

## STANDARDS UPDATE

### AAMI Standards Insider

The next [AAMI Standards Insider](#) webinar will be on **Thursday, June 1<sup>st</sup> from 1:00-2:00 PM ET**. The **one-hour FREE webinar** provides quarterly news and updates about AAMI's standards program and portfolio. [Registration](#) for the upcoming webinar and recordings of past webinars in the series – including the recent March 2<sup>nd</sup> session - are available on the [webpage](#). Check back soon for the June 1<sup>st</sup> webinar topics!

### Publications

**PUBLISHED! AAMI TIR45:2023** *Guidance on the use of AGILE practices in the development of medical device software*. Click [here](#) for more information.

**REAFFIRMED! AAMI TIR57:2016/(R)2023** *Principles for medical device security—Risk management*. Click [here](#) for more information.

**REAFFIRMED! AAMI TIR97:2019/(R)2023** *Principles for medical device security—Postmarket risk management for device manufacturers*. Click [here](#) for more information.

## NATIONAL STANDARDS

### *AAMI Call for Comments*

*If you would like to comment on one of the draft documents listed below, contact the individual indicated by email 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 18 June 2023*

**AAMI EQ56, Standard for a medical equipment management program** (revision of an American National Standard). Specifies characteristics of a management program designed to support the safe and effective use of medical equipment used in an HDO. The document addresses the structure of such a program, the documentation that must be produced by the program, program staffing, and resources that should be allocated to those responsible for maintaining medical equipment. Definitions of terms and normative references

are also included, as are notes and rationale that expand the provisions of the document. Contact: [Michael Miskell](#)

## New Work

**AAMI ST-WG02, Radiation sterilization.** The working group is working on the developments of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems*. This document will provide guidance on simplified approaches for validation and routine maintenance of single-use systems sterilized by radiation. Contact: [Mike Miskell](#).

**AAMI ST-WG03, Moist heat sterilization.** The working group is working on the development of AAMI TIR116/Ed.1, *Guidance on designation of a medical product to a device product family and acceptance of a product into a product family by equivalence using moist heat sterilization*. This document will provide guidance to medical device manufacturers about how to analyze the attributes of a medical device when assigning the medical device to a product family. This includes information on how to accept a new or modified medical device into a product family by equivalence. Discussion on product families for cleaning, disinfection, sterilization and human factors testing will be included. Contact: [Mike Miskell](#).

**AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings.** The working group is working on the developments of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. This document will provide healthcare personnel with guidance on point-of-use treatment, transportation, testing (where applicable), cleaning, disinfection, sterilization, packaging, and storage of tattoo machines and accessories used in healthcare settings. Contact: [Tommy Kim](#).

**AAMI ST-WG61, Chemical Sterilants Hospital Practices.** The working group is working on the developments of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. This document will provide guidance for healthcare facilities for the processing of medical devices using ultraviolet (UV) disinfection. The guidance is intended to provide comprehensive information and direction for healthcare personnel in the processing of reusable devices and accessories to render them safe for patient use. Contact: [Tommy Kim](#).

## 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:

**Industry:** *A member of a consensus body who, as an individual or organizational representative, is 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 shall be classified*

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*as an Industry Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.*

**User:** *A member of a consensus body who, as an individual or organizational representative, 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.*

**Regulatory:** *A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.*

**General interest:** *A member of a consensus body who, as an individual or organizational representative, has a general direct and 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 shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.*

**Other Interest:** *A member who does not fit into any of the preceding interest categories but who still has an identifiable material interest in, or specialized knowledge of 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 an Other Interest stakeholder. The particular interest shall be declared and documented.*

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

**AAMI BE-WG18, Attributes of medical devices relevant to biological risk assessment Working Group.** AAMI is seeking industry, user, general interest, and regulatory members for the newly formed working group to provide input on ISO TC/194/WG 18 activities. Contact: [Chenai Maguwah](#)

**AAMI BG, Blood/Gas Exchange Device Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in reaffirmation of 11658, *Cardiovascular implants and extracorporeal systems — Blood/tissue contact surface modifications for extracorporeal perfusion systems* and revision of ISO 7199, *Cardiovascular implants and artificial organs — Blood-gas exchangers Blood-gas exchangers* and to provide input on ISO TC150/SC2/WG4 activities Contact: [Jill Zajac](#)

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**AAMI BP, Blood Pressure Monitoring Committee.** The committee is seeking regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI BP22-1994 (R2016), *Blood pressure transducers*. Contact: [Ladan Bulookbashi](#)

**AAMI CI, Cochlear Implants Committee.** The committee is seeking industry, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI CI86-2017, *Cochlear implant systems—Requirements for safety, functional verification, labeling and reliability reporting*. Contact: [Ladan Bulookbashi](#)

