NATIONAL STANDARDS

Recently Published

AAMI/ISO FDIS 14971:2019, *Medical devices—Application of risk management to medical devices*
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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: http://my.aami.org/store/.

Comments due June 17

AAMI/IEC 80601-2-77, Medical electrical equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment (identical adoption as American National Standard). This standard applies to the basic safety and essential performance of robotically assisted surgical equipment (RASE) and robotically assisted surgical system (RASS). This document does not apply to X-ray based image guided radiotherapy equipment. Contact: hchoe@aami.org.

AAMI/IEC 80601-2-78, Medical electrical equipment – Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation. This standard applies to the general requirements for the basic safety and essential performance of medical robots that physically interact with a patient to support or perform rehabilitation, assessment, compensation or alleviation related to the patient's movement functions following an impairment. Contact: hchoe@aami.org.

Comments due July 8

AAMI/BE83, Biological evaluation of medical devices – Part 18: Chemical characterization of materials (reaffirmation of an American National Standard). This standard describes a framework for the identification of a material and the identification of a material and the identification and of its chemical constituents. Contact: abenedict@aami.org.

AAMI/RT3, Radiation therapy machine characterization (new AAMI standard). This standard defines a standard XML format for publishing and reporting the physical parameters of a C-Arm Radiation

Therapy Linear Accelerator or the physical parameters in a software model of such a device. Contact: csidebottom@aami.org.

Comments due July 29

AAMI/IEC 80601-2-49, Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors (adoption of an international standard as a new American National Standard). Applies to the safety requirements of multifunction patient monitoring equipment. The scope is restricted to medical electrical equipment having either more than one applied part or more than one single function, intended for connection to a single patient. This standard does not specify requirements for individual monitoring functions. Contact: jmoyer@aami.org.

New Work

AAMI Cardiac Rhythm Management Devices Committee. A new work item has been approved on the development of a technical information report (TIR), AAMI TIR107, *Cardiovascular implantable electronic devices – Battery longevity management and reporting*. This document will provide guidance on methods to communicate battery longevity status for cardiovascular implantable electronic devices (CIEDs). Specifically, the TIR will provide guidance to manufacturers on:

1) communication of remaining battery longevity prior to the CIED's Recommended Replacement Time (RRT),
2) accuracy of pre-RRT battery longevity estimates,
3) duration of the Prolonged Service Period (PSP) between RRT and End of Service (EOS), and
4) device functionality during the PSP period.

For information on this project or to join the consensus body, contact jmoyer@aami.org.

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, Cardiac Rhythm Management Devices – seeking users, regulatory, and general interest members. This committee is working on the development of a new document, AAMI TIR107, *Cardiovascular implantable electronic devices – Battery longevity management and reporting*. Contact: jmoyer@aami.org.

AAMI ST/WG 93, Cleaning of Reusable Medical Devices – seeking users. This committee is working on the development of AAMI ST98, *Cleaning validation of health care products -- Requirements for development and validation of a cleaning process for medical devices.* Contact: abenedict@aami.org.

AAMI/QM-WG02, General aspects stemming from the application of quality principles to medical devices Working Group – seeking users and general interest. The committee is working on the adoption of ISO 20417, *Medical devices -- Information to be provided by the manufacturer*. Contact: wvargas@aami.org.

AAMI/MP, Multiparameter Patient Monitoring Equipment – seeking users and regulators. This committee is working on the adoption of AAMI/IEC 80601-2-49, *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors*. Contact: jmoyer@aami.org.

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). Agendas for open meetings are usually available from AAMI Central. (Visit https://standards.aami.org/higherlogic/ws/public*, find the committee or working group and look under "Upcoming Shared Events" or "Recently Shared Documents"). 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.*

July 2019

AAMI/ST/WG84, Endoscope Reprocessing Working Group (open meeting – registration required), 8 July 2019, 8:00 – 5:00, AAMI, Arlington, VA. Contact: abenedict@aami.org.

AAMI/ST/WG12, Endoscope Reprocessing Working Group (open meeting – registration required), 9 July 2019, 8:00 – 5:00, AAMI, Arlington, VA. Contact: lwaggoner@aami.org.

AAMI/CN/WG01, Luer activated valves (open meeting – registration required), 9-11 July 2019, 9:30 – 5:00, AAMI, Arlington, VA. Contact: celliott@aami.org.

AAMI/DP, Medical Device Particulates Committee (open meeting - registration required). 6-7 November 2019, 9:00am – 5:00 pm, Arlington, VA. Contact: cbernier@aami.org.

August 2019

AAMI/SM-WG01, Software Working Group (open meeting - registration required). 2-3 August 2019, 9:00am – 5:00 pm, Arlington, VA. Contact: wvargas@aami.org

November 2019

AAMI/RD, Renal Disease and Detoxification Committee (open meeting - registration required). 11 November 2019, 9:00am – 5:00 pm, Arlington, VA. Contact: cbernier@aami.org.

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in ANSI Standards Action: http://www.ansi.org/news_publications/periodicals/standards_action/standards_action.aspx?menuid=7

International Committee and Working Group Meetings

Call or email the indicated staff person at AAMI for more information about upcoming international standards meetings.

June 2019

ISO/TC 198/WG 1, Industrial ethylene oxide sterilization (closed meeting), 17-18 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: lwaggoner@aami.org.

