STANDARDS UPDATE

AAMI Standards Insider

Join us, for the next AAMI Standards Insider webinar 17 Aug 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

Check the next edition of the SMO for any new publications.

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 24 July 2023

AAMI/ISO 10993-3, Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (reaffirmation of an identical national adoption of ISO 10993-3:2014) Specifies strategies for hazard identification and tests on medical devices for genotoxicity, carcinogenicity, and reproductive and developmental toxicity. Contact: Chenai Maguwah

AAMI/ISO 10993-4, Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (reaffirmation of an identical national adoption of ISO 10993-4:2017) Specifies general requirements for evaluating the interactions of medical devices with blood. Contact: Chenai Maguwah

AAMI/ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (reaffirmation of an identical national adoption of ISO 10993-5:2009) Describes test methods to assess the in vitro cytotoxicity of devices. These methods specify the incubation of cultured cells either directly or through diffusion with extracts of the device, and/or in contact with a device. These methods are

designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters. Contact: Chenai Maguwah

AAMI/ISO 10993-13, Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (reaffirmation of an identical national adoption of ISO 10993-13:2010) Describes general requirements for the design of tests in a simulated environment for identifying and quantifying degradation products from finished polymeric medical devices ready for clinical use. Contact: Chenai Maguwah

AAMI/ISO 10993-14, Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics (reaffirmation of an identical national adoption of ISO 10993-14:2001) Specifies two methods for obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification. Contact: Chenai Maguwah

AAMI/ISO 10993-16, Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (reaffirmation of an identical national adoption of ISO 10993-16:2017) Provides principles on designing and performing toxicokinetic studies relevant to medical devices. Annex A describes the considerations for inclusion of toxicokinetic studies in the biological evaluation of medical devices. Contact: Chenai Maguwah

AAMI/ISO 22442-3, Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (reaffirmation of an identical national adoption of ISO 22442-3:2007) Specifies requirements for the validation of the elimination and/or inactivation of viruses and TSE agents during the manufacture of medical devices (excluding in-vitro diagnostic medical devices) utilizing animal tissue or products derived from animal tissue, which are non-viable or have been rendered non-viable. Does not cover other transmissible and non-transmissible agents. Contact: Chenai Maguwah

AAMI/ISO 13022, Medical products containing viable human cells — Application of risk management and requirements for processing practices (reaffirmation of an identical national adoption of ISO 13022:2012) Specifies a procedure to identify the hazards and hazardous situations and to manage the risk associated with viable cellular component(s) of products regulated as medicinal products, biologics, medical devices and active implantable medical devices or combinations thereof. Covers viable human materials of autologous as well as allogeneic human origin. Contact: Chenai Maguwah

Comments due 2 August 2023

AAMI ST58, *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

Comments due 5 September 2023

AAMI/ISO 10993-2, Biological evaluation of medical devices — Part 2: Animal welfare requirements (identical national adoption of ISO 10993-2:2022) This document specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices. It is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves. Contact: Chenai Maguwah

AAMI/ISO 10993-9, Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (identical national adoption of ISO 10993-9:2019) This document provides general principles for the systematic evaluation of the potential and observed degradation of medical devices through the design and performance of in vitro degradation studies. Information obtained from these studies can be used in the biological evaluation described in the ISO 10993 series. This document is applicable to both materials designed to degrade in the body as well as materials that are not intended to degrade. Contact: Chenai Maguwah

AAMI/ISO 10993-10, Biological evaluation of medical devices — Part 10: Tests for skin sensitization (identical national adoption of ISO 10993-10:2021) This document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization. Contact: Chenai Maguwah

AAMI/ISO 10993-12, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (identical national adoption of ISO 10993-12:2021) This document specifies requirements and gives guidance on the procedures in the preparation of samples and the selection of reference materials for medical device testing primarily in biological test systems primarily in accordance with one or more parts of the ISO 10993 series. Contact: Chenai Maguwah

AAMI/ISO 10993-23, Biological evaluation of medical devices — Part 23: Tests for irritation (identical national adoption of ISO 10993-23:2021) This document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation. The tests are designed to predict and classify the irritation potential of medical devices, materials or their extracts according to ISO 10993-1 and ISO 10993-2. Contact: Chenai Maguwah

