

STANDARDS UPDATE

NEW! We will be updating our Committee Central platform later in 2021! More information coming soon.

NATIONAL STANDARDS

Recently Published

NEW! AAMI TIR76:2021, *Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VDmax SD-S*. [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 June 28, 2021

AAMI/ISO 13408-3, *Aseptic processing of health care products—Part 3: Lyophilization* (reaffirmation of an American National Standard). This standard specifies requirements for and offers guidance on equipment, processes, programmes and procedures for the control and validation of lyophilization as an aseptic process. It does not address the physical/chemical objectives of a lyophilization process. Contact: [Amanda Benedict](#)

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 the cleaning instructions that are provided by the medical device manufacturer for processing medical devices. Contact: [Amanda Benedict](#)

Comments due July 5, 2021

AAMI ST91, *Flexible and semi-rigid endoscope processing in healthcare facilities* (revision of an American National Standard). This standard provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use. Contact: [Amanda Benedict](#)

Comments due July 19, 2021

AAMI CN27, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications* (new American National Standard). Covers Luer activated valves (LAVs) for intravascular applications, which open and permit access to the fluid conduit when a male Luer connector is inserted. This standard applies only to the valve end of LAVs. This standard applies to LAVs as stand-alone devices or as components of a medical device. Contact: [Colleen Elliott](#)

AMI ST8, *Hospital steam sterilizers* (revision of an American National Standard). Applies to steam sterilizers that are intended for use in hospitals and other health care facilities and that have a volume greater than 56.63 liters (L) (2 cubic feet [ft³]). Contact: [Cliff Bernier](#)

AAMI ST55, *Table-top steam sterilizers* (reaffirmation of an American National Standard). Establishes minimum construction and performance requirements for small tabletop steam sterilizers that use saturated steam as the sterilizing agent and that have a volume less than or equal to 56.63 liters (2 cubic feet). Contact: [Cliff Bernier](#)

AAMI/ISO 18472, *Sterilization of health care products - Biological and chemical indicators - Test equipment* (identical national adoption of ISO 18472:2018). Specifies the requirements for test equipment to be used to: - test biological indicators for steam, ethylene oxide gas and dry heat sterilization processes for conformity to the requirements given in ISO 11138 series; - test chemical indicators for steam, ethylene oxide gas, dry heat and vaporized hydrogen peroxide sterilization processes for conformity to the requirements given in ISO 11140-1:2014. This document also provides informative methods useful in characterizing the performance of biological and chemical indicators for intended use and for routine quality control testing. Contact: [Cliff Bernier](#)

AAMI/ISO 5840-1, *Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements* (identical national adoption of ISO 5840-1:2021 and revision of ANSI/AAMI/ISO 5840-1-2015). Applicable to heart valve substitutes intended for implantation and provides general requirements. Subsequent parts of the ISO 5840 series provide specific requirements. Applicable to newly developed and modified heart valve substitutes and to the accessory devices, packaging, and labelling required for their implantation and for determining the appropriate size of the heart valve substitute to be implanted. Contact: [Cliff Bernier](#)

AAMI/ISO 5840-2, *Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes* (identical national adoption of ISO 5840-2:2021 and revision of ANSI/AAMI/ISO 5840-2-2015). Applicable to heart valve substitutes intended for implantation in human hearts, generally requiring cardiopulmonary bypass and generally with direct visualization. Applicable to both newly developed and modified surgical heart valve substitutes and to the accessory devices, packaging, and labelling required for their implantation and for determining the appropriate size of the surgical heart valve substitute to be implanted. Contact: [Cliff Bernier](#)

ISO 5840-3, *Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques* (identical national adoption of ISO 5840-3:2021 and revision of ANSI/AAMI/ISO 5840-

AAMI Standards Monitor Online

25 June 2021

3-2012). Applicable to all devices intended for implantation as a transcatheter heart valve substitute. Applicable to transcatheter heart valve substitutes and to the accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted. Contact: [Cliff Bernier](#)

AAMI/ISO 25539-2, Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (identical national adoption of ISO 25539-2:2020 and revision of ANSI/AAMI/ISO 25539-2-2012). Specifies requirements for the evaluation of stent systems (vascular stents and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer, based upon current medical knowledge. Guidance for the development of in vitro test methods is included. Contact: [Cliff Bernier](#)

