AAMI Standards Monitor Online
15 May 2018

National Standards

Newly Published Documents

AAMI EQ93:2018 (PS), Medical equipment management--Vocabulary used in medical equipment programs (new provisional standard)
Available for free download from: http://my.aami.org/store/detail.aspx?id=EQ93-PDF

New work/Call for participation

AAMI ST98, Cleaning Validation of health care products -- Requirements for development and validation of a cleaning process for medical devices (new proposed American National Standard). Covers the requirements to validate the cleaning instructions that are provided by the medical device manufacturer for processing medical devices. Staff contact: abenedict@aami.org.

AAMI Call for Comments

If you would like to comment one of the draft documents listed below, contact the individual indicated by e-mail or click on the indicated URL to download the draft. These copies are free.

Published documents proposed for reaffirmation can be purchased from the AAMI Store: http://my.aami.org/store/.

Comments due 31 May 2018

AAMI/ISO CDV-2 14117, Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices (revision of an American National Standard). Specifies a comprehensive test methodology for the evaluation of the electromagnetic (EM) compatibility of active implantable cardiovascular devices. The devices addressed by this standard include those that provide one or more therapies for bradycardia, tachycardia, and cardiac resynchronization. This document details test methods appropriate for the interference frequencies at issue. It specifies performance limits or requires disclosure of performance in the presence of EM emitters, where indicated. *Contact:* jmoyer@aami.org. Download from:
https://standards.aami.org/higherlogic/ws/public/document?document_id=14011&wg_abbrev=PUBLIC_REV

AAMI/ISO CDV-3 18250-3, Medical devices -- Connectors for reservoir delivery systems for healthcare applications -- Part 3: Enteral applications (new American National Standard). Specifies dimensions and requirements for the design and functional performance of connectors intended to be used on enteral reservoirs. Contact: celliott@aami.org. Download from:
https://standards.aami.org/higherlogic/ws/public/document?document_id=14113

AAMI CDV-1 HE75, Human factors engineering - Design of medical devices (reaffirmation of an American National Standard). Provides detailed human factors engineering (HFE) design guidance to those who are responsible for HFE work within medical device companies. It contains extensive design guidance, examples, checklists, and case studies. *Contact*: jmoyer@aami.org. Purchase from:
http://my.aami.org/store/detail.aspx?id=HE75

AAMI/ISO FS 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (revision of an American National Standard). Describes the general principles governing the biological evaluation of medical devices within a risk management framework; the general categorization of devices based on the nature and duration of their contact with the body; the evaluation of existing relevant data from all sources; the identification of gaps in the available data set on the basis of a risk analysis; the identification of additional data sets necessary to analyze the biological safety of the medical device; and the assessment of the biological safety of the medical device. *Contact:* abenedict@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/document?document_id=14103&wg_abbrev=PUBLIC_REV

Comments due 29 June 2018

AAMI/ISO CDV-1 11737-2, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (revision of an American National Standard). Specifies the general criteria for tests of sterility on medical devices that have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process. These tests are intended to be performed when defining, validating or maintaining a sterilization process. Contact: jmoyer@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/document?document_id=14187&wg_id=PUBLIC_REV

AAMI/ISO CDV-3 18250-8, Medical devices -- Connectors for reservoir delivery systems for healthcare applications -- Part 8: Citrate-based anticoagulant solution for apheresis applications (new American National Standard). Specifies dimensions and requirements for the design and functional performance of apheresis AC reservoir connectors. Contact: celliott@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/documents?view=

AAMI/ISO CDV-2 18250-6, Medical devices -- Connectors for reservoir delivery systems for healthcare applications -- Part 6: Neural applications (new American National Standard). specifies the connectors recommended for the outlet ports of neural reservoirs and inlet ports of neural giving sets. Contact: celliott@aami.org. Download from: https://standards.aami.org/higherlogic/ws/public/documents?view=

Consensus Body Members Needed

The committees listed below are seeking new members in the user stakeholder interest category to participate in the development of their documents.

