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L@b Brief Standards Newsletter – May and June 2022

DESIGNATED STANDARDS

The following standards for electrical equipment designed for use within certain voltage limits in support of the Electrical Equipment (Safety) Regulations 2016 have been listed on GOV.UK as notice of proposal to designate:

- **EN IEC 61010-2-010:2020 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials**
- **EN IEC 61010-2-081:2020 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes**

NEW WORK ITEMS PROPOSED

Guidelines for good practices in laser diffraction measurements is open for public comment. If you have not used this system before, register here and go here to comment.

Guidelines for acoustic measurements of rheological properties proposed to advance to approved item stage.

Manufacturers' considerations for in vitro diagnostic medical devices in a public health crisis.

Specifications for pre-examination processes for human specimens - Isolated microbiome DNA.

Specifications for pre-examination processes for venous whole blood – Isolated circulating cell free RNA from plasma.

Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood — DNA, RNA and proteins.

Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA.

NEW WORK ITEMS ACCEPTED

Guidance on the validation and verification of quantitative and qualitative methods

Revision of EN 13060:2014+A1:2018 Small steam sterilizers

EN 556-1 revision Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices

EN 556-2 revision Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 2: Requirements for aseptically processed medical devices

IEC TS 63191 ED1 Demand side power quality management

STANDARDS TO BE REVISED OR OUT FOR REVIEW

STERILISING

ISO 11140-4:2007 ISO 11140-4:2007 Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration the proposal to revise has been approved.

ISO 11140-3-2007 & Cor.1-2007 ISO 11140-3:2007/COR 1:2007 Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test — Technical Corrigendum 1 has been approved for revision.

ISO 11607-1/DAmd1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems a proposal to make additional changes has been approved.

ISO 11607-2/DAmd1 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes a proposal for additional changes has been approved.

ISO 11137-3_2017 Sterilization of health care products - Radiation - Part 3- Guidance on dosimetric aspects of development, validation and routine control

PARTICLE CHARACTERISATION

ISO 20998-3_2017 Measurement and characterization of particles by acoustic methods - Part 3- Guidelines for non-linear theory.

ISO 13317-3_2001 Determination of particle size distribution by gravitational liquid sedimentation methods - Part 3- X-ray gravitational technique

ISO 9276-3_2008 Representation of results of particle size analysis - Part 3 - Adjustment of an experimental curve to a reference model.

ISO 9276-6_2008 Representation of results of particle size analysis - Part 6 - Descriptive and quantitative representation of particle shape and morphology.

ISO 7806_1983 Industrial plate screens - Codification for designating perforations.

ISO 10630_1994 Industrial plate screens - Specifications and test methods.

ISO 14315_1997 Industrial wire screens - Technical requirements and testing.

ISO 7805-1_1984 Industrial plate screens - Part 1- Thickness of 3 mm and above.

ISO 7805-2_1987 Industrial plate screens - Part 2- Thickness below 3 mm.

ISO 13317-2_2001 Determination of particle size distribution by gravitational liquid sedimentation methods - Part 2- Fixed pipette method.

ISO 4783-1_1989 Industrial wire screens and woven wire cloth - Guide to the choice of aperture size and wire diameter combinations - Part 1- Generalities.

ISO 4783-2_1989 Industrial wire screens and woven wire cloth - Guide to the choice of aperture size and wire diameter combinations - Part 2- Preferred combinations for woven wire cloth

ISO 4782_1987 Metal wire for industrial wire screens and woven wire cloth

IVDs etc

ISO 8536-15 2022 Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use has been approved for amendment.

ELECTRICAL

IEC TS 63383 ED1 Cybersecurity aspects of devices used for power metering and monitoring, power quality monitoring, data collection and analysis has received comments from the UK.

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DRAFT STANDARDS

LAB GENERAL

FprEN 16589-1:2022 Laboratory local exhaust devices — Part 1: Articulated extraction arm will be circulated for formal vote after review of final comments.

FprEN 14175-8 Fume cupboards - Part 8: Fume cupboards for work with radioactive materials has been approved.

ISO/CD 4802-2 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification has been approved for circulation as a DIS.

ISO/CD 4802-1 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification has been approved for circulation as a DIS.

STERILISING

ISO 11139:2018 Amd 1 Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards - Amendment 1 is being considered for circulation as a DIS.

ISO/DIS 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 this has been approved for circulation as an FDIS.

EN 17180 Sterilizers for medical purposes - Low temperature vaporised hydrogen peroxide sterilizers - Requirements and testing has been circulated for comment.

ISO/DIS 11737-3, Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing has been approved.

PARTICLE CHARACTERISATION

ISO/DIS 23484 Determination of particle concentration by small angle X-ray scattering (SAXS) is out for voting until 5 September.

ISO/CD 13318-1:2022(E) Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 1: General principles and guidelines is out for review at committee document stage.

ISO/DIS 9277 (Ed 3) Determination of the specific surface area of solids by gas adsorption — BET method has been approved for publication.