AAMI/ISO 80369-6, Small-bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications (reaffirmation of an American National Standard). Specifies requirements for small-bore connectors intended to be used for connections in neuraxial applications. Neuraxial applications involve the use of medical devices intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes. Contact: [Colleen Elliott](#)

New Work

AAMI CN, Small bore connectors Committee. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-1/Ed.3, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*. 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: [Ovidiu Munteanu](#)

AAMI QM-WG01, Application of Quality Systems to Medical Devices Working Group. The working group is working on the development of AAMI CR510, *Consensus Report on Compliant Use of Cloud Computing for Quality Systems and Medical Devices*. This Consensus Report will provide guidance to multiple stakeholders regarding the appropriate and compliant use of cloud computing both as a component of medical devices and in support of quality systems. Contact: [Joe Lewelling](#)

AAMI TIB, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use. The committee has recently approved development of an AAMI Technical Information Report (TIR), *Guidance for Closed System Transfer Device Testing with Hazardous Drugs*. This TIR seeks to provide guidelines for physical and chemical compatibility of the drug with the Close System Transfer Device (CSTD), which may include but not limited to holdup volume, coring/fragmentation of the vial rubber stopper, microbial ingress, stability/shelf-life, and usability. Contact: [AAMI Standards](#)

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 CN, Small bore connectors Committee. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-1/Ed.3, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*; AAMI/ISO 80369-2/Ed.1, *Small-bore connectors for liquids and gases in healthcare applications – Part 2: Connectors for respiratory applications*; and AAMI/ISO 80369-20/Ed.2, *Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods*. Contact: [Colleen Elliott](#)

AAMI CN-WG01, Luer activated valves. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI CN27, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*. Contact: [Colleen Elliott](#)

AAMI Standards Monitor Online

25 June 2021

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: [Amanda Benedict](#)

AAMI ST-WG06, Chemical indicators. The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of the national adoptions of several parts of the ISO 11140 series. Contact: [Amanda Benedict](#)

AAMI ST-WG12, Instructions for reusable device reprocessing. The working group is seeking user, regulatory and general interest members to participate in the national adoptions of the ISO 17664 series. Contact: [Amanda Benedict](#)

AAMI ST-WG13, Washer-disinfectors. The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of AAMI ST15883-2 and AAMI ST15883-3. Contact: [Amanda Benedict](#)

AAMI ST-WG42, Dry heat sterilization. The working group is seeking user, regulatory and general interest members to participate in the reaffirmation of AAMI/ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation, and routine control of a sterilization process for medical devices*. Contact: [Amanda Benedict](#)

AAMI ST-WG43, Hospital steam sterilizers. The working group is seeking user, regulatory and general interest members to participate in the reaffirmation of AAMI ST55, *Table-top steam sterilizers* and the revision of AAMI ST8, *Hospital steam sterilizers*. Contact: [Amanda Benedict](#)

AAMI ST-WG84, Endoscope reprocessing. The working group is seeking regulatory and general interest members to participate in the development of AAMI ST91/Ed.2, *Flexible and semi-rigid endoscope processing in health care facilities* and AAMI TIR99/Ed.1, *Dilators, transesophageal and ultrasound probes processing in health care facilities*. Contact: [Amanda Benedict](#)

AAMI ST-WG 91, Resistometers. The working group is seeking user, industry, and regulatory/general interest stakeholders to participate in the US adoption of ISO 18472:2018, *Sterilization of health care equipment – Biological and chemical indicators – Test equipment*. Contact: [Cliff Bernier](#)

AAMI TIB, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use. The committee and its affiliated working groups are seeking user, industry, and general interest/regulator members to participate in developing the US position towards documents under development in ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, and other projects*. Contact: [AAMI Standards](#)

AAMI/CV, Cardiac valves. The committee is seeking user, industry, and general interest/regulator members to participate in the US adoption of ISO 5840-1:202x, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*; ISO 5840-2:202x, *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes*; ISO 5840-3:202x, *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter*

AAMI Standards Monitor Online

25 June 2021

techniques; and the revision of ISO 5910:2018, *Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices*. Contact: [Cliff Bernier](#)

AAMI/VP, Vascular Prostheses. The committee is seeking user, industry, and general interest/regulator members to participate in the US adoption of ISO 25539-2:2020, *Cardiovascular implants — Endovascular devices — Part 2: Vascular stents*; the revision of ISO 25539-3, *Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters*; and the development of ISO 25539-4, *Cardiovascular implants — Endovascular devices — Part 4: Application of ISO 17327-1 for coated endovascular devices*. Contact: [Cliff Bernier](#)

