STANDARDS UPDATE

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

REAFFIRMED! AAMI TIR67:2018/(R)2022, *Promoting safe practices pertaining to the use of sterilant and high-level disinfectant chemicals in healthcare facilities* is available here.

REAFFIRMED! AAMI TIR68:2018/(R)2022, *Low and intermediate level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental s surfaces* is available here.

PUBLISHED! ANSI/AAMI 2700-2-1:2022, *Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging* is available here.

PUBLISHED! ANSI/AAMI HIT1000-1:2022, *Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements* is available here.

PUBLISHED! AAMI TIR100:2021, *End-to-end microbiological quality and sterility assurance* is available here.

PUBLISHED! AAMI TIR104:2022, *Guidance on transferring health care products between radiation sterilization source* is available here.

PUBLISHED! AAMI CR34971:2022, *Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning* is available here.

PUBLISHED! ANSI/AAMI ES60601-1: 2005/A2:2021, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, Amendment* 2 is available here.

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

PUBLISHED! ANSI/AAMI/IEC 60601-1-8:2006/A2:2021, *Medical Electrical Equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, Amendment* 2 is available here.

PUBLISHED! ANSI/AAMI HA60601-1-11:2015/A1:2021, *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for*

medical electrical equipment and medical electrical systems used in the home healthcare environment, Amendment 1 is available here.

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

AAMI Standards Insider

The AAMI Standards Insider webinar series was last held on **Thursday, February 24th from 1:00-2:00 PM ET**. This **one-hour FREE webinar** provided news and updates about AAMI's standards program and portfolio. The next webinar will be held on **Thursday, May 19th 2022,** from **1:00-2:00 PM ET**. Register here.

NATIONAL STANDARDS

AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by email to receive a PDF copy of the draft. These copies are free.

Published documents proposed for reaffirmation can be purchased from the AAMI Store.

Comments due May 30, 2022

AAMI/ISO CDV-1 11138-8, *Sterilization of health care products—Biological indicators—Part 8: Method for validation of a reduced incubation time for a biological indicator* (identical national adoption of ISO 11138-8:2021). Specifies the requirements for a test method to be utilized to establish or confirm a reduced incubation time (RIT) that is shorter than the 7-day reference incubation time specified in 7.3.2 of ISO 11138-1:2017 for biological indicators used to monitor moist heat sterilization processes or ethylene oxide (EO) sterilization processes. Contact: Jody Allen

AAMI/ISO 11138-1, *Sterilization of health care products—Biological indicators—Part 1: General requirements* (reaffirmation of an American National Standard). Specifies general requirements for production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes. Contact: Jody Allen

AAMI/ISO 11138-2, *Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes* (reaffirmation of an American National Standard). Specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas as the sterilizing agent, either as pure ethylene oxide gas or mixtures of this gas with diluent gases, at sterilizing temperatures within the range of 29 °C to 65 °C. Contact: Jody Allen

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). 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: Jody Allen

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). Specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilization processes employing dry heat as the sterilizing agent at sterilizing temperatures within the range of 20 °C to 180 °C. Contact: Jody Allen

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). 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: Jody Allen

AAMI/ISO CDV-1 15223-1, *Medical devices–Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements* (identical national adoption of ISO 15223-1:2021, to supersede ANSI/AAMI/ISO 15223-1:2016). Specifies symbols used to express information supplied for a medical device. This document is applicable to symbols used in a broad spectrum of medical devices, that are available globally and need to meet different regulatory requirements. These symbols can be used on the medical device itself, on its packaging or in the accompanying information. The requirements of this document are not intended to apply to symbols specified in other standards. Contact: Amanda Benedict

New Work

AAMI EQ, Medical Equipment Management Committee. The committee is working on the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs.* This standard seeks to provide a recommended framework for new or established education programs in health care technology management (HTM). Contact: Jody Allen

AAMI SM-WG10, Cloud Computing. The AAMI Standards Board has approved the formation of a new working group under AAMI SM, Software and Information Technology, and authorized the group to begin work on a Technical Information Report based on the approved AAMI CR510:2021, Appropriate Use of Public Cloud Computing for Quality Systems and Medical Devices. This new WG is seeking members from the General interest, Industry, Regulatory and User categories to join. Contact: Ovidiu Munteanu

AAMI TIB, **Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use Committee**. The committee has recently approved development of a new AAMI Technical Information Report (TIR) on Guidance for Closed System Transfer Device Testing with Hazardous Drugs. This TIR seeks to provide guidelines for physical and chemical compatibility of the drug with the Closed System Transfer Device (CSTD), which may include but not limited to holdup volume, coring/fragmentation of the vial rubber stopper, microbial ingress, stability/shelf-life, and usability. TIB-WG04 is seeking cochairs, user, regulatory and general interest members to participate in the development of AAMI TIR112. Contact: Sam Alameda

Consensus Body Members Needed

The committees listed below are seeking new members in the indicated stakeholder interest category to participate in the development of their documents. Definitions of the various stakeholder groups are:

User: *An individual or organizational representative, who purchases, utilizes, or receives the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare; individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

Industry: *An individual or organizational representative involved in the commercial production, promotion, sale, use or distribution of materials, products, systems, or services covered in the scope of technical documents developed by AAMI; this interest category includes manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

Regulatory: *An individual or organizational representative involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI; this interest category includes those representing federal, state, local, foreign, or other government entities.*

General interest: *An individual or organizational representative with a general material interest in the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI and who does not fit into any of the preceding categories; this interest category can include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

