019, 9:00-5:00h, AAMI, Arlington, VA. Contact: jmoyer@aami.org.

AAMI/SM/WG03, Interoperabilty Working Group (open meeting – registration required), 12-14 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.

March 2019

ISO/TC 210/WG3, Symbols and nomenclature for medical devices (closed meetings), 26-28 March 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: wvargas@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.

ISO/TC 150/SC 2/WG 7, Cardiovascular absorbable implants (closed meeting), 10-11 April 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: cbernier@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 198/WG 2, Radiation sterilization (closed meeting), 16-17 May 2019, 09:00h to 17:00h, Denver, Colorado, USA. Contact: abenedict@aami.org.

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), 25-28 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.