

## STANDARDS UPDATE

**NEW!** We have completed transitioning our standards groups to the NEW AAMI Committee Central platform! Information is available [here](#).

## Publications

**NEWSWORTHY!!** AAMI/FDA/BSI International Conference on Medical Device Standards and Regulation will return “in-person” on 18-19 October 2022. Click [here](#) for more information.

**NEWSWORTHY!!** Publication of the New Editions of the Standards for Medical Device Interoperability, AAMI/UL 2800 Series | More information is available [here](#).

**PUBLISHED!** AAMI TIR104:2022, *Guidance on transferring health care products between radiation sterilization source* is available [here](#).

**REAFFIRMED!** AAMI TIR65:2015/(R)2022, *Sustainability of medical devices – Elements of a responsible life cycle* is available [here](#).

## AAMI Standards Insider

The [AAMI Standards Insider](#) webinar series was last held on **Thursday, May 19<sup>th</sup> from 1:00-2:00 PM ET**. This **one-hour FREE webinar** provided news and updates about AAMI’s standards program and portfolio. The next webinar will be held on Thursday, **August 18<sup>th</sup> from 1:00-2:00 PM ET**. Registration for upcoming webinars and recordings of past webinars are available [here](#).

## 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 12 September 2022*

**ANSI/AAMI ST79:2017 & A1:2020, A2:2020, A3:2020, & A4:2020, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*** (reaffirmation of an American National Standard and amendments). This document includes guidance for sterile processing facility design,

personnel, receiving, transporting, handling, cleaning, decontamination, preparation, packaging, steam sterilization of reusable medical devices, quality process improvement and new product evaluation.

Contact: [Amanda Benedict](#)

### *Comments due 26 September 2022*

**ANSI/AAMI/ISO 11737-1:2018/A1, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1** (proposed amendment to an American National Standard). This amendment revises B.3.3.4 and corrects formula B.1. Contact: [Amanda Benedict](#)

**AAMI CDV-2 ST108, Water for the processing of medical devices** (proposed new American National Standard). Covers the selection and maintenance of effective water quality suitable for processing medical devices. It provides guidelines for selecting the water quality necessary for the processing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations. Contact: [Jody Allen](#)

**AAMI CDV-1 ST24, General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities** (revision of an American National Standard). Covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems. Contact: [Jody Allen](#)

### **New Work**

**AAMI TIB, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use Committee.** The committee has recently approved development of a new AAMI Technical Information Report (TIR) on Guidance for Closed System Transfer Device Testing with Hazardous Drugs. This TIR seeks to provide guidelines for physical and chemical compatibility of the drug with the Closed System Transfer Device (CSTD), which may include but not limited to holdup volume, coring/fragmentation of the vial rubber stopper, microbial ingress, stability/shelf-life, and usability. TIB-WG04 is seeking cochairs, user, regulatory and general interest members to participate in the development of AAMI TIR112. We are currently scheduled for a meeting on 20 July, 10:30 – 11:30 am (CST), if interested in attending email. Contact: [Sam Alameda](#)

### *Consensus Body Members Needed*

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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:

**User:** *An individual or organizational representative, who 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; individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

**Industry:** *An individual or organizational representative 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; this interest category includes manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

**Regulatory:** *An individual or organizational representative involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI; this interest category includes those representing federal, state, local, foreign, or other government entities.*

**General interest:** *An individual or organizational representative with a general 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; this interest category can include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

Please contact the staff person indicated for more information on how to join.

**AAMI EQ, Medical equipment management.** The committee is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs*. Contact: [Jody Allen](#)

**AAMI ST-WG06, Chemical Indicators.** The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of the national adoptions of several parts of the ISO 11140 series. Contact: [Jody Allen](#)

**AAMI ST-WG13, Washer-disinfectors.** The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of AAMI ST15883-2 and AAMI ST15883-3. Contact: [Jody Allen](#)

**AAMI ST-WG84, Endoscope Reprocessing.** The working group is seeking regulatory and general interest members to participate in the development of AAMI TIR99/Ed.1, *Dilators, transesophageal and ultrasound probes processing in health care facilities*. Contact: [Jody Allen](#)

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**AAMI TIB, Transfusion, Infusion and Injection, and Blood Processing Equipment for Medical and Pharmaceutical Use.** The committee and its affiliated working groups are seeking user, industry, and general interest/regulator 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 CV, Cardiac Valves.** The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 5840-1:202x, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements*; ISO 5840-2:202x, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes*; ISO 5840-3:202x, *Cardiovascular implants — Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques*; and the revision of ISO 5910:2018, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices*. Contact: [Jill Zajac](#)

**AAMI VP, Vascular Prostheses.** The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 25539-2:2020, *Cardiovascular implants—Endovascular devices—Part 2: Vascular stents*; the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters*. Contact: [Jill Zajac](#)

**AAMI BG, Blood/Gas Exchange Device.** The committee is seeking user, industry, and general interest/regulator members to participate in the development of the following Cardiovascular implants and artificial organs documents: ISO 18193, *Cannulae for extracorporeal circulation*; Amendment 1 to ISO 18242:2016 *Centrifugal blood pumps for pulsatile pumps*; and revision of ISO 7199, *Blood-gas exchangers*. Contact: [Jill Zajac](#)

**AAMI VP-WG 01, Vascular Device-drug Combination Products.** The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO 12417-1:2015, *Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products—Part 1: General requirement*. Contact: [Jill Zajac](#)

