

NATIONAL STANDARDS

Recently Published

ANSI/AAMI/UL 2800-1:2019, *Standard for Safety for Medical Device Interoperability*

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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: <http://my.aami.org/store/>.

Comments due May 21

AAMI/ISO CDV-1 20417, Medical Devices - Information to be provided by the manufacturer (identical adoption as American National Standard). Specifies the requirements for information supplied by the manufacturer for a medical device or accessory, as defined in 3.1. This document includes the generally applicable requirements for identification, marking and documentation of a medical device or accessory. This document does not specify the language to be used for such information, nor does it specify the means by which the information is to be supplied. Contact: wvargas@aami.org. Download from:

https://standards.aami.org/higherlogic/ws/public/document?document_id=17648&wg_id=PUBLIC_REV

Comments due June 17

AAMI/IEC 80601-2-77, Medical electrical equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment (identical adoption as American National Standard). This standard applies to the basic safety and essential performance of robotically assisted surgical equipment (RASE) and robotically assisted surgical system (RASS). This document does not apply to X-ray based image guided radiotherapy equipment. Contact: hchoe@aami.org.

AAMI/IEC 80601-2-78, Medical electrical equipment – Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation. This standard applies to the general requirements for the basic safety and essential performance of medical robots that physically interact with a patient to support or perform

rehabilitation, assessment, compensation or alleviation related to the patient's movement functions following an impairment. Contact: hchoe@aami.org.

New Work

AAMI/SM-WG03, Interoperability Working Group. The committee is working on the revision of AAMI 2700-1/Ed. 1 (formerly ASTM F2761), *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*. This standard specifies general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE). This is the first of a series of standards which establishes requirements for design, verification, and validation processes of a model-based integration system for an Integrated Clinical Environment. Contact: wvargas@aami.org.

AAMI Combination Products Committee. A new work item has been approved on the development of a technical information report (TIR), AAMI TIR105, *Risk management guidance for combination products*. This document will provide guidance for the assessing risks for combination products (as defined by the U.S. under 21 CFR 3.2(e)) throughout their total product lifecycle. This document is intended to provide recommendations on best practices, recognizing that risk management requirements may vary across regulatory jurisdictions. For information on this project or to join the consensus body, contact hchoe@aami.org.

AAMI Washer Disinfector Working Group. The committee will be adopting ISO 15883-4, *Washer-disinfectors -- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes* as a new American National Standard. This document specifies the particular requirements, including performance criteria for washer-disinfectors (WD) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes. It also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which can be required to achieve the necessary performance criteria. The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring, and requalification of WD periodically and after essential repairs, are also specified. For information on this work or to join the consensus body, please contact abenedict@aami.org.

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*

AAMI Standards Monitor Online

3 May 2019

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 ST/WG 8, Microbiological Method – seeking users. This committee is working on the revision of AAMI ST72, *Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing*. Contact: jmoyer@aami.org.

AAMI ST/WG 93, Cleaning of Reusable Medical Devices – seeking users. This committee is working on the development of AAMI ST98, *Cleaning validation of health care products -- Requirements for development and validation of a cleaning process for medical devices*. Contact: abenedict@aami.org.

AAMI/CN/WG01, Luer activated valves. The committee is working on development of AAMI/CN27, General requirements for luer activated valves (LAVs) incorporated into medical devices for intravascular applications. Contact: celliot@aami.org.

AAMI/PB, Protective Barriers Committee – seeking users. The committee is working on the revision of AAMI/PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Contact: abenedict@aami.org.

AAMI/RD, Renal Disease and Detoxification Committee - seeking users. This committee is working on the revision of AAMI RD47, *Hospital steam sterilizers*. Contact: cbernier@aami.org.

AAMI Standards Monitor Online

3 May 2019

AAMI/QM-WG02, General aspects stemming from the application of quality principles to medical devices Working Group – seeking users and general interest. The committee is working on the adoption of ISO 20417, *Medical devices -- Information to be provided by the manufacturer*. Contact: wvargas@aami.org.

AAMI/SM-WG03, Interoperability Working Group – seeking users and general interest. The committee is working on the revision of AAMI 2700-1/Ed. 1, *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*. Contact: wvargas@aami.org.

AAMI ST/WG 13, Washer Disinfectors Working Group – seeking users and general interest. The committee is working on the adoption of ISO 15883-4, *Washer-disinfectors -- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes* as a new American National Standard. Contact: abenedict@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/higherlogic/ws/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 2019

AAMI Renal Disease and Detoxification Committee (open meeting – registration required), 6 May 2019, 9:00-5:00h, AAMI, Arlington, VA. Contact: cbernier@aami.org.

