GAMBICA
Lab Tech

L@b Brief Standards Newsletter – June 2021

A project plan has been published by CEN/CENELEC on progress with aligning standards with the new EU Medical Devices Regulations as below. Track one items will take the longest to review and are intended to be published in June 2024.

Project listed in draft StReq	Comments	Suggested Track
EN ISO 15883-1	In preparation, Annex with positive Assessment in Enquiry stage	Track 2
EN ISO 15883-2	Revision?	Track 1
EN ISO 15883-3	Revision?	Track 1
EN ISO 15883-4	Published, work on Annex necessary	Track 3
EN ISO 15883-5	Publication in preparation, work on Annex necessary	Track 3
EN ISO 15883-6	Revision?	Track 1
EN ISO 15883-7	Revision?	Track 1

Updates queried on NHSE/NHSI HTM 03-01 for design, operation and maintenance of systems for healthcare facilities

Updating of the HTM on design, operation and maintenance of healthcare facilities will impact on members specifying, supplying or testing LEV systems (fume cupboards, recirculatory filtration fume cabinets and microbiological safety cabinets) and clean rooms. There is a new requirement that only competent persons holding an in-date P601 certificate are allowed to perform annual testing and installation of microbiological safety cabinets.

In addition, microbiological safety cabinets with integral fans, are not recommended but appear to be allowed provided the extract ductwork is less than 2 m. However, such an installation are considered to be noisy and are not recommended for use in new buildings.

To ensure you are happy with the proposals you can download and review the Health Technical Memorandum 03-01 (2021 for design, operation and maintenance of systems for Healthcare Facilities Parts A and B here.

Health Technical Memorandum 03-01 (2021) supersedes all previous versions of Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' (2007). It also supersedes HTM 2025 (1994) and DV4 (1983).

The committee responsible has sought wider input before responding officially.

NEW WORK ITEMS PROPOSED

A number of new work items have been made available for public comment as part of an initiative to raise awareness of standards work. If you have not used the system before you will first need to register here. They are:

ISO/PWI 13317-5 Determination of particle size distribution by gravitational liquid sedimentation methods - Part 5: Optical gravitational technique.
To comment please click here.

ISO/TC 212 N 862, ISO/PWI TS 23824 Guidance on application of ISO 15189 in anatomic pathology.
To comment please click here.

ISO/PWI TS 7552-1 Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood -- Part 1: Isolated RNA.
To comment please click here.

ISO/PWI TS 7552-2 Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood -- Part 2: Isolated DNA.
To comment please click here.

ISO/PWI TS 7552-3 Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood -- Part 3: Preparations for analytical CTC staining.
To comment please click here.

ISO/NP 8417 Risk management of particulate contamination for devices with intravascular access.
To comment please click here.

Other New Work Items published this month include:

Electrical safety in low voltage distribution systems up to 1000V AC and 1500V DC – Equipment for testing, measuring or monitoring of protective measures – Part 18: DC EV Supply Equipment Monitoring Device is out for voting the UK is likely to abstain.

New work item cancelled **ISO 11138-5:2017/AWI Amd 1 Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low temperature steam and formaldehyde sterilization processes — Amendment 1: Annex C: Alternative method for determining the D-value of LTSF**

NEW WORK ITEMS ACCEPTED

None

STANDARDS TO BE REVISED OR OUT FOR REVIEW

A large number of standard which were up for review are to be re-confirmed rather than revised. These include:

BS 7288_2016, Specification for residual current devices with or without overcurrent protection for socket-outlets for household and similar uses

ISO 11140-3, Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

ISO 11140-4, 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
ISO 11140-5, Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests

ISO 15883-2, Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

ISO 15883-3, Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

ISO 15883-7:2016, Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

ISO 13408-3, Aseptic processing of health care products — Part 3: Lyophilization

ISO 18362, Manufacture of cell-based health care products — Control of microbial risks during processing

ISO 20857, Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

EN 285:2015, Sterilization - Steam sterilizers - Large sterilizers

ISO 8362-5:2016 Injection containers and accessories — Part 5: Freeze drying closures for injection vials

ISO 8362-6:2010 Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials

ISO 15375:2010 Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods

BS 3693_1992, Recommendations for design of scales and indexes on analogue indicating instruments

BS 4309_1968, Methods of measuring the performance of laboratory electric resistance furnaces

BS 2648_1955, Performance requirements for electrically-heated laboratory drying ovens

BS 2646-3_1993, Autoclaves for sterilization in laboratories -- Guide to safe use and operation reconfirmed (but in fact it is expected that this will be reviewed shortly)

BS 2646-4_1991, Autoclaves for sterilization in laboratories -- Guide to maintenance also reconfirmed (but in fact it is expected that this will be reviewed shortly)

BS 2646-2_1990, Autoclaves for sterilization in laboratories -- Guide to planning and installation also reconfirmed (but in fact it is expected that this will be reviewed shortly)

ISO/WD TS 5111, Quality of water for sterilizers, sterilization and washer-disinfectors, this working draft has been circulated for comment until 24 August.

An amendment has been recommended to **ISO 11139:2018, Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards**, to address terms in ISO 11139:2018 which need better definition.

DRAFT STANDARDS

The following items have been circulated for public comment as part of the initiative to make standards development more accessible. If you haven't input to a standard before, you will need to register here.

BS EN IEC 61557-13 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.
To comment, please click here.

BS EN IEC 61557-16 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.
To comment, please click here.

BS ISO 9277 Determination of the specific surface area of solids by gas adsorption -- BET method.
To comment, please click here.

Other standards released this month…
ISO/CD 11737-3.2 Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing is out for voting at committee stage. The UK intention is to approve.

prEN 16589-1 Laboratory local exhaust devices - Part 1: Articulated extraction arm is out for voting at enquiry stage until 9 August.

IEC 60477-2 ED2: Laboratory resistors. Part 2: Laboratory AC resistors is out for voting on circulation as an FDIS until 23 July, the UK is likely to abstain.

IEC 60477 ED2: Laboratory DC resistors also out for voting as an FDIS until 23 July, UK also minded to abstain.

ISO/DIS 15901-2 (Ed 2) Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 2: Analysis of nanopores by gas adsorption has been approved subject to going to FDIS as changes need to be made.

ISO/CD 13319-2 2021 Determination of particle size distribution — Electrical sensing zone method — Part 2 Tuneable resistive pulse sensing method is out for voting as a committee draft until 25 July, UK is likely to abstain.

ISO/DIS 4307 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA is to go to FDIS to allow final changes to be made.

ISO/DIS 21474-2 In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 2: Validation and verification is out for voting until 1 September.

IEC 60898-3/AMD1 ED1; Amendment 1 - Electrical accessories - Circuit-breakers for overcurrent protection for household and similar installations - Part 3; Circuit-breakers for DC operation is out for voting and the UK is likely to return a positive vote.

EN 61009-1:2012/FprAC Residual current operated circuit-breakers with integral overcurrent protection for household and similar uses (RCBOs) - Annex N - Additional requirements and tests for RCBOs consisting of one residual current protection function and several independent two-pole overcurrent protection functions the UK is also likely to support this proposal.

ISO/IEC TR 63306-2 ED1: Smart Manufacturing Standards Map (SM2) - Part 2: Catalogue approved.

FINAL DRAFTS

ISO/FDIS 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices has been approved for publication.

prEN ISO 20916 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice is out for voting for adoption as a European Standard, the UK is likely to approve.

IEC 62586-2/AMD1 ED2: Power quality measurement in power supply systems - Part 2: Functional tests and uncertainty requirements has been approved.

prEN ISO 16256 - Clinical laboratory testing and in vitro diagnostic test systems - Broth microdilution reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases is to skip formal vote and go straight to publication.

ISO 21501-4:2018/DAmd 1 Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces — Amendment 1 has been approved.

IEC 61557-17 ED1 Electrical safety in low voltage distribution systems up to 1000V AC and 1500V DC Equipment for testing measuring and monitoring of protective measures - Part 17: Non AC contact voltage indicators is out for approval to publish until 16 July.

IEC 60695-2-13 ED3 Fire hazard testing - Part 2-13 Glowing/hot-wire based test methods - Glow-wire ignition temperature (GWIT) test method for materials is out for final approval to publish until 2 July

IEC 61936-1 ED3 Power installations exceeding 1 kV AC and 1,5 kV DC - Part 1: AC will be published as a FDIS.

GAMBICA
Lab Tech

IEC 62586-2:2017/A1:202X Power quality measurement in power supply systems - Part 2: Functional tests and uncertainty requirements has been approved.

ISO/FDIS 20166-4 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: In situ detection techniques has been approved

ISO/FDIS 23118 Molecular in vitro diagnostic examinations — Specifications has also been approved.

STANDARDS RECONFIRMED

None

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN ISO 11737-1:2018+A1:2021 Incorporating corrigendum June 2018 Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products

BS EN ISO 23118:2021 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma

BS EN ISO 20184-3:2021 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue Part 3: Isolated DNA

STANDARDS WITHDRAWN

None

ENDS