**AAMI RD, Renal Disease and Detoxification.** The committee is seeking industry, user, and general interest/regulator members to participate in the revision of the ISO 23500:2019, *Preparation and quality management of fluids for haemodialysis and related therapies series standards: Part 1: General requirements; Part 2: Water treatment equipment for haemodialysis applications and related therapies; Part 3, Water for haemodialysis and related therapies; Part 4: Concentrates for haemodialysis and related therapies; Part 5, Quality of dialysis fluids for haemodialysis and related therapies*; and the revision of the ISO 8637, *Extracorporeal systems for blood purification series standards: Part 1, Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters*; and Part 3, *Plasmafilters*. Contact: [Jill Zajac](#)

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**AAMI HIT-WG02, Health IT Quality Systems Working Group.** The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed., *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: [Chenai Maguwah](#)

**AAMI AI, Artificial Intelligence.** The committee is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR34971, *Guidance on the Application of ISO 14971 to Artificial and Machine Learning*. Contact: [Hae Choe](#)

**AAMI SM-WG01, Software Working Group.** The group is seeking user, general interest, and regulatory members to participate in the development of TIR45: *Guidance on the use of AGILE practices in the development of medical device software*. Contact: [Ovidiu Munteanu](#)

**AAMI SM-WG03, Interoperability Working Group.** The group is seeking general interest, regulatory, and users. The committee is developing a new American national standard, AAMI Safe Remote Control of Medical Devices. Contact: [Ovidiu Munteanu](#)

**AAMI SM-WG05, Medical Device Security Working Group.** The group is seeking general interest, regulatory, and users. The committee is developing a new American national standard, AAMI SW96, *Standard for medical device security—Security risk management for device manufacturers*. Contact: [Ovidiu Munteanu](#)

**AAMI SM-WG10, Cloud Computing Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of a TIR based on the approved AAMI CR510:2021, *Appropriate Use of Public Cloud Computing for Quality Systems and Medical Devices*. Contact: [Ovidiu Munteanu](#)

**AAMI EV-WG05, Hospital Beds Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of IEC 80601-2-52 ED1: *Medical electrical equipment—Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*, and IEC 80601-2-89 ED1: *Medical electrical equipment—Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children*. Contact: [Ladan Bulookbashi](#)

## 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 ([www.aami.org](http://www.aami.org)). Note: If you plan to attend a meeting, please send a brief note to the*

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AAMI Standards Department at ([standards@aami.org](mailto:standards@aami.org)) indicating the name and date of the meeting so that staff can contact you in the event of a last-minute cancellation.

### **August 2022**

**AAMI EQ, Medical Equipment Management Committee** (open meeting – advanced registration REQUIRED). Every Friday, 15:00h to 16:30h EST, web meetings. Contact: [Jody Allen](mailto:Jody.Allen@aami.org)

### **September 2022**

**AAMI EQ, Medical Equipment Management Committee** (open meeting – advanced registration REQUIRED). Every Friday, 15:00h to 16:30h EST, web meetings. Contact: [Jody Allen](mailto:Jody.Allen@aami.org)

**AAMI Fall 2022 Sterilization Standards Week** (open meetings – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 12-15 September 2022, 08:00h to 17:00h EST, Arlington, VA and web meetings. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Industrial EO Sterilization Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 14 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Radiation Sterilization Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 13 September 2022, 13:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Moist Heat Sterilization Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 14 September 2022, 13:00h to 17:00h EST, and 15 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Packaging Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 12 September 2022, 13:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Microbiological Methods Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 12 September 2022, 13:00h to 17:00h EST, and 13 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Steam Sterilization Hospital Practices Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 12 September 2022, 13:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

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**Steam Sterilization Dental Practices Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 15 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Chemical Sterilization Hospital Practices Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 15 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Endoscope Reprocessing Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 13 September 2022, 08:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Water Quality for Reprocessing Medical Devices Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 14 September 2022, 08:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Compatibility of Materials Subject to Sterilization Working Group** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 13 September 2022, 08:00h to 17:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**Protective Barriers Committee** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 15 September 2022, 08:00h to 12:00h EST, Arlington, VA and web meeting. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

**US TAG to ISO/TC 198** (open meeting – advanced registration REQUIRED; public registration opens August 15<sup>th</sup> through the [AAMI Store](#)). 15 September 2022, 13:00h to 15:00h EST, Arlington, VA and web meetings. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

### ***November 2022***

**AAMI RD, Renal Disease and Detoxification Committee Infusion Device Committee** (open meeting). 6 -7 November 2022, Details to follow, Orlando FL, hybrid meeting. Contact: [Jill Zajac](#)

### ***March 2023***

**AAMI Spring 2023 Sterilization Standards Week** (open meetings – advanced registration REQUIRED; registration to open in January 2023). 20-24 March 2023, 08:00h to 17:00h EST, Arlington, VA and web meetings. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

### ***September 2023***

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**AAMI Fall 2023 Sterilization Standards Week** (open meetings – advanced registration REQUIRED; registration to open in July 2023). 18-23 September 2023, 08:00h to 17:00h EST, Arlington, VA and web meetings. Contact: [sterilization@aami.org](mailto:sterilization@aami.org)

## 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.*

#### **October/November 2022**

**IEC/TC 62, Electrical equipment in medical practice, and subcommittees 62A, 62B, 62C, and 62D** (closed meeting). 24 October-4 November 2022, 8:00h to 17:00h EST, Plenary meeting and meetings of affiliated working groups. Contact: [Hae Choe](#)

#### **December 2022**

**ISO/TC 198, Sterilization of health care products and meetings of affiliated groups** (closed meetings). 5-9 December 2022, 9:00h to 17:30h EST, Plenary meeting and meetings of affiliated working groups. Contact: [Amanda Benedict](#)

**ISO/TC 210, Quality management and corresponding general aspects for medical devices** (closed meetings). 12-16 December 2022, 9:00h to 17:30h EST, Plenary meeting and meetings of affiliated working groups. Contact: [Amanda Benedict](#)