

STANDARDS UPDATE

AAMI Standards Insider

Join us, for the next [AAMI Standards Insider](#) webinar 28 September 2023, 1:30pm (EST). The **one-hour FREE webinar** provides news and updates about AAMI's standards program and portfolio. Registration for the upcoming webinars and recordings of past webinars in the series is available on the [webpage](#).

Publications

NATIONAL ADOPTION! ANSI/AAMI/ISO 11138-8:2023; Sterilization of Health Care Products—Biological indicators—Part 8: Method for Validation of a Reduced Incubation Time for a Biological Indicator. Click [here](#) for more information.

PUBLISHED! ANSI/AAMI ST108:2023; *Water for the processing of medical devices* (supersedes AAMI TIR34:2014/(R)2021) Click [here](#) for more information.

PUBLISHED! AAMI/ISO TIR16775:2023; *Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607-1 and ISO 11607-2* (replaces AAMI/ISO TIR16775:2014) Click [here](#) for more information.

PUBLISHED! AAMI/ISO TIR21387:2023; *Sterilization of health care products—Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release*. Click [here](#) for more information.

REAFFIRMED! ANSI/AAMI/ISO 10993-11-2017 (R2023); Biological Evaluation of Medical Devices - Part 11: Tests for Systematic Toxicity. 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](#).

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](#).

AAMI ST-WG95, Water Quality for Reprocessing Medical Devices. The working group is working on the development of AAMI TIR119/Ed.1, *Guidance on Healthcare Implementation and Use of AAMI ST108*. This document will provide guidance for healthcare facilities concerning the technical information, testing and qualification of water systems defined by and built to meet the requirements of ST108. 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:

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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 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, Biological Evaluation Committee. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmations of AAMI/ISO 13022, *Medical products containing viable human cells — Application of risk management and requirements for processing practices*, AAMI/ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*, as well as the expedited adoptions of ISO 22442-1:2020, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management* and ISO 22442-2:2020, *Medical*

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devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling. Contact: [Chenai Maguwah](#)

AAMI BE-WG2, Degradation aspects related to biological testing Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-9:2019, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products* and ISO/TS 37137-1:2021, *Biological evaluation of absorbable medical devices — Part 1: General requirements* Contact: [Chenai Maguwah](#)

AAMI BE-WG8, Irritation and sensitization Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-10:2021, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization* and ISO 10993-23:2021, *Biological evaluation of medical devices — Part 23: Tests for irritation.* Contact: [Chenai Maguwah](#)

AAMI BE-WG9, Effects on blood Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the reaffirmation of AAMI/ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood.* Contact: [Chenai Maguwah](#)

AAMI BE-WG12, Sample preparation and reference materials Working Group. AAMI is seeking industry, user, general interest, and regulatory members to participate in the expedited adoption of ISO 10993-12:2021, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.* 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](#)

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*

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for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications. Contact: [Colleen Elliott](#)

AAMI CP, Combination Products Committee. The committee is seeking user, industry, and general interest/regulator members to contribute to the development and review of various TIRs Contact: [Jill Zajac](#)

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](#) or [Sam Alameda](#)

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](#)

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](#)

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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](#)

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](#)

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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, AAMI SW114 - *Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps*. 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 SP, Sphygmomanometer Committee The committee is seeking regulatory, and general interest members to participate in the identical adoption project for ISO 81060-3:2022/Ed.1, *Non-invasive sphygmomanometers – Part 3: Clinical investigation of continuous automated measurement type*. Contact: [Ladan Bulookbashi](#)

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](#).

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](#).

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AAMI ST-WG06, Chemical Indicators Working Group. The group is seeking user, general interest, and regulatory/government members to participate in the identical adoption project for 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*. Contact: [Tommy Kim](#)

AAMI ST-WG43, Hospital steam sterilizer Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of AAMI ST8/Ed.7, *Hospital steam sterilizers*. Contact: [Mike Miskell](#).

