

## STANDARDS UPDATE

### ➤ **Reaccreditation of AAMI under Revised Operating Procedures**

The Association for the Advancement of Medical Instrumentation (AAMI) is pleased to announce that it was reaccredited as an ANSI Accredited Standards Developing Organization (SDO) on July 24, 2024. This is a result of the recent audit performed on AAMI's standards operations. All ANSI accredited SDOs are required to undergo an audit and reaccreditation every five years. AAMI's next audit will be in 2029.

Accreditation by ANSI signifies that AAMI's voluntary consensus development standards procedures meet ANSI's requirements for openness and due process. Accreditation by ANSI is a prerequisite for a SDO to submit documents for approval as American National Standards (ANS).



### ➤ **Call for Abstracts for Sessions and Posters for the 2025 KILMER Conference**

The Association for the Advancement of Medical Instrumentation (AAMI) and the Parenteral Drug Association (PDA) are pleased to announce the call for abstracts for sessions and posters for the 2025 KILMER Conference, which will be held from 3 to 6 February 2025 in Orlando, Florida, USA.

The theme for the **2025 KILMER Conference** is ***Next Generation Microbiological Quality and Sterility Assurance***. We are seeking submissions broadly reflecting this theme and addressing topics related to industry ***innovations*** in sterilization, sterility assurance, and microbiological quality for medical devices and pharmaceuticals, including but not limited to the following areas:

- Emerging technologies or approaches for cleaning, disinfection and sterilization
- Microbiological quality control, aseptic and sterilization process validation and monitoring
- Microbiological or alternative testing methods
- Sterilization processes and modalities
- Pathways to facilitate or innovate regulatory approvals
- Quality control and assurance
- Materials compatibility
- Device and drug product packaging innovation
- Application of process control or parametric approaches
- Successes in industry-academia research partnerships
- Industry approaches and innovations for infection prevention and contamination control in clinical settings

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- Sustainability
- Leveraging pandemic or outbreak learnings (e.g., supply chain, etc.)
- Career development

Abstracts should be submitted [HERE](#) by 31 August 2024. Accepted proposals will be notified by 1 October 2024. Note that most sessions will be between 15-20 minutes, single presenter preferred. Proposals not accepted for a session may still be considered for a poster presentation.

We encourage all interested parties to submit their abstracts for consideration.

Questions may be directed to Amanda Benedict at [abenedict@aami.org](mailto:abenedict@aami.org).

## AAMI Standards Insider

AAMI's Standards Insider has been revamped. Please view our bimonthly video snippets for news and updates about AAMI's standards program and portfolio [here](#). If there are any topics that you would like the Standards team to address, please reach out to [Standards@aami.org](mailto:Standards@aami.org).

## AAMI Standards Management Platform (StMP)

Looking for training on **AAMI Standards Management Platform (StMP)**? Information is available [here](#).

## Publications

**PUBLISHED! ANSI/AAMI/ISO 13408-1:2023**; Aseptic processing of health care products—Part 1: General requirements. Click [here](#) for more information.

**PUBLISHED! ANSI/AAMI/ISO 20417:2021**; Medical devices—Information to be supplied by the manufacturer. Click [here](#) for more information.

**PUBLISHED! AAMI CR513:2024**; Guidance on radiation sterilization validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing. Click [here](#) for more information.

**PUBLISHED! ANSI/AAMI ST24:2024**; General-Purpose Ethylene Oxide Sterilizers With Automated Process Control And Ethylene Oxide Sterilant Sources Intended For Use In Health Care Facilities. Click [here](#) for more information.

