

## STANDARDS UPDATE

**NEWSWORTHY!** AAMI hosted the meetings of ISO/TC 198 and affiliated working groups in Arlington, Virginia, USA in early December 2022. Click [here](#) for a video interview with Emily Craven, director of sterility assurance at Boston Scientific, regarding the radiation sterilization standards ecosystem.

## AAMI Standards Insider

The next [AAMI Standards Insider](#) webinar will be held on **Thursday, February 16<sup>th</sup> from 1:00-2:00 PM ET**. The **one-hour FREE webinar** provides news and updates about AAMI's standards program and portfolio. Registration for the upcoming webinars and recordings of past webinars in the series – including the November 17<sup>th</sup> session - will be available on the webpage. Check back soon!

## Publications

**PUBLISHED!** Be sure to check back in the new year on publication of **ANSI/AAMI/ISO 18472:2022**, *Sterilization of health care products—Biological and chemical indicators—Test equipment*.

**PUBLISHED!** Be sure to check back in the new year on the publication of the national adoption of **ANSI/AAMI PB70:2022**, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

## 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 13 January 2023*

**AAMI/CDV-1 HIT1000-2, Health IT software and systems—Part 2: Application of quality systems principles and practices** (proposed new American National Standard) Specifies a process to build on the principles in existing quality systems principles and practices, as well as identify the specific roles and responsibilities needed to ensure health IT safety and quality as well as patient safety hazards associated with health IT software and systems, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Contact: [Chenai Maguwah](#)

**AAMI/CDV-1 HIT1000-3, Safety and effectiveness of health IT software and systems—Part 3: Application of risk management** (proposed new American National Standard) Identifies the core concepts and principles needed to maintain safe and effective health IT software and systems to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Contact: [Chenai Maguwah](#)

**AAMI /CDV-1 HIT1000-4, Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering** (proposed new American National Standard) Describes an approach to developing and validating a health IT system's user interface so that such systems are safe and effective. The intent is to promote good development practices without being overly prescriptive. As such, this standard covers the development, acquisition, integration, implementation, and operational use lifecycle stages. Additionally, this standard includes a section describing usability considerations for health IT system replacement and decommissioning. Contact: [Chenai Maguwah](#)

### *Comments due 30 January 2023*

**AAMI/ISO 10993-11, Biological evaluation of medical devices—Part 11: Tests for systemic toxicity** (reaffirmation of an American National Standard) Specifies requirements and gives guidance on procedures to be followed in the evaluation of the potential for medical device materials to cause adverse systemic reactions. Contact: [Chenai Maguwah](#)

**AAMI/ISO CDV-1 13004, Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method  $VD_{max}^{SD}$**  (proposed new American National Standard) Specifies a method or substantiating a selected sterilization dose of 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy or 35 kGy that achieves a sterility assurance level (SAL) of  $10^{-6}$  or less or radiation sterilization of health care products. This document also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose. Contact: [Tommy Kim](#)

### *Comments due 13 February 2023*

**AAMI EQ89, Guidance for the use of medical equipment maintenance strategies and procedures** (reaffirmation of an American National Standard) This standard is intended to provide basic information to health care technology management professionals by identifying and describing in general various maintenance strategies and methods for efficient, effective, and timely maintenance of medical equipment in health care facilities. The standard neither mandates nor requires that any of these specific strategies be used, but instead discusses in general the uses of these methods and their potential advantages and disadvantages. Contact: [standards@aami.org](mailto:standards@aami.org)

## 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. **The group will begin having monthly meetings beginning in 2023.** Contact: [Sam Alameda](#)

## Consensus Body Members Needed

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.

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**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: [standards@aami.org](mailto:standards@aami.org)

**AAMI ST-WG06, Chemical Indicators.** The working group is seeking user, regulatory and general interest members to contribute to development of the US positions towards the revisions of several parts of the ISO 11140 series. Contact: [standards@aami.org](mailto:standards@aami.org)

**AAMI ST-WG13, Washer-disinfectors.** The working group is seeking user, regulatory and general interest members to contribute to development of the US positions towards the revisions of ISO 15883-2 and ISO 15883-3. Contact: [standards@aami.org](mailto:standards@aami.org)

**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: [standards@aami.org](mailto:standards@aami.org)

**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 DPC-10, “Needles.”** The committee is seeking user, industry, and general interest/regulator members to contribute to the development of the US 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: [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](#)

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**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](#)

**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.1, *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: [Chenai Maguwah](#)

**AAMI BE-WG07 - Systemic toxicity Working Group.** The working group is seeking industry, user, general interest, and regulatory members to participate in the development of ANSI/AAMI/ISO 10993-11:2017 *Biological evaluation of medical devices—Part 11: Tests for systemic toxicity*. Contact: [Chenai Maguwah](#)

**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: [Chenai Maguwah](#)

**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: [Chenai Maguwah](#)

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**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*, AAMI TIR57, *Principles for medical device security—Risk Management* and AAMI TIR97, *Principles for medical device security—Postmarket risk management for device manufacturers*. Contact: [Chenai Maguwah](#)

**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: [Chenai Maguwah](#)

**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 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.*

#### **January 2023**

**AAMI/ID Committee, Infusion Device** (open meeting) 13 January 2023, 13:00h to 15:00h EST, web meeting. Contact: [Ladan Bulookbashi](#)

**AAMI/PC-WG03, Pacemaker & ICD MRI Compatibility** (open meeting) 19 January 2023, 10:00h to 11:30h EST, web meeting. Contact: [Ladan Bulookbashi](#)

#### **March 2023**

**AAMI Spring 2023 Sterilization Standards Week** (open meetings; hybrid – 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 Standards](#)

#### **September 2023**

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## 16 December 2022

**AAMI Fall 2023 Sterilization Standards Week** (open meetings; hybrid – advanced registration REQUIRED; registration to open in July 2023). 11-14 September 2023, 08:00h to 17:00h EST, Arlington, VA, and web meetings. Contact: [Sterilization Standards](#)

## 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.*

#### **December 2022**

**ISO/TC 210, Quality management and corresponding general aspects for medical devices** (closed meetings). 12-16 December 2022, 09:00h to 17:30h EST, Plenary meeting, and meetings of affiliated working groups. Contact: [Amanda Benedict](#)

#### **January 2023**

**AAMI TIB-WG04, TIR112- Closed System Transfer Device (CSTD)** will conduct a Microsoft Teams meeting. 4 January 2023, 09:00 CST. The group will begin having monthly meetings beginning in 2023. Contact: [Sam Alameda](#)

**ISO/TC 215 – IEC/SC 62A/JWG 7 in conjunction with ISO/TC 215, Health Informatics** (closed meetings). 9-13 January 2023, 8:30h to 17:00h, Sapporo, Japan. Contact: [Hae Choe](#)

**ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care** (closed meeting). 29 January 2023, 17:00h to 20:00h EDT, Plenary meeting. Contact: [Colleen Elliott](#)

#### **February 2023**

**ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care** (closed meeting). 2 February 2023, 17:00h to 20:00h EDT, Plenary meeting. Contact: [Colleen Elliott](#)