NATIONAL STANDARDS

Recently Published

NEW! AAMI/ISO 13485:2016, Medical Devices – A Practical Guide, Advice from ISO/TC 210. Purchase here.

NEW! ANSI/AAMI RD47:2020, *Reprocessing of hemodialyzers*. Purchase here.

NEW! Preorder: AAMI/ISO DTIR24971:2020, *Medical devices—Guidance on the application of ISO 14971.* Purchase here.

NEW! Preorder: AAMI/ISO DTIR20416:2020, *Medical devices – Post-market surveillance for manufacturers*. Purchase here.

AAMI CR500:2019, *Basic Introduction to the IEC 60601 Series*. Purchase here.

ANSI/AAMI/ISO 11737-2:2019, *Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*. Purchase here.

ANSI/AAMI/ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements*. Purchase here.

ANSI/AAMI/ISO 80369-3:2016/Amd.1, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications — Amendment 1*. Purchase here.

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 March 2, 2020

AAMI/ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements* (reaffirmation of an American National Standard). Specifies general requirements and test methods for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process. Contact: Amanda Benedict

Comments due March 12, 2020

AAMI AT6, Autologous transfusion devices (reaffirmation of an American National Standard). Establishes labeling and performance requirements, test methods, and terminology that will help define a reasonable level of safety and efficacy for autologous transfusion devices. Specifically, it includes requirements for sterile, disposable systems and associated electromechanical hardware designed to collect and filter or process, or both, extravasated blood for reinfusion of erythrocytes or filtered whole blood into the patient's circulation. Aspects of these systems related to collection, anticoagulation (systemic and device), storage, processing and filtration, and reinfusion are within the scope of this standard. Contact: cbernier@aami.org

AAMI BF7, Blood transfusion micro-filters (reaffirmation of an American National Standard). Contains labeling requirements, performance requirements, test methods, and terminology for disposable blood transfusion micro-filters for use with adult populations to remove microaggregates from blood or blood products during transfusion. Contact: cbernier@aami.org

AAMI BF64, Leukocyte reduction filters (reaffirmation of an American National Standard). Contains labeling requirements, performance requirements, test methods, and terminology for disposable filters used for the reduction of leukocytes from blood or blood components. Contact: cbernier@aami.org

Comments due March 23, 2020

AAMI ST79:2017/A.3-202x, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities - Amendment 3* (addenda to an American National Standard). Provides content Modifies content pertaining to frequency of cleaning for routine care of sterilizers for sterile processing areas in health care facilities. Contact: Amanda Benedict.

AAMI ST79:2017/A.4-202x, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities - Amendment 4* (addenda to an American National Standard). Provides content addressing recording BI lot numbers in sterilizer records for sterile processing in health care facilities. Contact: Amanda Benedict.

New Work

AAMI NS/WG 1, ICP Device Working Group will be reviewing ANSI/AAMI NS28:1988(R2015), *Intracranial pressuring monitoring devices*, to determine whether or not the document requires revision. Contact: Jennifer Moyer

AAMI/CN, Small Bore Connectors Committee is working on the revision of AAMI/ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.* Contact: Colleen Elliott

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 95, Water Quality for Reprocessing Medical Devices. The working group is converting AAMI TIR34, *Water for the reprocessing of medical devices*, to AAMI ST108/Ed.1, *Water for the processing of medical devices*. The standard will provide binding requirements rather than just guidance. Contact: Amanda Benedict.

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.*
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> **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 NS/WG 1, ICP Device Committee. The committee is seeking new members of all interest categories – users, industry, regulatory, and general interest – to participate in the review of ANSI/AAMI NS28:1988(R2015), *Intracranial pressuring monitoring devices*. Contact: Jennifer Moyer

AAMI/CN, Small Bore Connectors Committee. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.* Contact: Colleen Elliott

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.

February 2020

AAMI Software Working Group- SM-WG01 (open meeting – registration required). 19-20 February 2020. 11:00 h to 17:00 h. 9:00 h to 16:00 h, AAMI, Arlington, Virginia, USA. *Contact: Wil Vargas*

HIT Committee (open meeting – registration required). 18-20 February 2020. 9:00 h to 17:00 h. 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: Emily Hoefer*

AAMI Chemical Indicators Working Group (open meeting). 24 February 2020. 11:00 h to 13:00 h. Web meeting. *Contact: Amanda Benedict*

March 2020

AAMI Sterilization Standards Week - details to come! (open meetings – advance registration will be required) 16-19 March 2020, AAMI, Arlington, VA, USA. *Contact: Amanda Benedict*

April 2020

Infusion Device Committee (open meeting). 28-30 April 2020. 9:00 to 17:00 h, Minneapolis, MN. *Contact: Jennifer Moyer*

October 2020

AAMI Sterilization Standards Week - details to come! (open meetings – advance registration will be required) 12-16 October 2020, AAMI, Arlington, VA, USA. *Contact: Amanda Benedict*

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.

February 2020
ISO/TC 198/WG 3, Moist heat sterilization (closed meeting), 10-12 February 2020, 09:00h to 17:00h, AAMI, Arlington, Virginia, USA. *Contact: Amanda Benedict*

March 2020

IEC/SC 62D/MT 20, Haemodialysis equipment (closed meeting), 2-3 March 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: hchoe@aami.org*

ISO/TC 150/SC 6/WG 1, Fundamental standard (closed meeting), 2-3 March 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: Jennifer Moyer*

ISO/TC 150/SC 6/JWG 2, Effects of magnetic resonance imaging on active implantable medical devices (closed meeting), 4-6 March 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: Jennifer Moyer*

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

ISO/TC 150/SC 6/WG 5, Implantable neurostimulators (closed meeting), 15-17 April 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia. *Contact Jennifer Moyer*

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.*

May 2020

IEC/SC 62D - ISO/TC 121/SC 3/JWG 7, Non-invasive sphygmomanometers (closed meeting), 11-15 May 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: hchoe@aami.org*

ISO/TC 121, Anaesthetic and respiratory equipment and affiliated groups (closed meetings), 18-22 May 2020, 9:00h to 17:00h, BSI, London, UK. *Contact: Colleen Elliott*

ISO/TC 194, Biological and clinical evaluation of medical devices and affiliated groups (closed meetings), 25-29 May 2020, 9:00h to 17:00h, Qingdao, China. *Contact: Colleen Elliott*

June 2020

IEC/SC 62D - ISO/TC 173/JWG 4, Medical beds (closed meeting), 8-11 June 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: hchoe@aami.org*

ISO/TC 150/SC 6/WG 4, Implantable infusion pumps (closed meeting), 15-16 June 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia. *Contact: Jennifer Moyer*

ISO/TC 150/SC 6/JWG 2, Effects of magnetic resonance imaging on active implantable medical devices (closed meeting), 17-19 June 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: Jennifer Moyer*