

## STANDARDS UPDATE

**NEWSWORTHY!** **ISO/TC 121**, Renewed attention on ventilators is just the beginning, click [here](#) for more information.

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

## 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

**REAFFIRMED!** The following consensus reports have been reaffirmed as of 6 October 2022 under the AAMI COVID-19 Response Team and are available [here](#).

- AAMI CR501:2020/(R)2022, *Emergency Use Ventilator (EUV) Design Guidance*
- AAMI CR502:2020/(R)2022, *End User Disclosures for Emergency Use Ventilators (EUVs)*
- AAMI CR503:2020/(R)2022, *Emergency Use Resuscitator Systems Design Guidance*
- AAMI CR504:2020/(R)2022, *End User Disclosures for Emergency Use Resuscitator Systems*
- AAMI CR505:2020/(R)2022, *Emergency Use CPAP/BiPAP Design Guidance*
- AAMI CR506:2020/(R)2022, *End User Disclosure for CPAP/BiPAP*
- AAMI CR507:2020/(R)2022, *Basic Safety of Emergency Use Medical Devices*
- AAMI CR508:2020/(R)2022, *Emergency Use Ventilatory Assistance Helmet (VAH) Design Guidance*
- AAMI CR509:2020/(R)2022, *End User Disclosures for Emergency Use Ventilatory Assistance Helmet (VAH)*
- AAMI CR511:2020/(R)2022, *Emergency use Guidance for Remote Control of Medical Devices*

## 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 28 November 2022***

**AAMI ST90, *Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*** (reaffirmation of an American National Standard). This document specifies minimum requirements for quality management systems (QMSs) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and nonmanufacturer-related device failures. Contact: [Jody Allen](#)

### ***Comments due 6 December 2022***

**AAMI HE75, *Human factors engineering—Design of medical devices*** (revision of an American National Standard). This standard addresses a broad range of human factors engineering topics as they relate to the design and evaluation of medical devices. This document is expected to be useful to human factors and usability engineering specialists, software developers, industrial, biomedical, mechanical, and electrical engineers and other development personnel. There are significant updates being proposed in this revision of the 2009 document. Contact: [Hae Choe](#)

### ***Comments due 13 January 2023***

**AAMI HIT1000-2, *Health IT software and systems—Part 2: Application of quality systems principles and practices*** 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 HIT1000-3, *Safety and effectiveness of health IT software and systems—Part 3: Application of risk management*** 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 HIT1000-4, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering*** Describes an approach to developing and validating a health IT system's user

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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](#)

### 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*

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*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: [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 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

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

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

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

**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

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AAMI CR510:2021, *Appropriate Use of Public Cloud Computing for Quality Systems and Medical Devices*.  
Contact: [standards@aami.org](mailto:standards@aami.org)

**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.*

#### **December 2022**

**AAMI ST, Industrial moist heat sterilization Working Group** (open meeting). 1 December 2022, 13:00h to 17:00h EST. Contact: [Tommy Kim](#)

**AAMI CN, Small-bore Connectors Committee** (open meeting). 6 December 2022, 13:00h to 16:00h EST. Contact: [Colleen Elliott](#)

**AAMI COVID-19 Response Team** (open meeting). 7 December 2022, 15:00h to 16:00h EST, web meeting. Contact: [Colleen Elliott](#)

**AAMI AR, Anaesthetic and respiratory equipment Committee and AR/Working Groups** (open meeting). 7 December 2022, 16:00h to 17:00h EST, web meeting. Contact: [Colleen Elliott](#)

#### **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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**AAMI Fall 2023 Sterilization Standards Week** (open meetings; hybrid – advanced registration REQUIRED; registration to open in July 2023). 18-22 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 198, Sterilization of health care products and meetings of affiliated groups** (closed meetings). 5-9 December 2022, 09:00h to 17:30h EDT, Plenary meeting, and meetings of affiliated working groups. Contact: [Amanda Benedict](#)

**ISO/TC 121/SC1, Breathing attachments and anaesthetic machines** (closed meeting). 9 December 2022, 02:00h to 06:00h EDT. Contact: [Colleen Elliott](#)

**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](#)

**ISO/TC 150 Implants for surgery** (closed meetings). 6-7 December 2022, 08:00h to 10:00h EST, Plenary meeting. Contact: [Jill Zajac](#)

#### **January 2023**

**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](#)

**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](#)

#### **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](#)