

## STANDARDS UPDATE

### AAMI Standards Insider

We appreciate everyone who joined us for the AAMI Standards Insider webinar, hosted on 28 September 2023, 1:30pm (EST). 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 is available on the [webpage](#).

### Publications

**REAFFIRMED! AAMI TIR 17:2017/(R)2023**, Compatibility of materials subject to sterilization. Click [here](#) for more information.

**REAFFIRMED! ANSI/AAMI/ISO 10993-3:2014/(R)2023**, Biological evaluation of medical devices—Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. Click [here](#) for more information.

**REAFFIRMED! ANSI/AAMI/ISO 10993-5:2009/(R)2022**, Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity. Click [here](#) for more information.

**REAFFIRMED! ANSI/AAMI/ISO 10993-13:2010/(R)2019**, Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric devices. Click [here](#) for more information.

**REAFFIRMED! ANSI/AAMI/ISO 10993-14:2001/(R)2019**, Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics. Click [here](#) for more information.

**REAFFIRMED! ANSI/AAMI/ISO 10993-16:2020/(R)2022**, Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables. 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 28 November 2023](#)**

**AAMI ST40, Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities.** (reaffirmation of an American National Standard) This recommended practice provides guidelines for decontamination and dry heat sterilization procedures used in dentists' and physicians' offices, laboratories, ambulatory care clinics, and other health care facilities. These guidelines are intended to promote the assurance of sterility by identifying the special considerations that apply to this method of sterilization and by providing recommendations on the proper use of table-top dry heat sterilization processing equipment. This recommended practice also covers facility design considerations, personnel considerations, work practices, and other variables that affect sterility assurance. Contact: [Mike Miskell](#)

**AAMI ST50, Dry heat (heated air) sterilizers.** (reaffirmation of an American National Standard) This standard applies to dry heat (heated air) sterilizers that are intended for use in dental and medical offices, laboratories, ambulatory-care clinics, hospitals, and other health care facilities. Contact: [Mike Miskell](#)

**AAMI/ISO 22441:202X, Sterilization of health care products -- Low temperature vaporized hydrogen peroxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.** (proposed identical national adoption of ISO 22441:2022) This document provides requirements for the development, validation and routine monitoring and control of a low temperature sterilization process for medical devices using vaporized hydrogen peroxide (VH<sub>2</sub>O<sub>2</sub>) as the sterilizing agent. It is also intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, organizations performing process validation of VH<sub>2</sub>O<sub>2</sub> sterilization, and organizations responsible for sterilizing medical devices. Contact: [Mike Miskell](#)

**AAMI/ISO 11607-1:2019/Amd 1:202X, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging.** (proposed identical national adoption of ISO 11607-1:2019/Amd 1:2023) This amendment narrows the scope to AAMI/ISO 11607-1:2019 and revises some terms and definitions, general requirements, design and development for packaging systems, and annexes relating to risk management. Contact: [Mike Miskell](#)

**AAMI/ISO 11607-2:2019/Amd 1:202X, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.** (proposed identical national adoption of ISO 11607-2:2019/Amd 1:2023) This amendment narrows the scope to AAMI/ISO 11607-

2:2019 and revises some terms and definitions, general requirements, and annexes relating to risk management. Contact: [Mike Miskell](#)

## **Comments due 19 December 2023**

**AAMI/ISO 13408-1:202X, Aseptic processing of health care products — Part 1: General requirements.** (proposed identical national adoption of ISO 13408-1:2023) This document specifies the general requirements for, and offers guidance on, processes, programs and procedures for development, validation and routine control of aseptic processing of health care products. This document includes requirements and guidance relative to the overall topic of aseptic processing. Contact: [Mike Miskell](#)

**AAMI/ISO 11137-2, Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.** (reaffirmation of an American National Standard) This document specifies methods for determining the minimum dose needed to achieve a specified requirement for sterility and methods to substantiate the use of 25 kGy or 15 kGy as the sterilization dose to achieve a sterility assurance level, SAL, of 10<sup>-6</sup>. This document also specifies methods of sterilization dose audit used to demonstrate the continued effectiveness of the sterilization dose. This document defines product families for sterilization dose establishment and sterilization dose audit. Contact: [Mike Miskell](#)

**AAMI/ISO 11137-2:2013/Amd 1:202X, Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose—Amendment 1.** (proposed identical national adoption of ISO 11137-2:2013/Amd 1: 2022) This amendment adds new normative references, adds a subclause to clause 6 Methods of dose establishment, updates clause 9 title, updates subclause 9.1 title and text. Contact: [Mike Miskell](#)

## **Comments due 1 January 2024**

**AAMI/ISO 11138-3, Sterilization of health care products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes.** (reaffirmation of an American National Standard) This document specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilization processes employing moist heat as the sterilizing agent. Contact: [Tommy Kim](#)

**AAMI/ISO 11138-4, Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes.** (reaffirmation of an American National Standard) This document provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods intended for use in assessing the performance of sterilization processes

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employing dry heat as the sterilizing agent at sterilizing temperatures within the range of 120°C to 180°C.

