AAMI Standards Monitor Online
24 February 2023

STANDARDS UPDATE

AAMI Standards Insider

The next AAMI Standards Insider webinar has been rescheduled to **Thursday, March 2nd from 1:00-2:00 PM ET**. The **one-hour FREE webinar** provides news and updates about AAMI's standards program and portfolio. Registration for the upcoming webinars and recordings of past webinars in the series – including the November 17th session - will be available on the webpage. Check back soon!

Publications

PUBLISHED! **ANSI/AAMI/ISO 18472:2022**, *Sterilization of health care products—Biological and chemical indicators—Test equipment.* Click here for more information.

PUBLISHED! **ANSI/AAMI/ISO 5840-1:2022**, Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements. Click here for more information.

PUBLISHED! **ANSI/AAMI/ISO 5840-2:2022**, Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes. Click here for more information.

PUBLISHED! **ANSI/AAMI/ISO 5840-3:2022**, Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques. Click here for more information.

NATIONAL STANDARDS

AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by email 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 20 March 2023

AAMI 80369-3:2016, Small-bore connectors for liquids and gases in healthcare applications: Part 3: Connectors for enteral applications and AAMI 80369-3:2016/Amd1:2019 (reaffirmation of an American National Standard). This document Specifies the dimensions and requirements for the design and

functional performance of small-bore connectors intended to be used for connections on enteral medical devices and accessories. Contact: Colleen Elliott

AAMI ST108, Water for the processing of medical devices (proposed new American National Standard) This standard covers the selection and maintenance of effective water quality suitable for processing medical devices. It provides guidelines for selecting the water quality necessary for the processing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations. Contact: Tommy Kim

Comments due 3 April 2023

AAMI BP22-1994 (R2016), Blood pressure transducers (reaffirmation of an American National Standard). This standard provides performance and safety requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture, and provides disclosure requirements to permit the user to determine the compatibility between the transducer and blood pressure monitor. This standard is a combined revision of two American National Standards (ANSI/AAMI BP22-1986 and ANSI/AAMI BP23-1986.) Contact: Ladan Bulookbashi

AAMI CI86-2017, Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting (reaffirmation of an American National Standard). This standard establishes minimum requirements for those active implantable medical devices known as cochlear implants or cochlear prostheses, which are intended to treat hearing impairment by means of electrical stimulation of the cochlea. Devices that treat hearing impairment other than by including electrical stimulation of the cochlea are not covered by this standard. This standard applies to the electrical stimulation component(s) of combination devices that treat hearing impairment using multiple means, including electrical stimulation. The tests specified in this standard are industry-accepted tests and are to be carried out on samples of devices to show compliance. This standard is also applicable to non-implantable parts and accessories of the devices, including fitting and diagnostic components. General and specific requirements are provided with regard to design verification, post-implantation device testing, reliability assessment and reporting, packaging and labeling, protections of the patient associated with design issues and device malfunctions, and protections of the device associated with environmental challenges arising from transport, storage, handling during implantation, unrelated medical treatments, and normal use. Contact: Ladan Bulookbashi

AAMI NS4-2013 (R2017), Transcutaneous electrical nerve stimulators (reaffirmation of an American National Standard). This standard establishes labeling, safety, and performance requirements and referee tests for transcutaneous electrical stimulators (including TENS) intended for use in the treatment

of pain syndrome. Also covered are labeling requirements for patient leads and electrodes. Contact: Ladan Bulookbashi

Comments due 10 April 2023

AAMI/ISO 13004, Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method VD_{max}^{SD} (identical national adoption of ISO 13004:2022) Specifies a method or substantiating a selected sterilization dose of 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy or 35 kGy that achieves a sterility assurance level (SAL) of 10^{-6} or less or radiation sterilization o health care products. This document also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose. Contact: **Tommy Kim**

AAMI/ISO 20417, Medical devices — Information to be supplied by the manufacturer (identical national adoption of ISO 20417:2021) Specifies the requirements for information supplied by the manufacturer for a medical device or by the manufacturer for an accessory. This document includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory, and accompanying information. Contact: Amanda Benedict

New Work

AAMI TIB, ***Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use Committee***. The committee is working on an AAMI Consensus Report (CR) for *Guidance for Closed System Transfer Device Testing with Hazardous Drugs*. This CR seeks to provide guidelines for physical and chemical compatibility of the drug with the Closed System Transfer Device (CSTD), which may include, but not limited to holdup volume, coring/fragmentation of the vial rubber stopper, microbial ingress, stability/shelf-life, and usability. TIB-WG04 is seeking cochairs, user, regulatory, and general interest members to participate in the development of AAMI CR112. **The group holds monthly meetings** (1st Wednesday of every month, 10:00h to 11:00h EST). Contact: Sam Alameda

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.*

Commented [TK1]: Note: This is an reissue SMO PR because the original SMO PR was not for 45 days.

