

STANDARDS UPDATE

NEW! We have begun transitioning to the NEW AAMI Committee Central platform! Information is available [here](#).

NEW! Please join the AAMI Standards team on **Thursday, September 23 from 1:00-2:00 PM ET** for the inaugural session of the new [AAMI Standards Insider](#) webinar series. This **one-hour FREE webinar** is intended to provide news and updates about AAMI's standards program and portfolio. Please join us for introductions to the AAMI Standards staff, information about the migration of AAMI committees to the NEW AAMI Committee Central platform, and highlights and news from across AAMI's standardization activities. Registration for the event is [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 September 20, 2021

AAMI/ISO 14937, Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices (reaffirmation of an American National Standard). Specifies general requirements for the characterization of a sterilizing agent and for the development, validation and routine monitoring and control of a sterilization process for medical devices. Applies to sterilization processes in which microorganisms are inactivated by physical and/or chemical means. Intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of products to be sterilized and organizations responsible for sterilizing medical devices. Purchase from: [AAMI Store](#)

AAMI PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (revision of an American National Standard). Establishes minimum barrier performance requirements, a classification system, and associated labeling requirements for protective apparel, surgical drapes, and drape accessories intended for use in health care facilities. Contact: [Darren Robertson](#)

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 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* framework for new or established education programs in health care technology management (HTM). Contact: [Ovidiu Munteanu](#)

AAMI QM-WG01, Application of Quality Systems to Medical Devices Working Group. The working group is working on the development of AAMI CR510, *Consensus Report on Compliant Use of Cloud Computing for Quality Systems and Medical Devices*. This Consensus Report will provide guidance to multiple stakeholders regarding the appropriate and compliant use of cloud computing both as a component of medical devices and in support of quality systems. Contact: [Joe Lewelling](#)

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. TBN131_Agenda for the 21 September 2021 web meeting of AAMI TIB - kickoff meeting for AAMI TIR112, *Guidance for closed system transfer device testing with hazardous drugs* was posted to AAMI committee central. The kickoff meeting will be held on September 21st, 1:00 to 3:00 pm ET, via Microsoft Teams. 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*

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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: [Amanda Benedict](#)

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-WG42, Dry heat sterilization. The working group is seeking user, regulatory and general interest members to participate in the reaffirmation of AAMI/ISO 20857, *Sterilization of health care products – Dry heat – Requirements for the development, validation, and routine control of a sterilization process for medical devices*. Contact: [Amanda Benedict](#)

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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: [Amanda Benedict](#)

AAMI ST-WG84, Endoscope reprocessing. The working group is seeking regulatory and general interest members to participate in the development of AAMI ST91/Ed.2, *Flexible and semi-rigid endoscope processing in health care facilities* and AAMI TIR99/Ed.1, *Dilators, transesophageal and ultrasound probes processing in health care facilities*. Contact: [Amanda Benedict](#)

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*; and the development of ISO 25539-4, *Cardiovascular implants – Endovascular devices – Part 4: Application of ISO 17327-1 for coated endovascular devices*. Contact: [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](#)

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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* and the revision of ISO/TR 12417-2:2017, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 2: Local regulatory information*. 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: [AAMI Standards](#)

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: [AAMI Standards](#)

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](#)

UPCOMING MEETINGS

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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.

September 2021

AAMI TIB Committee/U.S. TAG to ISO/TC 76 (open meeting). 21 September 2021, 13:00h to 15:00h ET. Virtual. Contact: [Sam Alameda](#)

Chemical indicators Working Group (open meeting). 22 September 2021, 09:00h to 12:00h ET. Virtual. Contact: [Amanda Benedict](#)

Assurance of sterility Working Group (open meeting). 23 September 2021, 15:00h to 16:00h ET. Virtual. Contact: [Amanda Benedict](#)

Industrial EO sterilization Working Group (open meeting). 27 September 2021, 13:00h to 17:00h ET. Virtual. Contact: [Amanda Benedict](#)

Anaesthetic and respiratory equipment committee and affiliated working groups (open meeting). 29 September, 16:00h to 17:00h ET. Virtual. Contact: [Colleen Elliott](#)

October 2021

Multiparameter Patient Monitoring Equipment Committee (open meeting). 08 October 2021, 13:00h to 15:00h ET. Virtual. Contact: [Ladan Bulookbashi](#)

Radiation Sterilization Working Group (open meeting). 12 October 2021, 13:00h to 14:00h ET. Virtual. Contact: [Amanda Benedict](#)

November 2021

AAMI Renal Disease and Detoxification Committee (open meeting). 9 November 2021. Virtual. Contact: [Cliff Bernier](#)

INTERNATIONAL STANDARDS

Information on draft international standards under ballot can be found in [ANSI Standards Action](#).

International Committee and Working Group Meetings

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

September 2021

ISO/TC 150/SC 2/WG 1, Cardiac valves (closed meeting). 20 September to 23 September 2021. Zoom meeting. Contact: [Cliff Bernier](#)

ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification, and apheresis (closed meeting). 20 September to 24 September 2021. Zoom meeting. Contact: [Cliff Bernier](#)

ISO/TC 150/SC 2/WG 6, Vascular device-drug combination products (closed meeting). 21 September to 24 September 2021. Zoom meeting. Contact: [Cliff Bernier](#)

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 28 September 2021, 08:00 h to 11:00 h ET, Zoom meeting. Contact: [Amanda Benedict](#)

October 2021

ISO/TC 198/WG 2, Radiation sterilization (closed meeting), 4 October 2021, 11:00 h to 12:00 h ET, Zoom meeting. Contact: [Amanda Benedict](#)

ISO/TC 198/WG 1, Industrial EO sterilization (closed meeting), 19 October 2021, 13:00 h to 16:00 h IST, Zoom meeting. Contact: [Amanda Benedict](#)

November 2021

ISO/TC 198/WG 7, Packaging (closed meeting), 8/9 November 2021, 08:00 h to 11:00 h ET, Zoom meeting. Contact: [Amanda Benedict](#)

ISO/TC 198, Sterilization of health care products (closed meeting), 10 November 2021, 08:00 h to 11:00 h ET, Zoom meeting. Contact: [Amanda Benedict](#)

ISO/TC 198/WG 1, Industrial EO sterilization (closed meeting), 16 November 2021, 13:00 h to 16:00 h GMT, Zoom meeting. Contact: [Amanda Benedict](#)

December 2021

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](#)