STANDARDS UPDATE

AAMI Standards Insider

The next AAMI Standards Insider webinar will be on **Thursday, May 18th 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 recent March 2nd session - will be available on the webpage. Check back soon!

Publications

PUBLISHED! ANSI/AAMI SW96:2023, Standard for Medical Device Security – Security Risk Management for Device Manufacturers. Click here for more information.

REAFFIRMED! AAMI TIR63:2014/(R)2023, Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection. 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 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

Comments due 1 May 2023

AAMI/ISO 80369-5, Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications (reaffirmation 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 limb cuff inflation applications of medical devices and accessories. Limb cuff inflation applications include connections between a sphygmomanometer and its cuff. Contact: Colleen Elliott

AAMI/ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications (expedited adoption of ISO 80369-7:2021). This document 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: Colleen Elliott

New Work

AAMI ST-WG02, Radiation sterilization. The working group is working on the developments of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems*. This document will provide guidance on simplified approaches for validation and routine maintenance of single-use systems sterilized by radiation. Contact: Mike Miskell.

AAMI ST-WG03, Moist heat sterilization. The working group is working on the developments of AAMI TIR116/Ed.1, *Guidance on designation of a medical product to a device product family and acceptance of a product into a product family by equivalence using moist heat sterilization*. This document will provide guidance to medical device manufacturers about how to analyze the attributes of a medical device when assigning the medical device to a product family. This includes information on how to accept a new or modified medical device into a product family by equivalence. Discussion on product families for cleaning, disinfection, sterilization and human factors testing will be included. Contact: Mike Miskell.

AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings. The working group is working on the developments of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. This document will provide healthcare personnel with guidance

on point-of-use treatment, transportation, testing (where applicable), cleaning, disinfection, sterilization, packaging, and storage of tattoo machines and accessories used in healthcare settings. Contact: Tommy Kim.

AAMI ST-WG61, Chemical Sterilants Hospital Practices. The working group is working on the developments of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. This document will provide guidance for healthcare facilities for the processing of medical devices using ultraviolet (UV) disinfection. The guidance is intended to provide comprehensive information and direction for healthcare personnel in the processing of reusable devices and accessories to render them safe for patient use. Contact: Tommy Kim.

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 BE-WG18, Attributes of medical devices relevant to biological risk assessment Working Group. AAMI is seeking industry, user, general interest, and regulatory members for the newly formed working group to provide input on ISO TC/194/WG 18 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/ISO 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*; and in the expedited adoption of AAMI/ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*. 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 Working Group. 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-WG01, Healthcare Technology Management (HTM) Program Management working group. The working group is seeking general interest, industry, and regulatory members to participate in the

revision of ANSI/AAMI EQ56:2013, Recommended practice for a medical equipment management program. Contact: Mike Miskell

AAMI EQ-WG04, Alternative Equipment Maintenance Working Group. The working group is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ103/Ed.1, *Alternative equipment maintenance in healthcare delivery organizations.* Contact: Mike Miskell

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 HF, High Frequency Therapeutic Device Committee The working group is seeking regulatory, user and general interest members to participate in the adoption project for IEC 60601-2-2:2017/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. 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 IP, Implantable Infusion Pumps Committee The working group is seeking industry, regulatory, user and general interest members to participate in the adoption project for ISO 14708-04:2022 (Ed.2), *Implants for surgery—Active implantable medical devices—Part 4: Implantable infusion pumps*. Contact: Ladan Bulookbashi

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-WG02, Implantable neurostimulator Working Group The working group is seeking regulatory, user and general interest members to participate in the reaffirmation of ANSI/AAMI/ISO 14708-3:2017,

Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators. Contact: Ladan Bulookbashi

AAMI NS-WG03, Transcutaneous electrical stimulator Working Group 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

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, SW114, *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-WG02, Radiation sterilization. The working group is seeking general interest, regulatory, and user members to contribute to development of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems*. Contact: Mike Miskell.

AAMI ST-WG03, Moist heat sterilization. The working group is seeking general interest, regulatory, and user members to contribute to development of a new TIR AAMI TIR116/Ed.1, *Guidance on designation of a medical product to a device product family and acceptance of a product into a product family by equivalence using moist heat sterilization*. Contact: Mike Miskell.

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: Tommy Kim

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, ISO 15883-3 and ISO 15883-7, and consideration of national adoptions of the revised standards. Contact: Tommy Kim

AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. Contact: Tommy Kim

AAMI ST-WG 61, Chemical Sterilants Hospital Practices Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. Contact: Tommy Kim

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: 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 Working Group. 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.

April 2023

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

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility (open meeting) 20 April 2023, 10:00h to 11:30h EST, web meeting. Contact: Ladan Bulookbashi

May 2023

AAMI ST-WG02, Radiation Sterilization Working Group (open meeting) 2 May 2023, 14:00h to 17:00h EST, web meeting. Contact: Mike Miskell

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 3 May 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 CN, Small-bore connectors committee (open meeting) 4 May 2023, 13:00h – 15:00h Eastern, web meeting. Discuss US position on ISO/DIS 80369-20, *Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods* and other committee business. Contact: Colleen Elliott

AAMI Software, Health Information Technology, and Artificial Intelligence standards committees - plenary meeting to exchange information on work programs (open meeting) 9 May 2023, 13:00h to 15:30h EST, web meeting. Contact: Chenai Maguwah

AAMI PC, Cardiac Rhythm Management Device Committee (open meeting) 18 May 2023, 10:00h to 13:00h EST, web meeting. Contact: Ladan Bulookbashi

June 2023

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 7 June 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 COVID-19 response team (open meeting), 21 June 2023, 15:00h to 16:00h Eastern, web meeting. Discuss impacts of the end of the US public health emergency and other committee business. Contact: Colleen Elliott

AAMI AR, Anaesthetic and respiratory Committee and WGs (open meeting) 21 June 2023, 16:00h to 17:00h Eastern, web meeting. Discuss outcome of ISO/TC 121 plenary and affiliated meetings and other committee business. Contact: Colleen Elliott

AAMI EQ, Medical Equipment Committee and WGs (open meeting) 19 and 20 June 2023 (Dates and Times TBC), hybrid meeting. Contact: Mike Miskell

AAMI RD, Renal Disease and Detoxification Committee. (open meeting; hybrid) Date TBD June 2023, web meeting. Contact: Jill Zajac

July 2023

AAMI BE and associated WGs - Biological Evaluation Standards 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

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

April 2023

ISO/TC 150/SC2/WG5, Renal replacement, detoxification and apheresis (closed meetings). Virtual (tent.) 17-20 April 2023, 07:00h to 11:00h EST. Contact: Jill Zajac

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

ISO/TC 150/SC6/JWG1 (Joint with IEC/SC 62D WG), Cardiac pacemakers and implantable defibrillators (closed meetings). 18 May 2023, 14:00h to 17:00h EST, web meeting. Contact: Ladan Bulookbashi

September 2023

IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings (closed meetings). Seoul, Korea, 11-22 September 2023, 09:00h to 17:00h daily local time. Contact: Hae Choe

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