STANDARDS UPDATE

AAMI BE Week, Biological Evaluation Committee and Working Groups 1-19 (hybrid meeting) May 12 – 16 from 08:00h EST to 18:00h EST. Registration coming soon. Contact: Rose Kodzwa

AAMI March 2025 Spring Sterilization Standards Week. (open meeting, registration required) 17 March 2025 to 20 March 2025, hybrid meeting. The AAMI Sterilization Standards Committee and select AAMI Sterilization Working Groups will be convening to conduct business meetings to complete work on relevant sterilization projects. For more information and to register, please visit the AAMI Training & Events webpage. Contact: sterilization@aami.org

AAMI Standards Insider

AAMI's Standards Insider has been revamped. Please view our quarterly 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.

AAMI Standards Management Platform (StMP)

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

Publications

No publications currently.

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.

None currently.

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 EQ-WG01, HTM Program Management Working Group. The working group is developing a new AAMI Technical Information Report (TIR128); *Guidance on implementation and use of AAMI EQ56*. This TIR provides added insight and clarity into sections for assistance in compliance with AAMI EQ56:2024/Ed.3, *Standard for a medical equipment management program.* The TIR will specify clarity and provide guidance for sections on Leadership; Inventory Management; Medical Equipment Safety; Repair Program; Resources; Test Equipment; Service Continuity and Availability Management; and Change Management. Contact: Mike Miskell

AAMI EQ-WG03, Technology acquisition (TA) working group. The working group is developing a new AAMI Standard (EQ94)**,** *Healthcare technology acquisition.* This standard will provide guidance for healthcare delivery organizations on the acquisition of healthcare technology, with the goal of having a consistent process and standardized set of topics that should be covered in acquisition process. Ultimately, standardization will benefit both healthcare delivery organizations and vendors. Topics may include service documentation, risk management files, processes for making purchasing decisions (including who should be involved in those decisions), depreciation schedules, monitoring of hazard alerts/product recalls, and identifying technical specifications, and a standardized request for proposals (RFP). Contact: Mike Miskell

AAMI EQ-WG04, Alternate Equipment Management Working Group. The working group is developing a new AAMI Technical Information Report (TIR129); *Guidance on implementation and use of AAMI EQ103*. This TIR provides explanatory material for healthcare delivery organizations interested in establishing, implementing and sustaining an industry accepted AEM program compliant with AAMI EQ103:2024/Ed. 1, *Alternate Equipment Management (AEM) Program in Healthcare Delivery Organizations (HDOs)*. It includes checks and balances that help ensure safety and quality are not compromised in the process. Additional information included in this guidance document offers examples of potential methods for building an AEM program. This document includes discussions on metrics, data analysis, and risks associated with data quality. The TIR will not endorse any specific AEM strategies. Contact: Mike Miskell

AAMI ST-WG17, Cleaning and Disinfection. The newly established working group will be developing a new AAMI Technical Information Report (TIR127); *Disinfection Validation of healthcare products-Guidance for the development and validation of a disinfection process for reusable medical devices.* This document provides guidance to validate disinfection processes for semi-critical and non-critical devices that are developed by the medical device manufacturer. The document will include validation

methods that should be utilized for the validation and how Spaulding classification plays a role in the selection of the processes. Contact: Tommy Kim

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 EQ89:202X, Guidance for the use of medical equipment maintenance strategies and procedures. Contact: Mike Miskell

REVISION! AAMI EQ93:202X, Medical equipment management—Vocabulary used in medical equipment programs. Contact: Mike Miskell

Consensus Body Members Needed (Call for Members)

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.

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. The working group is seeking user, regulatory, and general interest members to participate in the development of ISO 10993-9:2019/ED.3, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO 10993-15:2019/ED.2, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys.* Contact: Rose Kodzwa

AAMI BE-WG04, Clinical Investigations Working Group. The working group is seeking industry, user, regulatory, and general interest members to participate in the development of ISO/CD 18969, *Clinical evaluation of medical devices*. Contact: Rose Kodzwa

AAMI BE-WG14, Material Characterization Working Group. The working group is seeking user, regulatory, and general interest members to participate in the systemic review of ISO/TC 194 10993-18:2020/ED2, *Biological evaluation of medical devices — Part 18 activities*. Contact: Rose Kodzwa

AAMI BE-WG19, Tissue Product Safety Working Group. The working group is seeking industry, user, regulatory, and general interest members for the newly formed working group to provide input on ISO/TC 194 NP 25695 activities. Contact: Rose Kodzwa

