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L@b Brief Standards Newsletter – November 2024

NEW WORK ITEMS PROPOSED

PWI - Direct shear testing method for critical state line (CSL) and wall yield locus (WYL) of powder bed. The project shall be led by Japan

PWI - Part 3 of ISO 13319 Determination of particle size distribution – Electrical sensing zone method – Part 3: Resistive pulse sensing method. The project shall be developed in WG 5 and led by China.

ISO/TC 336/SG 2 has developed a PWI on Laboratory Design: Concept & Principles.

ISO TC 336_SG2_V7 has developed a NWIP General Principles of Laboratory Design.

ISO/PWI TS 20327 Packaging for terminally sterilized devices — Receiving, handling, transporting, distributing and storing of packaged sterile medical devices under the control of health care facilities.

ISO/NP 25442 Sterilization of health care products — Test procedure for Measurement of temperature, pressure, and humidity in equipment.

ISO/NP TS 25443 Sterilization of health care products — Moist heat — Guidance for verification of a process challenge device (PCD) to a specific load configuration.

ISO/NP TS 25462 - Sterilization of health care products — Ethylene oxide — Guidance on the validation and routine processing of sterilization processes using alternative approach to parametric release.

NEW WORK ITEMS ACCEPTED

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

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

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

Revision of ISO 20166:2018, Parts 1-3, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 1: Isolated RNA, Part 2: Isolated proteins, Part 3: Isolated DNA.

Revision of ISO 20184:2018, Parts 1-2, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 1: Isolated RNA, Part 2: Isolated proteins.

Revision of ISO 20186:2019, Parts 1-3, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 1: Isolated cellular RNA, Part 2: Isolated genomic DNA, Part 3: Isolated circulating cell free DNA from plasma.

Revision of EN 86810:2018 Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods

PWI - In vitro diagnostic medical devices — Definition of analytical performance specifications for laboratory measurements based on medical requirements

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DRAFT STANDARDS

ISO 385:2005 (vers 4) Laboratory glassware — Burettes.

ISO 1773:1997 (Ed 2, vers 5) Laboratory glassware — Narrow-necked boiling flasks.

ISO 3585:1998 (Ed 3, vers 5) Borosilicate glass 3.3 — Properties.

ISO 4788:2005 (Ed 2, vers 4) Laboratory glassware — Graduated measuring cylinders.

ISO 4790:1992 (vers 6) Glass-to-glass sealings — Determination of stresses.

ISO 4794:1982 (vers 7) Laboratory glassware — Methods for assessing the chemical resistance of enamels used for colour coding and colour marking.

ISO 4800:1998 (Ed 2, vers 5) Laboratory glassware — Separating funnels and dropping funnels.

ISO 5649 Medical laboratories — Concepts and specifications for the design, development, implementation and use of laboratory-developed tests has been circulated and comments made on the text.

ISO 6556:2012 (Ed 2, vers 2) Laboratory glassware — Filter flasks.

ISO 7884-1:1987 (vers 6) Glass — Viscosity and viscometric fixed points — Part 1: Principles for determining viscosity and viscometric fixed points.

ISO 8536-3:2009 (Ed 3, vers 3) Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles.

ISO 8536-7:2009 (Ed 3, vers 3) Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles.

ISO/DIS 8536-16:2024 Infusion equipment for medical use - Part 16: Infusion sets for single use with volumetric infusion controllers has been approved at enquiry stage.

ISO 8871-1:2003 (vers 4) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates.

ISO 8871-3:2003 (vers 4) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count.

ISO 9276-1 - Representation of results of particle size analysis. Part 1: Graphical representation A draft for public comment has been loaded onto the BSI portal, to make comments you will need to register here.

ISO/CD 11040-8 Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes.

ISO/CD 11607-3 Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly.

ISO 11737-2:2019 (Ed 3) Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

ISO 13408-4:2005 (vers 4) Aseptic processing of health care products — Part 4: Clean-in-place technologies.

