

L@b Brief Standards Newsletter – January 2022

Extension to no physical committee meetings

ISO has extended the period of no physical meetings to end of March 2022 and are expected to extend it still further. IEC continue to have preference for virtual meetings. BSI has also extended the period of virtual only meetings at least until April 2022.

NEW WORK ITEMS PROPOSED

A New Work Item Proposal **PNW TS 85-820 ED1 on Demand side power quality management** has been loaded to the BSI Standards Development Portal for public comment. If you have not used this system before, you will need to register [here](#). To review the document, click [here](#).

NEW WORK ITEMS ACCEPTED

ISO/TC 212 N 906 Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices (laboratory-developed tests)

ISO/TC 212 N 905 Guidance on application of ISO 15189 in anatomic pathology

ISO/TC 212 N 904 Clinical laboratory testing and in vitro diagnostic test systems

ISO/TC 212 N 901 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 1: Isolated RNA

ISO/TC 212 N 902 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 2: Isolated DNA

ISO/TC 212 N 903 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 3: Preparations for analytical CTC staining

CEN/TC 102 N 2561 EN 17180: Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing

EN 14180:2014, Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

STANDARDS TO BE REVISED OR OUT FOR REVIEW

ISO 14887:2000 Sample preparation — Dispensing procedures for powders in liquids

ISO 11040-2:2011 (Ed 2, vers 2) Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges

ISO 11040-2:2011 Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges has been confirmed

ISO 8536-13:2016 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact has been confirmed

DRAFT STANDARDS

prEN 14470-1 Fire safety storage cabinets - Part 1: Safety storage cabinets for flammable liquids has been circulated at enquiry stage.

ISO/DIS 13408-1 Aseptic processing of health care products — Part 1: General requirements is out for voting until 10 March 22.

ISO/DIS 13004, Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method Vdmax has been approved at enquiry stage.

ISO/DIS 11737-3 Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing is out for voting at Enquiry stage until 31 March 22.

ISO/DTS 5111:2022 Quality of water for sterilizers, sterilization and washer disinfectors is out for voting until 2 March 22.

ISO/CD 20658 Medical laboratories — Requirements for collection and transport of samples is out for voting on its circulation as a DIS.

ISO/DIS 24072 Aerosol bacterial retention test method for air-inlet on administration devices has been circulated for voting at enquiry stage.

ISO/DIS 8872 Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods has been out for voting in January.

ISO 8536-2, Infusion equipment for medical use — Part 2: Closures for infusion bottles, including the resolved comments and the manuscript for DIS have been circulated for voting.

Draft amendment ISO 8362-2:2015/DAM 1: Injection containers and accessories — Part 2: Closures for injection vials AMENDMENT 1 is out for approval until 6 April.

ISO 3826-1:2019/CD Amd 1 Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers — Amendment 1 is currently out for voting.

ISO/CD 23484 - Determination of particle concentration by small angle X-ray scattering (SAXS) is out for voting as a new DIS.

ISO/CD 13319-2 - Determination of particle size distribution — Electrical sensing zone method — Part 2: Tuneable resistive pulse sensing method is out for voting for circulation as a DIS.

prEN ISO 18113-1:2021 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements has been approved at enquiry stage.

prEN ISO 18113-2:2021 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use has also been approved at enquiry stage.

prEN ISO 18113-3:2021 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use has also been approved at enquiry stage.

prEN ISO/DIS 18113-4:2021 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing has also been approved at enquiry stage.

prEN ISO 18113-5: 2021 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing has been approved at enquiry stage.

FprCEN TS 17742: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Isolated circulating cell free RNA from plasma has been approved at national vote stage.

FINAL DRAFTS

FprEN IEC 61010-2-012:2019 FprAA, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-012 - Particular requirements for climatic and environmental testing and other temperature conditioning equipment is out for voting for final publication.

IEC 62477-1 ED2: Safety requirements for power electronic converter systems and equipment - Part 1: General will be published as an FDIS by March 2022.

ISO/FDIS 20804 Determination of the specific surface area of porous and particulate systems by small-angle X-ray scattering (SAXS) is out for voting on its final publication.

FprCEN/TS 17811, Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA is out for approval to publish.

FprCEN/TS 17747 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins is out for voting, the UK is likely to approve.

FprCEN/TS 17742 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Isolated circulating cell free RNA from plasma was out for voting in December 21.

FprEN 14175-8:2021 Fume cupboards — Part 8: Fume cupboards for work with radioactive materials has been launched for formal vote.

ISO/FDIS 3749 Edition number 1 Glass syringes — Determination of extractable tungsten has been approved

STANDARDS RECONFIRMED

ISO 4802-1:2016 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification

ISO 4802-2:2016 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification

STANDARDS APPROVED

None

STANDARDS PUBLISHED

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

PD 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

PD 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

PD CEN ISO/TS 16775:2021 Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

STANDARDS WITHDRAWN

None

ENDS