AAMI defines the user stakeholder interest group as: *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 shall be classified as a User Interest stakeholder. Individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.*

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

Microbiological Methods – Users, regulatory, and general interest stakeholders needed for the revision of AAMI/ISO 11737-2:2009. See the public review listing above for details. Staff contact: jmoyer@aami.org.

Medical Equipment Management – Industry, regulatory, and general interest stakeholders needed to participate on this committee, which focuses on the management of health technologies in the healthcare setting. Additionally, this committee is seeking to add a co-chair. Staff contact: pbernat@aami.org.

Human Factors Engineering – Users, regulators, and general interest stakeholders needed for the reaffirmation of AAMI HE75:2013. See the public review listing above for details. Staff contact: jmoyer@aami.org

Reusable Surgical Textiles Processing Working Group- AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities*. Staff contact: abenedict@aami.org.

Liquid Chemical Sterilization Working Group- AAMI/ISO 14160, *Sterilization of health care products-Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives-Requirements for characterization, development, validation, and routine control of a sterilization process for medical devices.* Staff contact: abenedict@aami.org.

Rigid Sterilization Containers Working Group-Multiple documents, including AAMI ST77. Staff contact: abenedict@aami.org.

Chemical Sterilants Hospital Practices Working Group-Multiple documents, including AAMI ST58. Staff contact: abenedict@aami.org.

Hospital Steam Sterilizers Working Group- AAMI ST8, *Hospital steam sterilizers.* Staff contact: abenedict@aami.org.

Hospital EO Sterilizer Working Group- AAMI ST24, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities.* Staff contact: abenedict@aami.org.

Material Characterization Working Group– ANSI/AAMI BE83, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials;* AAMI/ISO TIR10993-19, *Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials*; ISO 10993-18, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials;* and ISO TS 10993-19, *Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials*. Staff contact: abenedict@aami.org.

Biological Evaluation Committee (U.S. Technical Advisory Group to ISO/TC 194)-Multiple standards and Technical Information Reports, particularly the ISO 10993 series. Staff contact: abenedict@aami.org.

Medical Equipment Management Committee-Multiple standards. Staff contact: pbernat@aami.org.

Biological Indicators Working Group-Multiple documents. Staff contact: cbernier@aami.org.

Blood Filter/Cell Salvaging Committee-Multiple documents. Staff contact: cbernier@aami.org.

Cardiac Occluders-Cardiovascular implants-Cardiac occluders. Staff contact: cbernier@aami.org.

Cardiovascular Absorbable Implants Committee-Revision of AAMI/ISO TIR 17137, *Cardiovascular implants and extracorporeal systems - Cardiovascular absorbable implants*. Staff contact: cbernier@aami.org.

Chemical Indicators Working Group-AAMI/ISO 11140-6, *Sterilization of health care products—Chemical indicators—Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers*. Staff contact: cbernier@aami.org.

Industrial Ethylene Oxide Sterilization Working Group-Multiple documents. Staff contact: cbernier@aami.org.

Cardiac Valve Prostheses Committee-AAMI/ISO 5840-3, *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques*. Staff contact: cbernier@aami.org.

Vascular Prostheses Committee-AAMI/ISO 25539-2, *Cardiovascular implants — Endovascular devices — Part 2: Vascular stents*. Staff contact: cbernier@aami.org.

Blood/Gas Exchange Device Committee-Multiple documents. Staff contact: cbernier@aami.org.

Renal Disease and Detoxification Committee-Multiple documents. Staff contact: cbernier@aami.org.

Medical Device Particulates Committee-Revision of AAMI TIR42, *Evaluation of particulates associated with vascular medical devices.* Staff contact: cbernier@aami.org.

Cardiovascular absorbable Implants Committee-Revision of AAMI/ISO TIR17137, Cardiovascular implants and extracorporeal systems - Cardiovascular absorbable implants. Staff contact: cbernier@aami.org

Interoperability Working Group – AAMI/SW92/Ed. 1, *Integrated Clinical System: Patient Controlled Analgesia (PCA)*, AAMI/TIR75/Ed. 1, *Factors to Consider When Multi-Vendor Devices Interact Via an Electronic Interface*, and AAMI/SW95/Ed.1, *Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) for Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical environment (ICE) — Particular requirements for the forensic (black box) data logger*. Staff contact: wvargas@aami.org.