AAMI/ISO 22442-1, Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (identical national adoption of ISO 22442-1:2020) This document applies to medical

devices other than in vitro diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives. Contact: Chenai Maguwah

AAMI/ISO 22442-2, Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling (identical national adoption of ISO 22442-2:2020) This document specifies requirements for controls on the sourcing, collection, and handling (which includes storage and transport) of animals and tissues for the manufacture of medical devices utilizing materials of animal origin other than in vitro diagnostic medical devices. It applies where required by the risk management process as described in ISO 22442-1. Contact: Chenai Maguwah

New Work

AAMI ST-WG02, Radiation sterilization. The working group is working on the developments of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems*. This document will provide guidance on simplified approaches for validation and routine maintenance of single-use systems sterilized by radiation. Contact: Mike Miskell.

AAMI ST-WG03, Moist heat sterilization. The working group is working on the development of 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*. This document will provide guidance to medical device manufacturers about how to analyze the attributes of a medical device when assigning the medical device to a product family. This includes information on how to accept a new or modified medical device into a product family by equivalence. Discussion on product families for cleaning, disinfection, sterilization and human factors testing will be included. Contact: Mike Miskell.

AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings. The working group is working on the developments of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. This document will provide healthcare personnel with guidance on point-of-use treatment, transportation, testing (where applicable), cleaning, disinfection, sterilization, packaging, and storage of tattoo machines and accessories used in healthcare settings. Contact: Tommy Kim.

AAMI ST-WG61, Chemical Sterilants Hospital Practices. The working group is working on the developments of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. This document will provide guidance for healthcare facilities for the processing of

medical devices using ultraviolet (UV) disinfection. The guidance is intended to provide comprehensive information and direction for healthcare personnel in the processing of reusable devices and accessories to render them safe for patient use. Contact: Tommy Kim.

AAMI ST-WG95, Water Quality for Reprocessing Medical Devices. The working group is working on the development of AAMI TIR119/Ed.1, *Guidance on Healthcare Implementation and Use of AAMI ST108*. This document will provide guidance for healthcare facilities concerning the technical information, testing and qualification of water systems defined by and built to meet the requirements of ST108. Contact: Tommy Kim.

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, 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: 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 reaffirmations of AAMI/ISO 10993-13, *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices*, AAMI/ISO 10993-14, *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*, as well as the expedited adoption of ISO/TS 37137-1:2021, *Biological evaluation of absorbable medical devices — Part 1: General requirements* Contact: Chenai Maguwah

AAMI BE-WG3, Animal protection aspects Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-2:2022, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*. Contact: Chenai Maguwah

AAMI BE-WG5, Cytotoxicity Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of AAMI/ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity* as well as the expedited adoption of ISO/TR 10993-55:2023, *Biological evaluation of medical devices — Part 55: Interlaboratory study on cytotoxicity*. Contact: Chenai Maguwah

AAMI BE-WG6, Mutagenicity, carcinogenicity and reproductive toxicity Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of ANSI/AAMI/ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity,*

carcinogenicity and reproductive toxicity as well as the expedited adoption of ISO/TR 10993-33:2015, *Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3*. Contact: Chenai Maguwah

AAMI BE-WG7, Systemic toxicity Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of AAMI/ISO TIR10993-20*, Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices*. 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 BE-WG13, Toxicokinetics study design Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of AAMI/ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*. Contact: Chenai Maguwah

AAMI BE-WG14, Material characterization Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-18:2020, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process* and ISO/TS 10993-19:2020, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*. Contact: Chenai Maguwah

AAMI BE-WG16, Pyrogenicity Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO/TR 21582:2021, *Pyrogenicity — Principles and methods for pyrogen testing of medical devices*. Contact: Chenai Maguwah

AAMI BE-WG17, Nanomaterials Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO/TR 10993-22:2017, *Biological evaluation of medical devices — Part 22: Guidance on nanomaterials*. Contact: Chenai Maguwah

