STANDARDS UPDATE

AAMI Standards Insider

Visit the AAMI's Standards Insider here to watch our quarterly video updates featuring news, highlights, and developments from AAMI's standards program and portfolio.

Have a topic you'd like us to cover in a future video? We welcome your suggestions—reach out to us at Standards@aami.org.

AAMI Standards Management Platform (StMP)

Looking for training on **AAMI Standards Management Platform** (**StMP**)? Information is available here. We're excited to announce that a "**Guide to Voting and Commenting on AAMI Draft Documents**" is now available in the "Help" section of StMP.

The guide offers clear, step-by-step instructions to support your engagement in the standards development process—whether you are casting a vote or providing comments on draft documents. Committee members are encouraged to review this guidance document and contact us at standards@aami.org with any questions or comments you may have.

Publications

PUBLISHED! Corrigendum 1 to ANSI/AAMI EQ110:2024; *Healthcare technology management (HTM) educational programs*. Click here for more information. *This corrigendum is made available free of charge.

PUBLISHED! AAMI CR515:2025; *Cybersecurity considerations unique to machine learning–enabled medical devices***,** available in the All Standards eSubscription package. Click here for more information.

PUBLISHED! ANSI/AAMI/IEC 80601-2-58:2024; 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. Click here for more information.

NATIONAL STANDARDS

AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by email to receive a PDF copy of the draft. These copies are free. Published documents proposed for reaffirmation can be purchased from the AAMI Store.

Comments due 10 November 2025

AAMI BP22-1994/(R)202X, *Blood pressure transducers* (reaffirmation of an American National Standard). This standard provides performance and safety requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture, and provides disclosure requirements to permit the user to determine the compatibility between the transducer and blood pressure monitor. This standard is a combined revision of two American National Standards (ANSI/AAMI BP22-1986 and ANSI/AAMI BP23-1986.) Contact: Ladan Bulookbashi

AAMI EC12:2000/(R)202X, *Disposable ECG electrodes* (Reaffirmation of American National Standard). This standard establishes minimum labeling, safety, and performance requirements for disposable electrodes usedfor diagnostic electrocardiography (ECG) or ECG monitoring. Contact: Ladan Bulookbashi

AAMI EC53:2013/(R)202X, *ECG trunk cables and patient leadwires* (Reaffirmation of American National Standard). The objective of this standard is to allow ECG TRUNK CABLES and PATIENT LEADWIRES to be interchanged between ECG DEVICES with isolated PATIENT connections by establishing a common interface between the TRUNK CABLE and the PATIENT LEADWIRE connectors. Performance and safety criteria for TRUNK CABLES and PATIENT LEADWIRES used with isolated PATIENT connectors are also specified. This standard's original scope related to TRUNK CABLES and PATIENT LEADWIRES used with cardiac monitors. The scope was extended to include PATIENT LEADWIRES used with other ECG DEVICES including diagnostic electrocardiographs, ambulatory ECG (Holter) recorders/event recorders and ECG telemetry. Contact: Ladan Bulookbashi

AAMI EC57:2012/(R)202X, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms* (Reaffirmation of American National Standard)***.*** This standard establishes a method for testing and reporting the performance of algorithms used to detect cardiac rhythm disturbances, including the ST segment. Contact: Ladan Bulookbashi

AAMI NS4:2013/(R)202X, *Transcutaneous electrical nerve stimulators* (reaffirmation of an American National Standard). This standard establishes labeling, safety, and performance requirements and referee tests for transcutaneous electrical stimulators (including TENS) intended for use in the treatment

of pain syndrome. Also covered are labeling requirements for patient leads and electrodes. Contact: Ladan Bulookbashi

New Work

Initiation of the following New Work Items has 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 HE, Human Factors Engineering. The committee is working on the development of AAMI TIR133: a new Technical Information Report for *Guidance on Use-Related Risk Analysis (URRA)* . The document will provide guidance on development of a robust Use-Related Risk Analysis (URRA) for use in the usability engineering process. Guidance should reiterate already established expectations as set forward by ISO 14971, IEC 62366-1, and FDA Human Factors guidance regarding what the URRA is required to contain and document. This guidance would establish a best practices approach to the URRA including, how to establish the flowdown from individual workflow use steps all the way to risk control measures Contact: Rachel Ann Porter

AAMI STWG-02, Radiation Sterilization Working Group. The working group is working on the development of AAMI TIR131: a new Technical Information Report for *Guidance for Use of Parametric Release in the Radiation Sterilization of Healthcare Products*. This document would establish guidelines for implementing and maintaining parametric release in healthcare product sterilization for all radiation modalities. Contact: Gigi Golriz.

AAMI STWG08, Microbiological Methods Working Group. The working group is working on the development of AAMI CR517: a new Consensus Report for Comparison of ANSI AAMI ST72_2019 and ISO 11737-3_2023. This document provides a summary of the differences between the two listed documents, which would help to facilitate the evaluation and implementation of ISO 11737-3:2023. Contact: Gigi Golriz.

AAMI CP, Combination Products Committee. The committee is developing the draft of AAMI TIR 132: a new Technical Information Report for *Bridging Approaches for Device Constituents in Drug Device Delivery Systems.* This document provides guidance on best practices for the management of device constituent platforms intended for use in drug-device delivery system development, production, and post market activities. Contact: Jill Zajac

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.

ADOPTION! **AAMI/IEC 60601-2-16:202X,** Medical Electrical Equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment (identical national adoption of IEC 60601-2-16:2025) Contact: Jill Zajac

ADOPTION! **AAMI/IEC 60601-2-39:202X,** Medical Electrical Equipment – Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment (identical national adoption of IEC 60601-2-39:2024) Contact: Jill Zajac

REAFFIRMATION! **AAMI EC12:2000/(R)202X***, Disposable ECG electrodes.* Contact: Ladan Bulookbashi

REAFFIRMATION! **AAMI EC53:2013/(R)202X,** *ECG trunk cables and patient leadwires.* Contact: Ladan Bulookbashi

REAFFIRMATION! **AAMI EC57:2012/(R)202X,** *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.* Contact: Ladan Bulookbashi

REAFFIRMATION! **AAMI TIR44:2012/(R)202X,** *Non-invasive blood pressure motion artifact—Testing and evaluation of NIBP device performance in the presence of motion artifact.* Contact: Ladan Bulookbashi

REVISION! **AAMI ST72:201X**, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing. Contact: Gigi Golriz

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. For a list of definitions of the various stakeholder interest categories, click here. See section 4.5 Interest categories (stakeholders). If you are interested in participating, please complete the AAMI Application for Committee Members. Please contact the staff person indicated for more information about the committee's activities.

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking, user, regulatory, and general interest members to participate in developing the US position and comments on ISO 25735, *Cardiovascular implants and artificial organs — Device output-parameter nomenclature and data format used in extracorporeal life support 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 revisions of AAMI TIR9:1992/(R)2019; *Evaluation of clinical systems for invasive blood pressure monitoring*, and 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 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 regulatory, user and general interest members to participate in the development of a new Technical Information Report (AAMI TIR132), *Bridging Approaches for Device Constituents in Drug Device Delivery Systems.* Contact: Jill Zajac

AAMI CV, Cardiac Valves Committee. The committee is seeking user, regulatory, and general interest members to participate in the U.S. adoption of ISO 5840-1,-2,-3:2021/Amd 1:2025 *Cardiovascular implants—Cardiac valve prostheses, and* ISO 5910: 2024, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair 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 EC_ECG Committee. The committee is seeking user, regulatory and general interest members to participate in the reaffirmation and potential revisions of AAMI TIR60 ED1:2014, *Common mode rejection in ECG monitoring*; AAMI TIR23 ED1:1999, *Signal averaging***;** ANSI/AAMI EC12 ED3:2000, *Disposable ECG electrodes***;** ANSI/AAMI EC57 ED3:2012, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms***;** and ANSI/AAMI EC53 ED2:2013, *ECG trunk cables and patient leadwires*. Contact: Ladan Bulookbashi

AAMI EV-WG08, Ultrasound Working Group. The working group is seeking industry, user, regulatory and general interest members to participate in the development of U.S. position and comments on drafts of IEC 60601-2-36 ED3, *Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy*. Contact: Ladan Bulookbashi

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 ED1,

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 ED1, *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 a new proposed American National Standard (AAMI EQ94), *Healthcare technology acquisition.* Contact: Mike Miskell

AAMI EQ-WG04, Alternate Equipment Management Working Group. The working group is seeking regulatory, industry, user, and general interest members to participate in the development of a new Technical Information Report (AAMI TIR129), *Guidance on implementation and use of AAMI EQ103.* Contact: Mike Miskell

AAMI Human Factors Engineering Committee (HE). The committee is seeking regulatory, user, and general interest members to participate in the development of the following new Technical Information Report: AAMI TIR133*, Guidance on Use-Related Risk Analysis (URRA)*. Contact: Rachel Porter

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, and 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 RD, Renal Disease and Detoxification Committee. The committee is specifically looking for additional members to represent user and general interest categories to participate in the development of a new Technical Information Report (AAMI TIR123) 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.* Contact: Jill Zajac

AAMI STWG02, Radiation Sterilization Working Group. The working group is seeking general interest, regulatory, and user members to participate in the development of a new Technical Information Report (AAMI TIR131), *Guidance for Use of Parametric Release in the Radiation Sterilization of AAMI HealthCare Products*. 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 following activities: Contact: Gigi Golriz.

- development of a new Consensus Report (AAMI CR517), Comparison of ANSI AAMI ST72_2019 and ISO 11737-3_2023
- development of AAMI TIR52 ED2, *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 ED1, *Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products*.

