NATIONAL STANDARDS

Recently Published

NEW! ANSI/AAMI MP80601-2-49:2020, *Medical electrical equipment—Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors.* 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/A1:2019, *Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications—Amendment 1*. Purchase here.

AAMI/ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical device*. Purchase here.

ANSI/AAMI/ISO 11138-7:2019, *Sterilization of health care products—Biological indicators—Part 7: Guidance for the selection, use and interpretation of results*. 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 April 13, 2020

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.

AAMI/ISO 10993-15, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys* (new American National Standard). Specifies general requirements for the design of tests for identifying and quantifying degradation products from final metallic medical devices or corresponding material samples finished as ready for clinical use. Applicable only to those degradation products generated by chemical alteration of the final metallic device in an in vitro degradation test. Because of the nature of in vitro tests, the test results approximate the in vivo behaviour of the implant or material. The described chemical methodologies are a means to generate degradation products for further assessments. Applicable to

both materials designed to degrade in the body as well as materials that are not intended to degrade. Contact: Colleen Elliott.

AAMI/ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process* (new American National Standard). Specifies a framework for the identification, and if necessary, quantification of constituents of a medical device, allowing the identification of biological hazards and the estimation and control of biological risks from material constituents, using a generally stepwise approach to the chemical characterization which can include one or more of the following: — the identification of its materials of construction (medical device configuration); — the characterization of the materials of construction via the identification and quantification of their chemical constituents (material composition); — the characterization of the medical device for chemical substances that were introduced during manufacturing (e.g. mould release agents, process contaminants, sterilization residues); — the estimation (using laboratory extraction conditions) of the potential of the medical device, or its materials of construction, to release chemical substances under clinical use conditions (extractables); — the measurement of chemical substances released from a medical device under its clinical conditions of use (leachables). Contact: Colleen Elliott.

AAMI/ISO 14155, *Clinical investigation of medical devices for human subject – Good clinical practice.* Addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices. For post-market clinical investigations, the principles set forth in this document can be followed as far as relevant, considering the nature of the clinical investigation (see Annex I). This document specifies general requirements intended to — protect the rights, safety and well-being of human subjects, — ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results, — define the responsibilities of the sponsor and principal investigator, and — assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices. Contact: Colleen Elliott.

AAMI PB70:202x, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* (revision of an American National Standard). Establishes minimum barrier performance requirements, a classification system, and associated labeling requirements for protective apparel, surgical drapes, and drape accessories intended for use in health care facilities. Contact: Amanda Benedict.

AAMI ST91:202x, *Flexible and semi-rigid endoscope processing in health care facilities* (revision of an American National 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.

AAMI ST98:202x, *Cleaning validation of health care products -- Requirements for development and validation of a cleaning process for medical devices* (proposed new American National Standard). Provides requirements to validate the cleaning instructions that are provided by the medical device manufacturer for processing medical devices. Contact: Amanda Benedict.

Comments due April 29, 2020

AAMI/ISO 15223-1/Ed.4, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (revision and parallel adoption of an American National Standard). Provides applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements. Contact: Wil Vargas.

Comments due May 25, 2020

AAMI/ISO 8637-1:2017, *Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators* (identical national adoption of ISO 8637-1 and revision of ANSI/AAMI/ISO 8637-2010 (R2015), AM1-2013 (R2015)). Specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators for use in humans. Contact: Cliff Bernier

AAMI/ISO 8637-2-2017, Extracorporeal systems for blood purification - Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (identical national adoption of ISO 8637-2 and revision of ANSI/AAMI/ISO 8638-2010 (R2015)). Specifies requirements for the blood circuit for devices used in extracorporeal blood filtration therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration, and transducer protectors (integral and non-integral) intended for use in such circuits. Contact: Cliff Bernier

AAMI/ISO 8637-3- 2017, Extracorporeal systems for blood purification - Part 3: Plasmafilters (identical national adoption of ISO 8637-3:2018). Specifies requirements for sterile, single-use plasmafilters, intended for use on humans. Does not apply to the extracorporeal circuits that may be used for plasmapheresis vascular access devices, oxygenators, or active medical devices. Does not address the replacement fluid. Contact: Cliff Bernier

AAMI/IEC 60601-2-16-2018, *Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment* (identical national adoption of IEC 60601-2-16-2018). Applies to the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment concerning electrical safety and patient safety. Includes all electromedical equipment that is intended to deliver a haemodialysis, haemodiafiltration and haemofiltration treatment to a patient suffering from kidney

failure, for use either by medical staff or by the patient or other trained personnel under the supervision of medical expertise. Contact: Cliff Bernier

