NATIONAL STANDARDS

Recently Published

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.

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 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

Comments due July 13, 2020

AAMI EC12, Disposable ECG electrodes (reaffirmation of an American National Standard). Establishes minimum labeling, safety, and performance requirements for disposable electrodes used for diagnostic electrocardiography (ECG) or ECG monitoring. Purchase from: https://my.aami.org/store/detail.aspx?id=EC12

AAMI EC53, ECG trunk cables and patient leadwires (reaffirmation of an American National Standard). The objective of this standard is to allow ECG trunk cables and patient leadwires to be interchanged between ECG devices with isolated patient connections by establishing a common interface between the trunk wire cable and the patient leadwire connectors. Performance and safety criteria for trunk cables and patient leadwires used with isolated patient connectors are also specified. This standard's original scope related to trunk cables and patient leadwires used with cardiac monitors. The scope was extended to include patient leadwires used with other ECG devices including diagnostic electrocardiographs, ambulatory ECG (Holter) recorders/event recorders and ECG telemetry. Purchase from: https://my.aami.org/store/detail.aspx?id=EC53-PDF

AAMI EC57, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms (reaffirmation of an American National Standard). This standard established a method for testing and reporting the performance of algorithms used to detect cardiac rhythm disturbances, including the ST segment. Purchase from: https://my.aami.org/store/detail.aspx?id=EC57-PDF

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 SP, Sphygmomanometer Committee. The committee is working on the adoption of ISO 81060-2:2019/Amd 1, *Non-invasive sphygmomanometers - Clinical investigation of intermittent automated measurement type – Amendment 1*. Contact: Jennifer Moyer

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.*
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> **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 SP, Sphygmomanometer Committee. The committee is seeking user and regulatory members to participate in the work to adopt ISO 81060-2:2019/Amd 1, *Non-invasive sphygmomanometers - Clinical investigation of intermittent automated measurement type – Amendment 1*. Contact: Jennifer Moyer

AAMI EC, ECG Committee. The committee is seeking user and regulatory members to participate in the reaffirmations of AAMI EC12, Disposable ECG electrodes, AAMI EC53, ECG trunk cables and patient leadwires, and AAMI EC57, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms. 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/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/RD, Renal Disease and Detoxification Committee. The committee is seeking industry and general interest/regulator members to participate in the revision 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 industry and 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/VP-WG 01, Vascular Device-Drug Combination Products. The committee is seeking industry, user 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/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/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/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.

June 2020

AAMI Medical Device Particulates Committee (open meeting) 3-5 June 2020. 12:30 to 17:00h, web meeting. Contact: Cliff Bernier

AAMI Endoscope Reprocessing Working Group (ST/WG 84) (open meeting) 15 and 17 June 2020, 11:00h to 14:00h ET, and 19 June 2020, 10:00h to 13:00h ET, web meeting. *Contact: Amanda Benedict*

Cardiac Rhythm Management Devices Committee (open meeting) 18 June 2020. 11:00 to 13:30 h, web meeting. Contact: Jennifer Moyer

AAMI Packaging Working Group (ST/WG 7) (open meeting) 25 June 2020. 13:00h to 16:00h ET, web meeting. *Contact: Amanda Benedict*

AAMI Radiation Sterilization Working Group (ST/WG 7) (open meeting) 29 and 30 June 2020. 11:00h to 14:00h ET, web meeting. *Contact: Amanda Benedict*

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.

May 2020

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), 9 and 11 June 2020, 8:00 h to 11:00 h, Zoom meeting. *Contact: Wil Vargas*

ISO/TC 198/WG 4, Biological indicators (closed meeting), 2 June 2020, 8:00 h to 13:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

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 16, Vaporized hydrogen peroxide sterilization (closed meeting), 15, 23 and 24June 2020, 8:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

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***

ISO/TC 198/WG 7, Packaging (closed meeting), 18 and 23 June 2020, 7:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 13, Washer disinfectors (closed meeting), 25 June 2020, 8:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 150/SC 2/WG 3, Vascular prostheses (closed meeting). 29 June 2020, 11:00 h to 1:00 h ET, Zoom meeting. Contact: Cliff Bernier