STANDARDS UPDATE

AAMI Standards Insider

AAMI's Standards Insider has been revamped. Please view our quarterly 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.

AAMI Standards Management Platform (StMP)

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

Publications

PUBLISHED! **ANSI/AAMI/ISO 11607-1:2019/A1:2023,** Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management. Click here for more information.

PUBLISHED! **ANSI/AAMI/ISO 11607-2:2019/A1:2023,** Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management. Click here for more information.

PUBLISHED! **ANSI/AAMI ST58:2024**; Chemical sterilization and high-level disinfection in health care facilities [supersedes ANSI/AAMI ST58:2013/(R)2018]. 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 November 18, 2024

AAMI/ISO 11135:2014 (R202x), Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices (reaffirmation of a national adoption). This standard specifies requirements for the

development, validation, and routine control of an ethylene oxide sterilization process for medical devices. Contact: Tommy Kim

AAMI/ISO 11140-1:2014 (R202x), Sterilization of health care products—Chemical indicators—Part 1: General requirements (reaffirmation of a national adoption). This standard specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances. Contact: Tommy Kim

AAMI/ISO 11140-3: 2007/(R)2015 (R202x), Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (reaffirmation of a national adoption) This standard specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1. Contact: Tommy Kim

AAMI/ISO 11140-4:2007/(R)2015, Sterilization of health care products - Chemical indicators - Part 4- Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration (reaffirmation of a national adoption). This standard specifies the performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick-type test for steam sterilizers for wrapped health care goods (instruments, etc., and porous loads). Contact: Tommy Kim

AAMI/ISO 11140-5:2007/(R)2015, Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick-type air removal tests (reaffirmation of a national adoption). This standard specifies the requirements for Class 2 indicators for Bowie and Dick-type air removal tests used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles. Additionally, this part of ISO 11140 includes test methods and equipment used to meet these performance requirements. Contact: Tommy Kim

AAMI/ISO 14117:2019, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices (reaffirmation of a national adoption) This standard specifies a comprehensive test methodology for the evaluation of the electromagnetic (EM) compatibility of active implantable cardiovascular devices. The devices addressed by this standard include those that provide one or more therapies for bradycardia, tachycardia, and cardiac resynchronization. This document details test methods appropriate for the interference frequencies at issue. It specifies performance limits or requires disclosure of performance in the presence of EM emitters, where indicated. Contact: Mike Miskell

AAMI RD47-2020 (R202x), Reprocessing of hemodialyzers (reaffirmation)
This standard is addressed to the physician responsible for reprocessing hemodialyzers. It covers personnel and patient considerations, records, equipment, physical plant and environmental safety, reprocessing material, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, and

quality assurance and quality control. This document does not endorse either single use or reuse of dialyzers. Contact: Jill Zajac

Comments due December 9, 2024

AAMI ST8-202X, Hospital steam sterilizers (revision of ANSI/AAMI ST8-2013 (R2018) (Revision). This standard applies to steam sterilizers that are intended for use in hospitals and other health care facilities and that have a volume greater than 56.63 liters (L) (2 cubic feet [ft^3]). Contact Gigi Golriz

Comments due December 30, 2024

AAMI HE75-202X, Human Factors Engineering – Design of Medical Devices (revision of HE75:2009) (Revision). This standard provides detailed human factors engineering (HFE) design guidance to those who are responsible for HFE work within medical device companies. It contains extensive design guidance, examples, checklists, and case studies. Contact Rachel Ann Porter

AAMI/ISO 15882:2008/(R)2013, Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results (reaffirmation of national adoption). This document provides guidance for the selection, use and interpretation of results of chemical indicators used in process definition, validation and routine monitoring and overall control of sterilization processes. AAMI/ISO 15882:2008 applies to indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor one or more of the variables required for a sterilization process. These chemical indicators are not dependent for their action on the presence or absence of a living organism. Contact: Tommy Kim.

AAMI ST65:2008/(R)2018, Processing of reusable surgical textiles for use in health care facilities (reaffirmation of standard). This standard provides guidelines for the proper handling, processing, and preparation of reusable surgical textiles either on-site or off-site for use in health care facilities. This recommended practice specifically addresses design criteria for functional work areas; staff qualifications, education, training, dress codes, and other personnel considerations; receiving and handling of soiled surgical textiles; laundry processing considerations; transport of both soiled and clean surgical textiles; installation, care, and maintenance of laundry equipment; quality control; and

regulatory considerations. Definitions of terms and a bibliography are also provided. Contact: Tommy Kim.

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 PC-WG01, Transvenous Cardiac Leads Working Group. The working group is developing the following two new AAMI Standards (Contact: Mike Miskell):

- AAMI PC85; *Requirements for Fatigue Performance of Cardiac Rhythm Management Leads*. This standard outlines requirements for characterizing the fatigue performance of cardiac leads based on benchtop fatigue testing and bending stiffness measurements, focusing on conductor integrity. It excludes polymer and elastomeric components, bonds, biodegradation, and corrosion. Methods are provided for measuring lead bending stiffness and fatigue strength in different regions, for preconditioning leads, and for accepting fatigue performance through comparison with proven designs or using a Bayesian model to predict survival rates based on lead stiffness.

- AAMI PC125; *Implantable leads—Perforation propensity—Requirements and test methods*. This standard establishes a method to assess the perforation propensity of permanently implantable cardiac pacing and defibrillation leads for transvenous use in the right atrium or ventricle, excluding preformed "J"-shaped and left bundle branch area pacing leads. It focuses on the acute phase post-implantation, prior to fibrotic encapsulation, and does not address all aspects of perforation propensity, such as implant technique or patient-specific factors. The methods and criteria are based on conventional leads and may not apply to novel designs or unique clinical applications.

AAMI RD, Renal Disease and Detoxification Committee. The committee is developing a new AAMI Technical Information Report (TIR123); *User Considerations - Design of Activated Carbon Systems for Hemodialysis with Non-Continuous Flow – Empty-Bed Contact Time (EBCT) Calculation.* This TIR provides guidance for how the non-continuous flow of fluids impacts the calculation of EBCT and addresses other considerations when working with filters in this type of system. EBCT is a calculated value which assumes continuous flow through the carbon bed. This TIR will provide guidance on the application of ISO 23500 and educate users in clinics. Contact: Jill Zajac

AAMI ST-WG11, General Criteria for Sterilization Processes and Sterilizing Equipment Working Group. The working group will be developing a series of AAMI Technical Information Reports (AAMI TIR124-X); *Guidance on transferring health care products between gas or vapor sterilization modalities*. These series provide guidance on alignment of various gas and vapor sterilization modalities with ISO 14937 and other

relevant standards for industrial sterilization (not health care; not decontamination) where there is a gap in guidance relative to the validation, routine control, biological indicators and sterilant residuals for the modality. Examples of such modalities can be found in AAMI TIR17. Each part of this series will focus on a specific modality. Contact: Gigi Golriz.

AAMI ST-WG61, Chemical Sterilants Hospital Practices Working Group. The working group will be developing a new AAMI Technical Information Report (AAMI TIR121); *Guidance on cleaning and disinfection of patient care equipment in patient care areas to render safe for handling and next patient use.* This TIR provides guidance to health care personnel who perform cleaning and low-level and intermediate level disinfection of patient care equipment outside of the sterile processing area. Excludes devices and materiel addressed by ANSI/AAMI ST79 and ANSI/AAMI ST91 and environmental surfaces. Contact: Tommy Kim

AAMI ST-WG96, Compatibility of Materials Subject to Sterilization Working Group. The working group will be developing a new AAMI Technical Information Report (AAMI TIR122); *Considerations for Material Retention of Sterilant Residuals in Ethylene Oxide Sterilization*. This TIR provides: fundamental background on factors that may affect sterilant residual retention by device materials; data showing relative retention of sterilant residuals retained by various materials after processing in ethylene oxide; guidelines on how to address the impact of medical device material selection or material changes on the potential for sterilant residual retention; and provides data on the impact of cycle attributes and aeration conditions (e.g. temperature, vacuum changes, etc.) on retained EO residuals. It will clarify differences in the effects of EO retention by materials between occupational or environmental EO exposure and exposure to patients through sterilized devices. Contact: Gigi Golriz.

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.

REVISION! AAMI TIR12:202X, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers. Contact: Gigi Golriz.

REVISION! AAMI TIR57:202X, Principles for medical device security – Risk management. Contact: Rose Kodzwa

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. The working group is seeking user, regulatory, and general interest members to participate in the development of ISO 10993-9:2019/ED.3, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO 10993-15:2019/ED.2, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys.* Contact: Rose Kodzwa

AAMI BE-WG08, Irritation and sensitization Working Group. The working group 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-WG19, Tissue Product Safety Working Group. The working group 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, user, regulatory, and general interest members to participate in the development of ISO 18193:2021, *Cardiovascular implants and artificial organs — Cannulae for extracorporeal Circulation Amendment 1 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 US adoption of AAMI/ISO 5910: 2024, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.* Contact: Jill Zajac

AAMI DP, Medical Device Particulates Committee. The committee is seeking user, industry, regulatory and general interest categories to participate in review and reaffirmation of AAMI TIR42:2021; *Evaluation of particulate associated with vascular medical devices* Contact: Jill Zajac

AAMI DPC-10, Needles Working Group. The working group 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-WG01, HTM Program Management Working Group. The working group is seeking regulatory and general interest members to participate in the revision of AAMI EQ89:2015/Ed.1, *Guidance for the use of medical equipment maintenance strategies and procedures.* Contact: Mike Miskell

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 EQ-WG03, Technology Acquisition Working Group. The working group is seeking regulatory and general interest members to participate in the development of AAMI EQ94:202X/Ed.1, *Healthcare technology acquisition.* 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 committee 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: Rose Kodzwa

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: Rose Kodzwa

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: Rose Kodzwa

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-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-WG01, Transvenous Cardiac Leads Working Group. The working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of two new AAMI standards: AAMI PC86, *Requirements for Fatigue Performance of Cardiac Rhythm Management Leads;* and AAMI PC125, *Implantable leads—Perforation propensity—Requirements and test methods.* Contact: Mike Miskell

AAMI PC-WG02, EMC Test Protocols for Pacemakers, ICDs & CRTs Working Group. The working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in reaffirmation of AAMI/ISO 14117:2019, *Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*. Contact: Mike Miskell

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. The 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. The 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 specifically looking for additional members to represent user, general, and regulatory interest categories to participate in the development of a new Technical Information Report on *User Considerations - Design of Activated Carbon Systems with Non-Continuous Flow – Empty-Bed Contact Time (EBCT) Calculation*, and identical adoption of the ISO 23500 parts 1-5:2024, *Preparation and quality management of fluids for haemodialysis and related therapies standards* and identical adoption of ISO 8637-1 through -3, *Extracorporeal systems for blood purification series standards.* Contact: Jill Zajac

AAMI SM-WG03, Interoperability Working Group. The working 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 working 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 working 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 working 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 working 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-WG01, Industrial Ethylene Oxide Sterilization Working Group. The working group is seeking user, general interest, and regulatory/government members to participate in the reaffirmation of AAMI/ISO 11135:2014, *Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*. Contact: Tommy Kim.

AAMI ST-WG06, Chemical Indicators Working Group. The working group is seeking general interest and regulatory/government members to participate in the reaffirmations of AAMI/ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, AAMI/ISO 11140-3: 2007/(R)2015, *Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*, AAMI/ISO 11140-4:2007/(R)2015, *Sterilization of health care products - Chemical indicators - Part 4- Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*, AAMI/ISO 11140-5:

2007/(R)2015, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick-type air removal tests, and* AAMI/ISO 15882:2008/(R)2013*, Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results.* Contact: Tommy Kim.

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-WG11, General Criteria for Sterilization Processes and Sterilizing Equipment Working Group. The working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of a new series of Technical Information Reports (AAMI TIR124-X); *Guidance on transferring health care products between gas or vapor sterilization modalities*. Contact: Gigi Golriz.

AAMI ST-WG42, Dry heat sterilization Working Group. 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-WG45, Processing of tattoo machines and accessories in healthcare settings Working Group. The working 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-WG61, Chemical Sterilants Hospital Practices Working Group. The working group is specifically looking for additional members to represent general and regulatory interest categories to participate in development of a new Technical Information Report (AAMI TIR121); *Guidance on cleaning and disinfection of patient care equipment in patient care areas to render safe for handling and next patient use.* Contact: Tommy Kim

AAMI ST-WG83, Reusable Surgical Textiles Processing Working Group. The working group is specifically looking for additional members to represent general, regulatory, and user interest categories to participate in the reaffirmation of AAMI ST65:2008/(R)2018, Processing of reusable surgical textiles for use 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 ST-WG96, Compatibility of Materials Subject to Sterilization Working Group. The working group is specifically looking for additional members to represent user, general, and regulatory interest categories to participate in development of a new Technical Information Report (AAMI TIR122); *Considerations for Material Retention of Sterilant Residuals in Ethylene Oxide 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 VI, Cardiovascular Absorbable Implants Committee. The committee is seeking additional members in user, regulatory and general interest categories to participate in the development of the U.S. position towards documents under ISO/TC150/SC2/WG7 including the systematic review of ISO/TS 17137:2021, *Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants* Contact: Jill Zajac

AAMI VP, Vascular Prostheses Committee. The committee is specifically seeking user, industry, and general interest/regulator members to participate in the revision of ISO 7198:202x, *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 (Standards Monitor Online). Note: If you plan to attend a meeting, please reach out to the committee staff liaison listed below or contact the AAMI Standards Department at (standards@aami.org) indicating the name and date of the meeting.

November 2024

AAMI/UL JC2800, Medical Device Interoperability, (open meeting) 18 November 2024, 11:00h to 12:00h EST, web meeting. The committee meets weekly on Mondays to discuss revisions to AAMI/UL 2800-1:202X. Contact: Rose Kodzwa

AAMI ST-WG61, Chemical Sterilants Hospital Practices Working Group, (open meeting) 5 November 2024, 13:00h to 15:00h EST, 8 November 2024, 10:00h to 12:00h EST, web meeting. The working group is meeting to complete comment resolution for AAMI/WD-1 TIR118:202X. Contact: Tommy Kim.

AAMI ST-WG45 Processing of Tattoo Machines and Accessories in Healthcare Settings Working Group, (opening meeting) 6 November 2024, 13:00h to 14:00h EST, web meeting. The working group is meeting to discuss and determine the project plan for AAMI TIR117:202X. Contact: Tommy Kim.

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 6 November 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/UL JC2800, Medical Device Interoperability, (open meeting) 18 November 2024, 11:00h to 12:00h EST, web meeting. The committee meets weekly on Mondays to discuss revisions to AAMI/UL 2800-1:202X. Contact: Rose Kodzwa

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 21 November 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 SMWG05, Device Security working group (open meeting) 26 November 2024, 11:00h to 12:00h EST, web meeting. The WG meets monthly to discuss revisions to AAMI TIR57:202X. Contact: Rose Kodzwa

AAMI STWG12, Instructions for Reusable Device Reprocessing WG. (open meeting) November 12, 2024, 10:00h to 13:00h EST, web meeting. The group is meeting to discuss comment resolution to the revision of AAMI TIR12-202X. Contact: Gigi Golriz

AAMI STWG15, Assurance of Sterility WG. (open meeting) November 13, 2024, 13:00h to 15:00h EST, web meeting. The group is meeting to establish U.S position and discuss comments for ISO 19930. Contact: Gigi Golriz

December 2024

AAMI TIB-WG04, Elastomeric parts, components and packaging Working Group. (open meeting) 4 December 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 and draft CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: Sam Alameda

AAMI SP, Sphygmomanometer Committee. (open meeting) 05 December 2024, 08:30h to 10:30h EST, web meeting. The committee meets to discuss activities of ISO/TC 121/SC 3/JW 7, Non-invasive blood pressure monitoring equipment. Contact: Ladan Bulookbashi.

AAMI CP, Combination Products Committee. (open meeting) 09 December 2024, 14:30 to 16:00h EST, web meeting. The committee will discuss new work item proposals and upcoming work for the committee. Contact: Jill Zajac

AAMI CI, Cochlear Implants Committee. (open meeting) 16 December 2024, 11:00h to 14:00h EST, web meeting. The WG will meet to discuss the reaffirmation ballot for AAMI CI86:2017 and propose the US position and comments for the systematic review of 14708-7:2019. Contact: Mike Miskell

AAMI EQ-WG01, HTM Program Management Working Group. (open meeting) 18 December 2024, 13:30h to 16:30h EST, web meeting. The WG will meet for project development and timeline planning. Contact: Mike Miskell

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility Working Group. (open meeting) 19 December 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.

November 2024

ISO/TC 121/SC6, Medical gas supply systems. (closed meetings). Vienna, Austria, November 18-22. Contact: Colleen Elliott. (**NOTE:** ISO/TC 121/SC meetings postponed until February 2025)

November 2025

IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings. (closed meetings). Milan, Italy, (Tentatively November 3-14, 2025), 09:00h to 17:00h daily local time. Contact: Colleen Elliott or Ladan Bulookbashi