AAMI/IEC 60601-2-39-2018, *Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment* (identical national adoption of IEC 60601-2-39-2018). Applies to the basic safety and essential performance of peritoneal dialysis medical electrical equipment. Applies to peritoneal dialysis equipment intended for use either by medical staff or under the supervision of medical experts, including peritoneal dialysis equipment operated by the patient, regardless of whether the peritoneal dialysis equipment is used in a hospital or domestic environment. Contact: Cliff Bernier

AAMI/IEC 62366-1:2015/Amd 1, *Medical devices - Part 1: Application of usability engineering to medical devices – Amendment 1* (identical national adoption of IEC 62366-1:2015/Amd 1). Contact: Jennifer Moyer

New Work

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.

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 HE, Human Factors Engineering Committee. The committee is seeking user and regulatory members to participate in the development of AAMI/IEC 62366-1:2015/Amd 1, *Medical devices - Part 1: Application of usability engineering to medical devices – Amendment 1*. 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 HE, Human Factors Engineering Committee. The committee is seeking user, regulatory and general interest members to participate in the review of ANSI/AAMI HE75:2009/(R)2018 *Human factors engineering—Design of medical devices.* 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.

AAMI/CV, Cardiac valves. The committee is seeking general interest/regulator members to participate in the revision of ISO 5910, *Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices.* Contact: Cliff Bernier.

AAMI/VP, Vascular Prostheses. The committee is seeking user and general interest/regulator members to participate in 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/RD, Renal Disease and Detoxification Committee. The committee is seeking general interest/regulator members to participate in the US adoption of ISO 8637-1:2017, *Extracorporeal systems for blood purification* series, including *Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*; ISO 8637-2:2017*: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*; and ISO 8637-3:2017*: Plasmafilters,* and the revision of these standards, which has been initiated. The committee is also seeking general interest/regulator members to participate in the US adoption of IEC 60601-2-16-2018, *Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment* and IEC 60601-2-39-2018, *Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment*. Contact: Cliff Bernier

AAMI/CO, Cardiac Occluders. The committee is seeking industry, user, and general interest/regulator members to participate in the development of ISO 22679, *Cardiovascular implants — Transcatheter cardiac occluders.* Contact: Cliff Bernier

AAMI/BG, Blood/Gas Exchange Device Committee. The committee is seeking industry, user, 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/VI, Cardiovascular absorbable implants. The committee is seeking industry, user, and general interest/regulator members to participate in the revision of ISO/TS 17137:2019, *Cardiovascular implants and extracorporeal systems - Cardiovascular absorbable implants*. Contact: Cliff Bernier

AAMI/QM-WG03, Symbols and nomenclature for medical devices Working Group. The committee is seeking user, general interest, and regulator members to participate in the revision of ISO 15223-1/Ed.4, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*. Contact: Wil Vargas

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.

April 2020

ST/WG 11 Committee (open meeting) 14 April 2020. 11:00 to 14:00h ET. Web meeting. *Contact: Amanda Benedict*

Infusion Device Committee (open meeting) 29 April 2020. 14:00 to 16:00 h. Web meeting. Contact: Jennifer Moyer

May 2020

Renal Disease and Detoxification Committee (open meeting). 4 May 2020. 9:00 to 17:00h, web meeting. Contact: Cliff Bernier

June 2020

AAMI Medical Device Particulates Committee (open meeting) 4-5 June 2020. 9:00 to 17:00h, AAMI, Arlington, VA, USA. Contact: Cliff Bernier

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.

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* ***CANCELED***

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* ***CANCELED***

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 27-29 April 2020, 8:00 h to 12:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/ 198/WG 13, Washer-disinfectors (closed meeting), 30 April 2020, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

May 2020

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 5 May 2020, 8:00 h to 12:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

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: Hae Choe* ***CANCELED***

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* ***CANCELED***

ISO/ 198/WG 13, Washer-disinfectors (closed meeting), 19 May 2020, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

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* ***CANCELED***

June 2020

ISO/TC 210/WG 3, Symbols and nomenclature for medical devices (closed meeting), 2-3 June 2020, 9:00 h to 17:00 h, AAMI, Arlington, Virginia, USA. *Contact: Wil Vargas* ***CANCELED***

ISO/TC 198/WG 11, General criteria for sterilization processes and sterilizing equipment (closed meeting), 3-4 June 2020, 8:00 h to 12:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

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: Hae Choe* ***CANCELED***

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 15-16 June 2020, 9:00 h to 17:00 h, DIN, Berlin, Germany. *Contact: Amanda Benedict* ***CANCELED***

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* ***CANCELED***