STANDARDS UPDATE

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

NEW! The second session of the new AAMI Standards Insider webinar series was held on **Thursday, November 18th 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, February 17th, 2022 from 1:00-2:00 PM ET**.

PUBLISHED! ANSI AAMI CN27:2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*

PUBLISHED! ANSI AAMI SW96:2021, *Standard for medical device security — Security risk management for device manufacturers*

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 December 31, 2021

AAMI/ISO 17664-1, *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices* (identical national adoption of ISO 17664-1 and revision of ANSI/AAMI/ISO 17664-2017) Specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires sterilization or disinfection to ensure that the device is safe and effective for its intended use. This includes information for processing prior to use or reuse of the medical device. Applicable for medical devices that are intended for invasive or other direct patient contact or that otherwise present the risk of transmission of infectious agents. Processing instructions are not defined in this standard. Rather, this International Standard specifies requirements to assist manufacturers of medical devices in providing detailed instructions for processing that consists of the following activities where applicable: pre-treatment at the point of use; preparation, cleaning, disinfection; drying; inspection, maintenance and testing; packaging; sterilization; storage; transportation. Contact: Amanda Benedict

AAMI/ISO 17664-2, *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices* (identical national adoption of ISO 17664-2 and revision of ANSI/AAMI/ISO 17664-2017) Specifies requirements for the information to be provided by the medical device manufacturer for the processing of medical devices not intended for direct patient contact. This includes information for processing prior to use or reuse of the medical device. Contact: Amanda Benedict

New Work

AAMI CN, Small bore connectors Committee. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-1/Ed.3, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements.* Contact: Colleen Elliott

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: Ovidiu Munteanu

AAMI SM-WG09 – Cloud Computing WG. 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 CR 510:2021, 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. The committee has recently approved development of an AAMI Technical Information Report (TIR), 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 Close 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. The kickoff meeting for AAMI TIR112, Guidance for closed system transfer device testing with hazardous drugs was held on September 21st and was a success. The committee is seeking user, regulatory and general interest members to participate in the development of 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 CN, Small bore connectors. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-1/Ed.3, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*; AAMI/ISO 80369-2/Ed.1, *Small-bore connectors for liquids and gases in healthcare applications – Part 2: Connectors for respiratory applications*; and AAMI/ISO 80369-20/Ed.2, *Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods*. Contact: Colleen Elliott

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: Ovidiu Munteanu

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: Amanda Benedict

AAMI ST-WG12, Instructions for reusable device reprocessing. The working group is seeking user, regulatory and general interest members to participate in the national adoptions of the ISO 17664 series. Contact: Amanda Benedict

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: Amanda Benedict

AAMI ST-WG43, Hospital steam sterilizers. The working group is seeking user, regulatory and general interest members to participate in the reaffirmation of AAMI ST55, *Table-top steam sterilizers* and the revision of AAMI ST8, *Hospital steam sterilizers.* Contact: Cliff Bernier

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 ST-WG 91, Resistometers. The working group is seeking user, industry, and regulatory/general interest stakeholders to participate in the US adoption of ISO 18472:2018, Sterilization of health care equipment – Biological and chemical indicators – Test equipment. Contact: Cliff Bernier

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 US 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 US 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: Cliff Bernier

AAMI VP, Vascular Prostheses. The committee is seeking user, industry, and general interest/regulator members to participate in the US 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*: Cliff Bernier

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: Cliff Bernier

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 requirements* . Contact: Cliff Bernier

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: Cliff Bernier

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: Jody Allen

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-WG05, Medical Device Security Working Group. The group is seeking general interest, regulatory/government, 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 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 SM-WG09 – Cloud Computing WG. The group is seeking industry, user, general interest, and regulatory members to participate in the development of a TIR based on the approved AAMI CR 510:2021, Appropriate Use of Public Cloud Computing for Quality Systems and Medical Devices. Contact: Ovidiu Munteanu

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 (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.

December 2021

Steam sterilization hospital practices working group (open meeting), 10 December 2021, 13:00 h to 16:00 h ET, web meeting. Contact*:* Amanda Benedict

Steam sterilization hospital practices working group (open meeting), 13 December 2021, 11:00 h to 14:00 h ET, web meeting. Contact*:* Amanda Benedict

Sphygmomanometer committee (open meeting), 14 December 2021, 16:00 h to 17:30 h ET, web meeting. Contact*:* Ladan Bulookbashi

Lens removal and vitrectomy devices working group (open meeting), 16 December 2021, 14:00 h to 16:00 h ET, web meeting. Contact*:* Ladan Bulookbashi

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.

December 2021

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 14 December 2021, 06:00 h to 08:00 h MST, Zoom meeting. Contact*:* Amanda Benedict

ISO/TC 198/WG 1, Industrial EO sterilization (closed meeting), 14 December 2021, 13:00 h to 16:00 h GMT, Zoom meeting. Contact*:* Amanda Benedict