

AAMI Standards Monitor Online

15 January 2018

National Standards

Newly Published Documents

New work/Call for participation

AAMI/IEC 80601-2-49, *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors*. The AAMI Multiparameter Patient Monitoring Equipment Committee is undertaking the adoption of IEC 80601-2-49. The committee needs additional users for input into the process. Please contact Jennifer Moyer (jmoyer@aami.org) for information on how to join this consensus body.

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 2 March 2018

AAMI ST24, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities* (reaffirmation of an American National Standard). This standard covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems. *Contact:* abenedict@aami.org. Purchase from: <http://my.aami.org/store/detail.aspx?id=ST24-PDF>

AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities* (reaffirmation of an American National Standard). This standard provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other healthcare facilities. Included within the scope of this standard are functional and physical design criteria; staff qualifications and education; criteria for selecting LCSs/HLDs and gaseous chemical sterilizers; safety and efficacy considerations in the use; quality control methods; and quality process improvement. *Contact:* abenedict@aami.org. Purchase from: <http://my.aami.org/store/detail.aspx?id=ST58-PDF>

AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities* (reaffirmation of an American National Standard). This recommended practice provides guidelines for the proper handling, processing, and preparation of reusable surgical textiles either on-site or off-site for use in health care facilities. This recommended practice specifically addresses design criteria for functional work areas; staff qualifications, education, training, dress codes, and other personnel considerations; receiving and handling of soiled surgical textiles; laundry processing considerations; transport of both soiled and clean

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surgical textiles; installation, care, and maintenance of laundry equipment; quality control; and regulatory considerations. Definitions of terms and a bibliography are also provided. *Contact:* abenedict@aami.org.
Purchase from: <http://my.aami.org/store/detail.aspx?id=ST65-PDF>

AAMI ST77, *Containment devices for reusable medical device sterilization* (reaffirmation of an American National Standard). This standard covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument organizers. *Contact:* abenedict@aami.org.
Purchase from: <http://my.aami.org/store/detail.aspx?id=ST77-PDF>

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.

Reusable Surgical Textiles Processing Working Group- AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities*. 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 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.

Multiparameter Patient Monitoring Equipment Committee – Adoption of AAMI/IEC 80601-2-49, *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors*. Staff contact: jmoyer@aami.org.

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

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

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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.

Mechanical Circulatory Support Systems Committee-AAMI/ISO 14708-5, *Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices*. 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.

AAMI Health IT Committee – The committee is developing AAMI/HIT1000-1, *Health IT software and systems — Part 1: Fundamental concepts and principles*, and is seeking additional user and general interest representatives (especially clinical representatives) as well as representatives from EHR and other health IT system producer and vendor representatives. Staff contact: jljewelling@aami.org

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AAMI Health IT Quality System Working Group– The committee is developing AAMI/HIT1000-2, *Health IT software and systems — Part 2: Application of quality systems principles and practices*, and is seeking additional user and general interest representatives (especially clinical representatives) as well as representatives from EHR and other health IT system producer and vendor representatives. Staff contact: jljewelling@aami.org

AAMI Health IT Risk Management Working Group– The committee is developing AAMI/HIT1000-3, *Health IT software and systems — Part 3: Application of risk management*, and is seeking additional user and general interest representatives (especially clinical representatives) as well as representatives from EHR and other health IT system representatives. Staff contact: jljewelling@aami.org

AAMI Health IT Usability Working Group– The committee is developing AAMI/HIT1000-4, *Health IT software and systems — Part 4: Application of human factors engineering*, and is seeking additional user and general interest representatives (especially clinical representatives) as well as representatives from EHR and other health IT system producer and vendor representatives. Staff contact: jljewelling@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.

January 2018

Luer activated valves Working Group (open meeting), 16-18 January 2018, 9:00 to 17:00 h, CAMLS, Tampa, FL. Contact: celliott@aami.org.

March 2018

Human Factors Engineering Committee (open meeting – [advance registration required for both in-person and remote participation](#)). 5-6 March 2018, 9:00 to 17:00 h, AAMI, Arlington, VA. Contact: jmoyer@aami.org

Sterilization Standards Week (open meeting – [advance registration required](#)), 19-22 March 2018, 8:00 to 17:00 h, Hyatt Regency Baltimore Inner Harbor, Baltimore, MD. Contact: abenedict@aami.org

Combination Products Committee (open meeting – [advance registration required](#)), 23 March 2018, 9:30 to 16:00 h, AAMI, Arlington, VA. Contact: hchoe@aami.org

Biological Evaluation Committee (open meeting – [advance registration required](#)), 26 March 2018, 9:00 to 17:00 h, WebEx. 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

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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

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.

January 2018

IEC/SC 62A/WG 20, Environmental protection (closed meeting) 16 - 18 January 2018, 9:00 to 17:00 h, Tokyo, Japan. *Contact:* hchoe@aami.org

ISO/TC 198/WG 16, Vaporized hydrogen peroxide sterilization (closed meeting), 17 January 2018, 8:00 to 9:30 h, WebEx. *Contact:* abenedict@aami.org.

ISO/TC 121/SC3, Lung ventilators and related equipment (and affiliated (J)WGs) (closed meetings), 22-26 January 2018, Tokyo, Japan. *Contact:* celliot@aami.org.

ISO/TC 150/SC 2/WG 1, Cardiac valves (closed meeting) 25-27 January 2018, 9:00 to 17:00 h, Fort Lauderdale, FL USA. *Contact:* cbernier@aami.org

ISO/TC 150/SC 2/WG 3, Vascular prostheses (closed meeting) 9-11 January 2018, 9:00 to 17:00 h, Phoenix, AZ USA. *Contact:* cbernier@aami.org

February 2018

ISO/TC 198/WG 8, Microbiological Methods (closed meeting), 12-13 February 2018, 9:00 to 17:00 h, Berlin, Germany. *Contact:* abenedict@aami.org

ISO/TC 198/WG 7, Packaging (closed meeting), 27 February – 1 March 2018, 9:00 to 17:00 h, Nordhavn, Denmark. *Contact:* abenedict@aami.org.

March 2018

ISO/TC 150/SC 6/WG 4, Implantable infusion pumps (closed meeting). 7-8 March 2018, 9:00 to 17:00 h, AAMI, Arlington, VA, USA. *Contact:* jmoyer@aami.org.

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April 2018

ISO/TC 198/WG 3, Moist Heat Sterilization (closed meeting), 9-10 April 2018, 9:00 to 17:00 h, AAMI, Arlington, VA, USA. *Contact:* abenedict@aami.org

ISO/TC 198/WG 12, Information for Reprocessing of Resterilizable Devices (closed meeting), 11-12 April 2018, 9:00 to 17:00 h, AAMI, Arlington, VA, USA. *Contact:* abenedict@aami.org

IEC/TC 62, Electrical equipment in medical practice, (affiliated sub-committees, WGs, JWGs, and MTs) (closed meeting) 9 - 20 April 2018, 9:00 to 17:00 h, London, UK. *Contact:* hchoe@aami.org

IEC/SC 62D/JWG 35 and JWG 36, Medical robots for surgery and rehabilitation (closed meeting) 23 – 27 April 2018, 9:00 to 17:00 h, Ausburg, Germany. *Contact:* hchoe@aami.org

May 2018

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

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

September 2018

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