Contact: [Tommy Kim](#)

**AAMI/ISO 11138-5, Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes.** (reaffirmation of an American National Standard) This document Specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilization processes employing low-temperature steam and formaldehyde as the sterilizing agent.

Contact: [Tommy Kim](#)

**AAMI ST58:202X, Chemical sterilization and high-level disinfection in health care facilities.** (revision of an American National Standard) This standard provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use in hospitals and other health care facilities. These guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment. Contact:

[Tommy Kim](#)

## New Work

**AAMI AI, Artificial Intelligence Committee.** The committee will work on the development of AAMI AI120/Ed.1, *Bias Management for Machine Learning Systems*. This new standard will provide a methodology (based on ISO 14971) to identify and manage unwanted bias in the performance of Machine Learning (ML) systems. Contact: [Rachel Porter](#)

**AAMI AI, Artificial Intelligence Committee.** The committee will work on the development of AAMI CR515/Ed.1, *Taxonomy of Medical Device Machine Learning Cybersecurity Threats and Protection Techniques*. This new consensus report will identify the unique cybersecurity threats and vulnerabilities along with potential controls for Machine Learning (ML) based medical devices. This would include a discussion about different types of attacks on ML systems, for e.g., privacy attacks, poisoning attacks, and availability attacks, as well as a discussion about the vulnerabilities that enable such attacks. An analysis of the vulnerabilities that can manifest throughout the data lifecycle will also be presented. Potential controls to mitigate these threats and vulnerabilities will also be explored. Contact: [Rachel Porter](#)

## 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:

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**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 AI, Artificial Intelligence Committee.** AAMI is seeking user, regulatory, and general interest members to participate in the development of a new standard, AAMI AI120 – *Bias Management for Machine Learning (ML) Systems*. Contact: [Rachel Porter](#)

**AAMI BE, Biological Evaluation Committee.** AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmations of AAMI/ISO 13022, *Medical products containing viable human cells — Application of risk management and requirements for processing practices*, AAMI/ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3:*

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*Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents, as well as the expedited adoptions of ISO 22442-1:2020, Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management and ISO 22442-2:2020, Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling.* Contact: [Chenai Maguwah](#)

**AAMI BE-WG2, Degradation aspects related to biological testing Working Group.** AAMI is seeking industry, user, general interest, and regulatory 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: [Chenai Maguwah](#)

**AAMI BE-WG8, Irritation and sensitization Working Group.** AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-10:2021, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization* and ISO 10993-23:2021, *Biological evaluation of medical devices — Part 23: Tests for irritation.* Contact: [Chenai Maguwah](#)

**AAMI BE-WG9, Effects on blood Working Group.** AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of AAMI/ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood.* Contact: [Chenai Maguwah](#)

**AAMI BE-WG12, Sample preparation and reference materials Working Group.** AAMI is seeking industry, user, general interest, and regulatory 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: [Chenai Maguwah](#)

**AAMI BG, Blood/Gas Exchange Device Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO 7199, *Cardiovascular implants and artificial organs — 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: [Ladan Bulookbashi](#)

**AAMI CN, Small Bore Connectors Committee.** The committee is seeking user, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI/ISO 80369-5, *Small-*

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*bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications; and in the expedited adoption of AAMI/ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.* Contact: [Colleen Elliott](#)

**AAMI CP, Combination Products Committee.** The committee is seeking user, industry, 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, industry, and general interest/regulator members to participate in the US adoption 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-WG01, Healthcare Technology Management (HTM) Program Management working group.** The working group is seeking general interest, industry, and regulatory members to participate in the revision of ANSI/AAMI EQ56:2013, *Recommended practice for a medical equipment management program*. Contact: [Mike Miskell](#)

**AAMI EQ-WG04, Alternative Equipment Maintenance Working Group.** The working group is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ103/Ed.1, *Alternative equipment maintenance in healthcare delivery organizations*. Contact: [Mike Miskell](#)

**AAMI EQ-WG05, HTM Education Programs Working Group.** The working group 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: [Mike Miskell](#)

**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](#)

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**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](#)

**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: [Ladan Bulookbashi](#)

**AAMI MC, Mechanical Circulatory Support Systems Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in the development of documents under ISO/TC150/SC2/WG2 including the early 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: [Ladan Bulookbashi](#)

**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 QM-WG02, General aspects from medical devices** This working group is seeking user and general interest/regulatory members to participate in the national adoption of ISO 20417, *Medical devices — Information to be supplied by the manufacturer*. Contact: [Amanda Benedict](#)

**AAMI RD, Renal Disease and Detoxification Committee.** The committee is seeking industry, user, and general interest/regulator members to participate in the development of new TIRs including backflow prevention, wall boxes, and water distribution loops; a TIR on empty bed contact time calculation and



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carbon sizing, input on 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 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: [Chenai Maguwah](#)

**AAMI SM-WG05, Medical Device Security Working Group.** The group is seeking general interest, regulatory, and users to participate in the future revisions of AAMI TIR57, *Principles for medical device security—Risk Management* and AAMI TIR97, *Principles for medical device security—Postmarket risk management for device manufacturers.* Contact: [Chenai Maguwah](#)