Commented [AB2R1]: @Thomas Kim if you're calculating 45 days from Friday (when SMO is supposed to be issued), it is 10 April 2023.

Commented [TK3R1]: @Amanda Benedict thank you for fixing this!

Commented [HC4R1]: @Amanda Benedict @Thomas Kim i think this is a national adoption of ISO 13004:2022? just fixed from new american national standard.

Commented [AB5R1]: @Hae Choe @Thomas Kim @Sam Alameda correct and I adjusted the listing for 20417 to match.

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 BE-WG07, Systemic Toxicity Working Group. The working group is seeking industry, user, general interest, and regulatory members to participate in the development of ANSI/AAMI/ISO 10993-11:2017 *Biological evaluation of medical devices—Part 11: Tests for systemic toxicity*. Contact: Chenai Maguwah

AAMI BE-WG18, Attributes of medical devices relevant to biological risk assessment. AAMI is seeking industry, user, general interest, and regulatory members for the newly formed working group to provide input for ISO TC/194/WG18 activities. Contact: Chenai Maguwah

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking user, industry, 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: Jill Zajac

AAMI BP- Blood Pressure Monitoring Committee The committee is seeking regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI BP22-1994 (R2016), *Blood pressure transducers*. Contact: Ladan Bulookbashi

AAMI CI-Cochlear Implants Committee The committee is seeking industry, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI CI86-2017, *Cochlear implant systems—Requirements for safety, functional verification, labeling and reliability reporting*. Contact**:** Ladan Bulookbashi

AAMI CN – Small bore connectors committee The committee is seeking user, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI 80369-3:2016, *Small-*

bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications and AAMI 80369-3:2016/Amd1:2019. Contact: Colleen Elliott

AAMI CV, Cardiac Valves Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the US adoption of amendments to ISO 5840-1:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements;* ISO 5840-2:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes;* and ISO 5840-3:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques;* and the revision of ISO 5910:2018, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.* Contact: Jill Zajac

AAMI DPC-10, Needles Committee. The committee is seeking user, industry, and general interest/regulator members to contribute to the development of the U.S. positions towards the revisions of ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices* and ISO 7864:2016, S*terile hypodermic needles for single use*. Contact: Jill Zajac

AAMI EQ-WG05, HTM Education Programs Working Group. The working group 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: Mike Miskell

AAMI EV-WG05, Hospital Beds Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of IEC 80601-2-52 ED1: *Medical electrical equipment—Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*, and IEC 80601-2-89 ED1: *Medical electrical equipment—Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children.* Contact: Ladan Bulookbashi

AAMI HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed.1, *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: Chenai Maguwah

AAMI MC, Mechanical Circulatory Support Systems Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the development of documents under ISO/TC150/SC2/WG2 including the early revision of ISO 14708-5:2020, *Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices*. Contact: Jill Zajac

AAMI NS-WG03 - Transcutaneous electrical stimulator WG The working group is seeking industry, regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI NS4-2013 (R2017), *Transcutaneous electrical nerve stimulators*. Contact: Ladan Bulookbashi

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AAMI QM-WG02, General aspects from medical devices This working group is seeking user and general interest/regulatory members to participate in the national adoption of ISO 20417, *Medical devices — Information to be supplied by the manufacturer.* Contact: Amanda Benedict

AAMI RD, Renal Disease and Detoxification Committee. The committee is seeking industry, user, and general interest/regulator members to participate in the revision of the ISO 23500:2019, *Preparation and quality management of fluids for haemodialysis and related therapies series standards: Part 1: General requirements*; *Part 2: Water treatment equipment for haemodialysis applications and related therapies*; *Part 3, Water for haemodialysis and related therapies; Part 4: Concentrates for haemodialysis and related therapies; Part 5, Quality of dialysis fluids for haemodialysis and related therapies*; and the revision of the ISO 8637, *Extracorporeal systems for blood purification series standards: Part 1, Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters; and Part 3, Plasmafilters*. Contact: Jill Zajac

AAMI SM-WG03, Interoperability Working Group. The group is seeking general interest, regulatory, and users. The committee is developing a new American National Standard, *AAMI Safe Remote Control of Medical Devices*. Contact: Chenai Maguwah

AAMI SM-WG05, Medical Device Security Working Group. The group is seeking general interest, regulatory, and users to participate in the reaffirmation of AAMI TIR57, *Principles for medical device security—Risk Management* and AAMI TIR97, *Principles for medical device security—Postmarket risk management for device manufacturers.* Contact: Chenai Maguwah

AAMI SM-WG10, Cloud Computing Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of a new TIR based on the approved AAMI CR510:2021, *Appropriate use of public cloud computing for quality systems and medical devices*. Contact: Chenai Maguwah