**PUBLISHED!** **ANSI/AAMI/ISO 11607-1:2019/A1:2023**, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management

**PUBLISHED!** **ANSI/AAMI/ISO 11607-2:2019/A1:2023**, Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management

## 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 September 2024*

**AAMI/ISO 8637-1:202x, Extracorporeal systems for blood purification Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators** (identical national adoption of ISO 8637-1:2024 Ed 2.) Contact: [Jill Zajac](#)

**AAMI/ISO 8637-2:202x, Extracorporeal systems for blood purification Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators** (identical national adoption of ISO 8637-2:2024 Ed 2.) Contact: [Jill Zajac](#)

**AAMI/ISO 8637-3:202X, Extracorporeal systems for blood purification Part 3: Plasmafilters** (identical national adoption of ISO 8637-3:2024 Ed 2.) Contact: [Jill Zajac](#)

**AAMI EQ93, Medical equipment management - Vocabulary used in medical equipment programs** (reaffirmation of an American National Standard). This standard provides consensus definitions for key terms used in medical equipment management around the maintenance, repair and servicing of

medical devices, so that all stakeholders involved in the regulation, management and use of medical devices have common understanding when they are used. Contact: [Mike Miskell](#)

## New Work

*Initiation of the following New Work Items have been approved and added to AAMI's standards work program in the past three months. Directly and materially interested parties wishing to receive more information or to submit comments are to contact the individual indicated by email.*

**AAMI PC-WG01, Transvenous Cardiac Leads Working Group.** The Working Group is developing the following two new AAMI Standards (Contact: [Mike Miskell](#)):

- **AAMI PC86; Requirements for Fatigue Performance of Cardiac Rhythm Management Leads.** This standard outlines requirements for characterizing the fatigue performance of cardiac leads based on benchtop fatigue testing and bending stiffness measurements, focusing on conductor integrity. It excludes polymer and elastomeric components, bonds, biodegradation, and corrosion. Methods are provided for measuring lead bending stiffness and fatigue strength in different regions, for preconditioning leads, and for accepting fatigue performance through comparison with proven designs or using a Bayesian model to predict survival rates based on lead stiffness.
- **AAMI PC125; Implantable leads—Perforation propensity—Requirements and test methods.** This standard establishes a method to assess the perforation propensity of permanently implantable cardiac pacing and defibrillation leads for transvenous use in the right atrium or ventricle, excluding preformed “J”-shaped and left bundle branch area pacing leads. It focuses on the acute phase post-implantation, prior to fibrotic encapsulation, and does not address all aspects of perforation propensity, such as implant technique or patient-specific factors. The methods and criteria are based on conventional leads and may not apply to novel designs or unique clinical applications.

**AAMI RD, Renal Disease and Detoxification Committee.** The committee will be developing a new AAMI Technical Information Report (TIR123); *User Considerations - Design of Activated Carbon Systems with Non-Continuous Flow – Empty-Bed Contact Time (EBCT) Calculation*. This TIR provides guidance for how the non-continuous flow of fluids impacts the calculation of EBCT and addresses other considerations when working with filters in this type of system. EBCT is a calculated value which assumes continuous flow through the carbon bed. This TIR will provide guidance on the application of ISO 23500 and educate users in clinics. Contact: [Jill Zajac](#)

**AAMI ST-WG11, General Criteria for Sterilization Processes and Sterilizing Equipment Working Group.** This Working Group will be developing a series of AAMI Technical Information Reports (AAMI TIR124-X); *Guidance on transferring health care products between gas or vapor sterilization modalities*. These series

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provide guidance on alignment of various gas and vapor sterilization modalities with ISO 14937 and other relevant standards for industrial sterilization (not health care; not decontamination) where there is a gap in guidance relative to the validation, routine control, biological indicators and sterilant residuals for the modality. Examples of such modalities can be found in AAMI TIR17. Each part of this series will focus on a specific modality. Contact: [Gigi Golriz](#).