AAMI/PC/WG 2, Transvenous Cardiac Leads (open meeting), 6-7 May 2019, 9:00–5:00h, Intercontinental San Francisco, San Francisco, CA. Contact jmoyer@aami.org.

AAMI/PC, Cardiac Rhythm Management Devices (open meeting), 7 May 2019, 9:00–5:00h, Intercontinental San Francisco, San Francisco, CA. Contact jmoyer@aami.org.

AAMI/ST/WG 93, Cleaning of reusable medical devices (open meeting), 8 May 2019, 11:00–13:00h, web meeting. Contact abenedict@aami.org.

AAMI/ST/WG 93, Cleaning of reusable medical devices (open meeting), 10 May 2019, 11:00–13:00h, web meeting. Contact abenedict@aami.org.

AAMI/ST/WG 7, Packaging (open meeting), 13 May 2019, 11:00–13:00h, web meeting. Contact abenedict@aami.org.

AAMI Standards Monitor Online

3 May 2019

AAMI/ST/WG 61, Chemical sterilants hospital practices (open meeting), 23 May 2019, 11:00–13:00h, web meeting. Contact abenedict@aami.org.

June 2019

AAMI/SM/WG05, Device Security Working Group (open meeting – registration required), 10-11 June 2019, 9:00 – 5:00, AAMI, Arlington, VA. Contact: wvargas@aami.org.

AAMI/ID, Infusion Devices (open meeting – [registration required](#)), 11-13 June 2019, 9:00-5:00h, AAMI, Arlington, VA. Contact: jmoyer@aami.org.

AAMI/SM/WG03, Interoperability Working Group (open meeting – registration required), 12-14 June 2019, 9:00 – 5:00, AAMI, Arlington, VA. Contact: wvargas@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 2019

ISO/TC 198/WG 2, Radiation sterilization (closed meeting), 16-17 May 2019, 09:00h to 17:00h, Denver, Colorado, USA. Contact: abenedict@aami.org.

ISO/TC 150/SC 2/WG 1, Cardiac valves (closed meeting), 17-19 May 2019, 9:00 h to 5:00 h, Amsterdam, the Netherlands. Contact: cbernier@aami.org.

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 28 May 2019, 08:00 h to 11:00 h Eastern Standard Time, web meeting. Contact: abenedict@aami.org.

June 2019

ISO/TC 198/WG 1, Industrial ethylene oxide sterilization (closed meeting), 17-18 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: lwaggoner@aami.org.

IEC/SC 62D/MT20, Haemodialysis equipment (closed meeting), 17-18 June 2019, 09:00 h to 17:00 h, Budapest, Hungary. Contact: hchoe@aami.org.

ISO/TC 198/WG 11, General criteria for sterilization processes and sterilizing equipment (closed meeting), 17-18 June 2019, 09:00h to 17:00h, London, UK. Contact: abenedict@aami.org.

AAMI Standards Monitor Online

3 May 2019

ISO/TC 198/WG 13, Washer-disinfectors (closed meeting), 20 June 2019, 09:00 h to 12:00 h Eastern Standard Time, web meeting. Contact: abenedict@aami.org.

ISO/TC 198/WG 9, Aseptic processing (closed meeting), 25-28 June 2019, 09:00 h to 17:00 h, Arlington, VA, USA. Contact: abenedict@aami.org.

ISO/TC 210/WG6, Application of post market surveillance systems to medical devices (closed meetings), 24-26 June 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: wvargas@aami.org.

September 2019

ISO/TC 210/WG2, General aspects stemming from the application of quality principles to medical devices (closed meetings), 30 September – 4 October 2019, 9:00 h to 17:00 h, Arlington, Virginia. Contact: wvargas@aami.org.

October 2019

ISO/TC 210 and related working groups (WG1, WG3, WG6, JWG1), Quality management and corresponding general aspects for medical devices (closed meetings), 7-11 October 2019, 9:00 h to 17:00 h, London, United Kingdom. Contact: wvargas@aami.org

ISO/TC 150/SC 2 and related working groups, Cardiovascular implants and extracorporeal systems (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: cbernier@aami.org.

ISO/TC 150/SC 6 and related working groups, Active implants (closed meetings), 14-18 October 2019, 9:00 h to 17:00 h, Lund, Sweden. Contact: jmoyer@aami.org

IEC/TC 62, related Sub-committees and working groups, Electrical equipment in medical practice (closed meetings), 14-25 October 2019, 9:00 h to 17:00 h, Shanghai, China. 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.