**AAMI SM-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: [Chenai Maguwah](#)

**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: [Chenai Maguwah](#)

**AAMI SM-WG10, Cloud Computing Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of a new TIR, AAMI TIR115: *Cloud – Guidance for the appropriate use of public cloud computing to enable medical device functions.* Contact: [Chenai Maguwah](#)

**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-WG02, Radiation sterilization working group.** The working group is seeking general interest, regulatory, and user members to contribute to development of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems,* reaffirmation of ANSI/AAMI/ISO 11137-2:2013/(R)2019, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization*

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*dose, national adoption of AAMI/ISO 11137-2:2013/Amd 1:202X, Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose—Amendment 1.* Contact: [Mike Miskell](#).

**AAMI ST-WG03, Industrial moist heat sterilization working group.** The working group is seeking general interest, regulatory, and user members to contribute to development of a new TIR AAMI TIR116/Ed.1, *Guidance on designation of a medical product to a device product family and acceptance of a product into a product family by equivalence using moist heat sterilization.* Contact: [Mike Miskell](#).

**AAMI ST-WG04, Biological indicators working group.** The working group is seeking general interest, regulatory, and user members for the reaffirmation of AAMI/ISO 11138-3, Sterilization of health care products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes, AAMI/ISO 11138-4, Sterilization of health care products-Biological indicators-Part 4: Biological indicators for dry heat sterilization processes, AAMI/ISO 11138-5, Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes. Contact: [Tommy Kim](#).

**AAMI ST-WG07, Packaging working group.** The working group is seeking general interest, regulatory, and user members to participate in the national adoption of ISO 11607-1:2019/Amd 1:2023, Ed. 2, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ISO 11607-2:2019/Amd 1:2023, Ed.2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.* Contact: [Mike Miskell](#).

**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.* Contact: [Mike Miskell](#).

**AAMI ST-WG09 – Aseptic processing working group.** The working group is seeking general interest, regulatory, and user members to participate in the national adoption of ISO 13408-1:2023, Ed. 3, *Aseptic processing of health care products — Part 1: General requirements.* Contact: [Mike Miskell](#).

**AAMI ST-WG16 - Vaporized Hydrogen Peroxide Sterilization working group.** The working group is seeking general interest, regulatory, and user members to participate in the national adoption of ISO 22441:2022, Ed. 1, *Sterilization of health care products -- Low temperature vaporized hydrogen peroxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.* Contact: [Mike Miskell](#).

**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* and ANSI/AAMI ST50:2004/(R)2018, Ed. 2, *Dry heat (heated air) sterilizers.* Contact: [Mike Miskell](#).

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**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: [Mike Miskell](#).

**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-WG91, Resistometer Working Group.** The group is seeking user, general interest, and regulatory/government members to participate in the reaffirmation of AAMI/ISO 18472:2018, *Sterilization of health care products—Biological and chemical indicators—Test equipment*. Contact: [Tommy Kim](#)

**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, 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 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*. 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](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.*

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### **November 2023**

**AAMI EQ-WG01, HTM Program management working group** (open meeting) 27 November 2023, 13:00h to 15:00h EST, 29 and 30 November 2023, 15:00h to 17:00h EST, virtual meetings. Contact: [Mike Miskell](#)

### **December 2023**

**AAMI SP, Sphygmomanometer Committee** (open meeting) 5 December 2023, 12:00h to 13:30h EST, virtual meeting. The committee meets to obtain updates on the activities of Joint Working Group 7 of ISO/TC 121/SC 3-IEC/SC 62D, Non-invasive blood pressure monitoring equipment. Contact: [Ladan Bulookbashi](#)

**AAMI EQ-WG04, Alternative equipment maintenance working group** (open meeting) 7 December 2023, 10:00h to 13:00h EST, virtual meeting. Contact: [Mike Miskell](#)

**AAMI EQ-WG05, HTM Education programs working group** (open meeting) 7 December 2023, 14:00h to 16:00h EST, virtual meeting. Contact: [Mike Miskell](#)

**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 13 December 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1<sup>st</sup> 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](#)

### **January 2024**

## **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 2023**

**ISO/TC 150/SC2/WG4 Blood WG 4 Blood/gas exchangers**, WG meeting (closed meetings). Virtual, 29th November 2023, 9:00h to 11:00h EDT time. Contact: [Jill Zajac](#)

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**ISO/TC 150/SC2/WG3 Vascular prostheses**, WG meeting (closed meetings). Virtual, 30th November 2023, 10:00h to 12:00h EDT time. Contact: [Jill Zajac](#)

### ***December 2023***

**ISO/TC 210, Quality management and corresponding general aspects for products with a health purpose including medical devices** and affiliated (J)WG meetings (closed meetings). Paris, France, 5-8 and 11-15 December 2023, 09:00h to 17:00h daily local time. Contact: [Amanda Benedict](#)

### ***February 2024***

**ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care and JWG12** (closed meetings). Sydney, Australia, 5 - 9 February 2024. Contact: [Colleen Elliott](#)