

## STANDARDS UPDATE

### AAMI Standards Insider

The next [AAMI Standards Insider](#) webinar will be on **Thursday, June 1<sup>st</sup> 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 2<sup>nd</sup> session - will be available on the webpage. Check back soon!

### Publications

**REAFFIRMED! AAMI TIR57:2016/(R)2023** *Principles for medical device security—Risk management*. Click [here](#) for more information.

**REAFFIRMED! AAMI TIR97:2019/(R)2023** *Principles for medical device security—Postmarket risk management for device manufacturers*. 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 1 May 2023*

**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). 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](#)

## ***Comments due 18 June 2023 (public review opening 4 May 2023)***

**AAMI EQ56, Standard for a medical equipment management program** (revision of an American National Standard). Specifies characteristics of a management program designed to support the safe and effective use of medical equipment used in an HDO. The document addresses the structure of such a program, the documentation that must be produced by the program, program staffing, and resources that should be allocated to those responsible for maintaining medical equipment. Definitions of terms and normative references are also included, as are notes and rationale that expand the provisions of the document. Contact: [Michael Miskell](#)

## **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 development 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 Standards Monitor Online

28 April 2023

**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, *Sterile 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*

# AAMI Standards Monitor Online

28 April 2023

*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*

## AAMI Standards Monitor Online

28 April 2023

*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 Standards Monitor Online

28 April 2023

**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 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](http://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](mailto: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.*

### **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 Standards Monitor Online

28 April 2023

**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 1<sup>st</sup> 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 ST-WG86, Quality systems for device processing Working Group** (open meeting) 4 May 2023, 14:00h to 15:00H Eastern, web meeting, Discuss reaffirmation ballot results and comments for ST90, *Processing of health care products—Quality management systems for processing in health care facilities*. Contact: [Tommy Kim](#)

**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](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group** (open meeting) 25 May 2023, 10:00h to 11:30h EST, web meeting. Contact: [Ladan Bulookbashi](#)

**AAMI CP, Combination Products committee** (open meeting) Date TBD May 2023, web meeting. Contact: [Jill Zajac](#)

## **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 1<sup>st</sup> Wednesday of every month, from 10:00h to 11:00h EST. Contact: [Sam Alameda](#)

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

**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 Standards Monitor Online

28 April 2023

**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) 18 –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.*

#### **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/TC150/SC2/WG 5, Renal replacement, detoxification and apheresis** (closed meetings). 15-17 May 2023, 8:00h to 12:00h EST, web meeting. Contact [Jill Zajac](#)

**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](#)

# AAMI Standards Monitor Online

28 April 2023

***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](#)