

## STANDARDS UPDATE

**AAMI BE Week, Biological Evaluation Committee and Working Groups 1-19** (hybrid meeting) May 12 – 16 from 08:30h EST to 17:00h EST. Register [online](#). Contact: [Rose Kodzwa](#)

## 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](mailto:Standards@aami.org).

## AAMI Standards Management Platform (StMP)

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

## Publications

**REAFFIRMED!** **ANSI/AAMI EQ93:2019/(R)2025**; Medical equipment management—Vocabulary used in medical equipment programs. [Click here](#) for more information.

**REAFFIRMED!** **ANSI/AAMI/ISO 14117:2019/(R)2025**; Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices. [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.

**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.*

**Currently, there is no New Work. Please check back on 5/23/2025.**

## ***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,*

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*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 user, 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](#)

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**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/DAmD 1, Amendment 1 *Cardiovascular implants and artificial organs — Cannulae for extracorporeal Circulation* 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](#)

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**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 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*

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*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](#)

**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](#).

**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](#)

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**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*

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*committee staff liaison listed below or contact the AAMI Standards Department at ([standards@aami.org](mailto:standards@aami.org)) indicating the name and date of the meeting.*

## **May 2025**

**AAMI EQ-WG05, HTM Education Programs Working Group.** (open meeting) 5 May 2025, 10:00h to 13:00h EDT, web meeting. The WG will meet to discuss potential updates to ANSI/AAMI EQ110:2024. Contact: [Mike Miskell](#)

**AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group.** (open meeting) 7 May 2025, 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 and draft CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI BE Week, Biological Evaluation Committee and Working Groups 1-19.** (hybrid meeting) May 12 – 16 from 08:30h EST to 17:00h EST at the AAMI office in Arlington VA. Registration is now open. 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](#)

**AAMI ST-WG12, Instructions for Reusable Device Reprocessing Working Group.** (open meetings) 7 May 2025 and 14 May 2025 from 12:00h EST to 15:00h EST virtual meetings. The purpose of this meeting is to address comments for the revision of AAMI TIR12, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers. Contact: [Gigi Golriz](#)

## **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 1<sup>st</sup> 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](#)

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**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 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 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](#)

## 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.*

#### **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](#)

#### **September 2025**

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

#### **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](#)