NATIONAL STANDARDS

Recently Published

NEW! ANSI/AAMI/IEC 62366:2015/Amd 1:2020, *Medical devices—Part 1: Application of usability engineering to medical devices—Amendment 1.* Purchase here.

AAMI/ISO TIR24971:2020, *Medical devices—Guidance on the application of ISO 14971*. 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 August 10, 2020

AAMI 2700-2-1, 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 or forensic Data logging (new American National Standard). This document provides general functional, performance, and interoperability requirements of ICE data logging systems including the recording and storage of data in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers can play an important role in maintaining and improving the basic safety and essential performance of integrated clinical environments by enabling the forensic assessment of the ICE system and its components. Contact: wvargas@aami.org

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: hchoe@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.*
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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/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 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/SM-WG03, Interoperability Working Group. The committee is seeking user, general interest, and regulator members to participate in the development of AAMI 2700-2-1, *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 or forensic Data logging*. 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.

August 2020

ST-WG 8, Microbiological Methods Working Group (remote open meeting). 7 August 2020, 11:00 h to 14:00 h ET, and 10 August 2020, 13:00 h to 15:00 h ET. *Contact: Amanda Benedict.*

Infusion Device Committee (remote open meeting). 11 August 2020, 13:30 h to 15:30 h ET. *Contact: Jennifer Moyer.*

September 2020

Infusion Device Committee (remote open meeting). 1 September 2020. 13:30 h to 15:30 h ET. *Contact: Jennifer Moyer*.

October 2020

AAMI Sterilization Standards Week - details to come! (open meetings – advance registration will be required) 12-16 October 2020, AAMI, Arlington, VA, USA. Please note that these meetings are currently planned as being held in-person with a remote participation option; it might be necessary to change to fully remote meetings, depending on circumstances closer to the date of the meetings. *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.

August 2020

ISO/TC 150/SC 6/WG 4, Implantable infusion pumps (remote closed meeting), 5 August 2020 and 12 August 2020, 11:00 h to 13:00 h ET, Zoom meeting. *Contact: Jennifer Moyer*

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 24/25 August 2020, 09:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

September 2020

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 1/2 September 2020, 09:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*