**AAMI CN, Small Bore Connectors Committee.** The committee is seeking user, regulatory, and general interest members to participate in the reaffirmation and future revision of AAMI/ISO 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*; and in the expedited adoption of AAMI/ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*. Contact: [Colleen Elliott](#)

**AAMI CV, Cardiac Valves Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in the US adoption of amendments to ISO 5840-1:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements*; ISO 5840-2:2021, *Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes*; and ISO 5840-3:2021, *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: [Jill Zajac](#)

**AAMI DPC-10, Needles Working Group.** The committee is seeking user, industry, and general interest/regulator members to contribute to the development of the U.S. positions towards the revisions of ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices* and ISO 7864:2016, *Sterile hypodermic needles for single use*. Contact: [Jill Zajac](#)

**AAMI EQ-WG01, Healthcare Technology Management (HTM) Program Management working group.** The working group is seeking general interest, industry, and regulatory members to participate in the revision of ANSI/AAMI EQ56:2013, *Recommended practice for a medical equipment management program*. Contact: [Mike Miskell](#)

**AAMI EQ-WG04, Alternative Equipment Maintenance Working Group.** The working group is seeking industry, regulatory and general interest members to participate in the development of AAMI EQ103/Ed.1, *Alternative equipment maintenance in healthcare delivery organizations*. Contact: [Mike Miskell](#)

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**AAMI EQ-WG05, HTM Education Programs Working Group.** The working group 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: [Mike Miskell](#)

**AAMI EV-WG05, Hospital Beds Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of IEC 80601-2-52 ED1: *Medical electrical equipment—Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*, and IEC 80601-2-89 ED1: *Medical electrical equipment—Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children*. Contact: [Ladan Bulookbashi](#)

**AAMI HF, High Frequency Therapeutic Device Committee** The working group is seeking regulatory, user and general interest members to participate in the adoption project for IEC 60601-2-2:2017/AMD1:2023, *Amendment 1 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. Contact: [Ladan Bulookbashi](#)

**AAMI HIT-WG01, Health IT Risk Management Working Group.** The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-3/Ed.1, *Safety and effectiveness of health IT software and systems—Part 3: Application of risk management*. Contact: [Chenai Maguwah](#)

**AAMI HIT-WG02, Health IT Quality Systems Working Group.** The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-2/Ed.1, *Health IT software and systems—Part 2: Application of quality systems principles and practices*. Contact: [Chenai Maguwah](#)

**AAMI HIT-WG03, Health IT Usability Working Group.** The working group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI HIT1000-4/Ed.1, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering*. Contact: [Chenai Maguwah](#)

**AAMI IP, Implantable Infusion Pumps Committee** The working group is seeking industry, regulatory, user and general interest members to participate in the adoption project for ISO 14708-04:2022 (Ed.2), *Implants for surgery—Active implantable medical devices—Part 4: Implantable infusion pumps*. Contact: [Ladan Bulookbashi](#)

**AAMI MC, Mechanical Circulatory Support Systems Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in the development of documents under ISO/TC150/SC2/WG2 including the early revision of ISO 14708-5:2020, *Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices*. Contact: [Jill Zajac](#)

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**AAMI NS-WG02, Implantable neurostimulator Working Group** The working group is seeking regulatory, user and general interest members to participate in the reaffirmation of ANSI/AAMI/ISO 14708-3:2017, *Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators*. Contact: [Ladan Bulookbashi](#)

**AAMI NS-WG03, Transcutaneous electrical stimulator Working Group** The working group is seeking industry, regulatory, user and general interest members to participate in the reaffirmation and future revision of AAMI NS4-2013 (R2017), *Transcutaneous electrical nerve stimulators*. Contact: [Ladan Bulookbashi](#)

**AAMI QM-WG02, General aspects from medical devices** This working group is seeking user and general interest/regulatory members to participate in the national adoption of ISO 20417, *Medical devices — Information to be supplied by the manufacturer*. Contact: [Amanda Benedict](#)

**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: [Jill Zajac](#)

**AAMI SM-WG03, Interoperability Working Group.** The group is seeking general interest, regulatory, and users. The committee is developing a new American National Standard, SW114, *Safe Remote Control of Medical Devices*. Contact: [Chenai Maguwah](#)

**AAMI SM-WG05, Medical Device Security Working Group.** The group is seeking general interest, regulatory, and users to participate in the future revisions of AAMI TIR57, *Principles for medical device security—Risk Management* and AAMI TIR97, *Principles for medical device security—Postmarket risk management for device manufacturers*. Contact: [Chenai Maguwah](#)

**AAMI SM-WG10, Cloud Computing Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of a new TIR, AAMI TIR115: *Cloud – Guidance for the appropriate use of public cloud computing to enable medical device functions*. Contact: [Chenai Maguwah](#)

**AAMI ST-WG02, Radiation sterilization.** The working group is seeking general interest, regulatory, and user members to contribute to development of AAMI CR513/Ed.1, *Guidance on radiation validation and routine maintenance for single-use systems*. Contact: [Mike Miskell](#).