### **AAMI ST-WG61, Chemical Sterilants Hospital Practices Working Group.**

The Working Group will be developing a new AAMI Technical Information Report (AAMI TIR121); *Guidance on cleaning and disinfection of patient care equipment in patient care areas to render safe for handling and next patient use*. This TIR provides guidance to health care personnel who perform cleaning and low-level and intermediate level disinfection of patient care equipment outside of the sterile processing area. Excludes devices and materiel addressed by ANSI/AAMI ST79 and ANSI/AAMI ST91 and environmental surfaces. Contact: [Tommy Kim](#)

**AAMI ST-WG96, Compatibility of Materials Subject to Sterilization Working Group.** The Working Group will be developing a new AAMI Technical Information Report (AAMI TIR122); *Considerations for Material Retention of Sterilant Residuals in Ethylene Oxide Sterilization*. This TIR provides: fundamental background on factors that may affect sterilant residual retention by device materials; data showing relative retention of sterilant residuals retained by various materials after processing in ethylene oxide; guidelines on how to address the impact of medical device material selection or material changes on the potential for sterilant residual retention; and provides data on the impact of cycle attributes and aeration conditions (e.g. temperature, vacuum changes, etc.) on retained EO residuals. It will clarify differences in the effects of EO retention by materials between occupational or environmental EO exposure and exposure to patients through sterilized devices. Contact: [Gigi Golriz](#).

## Project Initiation Notice

*The following projects have been initiated by AAMI in the past three months. Directly and materially interested parties wishing to receive more information or to submit comments are to contact the individual indicated by email.*

**REVISION! AAMI TIR12:202x**, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers. Contact: [Gigi Golriz](#).

**AMENDMENT! AAMI ST91:2021**, Flexible And Semi-Rigid Endoscope Processing In Health Care Facilities. Contact: [Tommy Kim](#)

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**ADOPTION!** **AAMI/ISO 8637-1:202x**, Extracorporeal systems for blood purification Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (identical national adoption of ISO 8637-1:2024 Ed 2.)

**ADOPTION!** **AAMI/ISO 8637-2:202x**, Extracorporeal systems for blood purification Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (identical national adoption of ISO 8637-2:2024 Ed 2.) Contact: [Jill Zajac](#)

**ADOPTION!** **AAMI/ISO 8637-3:202X**, Extracorporeal systems for blood purification Part 3: Plasmafilters (identical national adoption of ISO 8637-3:2024 Ed 2.) Contact: [Jill Zajac](#)

## **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:

**Industry:** *A member of a consensus body who, as an individual or organizational representative, is 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 shall be classified as an Industry Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

**User:** *A member of a consensus body who, as an individual or organizational representative, 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 shall be classified as a User Interest stakeholder. Individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

**Regulatory:** *A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.*

**General interest:** *A member of a consensus body who, as an individual or organizational representative, has a general direct and 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 shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

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**Other Interest:** *A member who does not fit into any of the preceding interest categories but who still has an identifiable material interest in, or specialized knowledge of the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as an Other Interest stakeholder. The particular interest shall be declared and documented.*

Please contact the staff person indicated for more information on how to join.

**AAMI BE-WG02, Degradation aspects related to biological testing Working Group.** AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-9:2019, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO/TS 37137-1:2021, *Biological evaluation of absorbable medical devices — Part 1: General requirements* Contact: [Rose Kodzwa](#)

**AAMI BE-WG08, Irritation and sensitization Working Group.** AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-10:2021, *Biological evaluation of medical devices — Part 10.* Contact: [Rose Kodzwa](#)

**AAMI BE-WG11, Allowable limits for leachable substances Working Group.** AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-17:2023, *Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents.* Contact: [Rose Kodzwa](#)

**AAMI BE-WG12, Sample preparation and reference materials Working Group.** AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-12:2021, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.* Contact: [Rose Kodzwa](#)

**AAMI BE-WG19, Tissue Product Safety Working Group.** AAMI is seeking industry, user, regulatory, and general interest members for the newly formed working group to provide input on ISO TC/194/WG 19 activities. Contact: [Rose Kodzwa](#)

**AAMI BG, Blood/Gas Exchange Device Committee.** The committee is seeking industry, user, regulatory, and general interest members to participate in the revision of ISO 7199, *Cardiovascular implants and artificial organs — Blood-gas exchangers* and to provide input on ISO TC150/SC2/WG4 activities 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*



