STANDARDS UPDATE

Looking for training on **AAMI Standards Management Platform** (**StMP**)? Information is available here.

AAMI Standards Insider

AAMI's Standards Insider has been revamped. Please view our bimonthly video snippets for news and updates about AAMI's standards program and portfolio here. If there are any topics that you would like the Standards team to address, please reach out to Standards@aami.org.

Publications

PUBLISHED! ANSI/AAMI ST24:2024; General-Purpose Ethylene Oxide Sterilizers With Automated Process Control And Ethylene Oxide Sterilant Sources Intended For Use In Health Care Facilities. Click here for more information.

PUBLISHED! AAMI TIR48:2024; Quality management systems (QMS) recommendations on application of the U.S. FDA's CGMP final rule on combination products. Click here for more information.

PUBLISHED! AAMI TIR99:2024; Processing of Dilators, Transesophageal and Ultrasound Probes In Health Care Facilities. 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 15 July 2024

AAMI/IEC 80601-2-58-202X, 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 (identical national adoption of IEC 80601-2-58:2024 and revision of ANSI/AAMI/IEC 80601-2-58-2014. Applies to the basic safety and essential performance of lens removal devices and

vitrectomy devices for ophthalmic surgery and associated accessories that can be connected to this medical electrical equipment (ME equipment). Contact: Ladan Bulookbashi

AAMI/IEC 80601-2-77-2020/A1, Amendment 1 - Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment (identical national adoption of IEC 80601-2-77:2019/AMD1:2023). Applies to the basic safety and essential performance of Robotically Assisted Surgical Equipment (RASE) and Robotically Assisted Surgical Systems (RASS), referred to as ME Equipment and ME Systems together with their interaction conditions and interface conditions. Contact: Ladan Bulookbashi

BSR/AAMI/IEC 80601-2-78-2020/A1, Amendment 1 - Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation (identical national adoption of IEC 80601-2-78:2019/AMD1:2024). Applies to the general requirements for basic safety and essential performance of medical robots that physically interact with a patient with an impairment to support or perform rehabilitation, assessment, compensation or alleviation related to the patient's movement functions, as intended by the manufacturer. Contact: Ladan Bulookbashi

AAMI/ISO 23500-1-202x, Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements (identical national adoption of ISO 23500-1:2024 and revision of ANSI/AAMI/ISO 23500-1-2019). This document specifies the general requirements for the preparation of fluids for haemodialysis and related therapies and substitution fluid for use in online therapies, such as haemodiafiltration and haemofiltration, for dialysis practitioners. It provides guidance on the user's responsibility for fluids used in haemodialysis and related therapies once the equipment used in its preparation has been delivered and installed. Contact: Jill Zajac

AAMI/ISO 23500-2-202x, **Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies** (identical national adoption of ISO 23500-2:2024 and revision of ANSI/AAMI/ISO 23500-2-2019). This document specifies requirements and recommendations for individual water treatment devices and water treatment systems assembled from one or more of such devices. This document is directed at the individual or company that specifies the complete water treatment system and, the supplier who assembles and installs the system. Since systems can be assembled from a number of individual water treatment devices, the provisions of this document are also directed at the manufacturers of these devices, provided that the manufacturer indicates that the device is intended to be used to supply water for haemodialysis and related therapies. Contact: Jill Zajac

AAMI/ISO 23500-3-202x, Preparation and quality management of fluids for haemodialysis and related therapies — Part 3:Water for haemodialysis and related therapies (identical national

adoption of ISO 23500-3:2024 and revision of ANSI/AAMI/ISO 23500-3-2019). This document specifies the minimum chemical and microbiological quality requirements, for water used for preparation of dialysis fluids, concentrates, and for the reprocessing of haemodialysers, together with the necessary steps to ensure conformity with the requirements. It provides guidance for the ongoing monitoring of the purity of such water in terms of chemical and microbiological quality. This document is applicable to - water used in the preparation of dialysis fluids for haemodialysis, haemodiafitraytion and haemofiltration and the reprocessing of haemodialysers - water used in the preparation of concentrates. Contact: Jill Zajac

AAMI/ISO 23500-4-202x, Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies (identical national adoption of ISO 23500-4:2024 and revision of ANSI/AAMI/ISO 23500-4-2019). This document specifies chemical and microbiological requirements for concentrates used for haemodialysis and related therapies and applies to the manufacturer of such concentrates. This document is applicable to - concentrates in both liquid and powder forms. - additives, also called spikes, which are chemicals that can be added to the concentrate to supplement or increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. - equipment used to mix acid and bicarbonate powders into concentrate at the user's facility. Contact: Jill7 Zajac

AAMI/ISO 23500-5-202x, Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies (identical national adoption of ISO 23500-5:2024 and revision of ANSI/AAMI/ISO 23500-5-2019). This document specifies minimum chemical and microbiological quality requirements for dialysis fluids used in haemodialysis and related therapies. This document applies to - dialysis fluids used for haemodialysis and haemodiafiltration, - substitution fluid produced online for haemodiafiltration and haemofiltration based on dialysis fluid. Contact: Jill Zajac