AAMI/BG, Blood/Gas Exchange Device Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the development of the following Cardiovascular implants and artificial organs documents: ISO 18193, *Cannulae for extracorporeal circulation*; Amendment 1 to ISO 18242:2016 *Centrifugal blood pumps for pulsatile pumps*; and revision of ISO 7199, *Blood-gas exchangers*. Contact: [Cliff Bernier](#)

AAMI/VP-WG 01, Vascular Device-Drug Combination Products. The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO 12417-1:2015, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements* and the revision of ISO/TR 12417-2:2017, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 2: Local regulatory information*. Contact: [Cliff Bernier](#)

AAMI/RD, Renal Disease and Detoxification Committee. The committee is seeking industry, user, and general interest/regulator members to participate in the revision of the ISO 23500:2019, Preparation and quality management of fluids for haemodialysis and related therapies series standards: Part 1: General requirements; Part 2: Water treatment equipment for haemodialysis applications and related therapies; Part 3, Water for haemodialysis and related therapies; Part 4: Concentrates for haemodialysis and related therapies; Part 5, Quality of dialysis fluids for haemodialysis and related therapies; and the revision of the ISO 8637, Extracorporeal systems for blood purification series standards: Part 1, Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators; Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters; and Part 3, Plasmafilters. Contact: [Cliff Bernier](#)

AAMI/HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed., *Health IT software and systems — Part 2: Application of quality systems principles and practices*. Contact: [Emily Hoefler](#)

AAMI AI, Artificial Intelligence Committee. The committee is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR 34971, *Guidance on the Application of ISO 14971 to Artificial and Machine Learning*. Contact: [Emily Hoefler](#)

AAMI/SM-WG05, Medical Device Security Working Group – seeking general interest, reg/govt and users. The committee is developing a new American national standard, AAMI SW96, Standard for

medical device security — Security risk management for device manufacturers. Contact: [Ovidiu Munteanu](#)

AAMI/EV-WG05, Hospital Beds Working Group- seeking industry, user, general interest, and regulatory members to participate in the development of IEC 80601-2-52 ED1: *Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*, and IEC 80601-2-89 ED1: *Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children*. Contact: [Ladan Bulookbashi](#)

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.

June 2021

AAMI Packaging Working Group (open meeting). 28 June 2021, 11:00h to 15:00h ET. Virtual Meeting. Contact: [Amanda Benedict](#)

July 2021

AAMI High Frequency Therapeutic Device Committee (open meeting). 06 July 2021, 15:00h to 17:00h ET. Virtual Meeting. Contact: [Ladan Bulookbashi](#)

September 2021

AAMI Sterilization Standards meetings (open meetings). 13-17 September 2021, 08:00h to 17:00h ET. Schedule of meetings TBD. AAMI, Arlington, VA. 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.

June 2021

ISO/TC 198/WG 3, Industrial moist heat sterilization (closed meetings), 28, 30 June 2021, 13:00 h to 16:00 h BST, Zoom meeting. Contact: [Amanda Benedict](#)

AAMI Standards Monitor Online

25 June 2021

July 2021

ISO/TC 198/WG 9, Aseptic processing (closed meeting), 1 July 2021, 12:00 h to 16:00 h CEST, Zoom meeting. *Contact:* [Amanda Benedict](#)

ISO/TC 198/WG 1, Industrial EO sterilization (closed meeting), 13 July 2021, 13:00 h to 15:00 h IST, Zoom meeting. *Contact:* [Amanda Benedict](#)

ISO/TC 121, Anaesthetic and respiratory equipment (closed meeting), 16 July 2021, Zoom meeting. *Contact:* [Colleen Elliott](#)

ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification and apheresis (closed meeting). 20 July to 22 July 2021. Zoom meeting. *Contact:* [Cliff Bernier](#)

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 22 July 2021, 08:00 h to 11:00 h ET, Zoom meeting. *Contact:* [Amanda Benedict](#)

August 2021

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 26 August 2021, 08:00 h to 11:00 h ET, Zoom meeting. *Contact:* [Amanda Benedict](#)

September 2021

ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification and apheresis (closed meeting). 20 September to 24 September 2021. Zoom meeting. *Contact:* [Cliff Bernier](#)