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

AAMI EQ, Medical equipment management. The committee is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs.* Contact: Jody Allen

AAMI ST-WG06, Chemical Indicators. The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of the national adoptions of several parts of the ISO 11140 series. Contact: Jody Allen

AAMI ST-WG13, Washer-disinfectors. The working group is seeking user, regulatory and general interest members to participate in the reaffirmations of AAMI ST15883-2 and AAMI ST15883-3. Contact: Jody Allen

AAMI ST-WG84, Endoscope Reprocessing. The working group is seeking regulatory and general interest members to participate in the development of AAMI TIR99/Ed.1, *Dilators, transesophageal and ultrasound probes processing in health care facilities.* Contact: Jody Allen

AAMI TIB, Transfusion, Infusion and Injection, and Blood Processing Equipment for Medical and Pharmaceutical Use. The committee and its affiliated working groups are seeking user, industry, and general interest/regulator members to participate in developing the U.S. position towards documents under development in ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, and other projects. Contact: Sam Alameda

AAMI CV, Cardiac Valves. The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 5840-1:202x, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements;* ISO 5840-2:202x, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes;* ISO 5840-3:202x, *Cardiovascular implants — Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques;* and the revision of ISO 5910:2018, *Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.* Contact: Jill Zajac

AAMI VP, Vascular Prostheses. The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 25539-2:2020, *Cardiovascular implants—*

Endovascular devices—Part 2: Vascular stents; the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters.* Contact: Jill Zajac

AAMI BG, Blood/Gas Exchange Device. The committee is seeking user, industry, and general interest/regulator members to participate in the development of the following Cardiovascular implants and artificial organs documents: ISO 18193, *Cannulae for extracorporeal circulation*; Amendment 1 to ISO 18242:2016 *Centrifugal blood pumps* for pulsatile pumps; and revision of ISO 7199, *Blood-gas exchangers.* Contact: Jill Zajac

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

AAMI RD, Renal Disease and Detoxification. The committee is seeking industry, user, and general interest/regulator members to participate in the revision of the ISO 23500:2019 , *Preparation and quality management of fluids for haemodialysis and related therapies series standards: Part 1: General requirements*; *Part 2: Water treatment equipment for haemodialysis applications and related therapies*; *Part 3, Water for haemodialysis and related therapies; Part 4: Concentrates for haemodialysis and related therapies; Part 5, Quality of dialysis fluids for haemodialysis and related therapies*; and the revision of the ISO 8637, *Extracorporeal systems for blood purification series standards: Part 1, Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters*; and Part 3, *Plasmafilters*. Contact: Jill Zajac

AAMI HIT-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., *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: Ovidiu Munteanu

AAMI AI, Artificial Intelligence. The committee is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR 34971, *Guidance on the Application of ISO 14971 to Artificial and Machine Learning*. Contact: Hae Choe

AAMI SM-WG01 - Software Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of TIR45: *Guidance on the use of AGILE practices in the development of medical device software.* Contact: Ovidiu Munteanu

AAMI SM-WG03 - Interoperability Working Group. The group is seeking general interest, regulatory, and users. The committee is developing a new American national standard, AAMI Safe Remote Control of Medical Devices. Contact: Ovidiu Munteanu

AAMI SM-WG05 - Medical Device Security Working Group. The group is seeking general interest, regulatory, and users. The committee is developing a new American national standard, AAMI SW96, *Standard for medical device security—Security risk management for device manufacturers*. Contact: Ovidiu Munteanu

AAMI SM-WG10 - Cloud Computing Working Group. The group is seeking industry, user, general interest, and regulatory members to participate in the development of a TIR based on the approved AAMI CR510:2021, *Appropriate Use of Public Cloud Computing for Quality Systems and Medical Devices*. Contact: Ovidiu Munteanu

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

AAMI SU, Sustainability. The committee is seeking user, industry, and general interest/regulatory members to participate in the reaffirmation of AAMI TIR65, *Sustainability of medical devices – Elements of a responsible product life cycle*. Contact: Chenai Maguwah

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.

May 2022

AAMI SU, Sustainability Committee (open meeting). 25 May 2022, 11:30h to 13:00h EDT, Web meeting. Contact: Chenai Maguwah

June 2022

AAMI SP, Sphygmomanometer Committee (open meeting). 6 June 2022, 11:00h to 12:30h EDT, web meeting. Contact: Ladan Bulookbashi

AAMI EQ, Medical Equipment Management Committee (open meeting – advanced registration REQUIRED). 6 June 2022, 13:00h to 17:00h CST and 7 June 2022, 08:00h to 17:00h CST, San Antonio, TX and web meeting. Contact: Jody Allen

September 2022

AAMI Fall 2022 Sterilization Standards Week (open meetings – advance registration REQUIRED; registration to open in early July). 12-15 September 2022, 08:00h to 17:00h ET, Arlington, VA and web meetings. Contact: sterilization@aami.org

INTERNATIONAL STANDARDS

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

International Committee and Working Group Meetings

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

April 2022

ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care (closed meeting), 14 April 2022, 17:00h to 19:00h EDT. Contact*:* Colleen Elliott

May 2022

ISO/TC 150/SC 6/JWG 1, Cardiac pacemakers and implantable defibrillators (closed meeting), 24 May 2022, 9:00h to 17:00h EDT, hybrid meeting. Contact*:* Ladan Bulookbashi

July 2022

ISO/TC 121, Anaesthetic and respiratory equipment and affiliated groups (closed meetings), 11-15 July 2022, St. John's, Newfoundland, Canada. Contact*:* Colleen Elliott