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking, user, regulatory, and general interest members to participate in the development of ISO 18193:2021, *Cardiovascular implants and artificial organs — Cannulae for extracorporeal Circulation Amendment 1 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**:** 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. The committee is seeking 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 working group is seeking user, industry, and general interest/regulator members to contribute to the development of the U.S. positions towards the revisions of ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices* and ISO 7864:2016, S*terile hypodermic needles for single use*. Contact: Sam Alameda

AAMI EQ-WG01, HTM Program Management Working Group. The working group is seeking regulatory, industry, user, 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* and the development of AAMI TIR128:202X/Ed.1, *Guidance on implementation and use of AAMI EQ56.* Contact: Mike Miskell

AAMI EQ-WG02, Servicing Vocabulary Working Group. The working group is seeking regulatory, industry, user, and general interest members to participate in the revision 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, industry, user, and general interest members to participate in the development of AAMI EQ94:202X/Ed.1, *Healthcare technology acquisition.* Contact: Mike Miskell

AAMI EQ-WG04, Alternate Equipment Management Working Group. The working group is seeking regulatory, industry, and general interest members to participate in the development of AAMI TIR129:202X/Ed.1, *Guidance on implementation and use of AAMI EQ103.* 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

AAMI HF, High Frequency Therapeutic Device Committee. The committee 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: Rose Kodzwa

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: Rose Kodzwa

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: Rose Kodzwa

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-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-WG01, Transvenous Cardiac Leads Working Group. The 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 Working Group. The 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. The 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 parts 1-5:2024, *Preparation and quality management of fluids for haemodialysis and related therapies 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 working 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 working 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-WG10, Cloud Computing Working Group. The working 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-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. The 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-WG17, Cleaning and disinfection (CD) Working Group. The newly established working group is seeking members to represent user, general interest, regulatory, and industry interest categories to participate in the development of a new AAMI Technical Information Report (AAMI TIR127); *Disinfection Validation of healthcare products- Guidance for development and validation of a disinfection process for reusable medical devices*. Contact: Tommy Kim

AAMI ST-WG42, Dry heat sterilization Working Group. 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 working 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-WG61, Chemical Sterilants Hospital Practices Working Group. The 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-WG83, Reusable Surgical Textiles Processing Working Group. The working group is specifically looking for additional members to represent general, regulatory, and user interest categories to

participate in the reaffirmation of AAMI ST65:2008/(R)2018, Processing of reusable surgical textiles for use 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. The 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, 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 7198:202x, *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) indicating the name and date of the meeting.

March 2025

AAMI EQ-WG03, Technology Acquisition Working Group. (open meeting) 3 March 2025, 10:00h to 12:00h EST, web meeting. The WG is meeting to discuss the development of a new standard, AAMI EQ94. Contact: Mike Miskell

AAMI EQ, Medical Equipment Management Committee. (open meeting) 4 March 2025, 14:00h to 16:00h EST, web meeting. The committee is meeting to review progress made on various active projects in AAMI EQ WGs. Contact: Mike Miskell

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 5 March 2025, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST, to discuss and draft CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: Sam Alameda

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 20 March 2025, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

AAMI March 2025 Spring Sterilization Standards Week. (open meeting, registration required) 17 March 2025 to 20 March 2025, hybrid meeting. The AAMI Sterilization Standards Committee and select AAMI Sterilization Working Groups will be convening to conduct business meetings to complete work on relevant sterilization projects. For more information and to register, please visit the AAMI Training & Events webpage. Contact: sterilization@aami.org

AAMI SMWG03, Interoperability Working Group. (open meeting) 6 March 2025, 13:00h to 14:00h EST, web meeting. The WG meets the first and third Thursday of every month to discuss the development of a new technical information report AAMI TIR115:202X, *Remote Control of Medical Devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. Contact: Rose Kodzwa

AAMI SMWG05, Device Security Working Group. (open meeting) 25 March 2025, 13:00h to 14:00h EST, web meeting. The WG meets the last Tuesday of every month to discuss the revision of AAMI TIR57:2016/(R)2023, *Principles for medical device security—Risk Management.* Its task group meets every Tuesday at 12:00h to 13:00h to develop a new technical information report AAMI TIR126:202X *Security Risk Estimation for Medical Devices.* Contact: Rose Kodzwa

April 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 2 April 2025, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST, to discuss and draft CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: Sam Alameda

***AAMI RD,* Renal Disease and Detoxification Committee Infusion Device Committee.** (open meeting). 14 April 2025 13:00h to 15:30h EDT, web meeting. More details to follow. Contact: Jill Zajac

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 17 April 2025, 10:00h to 11:30h EDT, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

