

STANDARDS UPDATE

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.

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

Publications

REAFFIRMED! AAMI TIR35: 2016/(R)2021, *Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits* is available [here](#).

PUBLISHED! ANSI/AAMI ST98:2022, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices* is available [here](#).

PUBLISHED! AAMI/ISO TIR11137-4:2022, *Sterilization of health care products—Radiation—Part 4: Guidance on process control* is available [here](#).

PUBLISHED! ANSI/AAMI/IEC 60601-1-2:2014 & A1:2021, *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests*, including Amendment 1 is available [here](#).

PUBLISHED! ANSI/AAMI/IEC 60601-1-8:2006 & A1:2013 & A2:2021, *Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*, including Amendments 1 and 2 is available [here](#).

PUBLISHED! ANSI/AAMI/IEC 60601-1-12:2016 & A1:2021, *Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance— Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in emergency medical services environment*, including Amendment 1 is available [here](#).

PUBLISHED! ANSI/AAMI HA60601-1-11:2015 & A1:2021; IEC 60601-1-11:2015 MOD, *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*, including Amendment 1 is available [here](#).

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PUBLISHED! ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021; IEC 60601-1:2005 MOD, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, including Amendments 1 and 2 is available [here](#).

AAMI Standards Insider

The [AAMI Standards Insider](#) webinar series was last held on **August 18th**. This **one-hour FREE webinar** provided news and updates about AAMI's standards program and portfolio. The next webinar will be held on **Thursday, November 17th, 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 26 September 2022

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](#)

Comments due 17 October 2022

AAMI/ISO 11137-3, Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control (reaffirmation of an American National Standard). This part of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 and in ISO/TS 13004 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described. Contact: [Amanda Benedict](#)

AAMI/ISO 16142-2, Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards (reaffirmation of an American National Standard). Considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance. Contact: [Amanda Benedict](#)

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](#)

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. Contact: [Sam Alameda](#)

AAMI HIT-WG01, Health IT Risk Management Working Group. The working group will be moving to update and convert AAMI HIT1000-3/Ed.1, *Safety and effectiveness of health IT software and systems—*

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Part 3: Application of risk management from a provisional standard to a full American National Standard. The standard will identify 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. This WG is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-3/Ed.1. Contact: [Chenai Maguwah](#)

AAMI HIT-WG02, Health IT Quality Systems Working Group. The working group is developing AAMI HIT1000-2/Ed.1, *Health IT software and systems—Part 2: Application of quality systems principles and practices*. This standard will specify 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. This WG is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed.1. Contact: [Chenai Maguwah](#)

AAMI HIT-WG03, Health IT Usability Working Group. The working group will be moving to updated and convert AAMI HIT1000-4/Ed.1, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering* from a provisional standard to a full American National Standard. The standard will describe an approach to developing and validating a health IT system's user interface so that such systems are safe and effective. This WG is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-4/Ed.1. Contact: [Chenai Maguwah](#)

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.*

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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](#)

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—*

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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](#)

AAMI HIT-WG01, Health IT Risk Management Working Group. The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-3/Ed.1, *Safety and effectiveness of health IT software and systems—Part 3: Application of risk management*. Contact: [Chenai Maguwah](#)

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 HIT-WG03, Health IT Usability Working Group. The working group is seeking industry, user, general interest, and regulatory members to participate in the development of - AAMI HIT1000-4/Ed.1, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering*. Contact: [Chenai Maguwah](#)

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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). Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department at (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.

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

AAMI ID, Infusion Device Committee (open meeting). 23 September 2022, 13:00h to 15:00h EST, web meeting. Contact: [Ladan Bulookbashi](#)

October 2022

AAMI CP, Combination Products Committee (open meeting). 3 October 2022, 09:30h to 15:30h EST, web meeting. Contact: [Jill Zajac](#)

US TAG to ISO/TC 210 (AAMI Quality Management and Corresponding General Aspects for Medical Devices) (open meeting). 4 October 2022, 14:00h to 16:00h EST, web meeting. Contact: [Amanda Benedict](#)

Combined meeting of the US TAGs for IEC/TC 62 and subcommittees (Electrical equipment in medical practice) (open meeting). 7 October 2022, 13:00h to 16:00h EST, web meeting. Contact: [Hae Choe](#)

AAMI SP, Sphygmomanometer Committee (open meeting). 10 October 2022, 11:00h to 12:30h EST, web meeting. Contact: [Ladan Bulookbashi](#)

AAMI PC, Cardiac Rhythm Management Device Committee (open meeting – advanced registration REQUIRED). 12 October 2022, 09:00h to 17:00h EST, Arlington, VA, and web meeting. Contact: [Ladan Bulookbashi](#)

AAMI CN, Small-bore Connectors Committee (open meeting). 27 October 2022, 10:00h to 13:00h EST, web meeting. Contact: [Colleen Elliott](#)

November 2022

AAMI RD, Renal Disease and Detoxification Committee Infusion Device Committee (open meeting). 6 -7 November 2022, DaVita Airport Dialysis/Training center Orlando FL, hybrid meeting. More details to follow. Contact: [Jill Zajac](#)

December 2022

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

March 2023

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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

September 2023

AAMI Fall 2023 Sterilization Standards Week (open meetings – 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@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, 08:00h 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, 09:00h 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, 09:00h to 17:30h EST, Plenary meeting, and meetings of affiliated working groups. Contact: [Amanda Benedict](#)