Device Security Working Group – AAMI/SW96, *Medical Devices - Application of security risk management to medical devices*, AAMI/TIR97, *Principles for medical device security – Post-market security management for device manufacturers*. Staff contact: wvargas@aami.org.

Luer activated valves Working Group – The committee is developing AAMI/CN27, General requirements for Luer activated valves incorporated into medical devices which covers intravascular and hypodermic applications. Users with clinical expertise are being sought to participate on the committee. The next meeting is scheduled to take place in January 2018. Staff contact: celliott@aami.org.

Software Working Group – Revision of AAMI/TIR45, *Guidance on the use of agile practices in the development of medical device software*. Staff contact: wvargas@aami.org.

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). Agendas for open meetings are usually available from AAMI Central. (Visit https://standards.aami.org/kws/public*, find the committee or working group and look under "Upcoming Shared Events" or "Recently Shared Documents"). 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.*

May 2018

Renal Disease and Detoxification Committee (open meeting). 18 May 2018, 9:00 to 17:00 h, AAMI HQ, Arlington, VA. Staff contact: cbernier@aami.org.

June 2018

Instructions for Reusable Medical Device Reprocessing Working Group (open meeting – advance registration required), 4 June 2018, 8:00 to 14:00 h, Westin Long Beach, Long Beach, CA. *Contact*: jmoyer@aami.org

ECG Committee (open meeting – advance registration required), 4 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. *Contact*: hchoe@aami.org

Luer activated valves working group, (open meeting – advance registration required), 4 June 2018 to 6 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. Contact: celliott@aami.org – RESCHEDULED – see below

Cleaning of Reusable Medical Devices Working Group (open meeting – advance registration required), 5 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. *Contact*: abenedict@aami.org

Defibrillator Committee (open meeting – advance registration required), 5 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. *Contact*: hchoe@aami.org

Medical Device Particulates Committee (open meeting – advance registration required), 5 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. Staff contact: cbernier@aami.org.

Device Security Working Group (open meeting – advance registration required), 5-7 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. Contact: wvargas@aami.org

Medical Device Alarms Committee (open meeting – advance registration required), 6 June 2018, 9:00 to 17:00 h, Westin Long Beach, Long Beach, CA. *Contact*: jmoyer@aami.org

Infusion Device Committee (open meeting – advance registration required), 6-8 June 2018, 9:00 start time, adjourning not later than 12:00 h on 8 June, Westin Long Beach, Long Beach, CA. *Contact*: jmoyer@aami.org

Software and Information Technology Committee (open meeting – advance registration required), 8 June 2018, 9:00 to 12:00 h, Westin Long Beach, Long Beach, CA. Contact: wvargas@aami.org

Interoperability Working Group (open meeting), 18-22 June 2018, 9:00 to 17:00 h, AAMI HQ, Arlington, VA. Contact: wvargas@aami.org

Luer activated valves working group, (open meeting – advance registration required), 26-28 June 2018, 9:30 to 16:30 h, AAMI HQ, Arlington, VA. Contact: celliott@aami.org

July 2018

Endoscope Reprocessing Working Group (open meeting – advance registration required), 19-20 July 2018, 9:00 to 17:00 h, AAMI, Arlington, VA. *Contact*: Contact: abenedict@aami.org

August 2018

Biological Evaluation Committee (open meeting – advance registration required), 30 August 2018, 9:00 to 17:00 h, AAMI, Arlington, VA. *Contact*: Contact: abenedict@aami.org

October 2018

Sterilization Standards Week (open meeting – advance registration required), 22-25 October 2018, 8:00 to 17:00 h, Hyatt Regency Baltimore Inner Harbor, Baltimore, MD. Contact: abenedict@aami.org