AAMI PC/CRMD, Cardiac Rhythm Management Device Committee. (open meeting) San Diego, California, USA. 24 April 2025, 07:00h to 14:00h PDT, hybrid meeting. The PC/CRMD committee will meet to discuss progress on committee work and from AAMI PC-WGs activity. Contact: Mike Miskell

May 2025

AAMI BE Week, Biological Evaluation Committee and Working Groups 1-19. (hybrid meeting) May 12 – 16 from 08:00h EST to 18:00h EST. Registration coming soon. Contact: Rose Kodzwa

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 15 May 2025, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

June 2025

AAMI EQ-WG01, HTM Program Management Working Group. (open meeting). New Orleans, Louisiana, USA. 18 June 2025, 08:00h to 17:00h CDT, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 EQ89 and AAMI/WD-1 TIR128. Contact: Mike Miskell

AAMI EQ-WG03, Technology Acquisition Working Group. (open meeting). New Orleans, Louisiana, USA. 18-19 June 2025, 14:00h to 17:00h and 08:00h to 14:30h CDT, respectively, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 EQ94. Contact: Mike Miskell

AAMI EQ-WG04, Alternate Equipment Management Working Group. (open meeting). New Orleans, Louisiana, USA. 18-19 June 2025, 14:00h to 17:00h and 09:00h to 14:30h CDT, respectively, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 TIR129. Contact: Mike Miskell

AAMI EQ-WG02, Servicing Vocabulary Working Group. (open meeting). New Orleans, Louisiana, USA. 19 June 2025, 08:00h to 14:00h CDT, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 EQ93. Contact: Mike Miskell

AAMI EQ, Medical Equipment Management Committee. (open meeting). New Orleans, Louisiana, USA. 19 June 2025, 15:00h to 17:30h CDT, hybrid meeting. The Committee will meet to review working group progress and steering for future AAMI EQ and EQ WGs projects. Contact: Mike Miskell

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 19 June 2025, 10:00h to 11:30h EDT, 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.

March 2025

ISO TC 210, Quality Management and Corresponding General Aspects for Products with a Health Purpose Including Medical Devices. (closed meeting)**.** Tokyo, Japan, 3-7 March 2025, 08:00h – 12:00h**.** Contact: Rachel Ann Porter

ISO/TC 150/SC2/WG-5, Renal replacement, detoxification and apheresis (closed meetings). Web meeting. 17 – 18 March 2025**,** 08:00h to 11:00h EST Contact: Jill Zajac

ISO/TC 210/JWG 3 – IEC/SC 62A/JWG4, Usability. (closed meetings). Arlington, Virginia, USA, 24-28 March 2025, 09:00h to 17:00h EDT. Contact: Colleen Elliott

ISO/TC 150/SC 6/JWG 1, Joint ISO/TC 150/SC 6 - IEC/SC 62D WG: Cardiac pacemakers and implantable defibrillators. (closed meetings). Arlington, Virginia, USA, 25-26 March 2025, 09:00h to 17:00h EDT. Contact: Mike Miskell

IEC/SC 62A, Common aspects of medical equipment, software, and systems, WGs 37-48 for IEC 60601-1 Ed.4 (closed meetings). Arlington, Virginia, USA, 30 March – 4 April 2025, 09:00h to 17:00h EDT. Contact: Colleen Elliott

April 2025

IEC/SC 62A/MT49, Health software. (closed meetings) Arlington, Virginia, USA, 7-9 April 2025, 09:00h to 17:00h EDT. Contact: Colleen Elliott

ISO/TC 121/SC3/JWG10 - IEC/SC 62D/JWG5, Oximeters. (closed meetings) Arlington, Virginia, USA, 7-11 April 2025, 09:00h to 17:00h EDT. Contact: Colleen Elliott

ISO/TC ISO/TC 150/SC2/WG1, Cardiac Valves. (closed meetings) Irvine, California 8-10 April 2025, 09:00h to 17:00h PST, hybrid meeting. Contact: Jill Zajac

May 2025

ISO/TC 121, Anaesthetic and respiratory equipment, and affiliated SC and (J)WG meetings. (closed meetings). Paris France. 12 – 16 May, approx. 09:00h to 17:00h daily local time. Contact: Colleen Elliott

November 2025

IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings. (closed meetings). Milan, Italy, (Tentatively 3 – 14 November), 09:00h to 17:00h daily local time. Contact: Colleen Elliott or Ladan Bulookbashi

ISO/TC 121/SC2, Airway devices and related equipment and ISO/TC 121/SC6, Medical gas supply systems and affiliated WGs (closed meetings). Arlington, Virginia, USA, 17-21 November 2025, 09:00h to 17:00h EDT. Contact: Colleen Elliott