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L@b Brief Standards Newsletter – October 2021

Particle characterisation and sieving
The ISO committee working on sieving and particle characterisation, ISO/TC 24/SC 4 are seeking approval to hold a hybrid plenary meeting in Berlin with some members actually travelling to Germany to take part. The UK BSI is still holding all meetings virtually, which has made for huge time savings, so it will be interesting to see whether the move back to in-person meetings will be welcomed or not.

Possible problem with circuit breaker standard
A Spanish Regional Market Authority is currently carrying out a market surveillance campaign related to MCBs according to EN 60898-1. EN 60898-1:2019 **Electrical accessories. Circuit-breakers for overcurrent protection for household and similar installations. Circuit-breakers for a.c. operation**.When performing the short circuit test, they came across a potential deficiency in the standard, regarding subclause 9.12.9.2, Test in free air. They consider that the fact that the grid distance "a" is not available in the documentation attached to the product and that the upper limit for this distance is not specified for short circuit currents greater than 3000A may be a safety issue, that would imply a non-conformity with the safety objectives 1.a) and 3.c) of 2014/35/UE (LVD).

Pressure equipment in OJEU
The European Commission has cited some new references in the OJEU to pressure equipment. New Commission Decision concerning references of harmonised standards under Directive/Regulation 2014/68/EU - Pressure equipment (PED) was published in the Official Journal of the European Union this October.

NEW WORK ITEMS PROPOSED
None

NEW WORK ITEMS ACCEPTED
IEC 61557-18 ED1: 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 18: dc ev supply equipment monitoring device.

A request to amend **ISO 3826-1:2019 Plastic collapsible containers for human blood and blood components — Part 1: Conventional containers** has been accepted. The intended Amendment will provide an extension of the Clause on the thermal stability. It will clarify that the instructions for use shall indicate if the plastics container is intended for freezing and/or irradiation applications.

It has been agreed to adopt a new project for revision of the European Annex in **EN ISO 23640:2015 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents.**

It has been agreed to amend **IEC 61010-1:2010 Ed 3 Safety requirements for electrical equipment for measurement, control, and laboratory use - General requirements** to make an Amendment 2.

STANDARDS TO BE REVISED OR OUT FOR REVIEW
ISO 1135-4:2015: Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed and

ISO 1135-5:2015: Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus are both to be revised.

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DRAFT STANDARDS

ISO/DIS 15189 Medical laboratories — Requirements for quality and competence is out for voting until 11 January 2022.

IEC 60477-1 ED1: Laboratory resistors - Part 1: Laboratory DC resistors and **IEC 60477-2 ED2: Laboratory resistors - Part 2: Laboratory AC resistors** both these committee drafts will be registered as final drafts (FDIS) by the end of December.

ISO/DIS 13004 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmax SD is out for voting until 11 January 2022.

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 has been approved at enquiry stage.

ISO/CD 11607-2: 2019 Amd 1 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes – Amendment 1 was approved at CD stage.

ISO 8362-2:2015/CD Amd 1 Injection containers and accessories — Part 2: Closures for injection vials — Amendment 1 has been out for voting to be circulated as a DIS during October.

ISO DTS 5798 Quality Practice for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods is out for voting at WD stage until 10 November.

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 circulated to national committees for voting until 11 November.

ISO/DIS 26824 Particle characterization of particulate systems — Vocabulary (Revision of ISO 26824:2013) has been approved and will either go to FDIS or direct to publication.

IEC 62606/AMD2 ED1; Amendment 2 - General requirements for arc fault detection devices is out for national voting, UK is likely to approve.

IEC 60755-1 ED1; General safety requirements for residual current operated protective devices - Part 1; Residual current operated protective devices for DC systems is out for national voting and the UK is likely to approve.

IEC 61543 ED2; Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility is out for national voting, the UK is likely to approve.

prEN IEC 61543prAA Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility is also likely to be approved at national vote.

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 is also likely to be approved at national vote stage.

BS 6396 Electrical systems in furniture – Specification – a draft for public comment has been made available. If you would like a copy of the standard please get in touch: Jacqueline.balian@gambica.org.uk. Comments should be submitted here before the 21st December 2021.

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FINAL DRAFTS

ISO/FDIS 15901-2 Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 2: Analysis of nanopores by gas adsorption.

A new annex ZA has been approved for **EN IEC 61010-2-011:2021/A11:202X Safety requirements for refrigerating equipment** and it is asked that the standard be made available without further delay.

ISO/DIS 8536-15, Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use, is out for voting until 18 May 2022.

ISO/FDIS 4307: Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA has been approved for publication.

FprEN ISO 4307: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for saliva - Isolated human DNA (ISO/FDIS 4307:2021) has been approved for publication.

STANDARDS RECONFIRMED

None

STANDARDS APPROVED

None

STANDARDS PUBLISHED

None

STANDARDS WITHDRAWN

None

ENDS