AAMI BE-WG18, Attributes of medical devices relevant to biological risk assessment Working Group. AAMI is seeking industry, user, general interest, and regulatory members for the newly formed working group to provide input on ISO TC/194/WG 18 activities. Contact: Chenai Maguwah

AAMI BG, Blood/Gas Exchange Device Committee. The committee is seeking user, industry, and general interest/regulator members to participate in reaffirmation of 11658, *Cardiovascular implants and extracorporeal systems — Blood/tissue contact surface modifications for extracorporeal perfusion systems* and 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**:** 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-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 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, S*terile hypodermic needles for single use*. Contact: Jill Zajac

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 EV-WG05, Hospital Beds Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of IEC 80601-2-52 ED1: *Medical electrical equipment—Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*, and IEC 80601-2-89 ED1: *Medical electrical equipment—Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children.* Contact: Ladan Bulookbashi

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 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 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, SW114, *Safe Remote Control of Medical Devices*. 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-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. 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*. Contact: Mike Miskell.

AAMI ST-WG03, Moist heat sterilization. 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-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-WG 61, Chemical Sterilants Hospital Practices Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the revision of ST58, *Chemical sterilization and high-level disinfection in health care facilities* and development of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. 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

AAMI VP-WG 01, Vascular Device-drug Combination Products Working Group. The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO 12417-1:2015, *Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products—Part 1: General requirement.* Contact: Jill Zajac

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.

August 2023

AAMI HE, Human Factors Engineering Committee (open meeting). 1-3 August 2023, 09:00h to 17:00h EST, Arlington, VA. Contact: Hae Choe

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 2 August 2023, 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 ST-WG44, Steam Sterilization Dental Practice (open meeting) 8 August 2023, 09:00h to 12:00h EST, web meeting and 17 August 2023, 09:00h to 12:00h EST, web meeting. The WG will meet virtually to continue comment resolution for AAMI/ADA WD-2 ST113. Contact: Tommy Kim

AAMI SP, Sphygmomanometer committee (open meeting) 21 August 2023, 11:30h to 13:00h EST, web meeting. The committee meets bimonthly to obtain updates on the activities of ISO/TC 121/SC 3-IEC/SC 62D Joint WG7, Non-invasive blood pressure monitoring equipment. Contact: Ladan Bulookbashi

AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group (open meeting) 24 August 2023, 10:00h to 11:30h EST, web meeting. The WG meets monthly to discuss revisions to ANSI/AAMI PC76:2021. Contact: Ladan Bulookbashi

September 2023

AAMI Fall 2023 Sterilization Standards Week (open meetings; hybrid – advanced registration REQUIRED; registration to open in July 2023). 12-15 September 2023, 08:00h to 17:00h EST, Arlington, VA, and web meetings. Contact: Sterilization Standards

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in ANSI Standards Action.

International Committee and Working Group Meetings

Call or email the indicated staff person at AAMI for more information about upcoming international standards meetings.

September 2023

IEC/TC 62, Medical equipment, software, and systems, and affiliated SC and (J)WG meetings (closed meetings). Seoul, Korea, 11-22 September 2023, 09:00h to 17:00h daily local time. Contact: Hae Choe or Ladan Bulookbashi

ISO/TC150/SC2/WG5, Renal replacement, detoxification and apheresis (closed meetings). Zoom, 18-20 September 2023, 8:00h to 12:00h EST Contact: Jill Zajac

October 2023

ISO/TC 194, Biological and clinical evaluation of medical devices and affiliated WG meetings (closed meetings). Arlington, US, 23-27 October 2023, 09:00h to 17:00h daily local time. Contact: Chenai Maguwah

November 2023

ISO/TC 150/SC6, Active Implants, and affiliated (J)WG meetings (closed meetings). AAMI Offices, Arlington, VA, 6-9 November 2023, 09:00h to 17:00h daily local time. Contact: Ladan Bulookbashi

ISO/TC 121/SC2, Airways and related equipment and ISO/TC 121/SC6, Medical gas supply systems (closed meetings). Dublin, Ireland (tent.) 13-17 November 2023, 09:00h to 17:00h daily local time. Contact: Colleen Elliott