November 2018

Cardiac Rhythm Management Devices Committee (open meeting), 15 November 2018, 9:00 to 17:00 h, AAMI, Arlington, VA. *Contact*: jmoyer@aami.org

December 2018

Luer activated valves working group (open meeting), 3-5 December 2018, 8:00 to 17:00 h (13:00 h on final day), Turin, Italy. Contact: celliott@aami.org

International Standards

Information on draft international standards under ballot can be found in ANSI Standards Action: http://www.ansi.org/news_publications/periodicals/standards_action/standards_action.aspx?menuid=7

International Committee and Working Group Meetings

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

May 2018

ISO/TC 150/SC 2/WG 8, Cardiac occluders (closed meeting). 22 May 2018, 7:00 to 9:00 h, WebEx. Staff contact: cbernier@aami.org.

ISO/TC 121, Anaesthetic and respiratory equipment and affiliated subcommittees and (J)WGs (closed meeting), 21-25 May 2018, 9:00 to 17:00 h, Lund, Sweden. *Contact:* celliott@aami.org

IEC/SC 62A/WG 20, Environmental protection (closed meeting) 22 - 24 May 2018, 9:00 to 17:00 h, Montreal, Canada. *Contact:* hchoe@aami.org

June 2018

IEC/SC 62D/JWG 35 and JWG 36, Medical robots for surgery and rehabilitation (closed meeting) 4 – 8 June 2018, 9:00 to 17:00 h, Kyoto, Japan. *Contact:* hchoe@aami.org

ISO/TC210/JWG1 "Joint ISO/TC210-IEC/SC62A", Application of risk management to medical devices (closed meeting) 4 – 6 June 2018, 9:00 to 17:00 h, Long Beach, California, United States. *Contact:* wvargas@aami.org

ISO 80369-2 testing task group (tentative) (closed meeting), 7-8 June 2018, 9:00 – 17:00 h. Westin Long Beach, Long Beach, CA. *Contact:* celliott@aami.org - Canceled

ISO/TC 150/SC 6/WG 6, Circulatory support devices (closed meeting), 12 June 2018. AAMI HQ, Arlington, VA. Staff contact: cbernier@aami.org.

ISOIEC/SC 62A/MT 23, Electromagnetic compatibility (closed meeting) 18 – 21 June 2018, 9:00 to 17:00 h, Stockholm, Sweden. *Contact:* hchoe@aami.org

ISO/TC210/WG6, Application of post market surveillance systems to medical devices (closed meeting) 25-27 June 2018, 9:00 to 17:00 h, Minneapolis, Minnesota, United States.
Contact: wvargas@aami.org

September 2018

ISO/TC 150/SC 2 and related working groups (closed meetings), 10-14 September 2018, San Diego, CA, USA. *Contact:* cbernier@aami.org.

ISO/TC 150/SC 6 and related working groups (closed meetings), 10-14 September 2018, San Diego, CA, USA. *Contact:* jmoyer@aami.org

ISO/TC 198 and related working groups (closed meetings), 17-21 September 2018, London, UK.
Contact: abenedict@aami.org

November 2018

ISO/TC 210, Quality management and corresponding general aspects for medical devices, and related working groups (closed meetings), 12-16 November 2018, Seoul, South Korea, USA.
Contact: wvargas@aami.org

IEC/SC 62A/WG 20, Environmental protection (closed meeting), 13–15 November 2018, 9:00 to 17:00 h, New York, NY. *Contact:* hchoe@aami.org

Miscellaneous

Introducing our new Standards FAQs page!
Please visit the AAMI website at www.aami.org/standardsfaqs to quickly get answers to commonly asked questions. If your question and answer is not listed on the website, please complete and submit the online form and someone will get back to you within three business days. Please note that as a standards developing organization accredited under ANSI, AAMI is procedurally prohibited from providing interpretations of standards and/or interpreting whether specific actions are in conformance with the standards. We do not have the technical expertise on staff to advise about specific practices and can only point you to content in the standards that might be helpful.

For questions of a technical nature, we suggest you reach out to any number of consultants in the AAMI Buyers Guide that can be found on www.aami.org/buyersguide.