Comments due 26 August 2024

AAMI EQ93, 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 (reaffirmation of an American National Standard). This standard provides consensus definitions for key terms used in medical equipment management around the maintenance, repair and servicing of

medical devices, so that all stakeholders involved in the regulation, management and use of medical devices have common understanding when they are used. Contact: Mike Miskell

New Work

Initiation of the following New Work Items have 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 SM-WG05, Medical Device Security Working Group. The working group is developing a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices*. This consensus report will provide guidance for security risk estimation within the context defined by ANSI/AAMI SW96: 2023 *Standard for medical device security—Security risk management for device manufacturers*. Contact: Rose Kodzwa.

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.

AMENDMENT! AAMI ST91:2021, Flexible And Semi-Rigid Endoscope Processing In Health Care Facilities. Contact: Tommy Kim

ADOPTION! AAMI/ISO 8637-1:202x, Extracorporeal systems for blood purification Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (identical national adoption of ISO 8637-1:2024 Ed 2.) Contact: Jill Zajac

ADOPTION! AAMI/ISO 8637-2:202x, Extracorporeal systems for blood purification Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (identical national adoption of ISO 8637-2:2024 Ed 2.) Contact: Jill Zajac

ADOPTION! AAMI/ISO 8637-3:202X, Extracorporeal systems for blood purification Part 3: Plasmafilters (identical national adoption of ISO 8637-3:2024 Ed 2.) Contact: Jill Zajac

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:

Industry: *A member of a consensus body who, as an individual or organizational representative, is 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 shall be classified as an Industry Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

User: *A member of a consensus body who, as an individual or organizational representative, 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 shall be classified as a User Interest stakeholder. Individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

Regulatory: *A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.*

General interest: *A member of a consensus body who, as an individual or organizational representative, has a general direct and 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 shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

Other Interest: *A member who does not fit into any of the preceding interest categories but who still has an identifiable material interest in, or specialized knowledge of the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as an Other Interest stakeholder. The particular interest shall be declared and documented.*

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

AAMI BE-WG02, Degradation aspects related to biological testing Working Group. AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-9:2019, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO/TS 37137-1:2021, *Biological evaluation of absorbable medical devices — Part 1: General requirements* Contact: Rose Kodzwa

AAMI BE-WG08, Irritation and sensitization Working Group. AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-10:2021, *Biological evaluation of medical devices — Part 10*. Contact: Rose Kodzwa

AAMI BE-WG11, Allowable limits for leachable substances Working Group. AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-17:2023, *Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents*. Contact: Rose Kodzwa

AAMI BE-WG12, Sample preparation and reference materials Working Group. AAMI is seeking user, regulatory, and general interest members to participate in the expedited adoption of ISO 10993-12:2021, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*. Contact: Rose Kodzwa

AAMI BE-WG19, Tissue Product Safety Working Group. AAMI is seeking industry, user, regulatory, and general interest members for the newly formed working group to provide input on ISO TC/194/WG 19 activities. Contact: Rose Kodzwa

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking industry, user, regulatory, and general interest members to participate in the revision of ISO 7199, C*ardiovascular implants and artificial organs — Blood-gas exchangers Blood-gas exchangers 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 reaffirmation and future revision of AAMI CI86-2017, *Cochlear implant systems—Requirements for safety, functional verification, labeling and reliability reporting*. Contact**:** Mike Miskell

AAMI CP, Combination Products Committee. The committee is seeking user, regulatory, and general interest/regulator members to contribute to the development and review of various TIRs Contact: Jill Zajac

AAMI CV, Cardiac Valves Committee. The committee is seeking user, regulatory, and general interest members to participate in user input on the US position of amendments to ISO 5840-1:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements;* ISO 5840-2:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes;* and ISO 5840-3:2021, *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 Working Group. The committee 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 EQ-WG02, Servicing Vocabulary Working Group. The working group is seeking regulatory and general interest members to participate in the reaffirmation of AAMI EQ93:2019/Ed. 1, *Medical equipment management - Vocabulary used in medical equipment programs.* Contact: Mike Miskell

AAMI EV-WG13, Lens Removal and Vitrectomy Devices Working Group. The working group is seeking additional members from regulatory, user and general interest categories to participate in the identical adoption project for IEC 80501-2-58:2024, *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.* Contact: Ladan Bulookbashi

AAMI HF, High Frequency Therapeutic Device Committee The working group is seeking regulatory, user and general interest members to participate in the adoption project for IEC 60601-2-2:2017/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. Contact: Ladan Bulookbashi

AAMI HIT-WG01, Health IT Risk Management Working Group. The working group is seeking 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: Amir Aboutaleb or Matt Williams

AAMI HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking 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: Amir Aboutaleb or Matt Williams

AAMI HIT-WG03, Health IT Usability Working Group. The working group is seeking 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: Amir Aboutaleb or Matt Williams

