

## STANDARDS UPDATE

**NEW!** We have completed transitioning our standards groups to the **NEW AAMI Standards Management Platform (StMP)**. Information is available [here](#).

### Join us

The inaugural **AAMI neXus: A Global Event Advancing Medical Device Standards Development, Adoption, and Application** February 20-23, 2024, in Washington, DC! If you are actively involved or want to be involved in the development and adoption of medical device standards as a manufacturer, regulator, or healthcare professional, AAMI neXus will offer you unparalleled engagement opportunities and information. At **AAMI neXus** you will hear directly from and interact with the industry and regulatory leaders who are driving both **Development** and **Adoption** of existing standards, as well as planning future standards works. This is your chance to get involved and help shape the future of medical device standards!

### 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).

### Publications

**PUBLISHED! AAMI TIR16:2023**, Microbiological Aspects of Ethylene Oxide Sterilization. Click [here](#) for more information.

**PUBLISHED! AAMI/ISO TIR10993-19:2020**; Biological evaluation of medical devices—Part 19: Physico-chemical, morphological and topographical characterization of materials. Click [here](#) for more information.

**REAFFIRMED! AAMI TIR12:2020/(R)2023**, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers. Click [here](#) for more information.

**REAFFIRMED! AAMI/ISO TIR11137-4:2022/(R)2023**, Sterilization of health care products—Radiation—Part 4: Guidance on process control. Click [here](#) for more information.

**REAFFIRMED! AAMI/ISO TIR10993-20:2006/(R)2021**, Biological Evaluation Of Medical Devices — Part 20: Principles And Methods For Immunotoxicology Testing Of Medical Devices. 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 18 February 2024*

**AAMI TIR66/Ed.1 - Guidance for the creation of physiologic waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms.** (reaffirmation of an American National Standard). This document provides guidance to MANUFACTURERS that change existing or create new ALARM SYSTEM algorithms as to how to create evidence that demonstrates a reasonable assurance of the safety and efficacy of the algorithm. This document also provides guidance to authorities having jurisdiction for the assessment of such evidence. Contact: [Rachel Ann Porter](#)

### *Comments due 19 February 2024*

**AAMI/ISO 10993-17:202X/Ed.2, Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents** (identical national adoption of ISO 10993-17:2023) This document specifies the process and requirements for the toxicological risk assessment of medical device constituents. The methods and criteria used to assess whether exposure to a constituent is without appreciable harm are also specified. The toxicological risk assessment can be part of the biological evaluation of the final product, as described in ISO 10993-1. The process described in this document applies to chemical characterization information obtained in line with ISO 10993-18. When a toxicological risk assessment of either the compositional information or analytical chemistry data (e.g. extractable data or leachable data) are required to determine whether the toxicological risks related to the constituents are negligible or tolerable. Contact: [Amir Aboutaleb](#) or [Matt Williams](#)

**AAMI/ISO 11737-1, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products** (reaffirmation of an American National Standard). This document specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package. Contact: [Mike Miskell](#)

### *Comments due 11 March 2024*

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**AAMI ST24, General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities** (revision of an American National Standard). Covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems. Contact: [Tommy Kim](#)

**AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities** (revision of an American National Standard) This standard provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use in hospitals and other health care facilities. These guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment. Contact: [Tommy Kim](#)

### **Comments due 1 April 2024**

**AAMI/ISO 11607-1, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems** (reaffirmation of an American National Standard). This document specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use. It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized. Contact: [Mike Miskell](#)

**AAMI/ISO 11607-2, Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes** (reaffirmation of an American National Standard). This document specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems. It is applicable to industry, to health care facilities, and to wherever medical devices are packaged and sterilized. Contact: [Mike Miskell](#)

**AAMI/ISO TIR22456, Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products** (reaffirmation of an American National Standard). This document provides guidance for bioburden testing and tests of sterility for biologics and tissue-based products, where this testing is in relation to product sterilization. It is intended to be used in conjunction with ISO 11737-1 and ISO 11737-2.

