AAMI Standards Monitor Online
23 May 2025

STANDARDS UPDATE

Check out our New Work section for our three new works.

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

REAFFIRMED! **AAMI CI86: 2017/(R)2025;** Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting. Click here for more information

REAFFIRMED! **AAMI TIR43:2021/(R)2025**; Ultrapure dialysis fluid for hemodialysis and related therapies. Click here for more information.

REAFFIRMED! **AAMI TIR58:2021/(R)2025**; Water testing methodologies. Click here for more information.

REAFFIRMED! **AAMI TIR61:2014/(R)2025**; Generating reports for human factors design validation results for external cardiac defibrillators. Click here for more information.

REAFFIRMED! **AAMI TIR62:2014/(R)2025**; Generating reports for the purpose of submitting defibrillation waveform data for evaluation. Click here for more information.

REAFFIRMED! **AAMI TIR72:2017/(R)2025**; Dialysis fluid chemical composition Click here for more information.

REAFFIRMED! **AAMI TIR77:2018/(R)2025**; Sorbent-based regenerative hemodialysis systems Click here for more information.

PUBLISHED! **AAMI TIR109:2025**; External transport of reusable medical devices for processing. 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.

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 HE, Human Factors Engineering. The committee is working on the development of AAMI TIR130: a new Technical Information Report for *Improving Accessibility and Usability of At-Home In Vitro Diagnostic_IVD_Test* . The document will provide guidance to manufacturers in the design of at-home IVD test kits – covering all aspects of the testing process, from test kit acquisition to product disposal – that are more accessible for users that have no vision or low vision or have a reduced range of manual dexterity or fine motor skills. Test kits that incorporate these improvements would also offer better usability for all users. Contact: Rachel Ann Porter

AAMI STW-G02, 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 STW-G08, 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.

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/ISO 5840-1:2021/AMD1 *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements* Amendment 1 (identical national adoption of ISO 5840-1:2021/Amd 1:2025.) Contact: Jill Zajac

ADOPTION! AAMI/ISO 5840-2:2021/AMD1 *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes* Amendment 1 (identical national adoption of ISO 5840-2:2021/Amd 1:2025.) Contact: Jill Zajac

ADOPTION! AAMI/ISO 5840-3:2021/AMD1 *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques* Amendment 1 (identical national adoption of ISO 5840-3:2021/Amd 1:2025.) Contact: Jill Zajac

REVISION! AAMI CI86 ED2:202X, *Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting.* 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-WG13, Toxicokinetics Study Design Working Group. The working group is seeking users, regulatory, and general interest members to participate in the revision of ISO 10993-16 ED4, *Biological evaluation of medical devices — Part 16: Toxicokinetic evaluation for degradation products and leachables.* 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 contribute to the development of the U.S. position towards ISO 25695 ED1, *Medical devices utilizing bioengineered biological substances — Application of risk management*. Contact: Rose Kodzwa

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 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 revision of AAMI CI86:2017, *Cochlear implant systems—Requirements for safety, functional verification, labeling and reliability reporting*. Contact**:** Mike Miskell

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 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, *Sterile 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 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 EQ-WG05, HTM Education Programs Working Group. The working group is seeking regulatory, industry, user, and general interest members to participate in the development of an amendment for AAMI EQ110, *Healthcare technology management (HTM) educational programs*. Contact: Mike Miskell

AAMI HE, Human Factors Engineering. The committee is seeking regulatory, user, and general interest members to participate in the development of a new Technical Information Report (AAMI TIR130), *Improving Accessibility and Usability of At-Home In Vitro Diagnostic_IVD_Test*. 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 SM-WG03, Interoperability Working Group. The working group is seeking general interest, regulatory, and users. The committee is developing a new proposed 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 technical information report AAMI TIR126:202X, *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 ED1, *Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type*. Contact: Ladan Bulookbashi

STWG02, Radiation Sterilization Working Group. The working group is seeking general interest, regulatory, and user members to participate in the development of AAMI TIR131: Proposal for a new Technical Information Report for *Guidance for Use of Parametric Release in the Radiation Sterilization of Healthcare Products* [SBN115]. Contact: Gigi Golriz.

AAMI ST-WG08, Microbiological methods Working Group. The working group is seeking general interest, regulatory, and user members to participate in the development of AAMI TIR52 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*. Contact: Gigi Golriz.

- The working group is seeking general interest, regulatory, and user members to participate in the development of CR517: *Proposal for a new Consensus Report for Comparison of ANSI AAMI ST72_2019 and ISO 11737-3_2023* [SBN116]. 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 ED2, *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 a new Technical Information Report (AAMI TIR117), *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-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, 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 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.

June 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 4 June 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 CI, Cochlear implants committee. (open meeting). 3 June 2025, 15:00h to 17:00h EDT, web meeting. The committee will meet for the revision of AAMI CI86. Contact: Mike Miskell

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 continue preparation of 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 continue preparation of 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 continue preparation of 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 continue preparation of 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

AAMI ST-WG08, Microbiological Methods Working Group. (open meetings). 11, 18 and 25 June 2025 from 11:00h EST to 14:00h EST. The purpose of these meetings is to resolve comments for AAMI TIR52, *Environmental monitoring for terminally sterilized healthcare products*. Contact: Gigi Golriz

July 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 2 July 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) 17 July 2025, 10:00h to 11:30h EDT, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

August 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 6 August 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) 21 August 2025, 10:00h to 11:30h EDT, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

September 2025

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 3 Sept 2025, 10:00h to 11:00h EST, web meeting. (Tentative user panel discussion follow-up meeting), to discuss CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: Sam Alameda

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

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 ISO/TC 150/SC2, Cardiovascular implants and extracorporeal systems, and affiliated WG meetings. (closed meetings). Caparica Portugal 22 – 26 September, approx. 09:00h to 17:00h daily WET time. Contact: Jill Zajac

October 2025

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