IEC/SC 62D/MT20, Haemodialysis equipment (closed meeting), 17-18 June 2019, 09:00 h to 17:00 h, Budapest, Hungary. Contact: hchoe@aami.org.

ISO/TC 198/WG 11, General criteria for sterilization processes and sterilizing equipment (closed meeting), 17-18 June 2019, 09:00h to 17:00h, London, UK. Contact: abenedict@aami.org.

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 20 June 2019, 09:00 h to 12:00 h Eastern Standard Time, web meeting. Contact: abenedict@aami.org.

ISO/TC 198/WG 9, Aseptic processing (closed meeting), 25-28 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: abenedict@aami.org.

ISO/TC 210/WG6, Application of post market surveillance systems to medical devices (closed meetings), 24-26 June 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: wvargas@aami.org.

October 2019

ISO/TC 210/WG2, General aspects stemming from the application of quality principles to medical devices (closed meetings), 2 – 4 October 2019, 9:00 h to 17:00 h, Delft, Netherlands. Contact: wvargas@aami.org.

ISO/TC 210 and related working groups (WG1, WG3, WG6, JWG1), Quality management and corresponding general aspects for medical devices (closed meetings), 7-11 October 2019, 9:00 h to 17:00 h, London, United Kingdom. Contact: wvargas@aami.org

ISO/TC 194/WG3, 6, 8, 10, 11, 12, Biological evaluation working groups (closed meetings), 14-17 October 2019, 9:00 h to 17:00 h, AAMI, Arlington, VA. Contact: celliott@aami.org.

ISO/TC 150/SC 2 and related working groups, Cardiovascular implants and extracorporeal systems (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: cbernier@aami.org.

ISO/TC 150/SC 6 and related working groups, Active implants (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: jmoyer@aami.org

IEC/TC 62, related Sub-committees and working groups, Electrical equipment in medical practice (closed meetings), 14-25 October 2019, 9:00 h to 17:00 h, Shanghai, China. Contact: hchoe@aami.org

November 2019

I**SO/TC 121/SC2, Airways and related equipment** (closed meeting), week of 18 November 2019 (exact days TBA), 9:00 h to 17:00 h, Schiedam, The Netherlands. Contact: celliott@aami.org.

ISO/TC 121/SC6 and related WGs, Medical gas supply systems (closed meeting), 18-22 November 2019, 9:00 h to 17:00 h, Schiedam, The Netherlands. Contact: celliott@aami.org.

December 2019

I**SO/TC 198, Sterilization of health care products and affiliated working groups** (closed meeting), 2-6 December 2019, 9:00 h to 17:00 h, Seoul, Korea. Contact: abenedict@aami.org.

ACI AAMI Credentials Institute

AAMI's Industrial Sterilization Certification: Advance your Career with a Sterilization Credential

Stand out among your peers by earning a Certified Industrial Sterilization Specialist certification in each of the three specialties: Ethylene Oxide | Radiation | Moist Heat. As in most professions, taking the initiative to earn and maintain a credential shows an individual's devotion to the field, specialized knowledge base, and pride in professional development.

An interested and eligible candidate for the CISS certification programs should have a keen understanding of the following topic areas relating to the specialty of their choice:

- Quality Management Systems
- Sterilization Agent, Process, and Equipment Characterizations
- Product and Process Definition
- Validation
- Routine Monitoring, Control, and Product Release
- Maintaining Process Effectiveness

Start preparing now for the next testing window that will be held November 1-15! For more information regarding eligibility, exam content, and the application process, visit www.aami.org/aci and click on the ACI Certification Candidate Handbook. To reach an ACI representative, email aci@aami.org.

2019 World Standards Day Paper Competition

Initiated by the Standards Engineering Society in 1990, the U.S. Celebration of World Standards Day is now a joint effort between the private and public sector. The American National Standards Institute (ANSI) and the National Institute of Standards and Technology (NIST) co-chair the event with participation by some 50 trade associations, professional societies, standards development organizations, corporations, and government agencies. AAMI is a proud participant.

The U.S. Celebration of World Standards Day includes a reception, exhibits, dinner, and presentation of the Ronald H. Brown Standards Leadership Award. Named after the late U.S. Secretary of Commerce, the award recognizes demonstrated leadership in promoting the important role of standardization in eliminating global barriers to trade.

The World Standards Day Paper Competition is open to any individual in the private sector, government, or academia, including employees of standards developing organizations. Entrants must reside in the U.S. If employed, they must be employed by a **U.S.-based organization and must work at a location in the U.S.**

If you are interested in submitting a paper, click here for the rules.

MISCELLANEOUS

Introducing our new Standards FAQs page!
Please visit the AAMI website at www.aami.org/standardsfaqs to quickly get answers to commonly asked questions. If your question and answer is not listed on the website, please complete and submit the online form and someone will get back to you within three business days. Please note that as a standards developing organization accredited under ANSI, AAMI is procedurally prohibited from providing interpretations of standards and/or interpreting whether specific actions are in conformance with the standards. We do not have the technical expertise on staff to advise about specific practices and can only point you to content in the standards that might be helpful.

For questions of a technical nature, we suggest you reach out to any number of consultants in the AAMI Buyers Guide that can be found on www.aami.org.