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Guidance in this document can be applicable to biologics and tissue-based products that are not sterile but are microbiologically controlled. Contact: [Mike Miskell](#)

**AAMI ST77, Containment devices for reusable medical device sterilization** (revision of an American National Standard). This document applies to containment devices intended for use in sterilizing reusable medical devices in health care facilities. It applies to containment devices intended for use in sterilizing reusable medical devices in health care facilities. This standard covers the design, performance, and labeling criteria for reusable rigid sterilization containers and instrument organizers intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. Definitions of terms, normative references, and informative annexes are also included, as well as the rationale and relevant test methods for the provisions of the standard. Contact: [Mike Miskell](#)

### New Work

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

**AAMI SM-WG05, Medical Device Security Working Group.** The working group is developing a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices*. This consensus report will provide guidance for security risk estimation within the context defined by ANSI/AAMI SW96: 2023 *Standard for medical device security—Security risk management for device manufacturers*. Contact: [Amir Aboutaleb](#) or [Matt Williams](#).

### Project Initiation Notice

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

**AMENDMENT! AAMI PC76:2021/A1:202X**, Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging (Addenda to ANSI/AAMI PC76:2021). Contact: [Mike Miskell](#)

**ADOPTION! ANSI/AAMI/ISO 23500-1:202X**, Preparation and quality management of fluids for haemodialysis and related therapies Part 1: General requirements. (identical national adoption of ISO 23500-1:2024) Contact: [Jill Zajac](#)

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**ADOPTION!** ANSI/AAMI/ISO 23500-2:202X, Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies (identical national adoption of ISO 23500-2:2024) Contact: [Jill Zajac](#)

**ADOPTION!** ANSI/AAMI/ISO 23500-3:202X, Preparation and quality management of fluids for haemodialysis and related therapies Part 3: Water for haemodialysis and related therapies (identical national adoption of ISO 23500-3:2024) Contact: [Jill Zajac](#)

**ADOPTION!** ANSI/AAMI/ISO 23500-4:202X, Preparation and quality management of fluids for haemodialysis and related therapies Part 4: Concentrates for haemodialysis and related therapies (identical national adoption of ISO 23500-4:2024) Contact: [Jill Zajac](#)

**ADOPTION!** ANSI/AAMI/ISO 23500-5:202X, Preparation and quality management of fluids for haemodialysis and related therapies Part 5: Quality of dialysis fluid for haemodialysis and related therapies (identical national adoption of ISO 23500-5:2024) 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*

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*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.*

**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 AI, Artificial Intelligence Committee.** AAMI is seeking user, regulatory, and general interest members to participate in the development of a new standard, AAMI AI120 – *Bias Management for Machine Learning (ML) Systems*. Contact: [Rachel Porter](#)

**AAMI BE-WG2, 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: [Amir Aboutaleb](#) or [Matt Williams](#)

**AAMI BE-WG8, 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: [Amir Aboutaleb](#) or [Matt Williams](#)

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

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

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

**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*

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*artificial organs — Blood-gas exchangers* *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 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 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 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: [Sam Alameda](#)

**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](#)



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**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 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](#)

**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: [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,



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*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 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 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 user, and general interest/regulator members to participate in the development of new TIRs including backflow prevention, wall boxes, and water distribution loops; a TIR on empty bed contact time calculation and carbon sizing, and input on the adoption of the ISO 23500-1 through -5:2024, *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 SW114 - *Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. Contact: [Amir Aboutaleb](#) or [Matt Williams](#)

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

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

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

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

**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-WG02, Radiation sterilization working group.** 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*, reaffirmation of ANSI/AAMI/ISO 11137-2:2013/(R)2019, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*. Contact: [Mike Miskell](#).

**AAMI ST-WG03, Industrial moist heat sterilization working group.** The working group is seeking general interest, regulatory, and user members to participate in the adoption project for ISO 17665:202X (Ed.2), *Sterilization of health care products—Moist heat—Requirements for the development, validation and routine control of a sterilization process for medical devices*. Contact: [Mike Miskell](#).

**AAMI ST-WG04, Biological indicators working group.** The working group is seeking general interest, regulatory, and user members for the reaffirmation of AAMI/ISO 11138-3, *Sterilization of health care products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes*, AAMI/ISO 11138-4, *Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes*, AAMI/ISO 11138-5, *Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*. Contact: [Tommy Kim](#).

