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L@b Brief Standards Newsletter – January 2025

NEW WORK ITEMS PROPOSED

ISO/PWI TS 19684 Characterization of liquid dispersion homogeneity.

ISO/PWI TS 25646 In vitro diagnostic medical devices — Definition of analytical performance specifications for laboratory measurements based on medical requirements.

ISO/PWI TS 25725 Design and workflow requirements for NGS-based oncology application.

NEW WORK ITEMS ACCEPTED

N677 Requirements for open platform polymerase chain reaction (PCR) In Vitro Diagnostic Medical Device (IVD) examinations for tuberculosis diagnosis and antimicrobial susceptibility testing – General Guidance for Design, Development and Manufacture.

N 1216 Guidance for emerging technologies intended for medical laboratory use.

EN 15154-3 Emergency safety showers - Part 3: Non plumbed-in body showers.

EN 15154-4 Emergency safety showers - Part 4: Non plumbed-in eyewash units.

EN ISO 25379-1, In vitro diagnostic Next Generation Sequencing (NGS) workflows -- Part 1: Human DNA examination.

EN ISO 25379-2, In vitro diagnostic Next Generation Sequencing (NGS) workflows -- Part 2: Human RNA examination.

DRAFT STANDARDS

ISO 8655-7:2022/FDAmd 1 (Ed 2)Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume — Amendment 1 has been approved at national vote.

ISO/DIS 9276-1 (Ed 3) Representation of results of particle size analysis — Part 1: Graphical representation has been circulated for national vote.

ISO/CD 11040-8 Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes has been circulated for voting – views were divided.

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ISO/CD 11138-6.2 Sterilization of health care products — Biological indicators — Part 6: Biological indicators for hydrogen peroxide sterilization processes has been circulated for committee review.

ISO/CD 11737-1.2, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products is open for voting until 23 March.

ISO/CD 13926-1 Cartridge systems — Part 1: Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use has been circulated for comment.

prEN 14056-1 Laboratory furniture - Recommendations for design and installation - Part 1: General has been approved at national vote stage.

prEN 15154-1 Emergency safety showers - Part 1: Plumbed-in body showers for laboratories has been approved at enquiry stage.

prEN 15154-2 Emergency safety showers - Part 2: Plumbed-in eye-wash units has been approved at enquiry stage.

ISO/CD 15883-6 Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment has been approved as a DIS.

prEN 17180 Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing, has been circulated for national vote.

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

ISO/DIS 18704:2024 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA is out for voting at enquiry stage.

ISO/CD 19253.2 Sterilization of health care products — Moist heat — Requirements for sterilizers used for the terminal sterilization of aqueous liquid in sealed containers has been circulated for committee review.

ISO/CD 23640 In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents has been circulated for comment.

ISO 35001 — Biorisk management for laboratories and other related organisations — Implementation guidance has been circulated for voting.

IEC 60601-1/FRAG2 ED4 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Physical environment hazard (Fragment 2) a draft has been circulated.

IEC 60601-1/FRAG3 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – User interface hazards (Fragment 3) a draft has been circulated.

BS ISO 21501-1 - Determination of particle size distribution — Single particle light interaction methods —. Part 1: Light scattering aerosol spectrometer has been made available for public comment. Register here.

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FINAL DRAFTS CIRCULATED

FprEN 868-2 Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods.

FprEN 868-3 Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods.

FprEN 868-4 Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods.

FprEN 868-6 Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods.

FprEN 868-7 Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods.

ISO/FDIS 8871-5 (Ed 3) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing has been circulated for voting.

ISO/FDIS 11137-1:2024 Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

FprEN 14180 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing has been approved at formal vote.

ISO/FDIS 15883-7:2024 Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment a majority have voted to approve the technical draft.

ISO/FDIS 15883-7 (Ed 2) Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment.

STANDARDS OUT FOR REVIEW

ISO 15190:2020 (Ed 2) Medical laboratories — Requirements for safety.

ISO 13317-4:2014 (vers 2) Determination of particle size distribution by gravitational liquid sedimentation methods — Part 4: Balance method.

ISO 13320:2020 (Ed 2) Particle size analysis — Laser diffraction methods.

EN 14175-4:2004 Fume cupboards - Part 4: On-site test methods.

EN 15154-5:2019 Emergency safety showers - Part 5: Water overhead body showers for sites other than laboratories.

CEN/TS 17688-1:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1: Isolated cellular RNA.

CEN/TS 17688-2:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins.

CEN/TS 17688-3:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 3: Isolated genomic DNA.

ISO 18153:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials has been circulated with a proposal to withdraw the standard.

ISO/TS 19930:2017 (vers 2) Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6.

ISO 28620:2020 (Ed 2) Medical devices — Non-electrically driven portable infusion devices.

STANDARDS RECONFIRMED

ISO 8536-4:2019 (Ed 6) Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed.

ISO 9276-2:2014 Representation of results of particle size analysis — Part 2: Calculation of average particle sizes/diameters and moments from particle size distributions.

ISO 13099-3:2014 Colloidal systems — Methods for zeta potential determination — Part 3: Acoustic methods.

ISO 13322-1:2014 Particle size analysis — Image analysis methods — Part 1: Static image analysis methods.

ISO 18747-2:2019 Determination of particle density by sedimentation methods — Part 2: Multi-velocity approach.

ISO 20166-1 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 1: Isolated RNA.

ISO 20166-2 Molecular in vitro diagnostic examinations — Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 2: Isolated proteins.

ISO 20166-3 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 3: Isolated DNA.

ISO 20184-1 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 1: Isolated RNA.

ISO 20184-2 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 2: Isolated proteins.

ISO 20186-1 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 20186-3 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma.

ISO 3826-1:2019 (Ed 3) Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers.

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN ISO 5649:2024 - Medical laboratories. Concepts and specifications for the design, development, implementation, and use of laboratory-developed tests.

BS EN ISO 8655-7:2022+A1:2024 - Piston-operated volumetric apparatus. Alternative measurement procedures for the determination of volume.

BS ISO 13317-5:2025 - Determination of particle size distribution by gravitational liquid sedimentation methods. Photosedimentation techniques.

STANDARDS WITHDRAWN

ISO 15198:2004 Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer.