

L@b Brief Standards Newsletter – September 2022

Harmonisation of IVD standards

The following standards have been circulated for voting on harmonisation and the preparation of Annex Zs.

- EN14136 2004: Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures.
- EN13975 2003: Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects.
- EN13641 2002: Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
- EN13612 2002: Performance evaluation of in vitro diagnostic medical devices.
- EN 13532 2002: General requirements for in vitro diagnostic medical devices for self-testing.

Designation of standards in support of the Electrical Equipment (Safety) Regulations 2016

The following standards have gone through the internal checking process of BEIS OPSS and are currently on GOV.UK as notices of proposal to designate by 26 October 2022.

- EN IEC 61010-2-011:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-011: Particular requirements for refrigerating equipment.
- EN IEC 61010-2-032:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-032: Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement.
- EN IEC 61010-2-033:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-033: Particular requirements for hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage.
- EN IEC 61010-2-040:2021 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.
- EN IEC 61010-2-091:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems.

You can access the full proposal here: [Proposal to Amend 0070/22: Designated Standards - Low Voltage Equipment \(publishing.service.gov.uk\)](https://www.gov.uk/proposals-to-amend/0070/22-designated-standards-low-voltage-equipment)

NEW WORK ITEMS PROPOSED

EN 16589-2 Rotary shaft lip-type seals incorporating thermoplastic sealing elements — Part 2: Vocabulary.

ISO/NP 19253 Sterilization of health care products — Application of ISO/TS 22421 to the requirements for sterilizers used for the terminal sterilization of health care products containing aqueous liquid in sealed containers.

ISO 18362: Manufacture of cell-based health care products — Control of microbial risks during processing voting on adoption into the new work programme of CEN/TC 204 is open until 21 November.

NEW WORK ITEMS ACCEPTED

ISO 13004: Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD.

ISO/TR 6037: Automated liquid handling systems – Uncertainty of the measurement procedures.

TS 85-820 ED1: Demand side power quality management.

STANDARDS TO BE REVISED OR OUT FOR REVIEW

LAB GENERAL

ISO 383:1976 (vers 6) Laboratory glassware — Interchangeable conical ground joints is out for review until 18 January.

ISO 641:1975 (vers 6) Laboratory glassware — Interchangeable spherical ground joints is out for review until 18 January

ISO 1772:1975 (vers 7) Laboratory crucibles in porcelain and silica is out for review until 18 January.

ISO 1775:1975 (vers 7) Porcelain laboratory apparatus — Requirements and methods of test is out for review until 18 January is out for review until 18 January.

ISO 4791-1:1985 (vers 6) Laboratory apparatus — Vocabulary relating to apparatus made essentially from glass, porcelain or vitreous silica — Part 1: Names for items of apparatus is out for review until 18 January

ISO 4793:1980 (vers 6) Laboratory sintered (fritted) filters — Porosity grading, classification and designation is out for review until 18 January

ISO 4796-3:2000 (vers 4) Laboratory glassware — Bottles — Part 3: Aspirator bottles is out for review until 18 January

ISO 4801:1979 (vers 8) Glass alcoholometers and alcohol hydrometers not incorporating a thermometer is out for review until 18 January

ISO 13130:2011 (vers 2) Laboratory glassware — Desiccators is out for review until 18 January.

EN 14175-6:2006 Fume cupboards - Part 6: Variable air volume fume cupboards.

EN 15154-2:2006 Emergency safety showers - Part 2: Plumbed-in eye wash units.

ISO 7057:1981 (vers 6) Plastics laboratory ware — Filter funnels is out for review until 18 January

EN 14175-6:2006 Fume cupboards - Part 6: Variable air volume fume cupboards is out for review until 18 January

EN 15154-2:2006 Emergency safety showers - Part 2: Plumbed-in eye wash units is out for review until 18 January

STERILISING

ISO 15882:2008 (Ed 2, vers 3) Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results systematic review ballot closes on 18 January

ISO 15883-6:2011, Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment – voting has closed.