IVDs etc

ISO/CD 11040-4 Ballot type CD Ballot title Prefilled syringes — Part 4: Glass barrels for injectables and sterilized sub assembled syringes ready for filling has been approved for circulation as a DIS.

prEN ISO and ISO DIS 8536-2 Infusion equipment for medical use - Part 2: Closures for infusion bottles has been approved at enquiry stage.

ISO/CD 11040-7 Prefilled syringes — Part 7: Packaging systems for sterilized sub assembled syringes ready for filling has been approved for circulation as a DIS.

ISO 3826-1:2019/DAM 1 Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers AMENDMENT 1 is out for voting until 8 September.

ELECTRICAL

IEC/CDV 61010-2-034 ED2, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-034: Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength – the UK has provided comments on this draft so it is likely to go to FDIS as revisions will be required.

IEC 61010-031 ED3 CDV, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test has been circulated for comment.

IEC 61557-7/AMD1 ED3: Amendment 1 - Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC - Equipment for testing, measuring or monitoring of protective measures - Part 7: Phase sequence is out for voting until 7 August.

IEC 61557-9 ED4: Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. - Equipment for testing, measuring or monitoring of protective measures - Part 9: Equipment for insulation fault location in IT systems is out for voting until 7 August.

IEC 61557-14 ED2: Electrical safety in low voltage distribution systems up to 1 000 V a.c and 1 500 V d.c - Equipment for testing, measuring or monitoring of protective measures - Part 14: Equipment for testing the safety of electrical equipment of machinery has been circulated for approval to move to FDIS stage.

IEC 61557-16 ED2: Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c - Equipment for testing, measuring or monitoring of protective measures - Part 16: Equipment for testing the effectiveness of the protective measures of electrical equipment and/or medical electrical equipment has been circulated for final voting. If approved it will go straight to publication without requiring consideration at FDIS stage.

IEC 61558-2-3 ED3 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-3: Particular requirements and tests for ignition transformers for gas and oil burners is out for voting until 19 September.

IEC 61558-2-7 ED3 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-7: Particular requirements and tests for transformers and power supply units for toys is out for committee vote until 18 September.

IEC 61558-2-13 ED3 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-13: Particular requirements and tests for auto transformers and power supply units incorporating auto transformers for general applications has been approved at committee vote stage.

prEN IEC 60688:2021 Electrical measuring transducers for converting AC and DC electrical quantities to analogue or digital signals has been approved at committee vote stage.

IEC 60755-1 ED1 General safety requirements for residual current operated protective devices - Part 1: Residual current operated protective devices for DC systems has been approved for registration as an FDIS.

IEC 61543 ED2 Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility will be registered as an FDIS.

IEC 62606/AMD2 ED1 Amendment 2 - General requirements for arc fault detection devices has been approved for registration as an FDIS.

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IEC 62873-3-3 ED2 Residual current operated circuit-breakers for household and similar use - Part 3-3: Specific requirements for devices with screw-type terminals for external untreated aluminium conductors and with aluminium screw-type terminals for use with copper or with aluminium conductors has been approved for circulation as an FDIS.

FINAL DRAFTS

ISO/FDIS 24166-1 Snap-on Bottles for Metering Pumps — Part 1: Tubing Glass.

ISO/FDIS 24166-2 Snap-on Bottles for Metering Pumps — Part 2: Moulded Glass.

ISO/FDIS 24166-3 Snap-on bottles for metering pumps - Part 3: Plastic.

ISO/FDIS 26824 Particle characterization of particulate systems a Vocabulary has been circulated for comments, the deadline for which has now passed.

ISO/FDIS 20998-2 Measurement and characterization of particles by acoustic methods — Part 2: Linear theory has been circulated for final vote to publish.

STANDARDS RECONFIRMED

ISO 22870:2016 (Ed 2) Point-of-care testing (POCT) — Requirements for quality and competence

ISO 8362-3:2001 (Ed 2, vers 4) Injection containers and accessories — Part 3: Aluminium caps for injection vials

ISO 3826-2:2008 (vers 3) Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets

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STANDARDS APPROVED

ISO/FDIS 22441, Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

EN 62423:2012/prAB Circuit breakers and similar devices for household and similar applications an updated annex ZA.

IEC 61009-1 Amend.1 Ed.2: Aptitude of RCBOs to withstand high surge currents and additional verifications of correct operation at residual currents between 5 IDn and 500 A.

IEC 62019 Ed. 1.0: Electrical accessories – Circuit-breakers and similar equipment for household use - Auxiliary contact units.

ISO 11137-2:2015/FprA1 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1.

IEC 62477-1 ED2 Safety requirements for power electronic converter systems and equipment - Part 1: General.

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STANDARDS PUBLISHED

PD CEN/TS 17747:2022 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood — DNA, RNA and proteins

BS ISO 21474-2:2022 In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids

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STANDARDS WITHDRAWN

None

ENDS