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-WG86, Quality System for Device Processing Working Group. The group is seeking general interest and regulatory/government members to participate in the reaffirmation of AAMI ST90, *Processing of health care products—Quality management systems for processing in health care facilities*. Contact: [Tommy Kim](#)

AAMI ST-WG62, Hospital EO sterilizer Working Group. The group is seeking user, general interest, and regulatory members to participate in the development of AAMI ST24/Ed.4, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use 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). Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department at (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.

September 2023

AAMI DPC - U.S. TAG for ISO-TC 84 (open meeting) 26 September 2023, 10:00h to 12:00h EST, web meeting. The TAG will meet virtually to discuss the current activities of DPC working groups and to determine US positions for the ISO TC/84 Plenary meeting. Contact: [Sam Alameda](#) or [Jill Zajac](#)

October 2023

AAMI BG, Blood/Gas Exchange Device Committee (open meeting) 3 October 2023, web meeting. The committee will meet to discuss the US position on ISO/DIS 7199, *Cardiovascular implants and artificial organs — Blood-gas exchangers* and to resolve comments. Contact: [Jill Zajac](#)

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 4 October 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of every month, from 10:00h to 11:00h EST, to discuss CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

AAMI QM (U.S. TAG to ISO/TC 210), Quality management and corresponding general aspects for products with a health purpose including medical devices (open meeting) 17 October 2023, 10:00h-12:00h EST, web meeting. The TAG will meet virtually to discuss the current activities of AAMI QM and affiliated working groups and to determine US positions for the ISO/TC 210 Plenary meeting. Contact: [Amanda Benedict](#)

US TAG to ISO/TC150/SC2, Cardiovascular implants and extracorporeal systems (open meeting) 17 October 2023, 14:00h-16:00h EST, web meeting. The TAG will meet virtually to discuss the current activities of DPC working groups and to determine US positions for the ISO TC150/SC2 Plenary meeting. Contact: [Jill Zajac](#)

November 2023

AAMI TIB-WG04, Elastomeric parts, components and packaging working group (open meeting) 1 November 2023, 10:00h to 11:00h EST, web meeting. The WG will meet virtually the 1st Wednesday of

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every month, from 10:00h to 11:00h EST, to discuss CR514, *Guidance for Closed System Transfer Device Testing with Hazardous Drugs (CSTD)*. Contact: [Sam Alameda](#)

AAMI RD, Renal Disease and Detoxification Committee (open meeting) 6 November 2023, 09:00h to 16:00h EST, Plymouth Meeting, PA, hybrid meeting. The committee will meet to discuss the US position on ISO/FDIS 8637-2 Extracorporeal systems for blood purification — Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators Contact: [Jill Zajac](#)

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.

October 2023

ISO/TC150/SC2/WG1, Cardiac Valves (closed meetings). Group will resolve comments for ISO/DIS 5910, Cardiovascular implants and extracorporeal systems - Cardiac Valve Prostheses – Cardiac Valve Repair Devices and discuss new projects. Galway, Ireland 09-12 October 2023, 9:00h to 18:00h EST Contact: [Jill Zajac](#)

ISO/TC 84 Plenary Meeting, Devices for administration of medicinal products and catheters and affiliated WG meetings (closed meetings). Frankfurt, DE 13 October 2023, 12:00h CEST Contact: [Jill Zajac](#)

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](#)

ISO/TC150/SC2, Plenary Meeting, Cardiovascular implants and extracorporeal systems (closed meetings). Zoom, 30th October 2023, 8:00h to 11:00h EST Contact: [Jill Zajac](#)

November 2023

ISO/TC 150/SC6, Active Implants, and affiliated (J)WG meetings (closed meetings). AAMI Offices, Arlington, VA, 6-9 November 2023, 09:00h to 17:00h daily local time. Contact: [Ladan Bulookbashi](#)

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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](#)

December 2023

ISO/TC 210, Quality management and corresponding general aspects for products with a health purpose including medical devices and affiliated (J)WG meetings (closed meetings). Paris, France, 5-8 and 11-15 December 2023, 09:00h to 17:00h daily local time. Contact: [Amanda Benedict](#)