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L@b Brief Standards Newsletter – January 2024

Lots of work started in December on establishing general study groups. There is to be one on General Principles of Laboratory Design, which will have a Swiss convenor (there will be a call for experts - max 2 per member body - to assist the group). There will be another on the Mobile Laboratory, the convenor will be Dr (Ms) Xiaodan TANG (China). Finally, ISO/TC 336 - laboratory design, has also agreed to launch study group Smart Laboratory, and is seeking a convenor.

Blood fridges

Meanwhile, work is underway to amend the scope of PC130 on standardisation on cold storage equipment for storing blood and blood products, reagents, medicines, vaccines, biological specimens etc in medical practice and research.
The products within the scope include:
- Medical use refrigerating and freezing storage cabinets temperature ranging from -180°C to +22°C (less than);
- Medical use refrigerating and freezing storage warehouses;
- Medical use cold transporting equipment, including road, sea and air transportation;
- Medical use liquid nitrogen storage equipment;
- Other special medical use cold storage cabinets, such as blood platelet constant-temperature oscillation storage cabinets, blood plasma quick freezers, etc.

PC 130 has added the following to it's scope: energy consumption measuring methods, commissioning, temperature verification and calibration, management specification, digitalization management and environmental aspects.

NEW WORK ITEMS PROPOSED

EN ISO 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers

ISO/NP 11138-6 – Sterilisation of health care products – biological indicators – Part 6 Biological indicators for hydrogen peroxide sterilisation processes. A proposal for public comment has been made available to access the portal to comment, please click here.

EN 15154-2 Emergency safety showers - Part 2: Plumbed-in eye wash units

EN ISO 15197: 2015 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus approval is being sought to revise Annex ZAs for these publications.

ISO/PWI 18972 - **Medical devices — Infusate compatibility — Requirements and assessment methods**

ISO/PWI TS 19673 - **Particle characterization — Colour image analysis methods** to comment, click here

EN ISO 23640: 2015 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents and

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NEW WORK ITEMS ACCEPTED

Amendment to ISO 8655-7:2022 Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume

EN 14056-1 Laboratory furniture — Recommendations for design and installation- Part 1: General.

EN 15154-1 Emergency safety showers - Part 1: Plumbed-in body showers for laboratories.

Revision of **ISO 3826-2, -3,-4** Plastics collapsible containers for human blood and blood components Part 2: Graphical symbols for use on labels and instruction leaflets.

NWIP 24051-1, Medical laboratories — Part 1: General principles for the application of artificial intelligence in medical laboratories.

ISO/PWI 24051-2 Medical laboratories — Part 2: Digital pathology and artificial intelligence (AI)-based image analysis.

DRAFT STANDARDS

prEN ISO 5649:2023 Medical laboratories - Concepts and specifications for the design, development, implementation, and use of laboratory-developed tests has been circulated for approval as a European Standard.

EN ISO 8655-7:2022/prA1 Piston-operated volumetric apparatus - Part 7: Alternative measurement procedures for the determination of volume - Amendment 1 a draft has been circulated for approval.

EN 14056-1:20YY(E) Laboratory furniture — Recommendations for design and installation a draft has been circulated with revised normative annexes and updated scope.

ISO/CD 21501-1 Determination of particle size distribution — Single particle light interaction methods — Part 1: Light scattering aerosol spectrometer has been circulated for comments.

prEN ISO 11135:2024 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices has been circulated for approval as a European standard.

ISO/DIS 11135.2 (Ed 3) Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices a draft has been circulated for comment.

ISO/DIS 1135-4 (Ed 7) Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed, has been approved at Enquiry Stage.

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ISO/DIS 1135-5 (Ed 2)Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus has been approved at enquiry stage.

ISO/DIS 8362-2 (Ed 4) Injection containers and accessories — Part 2: Closures for injection vials has been approved for publication.

ISO/DIS 8417 Risk management of particulate contamination for devices with intravascular access has been circulated for approval.

ISO/CD 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers has been initiated as a Committee Draft.

prEN ISO 15193:2023 In vitro diagnostic medical devices - Requirements for reference measurement procedures has been circulated for approval as a European Standard.

prEN ISO 15194: 2023 In vitro diagnostic medical devices - Requirements for certified reference materials and the content of supporting documentation has been circulated for approval as a European Standard.

ISO 17664-2:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

ISO/CD 18704 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for urine and other body fluids — Isolated cell free DNA, a committee draft has been circulated for comment.

FINAL DRAFTS

ISO/FDIS 8655-10 Piston-operated volumetric apparatus — Part 10: User guidance and requirements for competence, training, and POVA suitability has been approved for publication.

ISO/FDIS 13317-1 Determination of particle size distribution by gravitational liquid sedimentation methods — Part 1: General principles, requirements and guidance has been approved for publication.

STANDARDS OUT FOR REVIEW

EN 868-5:2018 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

EN 868-8:2018 Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

EN 868-9:2018 Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods

EN 868-10:2018 Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods

ISO 3310-2:2013 (Ed 5, vers 2)Test sieves — Technical requirements and testing — Part 2: Test sieves of perforated metal plate

ISO 11040-6:2019 (Ed 2) Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling

ISO 11138-7:2019 Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

ISO 11607-1:2019 (Ed 2) Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2:2019 (Ed 2) Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

ISO/TS 14411-1:2017 (vers 2)Preparation of particulate reference materials — Part 1: Polydisperse material based on picket fence of monodisperse spherical particles.

ISO 20186-1:2019 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 1: Isolated cellular RNA

ISO 20186-2:2019 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 2: Isolated genomic DNA

ISO/TS 22421:2021 Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

ISO/TS 22456:2021 Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

IEC 61010-2-020 Ed.3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges.

IEC 62304 ED1: Medical device software - Software life cycle processes.

STANDARDS RECONFIRMED

ISO 8362-1:2018 (Ed 4) Injection containers and accessories — Part 1: Injection vials made of glass tubing

ISO 11139:2018 Sterilisation of health care products – Vocabulary of terms used in sterilisation and related equipment and process standards. A majority voted to re-confirm this standard.

ISO 11737-1 Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products.

ISO 14488:2007 Particulate materials — Sampling and sample splitting for the determination of particulate properties.

ISO 18472:2018 (Ed 2) Sterilisation of health care products – biological and chemical indicators – test equipment – a majority voted to re-confirm this standard.

ISO 19001:2013 In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology.

ISO/TS 21387: 2020 Sterilisation of medical devices – guidance on the requirements for the validation and routine processing of ethylene oxide sterilisation processes using parametric release. A majority also voted to re-confirm this standard.

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN ISO 17664-2:2023 - Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices. Non-critical medical devices

BS ISO 4802-2:2023 - Glassware. Hydrolytic resistance of the interior surfaces of glass containers. Determination by flame spectrometry and classification.

BS ISO 4802-1:2023 - Glassware — Hydrolytic resistance of the interior surfaces of glass containers. Determination by titration method and classification.

BS EN ISO 15189:2022+A11:2023 - Medical laboratories. Requirements for quality and competence.

PD CEN/TS 17981-2:2023 - In vitro diagnostic Next Generation Sequencing (NGS) workflows. Human RNA examination.
PD CEN/TS 17981-1:2023 - In vitro diagnostic Next Generation Sequencing (NGS) workflows. Human DNA examination.

STANDARDS WITHDRAWN

ISO 21881:2019/Amd 1 Sterile packaged ready for filling glass cartridges —
Amendment 1 it has been decided to cancel this amendment and point instead to ISO 13926-2 “Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use.