**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*

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*devices—Part 2: Validation requirements for forming, sealing and assembly processes.* Contact: [Mike Miskell](#).

**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: [Mike Miskell](#).

**AAMI ST-WG16 - Vaporized Hydrogen Peroxide Sterilization working group.** The working group is seeking general interest, regulatory, and user members to participate in the national adoption of ISO 22441:2022, Ed. 1, *Sterilization of health care products -- Low temperature vaporized hydrogen peroxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.* Contact: [Mike Miskell](#).

**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* and ANSI/AAMI ST50:2004/(R)2018, Ed. 2, *Dry heat (heated air) sterilizers.* Contact: [Mike Miskell](#).

**AAMI ST-WG43, Hospital steam sterilizer Working Group.** The group is seeking user, general interest, and regulatory members to participate in the development of AAMI ST8/Ed.7, *Hospital steam sterilizers.* Contact: [Mike Miskell](#).

**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-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-WG91, Resistometer Working Group.** The group is seeking user, general interest, and regulatory/government members to participate in the reaffirmation of AAMI/ISO 18472:2018, *Sterilization of health care products—Biological and chemical indicators—Test equipment.* 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

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ST77:2013/(R)2018, Ed.2, *Containment devices for reusable medical device sterilization*. Contact: [Mike Miskell](#).

**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* 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 ([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.*

### **February 2024**

**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 21 February 2024, 10:00h to 11:00h EST, web meeting to discuss/develop CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI EQ-WG01, HTM Program Management Working Group** (open meeting) 26 February 2024, 14:00h to 16:00h EST, web meeting. The WG will resolve comments on the revision of AAMI EQ56:2013, *Recommended practice for a medical equipment management program*. Contact: [Mike Miskell](#)

### **March 2024**

**AAMI EQ-WG01, HTM Program Management Working Group** (open meeting) 4 March 2024, 14:00h to 16:00h EST, web meeting. The WG will resolve comments on the revision of AAMI EQ56:2013, *Recommended practice for a medical equipment management program*. Contact: [Mike Miskell](#)

# AAMI Standards Monitor Online

## 16 February 2024

**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 6 March 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 EQ, Medical Equipment Management Committee** (open meeting) 11 March 2024, 14:00h to 16:00h EST, web meeting. The committee will review AAMI EQ Working Groups' recent activity and discussed plans for upcoming document revisions. Contact: [Mike Miskell](#)

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

### **April 2024**

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 18 April 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: [Mike Miskell](#)

### **May 2024**

**AAMI PC, Cardiac Rhythm Management Device Committee** (open meeting; hybrid) 16 May 2024, 9:00h to 15:00h EST, Boston, MA. 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.*

### **March 2024**

**ISO/TC 210/JWG 1, Application of risk management to medical devices** (closed meetings). Arlington, Virginia, USA, 6-8 March 2024, 09:00h to 17:00h daily local time. Contact: [standards@aami.org](mailto:standards@aami.org)

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### ***April 2024***

**IEC/SC 62D/MT 23, Infusion pumps** (closed meeting). Arlington, Virginia, USA, April 22-26, 09:00h to 17:00h daily local time. Contact: [Ladan Bulookbashi](#)

**ISO/TC 150/SC 6/WG 1, Fundamental standards** (closed meeting). Arlington, Virginia, USA, April 23 and 24, 09:00h to 17:00h daily local time. Contact: [Ladan Bulookbashi](#)

**ISO/TC 150/SC 6/JWG 1, Cardiac pacemakers and implantable defibrillators** (closed meeting). Arlington, Virginia, USA, April 25 and 26, 09:00h to 17:00h daily local time. Contact: [Ladan Bulookbashi](#)

**IEC/SC 62A, Common aspects of medical equipment, software, and systems, and affiliated WGs** (closed meetings). Arlington, Virginia, USA, April 24 – May 3, 09:00h to 17:00h daily local time. Contact: [Colleen Elliott](#).

### ***May 2024***

**ISO/TC 121, Anaesthetic and respiratory equipment, and affiliated SCs and (J)WGs** (closed meetings). Luebeck, Germany, May 13 – 17, 09:00h to 17:00h daily local time. Contact: [Colleen Elliott](#).

### ***October 2024***

**IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings** (closed 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](#)