NATIONAL STANDARDS

Recently Published

AAMI TIR102:2019, *U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016, Quality Management Systems*
Purchase from: https://my.aami.org/store/SearchResults.aspx?searchterm=tir102&searchoption=ALL

AAMI/ISO FDIS 14971:2019, *Medical devices—Application of risk management to medical devices*
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ANSI/AAMI/ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging*
Purchase from: https://my.aami.org/store/detail.aspx?id=11607012019-PDF

ANSI/AAMI/ISO 11607-2:2019, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
Purchase from: https://my.aami.org/store/detail.aspx?id=11607022019-PDF

ANSI/AAMI/ISO 81060-2:2019, *Non-invasive sphygmomanometers – Pat 2: Clinical investigation of intermittent automated measurement type*
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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 October 07

AAMI/ISO 13485:2016, ***Medical devices - Quality management systems - Requirements for regulatory purposes*** (reaffirmation of an American National Standard). Specifies requirements for a quality management system for medical devices where an organization needs to demonstrate its ability to provide product that consistently meets customer and applicable regulatory requirements. Contact: wvargas@aami.org.

New Work

AAMI/SM-WG03, Interoperability Working Group. The committee is working on the development of AAMI 2700-2-1/Ed. 1 *Medical Devices and Medical Systems — Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging*. This standard provides requirements for system data logging capabilities in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers play important roles in the basic safety and essential performance of integrated clinical environments. Contact: wvargas@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 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/SM-WG03, Interoperability Working Group. The committee is working on the development of AAMI 2700-2-1/Ed. 1 *Medical Devices and Medical Systems — Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging*. This standard provides requirements for system data logging capabilities in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers play important roles in the basic safety and essential performance of integrated clinical environments. Contact: wvargas@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.*

September 2019

Combined meeting of the US TAGs for IEC/TC 62 and Subcommittees, Electrical equipment in medical practice (open meeting - registration required), 20 September 2019, AAMI Headquarters, Arlington, VA, USA. *Contact:* hchoe@aami.org

October 2019

AAMI Sterilization Standards Week and US TAG to ISO/TC 198 meeting (open meetings – advance registration REQUIRED), 21-25 October 2019, AAMI Headquarters, Arlington, VA, USA. *Contact:* abenedict@aami.org.

November 2019

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.

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.

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

IEC/SC 62A/MT23, Electromagnetic compatibility (closed meeting), 4-8 November 2019, 9:00 h to 17:00 h, Prague, Czech Republic. Contact: hchoe@aami.org

IEC/SC 62D – ISO/TC 173/JWG 4, Medical beds (closed meeting), 13-15 November 2019, 9:00 h to 17:00 h, Copenhagen, Denmark. Contact: hchoe@aami.org

IEC/SC 62A – ISO/TC 121/SC 3/JWG 2, Alarms (closed meeting), 18-22 November 2019, 9:00 h to 17:00 h, Dublin, Ireland. Contact: hchoe@aami.org

I**SO/TC 121/SC2, Airways and related equipment** (closed meeting), week of 21-22 November 2019, 9:00 h to 17:00 h, Luebeck, Germany (WG14 on 20 November). 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 meetings), 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.

Call for Papers – Summer 2020 *Horizons*

The Summer 2020 issue of *Horizons* (www.aami.org/Horizons) will focus on the importance of human factors in healthcare technology management, device design, standardization, manufacturing, and regulation. For more information, including important dates and details on submitting a paper, please visit www.aami.org/HorizonsCallForPapers.

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.