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**AAMI ST-WG03, Moist heat sterilization.** The working group is seeking general interest, regulatory, and user members to contribute to development of a new TIR AAMI TIR116/Ed.1, *Guidance on designation of a medical product to a device product family and acceptance of a product into a product family by equivalence using moist heat sterilization*. Contact: [Mike Miskell](#).

**AAMI ST-WG06, Chemical Indicators Working Group.** The working group is seeking user, regulatory and general interest members to contribute to development of the U.S. positions towards the revisions of several parts of the ISO 11140 series. Contact: [Tommy Kim](#)

**AAMI ST-WG13, Washer-disinfectors Working Group.** The working group is seeking user, regulatory and general interest members to contribute to development of the U.S. positions towards the revisions of ISO 15883-2, ISO 15883-3 and ISO 15883-7, and consideration of national adoptions of the revised standards. Contact: [Tommy Kim](#)

**AAMI ST-WG45, Processing of tattoo machines and accessories in healthcare settings Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR117/Ed.1, *Guidance for processing tattoo machines and accessories in the healthcare setting*. Contact: [Tommy Kim](#)

**AAMI ST-WG 61, Chemical Sterilants Hospital Practices Working Group.** The group is seeking industry, user, general interest, and regulatory members to participate in the development of AAMI TIR118/Ed.1, *Guidance on ultraviolet (UV) disinfection for medical devices in health care facilities*. Contact: [Tommy Kim](#)

**AAMI TIB, Transfusion, Infusion, and Injection, and Blood Processing Equipment for Medical and Pharmaceutical Use Committee.** The committee and its affiliated working groups are seeking user, industry, and general interest/regulator members to participate in developing the U.S. 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: [Sam Alameda](#)

**AAMI VP, Vascular Prostheses Committee.** The committee is seeking user, industry, and general interest/regulator members to participate in the U.S. adoption of ISO 25539-2:2020, *Cardiovascular implants—Endovascular devices—Part 2: Vascular stents*; the revision of ISO 25539-3, *Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters*. Contact: [Jill Zajac](#)

**AAMI VP-WG 01, Vascular Device-drug Combination Products Working Group.** 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 requirement*. Contact: [Jill Zajac](#)

## 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](http://www.aami.org)). Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department at ([standards@aami.org](mailto: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 2023**

**AAMI ST-WG02, Radiation Sterilization Working Group** (open meeting) 24 May 2023, 13:00h to 17:00h EST, web meeting. The WG will meet to discuss proposed US comments for ISO/DIS 11137-1. Contact: [Mike Miskell](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 25 May 2023, 10:00h to 11:30h EST, web meeting. The WG will meet to discuss revisions to [ANSI/AAMI PC76:2021](#). Contact: [Ladan Bulookbashi](#)

**AAMI ST-WG01, Industrial Ethylene Oxide Sterilization working group** (open meeting) 30 May 2023, 13:00h to 16:00h EST and 31 May 2023, 13:00h to 16:00h EST, web meeting. The WG will meet to discuss comments for ISO/DIS 11135. Contact: [Tommy Kim](#)

**AAMI ID, Infusion Device Committee** (open meeting) 31 May 2023, 1:30h to 3:30h EST, web meeting. The committee will meet to continue resolving comments on Working Draft-3 of AAMI/TIR 111 ED1, Infusion system performance related to occlusions and unintended boluses. Contact: [Ladan Bulookbashi](#)

#### **June 2023**

**AAMI ST-WG01, Industrial Ethylene Oxide Sterilization working group** (open meeting) 1 June 2023, 10:00h to 13:00h EST, web meeting. The WG will meet to discuss comments for ISO/DIS 11135. Contact: [Tommy Kim](#)

**AAMI CP, Combination Products** (open meeting) 6 June 2023 10:00h to 12:00h Eastern, web meeting. The committee will resolve comments for TIR 48 CDV2 Contact: [Jill Zajac](#)

**AAMI SP, Sphygmomanometer Committee** (open meeting) 7 June 2023, 1:00h to 3:00h EST, web meeting. The committee will meet to discuss National Adoption of [ISO 81060-3:2022](#). Contact: [Ladan Bulookbashi](#)



