NATIONAL STANDARDS

Recently Published

NEW! ANSI/AAMI/IEC 80601-2-77:2020, *Medical electrical equipment—Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment*. Purchase here.

NEW! ANSI/AAMI/IEC 80601-2-78:2020, *Medical electrical equipment—Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation*. Purchase here.

NEW! AAMI TIR105:2020, *Risk management guidance for combination products*. Purchase here.

ANSI/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*. Purchase here.

ANSI/AAMI/IEC 60601-2-39:2018, *Medical electrical equipment—Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment*. Purchase here.

ANSI/AAMI/ISO 8637-1:2017, *Extracorporeal systems for blood purification—Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*. Purchase here.

ANSI/AAMI/ISO 8637-2:2018, *Extracorporeal systems for blood purification— Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*. 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 October 26, 2020

AAMI PC76, *Active implantable medical devices – Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging* (proposed new American National Standard). Provide requirements and test protocols for implantable pacemakers and ICDs exposed to magnetic resonance imaging. Physicians are increasingly using magnetic resonance imaging as tool for differential diagnostic, thus exposing pacemakers and ICD patients to such equipment. Current product standards for implantable pacemakers and ICDs do not include requirements and test protocols for implantable pacemakers and ICDs, which would ensure patient safety during such procedures. Contact: jmoyer@aami.org

Comments due November 9, 2020

AAMI HIT1000-1, *AAMI HIT1000-1/Ed 1, Health IT Software and Systems – Part 1: Fundamental concepts and principles* (proposed new American National Standard from a provisional standard). Identifies the fundamental concepts and principles needed to maintain safe, secure and effective health IT software and systems. Identifies the roles, and defines the responsibilities, activities and best practices that are necessary for managing safety, security and effectiveness of health IT software and systems. Applies throughout the whole lifecycle of health IT software and systems and to all sizes and type of actors involved with that system. Contact: EHoefer@aami.org

Comments due November 16, 2020

AAMI/IEC 60601-2-20, Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (proposed revised American National Standard). Applies to the basic safety and essential performance of transport incubators. This standard does not apply to heating devices intended for physiotherapy, baby incubators, radiant warmers. Contact: jmoyer@aami.org

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: Amanda Benedict.

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 II, Infant Incubators. The committee will be working on the identical expedited adoption of the following documents:

- AAMI/IEC 60601-2-19, *Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators.* Applies to the basic safety and essential performance of infant incubators.
- AAMI/IEC 60601-2-21, *Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers*. Specifies safety requirements for infant radiant warmers.

- AAMI/IEC 60601-2-50, *Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment*. Applies to the basic safety and essential performance of infant phototherapy equipment.

To get involved in the development of these documents, please 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.*

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 PC/WG 3, Pacemaker & MRI Compatibility Working Group. The working group is seeking user, regulatory, and general interest members to participate in the development of AAMI PC76, *Active implantable medical devices – Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging*. 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: Amanda Benedict.

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/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/HIT, Health IT Committee. The working group is seeking industry, general interest, and regulator members to participate in the development of AAMI HIT1000-1/Ed., *Health IT Software and Systems – Part 1: Fundamental concepts and principles*. Contact: Emily Hoefer

AAMI/HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking industry, general interest, and regulator 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* (Provisional Standard). Contact: Emily Hoefer

AAMI/II, Infant Incubators. The committee is seeking users, regulatory, and general interest members to participate in the development of AAMI/IEC 60601-2-20, *Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators*. Contact: Jennifer Moyer

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.

October 2020

Quality systems for device processing Working Group (open web meeting). 26 October 2020, 14:00h to 16:00h ET. Virtual meeting. *Contact: Amanda Benedict, sterilization@aami.org.*

Endoscope reprocessing Working Group (open web meeting). 27 October 2020, 09:00h to 12:00h ET. Virtual meeting. *Contact: Amanda Benedict, sterilization@aami.org.*

Infusion Device Committee (open web meeting). 27 October 2020, 13:30 to 15:30 h. Contact: Jennifer Moyer.

Chemical sterilants hospital practices Working Group (open web meeting). 28 October 2020, 13:00h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict, sterilization@aami.org.*

AAMI October 2020 Sterilization Standards Closing Plenary and US TAG to ISO/TC 198 Web Meeting (open web meeting). 29 October 2020, 11:00h to 13:00h ET. Virtual meeting. *Contact: Amanda Benedict, sterilization@aami.org.*

November 2020

Vaporized hydrogen peroxide sterilization Working Group (open web meeting). 10November 2020, 11:00h to 14:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Cardiac Rhythm Management Devices (open remote meeting). 12 November 2020, 11:00 to 13:30 h. *Contact: Jennifer Moyer*

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.