ISO 15137:2005 (vers 4) Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods.

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

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

EN 15154-3:2009 Emergency safety showers - Part 3: Non plumbed-in body showers.

EN 15154-4:2009 Emergency safety showers - Part 4: Non plumbed-in eyewash units.

EN 15154-6:2019 Emergency safety showers - Part 6: Plumbed-in multiple nozzle body showers for sites other than laboratories.

ISO/TS 16775:2021 (Ed 2) Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2.

prEN 17242 Recirculatory Filtration Fume Cabinets has been approved at enquiry stage.

prEN ISO 18704 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA.

ISO/DIS 21501-1 (Ed 2) Determination of particle size distribution — Single particle light interaction methods — Part 1: Light scattering aerosol spectrometer a draft has been circulated for approval, voting closes on 18 January.

ISO 21501-2:2019 (Ed 2) Determination of particle size distribution — Single particle light interaction methods — Part 2: Light scattering liquid-borne particle counter.

ISO 21501-3:2019 (Ed 2) Determination of particle size distribution — Single particle light interaction methods — Part 3: Light extinction liquid-borne particle counter.

ISO/TS 22107:2021 Dispersibility of solid particles into a liquid.

ISO 22412 'Particle size analysis — Dynamic light scattering (DLS)' is to advance to FDIS ballot.

ISO/CD 23640 In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents.

ISO 24450:2005 (vers 4) Laboratory glassware — Wide-necked boiling flasks.

ISO/CD 24884 Electronic Instructions for Use for In Vitro Diagnostic Medical Devices (Minimum required information and means of delivery) has been circulated and comments received.

ISO/NP 25459 In vitro diagnostic medical devices — Requirements for determining commutability of certified reference materials used as secondary calibrators or trueness controls.

ISO 35001:2019 Biorisk management for laboratories and other related organisations.

IEC 61010-2-020 ED4: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges a draft has been circulated for comment.

FINAL DRAFTS

ISO/FDIS 5649 Medical laboratories — Concepts and specifications for the design, development, implementation and use of laboratory-developed tests.

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 circulated for approval.

Fpr EN ISO 125883-2 Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices.

Fpr EN ISO 125883-3 Washer-disinfectors – Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers has been approved at final vote.

prEN 14056-1 Laboratory furniture - Recommendations for design and installation - Part 1: General has been circulated for formal vote.

ISO/FDIS 15883- 2:2024 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices.

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ISO/FDIS 15883-3:2024 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers has been approved at final vote.

ISO/FDIS 21474-3 In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 3: Interpretation and reports.

STANDARDS OUT FOR REVIEW

ISO 13322-1:2014 (Ed 2, Vers 2) Particle size analysis — Image analysis methods — Part 1: Static image analysis methods.

ISO 15197:2013, In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

STANDARDS RECONFIRMED

ISO 21881:2019 Sterile packaged ready for filling glass cartridges.

ISO 21882 Sterile packaged ready for filling glass vials.

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN 556-2:2024 - Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices.

ISO/TS 7552-1:2024 - Molecular in vitro diagnostic examinations. Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood. Isolated RNA.

PD ISO/TR 8417:2024 - Risk management of particulate contamination for devices with intravascular access.

BS EN ISO 8536-13:2024 - Infusion equipment for medical use. Graduated flow regulators for single use with fluid contact.

BS ISO 13318-1:2024 - Determination of particle size distribution by centrifugal liquid sedimentation methods. General principles, requirements and guidance.

BS ISO 19996:2024 - Charge conditioning of aerosol particles for particle characterization and the generation of calibration and test aerosols.

BS ISO 21474-3:2024 - In vitro diagnostic medical devices. Multiplex molecular testing for nucleic acids. Interpretation and reports.

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PD ISO/TS 22583:2024 - Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment.

STANDARDS WITHDRAWN

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

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