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*implant systems—Requirements for safety, functional verification, labeling and reliability reporting.*

Contact: [Mike Miskell](#)

**AAMI CP, Combination Products Committee.** The committee is seeking user, regulatory, and general interest/regulator members to contribute to the development and review of various TIRs Contact: [Jill Zajac](#)

**AAMI CV, Cardiac Valves Committee.** The committee is seeking user, regulatory, and general interest members to participate in user input on the US position 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 US adoption of AAMI/ISO 5910: 2024, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices*. Contact: [Jill Zajac](#)

**AAMI DP, Medical Device Particulates Committee** is seeking additional members in user, industry, regulatory and general interest categories to participate in review and reaffirmation of AAMI TIR42:2021; *Evaluation of particulate associated with vascular medical 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: [Sam Alameda](#)

**AAMI EQ-WG01, HTM Program Management Working Group.** The working group is seeking regulatory and general interest members to participate in the revision of AAMI EQ89:2015/Ed. 1, *Guidance for the use of medical equipment maintenance strategies and procedures*. Contact: [Mike Miskell](#)

**AAMI EQ-WG02, Servicing Vocabulary Working Group.** The working group is seeking regulatory and general interest members to participate in the reaffirmation of AAMI EQ93:2019/Ed. 1, *Medical equipment management - Vocabulary used in medical equipment programs*. Contact: [Mike Miskell](#)

**AAMI EQ-WG03, Technology Acquisition Working Group.** The working group is seeking regulatory and general interest members to participate in the development of AAMI EQ94:202X/Ed. 1, *Healthcare technology acquisition*. Contact: [Mike Miskell](#)

**AAMI EV-WG13, Lens Removal and Vitrectomy Devices Working Group.** The working group is seeking additional members from regulatory, user and general interest categories to participate in the identical adoption project for IEC 80501-2-58:2024, *Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*. Contact: [Ladan Bulookbashi](#)



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**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-WG01, Health IT Risk Management Working Group.** The working group is seeking user, general interest, and regulatory members to participate in the development of AAMI HIT1000-3/Ed.1, *Safety and effectiveness of health IT software and systems—Part 3: Application of risk management*.

Contact: [Amir Aboutaleb](#) or [Matt Williams](#)

**AAMI HIT-WG02, Health IT Quality Systems Working Group.** The working group is seeking 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: [Amir Aboutaleb](#) or [Matt Williams](#)

Contact: [Amir Aboutaleb](#) or [Matt Williams](#)

**AAMI HIT-WG03, Health IT Usability Working Group.** The working group is seeking user, general interest, and regulatory members to participate in the development of AAMI HIT1000-4/Ed.1, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering*.

Contact: [Amir Aboutaleb](#) or [Matt Williams](#)

**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:

[Mike Miskell](#)

**AAMI MC, Mechanical Circulatory Support Systems Committee.** The committee is seeking user and general interest/regulatory members to participate in the development of documents under ISO/TC150/SC2/WG2 including the 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: [Mike Miskell](#)

**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](#)

Contact: [Ladan Bulookbashi](#)

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**AAMI PC-WG01, Transvenous Cardiac Leads Working Group.** This working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of two new AAMI standards: AAMI PC86; *Requirements for Fatigue Performance of Cardiac Rhythm Management Leads*; and AAMI PC125; *Implantable leads—Perforation propensity—Requirements and test methods*. Contact: [Mike Miskell](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility** This working group is seeking user, regulatory, general interest members to participate in the project to develop the first amendment to ANSI/AAMI PC76:2021, *Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging*. Contact: [Mike Miskell](#)

**AAMI RB, Robotics Committee.** This committee is seeking additional members from regulatory, user and general interest categories to participate in the identical adoption projects for IEC 80601-2-77:2019/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment*, and IEC 80601-2-78:2019/AMD1:2024, *Amendment 1 - Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation*. Contact: [Ladan Bulookbashi](#)

**AAMI RD, Renal Disease and Detoxification Committee.** The committee is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in the development of a new Technical Information Report on *User Considerations - Design of Activated Carbon Systems with Non-Continuous Flow – Empty-Bed Contact Time (EBCT) Calculation*, and identical adoption of the ISO 23500-1 through -5:2024, *Preparation and quality management of fluids for haemodialysis and related therapies series standards* and identical adoption of ISO 8637-1 through -3, *Extracorporeal systems for blood purification series standards*. 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 SW114 - *Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. Contact: [Rose Kodzwa](#)

**AAMI SM-WG05, Medical Device Security Working Group.** The group is seeking general interest, regulatory, and users to participate in the revisions of AAMI TIR57:2016/(R)2023, *Principles for medical device security—Risk Management* and a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices*. Contact: [Rose Kodzwa](#)

**AAMI SM-WG06, Wireless Working Group.** The group is seeking general interest, regulatory, and users to participate in the reaffirmation of AAMI TIR69:2017/(R)2020 – *Risk management of radio-frequency wireless coexistence for medical devices and systems*. Contact: [Rose Kodzwa](#)

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**AAMI SM-WG08, Software Defect Classification Working Group.** The group is seeking general interest, regulatory, and users to participate in the reaffirmation of ANSI/AAMI SW91:2018 – *Classification of defects in health software*. Contact: [Rose Kodzwa](#)

**AAMI SM-WG10, Cloud Computing Working Group.** The group is seeking user, general interest, and regulatory members to participate in the development of a new TIR, AAMI TIR115: *Cloud – Guidance for the appropriate use of public cloud computing to enable medical device functions*. Contact: [Rose Kodzwa](#)

**AAMI SP, Sphygmomanometer Committee** The committee is seeking regulatory, and general interest members to participate in the identical adoption project for ISO 81060-3:2022/Ed.1, *Non-invasive sphygmomanometers – Part 3: Clinical investigation of continuous automated measurement type*. Contact: [Ladan Bulookbashi](#)

**AAMI ST-WG07 – Packaging working group.** The working group is seeking general interest, regulatory, and user members to participate in the reaffirmations of ANSI/AAMI/ISO 11607-1:2019, Ed.2, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems* and AAMI/ISO 11607-2:2019, Ed.2, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes*. Contact: [Gigi Golriz](#).

**AAMI ST-WG08 – Microbiological methods working group.** The working group is seeking general interest, regulatory, and user members to participate in the development of AAMI TIR52/Ed.2, *Environmental monitoring for terminally sterilized healthcare products* and the reaffirmations of AAMI/ISO 11737-1, *Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products* and AAMI/ISO TIR22456:2022, Ed.1, *Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products*. Contact: [Gigi Golriz](#).

**AAMI ST-WG11, General Criteria for Sterilization Processes and Sterilizing Equipment Working Group.** This working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of a new series of Technical Information Reports (AAMI TIR124-X); *Guidance on transferring health care products between gas or vapor sterilization modalities*. Contact: [Gigi Golriz](#).

**AAMI ST-WG42 - Dry heat sterilization.** The working group is seeking general interest, regulatory, and user members to contribute to participate in the reaffirmation of ANSI/AAMI ST40:2004/(R)2018, Ed. 2, *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*. Contact: [Gigi Golriz](#).

**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

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development of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. Contact: [Tommy Kim](#)

**AAMI ST-WG61, Chemical Sterilants Hospital Practices Working Group.** This working group is specifically looking for additional members to represent general, and regulatory interest categories to participate in development of a new Technical Information Report (AAMI TIR121); *Guidance on cleaning and disinfection of patient care equipment in patient care areas to render safe for handling and next patient use*. Contact: [Tommy Kim](#)

**AAMI ST-WG86, Quality System for Device Processing Working Group.** The group is seeking general interest and regulatory/government members to participate in the amendment of AAMI ST90, *Processing of health care products—Quality management systems for processing in health care facilities*. Contact: [Tommy Kim](#)

**AAMI ST-WG94, Rigid sterilization container systems working group.** The working group is seeking general interest, regulatory, and user members to participate in the revision of ANSI/AAMI ST77:2013/(R)2018, Ed.2, *Containment devices for reusable medical device sterilization*. Contact: [Gigi Golriz](#).

**AAMI ST-WG96, Compatibility of Materials Subject to Sterilization Working Group.** This working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of a new Technical Information Report (AAMI TIR122); *Considerations for Material Retention of Sterilant Residuals in Ethylene Oxide Sterilization*. Contact: [Gigi Golriz](#).

**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 and general interest 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 VI, Cardiovascular Absorbable Implants Committee.** The committee is seeking additional members in user, industry, regulatory and general interest categories to participate in the development of the U.S. position towards documents under ISO/TC150/SC2/WG7 including the systematic review of ISO/TS 17137:2021, *Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants* Contact: [Jill Zajac](#)

**AAMI VP, Vascular Prostheses Committee.** The committee is specifically seeking user, industry, and general interest/regulator members to participate in the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters* the revision of ISO 7198 Cardiovascular

implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches 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 ([Standards Monitor Online](#)). Note: If you plan to attend a meeting, please reach out to the committee staff liaison listed below or contact the AAMI Standards Department at ([standards@aami.org](mailto:standards@aami.org)) indicating the name and date of the meeting.*

### **August 2024**

**US TAG to ISO/TC 150/SC 6, Active Implants** (open meeting) 28 August and 3 September 2024 (if needed), 14:00h to 17:00h EST and 13:00h to 16:00h EST, respectively, web meeting. The US TAG will discuss and propose the US position and comments to forward from ballot results to ISO/CD 14708-1, Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer, as well as determine the US consensus positions on the upcoming ISO/TC 150/SC 6 plenary agenda items. Contact: [Mike Miskell](#)

### **September 2024**

**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 4 September 2024, 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, to discuss CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI SP, Sphygmomanometer committee** (open meeting) 16 September 2024, 11:00h to 12:30h EST, web meeting. The committee will discuss ISO/TC 121/SC 3/JWG 7 related activities. Contact: [Ladan Bulookbashi](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 19 September 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: [Mike Miskell](#)

### **October 2024**

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**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 2 October 2024, 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, to discuss CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI PC/CRMD, Cardiac Rhythm Management Devices Committee** (open meeting) October /November 2024 (Dates and Times TBC), Arlington, VA/hybrid web meeting. Contact: [Mike Miskell](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 17 October 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: [Mike Miskell](#)

**AAMI RD, Renal Disease and Detoxification Committee** (open meeting) San Diego, CA. 28 October 2024 9h to 16:30h EST, The committee will discuss comments on the working draft of the new Technical Information Report on *User Considerations - Design of Activated Carbon Systems with Non-Continuous Flow – Empty-Bed Contact Time (EBCT) Calculation* and review reaffirmation ballot results Contact: [Jill Zajac](#)

### **November 2024**

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 21 November 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: [Mike Miskell](#)

## **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.

### **September 2024**

**ISO/TC 150, Implants for surgery and affiliated SC (including SC2 and SC6) and WG meetings** (closed meetings). Berlin, DE, September 9-13, 2024, 09:00h to 17:00h daily local time. Contact: [Jill Zajac](#) or [Mike Miskell](#)

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## ***October 2024***

**IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings.** London, UK, 14-18 and Edinburgh, Scotland, 21-25 October 2024, 09:00h to 17:00h daily local time. Contact: [Colleen Elliott](#) or [Ladan Bulookbashi](#)

## ***November 2024***

**ISO/TC 121/SC6, Medical gas supply systems** (closed meetings). Vienna, Austria, November 18-22. Contact: [Colleen Elliott](#). (**NOTE:** ISO/TC 121/SC meetings postponed until February 2025)