IVDs etc

ISO 13926-2:2017 (Ed 3) Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use is out for systematic review until 18 January

ISO/TS 22583:2019 Guidance for supervisors and operators of point-of-care testing (POCT) devices is out for review until 18 January

ISO/TS 23128:2019 Medical devices — Transfusion set and blood bag compatibility test method is out for review until 18 January

ISO/DIS 24072.2 Aerosol bacterial retention test method for air-inlet on administration devices, this draft is out for technical comments until 21 November.

ELECTRICAL

IEC 61557-10 ED2 – Electrical safety in Low Voltage distribution system up to 1 000 v ac and 1 500 v dc – equipment for testing, measuring or monitoring of protective measures – Part 10: combined measuring equipment work

DRAFT STANDARDS

LAB GENERAL

ISO/DIS 10991:2022 Microfluidics – Vocabulary has been approved as a draft European Standard.

ISO/DIS 13132 (Ed 2) Laboratory glassware — Petri dishes has been approved.

ISO/DTR 16153 (Ed 2) Determination of uncertainty for volume measurements of a piston-operated volumetric apparatus using a photometric method has been approved.

FprEN 16589-1 Laboratory local exhaust devices — Part 1: Articulated extraction arm the ballot on this standard is now closed.

ISO/DTR 20461 (Ed 2) Determination of uncertainty for volume measurements of a piston-operated volumetric apparatus using a gravimetric method has been approved.

STERILISING

ISO/CD 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices has been out for voting as a committee draft.

IVDs etc

FprCEN ISO/TS 5798 In vitro diagnostic test systems - Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods the ballot on this standard is now closed.

ELECTRICAL

IEC 61010-1/AMD2 ED3: Amendment 2 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements is out for voting until 18 November.

IEC 61010-2-030 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits is out for voting at enquiry stage until 6 December.

IEC 61010-2-032 ED5: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-032: Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement is out for voting at enquiry stage until 6 December

IEC 61010-2-033 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-033: Particular requirements for hand-held multimeters and other meters for domestic and professional use, capable of measuring mains voltage is out for voting at enquiry stage until 6 December.

EC 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 approved for publication

FINAL DRAFTS

IEC 61010-031 ED3: Safety requirements for electrical equipment for measurement, control and laboratory use Part 031: Safety requirements for hand-held and hand-manipulated probe assemblies for electrical test and measurement was out for voting until 28 October.

ISO/FDIS 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

STANDARDS RECONFIRMED

ISO 11138-3:2017, Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes has been confirmed at systematic review.

ISO 11138-4:2017, Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes has been confirmed.

ISO 11138-5:2017, Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes has been confirmed.

STANDARDS APPROVED

STERILISING

ISO 11607-2:2019/DAMd 1 (Ed 2) Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1.

ISO/FDIS 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.

ELECTRICAL

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.

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.

IEC 61557-13 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 13: Hand-held and hand-manipulated current clamps and sensors for measurement of leakage currents in electrical distribution systems.

IEC 61543 ED2: Residual current-operated protective devices (RCDs) for household and similar use – Electromagnetic compatibility.

FDIS IEC 62606/AMD2 ED1: Amendment 2 - General requirements for arc fault detection devices.

IEC 60755-1 ED1: General safety requirements for residual current operated protective devices - Part 1: Residual current operated protective devices for DC systems.

STANDARDS PUBLISHED

BS EN IEC 61010-2-012:2022+A11:2022 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for climatic and environmental testing and other temperature conditioning equipment.

BS ISO 13004:2022 Sterilization of health care products. Radiation. Substantiation of selected sterilization dose: Method VDmaxSD.

STANDARDS WITHDRAWN

ISO 6152:1982 Thermometers for use with alcoholometers and alcohol hydrometers

ENDS