NATIONAL STANDARDS

Recently Published

NEW! ANSI/AAMI/ISO 10993-16:2017, *Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables*. Purchase here.

REAFFIRMED! AAMI TIR74, *Change Summary For ISO 11135:2014, Sterilization Of Health Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices* was reaffirmed February 11, 2021.

AAMI Call for Comments

If you would like to comment on one of the draft documents listed below, contact the individual indicated by e-mail 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 March 15, 2021

AAMI/ISO 13408-5, Aseptic processing of health care products - Part 5: Sterilization in place (reaffirmation of an American National Standard). This standard specifies the general requirements for sterilization in place (SIP) applied to product contact surfaces of the equipment used in the manufacture of sterile health care products by aseptic processing and offers guidance on qualification, validation, operation and control. This document applies to processes where sterilizing agents are delivered to the internal surfaces of the equipment that can come in contact with the product. Contact: Amanda Benedict

Comments due April 26, 2021

AAMI/ISO 11140-3, Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (reaffirmation of an American National Standard). This standard specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g., instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1. Contact: Amanda Benedict

AAMI/ISO 11140-4, Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration (reaffirmation of an American National Standard). This standard specifies performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick test for steam sterilizers for wrapped health care goods (e.g., instruments and porous loads). Contact: Amanda Benedict

AAMI/ISO 11140-5, Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests (reaffirmation of an American National Standard). This standard specifies the requirements for an indicator and alternative test system used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles.. Contact: Amanda Benedict

AAMI ST15883-2, Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc (reaffirmation of an American National Standard). This standard specifies particular requirements for washer disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware. Contact: Amanda Benedict

AAMI ST15883-3, Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (reaffirmation of an American National Standard). This standard specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle. Contact: Amanda Benedict

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 (expedited national adoption of an international standard). This standard 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 (expedited national adoption of an international standard). This standard 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

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 (reaffirmation of an American National Standard). This standard specifies requirements for the development, validation and routine control of a dry heat sterilization process for medical devices. Also

specifies requirements and provides guidance in relation to depyrogenation processes using dry heat. 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: Amanda Benedict.

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. Contact: Jeff Linder.

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.*
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> **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.*
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> **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 Committee. 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 participation 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.

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: Jeff Linder.

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 stetnts;* 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 Committee. 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* 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/VI, Cardiovascular absorbable implants. The committee is seeking user, industry, and general interest/regulator members to participate in the revision of ISO/TS 17137:2019, *Cardiovascular implants and extracorporeal systems - Cardiovascular absorbable implants*. Contact: Cliff Bernier

AAMI/CO, Cardiac Occluders. The committee is seeking user, industry, and general interest/regulator members to participate in the development of ISO 22679, *Cardiovascular implants — Transcatheter cardiac occluders.* Contact: Cliff Bernier

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: Cliff Bernier

AAMI/HIT-WG02, Health IT Quality Systems Working Group. The working group is seeking industry, general interest, and regulator 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: Emily Hoefer

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.

March 2021

AAMI COVID-19 Response Team (open web meeting). 17 March 2021, 15:00h to 16:00h ET. *Contact: Colleen Elliott.*

AAMI Sterilization Standards meetings (open web meetings). 22 March through 1 April 2021, 08:00h to 17:00h ET. Virtual meetings. *Contact: Amanda Benedict.*

AAMI Sterilization Standards Meetings Opening Plenary (open web meeting). 22 March 2021, 09:00h to 11:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Radiation Sterilization Working Group (open web meeting). 22 March 2021, 13:00h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Industrial EO Sterilization Working Group (open web meeting). 23 March 2021, 13:00h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Steam Sterilization Hospital Practices Working Group (open web meeting). 24 March 2021, 09:00h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Compatibility of Materials Subject to Sterilization Working Group (open web meeting). 26 March 2021, 10:00h to 12:00h ET. Virtual meeting. *Contact: Cliff Bernier.*

Assurance of Sterility Working Group (open web meeting). 26 March 2021, 13:00h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Water Quality for Reprocessing Medical Devices Working Group (open web meeting). 29 March 2021, 11:30h to 17:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Endoscope Reprocessing Working Group (open web meeting). 30 March 2021, 09:00h to 12:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

April 2021

Industrial Moist Heat Sterilization Working Group (open web meting). 1 April 2021, 09:00h to 12:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

Sterilization Standards Meetings Closing Plenary/US TAG to ISO/TC 198 (open web meeting). 1 April 2021, 14:00h to 16:00h ET. Virtual meeting. *Contact: Amanda Benedict.*

May 2021

Cardiac Rhythm Management Devices (open web meeting). 6 May 2021, 11:00h to 13:30h ET. *Contact: Standards Department.*

Renal Disease and Detoxification Committee (open web meeting). 7 May 2021, 11:00h to 17:00h ET. *Contact: Cliff Bernier.*

September 2021

AAMI Sterilization Standards meetings (open web meetings). 13-17 September 2021, 08:00h to 17:00h ET. Schedule of meetings TBD. AAMI, Arlington, VA. *Contact: Amanda Benedict.*

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.

March 2021

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 16, 18 March 2021, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 7, Packaging (closed meeting), 30/31 March 2021, 07:00 h to 10:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

April 2021

ISO/TC 150/SC 2/WG 8, Cardiac occluders (closed meeting). 5 to 7 April 2021, Zoom meeting. *Contact: Cliff Bernier*

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 6, 8, 13, 15 April 2021, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

IEC/TC 62 and subcommittees, Electrical equipment in medical practice (closed meeting), 12 to 23 April 2021, Zoom meeting. *Contact: Hae Choe*

July 2021

ISO/TC 121, Anaesthetic and respiratory equipment (closed meeting), 16 July 2021, Zoom meeting. *Contact: Colleen Elliott.*