

## 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](mailto: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.

This 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](mailto:standards@aami.org) with any questions or comments you may have.

## Publications

**ADOPTION! 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 July 28, 2025

**AAMI ST65:2008/(R)202X**, Processing of reusable surgical textiles for use in health care facilities (reaffirmation of American National Standard). This document provides guidelines for the proper handling, processing, and preparation of reusable surgical textiles either on-site or off-site for use in health care facilities. Contact: [Tommy Kim](#)

**AAMI/ISO 11737-3**, Sterilization of health care products – Microbiological methods – Part 3: Bacterial endotoxin testing (identical national adoption of ISO 11737-3:2023 Ed.1). This document specifies general criteria to be applied in the determination of bacterial endotoxins test (BET) methods, using amebocyte lysate reagents. Contact [Gigi Golriz](#).

## 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 TIR130: a new Technical Information Report for *Best Practices for Designing Accessible At-Home Diagnostic Test Kits*. 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 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](#).

## ***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.*

## ***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 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](#)

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**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 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](#)

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**AAMI Human Factors Engineering Committee (HE).** The committee is seeking regulatory, user, and general interest members to participate in the development of a new Technical Information Report (AAMI TIR130), *Best Practices for Designing Accessible At-Home Diagnostic Test Kits*. 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-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 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

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(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-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-WG83, Reusable surgical textiles processing Working Group.** The working group is specifically looking for additional members to represent general and regulatory interest categories to participate in

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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 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](mailto:standards@aami.org)) indicating the name and date of the meeting.*



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## **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 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 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](#)

**AAMI RD, Renal Disease and Detoxification Committee** (open meeting) 21 August 2025, 13:00h to 2:30h EDT, web meeting. The group will review the US positions on ISO/DIS 8637 Parts 1-3 Contact: [Jill Zajac](#)

## **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](#)

## **December 2025**

**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.*



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### ***September 2025***

**ISO/TC 198/WG 12, Information for reprocessing of resterilizable devices.** (closed meeting) Arlington, Virginia, USA and by Zoom (18-19 September 2025), 09:00 to 17:00 daily local time. Contact: [Amanda Benedict](#)

**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 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 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](#)