AAMI IP, Implantable Infusion Pumps Committee The working group is seeking industry, regulatory, user and general interest members to participate in the adoption project for ISO 14708-04:2022 (Ed.2),

Implants for surgery—Active implantable medical devices—Part 4: Implantable infusion pumps. Contact: Mike Miskell

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-WG02, Implantable neurostimulator Working Group The working group is seeking regulatory, user and general interest members to participate in the reaffirmation of ANSI/AAMI/ISO 14708-3:2017, *Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators*. Contact: Mike Miskell

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-WG03, Pacemaker & ICD MRI Compatibility This working group is seeking user, regulatory, 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 RB, Robotics Committee. This committee is seeking additional members from regulatory, user and general interest categories to participate in the identical adoption projects for IEC 80601-2-77:2019/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment*, and IEC 80601-2-78:2019/AMD1:2024, *Amendment 1 - Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment*, compensation or alleviation. Contact: Ladan Bulookbashi

AAMI RD, Renal Disease and Detoxification Committee. The committee is seeking user, and general interest/regulator members to participate in the development of a TIR on empty bed contact time calculation and carbon sizing, and identical adoption of the ISO 23500-1 through -5:2024, *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 identical adoption projects for 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 SM-WG03, Interoperability Working Group. The group is seeking general interest, regulatory, and users. The committee is developing a new American National Standard, AAMI SW114 - *Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. Contact: Rose Kodzwa

AAMI SM-WG05, Medical Device Security Working Group. The group is seeking general interest, regulatory, and users to participate in the revisions of AAMI TIR57:2016/(R)2023, *Principles for medical device security—Risk Management* and a new consensus report (CR) with the title *Security Risk Estimation for Medical Devices.* Contact: Rose Kodzwa

AAMI SM-WG06, Wireless Working Group. The group is seeking general interest, regulatory, and users to participate in the reaffirmation of AAMI TIR69:2017/(R)2020 – *Risk management of radio-frequency wireless coexistence for medical devices and systems*. Contact: Rose Kodzwa

AAMI SM-WG08, Software Defect Classification Working Group. The group is seeking general interest, regulatory, and users to participate in the reaffirmation of ANSI/AAMI SW91:2018 – *Classification of defects in health software.* Contact: Rose Kodzwa

AAMI SM-WG10, Cloud Computing Working Group. The 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 SP, Sphygmomanometer Committee The committee is seeking regulatory, and general interest members to participate in the identical adoption project for ISO 81060-3:2022/Ed.1, *Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type*. Contact: Ladan Bulookbashi

AAMI ST-WG07 – Packaging working group. The working group is seeking general interest, regulatory, and user members to participate in the reaffirmations of ANSI/AAMI/ISO 11607-1:2019, Ed.2, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems* and AAMI/ISO 11607-2:2019, Ed.2, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes*. 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 development of AAMI TIR52/Ed.2, *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, Ed.1,

Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products. Contact: Gigi Golriz.

AAMI ST-WG42 - Dry heat sterilization. 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, Ed. 2, *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*. Contact: Gigi Golriz.

AAMI ST-WG43, Hospital steam sterilizer Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of AAMI ST8/Ed.7, *Hospital steam sterilizers*. Contact: Gigi Golriz.

AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. Contact: Tommy Kim

AAMI ST-WG86, Quality System for Device Processing Working Group. The group is seeking general interest and regulatory/government members to participate in the amendment of AAMI ST90, *Processing of health care products—Quality management systems for processing 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, Ed.2, *Containment devices for reusable medical device sterilization*. Contact: Gigi Golriz.

AAMI TIB, Transfusion, Infusion, and 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 VP, Vascular Prostheses Committee. 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* the revision of ISO 7198 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 (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.

July 2024

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group (open meeting) 18 July 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

AAMI CV, Cardiac Valves Committee. (open meeting) 22 July 2024, 10:30h to 12:00h EST, web meeting. The WG will review 5840-1:2021/DAmd1, 5840-2:2021/DAmd1 and 5840-3:2021/DAmd1 comments and discuss new work items. Contact: Jill Zajac

August 2024

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 7 August 2024, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST, to discuss 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) 15 August 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

September 2024

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 4 September 2024, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST, to discuss 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) 19 September 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Mike Miskell

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.

September 2024

ISO/TC 150, Implants for surgery and affiliated SC and WG meetings (closed meetings). Berlin, DE, September 9-13, 2024, 09:00h to 17:00h daily local time. Contact: Jill Zajac or Ladan Bulookbashi

October 2024

15 August 2024, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discus meetings). London, UK, 14-18 and Edinburgh, Scotland, 21-25 October 2024, 09:00h to 17:00h daily local time. Contact: Colleen Elliott or Ladan Bulookbashi

November 2024

ISO/TC 121/SC2, Airway devices and related equipment and ISO/TC 121/SC6, Medical gas supply systems (closed meetings). Vienna, Austria, November 18-22. Contact: Colleen Elliott.