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-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 ED2, *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*. Contact: Gigi Golriz.

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-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 ED2, *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, 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 potential revision 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 7198:2016, *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.

September 2025

AAMI EQ-WG03, Technology acquisition working group. (open meeting). 29 September 2025, 13:00h to 14:00h EDT, web meeting. The WG will meet for updates on the development of AAMI EQ94:202X. Contact: Mike Miskell

AAMI CI, Cochlear implants committee. (open meeting). 30 September 2025, 15:00h to 17:00h EDT, web meeting. The committee will meet for the revision of AAMI CI86. Contact: Mike Miskell

October 2025

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

AAMI EQ-WG05, HTM education programs working group. (open meeting). 3 October 2025, 13:00h to 14:00h EDT, web meeting. The WG will meet for updates on a corrigendum and potential revision to AAMI EQ110:2024. Contact: Mike Miskell

AAMI SP, Sphygmomanometer Committee. (open meeting). 6 October 2025, 11:00h to 14:00h EDT, web meeting. The committee will meet to finalize U.S. comments on ISO/CD 81060-7 ED1. Contact: Ladan Bulookbashi

AAMI EQ-WG04, Alternate equipment management working group. (open meeting). 8 October 2025, 13:30h to 14:30h EDT, web meeting. The WG will meet for updates on the development of AAMI TIR129:202X. Contact: Mike Miskell

AAMI EQ-WG01, HTM program management working group. (open meeting). 13 October 2025, 11:00h to 12:00h EDT, web meeting. The WG will meet for updates on the revision to AAMI EQ89:2015 and development of AAMI TIR128:202X. Contact: Mike Miskell

AAMI EQ-WG02, Servicing vocabulary working group. (open meeting). 15 October 2025, 11:00h to 12:00h EDT, web meeting. The WG will meet for updates on the revision to AAMI EQ93:2019. Contact: Mike Miskell

Technical Advisory Groups to IEC/TC 62, IEC/SC 62A, and IEC/SC 62D. (open joint meeting). 15 October 2025, 13:00h to 15:30h EDT, web meeting. The TAGs will meet to discuss the plenary meeting's agenda items and to form U.S. positions on voting items. Contact: Colleen Elliott or Ladan Bulookbashi

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 16 October 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 EQ, Medical equipment management committee. (open meeting). 17 October 2025, 13:00h to 14:00h EDT, web meeting. The committee will meet for updates on active AAMI EQ projects. Contact: Mike Miskell

AAMI MP, Multiparameter Patient Monitoring Equipment Committee. (open meeting). 27 October 2025, 13:00h to 14:30h EDT, web meeting. The committee will meet to discuss national adoption of IEC 80601-2-49:2018/AMD1:2024. Contact: Ladan Bulookbashi

November 2025

AAMI RD, Renal Disease and Detoxification Committee (open meeting) Houston, TX. 3 November 2025, 9:00h to 17:00h CST, hybrid meeting. Contact: Jill Zajac

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

AAMI CP, Combination Products Committee (open meeting) AAMI offices Arlington, VA, 6 November 2025, 9:00h to 17:00h EST, hybrid meeting. Contact: Jill Zajac

AAMI PC/CRMD, Cardiac Rhythm Management Device Committee. (open meeting). AAMI Center for Excellence, Arlington, VA. 19 November 2025, 09:00h to 12:30h EST, hybrid meeting. The committee will discuss updates from HRS, ISO, and other AAMI PC working groups, as well as continued discussion on PFAS. Contact: Mike Miskell

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

December 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 3 December 2025, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of

every month to discuss and draft CR514, Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD). Contact: Sam Alameda

AAMI AR, Anaesthetic and Respiratory equipment committee and AR/WGs. (open meeting), virtual. 10 December 2025, 15:00h to 16:00h. Contact: Colleen Elliott

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 2025

ISO/TC 150/SC 6/WG 5, Implantable neurostimulators (closed meeting). Virtual, 30 September 2025, 09:00h to 11:00h EDT. Contact: Mike Miskell

October 2025

ISO/TC 198, Sterilization of health care products, and affiliated WGs. (closed meetings) Hangzhou, China and by Zoom (20-24 October 2025), 09:00 to 17:30 daily local time. Contact: Amanda Benedict

ISO/TC 150/SC 6/JWG 1, Joint ISO/TC 150/SC 6 - IEC/SC 62D WG: Cardiac pacemakers and implantable defibrillators. (closed meeting) Zürich, Switzerland, 20-24 October 2025, 09:00h to 17:00h daily local time. Contact: mmiskell@aami.org

ISO/TC 210 WG 01 - Application of quality systems to medical devices. (closed meeting). Arlington, Virginia, USA, 27-31 October 2025, 8:00h to 17:00h EDT. Contact: Rachel Ann Porter

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

ISO/TC 194, Biological Evaluation. (closed meetings). Virtual, 18 November 2025, 11:00h to 15:00 h CET. Contact: Rose Kodzwa