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**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 7 June 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1<sup>st</sup> Wednesday of every month, from 10:00h to 11:00h EST, to discuss TIR 112, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 15 June 2023, 10:00h to 11:30h EST, web meeting. The WG will meet virtually the 3<sup>rd</sup> Thursday of every month to discuss revisions to [ANSI/AAMI PC76:2021](#). Contact: [Ladan Bulookbashi](#)

**AAMI EQ, Medical Equipment Management Committee** (open meeting) 19 June 2023, 16:00h to 17:00h EST, hybrid meeting. The Committee will meet to discuss the reaffirmation ballot of ANSI/AAMI EQ89:2015/(R)2023 and other AAMI EQ Committee/Working Group updates. Contact: [Mike Miskell](#)

**AAMI EQ-WG01, HTM Program Management Working Group** (open meeting) 19 and 20 June 2023, 17:00h to 20:00h and 11:00h to 15:00h EST respectively, hybrid meeting. The WG will meet to resolve comments for AAMI/CDV-2 EQ56. Contact: [Mike Miskell](#)

**AAMI EQ-WG05, HTM Education Programs Working Group** (open meeting) 20 June 2023, 11:00h to 15:00h EST, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 EQ110. Contact: [Mike Miskell](#)

**AAMI EQ-WG04, Alternative Equipment Maintenance Working Group** (open meeting) 20 June 2023, 16:00h to 20:00h Eastern, hybrid meeting. The WG will meet to resolve comments for AAMI/WD-1 EQ103. Contact: [Mike Miskell](#)

**AAMI COVID-19 response team** (open meeting) 21 June 2023, 15:00h to 16:00h Eastern, web meeting. Discuss impacts of the end of the US public health emergency and other committee business. Contact: [Colleen Elliott](#)

**AAMI AR, Anaesthetic and respiratory Committee and WGs** (open meeting) 21 June 2023, 16:00h to 17:00h Eastern, web meeting. Discuss outcome of ISO/TC 121 plenary and affiliated meetings and other committee business. Contact: [Colleen Elliott](#)

**AAMI RD, Renal Disease and Detoxification Committee** (open meeting) 29 June 2023 8:00 to 16:00 Eastern, hybrid meeting. The committee will resolve comments for ISO 8637-1 and 8637-3 Contact: [Jill Zajac](#)

## **July 2023**

**AAMI TIB-WG04, Elastomeric parts, components and packaging working group** (open meeting) 5 July 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1<sup>st</sup> Wednesday of every month,

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from 10:00h to 11:00h EST, to discuss TIR 112, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

**AAMI BE and associated WGs - Biological Evaluation Standards week**, (open meetings; hybrid – advanced registration REQUIRED) 18 –21 July 2023, 09:00h to 17:00h EST, Arlington, VA and web meetings. Contact: [Chenai Maguwah](#)

**AAMI PC-WG03, Pacemaker & ICD MRI Compatibility working group** (open meeting) 20 July 2023, 10:00h to 11:30h EST, web meeting. The WG will meet virtually the 3<sup>rd</sup> Thursday of every month to discuss revisions to [ANSI/AAMI PC76:2021](#). Contact: [Ladan Bulookbashi](#)

## ***September 2023***

**AAMI Fall 2023 Sterilization Standards Week** (open meetings; hybrid – advanced registration REQUIRED; registration to open in July 2023). 11-14 September 2023, 08:00h to 17:00h EST, Arlington, VA, and web meetings. Contact: [Sterilization Standards](#)

## **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.*

#### ***May 2023***

**ISO/TC 198/WG6, Chemical Indicators** (closed meetings). Virtual, 18 May and 22-23 May 2023, 08:00h to 16:00h daily EST. Contact: [Mike Miskell](#)

#### ***September 2023***

**IEC/TC 62, Medical equipment, software, and systems**, and affiliated SC and (J)WG meetings (closed meetings). Seoul, Korea, 11-22 September 2023, 09:00h to 17:00h daily local time. Contact: [Hae Choe](#)

**ISO/TC150/SC2/WG5, Renal replacement, detoxification and apheresis** (closed meetings). Zoom, 18-29 September 2023, 8:00h to 12:00h EST. Contact: [Jill Zajac](#)

#### ***October 2023***

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**ISO/TC 194, Biological and clinical evaluation of medical devices** and affiliated WG meetings (closed meetings). Arlington, US, 23-27 October 2023, 09:00h to 17:00h daily local time. Contact: [Chenai Maguwah](#)

### ***November 2023***

**ISO/TC 121/SC2, Airways and related equipment and ISO/TC 121/SC6, Medical gas supply systems** (closed meetings). Dublin, Ireland (tent.) 13-17 November 2023, 09:00h to 17:00h daily local time. Contact: [Colleen Elliott](#)