AAMI ST-WG06, Chemical Indicators Working Group. The working group is seeking user, regulatory and general interest members to contribute to development of the U.S. positions towards the revisions of several parts of the ISO 11140 series. Contact: standards@aami.org

AAMI ST-WG13, Washer-disinfectors Working Group. The working group is seeking user, regulatory and general interest members to contribute to development of the U.S. positions towards the revisions of ISO 15883-2 and ISO 15883-3. Contact: standards@aami.org

AAMI ST-WG84, Endoscope Reprocessing Working Group. The working group is seeking regulatory and general interest members to participate in the development of AAMI TIR99/Ed.1, *Dilators, transesophageal and ultrasound probes processing in health care facilities.* Contact: standards@aami.org

AAMI ST-WG95, Water Quality for Reprocessing Medical Devices Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI ST108, *Water for the processing of medical devices*. Contact: Tommy Kim

AAMI TIB, Transfusion, Infusion, and Injection, and Blood Processing Equipment for Medical and Pharmaceutical Use Committee. The committee and its affiliated working groups are seeking user, industry, and general interest/regulator members to participate in developing the U.S. position towards documents under development in ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, and other projects. Contact: Sam Alameda

AAMI VP, Vascular Prostheses Committee. The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 25539-2:2020, *Cardiovascular implants—Endovascular devices—Part 2: Vascular stents;* the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters.* Contact: Jill Zajac

AAMI VP-WG 01, Vascular Device-drug Combination Products Committee. The committee is seeking user, industry, 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 requirement.* Contact: Jill Zajac

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 at (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.

March 2023

AAMI/TIB-WG04, Elastomeric parts, components and packaging (open meeting) 1 March 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST. Contact: Sam Alameda

AAMI/PC-WG03, Pacemaker & ICD MRI Compatibility (open meeting) 9 March 2023, 10:00h to 11:30h EST, web meeting. Contact: Ladan Bulookbashi

AAMI/ID Committee, Infusion Device (open meeting) 10 March 2023, 14:00h to 16:00h EST, web meeting. Contact: Ladan Bulookbashi

AAMI Spring 2023 Sterilization Standards Week (open meetings; hybrid – advance registration REQUIRED). 20-23 March 2023, 08:00h to 17:00h EST, Arlington, VA, and web meetings. A hotel room block is available through 2 March 2023. Contact: Sterilization Standards

U.S. TAG to ISO/TC 198 (AAMI Sterilization Standards Committee) (open meeting; hybrid – advance registration REQUIRED). 23 March 2023, 13:00h to 15:00h EST, Arlington, VA, and web meeting. A hotel room block is available through 2 March 2023. Contact: Sterilization Standards

April 2023

AAMI/TIB-WG04, Elastomeric parts, components and packaging (open meeting) 5 April 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST. Contact: Sam Alameda

AAMI HE, Human Factors Engineering (open meeting) 11 to 13 April 2023, 09:00h to 17:00h EST, Arlington, VA. Contact: Hae Choe

May 2023

AAMI/PC - Cardiac Rhythm Management Device Committee (open meeting) 18 May 2023, 10:00h to 12:30h EST, web meeting. Contact: Ladan Bulookbashi

June 2023

AAMI/AR Anaesthetic and respiratory Committee and WGs (open meeting) 21 June 2023, 16:00h to 17:00h EST, web meeting. Contact: Colleen Elliott

July 2023

AAMI Biological Evaluation Week, (open meetings; hybrid) 17 –21 July 2023, 08:00h to 17:00h EST, Arlington, VA and web meetings. Contact: Chenai Maguwah

September 2023

AAMI Fall 2023 Sterilization Standards Week (open meetings; hybrid – advanced registration REQUIRED; registration to open in July 2023). 11-14 September 2023, 08:00h to 17:00h EST, Arlington, VA, and web meetings. Contact: Sterilization Standards

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in ANSI Standards Action.

International Committee and Working Group Meetings

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

March 2023

IEC/SC 62A, 60601-1 Design Specification Team (closed meeting). London, UK, 21 – 23 March 2028, 09:00h to 17:00h daily local time. Contact: Hae Choe

May 2023

ISO/TC 121, Anaesthetic and respiratory equipment and affiliated SC and (J)WG meetings (closed meetings). London, UK, 15-19 May 2023, 09:00h to 17:00h daily local time. Contact: Colleen Elliott

October 2023

ISO/TC 194, Biological and clinical evaluation of medical devices and affiliated WG meetings (closed meetings). Arlington, US, 23-27 October 2023, 09:00h to 17:00h daily local time. Contact: Chenai Maguwah

November 2023

ISO/TC 121/SC2, Airways and related equipment and ISO/TC 121/SC6, Medical gas supply systems (closed meetings). Dublin, Ireland (tent.) 13-17 November 2023, 09:00h to 17:00h daily local time. Contact: Colleen Elliott