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.

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 February 2, 2021

AAMI ES60601-1:2005/A1-2012/A2, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Amendment 2 (proposed amendment to an American National Standard). This standard applies to the general aspects of medical electrical equipment and specifies the safety and essential performance. This second Amendment provides guidance to the users of the 60601-1 on some of the issues that have been raised since the publication of the first Amendment. Contact: Hae Choe

AAMI/IEC 60601-1-2:2014/A1, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests, Amendment 1 (proposed amendment to an American National Standard). This is one of the collateral standards under the umbrella of IEC 60601-1 series and covers the general aspects dealing with electromagnetic disturbances. This Amendment updates references, terminology and some of the clauses since the publication of the standard. Contact: Hae Choe

AAMI/IEC 60601-1-8:2008/A2, 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, Amendment 2 (proposed amendment to an American National Standard). This is one of the collateral standards under the umbrella of IEC 60601-1 series and covers the general aspects dealing with medical alarms. This Amendment updates references, terminology and some of the clauses since the publication of the standard and Amendment 1. Contact: Hae Choe

AAMI/IEC 60601-1-12:2016/A1, Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for ME equipment and ME systems used in the emergency medical services environment, Amendment 1 (proposed amendment to an American National Standard). This is one of the collateral standards under the umbrella of IEC 60601-1 series and covers the general aspects dealing with medical electrical equipment and systems used in emergency medical services environment. This Amendment updates

references, terminology and some of the clauses since the publication of the standard. Contact: Hae Choe

AAMI HA60601-1-11:2015/A1, 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, Amendment 1 (proposed amendment to an American National Standard). This is one of the collateral standards under the umbrella of IEC 60601-1 series and covers the general aspects dealing with medical electrical equipment and systems used in home healthcare. This Amendment updates references, terminology and some of the clauses since the publication of the standard. Contact: Hae Choe

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

New Work

AAMI/CN, Small Bore Connectors Committee is working on the revision of AAMI/ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.* 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: 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.

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 AL, Medical Device Alarms Committee. The committee is seeking user and general interest members to participate in the U.S. adoption AAMI/IEC 60601-1-8:2008/A2, *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*, Amendment 2. Contact: Hae Choe.

AAMI EM, Electromagnetic Compatibility Committee. The committee is seeking user and general interest members to participate in the U.S. adoption AAMI/IEC 60601-1-2:2014/A1, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*, Amendment 1. Contact: Hae Choe.

AAMI ES, Electrical Safety Committee. The committee is seeking user and general interest members to participate in the U.S. adoption AAMI ES60601-1:2005/Amendment 2, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* Amendment 2. Contact: Hae Choe.

AAMI HA, Home Care and EMS Environments Committee. The committee is seeking user and general interest members to participate in the two U.S. adoptions - for AAMI HA60601-1-11:2015/Amendment 1, *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,* Amendment 1; and for AAMI/IEC 60601-1-12: 2016/A1*, Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for ME equipment and ME systems used in the emergency medical services environment*, Amendment 1. Contact: Hae Choe.

AAMI/CN, Small Bore Connectors Committee. The committee is seeking user, regulatory and general interest members to participate in the development of AAMI/ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.* Contact: Colleen Elliott

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-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, Health IT Committee. The working group is seeking industry, general interest, and regulator members to participate in the development of AAMI HIT1000-1/Ed., *Health IT Software and Systems – Part 1: Fundamental concepts and principles*. Contact: Emily Hoefer

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* (Provisional Standard). 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.

February 2021

Infusion Device Committee (open web meeting). 4 February 2021, 1:00h to 3:00h ET. *Contact: Standards Department.*

Sphygmomanometers Committee (open web meeting). 9 February 2021, 3:00h to 5:00h ET. *Contact: Standards Department.*

Industrial Moist Heat Sterilization Working Group (open web meeting). 22 and 23 February 2021, 12:00h to 15:00h ET. Virtual meetings. *Contact: Amanda Benedict.*

March 2021

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

May 2021

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

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.

February 2021

ISO/TC 198 ISO/NP TS 5111 (closed meeting), 8 February 2021, 09:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 7, Packaging (closed meeting), 9-10 February 2021, 07:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 1, Industrial EO sterilization (closed meeting), 23 February 2021, 08:00 h to 10:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 8, Microbiological methods (closed meeting), 24 February 2021, 09:00 h to 10:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

March 2021

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 2, 4, 9, 11, 16, 18 March 2021, 08:00 h to 11:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 4, Biological indicators (closed meeting), 8 March 2021, 09:00 h to 12:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

ISO/TC 198/WG 2, Radiation sterilization (closed meeting), 11 March 2021, 11:00 h to 12:00 h ET, Zoom meeting. *Contact: Amanda Benedict*

April 2021

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