NATIONAL STANDARDS

Recently Published

NEW! 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.

NEW! 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.

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

NEW! ANSI/AAMI/ISO 8637-2:2018, *Extracorporeal systems for blood purification— Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*. Purchase here.

ANSI/AAMI/ISO 8637-3:2018, *Extracorporeal systems for blood purification—Part 3: Plasmafilters*. Purchase here.

ANSI/AAMI/IEC 62366:2015+Amd 1:2020, *Medical devices—Part 1: Application of usability engineering to medical devices—including Amendment 1 (consolidated text)*. 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 September 21, 2020

AAMI/IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices (proposed reaffirmation of an American National Standard). This document specifies a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigates risks associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use. Contact: Hae Choe

Comments due October 5, 2020

AAMI/ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications (revision of an American National Standard). Specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections in intravascular applications or hypodermic connections in hypodermic applications of medical devices and accessories. Contact: celliott@aami.org

AAMI/ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods (proposed reaffirmation of an American National Standard). Specifies the test methods to evaluate the performance requirements for small-bore connectors specified in the ISO 80369- series. Contact: cellliott@aami.org

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

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.

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: Patrick Bernat.

AAMI HE, Human Factors Engineering Committee. This committee is seeking users and general interest members to participate in the development of the reaffirmation of AAMI/IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices.* Contact: Hae Choe

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-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: 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.

September 2020

Cleaning for Reusable Medical Devices Working Group (open web meetings). 17, 21, 25 and 29 September 2020. 12:00 h to 15:00 h ET. *Contact: Amanda Benedict*

Infusion Device Committee (open web meeting). 29 September 2020. 13:30 to 15:30 h ET. *Contact:* Jennifer Moyer

October 2020

AAMI Sterilization Standards Week - details to come! (open web meetings – advance registration will be required) 13-16 and 26-30 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.

September 2020

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 3/8/9/22 September 2020, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 2, Radiation sterilization (closed meeting), 15 September 2020, 10:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 7, Packaging (closed meeting), 15/16/17 September 2020, 07:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 1, Industrial ethylene oxide sterilization (closed meeting), 22 September 2020, 08:00 h to 10:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 9, Aseptic processing (closed meeting), 24 September 2020, 12:00 h to 16:00 h Berline time, Zoom meeting. *Contact: Amanda Benedict*

October 2020

ISO/TC 150/SC 6/JWG 1, Cardiac pacemakers and implantable defibrillators (closed meeting. 1 October 2020, 10:00 to 12:00 h ET, Zoom meeting. *Contact:* Jennifer Moyer

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 5 October 2020, 09:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 22 October 2020, 09:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 150/SC 6, Active implants (closed meeting), 22 October 2020, 11:00 to 13:00 h ET, Zoom meeting. *Contact:* Jennifer Moyer

MISCELLANEOUS

AAMI, in collaboration with the British Standards Institution, is launching an effort to develop standards for artificial intelligence (AI) and machine learning (ML) in medical technologies. In May of this year, AAMI published a whitepaper discussing the need for new standards and regulator initiatives to promote the safety, effectiveness, and availability of AI and ML in healthcare. (https://www.aami.org/detail-pages/press-release/aami-bsi-position-paper-sets-machine-learning-agenda)

There were seven recommendations made in the whitepaper. One of the most urgent was for guidance on applying ISO 14971, *Medical Devices—Application of Risk Management to Medical Devices,* when evaluating medical technology utilizing AI and, in particular, ML. AAMI and BSI have established a partnership to jointly develop a document which provides this guidance, as well as other needed AI standards identified in the whitepaper.

As a result of this initial work, AAMI is creating a new consensus body, tentatively called the AAMI Artificial Intelligence Committee (AAMI AI) to develop this work. Interested parties, including representatives of clinical practices, academia, regulatory authorities, and industry should contact standards@aami.org for more information about the project or participation on the committee.